Contact lens solutions

A report on the supply within the United Kingdom of contact lens solutions

MONOPOLIES AND MERGERS COMMISSION

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Note by the Department of Trade and Industry

In accordance with section 83(3) and (3A) of the Fair Trading Act 1973, the Secretary of State has excluded from the copies of the report, as laid before Parliament and as published, certain matters, publication of which appears to the Secretary of State to be against the public interest, or which he considers would not be in the public interest to disclose and which, in his opinion, would seriously and prejudicially affect certain interests. The omission is indicated by a note in the text.

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1 Summary

1.1. On 30 April 1992 we were asked to investigate the supply within the UK of contact lens solutions (CLS or 'solutions'): see Appendix 1.1. CLS are products used in the care of contact lenses, notably for cleaning, disinfecting, storing and rinsing. The reference covers all levels of supply: manufacturers and importers ('suppliers'), wholesalers and retailers.

1.2. Over 2 million people in the UK wear contact lenses and the value of the market for solutions is around £90 million at retail prices. Demand for solutions grew rapidly in the late 1980s but has slowed recently.

1.3. Government regulations play an important role in the CLS market. Two stand out—first, companies wishing to supply solutions have to obtain a product licence from the Medicines Control Agency (MCA) of the Department of Health (DoH), and secondly, CLS may only be sold at retail level by opticians and pharmacists because the MCA holds the view that expert advice should always be available at the point of sale. Opticians play a key role in the market because of the recommendations they make to customers at the time of fitting lenses. We estimate that opticians have about 60 per cent of the market at retail level, with the Dollond & Aitchison Group plc (D&A) and Boots Opticians Ltd (BOL), the two leading optical chains, taking about 10 per cent and 5 per cent respectively; and pharmacists 40 per cent, with Boots The Chemists Ltd (BTC) alone having 31 per cent. Because of the regulatory regime the UK is separate from the CLS markets in other countries.

1.4. The two leading suppliers are Allergan Ltd (Allergan), a subsidiary of the US company Allergan Inc, which has 38 per cent of the market; and CIBA Vision (UK) Ltd (CV-UK), part of the CIBA Vision group of the Swiss company CIBA-GEIGY AG, which has 34 per cent. Three other suppliers have shares in the range 6 to 9 per cent. Two of these are much stronger players in the CLS markets of certain other countries than they are in the UK. Few new products have been introduced in the last five years but retailers' sales of own-label solutions, which are simply 're-sleeved' versions of branded products, have risen sharply to take over a fifth of the retail market in 1992.

1.5. Among suppliers both Allergan and CV-UK are scale monopolists by virtue of the market shares quoted above. Allergan is the stronger company and has made very high profits over the past five years. We conclude that its pricing policy exploits its monopoly position and is against the public interest. The profitability of the CIBA Vision group on its UK CLS business has been modest in recent years and we have reached no adverse finding in relation to CV-UK's monopoly position.

1.6. At retail level BTC and BOL together (Boots) are a scale monopolist with 36 per cent of the market, far greater than the second largest retailer, D&A, with around 10 per cent. Boots buys CLS at the lowest prices of any retailer but sells all branded solutions at the recommended retail price (RRP) and gives only a small reduction, averaging 6 per

cent on a weighted basis, on its own-label solutions. As a result it enjoys substantial margins. We conclude that Boots' pricing policy for CLS is contrary to the public interest.

1.7. We also found a complex monopoly situation among retailers generally, in that a substantial majority of them (including Boots and D&A) sell branded solutions at or only just below RRP. We believe that many more retailers could sell branded solutions at less than the recommended price while still making a sufficient return, and that this situation too operates against the public interest.

1.8. We judge that the adverse effects we found would not exist, or would exist to a much lesser extent, if it were not for the regulatory regime. We found that the MCA product licensing regime has significantly slowed the introduction of new products on to the UK market, compared with other developed countries, with the effect of seriously inhibiting competition among suppliers. CLS will in the future be regulated under a recently-adopted EC Directive on Medical Devices, which is expected to lead to more products being allowed into the UK market, but this may not be fully implemented until 1998. There is also a lack of price competition among retailers which we consider would not be possible without the restriction on outlets.

1.9. Our preferred remedies therefore concern changes in that regime which would facilitate the entry of new products and new retailers and thus enable the market to work better. We recommend that the regulatory authorities should change the administration of product licences so as to give greater weight to factors influencing users' compliance with lens care regimes (ease of use, cost) and should implement the provisions of the EC Directive on Medical Devices well before 1998. We also recommend that the retailing of CLS should be opened up to all retailers who wish to sell them, subject to satisfying standards for storage and product recall.

1.10. If these recommendations are not adopted, we propose that direct price controls be placed on Allergan and Boots. Because of Boots' dominant position in the retail market, these controls would also stimulate price competition among retailers generally.

1.11. We found, finally, that many opticians give too little weight to the cost of particular types and brands of solutions in making their recommendations to customers, and fail to give customers information, before they decide to buy contact lenses, about the overall costs of lens care. We recommend that the relevant opticians' bodies should strengthen the guidelines they issue in order to deal with these deficiencies, and should monitor their observance.

2 The products, their regulation and their use

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History and development of contact lenses and contact lens care products

Contact lenses

2.1. Contact lenses are a removable form of lens worn directly against the eye. Like spectacles, their purpose is to correct defective vision but they have a number of advantages over lenses worn in frames in front of the eyes. In particular, they permit full peripheral vision; they produce little or no prismatic effect when the eyes move because the optical centre of the lens moves with the wearer's eye movements; and they cause minimal alteration in retinal image size. They also offer practical advantages; for example, they are generally more comfortable and safer to wear during sports and they do not steam up or get smudged or rain-spattered. An important consideration for many wearers is the natural appearance of contact lenses and the confidence they provide. Some are worn purely for cosmetic purposes; for example, tinted lenses can change the eye colour. Finally, a minority of users wear contact lenses for medical reasons; for example, following cataract surgery.

2.2. The first contact lenses, which were made of glass, were developed in the 1880s. It was not until around 1920, however, that they were produced commercially to correct visual defects. In the 1930s polymethyl-methacrylate (PMMA) was substituted for glass. These PMMA lenses are categorized as 'rigid' or 'hard' lenses.

2.3. The next development came in the late 1960s and early 1970s with the availability of more flexible polymers. Lenses made from these polymers are known as soft lenses or hydrogels since they consist of between 30 and 80 per cent water. Low water content lenses are made from polyhydroxethylmethacrylate. Medium and high water content lenses include extra materials such as polyvinyl pyrollidone and alkyl methacrylate. As the water content increases, the polymer becomes more oxygen-permeable, thus allowing the eye to 'breathe' more readily. For this reason, high water content lenses are generally more comfortable than those with low water content and can be worn for longer each day.

2.4. The extent to which oxygen can pass through a lens depends on the oxygen-permeability of the material and the lens thickness. Low water content lenses tend to be stronger than the higher water content lenses, but less oxygen-permeable. Higher water content lenses are correspondingly more fragile and more prone to accumulate deposits such as proteins. They also have a greater capacity to absorb preservatives (see paragraph 2.17) present in some contact lens solutions. These preservatives can accumulate in the lens and cause irritation to susceptible wearers.

2.5. Soft lenses tend to be more comfortable to wear than hard lenses and to fit more securely. They can accordingly be worn during vigorous activity such as contact sports.

2.6. In the 1980s an important modification was made to the rigid PMMA lens. By mixing PMMA with various substances such as fluorocarbons, or materials containing silicone, it was possible to create a rigid lens which nevertheless allowed oxygen to be transmitted through it to the cornea. These lenses are termed 'rigid gas-permeable' (RGP, or simply GP) lenses and have now largely superseded the original PMMA (or 'hard') lenses.

2.7. The Association of Contact Lens Manufacturers (ACLM) found that the majority of sales of lenses in 1991 was of low water content soft lenses; these accounted for 61.5 per cent of the total. High water content lenses accounted for 19.5 per cent of total sales in that year, and RGP lens sales for a further 17 per cent. The remainder (some 2 per cent) was of PMMA lenses. (These figures do not reflect the proportions of PMMA, RGP and soft lenses in the whole population of contact lens wearers because the mix of new fittings of lenses has been changing, particularly with the growth in popularity of soft, and especially disposable, lenses—see paragraph 2.62.)

2.8. Today, contact lenses can be used to correct a range of vision conditions, including myopia (short-sightedness), hyperopia (long-sightedness), astigmatism (distorted vision caused by an irregularly shaped cornea) and presbyopia (a loss of ability to shift focus between far and near objects; also called 'ageing eye').

Modes of contact lens wear

2.9. Most contact lenses, of all types, are worn on a 'daily-wear' basis; that is, they are removed at night and put back in again the next morning. Nevertheless, patterns of wear among those who remove their lenses overnight vary widely; for example, some people wear lenses only for sporting or social occasions, or only at weekends. Others alternate between contact lenses and spectacles. Since the introduction of more oxygen-permeable soft lenses, however, opticians have sometimes prescribed these lenses on a so-called 'extended-wear' basis; that is, the lenses would be worn continuously, including overnight, for a period of anything up to a month. The American company Johnson & Johnson in 1988 combined the concept of extended wear with that of disposability: its 'disposable' lenses were designed to be worn continuously for specified periods, usually of one week, and then discarded. Disposable lenses were made commercially viable by virtue of reduced manufacturing costs and the cost savings to the wearer resulting from the fact that the solutions normally required to clean and disinfect the lenses on removal (see paragraph 2.11) would not be needed for this form of extended wear.

2.10. Although disposable lenses worn on an extended-wear basis have the advantage of convenience and do not require the use of solutions, concern has been expressed in the optical and medical professions about the increased risk of ocular infection brought about by the wearing of lenses for extended periods and particularly overnight (see paragraph 2.74). As a result, extended-wear regimes are not widely employed in the UK, and when they are recommended, the period of continuous wear is usually no longer than one week. Instead, there has been a strong growth in 'frequent replacement lenses' which are designed to be worn on a daily-wear basis and to be replaced at planned regular intervals of between one and twelve months, depending on the regime prescribed. In this way, the lenses are discarded before lens deposits have built up; as a result, although daily cleaning and disinfection of the lens is still required, little or no specialist cleaning, ie protein removal, will be needed (see paragraph 2.13).

Contact lens solutions

2.11. A contact lens is a foreign body in the eye and increases the risk of ocular infection by interfering with the eye's natural defence mechanisms. The purpose of solutions is to clean, disinfect and condition (for example, lubricate) the lens, which is subject to contamination from handling, tears, materials such as cosmetics, soaps and hand creams, pollutants in the atmosphere and micro-organisms. Deposits of such materials on the lens surface can cause severe discomfort and irritation; they may also serve as a growth medium for micro-organisms. Use of appropriate solutions is intended to clean the lens, prevent the accumulation of deposits on the lens surface and render the lens free from microbial contamination, thus safeguarding ocular health.

2.12. Developments in solutions have followed advances in the lens market itself and particular types of solutions have been formulated for particular types of lenses. In accordance with UK regulations (see paragraph 2.24), all solutions should, however, be sterile and stable; non-toxic—that is, they must have no adverse effect on the eye if used in accordance with instructions and no serious or irreversible effect if not so used; be compatible with the type of lens being worn and able to maintain it in its original state; and, if marketed in multi-dose containers, should be so constituted as to be capable of remaining free of significant microbial contamination for a specified period after opening. Originally, the last requirement was met by the use of preservatives, but the development of preservative-free solutions has been an important feature of the market within the last ten years. Solutions also have to demonstrate efficacy and suitability for their intended purpose, such as disinfecting or cleaning.

2.13. Depending on lens type, solutions will be needed to carry out on a regular basis one or more of the following functions:

(a) *Surfactant cleaning.* This usually involves placing the contact lens in the palm of the hand (or between thumb and forefinger), adding a few drops of cleaning fluid, and then rubbing the lens gently to remove surface deposits; it is usually performed on a daily basis.

(b) *Disinfecting.* This is usually carried out after surfactant cleaning by immersion of the lens in the appropriate solution for a specified period.

(c) *Neutralizing.* Some disinfectants require neutralizing as a separate step before the lens can be inserted into the eye.

(d) *Rinsing.* The solution most frequently used for rinsing is saline and typically it will be used to rinse off a cleaning solution.

(e) *Soaking/storage.* A solution in which lenses are immersed to maintain them while not in use (the solution keeping the lenses disinfected and preventing dehydration).

(f) *Wetting and comfort.* These solutions are used typically with rigid lenses to aid insertion or to lubricate the lens during wear.

(g) *Periodic cleaning.* Typically the removal of protein deposits which have built up on the lens surface; it is usually recommended that this be performed on a weekly basis.

It should be noted that several of these functions, for example disinfecting and soaking/storage, may be performed by the same solution.

2.14. Some lens care products are marketed in tablet form. The CLS tablets are then made up into solutions by dissolving them in saline. We include these products in the term 'solutions' or 'CLS' throughout this report.

2.15. Apart from some disposable lenses worn on an extended-wear basis, all types of contact lenses require the use of solutions. Individual solutions are generally marketed as components of a 'lens care system' which consists of a range of solutions designed for one or more categories of lenses (PMMA, RGP or soft) and covering a number of different functions, as described in paragraph 2.13.

2.16. There are three quite different types of disinfecting systems:

(a) *Cold chemical system*. This system, which covers many products containing different chemicals and preservatives, is so called to distinguish it from the original system of disinfection by heating, now rarely used in the UK. The cold chemical system was an early form of disinfection for hard, RGP and soft lenses. It consists of a single disinfectant/soaking solution. After surfactant cleaning, the lens is rinsed with saline and soaked for four to six hours in the disinfectant (typically overnight) and then rinsed in saline before insertion. CLS in this system contain preservatives, which have a dual function: they disinfect the lens over the minimum recommended disinfection period and also act as a preservative for the product itself in order to prevent significant bacterial or fungal contamination when the bottle containing the solution has been opened. Commonly used preservatives in soft lens solutions are thiomersal and chlorhexidine, and in hard lens solutions, benzalkonium chloride. These antimicrobial agents have varying degrees of antifungal and antibacterial action. Preservatives such as these have been found to act as an irritant in a significant proportion of contact lens wearers, and in recent years there has accordingly been a move away from disinfecting systems using preservatives, particularly for soft lenses.

(b) *Hydrogen peroxide system*. This is now the most popular system of disinfection for soft lenses. The system typically consists of two solutions, a disinfectant and a rinse/neutralizer. After being cleaned with a surfactant cleaner and rinsed with saline, the lens is first soaked in a solution of hydrogen peroxide for a minimum of ten minutes. The second step is the neutralization (or breakdown) of the hydrogen peroxide, usually through soaking in the presence of a catalyst. This process may take from ten minutes to several hours or even overnight, depending on the particular product being used. The lens is then ready to insert into the eye. The neutralized solution is also used as a soaking solution for periods, for example overnight, when the lenses are not being worn, although lenses may be stored in unneutralized peroxide.

(c) *Chlorine system*. The chlorine system (which is used mainly for soft lenses) uses a disinfectant tablet dissolved in a saline solution. After surfactant cleaning and rinsing in saline, the lens is soaked in the chlorine solution for several hours. The chlorine solution also acts as an overnight soaking solution.

2.17. Products in the hydrogen peroxide and chlorine systems are almost all preservative-free in the UK (although preserved neutralizers are commonly available in other markets). In solutions other than disinfectants, preservatives serve the sole function of preserving the product itself from contamination. Because of the adverse reactions which some wearers experience as a result of preservatives being taken up by the lens—particularly a feature of soft lenses—suppliers have introduced new generations of solutions which are preservative-free. This has affected all types of solutions, and a wearer who is susceptible to preservatives will typically seek to use a full range of solutions which is preservative-free.

2.18. 'All-in-one' solutions combining cleaning, disinfecting and other functions for hard and soft lenses, based around older preservatives, have been available for a long time. The hydrogen peroxide system has generally been termed 'two-step' in the UK since two stages have hitherto been involved, disinfecting and neutralizing, whereas the chlorine system is a 'one-step' system. Recent developments in soft lens solutions, however, have included one-step hydrogen peroxide systems and all-in-one systems based on new, apparently less problematical, preservatives, under which the lenses are cleaned, disinfected and rinsed all in the same solution and sometimes also in one operation. Allergen's Oxysept 1 Step, for example, a one-step hydrogen peroxide system, was granted a UK product licence in 1992 and launched in January 1993. Other products of these types are available in a number of overseas markets but the manufacturers have been unable so far to obtain product licences in the UK (see paragraphs 2.28 and 2.29).

Regulatory framework

UK regulation

2.19. Before 1976 there were no statutory controls over the supply of contact lens solutions in the UK. On the basis largely of anecdotal reports, suspicion developed amongst optometrists and

ophthalmologists during the 1970s that infections in lens wearers could be related to use of ineffective or contaminated solutions. The result was the commissioning by the Department of Health and Social Security (DHSS) of a study at the University of Bath into the antimicrobial effectiveness of the then available care products. A high proportion was found to be defective, and this led to the setting up of a DHSS Working Party. A joint Statement of the Committee of Ophthalmic Opticians, Faculty of Ophthalmologists and DHSS was issued in 1975, and the following year an Order under the Medicines Act 1968 brought CLS under licensing control (see paragraph 2.24).

2.20. The Medicines Act 1968 requires, subject to certain exemptions, that a product licence be held before a medicinal product can be sold or supplied. Licensing is also applied to wholesale dealing, manufacture and assembly. Whether or not a product licence is granted is determined on the basis of quality, safety and efficacy and on no other criteria. The MCA (see paragraph 2.23) told us that considerations of cost, need and comparative efficacy were not permissible. The critical judgment was a risk:benefit assessment based on the condition for which the treatment or prophylaxis was intended.

2.21. Part III of the Medicines Act controls the sale or supply of medicinal products. It provides for Ministers to specify by Order two categories of medicines, prescription-only medicines (POM) (section 58) and general sale list (GSL) medicines (section 51). Medicines not designated as POM or GSL are only available for sale or supply through pharmacies and are classed as Pharmacy (P) medicines although there is no specified list of these medicines in UK legislation. Patient safety is the main guideline for classifying medicines. GSL classification is intended only for circumstances in which reasonable safety can be assured in the absence of professional advice. Eye drops and eye ointments are specifically excluded as a general product type from the GSL Order.

2.22. A further key provision of the Medicines Act is that, although 'medicinal product' is defined (as 'any substance or article ... for use by being administered to one or more human beings ... for a medicinal purpose'), the Act's provisions can be applied to products which are not medicines if it is considered that medicines-type controls are appropriate, normally for reasons of public health. The decision taken in 1975/76 (see paragraph 2.19) was that solutions should fall into this category.

2.23. The UK Health Ministers are the Licensing Authority responsible for administration of the Medicines Act, and the MCA operates as the agent of the Licensing Authority in fulfilling its responsibilities for medicines for human use under the Act. The MCA was established in 1989 by the reorganization of the Medicines Division of the DoH. One of the main reasons why it was set up was to speed up the processing of applications for licences. A new fee structure was introduced, designed to cover most of the running costs—previously fees had covered only about 60 per cent. This meant that there was a considerable increase in licence application fees. The Act makes provision for a Medicines Commission and other committees to be established to advise the Licensing Authority. Currently there are two advisory committees, the Committee on Safety of Medicines, which gives advice on the majority of medicinal products, and the Committee on Dental and Surgical Materials (CDSM), whose remit includes contact lens care products. The CDSM, appointed by Ministers, consists of independent experts, including surgeons, optical practitioners (see paragraphs 2.44 to 2.46), dental surgeons, and materials and pharmaceutical specialists.

2.24. The Order which brought CLS under licensing control, the Medicines (Specified Articles and Substances) Order 1976, also encompassed contact lenses, but this aspect of the Order has not been activated. So far as solutions were concerned, licence applications had to be submitted for all new products from 1 January 1980 and all products on the market from 1 July 1983 have had to be licensed.

2.25. By the deadline of July 1983, 141 applications for product licences had been submitted. The CDSM was obliged to introduce special procedures to cope with the number of applications and the number of appeals. Over 50 per cent of applications for a product licence were successful, ie they were adjudged to be of adequate quality, safety and efficacy. Inadequate products were distributed fairly evenly across product groups rather than being confined to a single type. The end result was that a number of unsatisfactory products were withdrawn from the UK market.

2.26. There was also the separate question of the permitted distribution channels for solutions. The view of the CDSM at the time was that the availability of professional advice at the point of sale of

solutions was essential. The two professions considered able to give such advice were opticians and pharmacists. However, opticians are not included as practitioners within the scope of the Medicines Act 1968. Accordingly, solutions could not be allocated to one of the three legal classifications for supply purposes, P, POM or GSL, if supply was to include opticians as well as pharmacists. Strictly speaking, therefore, solutions have no legal status under Part III of the Medicines Act (see paragraph 2.21). In practice, Medicines Act control over supply is achieved through a process under which the applicant for a product licence has to specify the route of supply. The only routes which have been approved are ophthalmologists, ophthalmic and dispensing opticians and registered pharmacies. On the two occasions on which applicants have sought a wider range of supply routes, the CDSM has ruled that the current restrictions should continue to apply.

2.27. During the course of our inquiry, the MCA consulted the CDSM again on the question of the route of sale or supply of solutions. The CDSM referred the matter to a working party which met on 4 February 1993; that working party took the view that on grounds of safety the current restriction should be maintained (see also paragraphs 5.15 and 5.18).

2.28. Manufacturers wishing to obtain a product licence for solutions must apply to the MCA, which registers the application and establishes that the necessary data in support of the application have been supplied. The application is then passed to a multidisciplinary team of assessors. If the assessors are satisfied as to the quality, safety and efficacy of the product, the licence will be granted. 85 per cent of all applications received by the MCA are granted a licence on this basis.

2.29. If the assessors are not satisfied, however, then the application is considered by the CDSM, which will have taken the advice of its subcommittees (chemistry, pharmacy and standards, and safety and efficacy) as necessary. The CDSM may then advise the Licensing Authority to grant a licence, request further information or refuse a licence. It may also recommend the grant of a licence on terms more restrictive than those requested by the applicant. For example, an applicant for a licence in respect of a solution to be used for disinfecting and rinsing of soft lenses may obtain a licence in respect of rinsing only. There is a right of appeal against refusal to grant a licence, firstly to the CDSM and, if unsuccessful, then to the Medicines Commission.

2.30. Apart from licensing, the range of MCA activities covers monitoring, inspection and enforcement, and contribution to developing EC legislation in relevant product areas. Since 1988, monitoring has included the Optometrists Yellow Card scheme under which adverse reactions to lenses or associated care products are submitted and assessed.

2.31. The MCA has clear time targets for processing applications and progress is reviewed frequently. Licence applications for solutions are now quickly picked up following validation (a check for correctness and completeness of the submission) and processed within three months if no committee advice is needed and within around six months if CDSM consultation is required (see paragraph 2.29). The MCA seeks to record the 'net' processing time of applications, ie excluding any time spent by the applicant in furnishing additional data or responding to deficiencies. The 'gross' time taken to obtain a licence can therefore greatly exceed these times. Assessment involves, *inter alia*, checking the proposed legal status and route of sale or supply, and an application would be referred for CDSM advice if a route other than through pharmacies or opticians were requested.

2.32. The costs of licensing work are borne by the applicants in the form of licensing charges. The principle that fees should be commensurate with the resource costs of assessment work is now well established and has the support of Ministers. Fees for licence applications vary greatly, according to whether or not a new active substance is being submitted. Most solutions are, however, classed as 'standard abridged' applications and attract a fee of £7,385. Simple or 'piggyback' applications require a fee of £2,090. In cases where a new route of administration or novel formulation render an application 'complex', the fee is £17,800. If a new active substance (NAS) is incorporated in a solution (ie a new substance never before used in humans), then despite the greater scientific and toxicological work involved, a concessionary fee of £17,850 is charged, compared with the £97,500 which would be imposed for an orthodox pharmaceutical. The MCA also levies an annual service charge which in the case of the majority of solutions is up to £265, depending on turnover of sales. Where the original application attracted a 'complex abridged' fee, or the 'concessionary NAS' fee applied and the product has a specified minimum turnover, the annual service charge is £5,275 for the first three or five years, respectively, after the licence is granted.

Specific regulations governing solutions

2.33. Regulations governing the labelling of solutions are set out in The Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979. Among its provisions are that certain particulars shall be shown on the label of the container holding the solutions or on the package holding the container or in a separate leaflet: for example, a recommended period within which the substance should be used after the container has been opened; and a warning in capital letters: 'Do not mix with other fluids except as directed'. A copy of these Regulations is in Appendix 2.1.

2.34. The Schedule to the Medicines (Contact Lens Fluids and Other Substances) (Advertising and Miscellaneous Amendments) Regulations 1979 lists the particulars which must be included in information sheets (advertisements) sent to pharmacists and opticians relating to CLS. They cover matters such as the active ingredients in the solution, the compatibility and incompatibility of the solution with different types of contact lenses, the possibilities of interaction between the solution and any lenses or other substance commonly applied to the eye, and the recommended period within which the solution should be used once the container has been opened (usually referred to as the 'in-use period' or the 'recommended period of use'). A copy of these Regulations is at Appendix 2.2.

2.35. The MCA issues guidance notes for applicants seeking product licences for solutions as part of its general guidelines for licence applicants. In the guidance on container size, it is stipulated that, among other matters:

> The volume in the container of a product intended for use on more than one occasion should normally be sufficient for not more than 28 days' use. Data should be provided to show the average rate of use of the product. If a period of use in excess of 28 days is proposed additional data will be required to show the suitability of the product for that longer period of use, unless a suitable pressurised delivery system is used.

A copy of the guidance notes is at Appendix 2.3.

EC legislation

2.36. In 1991 the EC embarked on a series of measures to harmonize the different national regulations governing medical devices so as to minimize barriers to trade in the forthcoming single European market. The measures comprise a number of directives, which cover a wide range of devices as diverse as powered implants, cotton swabs and X-ray machines. One of the directives, the general Directive on Medical Devices (the Directive), which includes contact lenses as 'devices', also brings accessories to medical devices within its scope. These are articles, of which CLS are examples, which are intended to be used with medical devices to enable those devices to be used as specified by the manufacturer. Although some products such as in-eye drops will remain as medicinal products, the majority of solutions will be regulated by the provisions of the Directive and will fall outside Medicines Act control. The current licensing system for solutions will accordingly cease to apply. A copy of relevant parts of the Directive is at Appendix 2.4.

2.37. The Directive had not been adopted at the time we completed our report, but a Common Position was reached by the EC Council of Ministers on 8 February 1993 and its provisions will take effect as from 1 January 1995. Member states will be required to bring in measures necessary to implement the Directive within five years from the date on which the Directive is published in the Official Journal of the EC. In the UK, the Directive's provisions are likely to be given effect through regulations made under the European Communities Act 1972 and the Consumer Protection Act 1987. The competent authority will be the Secretary of State for Health acting through the Medical Devices Directorate (MDD).

2.38. Once the Directive is in force, all medical devices covered by it will have to conform to the 'essential requirements' laid down in the Directive as to their design and construction before they can legally be placed on the market. They will have to bear a CE (Communauté Européenne) mark to show that they do so conform. Work is currently in progress to establish common standards in Europe and there is still considerable uncertainty as to the precise standards which will apply to solutions.

2.39. The forthcoming control of solutions under devices rather than pharmaceutical regulation will mean that the current restriction on retail outlets in the UK, and the labelling regulations, given effect through the Medicines Act, will no longer be enforceable under that piece of legislation. The Government has yet to decide what action it can and will take on these matters in the context of the Directive.

2.40. From 1 January 1995, when the provisions of the Directive take effect, until the end of the transitional period, manufacturers marketing solutions in the UK may choose whether to follow existing Medicines Act controls or to follow the provisions set out in the Directive. Since common standards have yet to be agreed (see paragraph 2.38), it is difficult to assess at this stage when the impact of the new system will be felt in terms of approval being given to particular solutions products.

2.41. It is widely considered that the UK product licensing standards for CLS are as stringent as any in the world and certainly more stringent than those prevailing in a number of other EC member states. It is likely therefore that solutions currently licensed by the MCA would succeed in meeting the new European standards. By the same token, it is possible that certain products without a UK product licence, which are marketed in other member states, will succeed in gaining entry to the UK market under the harmonized arrangements.

2.42. A further consequence of the replacement of the current regulatory regime for solutions by the provisions of the Directive is that the guidelines contained in the British and European Pharmacopoeias respectively will no longer apply to solutions. This is because the pharmacopoeias relate mainly to medicinal products, the Directive to devices. Solutions will have to conform with the essential requirements of the Directive by means of compliance with harmonized technical standards (which could, however, incorporate criteria similar to those in the pharmacopoeias). Some relaxation of the existing guidelines on preservative efficacy—the presence of an antimicrobial agent to prevent in-use contamination of the product—has taken place recently with the replacement of the British by the *European Pharmacopoeia* guideline on preservative efficacy. The revised preservative criterion will, however, affect solutions used prior to disinfection, such as cleaners and drops which go directly into the eye. The European guideline is more permissive than the British guideline and there is the possibility that some products which had not satisfied the British guideline will comply with its replacement. There are no pharmacopoeial guidelines on the disinfective capability of a product and so that performance characteristic will continue to be covered by UK performance criteria for the time being.

Role of opticians and pharmacists

2.43. As noted in paragraphs 2.26 and 2.27, the only permitted retail routes of supply for solutions in the UK are through opticians' practices and pharmacies. The role of the optometrist and dispensing optician is particularly important since he or she first prescribes and fits contact lenses and recommends the care system for the patient. Thereafter, the wearer may continue to purchase solutions from his or her practitioner (particularly if some sort of discount or lens replacement scheme is offered—see paragraphs 2.68 and 2.69), from other practitioners or from pharmacies.

Optical practitioners

2.44. Optical practitioners may be either optometrists or dispensing opticians. In order to practise as an optometrist or dispensing optician in the UK, it is necessary to be registered with the statutory body, the General Optical Council (GOC). Ophthalmic medical practitioners are fully-qualified doctors who specialize in the care of eyes. They are qualified to test sight and to prescribe spectacles and other appliances.

2.45. Optometrists, also known as ophthalmic opticians, are qualified to test sight and to prescribe and dispense spectacles and other appliances. Although trained to recognize abnormalities and diseases of the eye, they will refer these to the patient's medical practitioner or to hospital for treatment. The study of contact lenses is part of the training for optometrists, who are accordingly entitled to fit them once qualified. There is a higher diploma—the Diploma of Contact Lens Practice—which may be taken by optometrists wishing to specialize in contact lens practice.

2.46. Although the qualification of dispensing opticians entitles them to dispense, fit and supply spectacles, an additional qualification is required before they may fit contact lenses. This qualification is a specialist certificate awarded on examination by the Association of British Dispensing Opticians (ABDO), and a dispensing optician must obtain this speciality before being legally entitled to fit contact lenses. Some dispensing opticians established their experience and expertise with the GOC, and were granted certification based on that experience and expertise. Such certification was a transitional provision and the additional specialist qualification is now required.

2.47. Those wishing to begin wearing contact lenses will first need to undergo an eye examination. This will be carried out by an optometrist (or sometimes by a medical practitioner) and a separate fee is usually charged. The optometrist will assess the suitability of the patient for contact lens wear and consider which sort of lenses would be most suitable. The costs of the different lenses and of the necessary aftercare should be discussed with the patient at this stage (see the British College of Optometrists' (BCO) Guidelines, paragraph 2.53). If the patient decides to proceed, the optometrist issues a prescription. The fitting may be carried out either by an optometrist or by a dispensing optician, often members of the same practice. The patient will be shown how to insert and remove the lens and the aftercare products and procedures will also be explained.

2.48. The practitioner will often offer a free 'starter pack', consisting of small quantities of a range of solutions in the system of lens care which is recommended. Sometimes opticians will 'mix and match' solutions removed from different brands of starter pack, if they consider that particular products from different suppliers are clinically more suitable. Starter packs are provided free to opticians by their suppliers who hope that new patients, once started on their products, will continue to use them. From the new patient's point of view starter packs enable him or her to become accustomed to the aftercare system prescribed and readily to identify the solutions for subsequent purchase. At least one follow-up visit to the practitioner is usually made between two and four weeks after the initial fitting, so that any problems or queries can be dealt with. Statutory rules relating to opticians require them to provide aftercare for a minimum of six months after fitting. As explained in paragraph 2.68, it is common for patients to enter into some type of scheme which covers both the initial fitting of the lenses and aftercare visits for a predetermined period, typically six months or a year.

Professional conduct of optical practitioners

2.49. The BCO and ABDO are the professional bodies for ophthalmic and dispensing opticians respectively. Their public benefit roles include an examining function and the preparation and oversight of ethical guidelines which are set out in the codes of ethics and guidelines for professional conduct issued by them. Other professional bodies (including the Association of Optometrists (AOp) and the Federation of Ophthalmic and Dispensing Opticians (FODO)) have endorsed these guidelines. The GOC, which is the statutory body charged with promoting high standards of professional conduct, and the disciplinary body in the event of malpractice, has accepted these codes as representing the peer group view of proper professional conduct. The GOC has also made statutory rules with respect to the qualifications of opticians and other matters relating to contact lenses.

2.50. Chapter 5 of the BCO 1991 Code of Ethics and Guidelines (see Appendix 2.5) deals with contact lens practice. Paragraph 5.1.1 states that:

> Contact lens practice is a field where developments occur rapidly. Practitioners should therefore make every effort to keep abreast of these changes and, if they do not possess the right qualifications, give priority to achieving them. This is especially important because contact lenses, unlike spectacles, can induce changes which may have deleterious effects on vision and eye health.

2.51. Paragraph 5.3.1 states:

> For new contact lens patients the following procedures are usual:
>
> *(a)* assessment of suitability (including diagnostic and tolerance tests);

(b) issue of directions to fit, where appropriate;

(c) fitting lenses;

(d) dispensing lenses (including instruction on the safe insertion and removal of the lenses from the eyes together with an explanation of hygiene regimes); and

(e) aftercare.

2.52. Paragraph 5.6 deals with fitting and supply and imposes, *inter alia*, the following obligations on the optometrist:

In this stage of the procedure it is important to establish for each individual patient:

(a) the best possible vision;

(b) maximum comfort and appropriate wearing times;

(c) his or her minimal ocular response to contact lens wear; and

(d) an appropriate hygiene regime.

2.53. Paragraph 5.14 deals with contact lens fees and charges, and stresses the importance of making clear to the patient the ongoing costs which will be involved:

> Contact lens services to the public involve a range of essential functions, all of which, in the patients' best interests, must be carried out, but not all of which can be carried out in a single transaction, as in the supply of spectacles. It is essential, therefore, that before patients are asked to commit themselves to being supplied with contact lenses, they understand precisely what costs and fees will be involved both on supply and on a continuing basis. Where a single fee is charged it should be made clear what services will be covered by that fee, with particular reference to the length and nature of aftercare to be provided. It is professionally unacceptable to seek to attract patients by publicising a single fee for the supply of contact lenses when the fee does not cover all the services necessary to the supply.

Pharmacists

2.54. As noted earlier (paragraphs 2.26 and 2.27), it is the view of the CDSM that professional advice at the point of sale should be available to the purchaser of solutions, in view of the potential damage to the eyes that can result from misuse of solutions or from use of the wrong solution for a particular type of lens. It is expected that the availability of a pharmacist at the point of sale will enable consumers to obtain either specific advice about the solutions they are intending to purchase or at the very least a recommendation that the customer seek the advice of his or her optician before purchasing a particular solution. Pharmacists are also expected to be able to answer queries about the compatibility of solutions with certain other products (for example, eye drops or certain medicines) and about whether lenses should be worn while the wearer is suffering from certain medical conditions or taking certain medicines. They should also be able to recognize symptoms described by the customer that require medical or ophthalmic referral and should advise accordingly.

2.55. All retail pharmacy premises are required to be registered with the Royal Pharmaceutical Society of Great Britain (RPSGB) and whenever open for business must be under the personal control of a pharmacist. The RPSGB has powers to take action against pharmacists and pharmacy owners if professional standards are not met, and it issues guidelines on good pharmaceutical practice. In order to dispense National Health Service (NHS) prescriptions a retail pharmacy must also obtain a contract with the appropriate authority, previously the local NHS Family Practitioner Committee

(FPC) and now the local Family Health Service Authority (FHSA) in England and Wales and the Health Board in Scotland. Before October 1987 all pharmacists or companies meeting the specified legal requirements applying to the local FPC were awarded an NHS contract and permitted to set up a pharmacy. Following amendment of the NHS (General Medical and Pharmaceutical Services) Regulations with effect from 1 April 1987, an applicant to an FHSA or Health Board for admittance to its list must now show that a new pharmacy is necessary or desirable for the proper provision of pharmaceutical services in the area. These controls were introduced in order to limit the number of retail pharmacies so as to ensure a cost-effective system of distribution of prescribed medicines, and to reduce the practice of 'leap-frogging', whereby new pharmacies would be opened up close to a doctor's practice when a site became available whether or not there was a need for an additional pharmacy.

2.56. Pharmacists' training includes a three- or four-year undergraduate course followed by a year's postgraduate training. The undergraduate curriculum includes microbiology, pharmaceutics and the whole area of bacterial infection; this would include study of products for use in the eye. Those who undertake their pre-registration training in community pharmacy would gain more direct experience of contact lenses and solutions. Once qualified, the main vehicles for the pharmacist's continuing education and advice about solutions are *The Pharmaceutical Journal* and the *Chemist & Druggist*, which periodically feature articles on lenses and solutions. The subject would also be discussed from time to time at branch meetings throughout the country.

2.57. For assistants in pharmacies, the National Pharmaceutical Association (NPA) runs a training course for counter staff in pharmacies. Solutions would be covered as part of the general training on eye products. *The Pharmaceutical Journal* and the *Chemist & Druggist* also publish supplements specifically directed at pharmacy assistants, and the subject of contact lenses has been covered in such articles. The NPA also produces a comprehensive information leaflet which it makes available to its members.

2.58. Solutions are generally located in an area of the pharmacy near to or in sight of the pharmacy counter itself. The RPSGB has told the MMC that it expects solutions to be available for self-selection in pharmacies but to be placed on shelves adjacent to the medicines counter so that they are grouped with medicinal products rather than with cosmetic items.

2.59. One of the obligations set out in the Code of Ethics of the RPSGB (Obligation 1.12) relates to participation in the promotion of medicines:

> A pharmacist must not participate in any promotional methods or campaigns which:
>
> *(a)* encourage the public to equate medicines with ordinary items of commerce;
>
> *(b)* encourage a person to buy more of a medicinal product than is needed;
>
> *(c)* involve benefit to a charity dependent upon the purchase of a medicine;
>
> *(d)* undermine the exercise of professional judgement by the pharmacist or any other health care professional.

Numbers and characteristics of users

2.60. It is estimated that there are currently over 2 million contact lens wearers in the UK. According to an analysis in a Market Intelligence Report of May 1991 by Mintel Publications Ltd based on the British Market Research Bureau (BMRB)'s Target Group Index consumer market research data base, over half of all adults in the UK in 1990 wore spectacles, while only 4.1 per cent wore contact lenses. The data showed that women were more likely to wear contact lenses than men and that contact lens wear was much more prevalent among the under-45 age groups; it was most popular among the 25- to 34-year-olds. Contact lens wear was significantly less common among the over-55-year-olds. Contact lens wearers also tended to occupy the higher socio-economic groups, since whereas only 1.8 per cent in group E were found to be wearers, there were 6.3 per cent in groups AB.

Regional differences in the prevalence of contact lens wear were not marked, London having marginally the highest proportion of wearers.

2.61. The MMC's own survey of contact lens wearers was carried out for it in September 1992 by the BMRB (see Appendix 3.10). The BMRB had available from its Target Group Index a list of about 2,500 individuals known to have been wearing contact lenses in the last 2½ years. For the MMC's study, the BMRB carried out a telephone survey using a sample of 792 current contact lens wearers from this list.

2.62. In the MMC's survey, 53 per cent of the sample wore only soft lenses, 32 per cent used RGP lenses only, 9 per cent used only hard lenses, and the remainder used more than one lens type. 70 per cent of the sample wore lenses seven days a week, and 61 per cent of the sample used their lenses for 12 hours or more on each day they wore them.

2.63. 50 per cent of wearers in the MMC's survey had at some time changed one or more of the solutions they used; of these, over two-thirds had done so since 1989. 25 per cent of those who had switched gave as their reason that the new solution was cheaper than the one which had been replaced. 16 per cent of wearers had considered changing solutions but in the end had not done so. Over half of these said that they had considered changing because of the cost of their existing solutions.

2.64. A proportion of wearers of newly-fitted contact lenses decides not to continue wearing them after an initial trial over a short period. This may be for reasons of discomfort, inconvenience, cost, change of lifestyle or other factors. AOp told the MMC that approximately 5 per cent of patients stop wearing contact lenses within a year of purchasing them.

Opticians' recommendations, costs to consumers and compliance

2.65. Optometrists and dispensing opticians normally recommend a particular type of lens care system for their patients when prescribing contact lenses. They will usually also specify a brand.

2.66. The MMC arranged for their own survey of opticians to be carried out on their behalf by Research Surveys of Great Britain (RSGB) (see Appendix 3.8). They asked opticians, *inter alia*, to state the three most important reasons for recommending a particular disinfecting system. The MMC found that 78 per cent of them gave 'solution effectiveness' as one of the most important reasons for their recommendation of particular solutions for all three types of lenses. Other highly rated reasons were that the solution was 'less likely to cause irritation' than others and that it was 'easy to use'.

2.67. Around one-quarter of opticians in the MMC's survey gave 'reasonable cost to the customer' as one of the three most important reasons for their recommendation of solutions for all three types of lenses.

2.68. The annual costs of wearing and maintaining contact lenses vary considerably depending upon the type of lens purchased, who supplies them and the care system adopted (see paragraphs 3.191 to 3.196 for an assessment of the theoretical costs of solutions). Our survey of contact lens wearers found that, amongst those who wore their lenses seven days a week, the average actual cost of solutions varied from £50 a year for some wearers to over £200 a year for others (see Appendix 3.10, paragraph 15). The lower of those figures is considerably less than our estimated annual cost of £120 (not including protein remover) for the cheapest care system for soft lenses (see paragraph 3.192) and of £110 for the cold chemical system for hard/RGP lenses (again excluding protein remover) (see paragraph 3.195). These comparisons may lend support to the widely held view that non-compliance with care regimes is a feature of contact lens wear (see paragraph 2.71). In addition to these costs are the optician's fee for the eye test and initial fitting of the lenses and subsequent aftercare checks. Many opticians offer schemes under which an all-in fee is charged for the lenses and for a fixed number, or as many as are required, of aftercare visits during an initial period, often of one year. Opticians may also, or alternatively, offer discount schemes which entitle the wearer to discounts on the purchase of solutions on payment of an annual fee.

2.69. As already noted (paragraph 2.10), many wearers are offered frequent replacement schemes under which their lenses are replaced on a planned, regular basis, before deposits have built up. These schemes take a variety of forms and may or may not include solutions in the overall cost. Aftercare and compliance with hygiene regimes are likely to be reinforced by patients re-attending their optical practice at set intervals to collect replacement lenses.

2.70. Of the opticians in the MMC's own survey, a little under half operated a customer discount scheme, and the same proportion operated some kind of frequent replacement scheme.

Compliance

2.71. It is widely acknowledged in the professions involved in eye care and amongst manufacturers and retailers of solutions that failure to comply fully with care regimes is a serious and significant problem associated with contact lens wear. There are a variety of reasons why wearers fail to adhere to the regime of regular cleaning and disinfection of their lenses. The most commonly cited are the complexity of many care systems; the fact that they are demanding to follow in terms of the time involved and the regularity with which they must be carried out; failure on the part of wearers to understand fully the purpose of particular components of the care system, sometimes leading to misuse; and the cost of solutions.

2.72. We explored the extent to which wearers comply with lens care regimes in our survey of contact lens wearers (see Appendix 3.10). Although high percentages of wearers in the survey said that they cleaned their lenses every day on which they were worn, always used fresh solution for disinfecting and storing their lenses, and always used the recommended amount of solution, only two-thirds of our sample said that they never used their solutions after the use-by date. When we asked wearers how long their solutions normally lasted, a significant number was found to have used them longer than their use-by date. Our findings suggest that wearers are not as compliant as they think and that inertia and the cost of solutions are significant reasons for non-compliance.

2.73. Some wearers seem to escape obvious ill effects as a result of non-compliance with their lens care regime, but the consequences of failure to clean and disinfect lenses can range from irritation and discomfort to serious eye infections. Among the conditions which poor hygiene can encourage are 'red eyes'; allergic conjunctivitis, which is characterized by itchy eyes and a mucous discharge; corneal vascularization, a condition in which the blood vessels have begun to grow into the cornea; and microbial keratitis or corneal ulcer, the most serious and potentially sight-threatening complication, usually caused by bacterial or amoebic infection of the cornea.

2.74. The risks of corneal infection are now known to be significantly increased by the use of extended-wear lenses (see paragraph 2.10). It is thought that one of the factors that compromises the eye's ability to resist infection when extended-wear lenses are being worn is the restriction on the access of oxygen to the cornea. The recent steady increase in the numbers of cases of microbial keratitis among contact lens wearers is currently being investigated by a working party set up by the MDD.

2.75. Solutions manufacturers are continuously looking for ways to improve compliance by the development of simpler systems, typically systems in which two or more different functions are carried out by one solution or one process or both (see paragraph 2.18). At the same time, lens manufacturers have been developing the idea of a truly disposable lens which is used once, perhaps only for a few hours, and then discarded (see paragraph 2.87); this would overcome the need for any cleaning or disinfection of the lenses and hence for most solutions, except possibly comfort drops for lubrication purposes.

Compatibility between different brands of solutions

2.76. As already noted (paragraph 2.15), solutions are usually marketed as parts of complete lens care systems. Typically, suppliers of solutions will have one or more care systems for soft lenses and one or more for RGP and hard lenses. Some solutions, particularly surfactant cleaners, protein

removers and salines, may be recommended for use in more than one system. For example, one of the leading manufacturers, Allergan, has two systems for soft lenses: the Oxysept system which is available either as a one-step or a two-step hydrogen peroxide system, and the Hydrocare system, which is a cold chemical (preserved) system. With its Oxysept system Allergan recommends use of its daily surfactant cleaner LC-65 and its Ultrazyme tablets for weekly protein removal. With Hydrocare, it also recommends LC-65, but a different protein remover, Hydrocare Fizzy tablets. Allergan's saline solutions, Lens Plus and Oxysept, can be used to dissolve both Ultrazyme and Hydrocare Fizzy tablets and to rinse off LC-65. (Allergan also has systems for RGP and hard lenses.)

2.77. Again, retailers with own-label solutions typically buy solutions to make up a complete range and market them as parts of complete systems. For example, D&A, the largest multiple retailing optician, has a range of five lens care systems which it markets under the brand name One-2-One. These comprise a hydrogen peroxide system, One-2-One Rapide, which it markets as suitable for all types of lenses; a chlorine system, One-2-One Freshtab, for soft lenses only; and three cold chemical disinfecting systems for RGP and hard lenses only. Two different surfactant cleaners are recommended for use with one or other of the cold chemical disinfecting systems, depending on lens type, but D&A's saline can be used with any of its systems while protein remover can be used with either of the soft lens systems.

2.78. The question of compatibility between solutions arises in practice where contact lens wearers who may have been recommended a particular branded system by their optician wish to consider switching to another brand within the same system. Alternatively, they may wish to 'mix and match', ie to change some but not all of the brands within their existing system, possibly because the alternatives appear to be cheaper or because their existing solutions are causing irritation or discomfort. Or they may wish to change their lens care system.

2.79. There have been instances where patients have suffered a severe allergic reaction on switching systems. These have particularly involved lenses where the water content is 55 per cent or above. Very often, the reaction is not brought to the practitioner's attention until the patient notifies him or her of problems.

2.80. The extent to which it is safe to use solutions which are part of a system supplied by one manufacturer with those which are part of a system supplied by a different manufacturer is a complex question. It is not only the chemical compatibility between the solutions themselves which has to be taken into account, but also the effect of different solutions on the type of lens which is being worn and the effect of possibly different chemicals (eg preservatives) on the wearer's eyes. As already noted (paragraph 2.33), the UK labelling regulations reflect a general concern about mixing solutions together unless specifically directed: all solutions must carry the warning 'Do not mix with other fluids, except as directed'. The MCA told us that this warning was intended to alert wearers to the potential problems of physically mixing solutions, whether those solutions were of the same or different brands, or were fluids not intended for contact lens care, unless the instructions indicated that it was safe to do so. A number of suppliers of solutions, however, told us that they thought the warning referred to the use of one brand of solutions with another as part of a single lens care system.

2.81. Behind the warning against mixing solutions, however interpreted, is the presumption that, quite apart from instances where the supplier is aware that his product is incompatible with specific products of his competitors (see paragraph 2.83), suppliers are not generally in a position to know whether their products are compatible with those of their competitors since they do not know the precise chemical make-up of those products.

2.82. Some suppliers' solutions, typically salines packaged in aerosol cans, certain surfactant cleaners and protein removers are marketed as being suitable for all types of contact lenses or as compatible with all contact lens disinfection systems. For example, the instructions on Allergan's surfactant cleaner LC-65 state that it is 'suitable for use with all types of contact lenses and is compatible with all contact lens disinfection systems'. In other cases, the instructions on the pack may imply that the lens wearer is free to choose another brand. For example, the instructions on the pack of surfactant cleaner Miraflow, the product of another leading supplier, CV-UK, state: 'If Miraflow cleaning solution has been recommended by your practitioner, use as instructed prior to disinfecting your lens', suggesting that other surfactant cleaners might equally well have been recommended as

suitable. This comment also indicates that the use of a surfactant cleaner may not be recommended by all practitioners to all patients.

2.83. Problems of incompatibility are most likely to arise in the case of disinfecting systems. In particular, the two solutions which form a two-step hydrogen peroxide system are developed to be used together and the disinfecting solution of one brand may not be compatible with the neutralizing step of another brand. The use of incompatible products could, for example, lead to insufficient neutralization of the peroxide and hence severe pain when the lens is inserted in the eye. Another example of incompatibility arises when the neutralizing step of one brand is carried out with the lens case designed for use with another brand. Thus if Allergan's Oxysept 2 is used in a CIBA Vision lens case, the generation of more gas than the CIBA Vision case has been designed to withstand may lead in some cases to the fracturing or explosion of the case. Other problems may arise from switching lens cases, where the new lens case is more prone to accumulation of fungal growths than the existing case had been and rigorous cleaning is not undertaken.

2.84. Where a manufacturer produces own-label solutions for another supplier or a retailer, those solutions are usually identical with the manufacturer's branded product—for example, CIBA Vision's hydrogen peroxide 10.10 is currently identical with and could be mixed with the components of Boots' and D&A's own-label versions of this product. Similarly, the protein removal tablets which Allergan produces for Boots' own-label are exactly the same as its own Hydrocare Fizzy tablets. A list of suppliers' solutions and the identical solutions produced for other suppliers or retailers is at Appendix 2.6. Own-label retailers may hold their own product licence or may be included as a named distributor on the supplier's product licence. In the latter case, the same product licence number will appear on the packaging of both products.

2.85. The view of the optical and pharmaceutical professions is that contact lens wearers should switch brands of CLS only on the advice of their practitioner, who has the information, expertise and experience needed to make a judgment about compatibility.

Future developments

2.86. A number of factors will determine the size and strength of the future solutions market. As already noted, manufacturers are looking for ways to simplify aftercare systems, principally by reducing the number of separate operations required to carry out all the necessary care functions. Certain other one-step peroxides and all-in-one disinfecting and cleaning solutions are available in overseas markets and may in due course become available in the UK (see paragraphs 2.18 and 2.41).

2.87. Developments are also taking place in contact lenses themselves (see paragraphs 2.9 and 2.10). A truly disposable contact lens, worn once, perhaps only for a few hours, and then discarded, would remove the need for cleaning or disinfecting solutions altogether. Since some of the current problems with extended wear and monthly disposable lenses are thought to be attributable to inadequate cleaning and disinfection as the result of consumer non-compliance, the advantages to the consumer of a commercially viable, safe and effective daily disposable lens of this type would be considerable.

2.88. A further potential threat to solutions comes from recent developments in eye surgery designed to rectify defective vision. There are two main developments: radial keratotomy, a surgical technique to reduce myopia by flattening the cornea; and laser surgery which involves the use of excimer and other lasers to 'sculpt' the cornea to a new shape. Both methods promise to achieve considerable, permanent improvements in sight, but the extent to which they can or will obviate the need for corrective lenses (either spectacles or contact lenses) remains to be seen. Moreover, extensive data on these procedures is not yet available, and their safety over the longer term is unknown.

3 The markets

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Introduction

3.1. CLS are used mainly to clean, disinfect, rinse and store contact lenses to maintain ocular health and the quality of vision. We begin this chapter by describing the suppliers and the leading solutions. We then examine the structure of the market covering manufacturers/importers, wholesalers and retailers. And finally we explore the prices of solutions—those to consumers, and those to wholesalers and retailers.

3.2. We shall examine CLS at the three levels of manufacturer/importer ('supplier'), wholesaler and retailer. As in other industries, there is a degree of overlap between these three levels. For example, some suppliers have their own distribution arrangements and are therefore involved at the wholesale level. Some wholesalers have their own retail outlets and are therefore involved at the retail level. And some retailers have their own distribution systems and are therefore involved at the wholesale level. We shall look at these three levels in turn.

Suppliers

The companies

3.3. In this section we look briefly at the suppliers. Detailed descriptions can be found in paragraphs 4.2 to 4.52.

Allergan

3.4. Allergan is engaged in the sale, marketing and distribution of solutions, buying finished products from sister companies overseas. Allergan's ultimate parent (Allergan Inc) is a US corporation with its headquarters in California. As well as distributing solutions, Allergan sells contact lenses and pharmaceuticals and surgical products for the eye. Since 1989 Allergan has been the company with the largest annual sales of solutions in the UK. It offers CLS for all the lens care functions (see paragraph 2.13).

CV-UK

3.5. CV-UK is the UK sales and marketing arm of CIBA Vision, part of CIBA-GEIGY AG of Switzerland (CIBA-GEIGY). Its solutions are mainly manufactured by its sister company in the UK (CIBA Vision Lens Care Production Ltd—CVLCP). CV-UK was the top seller in 1988, since when it has been second to Allergan. It offers CLS for all the lens care functions apart from protein removal.

Alcon

3.6. Alcon Laboratories (UK) Ltd (Alcon), which is an importer and distributor of solutions, is part of the Alcon group of Nestlé SA, Switzerland. Its solutions are manufactured by third parties and to a lesser extent Alcon group companies overseas. In addition to the marketing of solutions, Alcon also distributes pharmaceuticals and surgical products. It supplies solutions for all the main lens care functions.

Sauflon

3.7. Sauflon Pharmaceuticals Ltd (Sauflon) is a privately-owned company which manufactures and distributes CLS as its main activity: it has a small business in other eyecare products. Sauflon began selling solutions on a small scale, mainly to retail outlets within the privately-owned optical group to which it belonged in 1972. Following demerger from that group, Sauflon commenced active marketing of solutions in 1987. It offers solutions for all the lens care functions.

B&L and M&L

3.8. Bausch & Lomb UK Limited (B&L) is engaged in the import and distribution of CLS, contact lenses, sunglasses and related accessories. Its ultimate parent is a US corporation with headquarters in New York. Whilst B&L's product range in the UK includes solutions for all the lens care functions, it does not currently market a preservative-free disinfectant. In April 1989 B&L acquired Madden & Layman Ltd (M&L) which also imports and sells solutions, under the Boston brand name, and in addition manufactures and sells contact lenses. The Boston CLS include only a surfactant cleaner and a disinfectant for hard/GP lenses.

S&NP

3.9. Smith & Nephew Pharmaceuticals Ltd (S&NP) is primarily engaged in the development and manufacture of ethical pharmaceuticals: solutions form only a small part of its overall business. S&NP offers a full range of solutions apart from a preservative-free disinfectant and a saline solution.

PBH

3.10. Pilkington Barnes-Hind Limited (PBH) is a wholly-owned subsidiary of Pilkington plc (Pilkington). PBH manufactures contact lenses and distributes CLS and other optical products. Its solutions are manufactured by Waverley Pharmaceutical Limited (Waverley) and CCL Industries Ltd (CCL). It markets solutions for all the care functions for soft lenses.

Smaller suppliers

3.11. The smaller suppliers include Waverley, Abatron Limited (Abatron), CCL and Core Technologies Limited (Core). Waverley's main activities are the manufacture, sale, packaging and distribution of sterile liquids and pharmaceutical products through its subsidiary Steripak Ltd. Waverley manufactures for other suppliers under contract. It currently produces solutions for CV-UK, PBH, Specsavers Optical Group Ltd (Specsavers, an optical franchise group), and Aspect Vision Care Ltd (Aspect, an optical wholesaler). Abatron imports, manufactures and distributes pharmaceutical products. It has two types of solutions, salines and protein cleaners, both of which are manufactured for it in the UK under contract. CCL was formed in September 1989 as the holding company for a group of businesses in the production and marketing of aerosols and liquid products. It manufactures CLS under licence. Core is a UK company which manufactures disinfectant tablets for B&L.

The international context

3.12. Most of the leading suppliers of solutions in the UK also supply solutions in other countries. Table 3.1 shows Allergan's estimate of the value of solutions (at suppliers' prices) and the position of the leading suppliers in the UK and in four other countries in 1991.

TABLE 3.1 **Market shares in the UK and selected other countries in 1991***

per cent

Supplier	*USA*	*Germany*	*France*	*Italy*	*UK*†
Alcon	19	25	7	7	10
Allergan	17	37	55	37	40
B&L	30	2	2	23	8
CIBA Vision	16	24	24	24	32
Other	18	12	12	9	10
Total	100	100	100	100	100
Total value ($m)	630	72	71	48	70

Source: Allergan.

*At suppliers' prices.

†See Tables 3.2 to 3.9 for our estimates of the size of the UK market and the shares held by the leading suppliers.

Note: Allergan estimates that the value of solutions in Japan in 1991 was $90 million. This estimate excludes the cost of electrically-heated disinfection units which are estimated to be used by 90 per cent of users of soft lenses in Japan. Outside Japan, use of such units is now very small: about 3 per cent in the USA and less than 1 per cent in the other countries in the table.

3.13. The value of solutions sold in the USA is much greater than in the other countries covered. The value of CLS sold in the UK is very similar to that in Germany and France.

3.14. B&L is the leading supplier in the USA accounting for 30 per cent (by value) of the solutions sold. The shares held by the other three named suppliers are very similar to each other. Allergan is the market leader in the other three countries; CV-UK is well represented in each of those three countries. B&L enjoys a high share in Italy, the home of its European production, and Alcon is the second leading supplier in Germany. A full account of the market shares in the UK is set out in Tables 3.3 to 3.9.

Production

Source of solutions

3.15. Of the leading suppliers, Alcon and B&L import most of their solutions whilst Allergan and M&L import all theirs. Most of CV-UK's and PBH's solutions, and all those offered by Sauflon, S&NP and the smaller suppliers (Abatron, Waverley and CCL), are manufactured in the UK. Allergan, as mentioned earlier, imports from sister companies, in Ireland and Texas; about 90 per cent of its solutions come from Ireland. Alcon told us that it sources most of its solutions from third parties. Neither B&L nor M&L manufactures solutions in the UK. B&L imported over 80 per cent of the solutions it sold, by value, in 1992 from its sister company in Italy. Its other solutions came from Allergan, CCL and Core (see paragraph 3.11). In 1992 nearly 80 per cent of the CLS sold by M&L were imported from B&L's sister company in Italy.

3.16. In the UK, on the other hand, CV-UK has recently built a new production facility for solutions in Macclesfield which according to press reports cost over £20 million. All PBH's solutions are manufactured in the UK by Waverley and CCL (see paragraph 3.11). A sister company of PBH manufactures solutions in the USA but these are not exported to the UK. One of the smaller manufacturers, Sauflon, has recently invested over £1 million in a new plant in Ashford in Kent. S&NP produces all its solutions in the UK. It began manufacturing CLS in the UK in 1965.

3.17. In 1988 just under 50 per cent of the solutions sold in the UK (at suppliers' prices) were imported. The proportion rose to just over 55 per cent in 1992.

Methods of manufacturing

3.18. To obtain a manufacturer's licence, companies have to comply with the DoH Guide to Good Pharmaceutical Manufacturing Practice. This lays down guidelines for sterile manufacture and quality control which are the same for solutions as for pharmaceutical products. The need for solutions to remain sterile in use has implications for the formulation and packaging of the products.

3.19. There are three manufacturing techniques for liquids. In the first, the sterile bottles are produced and are then automatically filled in a sterile area. The product is passed through sterilizing filters before filling. Throughout the whole process, the product is monitored by various in-process controls to ensure conformity to specifications. The second technique is a move away from the more conventional approach to the use of what are known as 'blow-fill-seal' machines where the container is made, filled and sealed in one process. The sterility of the one-piece container is achieved through an extrusion process. This all-in-one process is slower than the conventional filling machines. The third technique—terminal sterilization—is where the liquid is non-sterile when made and is then put into a container, the whole of which is sterilized. This method is used for aerosol salines, for instance. Procedures take place on highly automated production lines, usually dedicated to certain types of containers. Tablets are manufactured by compressing the raw materials, which have first been weighed, sieved and blended to given parameters such as weight, thickness, hardness, and friability. The tablets are made in a sterile environment with regular quality control checks.

Solutions

3.20. The different types of solutions are discussed in paragraph 2.13. In this section we look at the different brands of CLS. Many branded solutions have own-label equivalents, and these are discussed in paragraphs 3.113 to 3.126. A full list of solutions is set out in Appendix 3.1.

Surfactant cleaners

3.21. The best-selling surfactant cleaner is Allergan's LC-65 which can be used with all types of lenses. B&L's and M&L's (Boston) cleaners, for use with hard/GP lenses only, are the second highest-selling surfactant cleaners. CV-UK's Miraflow and Alcon's Pliagel, which can also be used with all types of lenses, are used by many wearers.

Disinfectants

3.22. There are three types of disinfectants: cold chemical, peroxides, and chlorine tablets (see paragraph 2.16). The latter two are usually referred to as oxidatives.

Peroxides

3.23. Peroxides consist of two solutions, a disinfectant, usually known as step 1, and a neutralizing solution, step 2 (see paragraph 3.81 for recent developments). The highest-selling peroxide is CV-UK's 10.10, which is closely followed by Allergan's Oxysept. The other branded peroxide is PBH's Perform. CV-UK's 10.10 is the only branded peroxide which is recommended for all types of lenses; the rest are recommended for soft lenses only. None of the suppliers offering peroxide disinfectants supplies chlorine tablets.

Chlorine tablets

3.24. The only two branded chlorine tablets are Alcon's Softab, the highest seller, and Sauflon's Aerotab. The tablets form a disinfecting solution when dissolved in saline. Chlorine tablets are for use mainly with soft lenses.

Cold chemical solutions

3.25. Allergan's Total, which is used with hard/GP lenses, is the highest-selling cold chemical disinfectant. (Total is an all-in-one solution, which means it can be used separately as a surfactant cleaner, a disinfectant and a wetting solution.) The second highest-selling cold chemical disinfectant is another Allergan product, Hydrocare Cleaning/Soaking, used with soft lenses only. This is followed by B&L's and M&L's (Boston) disinfectant, for use with hard/GP lenses. The only other notable sellers are CV-UK's Hydrosoak (for soft lenses) and Contactasoak (for hard/GP lenses).

Salines

3.26. Salines can be used with all types of lenses. Allergan has the highest-selling saline, Lens Plus; it also supplies Solusal, CDP Saline and the recently-launched Oxysept Saline. CV-UK has two saline solutions, Solar Saline, the second highest-selling saline, and CIBA Saline which it introduced in 1992 as its economy product. Other salines which are popular are Alcon's Aerosol Saline and Salette, and Sauflon's Saline.

Protein cleaners

3.27. Allergan offers the two highest-selling protein cleaners, Hydrocare Fizzy, which is the older product and is used by being dissolved in saline, and Ultrazyme, which was introduced in 1990. Ultrazyme can be used as other protein cleaners, by being dissolved in saline; alternatively, it can be dissolved in Oxysept 1 (the disinfecting CLS), thereby allowing the protein cleaning and the disinfection to be carried out at the same time. Ultrazyme is the only protein remover which can be used in this way, and it cannot, by a condition of its product licence, be recommended by Allergan for use with other suppliers' peroxide systems. The other branded protein tablets which are bought by many wearers are Alcon's Clen-zym and Abatron's Amiclair. B&L's Fizzy, which was supplied by Allergan and was the same product as Hydrocare Fizzy, was replaced in 1991 by Fizziclean which B&L imports from its sister company in Italy.

Discard dates

3.28. Most solutions are sold in sealed, multi-dose containers which, once opened, have a relatively short recommended life. The MCA Guidance Notes on Applications for Product Licences state that 'in most cases the volume in the container of a product intended for use on more than one occasion should normally be sufficient for not more than 28 days' use' (see paragraph 2.35). Labels must carry an instruction that any remaining fluid should be discarded after the recommended period (see paragraph 2.33). The period of 28 days tends to apply to surfactant cleaners, preserved disinfecting/storage solutions and the first step of some peroxides. The concept of a discard date does not apply to the second step of a peroxide system where this is packaged in vials containing the required amount of solution for each dosage, nor to aerosols.

3.29. A number of consumers have written to us complaining that if they follow the suppliers' recommendations they cannot use all their solutions by the discard date. We asked each supplier, and each retailer with own-label CLS, to list those of its solutions which would not be used up by the discard date if the consumer followed the recommended dosage. CV-UK, Allergan and Alcon told us that a minority of their solutions (surfactant cleaners for all three suppliers and in the case of Allergan some preserved solutions), if used as recommended, would not be exhausted by the discard dates: all the other suppliers, and all retailers with own-label solutions, said that their solutions would be exhausted by the discard dates (see Appendix 3.2).

3.30. Allergan stated that it markets four CLS which would not be used up by the discard date if the consumer followed the recommended dosage. It said that these solutions were of two types. The first type comprised Hydrocare Cleaning/Soaking in a 240ml bottle, Hydrocare Preserved saline also in a 240ml bottle, and Liquifilm in a 30ml bottle. Allergan told us that each of these three packs had low sales, and were not being promoted. The second type covered just one solution, the surfactant

cleaner LC-65. For this solution, Allergan said that it regarded the '28 days after opening discard date that the MCA requires to be recommended as quite simply unrealistically short'. Allergan believed that LC-65 in a 30ml container, when used at a standard rate by a single contact lens wearer, would remain a 'safe product' for the three months that would be required to use up the solution. Allergan told us that there had been no complaints or reports of ill effects resulting from the use of any of its products beyond the formal discard date. CV-UK estimated that if a consumer followed its recommendations and cleaned his or her lenses once a day, the contents of Miraflow in its 35ml container would only be used up in 58 days (compared with the discard date of 28 days). CV-UK told us that it was in the process of replacing its 35ml bottle with a 25ml one. Alcon said that, of its three daily cleaners (Pliagel, Clens, and Preflex) and the own-label daily cleaner it supplies to D&A, at most about 17ml would be needed for a 28-day period if the solutions were used as directed. Alcon told us that it supplied these solutions in 25ml bottles to accommodate a 'spillage allowance'.

Different sizes of container

3.31. Different types and brands of solutions are sold in different sized containers and this may make price comparisons difficult. For example, CV-UK's Miraflow (daily cleaner) is sold in 10ml and 35ml containers, and its Hydroclean and Contactaclean (daily cleaners) in 35ml containers, compared with some of its competitors which sell comparable solutions in 10ml, 15ml, 20ml, 25ml, 30ml and 60ml containers. The same sort of situation occurs with saline solutions, CV-UK selling its solutions in 115ml, 275ml and 360ml containers compared with its rivals which offer a range of containers including 90ml, 125ml, 240ml, 250ml, 300ml, 360ml, and 420ml. Cold chemical disinfectants are also marketed in different sized containers, CV-UK's 120ml container competing with, amongst others, 60ml, 110ml, 120ml, 175ml, 240ml and 250ml. Further details are set out in Appendix 3.3.

3.32. Price comparisons can be especially difficult when the purchaser has also to take into account discard dates and different recommended usage amounts for each type of solution which may be part of that purchaser's care system. For example, when comparing the price of Allergan's peroxide solutions (Oxysept 1 and 2) with the price of its cold chemical disinfectant for soft lenses (Hydrocare Cleaning/Soaking) a consumer would need to consider the following. Oxysept 1 is sold in 250ml containers (as well as other sizes) and Oxysept 2 is sold in 25 x 15ml vials (and other sizes) with a recommended daily dosage of 10ml for Oxysept 1 and 15ml for Oxysept 2, giving 25 days' supply of solutions. Hydrocare Cleaning/Soaking is sold in 120ml and 240ml containers and no daily usage is recommended; the instructions state 'Fill your lens case'. (Allergan in fact told us that it estimates that an average user will use between 2 and 5ml per procedure.) Thus for an average consumer a comparison of price per ml would be inappropriate. Moreover, if he or she were to use Allergan's estimated average figure, the consumer would not have used all the solution in the 240ml container by its discard date and this might be a factor to be included in the comparison. A final complication is that the Hydrocare method also calls for the use of a saline for rinsing.

Solutions sold as systems

3.33. Suppliers usually market their solutions as being part of a lens care system rather than as individual products (see Appendix 3.4). These systems include solutions for all or most of the different procedures the wearer has to perform when caring for his or her lenses. Some solutions are developed to be used together (see paragraph 2.83). 63 per cent of users in our consumer survey said that the solutions they used belonged to a single brand (see Appendix 3.10).

3.34. For example, Allergan markets its cold chemical solution for soft lenses, Hydrocare Cleaning/Soaking, as part of the Hydrocare system which also includes LC-65 (daily cleaner), Lens Plus (saline) and Hydrocare Fizzy (protein remover tablets). Similarly it markets its all-in-one solution for hard/GP lenses, Total, as being part of the Total system which includes LC-65 and Hydrocare Fizzy. Alcon told us that selling solutions in this way enabled customers to buy complete care systems whatever their lens type.

3.35. The policy of offering solutions as parts of care systems is adopted by retailers and wholesalers with their own-label solutions. For example, Boots markets its own-label cold chemical system

for hard/GP lenses as comprising Boots All-in-one solution, Boots Daily Cleaner, Boots Saline solution, and Boots Protein Remover tablets. The same applies to its cold chemical systems for soft lenses. Specsavers said that since it began to sell own-label solutions as a complete regime, the number of problem cases had fallen sharply because wearers had a system they could understand.

3.36. A further example is the Aspect range, which includes two care systems, a peroxide system, Prosept, for soft lenses and a cold chemical system, Prosol, for hard/GP lenses. Unlike any other supplier, Aspect offers its solutions only in either monthly or three-monthly self-contained packs which include Prosol Daily Cleaner and Prosol Intensive Cleaner (protein remover). Aspect told us that it began this policy as a marketing tool and to aid compliance. It said that it was about to end the policy as it had not proved to be a success.

Marketing and promotion

Starter packs

3.37. The main cost element in suppliers' marketing and promotion is the provision of free starter packs, which usually contain small quantities of a range of solutions that form part of the same care system, and which are intended for use by customers over a short period. All the leading suppliers offer starter packs. For example, Allergan's Oxysept starter pack contains Oxysept 1 (120ml), Oxysept 2 (10 vials), LC-65 (5ml), and Ultrazyme (2 tablets), together with various accessories. CV-UK has a similar starter pack for its 10.10 system, though as it does not supply a branded protein remover, the pack includes Alcon's Clen-zym. Starter packs are given free of charge by opticians when they recommend a particular brand of solution to customers and are frequently used by the opticians for the purpose of demonstrating the use of solutions.

3.38. Starter packs are usually given only to opticians and in small quantities to hospitals, normally free of charge, by suppliers and wholesalers. Some suppliers do charge, or have tried to charge, for their starter packs. Alcon told us that the only exception to its policy of not charging for its starter packs relates to Softab starter pack bags and cartons. Sauflon said that it would normally expect to charge for starter packs but that this was subject to negotiation. B&L told us that for a short time in 1992 it attempted to charge for starter packs containing solutions for soft lenses, but found that the position was untenable and had since reversed the decision. Opticians with own-label solutions stated that they paid their suppliers for the own-label starter packs which they (the opticians) gave to customers. Specsavers told us that its stance in negotiating with suppliers of its own-label solutions was that it would not pay any element of the suppliers' marketing costs, since these related to the suppliers' branded products: to request free starter packs would be inconsistent with this stance.

Other methods of promotion

3.39. Suppliers produce advertising material which compares the price and effectiveness of their products against those of their rivals. In one of its marketing booklets to opticians, Sauflon shows what it calls the 'True 31 day cost comparison' between non-preserved disinfectants. The booklet provides the following monthly costs to the customer: 10.10 at £17.62, Oxysept at £17.38, Perform at £16.41, Softab at £14.99, and Sauflon's Aerotab at £14.20. Both Allergan and CV-UK claim in their marketing material that peroxides are more effective than chlorine tablets. Allergan also states, in its marketing literature, that Oxysept 2 neutralizes more hydrogen peroxide than 10.10 Step 2 and that Oxysept 2 neutralizes in less time than 10.10. CV-UK told us that its marketing material dispelled Allergan's claims. Allergan's promotional literature also says that its Total solution is more effective and quicker to use than M&L's Boston disinfectant. Allergan told us that its sales of LC-65 had been affected by the claim of M&L, and its parent B&L, that their daily cleaners for hard/GP lenses were superior to LC-65.

Markets

Measurement and definition of the markets

3.40. There is no agreed volume measure used by the industry for combining tablets and liquid solutions. Allergan told us that it would be possible to find a viable method for measuring the volumes of any individual product type (eg cleaners, salines etc) but aggregation across product types by volume would not be meaningful. After considering a number of possibilities we decided to use a value measure when calculating shares of markets or sectors.

3.41. The products which our terms of reference require us to consider are solutions (and tablets designed to be made up into solutions) for use in connection with the cleaning, disinfecting, rinsing, lubricating, storage or wearing of contact lenses.

3.42. Both CV-UK and Allergan consider that these products do not provide an appropriate basis for a market definition. CV-UK told us that the definition of the market should be wider. It said that solutions used for the care of contact lenses fall into the larger sterile ophthalmic solutions market which includes eye washes, eye comfort drops, ophthalmic anti-allergic preparations and ophthalmic pharmaceutical products. CV-UK gave us the following three reasons why it believes the market should be so defined:

(a) five suppliers of solutions are also involved in the production, sale or marketing of other ophthalmic solutions;

(b) the technology of formulation and manufacture is common to all sterile ophthalmic solutions; and

(c) all sections of the sterile ophthalmic solutions market are currently covered by DoH regulations on production standards, sterility and preservative efficacy.

3.43. Allergan told us that it sees solutions as part of the wider market for 'vision products'. The better the performance and the lower the price of solutions, the more competitive contact lenses are with spectacles and the fewer lens users are likely to go over to disposable/frequent replacement contact lenses that involve little or no use of solutions. Allergan also said that, given the production synergies which exist between solutions and ophthalmic pharmaceuticals, it would be perfectly feasible for many suppliers of the latter to develop a range of solutions. Allergan provided us with the names of over 20 suppliers of ophthalmic pharmaceuticals in the UK which, in its view, could be seen as potential suppliers of solutions. We asked Allergan whether any of these companies had supplied solutions in the UK in the last five years. Allergan told us that two of these companies, although not themselves suppliers of solutions in the UK, are or have been associated with the solutions industry.

3.44. A more conventional approach to market definition would, however, start with demand for the product and draw distinctions between product groups on the basis of the extent to which one product was a good substitute for another. Solutions would then appear to divide into four product groups: protein cleaners, surfactant cleaners, salines, and disinfectants, since for the great majority of contact lens wearers the uses of each group of solutions are distinct; for similar reasons the solutions would themselves be distinct from pharmaceutical products. Thus protein remover solutions are used only to 'deep clean' lenses (ie to remove the build-up of protein and other deposits). Solutions allocated to the saline market are used mainly for rinsing, but also for dissolving chlorine tablets in order to disinfect lenses and for dissolving most protein remover tablets. Surfactant cleaner solutions are used as daily cleaners, and disinfecting solutions to disinfect lenses.

3.45. In a few cases there are problems of allocating solutions to product groups. The most obvious of these cases are the so-called all-in-one solutions (Allergan's Total, CV-UK's Complete Care and Boots' All-in-one). Sales of such solutions are currently very limited—partly because the MCA regulatory standards have so far excluded from the UK products of this kind that are suitable for soft lenses. The main role of these solutions is, however, disinfecting rather than cleaning. This latter point is supported by Allergan's decision to introduce in 1993 a new daily cleaner (Total Daily Cleaner) designed specifically for GP lenses and hence for use alongside Total as the disinfectant even though

Total has been offered for cleaning as well as disinfecting. CV-UK told us that one of its disinfecting solutions (Hydrosoak) could also be used for rinsing lenses. It did, however, say that in most cases patients would now use a saline solution for rinsing, as it is cheaper. CV-UK also said that its Lensept (a peroxide disinfecting solution) could be used as a surfactant cleaner. Again, it was CV-UK's view that this would now only be the case for a minority of users.

3.46. Alcon suggested that salines should be seen as being part of the disinfectant market as they were used to dissolve chlorine tablets in order to disinfect lenses. But since salines are also a medium for dissolving protein tablets and cannot by themselves carry out the disinfecting function, it may seem preferable to identify a separate market for salines, and not to treat them as part of the disinfectant market.

3.47. It could also be argued that solutions for use with hard/GP lenses should be distinguished, because of demand characteristics, from solutions for soft lenses. Thus CV-UK's Hydroclean (a surfactant cleaner for soft lenses) cannot be used as an alternative for its Contactaclean (a surfactant cleaner for hard lenses). Some solutions can be used with all types of lenses. This is the case for protein removers and salines, many surfactant cleaners, and for the leading peroxide solution. Examples of solutions in the surfactant cleaner market which can be used with all lenses are Allergan's LC-65 (the highest seller), CV-UK's Miraflow and Alcon's Pliagel. In the disinfecting market, CV-UK's 10.10 and its own-label equivalents can be used with all types of lenses. But it remains the case that many solutions are specific either to hard/GP or to soft lenses.

3.48. Factors relating to demand are not, however, the only ones that have to be taken into account. The range and types of solutions offered by the suppliers and the ease with which suppliers can produce, or arrange for production of, different solutions provide an indication of opportunities on the supply side. These factors may be referred to as 'supply characteristics'.

3.49. We have to consider whether there are any supply characteristics of solutions for hard/GP lenses that are different from those of solutions for soft lenses and which would thus impede a supplier of the one from becoming quickly a supplier of the other. The most obvious supply characteristic is the form of the product as liquid or tablet. Other important characteristics are the packaging of solutions. In these two respects the products within a supplier's range do not seem to differ whether they are to be used with soft or hard/GP lenses (see paragraph 3.31 for the different pack sizes between suppliers). For example, most salines are sold in aerosol containers irrespective of use. Again in the surfactant cleaner market, CV-UK, like other suppliers, produces a cleaner for hard/GP lenses (Contactaclean) in the same type and size of bottle (35ml) as its cleaner for soft lenses (Hydroclean). The same is true, as it is for other suppliers, for CV-UK's cold chemical disinfectants for hard/GP lenses (Contactasoak) compared with that for soft lenses (Hydrosoak), both being produced in similar 120ml containers. Such common characteristics may provide suppliers with a degree of flexibility in producing solutions for other types of lens and that in turn may be one of the reasons why suppliers which offer solutions to be used with soft lenses generally market solutions for hard lenses. For example, all the leading suppliers offer disinfecting solutions for all types of lens, and the same is true in the case of surfactant cleaners (with the exception of Allergan which will, however, introduce Total Daily Cleaner for use with hard/GP lenses in 1993).

3.50. Another aspect of market definition that needs to be considered is the geographical one, or more exactly whether the UK should be seen as part of a wider European market. Four of the leading suppliers in the UK (see paragraphs 3.12 to 3.14) are well represented in other European countries, and they also have manufacturing facilities elsewhere in Europe. Import penetration is also quite high in the UK. As stated in paragraph 3.17, in 1992 55 per cent of the solutions sold (at suppliers' prices) were imported. Allergan told us that the UK market is open to entry from suppliers that are established in other European markets. It gave as an example Oy Finnsusp AB, a Finnish company, which it said was an important supplier of solutions in the Nordic countries but had not yet chosen to extend its operations to the UK. However, the system of product licensing that operates in the UK (as described in Chapter 2 and discussed further in paragraphs 3.83 to 3.92) may have the effect of segregating supply to the UK from supply to other countries. Hence companies that have established a position in other European markets may not be able simply to transfer products to the UK market, but may have to undergo a process of product assessment, possibly involving the expenditure of significant research and development (R&D) costs, without any certainty of whether and when their product may be released for sale to UK consumers.

Period of analysis

3.51. Our analysis of the markets begins in 1988, which seems to be a natural starting point, and covers the five-year period to 1992. We decided to use 1988 as our base year since a number of suppliers told us either that they could not provide data for earlier years, or that such a task would be very time-consuming and the resulting estimates likely to contain serious errors.

3.52. Allergan provided us with value data covering solutions as a whole and by sector for all suppliers for 1986 which it compiled using its knowledge of the industry and data from the ACLM. It also provided similar data for 1990 and 1991. The ACLM collects data from its members on sales of contact lenses and solutions sold in the UK.

3.53. At the beginning of our inquiry we looked at, and discussed with the suppliers and the ACLM, the possibility of using ACLM data to estimate the sales of solutions as a whole and those of individual product markets and sectors. We were told by the suppliers and the ACLM that whilst ACLM data were the best available, they were not necessarily comparable over time. (Whilst most suppliers were members they might not have been for all the years covered.) Due to a need to clarify the position under EC law, publication of the market share data had been suspended for 1989. For these reasons we decided to ask the suppliers to provide us with their own data.

Value of solutions and the individual markets

3.54. Table 3.2, which is based on suppliers' prices, shows sales of solutions as a whole for each year between 1988 and 1992 and the percentage breakdown by product markets and by the two separate sectors of the disinfecting market (see paragraph 3.22).

TABLE 3.2 **Sales of solutions as a whole and by individual markets, 1988 to 1992**

per cent

Markets	*1988*	*1989*	*1990*	*1991*	*1992**
Surfactant cleaners	14	14	14	13	12
Oxidatives	34	39	41	45	48
Cold chemical	21	18	16	14	13
Disinfectant total	55	57	57	59	61
Salines	13	14	15	14	13
Protein cleaners	11	10	9	9	8
Other†	7	5	5	5	6
Total	100	100	100	100	100
Total value (£m)	22.7	30.9	38.7	44.0	49.7

Source: MMC calculations based on data provided by the suppliers.

*Estimate.
†Includes 'in-eye comfort', and wetting solutions.

3.55. Table 3.2 shows that the value of solutions sales more than doubled between 1988 (£22.7 million) and 1992 (£49.7 million).[1] The main change during the period was the increased share of solutions as a whole accounted for by disinfectants, this market increasing its share by six points. The two sectors of the disinfecting market moved in opposite directions, however; the oxidative sector increased its share by 14 percentage points whilst the cold chemical sector's share fell by 8 points. The proportion of the total solutions market accounted for by salines remained broadly constant during the period, whereas protein cleaners and surfactant cleaners experienced a slight fall.

[1]Allergan estimates that in 1986 solutions as a whole had a value of £15.8 million with the oxidative sector accounting for just over 11 per cent.

Market shares

3.56. The following tables (Table 3.3 to 3.9) show the shares of the markets held by the leading suppliers, in total and allocated between branded and own-label solutions. The figures also show the own-label solutions offered by retailers. The data are based on suppliers' prices. Later (see Table 3.15) we show the shares of the retail market accounted for by all solutions (both branded and own-label) sold by Boots and D&A at retail prices.

The surfactant cleaner market

3.57. Table 3.3 shows the changes in the surfactant cleaner market shares during 1988 to 1992.

TABLE 3.3 **The surfactant cleaner market (at suppliers' prices), 1988 to 1992**

per cent

Supplier		*1988*	*1989*	*1990*	*1991*	*1992**
A. Shares of the leading suppliers						
Allergan	Branded	42	45	41	37	34
	Own-label	0	0	0	1	1
	Total	42	45	41	38	35
B&L	Total	8	9	11	12	13
M&L†	Branded	N/A	6	11	10	11
	Own-label	N/A	0	0	2	3
	Total	N/A	6	11	12	14
B&L (incl M&L)	Total‡	8	16	22	25	27
CV-UK§	Branded	20	14	12	11	13
	Own-label	5	3	3	3	4
	Total	25	17	15	14	17
Alcon	Branded	18	15	12	10	8
	Own-label	0	0	3	5	4
	Total	18	15	15	15	12
Sauflon	Branded	4	5	3	3	2
	Own-label	0	0	1	3	4
	Total	4	5	4	6	6
S&NP	Total	2	2	2	2	2
PBH	Total	1	1	§	§	¶
Waverley	Own-label	0	0	¶	¶	¶
	Total	0	0	¶	¶	¶
Total		100	100	100	100	100
Total value (£m)		3.3	4.4	5.3	6.0	6.0
B. Shares of own-label						
D&A		0	0	3	7	7
Boots		5	3	4	4	5
Specsavers		0	0	1	3	4
Vision Express		0	0	0	¶	¶
Total own-label		5	3	8	14	16
Total value (£m)		0.15	0.13	0.43	0.81	0.95
C. Suppliers' shares of own-label						
Sauflon		0	0	11	21	27
Alcon		0	0	42	33	23
CV-UK		100	100	43	22	22
M&L		0	0	0	17	19
Allergan		0	0	0	5	7
Waverley		0	0	4	2	2
Total		100	100	100	100	100
Total value (£m)		0.15	0.13	0.43	0.81	0.95

Source: MMC calculations based on data provided by the suppliers.

*Estimate.
†Data for 1989 are for part of year only.
‡Data for M&L for 1988 are not available and those for 1989 cover part of year only.
§Data for 1988 are for a 14-month period.
¶Less than 0.5 per cent.

3.58. The market share figures show that there are now five significant competitors. Over the last five years Allergan, CV-UK and Alcon have lost market share, principally to B&L: CV-UK's loss of share being between 1988 and 1989.[1] The majority of B&L's solutions in this market, and all of its subsidiary M&L's, are for use with hard/GP lenses only. The growth in market share experienced by Sauflon is due mainly to its supply of own-label solutions. Sauflon's own-label solutions accounted for a larger share of the market in 1992 (4 per cent) than its branded solutions (2 per cent). In total own-label solutions took 16 per cent of the market in 1992 compared with 5 per cent in 1988.

3.59. CV-UK was the only supplier of own-label solutions in 1988 and 1989. Since this time other suppliers have entered this business to such an extent that by 1992 CV-UK was only one of four suppliers with around 20 to 25 per cent of the total. Allergan began supplying own-label solutions in this market in 1991.

Disinfecting market

3.60. Table 3.4 shows the shares in the disinfecting market.

TABLE 3.4 **The disinfecting market (at suppliers' prices), 1988 to 1992**

per cent

Supplier		*1988*	*1989*	*1990*	*1991*	*1992**
A. Shares of the leading suppliers						
CV-UK†	Branded	53	47	37	30	29
	Own-label	2	3	9	13	13
	Total	55	50	46	43	42
Allergan	Branded	31	35	35	38	37
	Own-label	0	0	0	‡	‡
	Total	31	35	35	38	37
B&L	Total	3	3	3	3	4
M&L§	Branded	N/A	2	3	3	3
	Own-label	N/A	0	0	‡	1
	Total	N/A	2	3	3	4
B&L (inc M&L)	Total¶	3	5	6	6	8
Alcon	Branded	6	5	6	5	5
	Own-label	0	0	1	1	1
	Total	6	5	7	6	6
Sauflon	Branded	2	3	2	2	2
	Own-label	0	0	‡	1	1
	Total	2	3	2	3	3
S&NP	Total	2	2	1	1	1
PBH	Total	1	‡	2	2	2
Waverley	Own-label	0	0	1	1	1
	Total	0	0	1	1	1
Aspect	Total	0	0	0	‡	‡
Total		100	100	100	100	100
Total value (£m)		12.4	17.4	22.2	25.7	30.3
B. Shares of own-label						
Boots		2	3	6	9	9
D&A		0	0	4	5	6
Specsavers		0	0	1	2	2
Vision Express		0	0	0	‡	‡
Total own-label		2	3	11	16	17
Total value (£m)		0.28	0.59	2.42	4.13	5.26
C. Suppliers' shares of own-label						
CV-UK		100	100	78	79	76
Sauflon		0	0	4	6	7
Alcon		0	0	12	7	6
M&L		N/A	0	0	3	5
Waverley		0	0	6	4	4
Allergan		0	0	0	1	2
Total		100	100	100	100	100
Total value (£m)		0.28	0.59	2.42	4.13	5.26

Source: MMC calculations based on data provided by the suppliers.

*Estimate.
†Data for 1988 are for a 14-month period.
‡Less than 0.5 per cent.
§Data for 1989 are for part of year only.
¶Data for M&L for 1988 are not available and those for 1989 cover part of year only.

[1]Allergan estimates that in 1986 it accounted for just over 45 per cent of this market, and CV-UK accounted for just over 27 per cent.

3.61. Table 3.4 indicates that the main changes in market shares are those affecting Allergan and CV-UK. Allergan's share increased by six percentage points between 1988 and 1992 whilst CV-UK's fell by 13 points. The main reason for these changes is the relative performance of Allergan and CV-UK in the oxidative sector which is set out in detail in Table 3.5. CV-UK's fall in market share has been reduced by its supply of own-label solutions which increased from 2 per cent of the market in 1988 to 13 per cent in 1992. In 1992 own-label solutions as a whole accounted for 17 per cent of the market, with Boots being the leading player with a market share of 9 per cent.

3.62. CV-UK is by far the leading supplier of own-label solutions in this market.

3.63. Tables 3.5 and 3.6 show suppliers' shares in the oxidative and cold chemical sectors respectively.

TABLE 3.5 **The oxidative sector (at suppliers' prices), 1988 to 1992**

per cent

Supplier		*1988*	*1989*	*1990*	*1991*	*1992**
A. Shares of the leading suppliers						
CV-UK†	Branded	70	59	44	34	33
	Own-label	0	3	10	15	15
	Total	70	62	54	49	48
Allergan	Total	19	28	32	37	37
Alcon	Branded	8	7	7	7	6
	Own-label	0	0	1	1	1
	Total	8	7	8	8	7
Sauflon	Branded	3	3	2	2	2
	Own-label	0	0	1	1	2
	Total	3	3	3	3	4
PBH	Total	0	0	2	2	3
Waverley	Own-label	0	0	1	1	1
	Total	0	0	1	1	1
Aspect	Total	0	0	0	‡	‡
Total		100	100	100	100	100
Total value (£m)		7.6	12.0	16.1	19.6	23.8
B. Shares of own-label						
Boots		0	3	6	11	10
D&A		0	0	5	6	7
Specsavers		0	0	1	2	2
Vision Express		0	0	0	‡	‡
Total own-label		0	3	12	19	19
Total value (£m)		0.00	0.32	1.98	3.64	4.54
C. Suppliers' shares of own-label						
CV-UK		0	100	78	81	80
Sauflon		0	0	5	7	8
Alcon		0	0	10	8	7
Waverley		0	0	7	4	5
Total		0	100	100	100	100
Total value (£m)		0.00	0.32	1.98	3.64	4.54

Source: MMC calculations based on data provided by the suppliers.

*Estimate.
†Data for 1988 are for a 14-month period.
‡Less than 0.5 per cent.

TABLE 3.6 **The cold chemical sector (at suppliers' prices), 1988 to 1992**

per cent

Supplier		*1988*	*1989*	*1990*	*1991*	*1992**
A. Shares of the leading suppliers						
Allergan	Branded	50	51	45	44	37
	Own-label	0	0	0	1	1
	Total	50	51	45	45	38
B&L	Total	7	9	11	14	17
M&L†	Branded	N/A	6	12	11	13
	Own-label	N/A	0	0	2	4
	Total	N/A	6	12	13	17
B&L (inc M&L)	Total‡	7	15	23	27	34
CV-UK§	Branded	27	19	17	16	15
	Own-label	6	5	6	5	6
	Total	33	24	23	21	21
Sauflon	Total	1	1	¶	¶	¶
S&NP	Total	5	6	5	5	5
PBH	Total	1	1	1	¶	¶
Alcon	Branded	3	2	1	1	1
	Own-label	0	0	2	¶	¶
	Total	3	2	3	1	1
Total		100	100	100	100	100
Total value (£m)		4.8	5.4	6.1	6.2	6.5
B. Shares of own-label						
Boots		6	5	6	6	7
D&A		0	0	1	2	4
Total own-label		6	5	7	8	11
Total value (£m)		0.28	0.27	0.44	0.49	0.72
C. Suppliers' shares of own-label						
CV-UK		100	100	80	64	51
M&L		N/A	0	0	25	35
Allergan		0	0	0	9	13
Alcon		0	0	20	2	1
Total		100	100	100	100	100
Total value (£m)		0.28	0.27	0.44	0.49	0.72

Source: MMC calculations based on data provided by the suppliers.

*Estimate.
†Data for 1989 are for part of year only.
‡Data for M&L for 1988 are not available and those for 1989 cover part of year only.
§Data for 1988 are for a 14-month period.
¶Less than 0.5 per cent.

3.64. Allergan has been gaining share in peroxides from CV-UK over the five-year period having itself entered this sector in 1987, two years after CV-UK.[1] In the oxidative sector the share accounted for by CV-UK's branded solutions fell from 70 per cent in 1988 to 33 per cent in 1992. In 1988 CV-UK did not supply own-label solutions, whereas by 1992 its supply of such solutions accounted for 15 per cent of the sector (and for just under one-third of CV-UK's overall share). Alcon and Sauflon have broadly maintained their more limited positions in this sector. Own-label peroxides were introduced in 1989 and, together with own-label chlorine tablets, by 1992 accounted for 19 per cent of the total.

3.65. CV-UK was again the first to supply own-label solutions but during the last five years Waverley has begun supplying own-label peroxides while Sauflon and Alcon have started to supply own-label chlorine tablets.

[1]Allergan estimates that in 1986 CV-UK had just over 87 per cent of this sector with the remainder being accounted for by Alcon.

3.66. In the cold chemical sector (see Table 3.6) by contrast it is B&L that has gained share significantly, mainly at the expense of CV-UK and Allergan, while S&NP has retained a much smaller share.

3.67. In 1988 and 1989 CV-UK was the only own-label supplier but by 1992 M&L and Allergan were also significant suppliers of own-label cold chemical solutions.

The saline market

3.68. Table 3.7 shows the changes in the shares of the saline market.

TABLE 3.7 **The saline market (at suppliers' prices), 1988 to 1992**

per cent

Supplier		*1988*	*1989*	*1990*	*1991*	*1992**
A. Shares of the leading suppliers						
Allergan†‡	Total	22	35	32	30	26
Sauflon	Branded	12	14	14	12	10
	Own-label	0	0	2	7	13
	Total	12	14	16	19	23
Alcon	Branded	22	20	16	15	18
	Own-label	0	0	6	8	5
	Total	22	20	22	23	23
CV-UK§	Total	36	25	25	20	21
B&L	Total	6	4	2	2	2
PBH	Total	1	2	1	1	1
Abatron	Total	1	¶	1	¶	¶
CCL	Total	0	0	1	5	4
Total		100	100	100	100	100
Total value (£m)		2.9	4.4	5.8	6.4	6.6
B. Shares of own-label						
D&A		0	0	6	9	10
Specsavers		0	0	2	6	7
Boots		0	0	1	5	4
Vision Express		0	0	0	¶	1
Total own-label		0	0	9	20	22
Total value (£m)		0.0	0.0	0.52	1.30	1.43
C. Suppliers' shares of own-label						
Sauflon		0	0	27	33	60
Alcon		0	0	62	41	23
CCL		0	0	11	26	17
Total		0	0	100	100	100
Total value (£m)		0.0	0.0	0.52	1.30	1.43

Source: MMC calculations based on data provided by the suppliers.

*Estimate.
†Allergan estimates that it accounted for over 50 per cent of the saline market in 1986.
‡Excludes Hydron solutions in 1988.
§Data for 1988 are for a 14-month period.
¶Less than 0.5 per cent.

3.69. The saline market is different from the others in that there is less scope for product differentiation, the solutions being much closer to commodities, and not requiring the same amount of R&D. The introduction of aerosol packaging was adopted rapidly by all suppliers a few years ago but requires only standard technology. In terms of market shares the four main suppliers appear to be fairly equally matched, and it is only in this market that Sauflon is among the leaders. Sauflon's (and Alcon's) main disinfecting solution is a chlorine tablet which has to be dissolved in saline. Sauflon is also responsible for the main change over the last five years, namely a substantial increase in share, largely at the expense of CV-UK. Sauflon began supplying own-label salines in 1990. In 1992 Sauflon's branded solutions took 10 per cent of the market whereas the own-label salines it supplied accounted for 13 per cent, giving Sauflon a total share of 23 per cent. The share of Sauflon's branded solution in 1992, 10 per cent, is less than its share in 1989, 14 per cent. Altogether own-label solutions

accounted for 22 per cent of the market in 1992, with nearly two-thirds supplied by Sauflon. D&A's position as the leading retailer of own-label salines may in part be due to the fact that, unlike Boots, it sells own-label chlorine tablets for disinfecting which have to be dissolved in saline.[1]

The protein cleaner market

3.70. The changes in the market shares of the protein cleaner market are shown in Table 3.8.

TABLE 3.8 **The protein cleaner market (at suppliers' prices), 1988 to 1992**

per cent

Supplier		*1988*	*1989*	*1990*	*1991*	*1992**
A. Shares of leading suppliers						
Allergan	Branded	74	66	66	62	65
	Own-label	0	0	0	3	5
	Total	74	66	66	65	70
Alcon	Branded	1	2	4	6	8
	Own-label	0	0	0	1	1
	Total	1	2	4	7	9
Sauflon	Branded	4	5	6	3	2
	Own-label	0	0	2	5	7
	Total	4	5	8	8	9
Abatron	Total	7	8	9	8	9
B&L	Total	5	6	5	5	3
S&NP	Branded	2	2	1	1	†
	Own-label	6	10	6	6	0
	Total	8	12	7	7	†
PBH	Total	1	1	1	†	†
Total		100	100	100	100	100
Total value (£m)		2.5	3.1	3.6	4.0	4.0
B. Shares of own-label						
Boots		6	7	6	9	6
Specsavers		0	0	2	4	6
D&A		0	0	0	1	1
Vision Express		0	0	0	†	†
Other		0	3	0	0	0
Total own-label		6	10	8	14	13
Total value (£m)		0.14	0.30	0.30	0.57	0.53
C. Suppliers' shares of own-label						
Sauflon		0	0	25	33	51
Allergan		0	0	0	24	41
Alcon		0	0	0	4	8
S&NP		100	100	75	39	0
Total		100	100	100	100	100
Total value (£m)		0.14	0.30	0.30	0.57	0.53

Source: MMC calculations based on data provided by the suppliers.

*Estimate.
†Less than 0.5 per cent.

3.71. The market share of Allergan's branded solutions fell by 12 percentage points between 1988 and 1991, though it still took more than 60 per cent of the market.[2] Allergan reinforced its position by the introduction in May 1990 of Ultrazyme, a product mainly for Oxysept users which from a marketing point of view has the combined benefits of deterring Oxysept users from moving over to other, cheaper protein cleaners and also enhancing the Oxysept-based system against CV-UK's 10.10. In 1992 Ultrazyme alone took 29 per cent of this market and Allergan's Hydrocare Fizzy 36 per cent, with the remainder of Allergan's overall 70 per cent market share (5 per cent) accounted for by Boots' own-label solutions (supplied by Allergan). Alcon and Sauflon have become significant players in the

[1]D&A's highest-selling own-label disinfecting solution is a peroxide solution, One-2-One Rapide.

[2]Allergan estimates that in 1986 it accounted for just under 88 per cent of the protein remover market.

market whilst Abatron's share has remained at about 8 per cent. Own-label solutions accounted for most of Sauflon's market share in 1992. In 1992 just over 13 per cent of the market was taken by own-label solutions. There are two reasons why the share of own-label solutions in 1992 may be lower than expected. First, Boots may be in a transitional period having changed its supplier of own-label solutions in 1991 from S&NP to Allergan. Secondly, D&A has not built up its own-label protein cleaners to the same extent as the other retailers.

3.72. S&NP was the only supplier of own-label solutions in 1988 and 1989. In 1992 S&NP did not supply any such solutions, having lost its main customer, Boots, to Allergan. Partly as a result of this change, Allergan was one of the two leading suppliers of own-label solutions in 1992, the other being Sauflon.

Solutions as a whole

3.73. Combining the shares in the four product markets with the remaining solutions (in-eye comfort and wetting) gives the situation for solutions as a whole as shown in Table 3.9.

TABLE 3.9 **The total market (at suppliers' prices), 1988 to 1992**

per cent

Supplier		*1988*	*1989*	*1990*	*1991*	*1992**
A. Shares of leading suppliers						
Allergan	Branded	34	38	37	38	37
	Own-label	0	0	0	1	1
	Total	34	38	37	39	38
CV-UK†	Branded	40	35	29	24	25
	Own-label	3	3	6	8	9
	Total	43	38	35	32	34
Alcon	Branded	9	8	8	7	7
	Own-label	0	0	2	3	2
	Total	9	8	10	10	9
B&L	Total	4	4	4	4	4
M&L‡	Branded	N/A	2	3	3	3
	Own-label	N/A	0	0	§	1
	Total	N/A	2	3	3	4
B&L (inc M&L)	Total¶	4	6	7	7	8
Sauflon	Branded	4	4	4	3	3
	Own-label	0	0	1	3	3
	Total	4	4	5	6	6
S&NP	Branded	3	3	2	2	2
	Own-label	1	1	1	1	0
	Total	4	4	3	3	2
PBH	Total	1	1	1	1	1
Other	Total	1	1	2	2	2
Total		100	100	100	100	100
Total value (£m)		22.7	30.9	38.7	44.0	49.7
B. Shares of own-label						
Boots		3	4	5	8	8
D&A		0	0	4	5	6
Specsavers		0	0	1	3	3
Vision Express		0	0	0	§	§
Other		0	§	0	0	0
Total own-label		3	4	10	16	17
Total value (£m)		0.70	1.14	3.81	6.99	8.36
C. Suppliers' shares of own-label solutions						
CV-UK		80	74	58	52	53
Sauflon		0	0	10	15	21
Alcon		0	0	20	16	11
Allergan		0	0	0	3	4
M&L		N/A	0	0	4	5
Waverley		0	0	4	2	3
CCL		0	0	2	5	3
S&NP		20	26	6	3	0
Total		100.0	100.0	100.0	100.0	100.0
Total value (£m)		0.70	1.14	3.81	6.99	8.36

Source: MMC calculations based on data provided by the suppliers.

*Estimate.
†Data for 1988 are for a 14-month period.
‡Data for 1989 are for part of year only.
§Less than 0.5 per cent.
¶Data for M&L for 1988 are not available and those for 1989 cover part of year only.

3.74. Allergan's share increased by four percentage points between 1988 and 1989 since which time it has remained broadly constant.[1] CV-UK's share fell by 11 percentage points between 1988 and 1991 but recovered a little in 1992. Sauflon has increased its share, mostly as a result of its supply of own-label solutions. Alcon and B&L have not experienced much change in their respective shares whilst S&NP has seen its share fall. Own-label solutions accounted for 17 per cent of all solutions sold by the suppliers in 1992 compared with 3 per cent in 1988. The shares shown for Boots and other retailers are for their own-label solutions (again at suppliers' prices). Later (see Table 3.15) we show the shares of the retail market accounted for by Boots and D&A (at retail prices). The numbers for Boots and D&A in Table 3.15 are rather higher than those in Table 3.9. This is because the retailers' shares in Table 3.9 are for own-label solutions only whereas the shares in Table 3.15 cover all solutions (both branded and own-label). At retail prices the share of the retail market accounted for by Boots is also higher than its share of the market at suppliers' prices because of the difference between Boots' gross profit margins (the prices at which it sells solutions minus the costs which it incurs in buying them) and those of other retailers, including D&A.

3.75. In 1988 the only suppliers of own-label solutions were CV-UK and S&NP. In 1992 most of the leading suppliers, apart from S&NP,[2] were providing own-label solutions.

Market entry and product innovation

Market entry

3.76. We have been told that there are a number of ways of entering the markets. These are:

(a) *Contracting-out the manufacture of solutions to other suppliers.* Allergan told us that 'toll manufacturers' specializing in the contract manufacture of pharmaceuticals operate extensively in the UK and elsewhere in Europe. It gave examples of such manufacturers as CCL (see paragraph 3.11) and Orion Farmos (Finland) which it said are used by Allergan, amongst others, for sterile filled aerosol cans; and Waverley (see paragraph 3.11), which makes and fills sterile plastic vials. Aspect entered the market in this way, its solutions being made by Waverley. There are cases where one supplier produces solutions for another supplier (eg S&NP produces Sauflon's protein removers; Allergan used to make B&L's protein removers). Retailers' own-label solutions are produced mainly by the leading suppliers such as CV-UK and Allergan but also by smaller suppliers such as Waverley and CCL.

(b) *Acquisition of an existing supplier.* An example of this approach is CIBA-GEIGY which in 1983 acquired Titmus Eurocon Ltd (Titmus Eurocon), and which greatly increased its presence in January 1988 when it purchased Coopervision Ltd (Coopervision) and Contactasol Ltd (Contactasol) (subsidiaries of the US group The Cooper Industries Inc, subsequently constituting CV-UK) and in the process acquired their solutions, including 10.10. PBH began supplying solutions in the UK in 1987 after Pilkington bought Barnes-Hind Ltd.

(c) *Entry from scratch.* Allergan said that this was possible but that it would be likely only by a supplier with a unique product advantage. Even in such circumstances, Allergan believed that this approach was improbable as the new entrant would, at least in the early stages, limit its own investment and risk by contracting-out much of the work. The closest example is Sauflon, which began supplying solutions after taking over a licensed product range and a small licensed manufacturing facility in Earl's Court.

3.77. Acquisitions of companies have also been used by the present leading suppliers to increase their share of markets. Four of the top seven suppliers (Allergan, Alcon, B&L and S&NP) were

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[1]Allergan estimates that it accounted for over 46 per cent of solutions sold in 1986 and that CV-UK accounted for over 32 per cent.

[2]S&NP does supply Sauflon, and Specsavers through Sauflon, with protein removers. To avoid double counting, solutions which are part of such arrangements between suppliers are assigned to the market share of the final supplier (eg the protein removers made by S&NP for Sauflon are defined as supplied by Sauflon).

selling solutions in the UK before 1980. Two of these have added to their solutions business by acquiring other companies active in solutions. In 1987 Allergan bought Hydron International (the principal business of which comprised the manufacture and marketing of contact lenses, but which also supplied CLS) and in 1989 B&L purchased M&L.

Product innovation

3.78. This section looks at product innovation of branded solutions; own-label CLS, for the most part, are identical to the branded solutions of the relevant supplier (see Appendix 2.6).

3.79. Over the last ten years the major product innovation has been the introduction of disinfectants which contain no preservatives—peroxides and chlorine tablets. Contactasol (see paragraph 3.76*(b)*) was the first supplier to market a preservative-free peroxide disinfectant when it launched 10.10 in 1985. Allergan responded by introducing Oxysept in 1987. The only other branded peroxide is PBH's Perform. Alcon introduced chlorine tablets in 1985. The only other supplier which offers chlorine tablets, Sauflon, introduced its version in 1987. The move to preservative-free products, which started with disinfectants, has continued with surfactant cleaners, examples being Miraflow (the first preservative-free surfactant cleaner) and LC-65. It has also extended to salines, with most suppliers now offering preservative-free versions.

3.80. Since 1988 there have been few major new products brought to the market, but a number of suppliers have introduced updated products into their range. Allergan introduced a new protein cleaner (Ultrazyme) in May 1990 (see paragraph 3.27), Lens Fresh (a comfort and wetting solution) in May 1992 and Oxysept Saline. CV-UK introduced a variation of its saline in 1992 (CIBA Saline). In May 1990 B&L marketed a new disinfectant (Optimeyes, a tablet for disinfecting certain soft lenses, which is dissolved in tap water) and in November 1991 it introduced its own protein remover (Fizziclean) to replace its branded version which had been supplied by Allergan. In January 1990 PBH began to sell a peroxide solution (Perform). Alcon introduced a protein cleaner (Clen-zym) in 1989 and a variation of a saline solution (Salette) in the same year. Sauflon and S&NP have not introduced any new products since 1988.

3.81. We have been told that there will be major changes in the near future with the introduction of so-called one-step peroxide products (Allergan's Oxysept One-Step and CV-UK's AOSept) and all-in-one or multipurpose CLS (B&L's Renu). Of these three solutions, only Oxysept One-Step has received the MCA's approval (and was on sale in the early part of 1993). [*Details omitted. See note on page iv.*]

Barriers to entry

3.82. We asked the suppliers if they felt that there were any barriers to entry. Allergan and S&NP told us that there were no barriers (but see paragraph 3.93). Four suppliers (CV-UK, B&L, Alcon and PBH) told us that the regulatory system was the main barrier. Sauflon, in overall terms a smaller company compared with the other suppliers, identified the costs it incurred when entering the market as a barrier.

Regulatory system

3.83. The four suppliers which described the regulatory system as a barrier told us that the system in the UK was the strictest in the world. They said that it took much longer to receive product approval in the UK than in other countries. Table 3.10 shows B&L's estimates of the time required to register solutions in the UK and selected other countries.

TABLE 3.10 **Time for product registration in the UK and selected overseas countries**

Time (months)

Countries	*Salines*	*Multipurpose solutions*	*Surfactant cleaners*	*Protein removers*
UK	36+	36+	24	48
Canada	NR	7	NR	NR
France	18	6	18	12
Italy	7	9	9	NR
Spain	18	24	24	18
Switzerland	6	6	6	16
USA	24	10	27	11

Source: B&L.

Note: NR = Not regulated.

3.84. According to B&L's estimates, product registration for salines, multipurpose CLS and protein cleaners takes substantially longer in the UK than in the other countries. For surfactant cleaners, the time taken in the UK is similar to that in the USA and Spain.

3.85. [

Details omitted. See note on page iv.

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3.86. B&L told us of a similar experience with its multipurpose solution, Renu. It said that it had submitted its application to the MCA in 1988 and it had not yet received the MCA's approval for a solution that was widely sold outside the UK. B&L stated that its Renu and Alcon's Opti-free (a disinfectant for soft lenses) were taking market share away from the peroxide disinfectants in countries outside the UK. It said that in Australia the introduction of Renu and Opti-free had reduced the market share held by Allergan from the high 30s per cent to the low 30s in a short space of time. B&L also told us that in Australia the price of Renu was over 50 per cent lower than some disinfecting systems and that when introduced into the UK the price of Renu would be about 75 per cent of the price of other solutions currently on the market. B&L added that it also wanted to introduce two other CLS (under the name Advance) into the UK, but as these solutions had similar chemical components to Renu it would not seek regulatory approval for them until Renu had been accepted by the MCA (see Appendix 3.5).

3.87. Alcon said that it had an application for a new product on which it had been working for four years and which was now being reviewed by the MCA. In Alcon's view, the MCA would not grant a licence for at least another year. Alcon also told us that it had another six solutions which it sold in other countries and which it would market in the UK if it could gain regulatory approval (see Appendix 3.5).

3.88. Other suppliers told us that they too had CLS which they sold in other countries but were unable to offer in the UK because the MCA had not approved them. Sauflon told us that it had five such products and PBH told us that it had two (see Appendix 3.5).

3.89. Allergan stated that the regulatory system in the UK applied to all suppliers and that the costs of compliance facing a new entrant were the same as those incurred by existing suppliers. It said that the system had been in operation since 1980 and that the rules were clear. It told us that its application for its one-step peroxide system had been submitted to the MCA in March 1992 and that it had been approved by the MCA and was on sale in the early part of 1993. Whilst Allergan told us that the product regulations were not a barrier to entry, the MCA had decided that Ultrazyme, Allergan's newest protein remover, could only be recommended for use with Oxysept, its peroxide solution, and not with any other peroxide, as Allergan believed it could.

3.90. The MCA told us that it believed that its licensing requirements:

(a) were straightforward and easily interpretable via well publicized guidelines;

(b) did not involve a large R&D investment, by contrast with orthodox pharmaceuticals;

(c) had been readily explained to potential applicants who wished to meet with MCA professional assessors either confidentially at the MCA or (at no cost) at public meetings; and

(d) were ultimately met by virtually all applicants whether experienced in pharmaceutical regulation or not.

3.91. After committee consideration of a product licence application, a meeting was held with the company concerned, if requested, to explain the basis of the queries raised. The MCA pointed out that if any company considered that some of the data requested by the MCA were unnecessary, a justification could be put forward for their omission. Occasionally the possibility of addressing the concerns in an alternative manner was explored if the company considered that the work envisaged was excessive.

3.92. The MCA said that licence applications for solutions were now quickly picked up following validation (a check for correctness and completeness of the submission) and processed within three months if no committee advice was needed (around six months if committee advice had to be sought—see paragraph 2.31). It contended that processing of UK licence applications was now as fast as, if not faster than, in any EC member state, and faster than the USA.

The size of the markets in the UK

3.93. Allergan told us that given the limited value of the CLS in the UK (£50 million at suppliers' prices—see Table 3.2) and the global nature of the industry, it was unlikely that any supplier would find it worthwhile to research and develop new solutions for sale exclusively in the UK.

Patents

3.94. Patents constitute a barrier to entry when they prevent other companies producing and marketing products based on the same or a similar formulation. The effect is reduced where licences of rights apply to patents. Patents can, however, also be an incentive to introducing new products by protecting the innovator's product. A number of CLS are covered by patents. This is true of the peroxide solutions of Allergan and CV-UK. Allergan told us that the UK patent was statutorily treated as if endorsed subject to licences of right, under which anyone could apply to use the invention on payment of a royalty which, in the absence of agreement, was fixed by the Comptroller-General of Patents, subject to appeal to the Patents Court. The same applied to Allergan's Hydrocare Fizzy protein remover. Allergan said that its patent on Ultrazyme had been revoked by the Opposition Division of the European Patent Office but that the decision was currently under appeal. If the patent was restored, it would expire in 2006. This patent was not subject to a 'licence of right'.

3.95. Alcon told us that it had patents on Pliagel, due to expire in 1993, and on Softab, due to expire in 2000. Alcon said that other suppliers did not have access to these patented CLS via patent licences. B&L told us that Renu was covered by a patent until 2008.

Solutions sold as systems

3.96. Most suppliers sell their solutions as parts of systems (see Appendix 3.4). This practice may mean that potential entrants, if they are to be successful, have to offer products making up at least one complete system. This would have the effect of increasing the cost of entry into the branded part of the market. On the other hand, D&A told us that it would consider buying individual products to include in its own-label systems and that this might provide a means of entry into the own-label part of the market for suppliers with a single product.

Discount structure

3.97. The discount structure (see paragraphs 3.216 to 3.224 and Appendix 3.12) of most suppliers is based on volumes sold—the higher the volume, the greater the discount. Such volume-related discounts may be part of a suppliers' standard discount structure or part of a retrospective scheme. In both cases the result may be that wholesalers and retailers are less willing to widen their range of CLS, particularly for smaller players, as this may lead to the volumes from other suppliers falling into a lower band and therefore generating smaller discounts.

R&D and promotional costs

3.98. Where R&D and promotional costs are high they can act as a barrier to new firms wishing to enter the market or as an obstacle to existing firms wishing to expand in the market. Allergan estimates that its expenditure on R&D is about [§] per cent of its turnover. It also said that promotional costs accounted for about [§] per cent of turnover. Promotion is usually aimed at opticians and not directly at consumers, although Allergan told us that by [§]. Allergan moreover ran television advertising campaigns in the South-East of England in 1991 and 1992, and a national newspaper campaign in autumn 1992; and it has regularly undertaken promotions of its solutions aimed at encouraging consumers to visit and consult opticians. The largest item in the promotion of solutions is the provision of starter packs (see paragraphs 3.37 and 3.38).

Supply to wholesalers and retailers

Current situation

3.99. The suppliers provided us with estimates of their sales of CLS (at suppliers' prices) to wholesalers and retailers in 1991 and 1992. The 1992 position is summarized in Table 3.11. Sales to wholesalers are shown separately for optical and pharmaceutical wholesalers (see paragraph 3.127). Direct sales to retailers are recorded separately for opticians (excluding BOL and D&A); BTC and BOL, together referred to as Boots; D&A; and others (including pharmacies other than BTC, and buying groups). The relationship between BTC and BOL is explained in paragraph 4.65.

TABLE 3.11 **Sales of solutions through each trade channel in 1992***

per cent

	Trade channels					
Supplier	*Opticians†*	*Optical wholesalers*	*Pharmaceutical wholesalers*	*Boots*	*D&A*	*Others‡*
Allergan	30	13	10	31	6	10
CV-UK	30	6	13	37	13	1
Alcon	22	20	7	28	23	0
B&L	56	33	0	0	11	0
M&L	17	32	5	14	32	0
Sauflon	84	5	0	0	11	0
PBH	73	23	0	0	1	3
S&NP	8	18	34	36	0	5
Total	34	13	10	28	11	4
Total value (£m)	16.8	6.3	4.9	14.2	5.7	1.8

Source: MMC calculations on data provided by the suppliers.

*Suppliers also provided us with data for 1991. This showed the following shares of total sales: opticians 33 per cent, optical wholesalers 14 per cent, pharmaceutical wholesalers 9 per cent, Boots 28 per cent, D&A 13 per cent, and others 3 per cent.

†Excludes BOL and D&A.

‡Includes pharmacies, other than BTC, and buying groups.

§Details omitted. See note on page iv.

3.100. The largest two trade channels are opticians (34 per cent) and Boots (28 per cent), though as explained above (see paragraph 3.74), at retail prices the Boots share works out at a considerably higher figure.

3.101. Boots and opticians are the two main trade channels for Allergan and CV-UK. Boots is the main trade channel for Alcon, accounting for 28 per cent of its solutions, while D&A, opticians, and optical wholesalers each receive about 20 per cent.

3.102. B&L's policy is to confine the retail sales of its solutions to optical outlets. In 1992 two-thirds of B&L's solutions were sold direct to opticians (including D&A) with the remainder being sold to optical wholesalers. In the same year, most of M&L's CLS went, directly or indirectly, to opticians; direct sales to opticians (including D&A but excluding BOL) accounted for 49 per cent and indirect sales (optical wholesalers) for 32 per cent.

3.103. Like B&L, Sauflon has a policy of confining the retail sales of its solutions to opticians. 95 per cent of Sauflon's solutions are supplied direct to opticians (including D&A) with the remainder going to optical wholesalers. Sauflon told us that it did not supply its CLS to Boots as this would conflict with its policy of not selling through chemists. S&NP's main trade channels are Boots (36 per cent) and pharmaceutical wholesalers (34 per cent).

3.104. All PBH's solutions are sold directly or indirectly to opticians. PBH told us that its reason for this was that, in order for a solution to achieve sales, it must first be introduced to contact lens wearers by the optician, in the form of a starter pack. It said that pharmacies in general did not become interested in stocking a solution and 'catching the passing trade' until that CLS had achieved a reasonable market share. PBH told us that its solutions had not yet attracted sufficient market share, and therefore 'passing trade', for it to consider changing its policy of concentrating its marketing effort within the optical sector of the market.

3.105. Table 3.11 also shows that the two leading suppliers use optical wholesalers less than most of the other suppliers do (the lower number for Sauflon may reflect the high proportion of Sauflon's sales which are own-label solutions). In 1992 6 per cent of CV-UK's solutions were sold to optical wholesalers; in the case of Allergan, optical wholesalers accounted for 13 per cent of its sales. Sales of solutions to optical wholesalers for the other leading suppliers apart from Sauflon ranged from 18 per cent (S&NP) to 33 per cent (B&L).

3.106. We estimate that just under 65 per cent of CLS (at suppliers' prices) were sold (directly and indirectly) to opticians in 1991 and 1992. Apart from the 34 per cent going to the opticians trade channel itself, our estimates are based on the assumption that opticians account for the following proportion of sales to the other trade channels: optical wholesalers over 90 per cent, pharmaceutical wholesalers nil, Boots 12 per cent (some branded solutions sold by BOL are supplied by optical wholesalers), D&A 100 per cent, and others 60 per cent.

Changes over time

3.107. We asked suppliers to estimate the changes over the last few years in the pattern of their sales to trade channels. Allergan told us that for its solutions, sales to pharmacies had grown from 30 per cent in 1989 to over 40 per cent in 1992. It further told us that in the early 1970s almost all sales of solutions were via opticians, and that it regarded the increased sales to pharmacies as the most prominent development in the distribution of solutions over the last two decades.

3.108. CV-UK said that its sales to opticians had fallen substantially over this period whilst sales to Boots had greatly increased.

3.109. Alcon told us that before the introduction of product licensing in the early 1980s, most CLS had been distributed direct to opticians or via pharmaceutical wholesalers. Since this time the role of the specialist optical wholesaler had increased and optical wholesalers now accounted for a significant proportion of sales to independent opticians.

3.110. Alcon told us that more recently, the main changes were the considerable increase in the proportion of its sales going to D&A and Boots with a corresponding fall in the proportion of solutions going to other opticians, optical wholesalers and pharmaceutical wholesalers: the significant growth of its sales of solutions to Boots reflected increased pharmacy sales.

3.111. The proportion of B&L's solutions sold direct to opticians other than D&A has fallen from about 60 per cent in 1989 to 56 per cent in 1992. During the same period, the proportion of B&L's solutions sold to optical wholesalers has increased from 21 to 33 per cent.

3.112. Sauflon said that it believed its sales to opticians had increased at a faster rate than those to optical wholesalers. The largest change for PBH was the increased proportion of its CLS supplied to optical wholesalers: in 1988 this accounted for less than 10 per cent of its sales, rising to over 30 per cent in 1991, but falling back to over 20 per cent in 1992. The only large change noted by S&NP was the fall in its sales through optical wholesalers.

Retailers' own-label solutions

3.113. The leading retailers of own-label solutions are Boots, D&A and Specsavers, each with its own large chain of opticians. The opticians outlets in these three groups have a policy of recommending their own-label CLS to new wearers of contact lenses. Vision Express UK Ltd (Vision Express, a group of opticians) also sells own-label solutions. Specialeyes Plc (a small group of opticians) sold its own-label solutions in a small number of its outlets for a short period in 1992.

Boots

3.114. BTC entered the CLS market in a very small way in 1968. Boots told us that when BOL was established in 1983 its product range was extended. Two years later, in 1985, Boots started selling its own-label solutions in its pharmacies and opticians outlets.

3.115. Boots told us that its group policy was to recommend its own-label CLS but that its opticians would recommend branded solutions if they were required for clinical reasons. Boots also said that it did not have a group policy of encouraging customers who were new to BOL, but not first-time wearers, to switch from their existing CLS to Boots' own-label solutions. It told us that its opticians would only change an existing wearer's solutions if these were proving to be inappropriate or causing adverse reactions.

3.116. In 1988, Boots' own-label solutions consisted of two cold chemical systems, one for hard/GP lenses and one for soft lenses. These were supplied by CV-UK. In the same year, Boots sold own-label protein removal tablets manufactured by S&NP. These were replaced by the effervescent version, supplied by Allergan, in October 1991. In 1989 Boots introduced its own-label peroxide system, provided by CV-UK and equivalent to CV-UK's 10.10 system. In 1990 Boots increased its product range by adding its own-label saline solutions. In 1991, through a supply arrangement with Allergan, Boots began to sell own-label versions of an all-in-one solution for hard/GP lenses, and a preservative-free daily cleaner.

D&A

3.117. D&A began selling branded CLS in 1967 and own-label solutions in 1990. D&A is supplied with own-label solutions by CV-UK, Alcon, Sauflon and M&L.

3.118. D&A told us that for new patients it generally recommended its own-label CLS where these were considered entirely suitable for the patient's requirements. It said that other solutions were recommended in other instances. D&A told us that existing contact lens wearers purchasing repeat supplies of other solutions were advised to continue to use these as appropriate. It also said that it encouraged its staff to make the customer aware of its own-label solutions where this was sensible because of the benefit these provided in cost savings; however, if patients wished to remain with their existing brands they were advised to do so.

Specsavers

3.119. Specsavers is a group of franchised stores which are operated independently by the owner/director who is on site. Specsavers began to sell own-label CLS about three years ago; it is supplied by Sauflon and Waverley.

Possible new entrants

3.120. Superdrug Stores Plc (Superdrug) and Lloyds Chemists Plc (Lloyds) told us that they have had a number of discussions with suppliers with a view to introducing own-label solutions as soon as the appropriate licences can be obtained. Superdrug told us that the application procedure is such that it did not expect to have a licence before 1994. UniChem PLC (UniChem) told us that it would be launching its own-label peroxide in the early part of 1993. The solution would be supplied by Waverley.

Suppliers' policies on own-label solutions

3.121. The importance of own-label CLS for certain suppliers is shown in Tables 3.3 to 3.9.

3.122. Most own-label solutions are produced by the leading suppliers and are identical to the suppliers' equivalent branded CLS (see Appendix 2.6).

3.123. Allergan told us that initially it had refused to supply own-label solutions, but that once these had begun to be produced by the other leading suppliers such as CV-UK and Alcon it had felt that it had no alternative but to enter this part of the market. Alcon told us that it would consider any requests for the supply of own-label solutions; each application would be considered on its merits.

3.124. B&L stated that in general terms the corporate policy of the B&L group was not to supply own-label CLS since it detracted from the 'value added' to B&L solutions as a brand name. It said that as the group produced solutions on a global basis, own-label solutions also created inefficient production runs and consequently higher unit costs. B&L told us that exceptions to the own-label policy were considered case by case in terms of cost and potential sales volume. B&L said that the own-label solutions supplied to D&A were the only instance of own-label supply that B&L had agreed to.

3.125. Sauflon told us that it started to supply own-label CLS because it was aware that other manufacturers were prepared to do the same. By supplying own-label solutions, Sauflon said that its market share at the distribution level had rapidly increased. S&NP told us that it was prepared to make own-label solutions available subject to the commercial and technical competence of the customer.

3.126. [

Details omitted. See note on page iv.

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Wholesalers

3.127. There are two types of wholesalers of CLS: optical wholesalers and pharmaceutical wholesalers. Optical wholesalers deal mainly with opticians whilst pharmaceutical wholesalers deal principally with pharmacists. As a result, the wholesalers mainly see themselves as competing against other

wholesalers of the same type and against the direct delivery of the suppliers. Competition mainly takes the form of price, speed of delivery and ability to give advice to retailers. Mid-Optic Limited (Mid-Optic), one of the leading optical wholesalers, told us that it could not compete against pharmaceutical wholesalers on price, and that it relied to a large extent on its greater knowledge of solutions and capacity to give independent advice.

3.128. There are eight optical wholesalers, most with a turnover of under £0.5 million a year. Three have a turnover of over £1 million, these being Martin Optical (Martin), Mid-Optic and Aspect. CLS account for a large proportion of most optical wholesalers' overall business. Mid-Optic told us that just over ten years ago there had been about 45 wholesalers of solutions.

3.129. In October 1990 Aspect began marketing its own-label CLS, Prosept (a peroxide disinfectant) and Prosol (a cold chemical disinfectant).

3.130. Solutions form a small proportion of pharmaceutical wholesalers' overall business. However, each of the two leading pharmaceutical wholesalers, AAH Pharmaceuticals Limited (AAH) and UniChem, has an annual turnover in CLS of well over £1 million.

Barriers to entry

3.131. We carried out a survey of wholesalers of solutions, both optical and pharmaceutical (see Appendix 3.6). We asked wholesalers if there were any barriers to entry or expansion or both. Five out of eight optical wholesalers told us that there were such barriers. Two told us that the cost of the wholesalers' licence was a barrier and two gave low profitability as a barrier. Of the 14 pharmaceutical wholesalers which offered views, 10 said that there were no barriers to entry and 12 said that there were no barriers to expansion.

Reduction in discounts to optical wholesalers in 1987

3.132. In March 1987 Allergan, companies now comprising CV-UK, and S&NP reduced discounts to optical wholesalers from 25 to 15 per cent. Mid-Optic told us that this reduction resulted in a loss of business for these wholesalers.

3.133. Allergan gave us three reasons which it said supported its belief that a discount greater than 15 per cent for optical wholesalers was not justified. First, at 15 per cent, Allergan recognized that it was more economical for it to service smaller optical outlets through wholesalers; at a higher level of discount it would rapidly become more economical for Allergan to deal directly. Secondly, Allergan believed that a discount of 15 per cent provided an adequate gross margin on which an efficient wholesaler could profitably distribute CLS, with a fully adequate level of service to its customers. Thirdly, there seemed to Allergan to be no adequate reason to give discounts at a higher level to optical wholesalers than to pharmaceutical wholesalers; reintroduction of a differential, in its view, would be likely to lead to unfair competition on the part of optical wholesalers for the solutions business of pharmacies.

3.134. One optical wholesaler, Aspect, told us that as a result of this reduction in discount, it now sourced all its supplies of Allergan and CV-UK solutions from retailers, at a higher discount (ie lower price) than it could obtain from the suppliers themselves. Allergan said that it had contemplated reducing the discount on solutions which were sold by retailers to wholesalers to the same level as that given to wholesalers; solutions supplied to retailers for sale to consumers would still receive the higher discount. Allergan said that such a reduction would be justified as the retailers were no longer carrying out the function for which Allergan intended the higher discounts; they therefore should receive the same discount as other wholesalers (see paragraphs 6.74 to 6.77).

Retailers

Surveys

3.135. In order to gain information about the retail level we arranged for three surveys, covering opticians, pharmacies, and contact lens wearers (consumers), to be carried out. Details of the surveys can be found at Appendices 3.7 to 3.10.

Opticians

3.136. Solutions account for a small proportion of opticians' turnover. 27 per cent of the opticians included in our opticians survey had a total turnover in their latest trading year of up to £100,000, and under half had a total turnover of between £100,000 and £300,000. Just over half of the opticians had a turnover relating to CLS of between £1,000 and £10,000 in their latest trading year.

3.137. The optician is the customer's main source of information on solutions, and hence plays a key role in providing advice to consumers. The role of the optician has been presented to us as that of a 'gatekeeper' between the supplier and customer, using his or her professional knowledge to choose the most suitable solution. The role of the optician distinguishes solutions from many other goods in that there is a separation between the person who, on the whole, decides what solutions should be used, and the person who pays for the solutions. In this respect the optician is in a position similar to that of a medical practitioner—but unlike the typical medical practitioner the optician sells the product as well as having an important role in choosing what the patient should buy.

3.138. 70 per cent of users in our consumers survey said that the optician recommended the type or brand of CLS they use, 59 per cent being recommended a particular brand and 11 per cent being recommended a particular type of solution. This compares with 13 per cent of wearers who decided to use their solution on the basis of cost, 1 per cent on the recommendation of a doctor, and less than half of 1 per cent on the recommendation of a pharmacist.

3.139. Suppliers see the successful promotion of their CLS to opticians and the recommendation of their solutions by opticians to customers as crucial to their success. Allergan told us that any supplier that failed to encourage opticians to provide initial recommendations for its products would expect to find its customer base eroded over time, eventually losing out on repeat as well as optician-advised purchases.

3.140. It is because of the importance of opticians in this industry that suppliers focus much of their attention on demonstrating to opticians the advantages of their products (see paragraphs 3.37 to 3.39 on suppliers' marketing and promotion). To achieve this goal suppliers may undertake some or all of the following:

(a) supply to opticians of literature demonstrating the technical superiority of their solutions;

(b) supply to opticians of comparative clinical data;

(c) inclusion of opticians in pre-market trials;

(d) presentation of clinical papers at symposia and conferences attended by opticians;

(e) the holding of regional meetings of opticians;

(f) participation in optical industry exhibitions; and

(g) direct mail shots to opticians.

3.141. We asked opticians to give us up to three reasons which they regarded as the most important when recommending a disinfecting system to their last three customers wearing hard/GP lenses and also to their last three customers wearing soft lenses. Table 3.12 shows the results.

TABLE 3.12 **The reasons that were most important to opticians in recommending a disinfecting system***

	Types of lenses	
	Hard/GP	*Soft*
(Base)	(299)	(296)
	Percentage of opticians	
Technically less likely to cause irritation to the eye	34	61
Solution effectiveness	78	78
Easy to use	61	45
Reasonable cost to the customer	28	25
Widely available	20	18
Few complaints from existing customers	25	20
Profitable to sell	2	4
Other	5	4

Source: MMC opticians survey.

*Averaged for the last three customers.

3.142. Table 3.12 shows that 78 per cent of opticians gave 'solution effectiveness' as one of the three most important reasons for their recommendation of solutions for both hard/GP and soft lenses. The second most popular category differed by type of lens. 61 per cent of opticians gave 'less likely to cause irritation' as one of the most important reasons for their recommendation of solutions for soft lenses compared with 34 per cent for hard/GP lenses. 61 per cent of opticians gave 'easy to use' as one of the most important reasons for their recommendation of CLS for hard/GP lenses compared with 45 per cent for soft lenses.

3.143. Only about one-quarter of opticians gave 'reasonable cost to the customer' as one of the three most important reasons for their recommendation of solutions for both hard/GP and soft lenses. For D&A the corresponding proportion was 44 per cent while for BOL the proportion was 38 per cent for hard/GP lenses and 11 per cent for soft lenses.

3.144. 67 per cent of opticians in the survey told us that in the last five years they had changed their advice as to the type of disinfecting system they normally recommend for soft lenses; this compares with 21 per cent for hard/GP lenses. 83 per cent of opticians recommend a cold chemical disinfecting solution for hard/GP lenses compared with 5 per cent for soft lenses, down from 47 per cent during the last five years. Three-quarters of opticians recommend a peroxide system for wearers of soft contact lenses, while 13 per cent advise a chlorine system.

3.145. 91 per cent of BOL's opticians and 77 per cent of D&A's opticians usually recommend a cold chemical disinfectant for hard/GP lenses. For soft lenses, virtually all of BOL's opticians normally recommend a peroxide disinfectant (the remainder typically advise chlorine tablets) whereas 81 per cent of D&A's opticians usually recommend a peroxide disinfectant, 10 per cent normally recommend chlorine tablets, and 2 per cent cold chemical disinfectants.

3.146. When asked whether most wearers of soft lenses could satisfactorily use certain systems, 93 per cent of opticians said that this was the case for peroxide systems, 79 per cent told us that this was the case for chlorine systems, and 50 per cent said the same for cold chemical systems. For BOL the proportions were 94 per cent for peroxides, 74 per cent for chlorine tablets and 37 per cent for cold chemical disinfectants. For D&A they were 79 per cent for peroxides, 67 per cent for chlorine tablets and 48 per cent for cold chemical disinfectants.

3.147. Virtually all opticians told us that they always, or nearly always, or mostly give advice to their customers on the likely future costs to them of buying CLS. However, 71 per cent of wearers in our consumer survey said that when they were first considering wearing contact lenses, the optician did not discuss with them the likely future cost of buying solutions. 28 per cent of the consumers whose opticians did discuss the likely future cost of buying solutions (8 per cent of all consumers) told us that the discussion took place after they had made their decision to wear lenses. Adding these two groups together gives the result that 79 per cent of wearers in our consumer survey said that the

optician did not discuss with them the likely future cost of buying CLS either when they were first considering wearing contact lenses or before they had made their decision to wear lenses.

3.148. The findings of the consumer survey on this topic for consumers who have been wearing lenses for one year or less are as follows: 53 per cent told us that opticians did not discuss the likely future cost; 36 per cent of the remainder (18 per cent of this group) told us that the discussion about likely future cost of solutions took place after they had made their decision to wear lenses. Therefore 71 per cent of this group of consumers said that the optician did not discuss with them the likely future cost of buying CLS either when they were first considering wearing contact lenses or before they had made their decision to wear lenses.

Pharmacists

3.149. Sales of solutions account for a small proportion of the total turnover of pharmacies. 7 per cent of pharmacies included in our pharmacies survey had a total turnover in their latest trading year of up to £100,000. A further 42 per cent had a total turnover of between £100,000 and £400,000. Just under two-thirds of pharmacies had a turnover relating to solutions of £5,000 or less in their latest trading year.

3.150. The pharmacist's role as a source of information on solutions is much less influential than that of the optician. We asked pharmacies how often in the week after they received our questionnaire their pharmacist(s) had been asked for advice in connection with eye problems and also specifically in connection with CLS. Table 3.13 shows the main findings.

TABLE 3.13 **Number of times pharmacists were asked for advice on eye problems and solutions**

*Number of times asked for advice**	*Type of advice*	
	Eye problems	*Solutions*
(Base)	(427)	(427)
	Percentage of pharmacies	
None	29	36
1 to 5	37	39
6 to 10	10	7
More than 11	12	5
Not answered	12	13
Mean	5.2	2.9

Source: RSGB.

*In the week after receiving our questionnaire.

3.151. These numbers suggest that about 60 per cent of pharmacists explicitly reported that they had been asked for advice about eye problems in the relevant weeks; the equivalent proportion for advice about solutions was about 50 per cent. In the average pharmacy the pharmacist will be asked for advice about eye problems by about five consumers per week and about CLS by about three consumers per week.

3.152. We asked pharmacies how often in the week after they received our questionnaire their pharmacist(s) had been asked for particular advice in connection with solutions. Table 3.14 summarizes the findings and Annex 1 of Appendix 3.9 contains the more detailed responses.

3.153. Table 3.14 shows that, in the week of the survey, the proportion of pharmacists who were asked for advice by consumers on specific areas of solutions—column *(a)*—ranged from 34 per cent (use of solutions with particular types of lenses) to 11 per cent (likely reaction to particular solutions). Column *(b)* shows that in a year a pharmacist in an average pharmacy receives between 14 enquiries ('on likely reaction to particular solutions') and 47 enquiries ('on use of solutions with particular types of lenses').

TABLE 3.14 **Number of times pharmacists were asked for particular advice on solutions***

	Advice sought (percentage of pharmacies) (a)	*Advice sought (implied average annual number of queries per pharmacy)† (b)*	*Advice sought and given with no referral to optician (percentage of number per pharmacy)† (c)*	*Advice sought and given with no referral to optician (implied average) (d)*	*(d) as a percentage of (b)‡ (e)*
(Base)	(427)	(427)	(427)	(427)	
Soreness or other problems where solutions were thought to be the cause	22	27	11	13	48
Likely reaction to particular solutions	11	14	7	7	48
Use of solutions with particular types of lenses	34	47	26	32	68
Use of solutions within the same brand range	15	28	10	12	43
Use of solutions with those of a different brand	23	39	18	27	69
Possibility of switching	29	36	19	28	77
Other specified areas	20	37	7	13	35

Source: MMC calculations.

*Based on the week after receiving our questionnaire.
†Weekly mean multiplied by 52.
‡Refers to unrounded data.

3.154. Column *(e)* of Table 3.14 shows the percentage of pharmacists who said that they answered consumers' questions on particular subjects without referring them to an optician, ranging from 77 per cent ('on the possibility of switching') to 43 per cent ('on the use of CLS within the same brand range').

3.155. 90 per cent of users in our consumer survey said that they had never asked a pharmacist for advice about solutions.

Number of outlets

3.156. For the reasons set out in paragraph 2.26, solutions can only be sold by opticians and pharmacies. Supermarkets can stock CLS only through in-house pharmacies. There are over 11,000 pharmacies and over 6,000 opticians in the UK, most of which sell solutions. D&A has the largest number of optical outlets (479), about 7 per cent of the total number; BOL with 287 opticians outlets accounts for about 4 per cent. Boots told us that about 40 per cent of its outlets are located in retail stores of BTC. Specsavers represents about a further 3 per cent.

3.157. BTC has the largest number of pharmacies (1,060), about 9 per cent of the total number. The second largest retail pharmacy chain is Lloyds, which accounts for about 7 per cent of the total number of outlets.

3.158. Boots is therefore the only retailer with a large number of both opticians and pharmacies. Its own-label solutions are recommended by its opticians and are also available from its pharmacies. Other retailers with own-label CLS or thinking of introducing own-label solutions (see paragraphs 3.117 to 3.120) do not, at present, have such coverage of both opticians and pharmacies.

The value of solutions at the retail level

3.159. There is no widely accepted estimate of the retail value of CLS. The market research company Nielsen produces an estimate of the value of sales of solutions (including VAT) through pharmacies. Its data, however, exclude sales by BTC. The management consultancy arm of Touche Ross carries out (for FODO) a regular survey of opticians which includes the value of their sales of solutions. This survey, whilst including the main opticians such as D&A and BOL, covers only 13 groups of opticians. Various market research reports have put the retail value of solutions in the early 1990s at between £66 million and £105 million.

3.160. Table 3.15 shows our estimate of the retail value of solutions and the shares held by Boots and D&A based on retail prices. The total values are derived from suppliers' estimates of the sales of their branded solutions to wholesalers and retailers valued at RRP, and the sales of own-label solutions to retailers at retail prices. Boots and D&A sales reflect company estimates. The total values will be somewhat overestimated as some opticians' prices are less than the RRP (see Table 3.22). The Boots share will be correspondingly understated since Boots sells all branded solutions at RRP, though for D&A, which sells branded products a little under RRP and also operates a discount scheme, the position is not clear cut.

TABLE 3.15 **The retail value of solutions and the shares of the leading retailers, 1988 to 1992**

per cent

Retailer	*1988*	*1989*	*1990*	*1991*	*1992**
BTC†	N/A	22	24	30	31
BOL†	N/A	7	8	6	5
Boots total†	N/A	29	32	36	36
D&A‡	N/A	N/A	N/A	12	10
Other	N/A	N/A	N/A	52	54
Total	N/A	N/A	N/A	100	100
Total value (£m)	40	55	70	79	91

Source: MMC calculations based on data provided by the suppliers, Boots and D&A.

*Estimate.
†Year ending the following March.
‡Year ending November.

3.161. The retail value of CLS more than doubled between 1988 (£40 million) and 1992 (£91 million).

3.162. Boots raised its share of retail solutions from 29 per cent in 1989 to 36 per cent in 1992, all the increase coming from its pharmacies, which expanded their share from 22 per cent in 1989 to 31 per cent in 1992. D&A accounted for 12 per cent of the retail value of solutions in 1991, falling to 10 per cent in 1992. Lloyds had about 1 per cent of the retail market in 1991.

3.163. We have estimated the proportion of the retail market accounted for by own-label solutions by incorporating data given to us by Boots and D&A and by adjusting the value of own-label CLS of Specsavers and Vision Express from suppliers' prices to retail prices. We estimate that in 1992 own-label solutions accounted for between 20 and 25 per cent of the retail market (compared with 17 per cent of the market at suppliers' prices—see Table 3.9).

3.164. In 1992 own-label solutions accounted for 35 per cent of Boots' total turnover of CLS (including both BOL and BTC). The proportion for BTC was 33 per cent and for BOL 45 per cent.

TABLE 3.16 **Growth in Boots' sales of solutions, 1989 to 1991**

	*1989**	*1990**	*1991**	*1992*†*
BTC:				
Branded	100	127	169	196
Own-label	100	169	254	320
Total	100	136	189	225
BOL:				
Branded	100	126	101	74
Own-label	100	279	395	373
Total	100	148	143	116
Boots group:				
Branded	100	127	152	166
Own-label	100	186	275	328
Total	100	139	178	200

Source: MMC calculations on data provided by Boots.

*Year ending the following March.
†Estimate.

3.165. Table 3.16 shows that own-label solutions sold by BOL experienced the largest growth between 1989 and 1992. Sales of branded solutions by BOL in 1992 were considerably lower than in 1989. Between 1989 and 1992 sales of own-label solutions by BTC have grown more than sales of branded CLS.

3.166. D&A estimates that, on the basis of volume, 65 per cent of its sales in 1992 were own-label solutions.

Retail sales by type of outlet

3.167. There is no widely accepted estimate of the proportion of retail sales of solutions through opticians or pharmacies. Various market research reports have suggested that in the early 1990s opticians accounted for about one-third of solutions sold and pharmacies for about two-thirds. We were told of one such estimate by Market Assessment (a market research company) which stated that in 1990 opticians accounted for 35 per cent of solutions sold, falling slightly to one-third in 1991. In its estimates, Market Assessment classified all sales by Boots as being pharmacy sales. Reallocation of the value of sales of CLS by BOL would increase the proportion of sales through opticians from one-third to about 40 per cent. Sauflon told us that market research companies estimated that in the early 1980s opticians accounted for just under two-thirds of solutions sold.

3.168. Allergan said that for solutions as a whole, pharmacy sales probably accounted for somewhat less than half of all sales, since some suppliers (including Sauflon and B&L) had opted to distribute

exclusively through opticians' outlets. 50 per cent of wearers in our consumer survey said that they normally buy their CLS from opticians, 40 per cent said that they normally buy them from pharmacies and 10 per cent told us that they buy solutions from both opticians and pharmacies.

3.169. We estimate that just under 60 per cent of solutions (at retail prices) were sold through opticians and just over 40 per cent through pharmacies in 1992. This compares with just under 65 per cent of CLS, at suppliers' prices, sold directly and indirectly to opticians and just under 35 per cent to pharmacies in 1992—see paragraph 3.106. We have estimated the proportion of solutions sold through the different types of outlets at retail prices by:

(a) using the value of solutions handled by Boots and D&A (as estimated by Boots and D&A respectively), which together accounted for 46 per cent of retail sales in 1992—see Table 3.15;

(b) using the assumptions in paragraph 3.106 to allocate the shares of the other trade channels to opticians and pharmacies, after adjusting for the retail value of Boots' and D&A's sales; and

(c) taking account of CLS sold by optical wholesalers to BOL.

Barriers to entry

3.170. As already noted, under the present regulatory system, only opticians and pharmacies are allowed to sell CLS (see paragraph 2.26).

3.171. There are regulations governing the opening of pharmacies (see paragraph 2.55). Since 1987 the total number of pharmacies has stayed broadly constant. There are currently some 70 pharmacies opening each year in England, although this is more or less matched by around 55 closures each year. Most new pharmacies are established at some distance from existing pharmacies; 61 per cent of the pharmacies that were set up in 1990 were more than half a mile from the nearest existing pharmacy.

3.172. No similar restrictions apply when an optician wishes to open an outlet.

3.173. Over 60 per cent of users in our consumer survey said that they did not find it inconvenient that solutions were sold only in opticians and pharmacies. However, 79 per cent of users said that they would like solutions to be sold in a wider variety of retail outlets. We asked suppliers what the effect on retail prices would be if there was a widening of the type of retail outlets allowed to sell solutions. Of the seven leading suppliers, three told us that prices would not change, three said that prices would fall, and one said that it did not know what would happen. We asked wholesalers the same question. Of the eight optical wholesalers, five said that there would be no change in prices, whilst three said that prices would fall. Of the 14 pharmaceutical wholesalers which gave a view, seven said that prices would fall and seven said that there would be no change.

Frequency of switching by consumers

3.174. 50 per cent of users in our consumer survey told us that they had made at least one change in the range of CLS they used. Of those wearing lenses for one year or less, 29 per cent had switched solutions; 38 per cent of those wearing lenses for between two and five years had made a change; and of those wearing lenses for six or more years, 62 per cent had switched.

3.175. Two-thirds of those who have switched solutions have changed their brand of disinfecting solution.

3.176. The most popular reason for switching solutions, given by 25 per cent of those who had made a change (12.5 per cent of the sample), was that the new solution was cheaper. Four of the reasons for switching CLS (changed type of lens, sore eyes, optician recommended new solution, and changed opticians) may be thought of as reasons where the consumer may not have taken the initiative to switch. If such users are excluded, the extent of switching falls from 50 to 27 per cent.

Pricing of solutions

RRP

3.177. All suppliers issue price lists which contain, first, the price at which they sell their CLS before deduction of any discount (known as 'trade price') and secondly RRP, both excluding and including VAT. These prices are widely circulated to retailers both by wholesalers and by the suppliers themselves. In the case of pharmacies, recommended prices are included in the journal *Chemist & Druggist*. Suppliers issue price lists early in the year. (See Appendix 3.11 for the dates of the changes in the RRP.)

Changes in the RRP between 1988 and 1992

3.178. Tables 3.17 to 3.20 show the changes in the suppliers' recommended prices, in the form of indices, in money terms, ie not adjusted for inflation.

Surfactant cleaners

3.179. Table 3.17 shows the changes in the RRP for surfactant cleaners.

TABLE 3.17 **Surfactant cleaners: changes in the RRP, 1988 to 1992***

Supplier	*Solution*	*Pack size*	*Type of lens*	*1988†*	*1989†*	*1990†*	*1991†*	*1992†*
				Indices‡				
Allergan	LC-65§	30ml	Both	100	100	104	112	117
CV-UK	Miraflow	35ml	Both	100	100	104	104	110
Alcon	Pliagel	25ml	Both	100	105	105	105	105
CV-UK	Hydroclean	35ml	Soft	100	110	121	133	146
Alcon	Preflex	25ml	Soft	100	105	108	108	108
Sauflon	Daily Cleaner§	60ml	Soft	100	107	115	125	134
S&NP¶	Prymeclean	10ml	Soft	100	108	114	134	141
B&L	Daily Cleaner	30ml	Soft	100	116	116	124	124
CV-UK	Contactaclean	35ml	Hard	100	110	121	133	147
Alcon	Clens	25ml	Hard	100	104	108	117	117
Sauflon	Steri-clens	60ml	Hard	100	108	116	126	135
S&NP¶	Transclean	10ml	Hard	100	106	112	131	141
B&L	RGP Cleaner	30ml	Hard	100	116	116	124	133
M&L	Boston Cleaner	30ml	Hard	100	106	106	152	162
RPI¤				100	108	116	126	131

Source: MMC calculations based on data provided by the suppliers.

*Calculated at a point in time as opposed to the annual average change.
†See Appendix 3.11 for dates of actual changes.
‡The price of each solution in 1988 (or in its first year if introduced after 1988) is used as its base of 100.
§RRP for other sized containers increased at a similar rate.
¶Prices in 1989 and 1990 refer to those in January and February respectively.
¤For January of each year.

3.180. The changes in the recommended prices between 1988 and 1992 range from an increase of 5 per cent (Alcon's Pliagel) to a rise of 62 per cent for M&L's Boston Cleaner (most of the increase occurring in the last two years).

Disinfectants

3.181. Table 3.18 shows the changes in the RRP for disinfectants between 1988 and 1992.

TABLE 3.18 **Disinfectants: changes in the RRP, 1988 to 1992***

Supplier	Solution	Pack size	Type of lens	1988†	1989†	1990†	1991†	1992†
				Indices‡				
Peroxides								
Allergan	Oxysept 1	250ml	Soft	100	104	108	118	122
	Oxysept 2	25x15 vials	Soft	100	104	108	117	123
	Oxysept 1 & 2	(see above)	Soft	100	104	108	117	123
CV-UK	10.10 C&D	250ml	Both	100	100	107	114	118
	10.10 R&N	25x15 vials	Both	100	105	113	119	123
	10.10 C&D & R&N	(see above)	Both	100	103	110	117	121
Chlorine tablets								
Alcon	Softab	32 tablets	Soft	100	108	119	129	134
Sauflon	Aerotab	32 tablets	Soft	100	108	116	125	135
Cold chemical								
Allergan	Cleaning & Soaking	120ml	Soft	100	105	112	124	135
	Cleaning & Soaking	240ml	Soft	100	101	108	119	129
CV-UK	Hydrosoak	120ml	Soft	100	110	121	133	146
Alcon	Flexsol	175ml	Soft	100	106	108	118	124
	Flexcare	250ml	Soft	100	105	107	107	113
Sauflon	Steri-sal 2	110ml	Soft	100	107	116	125	135
S&NP§	Prymesoak	120ml	Soft	100	106	123	143	151
B&L	Soflens	240ml	Soft	100	106	106	123	138
Allergan	Clean-N-Soak	120ml	Hard	100	105	112	127	138
CV-UK	Contactasoak	120ml	Hard	100	110	121	133	147
Alcon	Soaclens	120ml	Hard	100	106	109	109	109
Sauflon	Steri-soak	110ml	Hard	100	108	116	131	136
S&NP§	Transoak	120ml	Hard	100	108	127	148	160
B&L	RGP Wet & Soak	120ml	Hard	100	115	115	122	132
M&L	Boston	120ml	Hard	100	91	91	130	138
Allergan	Total	60ml	Hard	100	109	113	122	127
	Total	120ml	Hard	100	100	104	112	117
CV-UK	Complete Care	120ml	Hard	100	110	119	131	144
RPI¶				100	108	116	126	131

Source: MMC calculations based on data provided by the suppliers.

*Calculated at a point in time as opposed to the annual average change.
†See Appendix 3.11 for dates of actual changes.
‡The price of each solution in 1988 (or in its first year if introduced after 1988) is used as its base of 100.
§Prices in 1989 and 1990 refer to those in January and February respectively.
¶For January of each year.

3.182. The changes in the recommended prices between 1988 and 1992 range from a rise of 9 per cent (Alcon's Soaclens) to an increase of 60 per cent (S&NP's Transoak), both being for cold chemical CLS. Prices of the peroxide solutions (steps 1 and 2) have increased by just over 20 per cent between 1988 and 1992. The recommended prices of chlorine tablets have risen by about 35 per cent in the period.

Salines

3.183. The changes in the RRP for salines are shown in Table 3.19.

TABLE 3.19 **Salines: changes in the RRP, 1988 to 1992***

Supplier	Solution	Pack size	Type of lens	1988†	1989†	1990†	1991†	1992†
				Indices‡				
Allergan	Lens Plus§	240ml	Both	100	100	100	107	112
CV-UK	Solar saline§	275ml	Both	100	100	105	110	117
Alcon	Normol	250ml	Both	100	106	108	120	126
	Aerosol Saline	125ml	Both	100	107	112	119	128
	Aerosol Saline	240ml	Both	100	107	111	114	119
	Salette	125ml	Both	N/A	N/A	100	106	115
	Salette	240ml	Both	N/A	N/A	100	103	107
Sauflon	Saline§	300ml	Both	100	105	110	115	122
B&L	Saline	90ml	Both	100	103	103	101	101
	Saline	240ml	Both	100	103	103	83	83
RPI¶				100	108	116	126	131

Source: MMC calculations based on data provided by the suppliers.

*Calculated at a point in time as opposed to the annual average change.
†See Appendix 3.11 for dates of actual changes.
‡The price of each solution in 1988 (or in its first year if introduced after 1988) is used as its base of 100.
§RRP for other sized containers increased at a similar rate.
¶For January of each year.

3.184. The changes in the recommended prices between 1988 and 1992 range from a fall of 17 per cent (B&L's Saline) to an increase of 28 per cent (Alcon's Saline).

Protein cleaners

3.185. The changes in the RRP for protein cleaners are shown in Table 3.20.

TABLE 3.20 **Protein cleaners: changes in the RRP, 1988 to 1992***

Supplier	*Solution*	*Pack size*	*Type of lens*	*1988†*	*1989†*	*1990†*	*1991†*	*1992†*
				Indices‡				
Allergan	Hydrocare Fizzy§	24 tablets	Both	100	105	109	115	119
Alcon	Clen-zym	12 tablets	Both	N/A	100	100	100	108
Sauflon	Protein Removers	24 tablets§	Both	100	108	113	118	127
S&NP¶	Prymecare	8 tablets	Both	100	109	117	136	142
	Prymecare	16 tablets	Both	100	111	119	139	146
B&L§	Fizzy¤	12 tablets	Both	100	105	105	115	99
RPI**				100	108	116	126	131

Source: MMC calculations based on data provided by the suppliers.

*Calculated at a point in time as opposed to the annual average change.
†See Appendix 3.11 for dates of actual changes.
‡The price of each solution in 1988 (or in its first year if introduced after 1988) is used as its base of 100.
§RRP for other sized containers moved at a similar rate.
¶Prices in 1989 and 1990 refer to those in January and February respectively.
¤1992 data refers to Fizziclean.
**For January of each year.

3.186. B&L, whose cleaner was supplied by Allergan until 1991, increased the price of its Fizzy at a similar rate to that of Allergan between 1988 and 1991. In 1992 B&L introduced its new protein cleaner (Fizziclean), which is supplied by its sister company in Italy, the price of which was 16 percentage points below the price of its previous product in 1991. S&NP increased the recommended prices for its Prymecare by over 40 per cent between 1988 and 1992.

3.187. Many suppliers told us that the recommended prices of CLS had fallen when compared with the Retail Price Index (RPI). As most suppliers increase their RRP early in the year, Tables 3.17 to 3.20 show the RPI for January of each year in order to give a broad indication of how the changes in suppliers' recommended prices have compared with the movements in the RPI. Such a comparison shows that the prices of the leading preservative-free surfactant cleaners, peroxides, virtually all salines and protein cleaners have increased less than the RPI between 1988 and 1992. For example, between 1988 and 1992 the price of Allergan's Oxysept and CV-UK's 10.10 fell by about 6 per cent and that of Allergan's Hydrocare Fizzy fell by about 9 per cent when compared with the changes in the RPI. On the other hand many traditional solutions containing preservatives have experienced prices increasing by more than the changes in the RPI.

International price comparisons

3.188. We asked Allergan, CV-UK, B&L and Alcon to provide us with retail prices, excluding and including taxes, of solutions which were comparable with their leading products in the UK, in selected European countries, Australia, Japan and the USA. Comparing overseas prices with those in the UK was hindered, in many cases, by the lack of directly analogous products and pack sizes. Where equivalent solutions existed we compared prices using the high and the low monthly sterling exchange rate in 1992. The results of this exercise indicated that prices in the UK appear to be higher than those in the USA but lower than those in the other named countries.

Cost of using different types of solutions

3.189. We have compared the cost of using the three types of disinfectants (and salines where required) for soft lenses by adjusting the suppliers' recommended prices to a daily basis. In our price

comparisons we have initially excluded surfactant cleaners and protein cleaners on the grounds that they are required by all of the disinfectants for soft lenses.

3.190. We examined the cost of using a number of suppliers' solutions. One example is our comparison of the cost of using Allergan's Oxysept system (the one-month pack)—peroxide—with its Hydrocare Cleaning/Soaking (120ml)—cold chemical—and its Lens Plus Saline (360ml). We assumed that Cleaning/Soaking would be used for 28 days and Lens Plus for 90 days. The daily price of Oxysept works out at about 35p, compared with approximately 21p for the cold chemical system. The cost of using Oxysept is therefore 69 per cent higher than that of the cold chemical solution and saline.

3.191. We also calculated the daily cost of the chlorine treatment. We took the daily price of the monthly pack of Sauflon's chlorine tablet, Aerotab (assuming a dosage of one tablet per day), together with its saline (using its 420ml container and assuming a dosage of 14ml per day). The result was a price of just under 27p. The cost of using the one-month pack of Oxysept is therefore 30 per cent higher than Sauflon's chlorine tablets and saline CLS. Our estimates of the price differences between peroxides and chlorine tablets are broadly similar to those shown by Sauflon in its marketing material (see paragraph 3.39). S&NP told us that it estimates that the price of the one-month pack of Oxysept is double that of its Prymesoak (cold chemical disinfectant), with a 57 per cent excess in the case of the three-month pack of Oxysept.

3.192. We have also compared the price differences of care systems by adding the cost of using a surfactant cleaner to that of the monthly packs of the three types of disinfectant for soft lenses. As we are comparing costs between types of systems and not brands we have used a surfactant cleaner of a particular supplier—Allergan's LC-65. We have used the price of the 15ml container of LC-65 and assumed that this will be used by its discard date of 28 days (see paragraph 3.30). We estimate the following annual cost: about £170 for Oxysept; approximately £140 for Aerotab; and in the region of £120 for Hydrocare Cleaning/Soaking. On this basis, the cost of using Oxysept is 42 per cent higher than that of Hydrocare Cleaning/Soaking and 21 per cent higher than that of Aerotab (see paragraph 3.198 for the difference in the prices of solutions sold in larger pack sizes). The cost of using a protein cleaner on a weekly basis—Allergan's Hydrocare Fizzy—would increase the annual cost by just under £35.

3.193. During our inquiry we have seen a number of articles in *The Optician* discussing whether a surfactant cleaner is required with a peroxide disinfectant. This appears to be an ongoing debate in the industry, with differing views being expressed, and we are not qualified to say who is right. However, we note that Allergan's instructions for Oxysept state 'Remove lenses and clean with a surfactant cleaner such as LC-65'. Boots in its booklet for its own-label peroxide (which is identical to that of D&A) has similar instructions—'apply ... Boots Preservative Free Daily Cleaner'. And whilst 10.10 states 'If Miraflow has been recommended ...', CV-UK told us that this did not restrict the patient's ability to choose another surfactant cleaner. All of this seems to support our assumption that surfactant cleaners are seen by many in the industry as being required with peroxide disinfectants.

3.194. We carried out similar comparisons for other solutions, both branded and own-label, one of which was for D&A's solutions. D&A told us that our price comparisons between peroxides and chlorine tablets were inaccurate as it was generally recognized that the effectiveness of a chlorine system was only comparable with that of a peroxide system when compatible surfactant cleaners were used.

3.195. We estimate that the annual cost of solutions for hard/GP lenses is just under £110 (using Allergan's cold chemical disinfectant—Clean-N-Soak—and its surfactant cleaner. Again protein cleaners, used on a weekly basis, would increase the annual cost by just under £35.

Comparison of the RRP of Allergan and CV-UK

3.196. In 1992 the price of CV-UK's 10.10 was slightly higher than that of Allergan's Oxysept. Allergan's prices are higher than those of CV-UK for about half of the remaining products.

TABLE 3.21 **A comparison of the RRP of Allergan's and CV-UK's leading solutions during 1988 to 1992***

			1988†	1989†	1990†	1991†	1992†
Supplier	*Solution*	*Pack size*			*Indices‡*		
Allergan	Oxysept 1	250ml	100	100	100	100	100
CV-UK	10.10 C&D	250ml	110	106	109	107	106
Allergan	Oxysept 2	25x15 vials	100	100	100	100	100
CV-UK	10.10 R&N	25x15 vials	100	101	105	102	100
Allergan	Oxysept combined	(see above)	100	100	100	100	100
CV-UK	10.10 combined	(see above)	105	103	107	104	103
Allergan	LC-65	30ml	100	100	100	100	100
CV-UK	Miraflow	35ml	92	92	92	85	86
CV-UK	Contactaclean	35ml	69	76	80	82	86
CV-UK	Hydroclean	35ml	72	80	84	86	90
Allergan	LC-65	15ml	100	100	100	100	100
CV-UK	Miraflow	10ml	N/A	107	108	100	103
Allergan	Cleaning & Soaking	120ml	100	100	100	100	100
CV-UK	Hydrosoak	120ml	85	89	91	91	92
Allergan	Total	120ml	100	100	100	100	100
CV-UK	Complete Care	120ml	86	94	98	100	106
Allergan	Clean-N-Soak	120ml	100	100	100	100	100
CV-UK	Contactasoak	120ml	88	93	95	93	94
Allergan	Lens Plus	90ml	100	100	100	100	100
CV-UK	Solar saline	115ml	94	94	99	97	99
Allergan	Lens Plus	240ml	100	100	100	100	100
CV-UK	Solar saline	275ml	106	106	111	109	111

Source: MMC calculations based on data provided by the suppliers.

*Prices per ml are used where the suppliers have different sized bottles.
†See Appendix 3.11 for actual dates of price changes.
‡The RRP of Allergan solutions in each year is used as the base of 100.

Larger pack sizes

3.197. We were told by a number of suppliers that they had increased the size of their containers as a form of price competition, providing the consumer with cheaper CLS on a unit basis.

3.198. Allergan said that in 1990 it had introduced an economy pack of Oxysept 1, containing 360ml, offering a saving per dosage of 10 per cent compared with the standard size, 250ml. Allergan stated that CV-UK and Alcon had reacted to this development by producing three-month packs of 10.10 and Softab respectively, which offered further savings to the consumer. Allergan told us that it had responded by introducing a three-month pack of Oxysept, combining steps 1 and 2, which was priced at over 14 per cent below the price of CV-UK's three-month pack of 10.10 and just under 29 per cent lower than the price of Oxysept 1 and 2 when bought separately in the small pack sizes. In 1992 the price of Allergan's three-month pack of Oxysept was 9 per cent lower than that of CV-UK's three-month pack of 10.10 and 28 per cent below the price of the monthly packs of Oxysept.

Customer discount schemes

3.199. Solutions may be bought through customer discount schemes, which are mainly operated by opticians. D&A, which accounted for 10 per cent of retail sales of solutions in 1992, operates a discount scheme; Boots, which accounted for 36 per cent of retail sales of CLS in 1992, does not offer such a scheme. Just under half the opticians in the survey (including D&A) said that they operated a discount scheme. There are many types of schemes: customers may pay an annual fee for a percentage reduction in the price of solutions (and other optical products); some schemes involve no annual fee but are restricted to opticians' regular customers; and some schemes involve the optician issuing

vouchers related to the value of goods bought, these vouchers then being used by customers to obtain solutions (and other optical products). 97 per cent of pharmacists in our pharmacy survey did not operate a discount arrangement. 74 per cent of users in our consumer survey said that they did not buy solutions through a discount scheme.

3.200. We estimate that those opticians with discount schemes sold on average about 60 per cent of their CLS through their schemes. Therefore, solutions bought through these schemes accounted for about 29 per cent of solutions sold by opticians and 17 per cent of all solutions.

Retail prices

3.201. We asked opticians whether they sold branded CLS, excluding those bought through any discount scheme, at suppliers' recommended prices. Table 3.22 shows the results.

TABLE 3.22 **Pricing behaviour of opticians for branded solutions**

Pricing behaviour	*Percentage of opticians*	
(Base)	(324)	
All branded solutions sold at RRP:		
BOL	11	
Other opticians	29	
Total		40
Excluding sales through discount scheme all branded solutions sold at RRP		19
No discount scheme and some branded solutions sold at RRP		8
Discount scheme and some branded solutions sold at RRP		11
No branded solutions sold at RRP:		
D&A	15	
Other opticians	7	
Total		22
Total		100

Source: RSGB.

3.202. 40 per cent of opticians, including BOL, sold all branded CLS at the suppliers' recommended prices. Boots told us that its pricing policy for branded solutions stocked by BOL and BTC was to adopt suppliers' recommended prices. Of the opticians which did not sell any branded solutions at RRP, D&A told us that it priced branded solutions, excluding those sold through its discount scheme, at 2 per cent below the suppliers' RRP.

3.203. 92 per cent of pharmacies replying to our survey, including BTC and Lloyds, sold all branded solutions at RRP and virtually all of the remainder sold some branded solutions at suppliers' recommended prices. The NPA told us that it had contacted its members to find out why many of them charged RRP. It said that some pharmacists believed that because solutions were licensed products they were proprietary medicines and hence subject to resale price maintenance. It also told us that, because of the relatively high professional input in supplying advice about CLS, its members felt that selling solutions at RRP ensured that the time spent providing such advice was, at least to some extent, financially rewarded.

3.204. The findings of our opticians and pharmacies surveys taken together indicate that those retailers which sell branded CLS only at RRP represent approaching two-thirds of the retail market. These outlets comprise BTC (31 per cent of retail sales in 1992); BOL (5 per cent); Lloyds (1 per cent); opticians, other than BOL and D&A, which hold 19 per cent of the retail market; and pharmacies, other than BTC and Lloyds, which account for 6 per cent of the retail market. In addition some opticians price all branded CLS, excluding those sold through discount schemes, at full RRP, whilst D&A sells all branded CLS at 2 per cent below RRP except for those bought through its discount scheme. These two groups account for between a further 20 and 25 per cent of the retail market (D&A alone had 10 per cent in 1992).

3.205. The two surveys combined also indicate that virtually all retail outlets priced some branded CLS at, or close to, RRP. Sales of branded solutions at, or close to, RRP amount to less than total

retail sales due to a combination of sales of own-label CLS; sales of CLS through discount schemes; and sales at below suppliers' recommended prices. We estimate that branded solutions sold at, or close to, RRP accounted for approximately two-thirds of all CLS in 1991.

Pricing of own-label solutions

Boots

3.206. Boots told us that it has a policy of pricing its own-label solutions 5 per cent lower than the RRP of the comparable branded solutions of its suppliers. This was at the low end of the range of 5 to 15 per cent at which the Boots group as a whole prices own-label products below the corresponding branded goods. Boots said that its competitive analysis indicated that approximately a 5 per cent differential between the price of its own-label CLS and the price of comparable branded solutions was appropriate. As shown in Table 3.23, the actual price differences between CV-UK's branded CLS and the same solutions sold under the Boots label vary between 4 and 11 per cent. The three own-label solutions made for Boots by Allergan also fall into this range.

3.207. Boots provided us with its 1991 sales figures by volume and value for each of its own-label and branded solutions which it stocked. Boots suggested that the weighted average price for the own-label solutions was 12 per cent lower than that of the branded products. To make a direct comparison between the branded and the own-label sales, however, the same volumes for each type of product have to be used for each of the two categories. Using this method we have calculated that buyers of branded products in BTC paid 6.3 per cent more than they would have done if they had bought the corresponding own-label items. This figure provides some indication of the average savings that are possible in theory if consumers were willing and able to switch to Boots' own-label CLS from the branded products they currently use.

3.208. We noted that in other retailing sectors Boots sold some own-label (non-CLS) products at a price far more than 15 per cent below the recommended price of the branded alternative. For example, we found that a pack of 24 tablets of Boots' own-label paracetamol was priced at 59p compared with its price of £1.52 for the branded equivalent (Panadol), a saving of over 60 per cent.

3.209. The price of Boots' own-label peroxides increased by 9 per cent between 1989 and 1992; the price of its own-label cold chemical disinfectants rose by about 40 per cent between 1988 and 1992.

TABLE 3.23 **A comparison of the retail prices* of Boots' own-label solutions and the RRP* of CV-UK's equivalent branded products, 1989 to 1992**

Solution	*Pack size*	*1989†*	*1990†*	*1991†*	*1992†*
		Indices‡			
CV-UK 10.10 C&D	250ml	100	100	100	100
Boots C&D	250ml	N/A	96	95	95
CV-UK 10.10 R&N	25x15 vials	100	100	100	100
Boots R&N	25x15 vials	N/A	95	95	95
CV-UK Contactaclean	35ml	100	100	100	100
Boots Hard Lens Cleaner	35ml	91	91	93	95
CV-UK Hydroclean	35ml	100	100	100	100
Boots Soft Lens Cleaner	35ml	90	90	95	96
CV-UK Contactasoak	120ml	100	100	100	100
Boots Hard Lens Soak	120ml	88	88	92	92
CV-UK Hydrosoak	120ml	100	100	100	100
Boots Soft Lens Soak	120ml	89	89	95	95
CV-UK Contactasol	60ml	100	100	100	100
Boots Hard Lens Wetting	60ml	95	95	95	96
CV-UK Hydrosol	10ml	100	100	100	100
Boots Soft Lens Comfort	10ml	85	84	89	89

Source: MMC calculations based on data provided by the suppliers.

*Excluding VAT.

†See Appendix 3.11 for actual dates of CV-UK's price changes. The dates on which the Boots own-label prices changed are: July 1989, March 1990 (and April 1990 for the peroxides), January 1991 (and April 1991 for Boots Soft Lens Wetting solution), and February 1992.

‡The RRP of CV-UK's solutions in each year is used as the base of 100.

3.210. Table 3.23 indicates that with the exception of peroxides and Boots' hard lens wetting CLS, the prices of Boots' own-label solutions between 1989 and 1992 moved up closer to the prices of the equivalent branded solutions. In the case of the peroxides and the hard lens wetting solution there has been little change in the relative prices of the own-label and branded products.

3.211. The price of Boots' own-label peroxide is 5 per cent less than the price of CV-UK's equivalent product in the same sized containers. However, CV-UK markets 10.10 in a three-month pack whereas Boots only offers its own-label peroxide in a pack containing 25 days' supply. Comparing the cost of using CV-UK's three-month pack with that of Boots' smaller containers on a daily basis shows that Boots' own-label peroxide is 22 per cent higher than CV-UK's. The cost of using Boots' own-label CLS is also higher than some comparable solutions. For example, the cost of using Boots' own-label peroxides, on a daily basis, is 35 per cent higher than that of the three-month pack of Allergan's Oxysept and 7 per cent higher than that of Allergan's economy pack of Oxysept (containing 35 days' supply).

D&A

3.212. Table 3.24 compares the prices of D&A's own-label CLS with the prices charged by D&A for the equivalent branded solutions in 1991 and 1992. In 1991 D&A's prices for its own-label solutions were between 2 and 14 per cent lower than its prices of its suppliers' equivalent branded CLS. In 1992 the price advantage for own-label solutions amounted to between 1 and 9 per cent.

TABLE 3.24 **A comparison of the retail prices of D&A's own-label solutions and its prices for the equivalent branded solutions, 1991 and 1992**

		1991	*1992*
Solution	*Pack size*	*Indices**	
CV-UK 10.10 C&D	250ml	100	100
One-2-One Rapide Step 1	250ml	93	93
CV-UK 10.10 R&N	25x15 vials	100	100
One-2-One Rapide Step 2	25x15 vials	96	99
Alcon Aerosol Saline	125ml	100	100
One-2-One Saline	125ml	97	N/A
Alcon Aerosol Saline	240ml	100	100
One-2-One Saline	240ml	98	98
Sauflon Saline	420ml	100	100
One-2-One Saline	420ml	86	92
Alcon Pliagel	25ml	100	100
One-2-One Universal Cleaner	25ml	89	91
Alcon Clen-zym	12 tablets	100	100
One-2-One Polyzyme	12 tablets	98	91
Alcon Softab	32 tablets	100	100
One-2-One Freshtab	32 tablets	96	98
M&L Boston GP Cleaner	30ml	100	100
One-2-One GP Cleaner	25ml	97	97
M&L Boston Wetting & Soaking	120ml	100	100
One-2-One Wetting & Soaking	120ml	97	97

Source: MMC calculations based on data provided by D&A.

*D&A's price of the branded solutions in each year is used as the base of 100.

UniChem

3.213. The price of UniChem's own-label peroxide will be just under 14 per cent lower than the recommended price of the equivalent branded product.

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Influence of the suppliers on the prices of own-label solutions

3.214. Allergan provided us with a letter in which reference was made to Boots' agreeing with Allergan that its own-label solutions would be priced approximately 5 per cent below the RRP for the same products sold under Allergan's brand name. Boots and Allergan later said that no such agreement existed or had ever existed. Allergan wrote to Boots during our inquiry to assert that fact and pointed out to us that two of the three Boots own-label versions of Allergan-branded CLS were priced at 6 per cent and 7 per cent respectively below the RRP of the corresponding Allergan-branded product, the other being priced at 5 per cent below.

3.215. CV-UK told us that it recommended that own-label solutions should be priced no more than 5 per cent higher or 5 per cent lower than the respective branded solutions. CV-UK said that at the request of one retailer of own-label CLS (Boots), it had suggested to another retailer (D&A) that it would be self-defeating for it to sell at lower prices because this would only produce competitive retaliation (see paragraphs 6.135 to 6.137).

Discounts by suppliers

3.216. We now examine the structure of discounts. Suppliers have a standard discount which they give on orders above a specified minimum level, with certain customers receiving additional discounts. Table 3.25 shows the discounts offered by the leading suppliers in 1992 (see Appendix 3.12 and Tables 4.41, 4.43, 4.44 and 4.45 for further details). Unless otherwise stated, the discounts below refer to reductions to the suppliers' trade prices.

TABLE 3.25 **Discounts given by leading suppliers in 1992***

per cent

	Trade channel				
Supplier	*Opticians*	*Optical wholesalers*	*Pharmaceutical wholesalers*	*Boots*	*D&A*
Allergan	15–25	15	15	32.5	30
CV-UK	(15% standard discount with remainder subject to negotiation)				
Alcon	10–25	23.5	12.5	33–46	34
B&L	15–20	25	N/A	N/A	30
Sauflon†	(6–22% to its customers)				
S&NP	5–15	15	15	36–40	30
PBH‡	7.5–20	25§	N/A	N/A	N/A
Aspect	(15% to all customers)				

Source: The suppliers.

*Discounts are applied to the supplier's trade price.
†Discounts of 28–44 per cent to large customers.
‡25 per cent discount to large customers.
§To large optical wholesalers.
Note: N/A = Not applicable.

3.217. Allergan said that the discounts given to Boots and D&A were those demanded by these companies before any 'listing' was agreed. It told us that in the case of Boots, new product introductions were subject to a listing fee and an extra discount on the first order. Allergan said that optical wholesalers were encouraged to order in quantities over a certain value, currently £750 (£550 in 1991). It also said that pharmaceutical wholesalers ordered both its CLS and its range of ophthalmic pharmaceutical products, where common practice had led to minimum order requirements significantly lower than those available to optical wholesalers.

3.218. Allergan said that it waived the minimum order requirement for the 15 per cent discount given to some opticians, accounting for approximately 2 per cent, by value, of its customers. It stated that the opticians that received a discount of 25 per cent with delivery to a central point accounted for a further 3 per cent of its customers; and those receiving a discount of 25 per cent with deliveries to individual outlets accounted for another 1 per cent, again by value.

3.219. Allergan told us that the overall average discount on its solutions had remained around 24 to 25 per cent between 1988 and 1992. It had not changed the discounts granted to each of the trade channels during this period. Allergan added that it had increased its minimum order level to discourage small orders which it believed were better handled by the wholesaler.

3.220. CV-UK told us that customers who placed an order for 15 dozen or more units received a 15 per cent discount and free carriage. Discounts above this level were a result of negotiation where CV-UK took into account the range of CLS stocked, the ongoing support of promotional activity, and the distribution of free starter packs.

3.221. Alcon told us that in general its discounts were based on total purchase quantities; specific discounts might be individually negotiated by major customers. It also said that additional short-term promotional discounts might be available, again to individual customers.

3.222. B&L told us that in general terms its policy on discounts was structured around sales volumes and took into account lower distribution costs and economies of scale resulting from bulk orders. M&L said that its discounts were volume-related.

3.223. Sauflon told us that in general its discounts were based on total purchases. It also said that it negotiated special terms with multiple outlets which were capable of buying in much greater volumes.

3.224. S&NP stated that Boots and D&A received larger discounts on the basis that solutions were delivered to one depot. It said that when D&A branches ordered an S&NP pharmaceutical product that might not be stocked at the D&A central warehouse, D&A received a lower discount. Discounts to Boots had increased by between six and ten percentage points between 1988 and 1992 whereas the discounts to D&A and wholesalers had remained unchanged. S&NP told us that the increase in discounts given to Boots was the result of Boots' dominant position in the sale of S&NP's Transol system (Boots does not sell S&NP's Pryme system) and the level of discounts already given by other suppliers to Boots.

Mark-up between the trade price and the RRP

3.225. Retailers wishing to compare the value of different suppliers' discounts need to take into account the relationship between the RRPs and the trade prices. This is illustrated by the following example. Two solutions have a trade price of £1. The RRP for the first is £1.25 (25 per cent mark-up), and that for the second £1.35 (35 per cent mark-up). The retailer buys the first product for 85p (15 per cent discount) and the second for 90p (10 per cent discount). The first solution has the higher discount, but the second has the larger gross profit margin, 45p (135–90) compared with 40p (125–85). Table 3.26 shows the mark-up between the trade price (before any discount) and the RRP for each of the leading suppliers.

3.226. In general mark-ups range from 25 to 35 per cent (all of Allergan's and virtually all of CV-UK's products are in this band). There are some outliers with mark-ups above 35 per cent, the highest being B&L's protein cleaner.

Retrospective discounts

3.227. Allergan and CV-UK operate systems of retrospective discounts or targets. To qualify for such a discount, usually amounting to a further discount of 2 per cent, Allergan and CV-UK set sales targets. Once these targets are reached discounts are given.

TABLE 3.26 **Mark-up between suppliers' trade prices and RRP, 1992***

per cent

		Suppliers							
Type of solution	*Type of lens*	*Allergan*	*CV-UK*	*Alcon*	*B&L*	*M&L*	*Sauflon*	*S&NP*	*PBH*
Surfactant cleaner	All	35	33&35	34	N/A	N/A	N/A	N/A	N/A
	Soft	N/A	25	33	31	N/A	25	33	25
	Hard/GP	N/A	25	30	31	31	25	44	N/A
Disinfectant:									
Peroxide	Soft†	25	25	N/A	N/A	N/A	N/A	N/A	37&40‡
Chlorine tablet	Soft	N/A	N/A	28§	N/A	N/A	25	N/A	N/A
Cold chemical	Soft	35	25	32	35	N/A	25	31	25
	Hard/GP	35	26¶	34	31	31	25	38	N/A
Saline	All	25¤	25**	25–28††	23&29	N/A	25	N/A	26
Protein cleaner	All	35‡‡	N/A	33	49	N/A	25	29&45	25

Source: MMC calculations based on the suppliers' price lists.

*RRP minus trade price divided by the trade price, expressed as a percentage.
†CV-UK's 10.10 is for use with all lens types.
‡The RRP of the three-month pack is 30 per cent higher than the trade price.
§The RRP of the 12-week packs is 25 per cent higher than the trade price.
¶The RRP of Complete Care is 36 per cent higher than the trade price.
¤The RRP of CDP saline is 35 per cent higher than the trade price.
**CIBA Saline (360ml) has a mark-up of just under 24 per cent.
††The RRP of Normol is 33 per cent higher than the trade price.
‡‡The RRP of the 48-tablet pack of Fizzy is 25 per cent higher than the trade price.

3.228. Allergan told us that two optical wholesalers had taken up its offer of retrospective discounts and that one optical multiple [*] received a retrospective discount which was equivalent to 3.75 per cent of trade price, in addition to a discount of 25 per cent, with delivery to a central point. Allergan said that it believed retrospective discounts made it a more competitive operator in the market-place than would be the case if it restored a higher wholesale discount. The latter might have been appropriate when CLS were new products with low sales; but this had long ceased to be the case.

3.229. CV-UK told us that it offered retrospective discounts to seven customers (three optical wholesalers and four opticians) which represented 12 per cent of its sales in 1992. It said that the value of retrospective discounts was a small proportion of the total discounts offered to these customers. CV-UK stated that it introduced these arrangements at the beginning of 1992 because it understood that similar schemes were being used by some of its competitors.

3.230. Most of the other leading suppliers do not offer retrospective discounts.

Other financial incentives

3.231. The two leading suppliers offer other financial incentives for limited periods. These incentives are aimed primarily at wholesalers and retailers but some are targeted at wearers. Those directed at wholesalers and retailers include additional free solutions when a given quantity of solutions is bought; reduced promotional prices; gift vouchers; and free advertising material. Those targeted at wearers include 'banded packs', ie packs of one type of solution which include a free container of another type of CLS or a free lens case; and vouchers for solutions.

3.232. Of the other leading suppliers, Sauflon and B&L do not offer other financial incentives. Alcon, S&NP and PBH do offer such incentives but only to a small extent.

*Details omitted. See note on page iv.

4 Financial performance of the contact lens solutions industry

Scope of the chapter

4.1. In this chapter we discuss:

(a) the principal companies involved—paragraph 4.2;

(b) the financial results of the manufacturers/importers (suppliers)—paragraphs 4.3 to 4.54;

(c) the financial results of the principal wholesalers—paragraphs 4.55 to 4.64;

(d) the financial results of the principal retailers—paragraphs 4.65 to 4.87;

(e) the level of discount off trade price given by suppliers to wholesalers and retailers—paragraphs 4.88 to 4.99;

(f) the gross margin available to retailers—paragraphs 4.100 and 4.101;

(g) the comparative profit margins on turnover and return on capital employed (ROCE)—paragraphs 4.102 to 4.109; and

(h) the levels of expenditure on R&D in UK pharmaceutical companies—paragraph 4.110.

Principal companies involved

4.2. The manufacture/import and distribution of CLS is handled by seven main companies, namely:

(a) Allergan;

(b) CV-UK;

(c) Alcon;

(d) B&L together with its subsidiary M&L;

(e) Sauflon;

(f) PBH; and

(g) S&NP.

These companies supply, either directly or through optical and pharmaceutical wholesalers, opticians and pharmacists who retail CLS. The major retailers are BTC, its associated undertaking BOL, and the various opticians chains such as D&A and Specsavers.

Financial results of the suppliers

Allergan

4.3. Allergan is a wholly-owned subsidiary of Allergan Holdings Limited which in turn is ultimately wholly owned by Allergan Inc, a US corporation with headquarters in California. Allergan is engaged in sales, marketing and distribution, buying finished products mainly from sister companies in the UK and overseas for distribution to its UK customers. Allergan is organized into two divisions: Allergan Therapeutics which sells pharmaceuticals and surgical products for the eye, and Allergan Optical which sells contact lenses and CLS.

4.4. Allergan Inc's world-wide strategic marketing and R&D facilities are based in Irvine, California. Manufacturing of pharmaceutical products and CLS is undertaken at Waco (Texas), Westport (Ireland), and sites in Spain and Italy, and is co-ordinated on a world-wide basis in the USA. Manufacturing facilities at Waco and Farnborough, England, produce contact lenses for world-wide distribution. Allergan Inc was founded in 1948 and by 1975 CLS had become its main line of business. In 1980 Allergan Inc was acquired by SmithKline Beckman. In 1989, with sales exceeding US $800 million, Allergan Inc was spun off from SmithKline Beckman and became an independent public company with its stock traded on the New York Stock Exchange.

Profitability and ROCE

4.5. Allergan's turnover, net operating profit and average tangible capital employed for the years ended 30 November 1988 to 1992 (estimated figures for 1992) are given in Table 4.1. The net operating profit shown in the table is struck after deducting Allergan's full share of the group royalties, R&D and central overheads, not all of which are incorporated in Allergan's statutory accounts. Further, Allergan has treated operating leases as fixed assets (see paragraph 4.7). Again this treatment differs from that adopted in Allergan's statutory accounts in which UK standard accounting practice is followed. Turnover in CLS and other optical products shows consistent growth over the years 1988 to 1991. The estimated sales for other optical products in 1992 show a 6 per cent decline over the previous year due to the divestment in December 1991 of Allergan's ophthalmic diagnostic instrument division. Allergan commenced sales of contact lenses in 1990 taking over the existing business of Allergan Hydron Europe Ltd, a fellow subsidiary, with sales close to £[‡] million in each of the three years 1990 to 1992. Although CLS showed operating profits every year, other optical products incurred operating losses in 1989.

TABLE 4.1 **Allergan: turnover, net operating profit and capital employed (with operating leases capitalized and included in capital employed)**

£'000

	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992**
Turnover					
CLS—UK	7,973	12,023	14,839	17,269	18,742
Other optical products	3,207	3,876	12,016	13,221	12,367
Total	11,180	15,899	26,855	30,490	31,109
Net operating profit					
CLS—UK	1,504	1,582	1,725	3,379	4,128
Other optical products	116	-816	128	363	1,879
Total	1,620	766	1,853	3,742	6,007
Average capital employed					
CLS—UK	2,895	4,467	4,673	5,155	5,684
Other optical products	1,048	2,183	5,448	8,286	7,375
Total	3,943	6,650	10,121	13,441	13,059
					per cent
Net margin on turnover					
CLS—UK	18.9	13.2	11.6	19.6	22.0
Other optical products	3.6	-21.1	1.1	2.7	15.2
Total	14.5	4.8	6.9	12.3	19.3
ROCE†					
CLS—UK	52.0	35.4	36.9	65.5	72.6
Other optical products	11.1	-37.4	2.3	4.4	25.4
Total	41.1	11.5	18.3	27.8	46.0

Source: Allergan.

*Estimated.

†In this table and throughout the chapter ROCE is the percentage of net operating profit to average tangible capital employed. Average capital employed is the average of the opening and closing capital employed for each year unless otherwise stated.

‡Figure omitted. See note on page iv.

4.6. An extract of the information in Table 4.1 covering CLS only is set out in Table 4.2.

TABLE 4.2 **Allergan: turnover, net operating profit and capital employed in CLS activities (with operating leases capitalized and included in capital employed)**

					£'000
	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992**
Turnover	7,973	12,023	14,839	17,269	18,742
Net operating profit	1,504	1,582	1,725	3,379	4,128
Average capital employed	2,895	4,467	4,673	5,155	5,684
					per cent
Net margin on turnover	18.9	13.2	11.6	19.6	22.0
ROCE	52.0	35.4	36.9	65.5	72.6

Source: Allergan.

*Estimated.

ROCE

4.7. Allergan has told us that, prior to 1991, its normal practice was to lease most of its assets (including premises) rather than to purchase them, and that the majority of the assets concerned were leased on terms that qualified as operating leases rather than finance leases for accounting purposes. However, in preparing the financial information presented in Tables 4.1 and 4.2 Allergan has adjusted its statutory accounts by:

(a) including in the calculations of capital employed:

(i) the estimated book value of the assets acquired under operating leases as fixed assets; and

(ii) the related capital provided by the lessors under the operating leases as borrowings; and

(b) adding back the operating lease rentals charged in the statutory profit and loss account and substituting estimated depreciation on the assets concerned calculated in accordance with Allergan's normal depreciation policy.

This treatment of operating leases increases both the average capital employed and the operating profit but, because the increase in profit is not proportional to the increase in capital employed, the effect is to lower the return on average capital employed.

4.8. Under current accounting standards in both the UK and the USA a distinction is made between finance leases—where the relevant assets are capitalized and depreciated over their useful lives—and operating leases where the assets are not capitalized and payments under the leases are charged against profits.

4.9. There are sources of differences other than the treatment of operating leases between Allergan's accounts presented here and its statutory accounts. As indicated in paragraph 4.5, profits in Table 4.1 are adjusted for net royalties, R&D and central overheads. The total net operating profits of Allergan in Table 4.1 as adjusted are substantially below those shown in its statutory accounts (see paragraphs 4.16 and 4.17). Table 4.3 shows the changes made to the total net operating profits for CLS and all other activities together for the years ended 30 November 1988 to 1991. Statutory accounts for 1992 are not yet available but the estimated results for that year incorporate similar adjustments.

TABLE 4.3 **Allergan: adjustments to net operating profits**

£'000

	Years ended 30 November			
	1988	*1989*	*1990*	*1991*
Profit before interest and tax (PBIT) in statutory accounts	2,249	1,449	3,385	6,605
Adjustments:				
Net royalty expense	84	63	-19	-268
Corporate expenses	-366	-514	-864	-1,938*
Additional R&D	-438	-633	-1,116	-1,197
Profit per Table 4.4	1,529	365	1,386	3,202

Source: Allergan.

*The increase in 1991 compared with previous years arises from the merging in 1991 of corporate and international headquarters. Comparable figures are not available for 1988 to 1990.

4.10. Table 4.4 shows Allergan's turnover, net operating profit and capital employed based on standard accounting practice for the treatment of operating leases. This reverses the effect described in the last sentence of paragraph 4.7, so increasing the ROCE.

TABLE 4.4 **Allergan: turnover, net operating profit and capital employed (following standard accounting practice for the treatment of operating leases)**

£'000

	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992**
Turnover					
CLS–UK	7,973	12,023	14,839	17,269	18,742
Other optical products	3,207	3,876	12,016	13,221	12,367
Total	11,180	15,899	26,855	30,490	31,109
Net operating profit					
CLS–UK	1,440	1,303	1,548	3,150	3,928
Other optical products	89	-938	-162	52	1,630
Total	1,529	365	1,386	3,202	5,558
Average capital employed					
CLS–UK	1,445	1,896	1,970	2,135	2,383
Other optical products	433	1,027	2,590	3,772	3,057
Total	1,878	2,923	4,560	5,907	5,440
					per cent
Net margin on turnover					
CLS–UK	18.1	10.8	10.4	18.2	21.0
Other optical products	2.8	-24.2	-1.3	0.4	13.2
Total	13.7	2.3	5.2	10.5	17.9
ROCE					
CLS–UK	99.7	68.7	78.6	147.5	164.8
Other optical products	20.6	-91.3	-6.2	1.4	53.3
Total	81.4	12.5	30.4	54.2	102.2

Source: Allergan.

*Estimated.

4.11. Table 4.5 is an extract of turnover, net operating profit and capital employed on CLS activities only drawn from Table 4.4.

TABLE 4.5 **Allergan: turnover, net operating profit and capital employed in CLS activities (following standard accounting practice for the treatment of operating leases)**

£'000

	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992**
Turnover	7,973	12,023	14,839	17,269	18,742
Net operating profit	1,440	1,303	1,548	3,150	3,928
Average tangible capital employed	1,445	1,896	1,970	2,135	2,383
					per cent
Net margin on turnover	18.1	10.8	10.4	18.2	21.0
ROCE	99.7	68.7	78.6	147.5	164.8

Source: Allergan.

*Estimated.

4.12. The ROCE on the two accounting bases used by Allergan for the treatment of operating leases as set out in Tables 4.1 and 4.4 are compared in Table 4.6.

TABLE 4.6 **Allergan: percentage ROCE in CLS activities**

per cent

	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992**
Capital employed computation basis					
As for Table 4.1—with operating leases capitalized	52.0	35.4	36.9	65.5	72.6
As for Table 4.4—following standard accounting practice	99.7	68.7	78.6	147.5	164.8

Source: Allergan.

*Estimated.

Overall results of reference business—manufacture and distribution

4.13. The overall results of the Allergan Inc group on sales of CLS in the UK are set out in Table 4.7. This table shows the combined operating profit and average capital employed in Allergan Limited and Allergan Pharmaceuticals (Ireland) Limited Inc (API)—the manufacturing company from which Allergan obtains the bulk of its CLS—on sales of CLS in the UK. Appropriate proportions of the group's world-wide R&D expenditure and royalty expense relating to each year have been attributed to Allergan Limited in the computation of the operating profit. Section A of Table 4.7 has been drawn up on the basis that operating leases are capitalized (see paragraph 4.7) and section B follows standard accounting practice (see paragraph 4.8). The adjustments to the statutory accounts discussed in paragraph 4.9 still apply.

TABLE 4.7 **Allergan and API: operating profit and capital employed on sales of CLS in the UK**

	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992**
A. With operating leases capitalized					
Operating profit (£m)	3.1	4.1	4.1	5.0	6.2
Average capital employed (£m)	4.6	6.7	7.2	7.4	8.3
ROCE (%)	67.4	61.2	56.9	67.6	74.7
B. Following standard accounting practice					
Operating profit (£m)	3.1	3.8	3.9	4.7	6.0
Average capital employed (£m)	3.1	4.1	4.5	4.3	5.0
ROCE (%)	100.0	92.7	86.7	109.3	120.0
Turnover in CLS (£m)	8.0	12.0	14.8	17.3	18.7

Source: Allergan.

*Estimated.

4.14. Allergan has undertaken an exercise in relation to the reference business to determine what the historical cost net book value of its intangible assets would have been if it had capitalized both R&D expenditure and promotional expenditure and then amortized them over the periods expected to benefit, rather than writing off such expenditure in the year in which it was incurred as it has done in its statutory accounts in accordance with the company's accounting practice. For the purpose of this exercise R&D expenditure, including the additional charges (see paragraphs 4.16 and 4.17), has been assumed to be written off over ten years on a straight line basis, and promotional expenditure has been written off at 40 per cent per annum on a reducing balance basis. This results in promotional expenditure being written down by approximately 80 per cent after three years and fully written off after seven years. Table 4.8 shows the results arising from these adjustments to the figures given in Table 4.7. The effect is to increase both profits and capital employed but to reduce the ROCE compared with Table 4.7, as capital employed is increased proportionately more than profit.

TABLE 4.8 **Allergan and API: operating profit, capital employed and ROCE incorporating the effect of capitalizing R&D and promotional expenditure for the reference business**

	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992**
A. With operating leases capitalized					
Operating profit (£m)	3.8	4.8	4.6	5.3	6.6
Average capital employed (£m)	7.7	11.2	13.0	14.2	15.8
ROCE (%)	49.3	42.8	35.4	37.3	41.7
B. Following standard accounting practice for operating leases					
Operating profit (£m)	3.8	4.5	4.4	5.0	6.4
Average capital employed (£m)	6.2	8.6	10.3	11.1	12.5
ROCE (%)	61.3	52.3	42.7	45.0	51.2
Year-end average capitalized value of:					
R&D expenditure (£m)	1.7	2.5	3.3	4.0	4.5
Promotional expenditure (£m)	1.4	2.0	2.5	2.8	3.0

Source: Allergan.

*Estimated.

Transfer pricing

4.15. Allergan purchases the great majority of its CLS from API. The transfer prices for these and other products purchased from API are set annually by Allergan Inc and take effect from 1 December. Allergan Inc's objective in determining the transfer prices, which are denominated in US dollars, is to split the overall group profit on sales of all the products concerned equitably between Allergan and API. Profit for this purpose is struck after certain specified costs, such as manufacturing, freight, and promotion, selling and marketing expenditure, but before other costs, such as administration. Transfer prices from API to Allergan for each product are determined by splitting each product's selling price to Allergan's customers, as budgeted for the following year, so that Allergan retains the proportion of the selling price necessary to cover its specified costs and its share of the profit (as computed above). The balance of the selling price which represents API's specified costs and share of the profit is the transfer price between API and Allergan. The transfer price is thus determined not by costs and added profit margins but by budgeted sales prices and estimated costs of Allergan and API.

R&D expenditure

4.16. The Allergan group's world-wide R&D expenditure on CLS has averaged £[†] million a year over the five years 1988 to 1992. Allergan Inc's policy is to treat all R&D expenditure as current, ie it is not capitalized. Allergan's share of the Allergan Inc group R&D expenditure on CLS is determined by the proportion that its sales represent to world-wide sales. In the figures produced for this inquiry Allergan has adjusted the net operating profit to take account of its share of the group R&D expenditure, not all of which has been charged in Allergan's statutory accounts. Table 4.9 gives details of the group R&D expenditure and Allergan's full share of this. This full share has been allowed for in Allergan's operating profit figures, either by being already included in the statutory accounts or through the adjustments described in paragraph 4.9.

†Figure omitted. See note on page iv.

TABLE 4.9 **Allergan: share of Allergan Inc group CLS R&D expenditure**

	Group R&D on CLS £m	*Allergan's turnover as a percentage of Allergan group's world-wide turnover in CLS %*	*Allergan's share of group CLS R&D £'000**
1988	[	5.1	[
1989		6.8	
1990	†	8.8	†
1991		10.8	
1992 (estimated)	]	11.4	]

Source: Allergan.

*This is the total R&D allocated to Allergan in respect of CLS only. Some part of this total R&D has been charged in the statutory accounts. The balance not charged together with R&D on other products is shown in Table 4.3.

Share of corporate costs and royalties

4.17. The net royalty expenses and corporate costs have been dealt with in a similar way to that for R&D, with a charge to Allergan based on its proportion of world-wide sales of each business.

CV-UK

4.18. CV-UK is the UK sales and marketing arm of the CIBA Vision division (CIBA Vision) of CIBA-GEIGY. CIBA Vision's UK activity over the years 1987 to 1992 has been characterized by corporate acquisitions, restructuring and the development of a new production facility in Macclesfield. In 1983 CIBA Vision acquired Titmus Eurocon Kontaktlinsen GmbH from Alcon's European lens business. This company supplied CLS from its Munich plant to the UK up to 1988, with UK sales being carried out by Titmus Eurocon Ltd. In January 1988 CIBA-GEIGY acquired the lens care products business of a US company, Cooper Industries Inc, which carried on business in the UK through Contactasol and Coopervision. Contactasol became the UK solutions manufacturer and distributor for CIBA Vision taking on the CLS sales force of Titmus Eurocon, and was renamed CIBA Vision (UK) Ltd. CV-UK operated from Southampton. Coopervision became a dormant company. In May 1991 production at Southampton ceased following the commencement of production from late 1990 by a new company, CIBA Vision Lens Care Production Limited, at a newly-built factory in Macclesfield. CVLCP, in which according to press reports about £20 million was invested, was intended to be the sole in-house supplier of CLS for CIBA Vision in Europe. However, start-up problems at the factory in Macclesfield meant that CIBA Vision had to subcontract certain production and also had to continue to obtain some supplies from its Munich plant. CV-UK has said that the initial problems at CVLCP have been overcome, but it has now been decided to continue sourcing a small number of products from Munich as it is not practicable to make them in Macclesfield. Some subcontracting continues; this had been the intention from the start of the Macclesfield project.

Profitability and ROCE

4.19. An analysis of the results of CV-UK together with those of two other group companies, Titmus Eurocon and Dispersa Ltd (which conducts the other optical products business), for the accounting periods ended 31 December 1988 to 1992 (estimated) is shown in Table 4.10. Up to May 1991 the results include those of the manufacture of CLS at Southampton. Thereafter CV-UK has procured CLS products from CVLCP and from the CIBA Vision group company in Munich. The results of those companies are not included in Table 4.10. CV-UK is not able to separate the results on manufacturing CLS from its distribution activities for periods prior to May 1991.

†Figures omitted. See note on page iv.

TABLE 4.10 **CV-UK, Titmus Eurocon and Dispersa Ltd: turnover, net operating profit and capital employed**

£'000

	Periods ended 31 December				
	1988 (14 months)	*1989*	*1990*	*1991*	*1992**
Turnover					
CLS—UK	12,022	11,653	13,530	14,297	16,986
CLS—exports	858	1,316	1,181	318	170
Other optical products	3,071	3,348	3,953	4,900	5,934
Total	15,951	16,317	18,664	19,515	23,090
Net operating profit					
CLS—UK	823	1,412	3,040	1,998	1,155
CLS—exports	-32	-	60	18	40
Other optical products	35	-19	-394	-921	-458
Total	826	1,393	2,706	1,095	737
Average capital employed					
CLS—UK	1,067	2,540	3,156	3,318	3,616
CLS—exports	125	370	394	173	-7
Other optical products	-94	-29	196	108	548
Total	1,098	2,881	3,746	3,599	4,157
					per cent
Net margin on turnover					
CLS—UK	6.8	12.1	22.5	14.0	6.8
CLS—exports	-3.7	-	5.1	5.7	23.5
Other optical products	1.1	-0.5	-9.9	-18.8	-7.7
Total	5.2	8.5	14.5	5.6	3.2
ROCE					
CLS—UK	66.1†	55.6	96.3	60.2	31.9
CLS—exports	-21.6†	-	15.2	10.4	-
Other optical products	-	-	-201.0	-852.8	-83.6
Total	64.5†	48.4	72.2	30.4	17.7

Source: CIBA Vision.

*Estimated.
†The ROCE ratios for 1988 have been adjusted to reflect 12 months' operations.

4.20. Table 4.11 shows an extract from Table 4.10 covering turnover, operating profit and capital employed statistics for UK CLS only. The ROCE ranges from a high of 96.3 per cent in 1990 to a low of 31.9 per cent for 1992. CV-UK told us that the 1990 and 1991 results were favourably affected by the high utilization of the Southampton plant capacity with consequently lower unit costs. The high utilization arose from the need to build up stocks prior to closure of the Southampton facility following start-up of the Macclesfield plant. Other factors affected profits such as the use of fully depreciated equipment. CV-UK said that it was able to quantify some but not all of these effects. A provision of £1.0 million was set up in the 1990 accounts for reorganization expenses in Southampton, some £0.2 million of this provision being written back in 1991. Neither of these items has been included in the operating profit shown in Tables 4.10 and 4.11. The fluctuating results shown in the years 1988 to 1991 reflect the changes in corporate structure and organization, and closure of the Southampton plant.

TABLE 4.11 **CV-UK: turnover, net operating profit and capital employed in UK CLS activities**

£'000

	Periods ended 31 December				
	1988 (14 months)	*1989*	*1990*	*1991*	*1992**
Turnover	12,022	11,653	13,530	14,297	16,986
Net operating profit	823	1,412	3,040	1,998	1,155
Average capital employed	1,067	2,540	3,156	3,318	3,616
					per cent
Net margin on turnover	6.8	12.1	22.5	14.0	6.8
ROCE	66.1†	55.6	96.3	60.2	31.9

Source: CIBA Vision.

*Estimated.
†The ROCE ratio for 1988 has been adjusted to reflect 12 months' operations.

4.21. CIBA Vision told us that a more balanced view of the profitability and returns of its ongoing CLS business in the UK is given by combining the results of CV-UK with the UK-related business of CVLCP. The company has stated that the 1992 data should be regarded as indicative of the ongoing business, as start-up and closure effects had been reduced by 1992. Table 4.12 shows the results of CVLCP separately.

TABLE 4.12 **CVLCP: turnover, net operating profit and capital employed**

£'000

	Periods ended 31 December		
	1990	*1991*	*1992**
UK			
Turnover	1,846	7,760	10,902
Cost of sales	1,385	6,812	7,090
Gross profit	461	948	3,812
Operating costs	2,172	1,636	2,782
Net operating profit	-1,711	-688	1,030
Year-end capital employed	18,753	9,718	10,939
Average capital employed	9,376†	14,235	10,328
Exports			
Turnover	446	15,590	18,898
Cost of sales	334	13,684	9,110
Gross profit	112	1,906	9,788
Operating costs	525	4,960	4,823
Net operating profit	-413	-3,054	4,965
Year-end capital employed	4,462	18,952	18,604
Average capital employed	2,231	11,707	18,778
Total			
Turnover	2,292	23,350	29,800
Cost of sales	1,719	20,496	16,200
Gross profit	573	2,854	13,600
Operating costs	2,697	6,596	7,605
Net operating profit	-2,124	-3,742	5,995
Year-end capital employed	23,215	28,670	29,543
Average capital employed	11,607	25,942	29,106

Source: MMC from information supplied by CIBA Vision.

*Estimated.
†The average capital employed for 1990 is taken as half of the year-end capital employed.

4.22. An extract of the information in Tables 4.11 and 4.12 covering CLS in the UK is set out in Table 4.13.

TABLE 4.13 **CIBA Vision group in the UK: turnover, net operating profit and capital employed in UK CLS activities**

£'000

	Periods ended 31 December				
	1988 (14 months)	*1989*	*1990*	*1991*	*1992**
CV-UK					
Turnover	12,022	11,653	13,530	14,297	16,986
Net operating profit	823	1,412	3,040	1,998	1,155
Average capital employed	1,067	2,540	3,156	3,318	3,616
CVLCP					
Turnover to CV-UK			1,846	7,760	10,902
Net operating profit			-1,711	-688	1,030
Average capital employed			9,376	14,235	10,328
CV-UK and CVLCP combined					
Turnover†	12,022	11,653	13,530	14,297	16,986
Net operating profit	823	1,412	1,329	1,310	2,185
Average capital employed	1,067	2,540	12,532	17,553	13,944
					per cent
Net margin on turnover	6.8	12.1	9.8	9.2	12.9
ROCE	66.1‡	55.6	10.6	7.5	15.7

Source: MMC from information supplied by CIBA Vision.

*Estimated.
†After excluding sales from CVLCP to CV-UK.
‡The ROCE ratio for 1988 has been adjusted to reflect 12 months' operations.

4.23. The original estimates for 1992 provided to us by CIBA Vision for CVLCP followed the practice used for 1990 and 1991 of apportioning profit and year-end capital employed between sales to the UK and for export by reference to turnover or volume of sales. At a late stage of the inquiry, in January 1993, CIBA Vision told us that it had been able to allocate 1992 variable production costs and overheads in CVLCP more precisely between sales to the UK and sales for export, to reflect the fact that the product mix for the UK differed significantly from that of the export business. The resulting adjusted estimate, while maintaining the same total profit, reduced the profit arising on sales to CV-UK and increased the profit on export sales by the same amount. The new information indicated that, whereas CVLCP's net margin on turnover for both UK and export sales was previously assessed as being the same at 20 per cent, the net margin on export sales was now estimated at nearly three times that on sales to the UK (26 per cent and 9 per cent respectively).

4.24. As a consequence the group net margin on turnover on UK CLS sales in 1992 (Table 4.13) falls from the original 19.8 per cent to 12.9 per cent with ROCE declining from the original 24.1 to 15.7 per cent. There is a corresponding increase in ratios for CLS exports, but the ratios for the combined businesses of the group are unaltered as the overall profit has not changed. CIBA Vision has not amended the 1990 and 1991 figures from those originally submitted where the allocation for gross profit and operating costs were based on turnover ratios and sales volume ratios respectively.

4.25. CIBA Vision has given a number of explanations of the operating profit and capital employed figures in Table 4.13. These are:

(a) The profit in CVLCP on sales to CV-UK still held in stock by CV-UK at the end of the accounting period has not been eliminated on consolidation, and profits are therefore overstated. Conversely, if CV-UK reduces stocks of CVLCP products (as was expected in 1992), profit is understated.

(b) The rapid rise in capital employed in CLS (both for UK and export business) is largely due to investment in the new factory in Macclesfield. From commencement of production at Macclesfield in November 1990 there were both start-up costs and serious production difficulties which were not resolved until 1992. CIBA Vision has not been able to identify separately the effect of start-up costs and initial production difficulties on its profits. Production was initially devoted mainly to the UK, and the bulk of the losses and capital employed for 1990 has therefore been attributed to the UK. As production and export sales built up in 1991, a lower share of losses and a smaller proportion of capital employed have been allocated to the UK. CIBA Vision considers that the estimated position for 1992 is reasonably indicative of the out-turn expected for future years.

Transfer pricing

4.26. Within the CIBA Vision group all sales of goods between manufacturing and distribution companies are made on the basis of supply prices negotiated annually at arm's length between companies in co-operation with CIBA Vision Management AG. The objective is to achieve a supply price which is equal to a third-party supply price. In practice CIBA Vision aims to achieve this by taking the selling price to the distribution company's customer and reducing this price by allowances to cover costs and an element of profit. The supply price to the distribution company is the net of these elements and is expected to be close to that obtainable from an independent supplier.

R&D

4.27. CIBA Vision told us that no research or development is undertaken directly by either CV-UK or CVLCP. The only cost incurred by CV-UK in respect of R&D is the Central Research Overhead Contribution paid to CIBA-GEIGY. Payments to CIBA-GEIGY for the years 1988 to 1992 (estimated) are set out in Table 4.14.

TABLE 4.14 **CV-UK: payments to CIBA-GEIGY**

£'000

Description	*Years ended 31 December* 1989	1990	1991	1992*
Central research and central overhead contributions	[	†		]

Source: CIBA Vision.

*Estimated.

CIBA Vision told us that the payments are based on solutions turnover in the UK, compared with world-wide turnover in CLS products.

Alcon

4.28. Alcon, which is a UK importer and distributor of reference products, is part of the Alcon group of Nestlé SA, Switzerland. Alcon does not manufacture CLS, but sources from third parties and to a lesser extent from Alcon group companies in Puerto Rico, France, Belgium and Spain.

4.29. In addition to the distribution of CLS, Alcon also distributes pharmaceuticals and surgical products. Alcon neither manufactures nor sells spectacles or contact lenses. There is a small CLS export business to the Irish Republic.

4.30. The Alcon group is organized for management purposes into geographical areas each of which is managed by an area Vice President; head office of the Alcon group is at Fort Worth, Texas. The management of the UK company reports to the Vice President of the Europe, Middle East and Africa division. The Alcon group was acquired by Nestlé in 1977: Alcon group sales for 1991 exceeded $1 billion, less than 5 per cent of the overall Nestlé group sales.

Profitability and ROCE

4.31. Alcon's turnover, net operating profit and average capital employed for the three years ended 31 December 1991 are given in Table 4.15. Net operating PBIT is shown after charging exceptional items arising from the acquisition and sale of businesses. By an agreement with Coopervision International Ltd (Coopervision International) and Cilco (UK) Ltd in February 1989, Alcon acquired the surgical business and certain assets and liabilities of Coopervision International in the UK and Ireland for around £3.6 million. The 1989 acquisition of Coopervision International involved substantial provisions and office closure costs totalling £1.0 million, which were treated as an exceptional item. In January 1990 Galderma (UK) Ltd purchased the dermatological business of Alcon. This disposal gave rise to an exceptional credit of £0.1 million.

†Figures omitted. See note on page iv.

TABLE 4.15 **Alcon: turnover, net operating profit and average capital employed**

£'000

	Years ended 31 December		
	1989	*1990*	*1991*
Turnover			
CLS—UK	[		
CLS—exports			
Other products			
Total			
Net profit			
CLS—UK		*Figures omitted.*	
CLS—exports		*See note on page iv.*	
Other products			
Total			
Average capital employed			
CLS—UK			
CLS—exports			
Other products			
Total			]

per cent

Net margin on turnover			
CLS—UK	[		
CLS—exports*			
Other products			
Total			
		Figures omitted.	
ROCE		*See note on page iv.*	
CLS—UK			
CLS—exports*			
Other products			
Total			]

Source: Alcon.

*Where the ratios are distorted by the effect of showing figures to the nearest £'000, the actual figures have been used to calculate the relevant ratios.

4.32. An extract of the information in Table 4.15 covering CLS in the UK only is set out in Table 4.16.

TABLE 4.16 **Alcon: turnover, net operating profit and capital employed in UK CLS activities**

£'000

	Years ended 31 December		
	1989	*1990*	*1991*
Turnover	[	*Figures omitted.*	
Net operating profit		*See note on page iv.*	
Average capital employed			]

per cent

Net margin on turnover	[	*Figures omitted.*	
ROCE		*See note on page iv.*	]

Source: Alcon.

R&D expenditure

4.33. The majority of the Alcon group R&D expenditure is incurred in the USA, as are the main initial costs in trials and developing dossiers for health registration. Alcon told us that it does not have access to these costs. The R&D costs and health registration expenses charged by Alcon in its accounts are shown in Table 4.17.

TABLE 4.17 **Alcon: R&D and registration costs**

£'000

	Years ended 31 December	
	1990	*1991*
Turnover in CLS	[	
R&D		*
Registration costs		
Total		]
	per cent	
Percentage of turnover	[*	]

Source: Alcon.

4.34. Under a 1975 licence and royalty agreement, royalties are paid by Alcon for the right to sell Alcon group products under its trade marks. Payments are calculated at 6 per cent of net sales of all Alcon products sold in the UK and the Irish Republic.

B&L (and its subsidiary M&L)

4.35. B&L is a wholly-owned subsidiary of Bausch & Lomb Inc, a US corporation with headquarters in Rochester, New York. B&L is engaged in the import and resale of contact lenses, related accessories and sunglasses. The Bausch & Lomb group is the largest CLS supplier in the USA (which is estimated to account for about half of the contact lens market in the world) and the second largest supplier in Japan (which is the second biggest national CLS market after the USA). The healthcare segment of the Bausch & Lomb group (which includes CLS) provided 62 per cent of overall group sales in 1991 of $1.5 billion; CLS sales world-wide of $326 million were 21 per cent of group sales and contributed 39 per cent of the group operating profit of $247 million.

4.36. B&L has operated in the CLS market for more than ten years. In April 1989 it acquired M&L, which also imports and sells CLS and in addition manufactures and sells contact lenses. At the time of purchase, M&L had a wholesale solutions business, but this was sold in April 1991 to Mid-Optic. The financial results of the activities sold to Mid-Optic have been separated from those of the Bausch & Lomb group's CLS activities and shown under the description 'Other optical products'.

4.37. The Bausch & Lomb group manufactures CLS only in the USA (since 1971) and Italy (since 1984), with the Italian company mainly supplying the European market and the US company primarily its domestic market. In 1991 Bausch & Lomb group companies supplied 64 per cent of B&L's CLS requirements in the UK; the remaining 36 per cent were supplied for sale under the B&L label by third parties in the UK, principally Allergan and CCL. M&L distributes Boston solutions which until 1991 were imported from the Bausch & Lomb group in the USA but are now obtained from the group's Italian factory. In composition Boston solutions are the same as some B&L solutions, though presentation differs and pack sizes have varied in the past.

4.38. B&L follows a policy of supplying CLS only to the optical trade, though M&L sells to pharmacists as well as to opticians. Bausch & Lomb group policy is in general not to offer own-label products as this is seen as detracting from Bausch & Lomb products as a market name and leading to less efficient production runs. Exceptions are considered case by case in terms of cost and potential sales volume.

Profitability and ROCE

4.39. B&L and M&L handle different (though similar) products and are managed separately; however, for the purposes of our report their results have been combined. The combined turnover,

*Figures omitted. See note on page iv.

net operating profit and average capital employed for the periods to end December 1988 to 1991 are given in Table 4.18.

TABLE 4.18 **B&L and M&L: turnover, net operating profit and capital employed**

			£'000
	Years to end December		
	1989 (M&L 9 months)	*1990*	*1991*
Turnover			
CLS—UK	1,746	2,766	3,292
CLS—exports	57	81	97
Other products	8,015	10,516	9,912
Total	9,818	13,363	13,301
Net operating profit			
CLS—UK	346	475	465
CLS—exports	15	16	13
Other products	-1	-862	-1,448
Total	360	-371	-970
Average capital employed			
CLS—UK	400	525	536
CLS—exports	10	14	17
Other products	1,276	1,940	2,108
Total	1,686	2,479	2,661
			per cent
Net margin on turnover			
CLS—UK	19.8	17.2	14.1
CLS—exports	26.3	19.8	13.4
Other products	-	-8.2	-14.6
Total	3.7	-2.8	-7.3
ROCE			
CLS—UK	86.5	90.5	86.8
CLS—exports	150.0	114.3	76.5
Other products	-	-44.4	-68.7
Total	21.4	-15.0	-36.5

Source: MMC from information supplied by B&L and M&L.

4.40. In their management accounts B&L and M&L do not normally allocate balance sheet items or operating costs to product groups. The information for Table 4.18 has been produced as a special exercise by the companies. Wherever possible, direct allocation to product groups for net profit and capital employed has been used. Where direct allocation has not been possible, turnover has been used as the basis of allocation.

4.41. An extract of the information in Table 4.18 covering CLS in the UK only is set out in Table 4.19.

TABLE 4.19 **B&L and M&L: turnover, net operating profit, and capital employed in UK CLS activities**

			£'000
	Years to end December		
	1989 (M&L 9 months)	*1990*	*1991*
Turnover	1,746	2,766	3,292
Net operating profit	346	475	465
Average capital employed	400	525	536
			per cent
Net margin on turnover	19.8	17.2	14.1
ROCE	86.5	90.5	86.8

Source: MMC from information supplied by B&L and M&L.

Transfer pricing

4.42. As already mentioned, B&L and M&L now purchase the majority of their CLS from Bausch & Lomb IOM SpA in Italy. The transfer prices of these products are set, normally annually, on the basis of data collected by Bausch & Lomb group headquarters in Rochester. We have been told that in determining transfer prices, the objective of the Bausch & Lomb group is to approximate to arm's length prices, reflecting actual or expected market conditions. From forecast market data and operating plans the total profit from the sale of products to the Bausch & Lomb group is determined. B&L has stated that the resulting total profit is then split between group companies on varying bases depending on facts and circumstances, although no specific information on the methodology has been given.

R&D expenditure

4.43. B&L and M&L are not directly charged for R&D conducted centrally by the Bausch & Lomb group at Rochester, New York and Wilmington, Massachusetts. B&L has provided the details of group expenditure on research in CLS and in total in Table 4.20.

TABLE 4.20 **Bausch & Lomb Inc: group expenditure on R&D**

US $'000

	Years to end December		
	1989	*1990*	*1991*
Group R&D expenditure in CLS	6,225	6,350	10,300
Total group R&D expenditure	41,109	48,050	49,255
			per cent
Percentage of group CLS R&D to total group R&D	15.1	13.2	20.9
Percentage of total group CLS R&D to total group CLS turnover	N/A	N/A	3.2
Percentage of Bausch & Lomb total group R&D to total group turnover	3.4	3.5	3.2

Source: B&L.

Sauflon

4.44. Sauflon, which is a privately-owned company, manufactures and distributes CLS as its main activity. Sauflon has a small business in other eyecare products and in the past has received royalty income from licensing its products for the overseas market. In 1991 CLS business in the UK generated £2.516 million or 81 per cent of turnover of £3.1 million, and £274,000 or 79 per cent of net profit of £347,000, while a further 18 per cent of turnover and 19 per cent of net profit came from exports of CLS.

4.45. Sauflon originates from a large chain of retail opticians established in 1964. As the business grew it moved into the manufacture of contact lenses and CLS, but in 1985 the manufacturing side of the business experienced financial difficulties and the CLS manufacturing business was sold, becoming Sauflon. In 1990 Sauflon completed negotiations for the acquisition of a new manufacturing plant in Ashford, Kent, buying an existing factory from an insolvent company. The new factory was extended in 1991 with production starting there in January 1992; the original production facilities at Earl's Court, London, were closed in February 1992.

Profitability and ROCE

4.46. Sauflon's turnover, net operating profit and average capital employed for the three years to end October 1991 are given in Table 4.21.

TABLE 4.21 **Sauflon: turnover, net operating profit and capital employed**

£'000

	Years to end October		
	1989	*1990*	*1991*
Turnover			
CLS—UK	1,412	1,827	2,516
CLS—exports	467	540	548
Other optical products	146	54	40
Royalty income	350	100	0
Total	2,375	2,521	3,104
Net operating profit			
CLS—UK	-127	99	274
CLS—exports	-18	45	66
Other optical products	3	6	7
Royalty income	350	100	0
Total	208	250	347
*Average capital employed**			
CLS—UK	491	615	950
CLS—exports	285	354	451
Other optical products	65	37	20
Total	841	1,006	1,421
Net margin on turnover			
CLS—UK	-9.0	5.4	10.9
CLS—exports	-3.9	8.3	12.0
Other optical products	2.1	11.1	17.5
Royalties	100.0	100.0	-
Total	8.8	9.9	11.2
*ROCE**			
CLS—UK	-25.9	16.1	28.8
CLS—exports	-6.3	12.7	14.6
Other optical products	4.6	16.2	35.0
Total	24.7	24.9	24.4

Source: Sauflon.

*No capital employed has been allocated to royalty income, hence total ROCE is higher than for the main businesses shown because total profit includes royalty income with no related capital employed.

4.47. CLS exports include sales by Sauflon to its partly-owned subsidiary in the Netherlands, L&A Optical Services BV, but do not include onward sales by that company.

4.48. Since the grant of a DoH licence in 1987 for preservative-free solutions, Sauflon's UK sales of CLS have grown fivefold. In contrast, export sales, which had been developed pending the UK licence for the new solutions, have only increased by 25 per cent and in 1988 and 1989 were below the 1987 level. There was an extraordinary charge of £103,000 in 1991 (not taken into account in the results in Table 4.21) for the costs of financial restructuring and the raising of fresh capital. The acquisition of the new factory has considerably increased capital employed and has affected profit, although no depreciation was charged on plant not yet in use and some pre-opening expenses were capitalized. There is expected to be a non-recurring charge in 1992 for redundancy and write-off of plant following the closure of the London factory.

4.49. An extract of the information in Table 4.21 covering CLS in the UK only is given in Table 4.22.

TABLE 4.22 **Sauflon: turnover, net operating profit and capital employed in CLS in the UK**

£'000

	Years to end October		
	1989	*1990*	*1991*
Turnover	1,412	1,827	2,516
Net operating profit	-127	99	274
Average capital employed*	491	615	950
			per cent
Net margin on turnover	-9.0	5.4	10.9
ROCE	-25.9	16.1	28.8

Source: Sauflon.

*Includes plant not yet in use.

R&D

4.50. In its accounts Sauflon does not separate R&D expenditure from regulatory affairs expenditure such as work on product and manufacturing licences. Some R&D expenditure is written off in the year in which it is incurred, but some, together with costs of protecting Sauflon's title to products, has been capitalized and is being written off over five years, which is the expected minimum useful life of the products. The amounts of R&D on CLS included in the accounts of Sauflon are shown in Table 4.23.

TABLE 4.23 **Sauflon: R&D in CLS**

£'000

	Years to end October		
	1989	*1990*	*1991*
Capitalized in accounts	31	9	-
Written off in accounts as revenue	N/A	47	65
Written off as depreciation on amounts capitalized	5	9	10
Total charged to profit and loss account	N/A	56	75

Source: Sauflon.

PBH

4.51. PBH is a wholly-owned subsidiary of Pilkington, a UK listed company. Pilkington entered the CLS market with the purchase of the vision care business of Revlon Inc, whose products included contact lenses, CLS and spectacle lenses. The optical business was extended in 1989 with the purchase of the European and Asian contact lens business of Cooper Industries Inc. Cooper Industries Inc had been involved in the distribution of CLS, but this part of the business had been sold to CIBA Vision in January 1988. In the UK, PBH manufactures contact lenses for distribution world-wide, and it also distributes contact lenses and solutions; in Europe, PBH has an ophthalmic products distribution business. PBH sources all its CLS from two third-party manufacturers in the UK—CCL and Waverley. Under licence from PBH, Waverley also manufactures own-label products for Specsavers and Aspect. In the year to 31 March 1992 CLS turnover in the UK was 4 per cent of PBH's total turnover of £15.967 million. Summary financial data is given in Table 4.24.

TABLE 4.24 **PBH: summary of financial results on CLS activities**

£'000

	Years ended 31 March		
	1990	*1991*	*1992*
Turnover	316	423	639
Estimated net operating profit	-43	-14	-6
			per cent
Net margin on turnover	-13.6	-3.3	-0.9

Source: PBH.

S&NP

4.52. S&NP is a wholly-owned subsidiary of Smith & Nephew plc, a UK listed company. S&NP is primarily engaged in the development and manufacture of ethical pharmaceuticals. [*Details omitted. See note on page iv.*] There is a small amount of export sales of CLS through Smith & Nephew group companies overseas. Summary financial data is given in Table 4.25.

TABLE 4.25 **S&NP: summary of financial results on CLS activities**

£'000

	Years to end December		
	1989	*1990*	*1991*
Turnover	[	*	
Net operating profit			]
			per cent
Net margin on turnover	[	*	]

Source: S&NP.

Summary of results of suppliers

4.53. A summary of the results of each of the suppliers discussed in this section of the chapter is given at Appendix 4.1.

Product cost and profit profiles

4.54. Cost and profit profiles showing, for selected products, the build-up of supply costs and profits and retail profit by various trade channels are given at Appendix 4.2.

Financial results of the principal wholesalers

Kelvin Optical Supplies

4.55. Kelvin Optical Supplies (Kelvin) is a division of Aspect, having been purchased from Coopervision in 1988 and merged with Aspect's own CLS wholesale business. At the time of

*Figures omitted. See note on page iv.

acquisition, a major part of Kelvin's business was the supply to other wholesalers of Kelvin's own-label CLS which were manufactured for Kelvin by Coopervision (the supplying company is now part of CIBA Vision). Aspect has told us that the margin granted by Coopervision on these sales was progressively reduced and manufacture was discontinued with the consequent loss of the business with other wholesalers.

4.56. Kelvin's turnover and profit on its wholesale CLS business for the three years to 29 February 1992 are shown in Table 4.26.

TABLE 4.26 **Kelvin: summary of financial results**

£'000

	Years to end February		
	1990	*1991*	*1992*
Turnover	453	1,029	1,238
Gross profit	N/A	145	N/A
Net operating profit	2	-1	1
			per cent
Gross profit margin on turnover	N/A	14.1	N/A
Net margin to turnover	0.4	-0.1	0.1

Source: Aspect.

4.57. Kelvin distributes a full range of CLS, purchasing from ten suppliers. In the year to 28 February 1991 its four largest suppliers were Allergan (28 per cent), CIBA Vision (27 per cent), B&L, including M&L (18 per cent), and Alcon (12 per cent), a total of 85 per cent of its supplies. In the same year 81 per cent of sales were to opticians and 19 per cent to pharmacies (with the pharmacy percentage share falling further in the following year). Kelvin supplies individual branches of Boots with CLS, but does not sell to D&A.

4.58. Kelvin obtains a discount of 15 per cent off trade price from Allergan and CV-UK and 25 per cent from its other two main suppliers. When Kelvin receives 25 per cent discount, it grants discounts off trade price to its customers from nil (on orders of 5 dozen or below) to 10 per cent (over 20 dozen) and higher in exceptional circumstances. Where Kelvin receives a 15 per cent discount, it grants lower discounts on an individual customer basis. Kelvin also provides promotional offers and free gifts aimed at further motivating customers' purchases.

Mid-Optic

4.59. Mid-Optic is a privately-owned national wholesaler of CLS. Mid-Optic aims to supply all CLS (except retailers' own-label solutions) which are currently licensed. Because Mid-Optic supplies pharmacies as well as opticians it does not distribute Sauflon products. Opticians account for 90 per cent of turnover, hospital pharmacies for 6 per cent and ordinary pharmacies for 4 per cent.

4.60. In the year to 30 November 1991 Mid-Optic's largest suppliers were Allergan (42 per cent), CIBA Vision (22 per cent), B&L, including M&L (15 per cent), and Alcon (14 per cent), a total of 93 per cent of its supplies.

4.61. Mid-Optic's turnover and profit on its wholesale CLS business for the two years to 30 November 1991 are shown in Table 4.27.

TABLE 4.27 **Mid-Optic: summary of financial results**

	£'000	
	Years to end November	
	1990	*1991*
Turnover	2,332	2,908
Gross profit	N/A	529
Net operating profit	43	71
	per cent	
Gross margin on turnover	N/A	18.2
Net margin on turnover	1.8	2.4

Source: Mid-Optic.

4.62. Discounts received by Mid-Optic from its main suppliers are 15 per cent off trade price from Allergan and CV-UK and around 25 per cent off trade price from the other suppliers. When Mid-Optic receives a 25 per cent discount, it grants discounts up to 12.5 per cent, depending on the size of order, but these rates are not available on products where a discount of only 15 per cent is received.

Martin

4.63. Martin is a national wholesaler of CLS and is privately owned. Martin aims to distribute all available solutions to its customers, but until B&L's policy towards wholesalers was changed in April 1992, it was not able to supply that company's Optimeyes solutions. The four main suppliers in the year to 30 April 1991 were Allergan (36 per cent), CIBA Vision (20 per cent), B&L, including M&L (15 per cent), and Alcon (14 per cent), a total of 85 per cent of supplies. Martin told us that 99 per cent of its business was with opticians, the remaining 1 per cent being with hospital pharmacies. On B&L and Alcon products Martin grants discounts of up to 12.5 per cent according to size of order. A discount of 5 per cent is given on some Allergan and CV-UK products to retain business, otherwise trade prices apply.

4.64. The turnover and profit on Martin's CLS business for the year to 30 April 1992 is shown in Table 4.28.

TABLE 4.28 **Martin: summary of financial results**

	£'000
	1992
Turnover	[
Gross profit	*
Net operating profit	]
	per cent
Gross margin on turnover	[*
Net margin on turnover	]

Source: Martin.

*Figures omitted. See note on page iv.

Financial results of the principal retailers

BTC

4.65. BTC is a division of The Boots Company PLC. The division manages through a separate company—Boots The Chemists Limited—840 small stores, which concentrate on the core business areas of health and beauty, and 230 large stores which, as well as health and beauty products, include sound and vision, cook shop, and leisure and home merchandise. The major part of the division's business is undertaken by Boots The Chemists Limited. The activities not carried on by Boots The Chemists Limited are central buying, warehousing and distribution, and business centre operations which are BTC divisional activities.

4.66. Table 4.29 gives a summarized profit and loss account for the division covering the three years ended 31 March 1992. Total turnover has risen from £2,269 million in 1990 to £2,472 million in 1992. The division's 1992 turnover constituted some 67 per cent of The Boots Company PLC group turnover of £3,656 million. The gross profit percentage on supplies to retail stores (see paragraph 4.67) was 40.8, 42.0 and 42.6 per cent for the years 1990, 1991 and 1992 respectively. The gross profit percentage to turnover earned by BTC division moved from 38 per cent (£861 million) in 1990 to 40.5 per cent (£1,000 million) in 1992. Net PBIT averaged just over 9 per cent of turnover over the three years to 1992.

TABLE 4.29 **BTC: summarized management accounts**

£ million

	Years ended 31 March		
	1990	*1991*	*1992*
Supplies to retail stores	2,444.1	2,527.9	2,632.1
Less adjustments for opening and closing stock, shortages, price changes etc	-175.2	-167.3	-160.3
Turnover	2,268.9	2,360.6	2,471.8
Gross profit on supplies to retail stores	997.4	1,061.9	1,120.1
Less adjustments for gross profit on opening and closing stock, shortages, price changes etc	-136.2	-133.2	-119.6
Gross profit on turnover	861.2	928.7	1,000.5
Promotion, advertising, business centre and other costs	-127.3	-131.2	-135.4
Store gross profit	733.9	797.5	865.1
Store expenses	-453.1	-479.3	-521.4
Head office expenses	-90.8	-89.4	-97.5
Net PBIT	190.0	228.8	246.2
Percentage net profit to turnover	8.4	9.7	10.0

Source: BTC.

4.67. BTC told us that there was no comprehensive analysis of CLS sales or indeed of any other of its merchandise groups from its retail outlets. However, records were available of supplies to retail stores at retail prices. BTC said that these details provided a reasonable indication of levels of activity in CLS. Supplies to retail stores figures have been used in this report as a substitute for BTC turnover figures. The figures used exclude VAT. Except where otherwise stated the gross profit figures quoted in the sections dealing with BTC and BOL are the difference between supplies to retail stores at retail prices (excluding VAT) and the cost of purchase to BTC of those supplies. The difference in the three years 1990 to 1992 between this gross profit and the gross profit on turnover is given in paragraph 4.66. By comparison with the normal basis used to determine the gross margin to turnover, the use of supplies to retail stores as the basis for the calculation will tend to boost the gross margin percentage. This needs to be borne in mind when comparisons are made between the BTC profit margin data cited below and those of other businesses.

4.68. Table 4.30 shows supplies to retail stores and related gross profits on CLS in the three years ended 31 March 1992 together with an analysis of these results as between branded and Boots'

own-label sales. In each of the three years the gross profit percentage on Boots' own-label CLS was higher than the gross profit percentage on branded CLS (see paragraphs 4.71 and 4.72). Own-label supplies to BTC retail stores increased as a percentage of total supplies of CLS from 23 per cent in 1990 to 31 per cent in 1992.

TABLE 4.30 **BTC: supplies to retail stores (SRS) and related gross profit on branded and Boots' own-label CLS**

£'000

	Years ended 31 March		
	1990	*1991*	*1992*
SRS			
Branded	9,593	12,145	16,202
Boots' own-label	2,879	4,869	7,317
Total	12,472	17,014	23,519
			per cent
Percentage of SRS in year			
Branded	76.9	71.4	68.9
Boots' own-label	23.1	28.6	31.1
			£'000
Gross profit			
Branded	4,746	6,048	8,211
Boots' own-label	1,847	2,987	4,431
Total	6,593	9,035	12,642
			per cent
Gross profit percentage to SRS			
Branded	49.5	49.8	50.7
Boots' own-label	64.2	61.3	60.6
Total	52.9	53.1	53.8

Source: BTC.

4.69. In Table 4.31 the gross margins earned on CLS are compared with the gross margins earned on all supplies to retail stores of BTC. The table also shows the percentage of CLS supplies to total supplies and the percentage of gross profit earned on CLS to total related gross profit on all supplies to retail stores. The gross profit margin on CLS supplies to retail stores is significantly higher than the average gross profit margin on total supplies. The margin on CLS in 1990 was some 12 percentage points higher than the average margin, decreasing slightly to 11 percentage points in 1991 and 1992.

TABLE 4.31 **BTC: comparison of CLS supplies to retail stores (SRS) and related gross profit margins, with total SRS and related gross profits of BTC division**

per cent

	Years ended 31 March		
	1990	*1991*	*1992*
Percentage of CLS SRS to total divisional SRS	0.5	0.7	1.0
Percentage of gross profit on CLS to total divisional gross profit	0.7	0.9	1.1
Average gross profit margin on total divisional SRS	40.8	42.0	42.6
Gross profit margin on CLS	52.9	53.1	53.8

Source: BTC.

4.70. BTC has told us that its product costing system is not sufficiently developed to enable it to provide details of net PBIT earned on CLS. The company has also stated that ROCE is not calculated at product level. The returns in 1991 and 1992 on capital employed at the ends of those years for BTC as a whole are set out in Table 4.32. The data are extracted from summarized management accounts supplied by the company.

TABLE 4.32 **BTC: ROCE**

	Years ended 31 March	
	1991	*1992*
Capital employed at year end (£m)*	423.6	431.4
Net PBIT (£m)	228.8	246.2
Percentage return on year-end capital employed (%)†	54.0	57.1

Source: BTC.

*BTC told us that no balance sheet was prepared for the year ended 31 March 1990 and therefore it has not been possible to compute the return on *average* capital employed over the two years in question.

†BTC has said that, if an adjustment is made to include the value of property (which is held by a separate property subsidiary undertaking), the ROCE is 23.5 per cent for 1991 and 25.4 per cent for 1992 (see paragraph 4.108).

Supplies to retail stores and related gross profit—branded CLS

4.71. In the year to 31 March 1992 the gross margin earned by BTC on the individual branded CLS which it sells ranged from 46 to 58 per cent. The average gross margin on branded CLS for the years 1990, 1991 and 1992 were 49.5, 49.8 and 50.7 per cent respectively. A summary of supplies to retail stores and gross profit margins on branded CLS is given in Appendix 4.3.

Supplies to retail stores and related gross profit on Boots' own-label CLS

4.72. Supplies to retail stores of and gross profits on Boots' own-label CLS are also summarized in Appendix 4.3. The gross profit margins in respect of individual products in the year to 31 March 1992 ranged from 45 to 73 per cent, with the top selling line in 1992—preservative-free rinsing and neutralizing solution—earning the 45 per cent margin. The average in each of the three years 1990, 1991 and 1992 respectively was 64.2, 61.3 and 60.6 per cent. This reduction in average gross margins is accounted for by the disproportionate increase in sales of preservative-free rinsing and neutralizing solution with its lower percentage gross margin.

Gross margin differential between branded and own-label solutions

4.73. On the basis of information provided by BTC there is a differential of approximately 6 per cent at the retail price level between own-label CLS lines and comparable branded lines. A comparison of prices at retail level for the equivalent branded and Boots' own-label lines is given in paragraphs 3.206 to 3.211. As the data in paragraphs 4.71 and 4.72 and in Appendix 4.3 indicate, the 6 per cent differential is not, however, reflected in lower gross margins on Boots' own-label CLS; the gross margin on own-label lines have tended to exceed those on the branded range by at least ten percentage points.

4.74. BTC has said that own-label solutions which are based on branded products are usually sold at a discount to those branded products, but provide the customer with a cheaper alternative that would not exist if those own-label products were not available. BTC emphasized that, whilst own-label goods might have a higher percentage gross profit margin than the branded product, the goods were not in themselves more profitable as the retailer had to finance from the gross margin those overheads and costs (especially the marketing costs, for example the provision of free starter kits) that proprietary manufacturers bore themselves in respect of their own branded goods. BTC has estimated an average cost per pack of 23p for the additional costs involved with own-label CLS compared with branded CLS. The computation is based on the total number of own-label CLS packs supplied to stores in the year ended 31 March 1992 of 3.035 million. The costs include the cost of own-label starter packs purchased by BTC from its suppliers but provided free by BTC to BOL. The cost of starter packs represents 7.2p, with other promotion costs, such as display material, accounting for 11.8p. The cost of additional shelf space allocated to own-label and other similar costs make up the balance of 4p. The total costs based on 23p and 3.035 million packs (this figure includes supplies to

BOL) amount to £698,000. Adjustment of the combined BTC and BOL gross profit on own-label of £5.615 million (see Appendix 4.3) to take account of these costs results in a revised gross profit of £4.917 million or 52.7 per cent of supplies to retail stores. This compares with the gross profit on branded CLS of 50.7 per cent.

Profitability of the main businesses in BTC division

4.75. Table 4.33 compares the average gross profitability of solutions with that of the rest of Boots' Non-Dispensing Healthcare business (of which they form part), its Personal Care business and the rest of its businesses combined. Gross profit on CLS exceeded that achieved on the other product groups, the differences ranging from two to three percentage points in the case of other Non-Dispensing Healthcare to over ten percentage points with respect to the rest of the businesses (which include dispensing).

TABLE 4.33 **BTC summary of supplies to retail stores (SRS) and related gross profit (GP) across BTC businesses**

Business	*1990*			*1991*			*1992*		
	SRS £'000	*GP £'000*	*GP %*	*SRS £'000*	*GP £'000*	*GP %*	*SRS £'000*	*GP £'000*	*GP %*
CLS	12,472	6,593	52.9	17,014	9,035	53.1	23,519	12,642	53.8
All other Non-Dispensing Healthcare	210,279	105,157	50.0	230,597	115,984	50.3	258,216	131,395	50.9
Personal Care	482,400	206,000	42.7	512,600	229,900	44.8	540,700	253,000	46.8
Dispensing, Baby, Beauty, Foods, Sound/Vision, Leisure and Home	1,738,967	679,689	39.1	1,767,703	706,990	40.0	1,809,665	723,063	40.0
Total	2,444,118	997,438	40.8	2,527,914	1,061,909	42.0	2,632,100	1,120,100	42.6

Source: BTC.

BOL

4.76. BOL is a chain of retail opticians which sells CLS as part of its business. It is 100 per cent owned by The Boots Company PLC. BOL has expanded through several major acquisitions (Clement Clarke, Curry & Paxton, Miller & Santhouse). The branches of these chains have been either integrated into the BOL chain or else closed after acquisition. BOL is part of the Retail division of The Boots Company PLC. Most of BOL's supplies of CLS are obtained through BTC and in this way BOL enjoys largely the same procurement terms as BTC.

4.77. The summarized profit and loss accounts for each of the years ended 31 March 1990 to 1992 for BOL are given in Table 4.34. Turnover, which includes spectacles and frames, lenses and other optical products as well as CLS, has risen from £50 million in 1990 to £84 million in 1992. Net PBIT has increased from £1.8 million (3.6 per cent of turnover) in 1990 to £5.8 million (6.9 per cent of turnover) in 1992.

TABLE 4.34 **BOL: summarized profit and loss accounts**

£ million

	Years ended 31 March					
	1990	*% to turnover*	*1991*	*% to turnover*	*1992*	*% to turnover*
Turnover	49.9	100.0	73.8	100.0	84.0	100.0
Cost of sales	-15.2	-30.5	-20.8	-28.2	-23.9	-28.4
Gross profit	34.7	69.5	53.0	71.8	60.1	71.6
Selling, distribution and branch costs	-30.6	-61.3	-45.1	-61.1	-49.7	-59.2
Administrative expenses	-2.3	-4.6	-4.3	-5.8	-4.6	-5.5
Net PBIT	1.8	3.6	3.6	4.9	5.8	6.9

Source: BOL.

Turnover of and gross profit on branded and own-label CLS

4.78. BOL has told us that it follows the same retail pricing practices for CLS as BTC, including the 6 per cent differential in retail prices between own-label and equivalent branded products. Table 4.35 shows supplies to BOL stores (SRS) and gross profit on branded and own-label CLS. The gross profit percentages to SRS are close to the overall average gross profit percentage earned by BTC. It will be seen from Table 4.35 that the turnover of Boots' own-label has grown significantly during the period. As a percentage of total CLS supplies to BOL stores, own-label has increased from 14 per cent in 1990 to 39 per cent in 1992; there has also been a rise in BOL's gross margins on CLS, in large part, it appears, because of the high margins earned on own-label solutions.

TABLE 4.35 **BOL: summary of supplies to retail stores (SRS) and gross profit (GP) on branded and Boots' own-label CLS**

	Years ended 31 March								
	1990			*1991*			*1992*		
	SRS £'000	*GP £'000*	*GP %*	*SRS £'000*	*GP £'000*	*GP %*	*SRS £'000*	*GP £'000*	*GP %*
Branded supplied through BTC	1,928	946	49.1	2,412	1,180	48.9	1,941	984	50.7
Branded sourced by BOL	1,190	526	44.2	1,520	661	43.5	1,221	507	41.5
Total branded	3,118	1,472	47.2	3,932	1,841	46.8	3,162	1,491	47.2
Boots' own-label all supplied through BTC	509	315	61.9	1,421	820	57.7	2,009	1,184	58.9
	3,627	1,787	49.3	5,353	2,661	49.7	5,171	2,675	51.7
							per cent		
	SRS	*GP*		*SRS*	*GP*		*SRS*	*GP*	
Shares of CLS SRS and GP:									
Branded	86.0	82.4		73.5	69.2		61.1	55.7	
Boots' own-label	14.0	17.6		26.5	30.8		38.9	44.3	

Source: BOL.

Note: Information by product line and pack size has not been provided by BOL.

D&A

4.79. D&A is a wholly-owned subsidiary of Gallaher Ltd which in turn is wholly owned by American Brands Inc of Delaware, USA. The main business of D&A is the operation of a UK chain of retail opticians which prescribes and dispenses spectacles and contact lenses and sells accessories such as CLS. D&A also manufactures and sells ophthalmic and medical instruments and has overseas interests. In the year to 30 November 1991 the UK retail chain generated CLS turnover of £9.1 million out of total retail sales of £144 million and a D&A group turnover of £240 million. CLS sales were therefore 6.3 per cent of the sales of the retail chain and 3.8 per cent of all D&A sales.

4.80. D&A started selling branded CLS in 1967 and the group entered the own-label market in 1990; D&A now has a range of nine products under the One-2-One name. Solutions sales are recorded by D&A with sales of accessories which include sunglasses, cases, spectacles chains and cleaning cloths. D&A does not analyse accessory sales by product or between own-label and branded products. For the purpose of this report sales of CLS have therefore been estimated by D&A from its management information system. They are referred to as supplies to retail stores in this chapter.

Profitability and ROCE

4.81. D&A's turnover and net operating profit for the periods ended in the years 1989 to 1991 are given in Table 4.36.

TABLE 4.36 **D&A: turnover and net operating profit**

£'000

	30.9.89 (52 weeks)	*24.11.90 (60 weeks)*	*30.11.91 (53 weeks)*
Turnover	202,780	248,507	240,258
Net operating profit*	1,030	-949	11,643
*After charging exceptional items	-920	-4,450	-935

Source: D&A.

4.82. D&A has provided details of the estimated profitability of CLS for 1991 and 1992 (years to end November) at the gross margin level and this is shown in Table 4.37. Retail branch expenses and capital employed are not allocated to product groups or to individual products. No information on net profitability or ROCE on CLS is therefore available.

TABLE 4.37 **D&A: estimated turnover and gross profit on CLS and other accessories with actual turnover and gross profit on other product groups**

£'000

	1991			*1992*		
	Turnover	*Gross profit*	*%*	*Turnover*	*Gross profit*	*%*
CLS	9,093	3,073	33.8	8,733	2,629	30.1
Other accessories	[					
Spectacles sales		*Figures omitted. See note on page iv.*				
Contact lens sales						]
Contact lens care scheme premiums	[			[		
Sight tests	†			†		
UK optics chain	]			]		

Source: D&A.

The gross profit percentage on CLS as a whole (Table 4.37) appears low compared with that shown on selected branded and own-label products in Tables 4.38 and 4.39. This is partly explained by the discounts given on CLS which are supplied by D&A to patients using its contact lens care scheme.

Supplies to retail stores and gross profit

Branded CLS

4.83. The gross margin earned by D&A on six selected branded products varies from 40.2 to 51.1 per cent with an average of 42.4 per cent for 1991 and 43.0 per cent for 1992. Details are given in Table 4.38.

TABLE 4.38 **D&A: summary of supplies to retail stores (SRS) (excluding VAT) and gross profit (GP) on branded CLS**

			1991			*1992*		
Product		*Pack size*	*SRS £'000*	*GP £'000*	*GP% to SRS*	*SRS £'000*	*GP £'000*	*GP% to SRS*
10.10 Step 1	(C)	250ml	172.6	73.7	42.7	152.5	66.0	43.3
10.10 Step 2	(C)	25 x 15ml	291.4	124.6	42.8	247.0	106.8	43.2
Softab	(Al)	32 tabs	91.1	39.7	43.6	78.6	34.7	44.1
Aerotab	(S)	32 tabs	57.0	29.1	51.1	53.9	27.0	50.1
Clen-zym	(Al)	12 tabs	49.3	21.7	44.0	31.5	14.2	45.1
Hydrocare Fizzy	(A)	24 tabs	389.6	156.5	40.2	251.7	101.7	40.4
			1,051.0	445.3	42.4	815.2	350.4	43.0

Source: D&A.

Note: (A) = Allergan; (C) = CIBA Vision; (Al) = Alcon; (S) = Sauflon.

†Figures omitted. See note on page iv.

Own-label CLS

4.84. The SRS and gross profit on four of D&A's own-label products are set out in Table 4.39. The gross profit percentage ranges between 40 and 59 per cent. The averages for the years 1991 and 1992 were 48.3 per cent and 50.6 per cent respectively. Rapide R&N solution is the low margin earner bringing down the average, although because Rapide R&N and C&D have to be used together, the combined margin of 50 per cent (1992) is a more appropriate ratio.

TABLE 4.39 **D&A: summary of supplies to retail stores (SRS) (excluding VAT) and gross profit (GP) on own-label CLS**

		1991			*1992*		
Product	*Pack size*	*SRS £'000*	*GP £'000*	*GP% to SRS*	*SRS £'000*	*GP £'000*	*GP% to SRS*
Rapide C&D	250ml	553.3	322.5	58.3	888.4	524.3	59.0
Rapide R&N	25 x 15ml	894.8	364.7	40.8	986.7	413.0	41.9
Freshtab	32 tabs	354.4	183.8	51.9	497.5	262.9	52.8
Polyzyme	12 tabs	1.0	0.5	50.0	118.5	59.9	50.5
		1,803.5	871.5	48.3	2,491.1	1,260.1	50.6

Source: D&A.

Lloyds

4.85. Lloyds operates the second largest chain of retail pharmacies (after Boots) with 867 pharmacies at October 1992. There are also four Lloyds Eyecare Centres trading as opticians. Turnover in contact lens care products for the year ended 30 June 1992 was estimated by Lloyds to be £1.8 million, a small proportion of Lloyds' total turnover. Lloyds stocks mainly Allergan and CIBA Vision products—58 per cent and 40 per cent of purchases respectively for the year to 30 June 1992—with a further 2 per cent supplied by S&NP. Lloyds began selling solutions in its first pharmacy in 1973. Lloyds has grown rapidly to its present size of 867 pharmacies from only 141 in 1987; the number increased to the present level of 867 from 656 at the end of the 1991 financial year.

Turnover and gross profit

4.86. Lloyds' estimated CLS turnover and gross profit for the years ended 30 June 1991 and 1992 are given in Table 4.40.

TABLE 4.40 **Lloyds: CLS turnover and gross profit**

	£'000	
	Years ended 30 June	
	1991	*1992*
Turnover	563	1,807
Gross profit	206	662
	per cent	
Gross margin on turnover	36.6	36.6

Source: Lloyds.

4.87. Retail pharmacy expenses and capital employed are not allocated to product groups or individual products, so no information on net profitability or ROCE on CLS is available.

Discounts off trade prices given by suppliers to wholesalers and retailers

Discounts to trade channels

Allergan

4.88. The actual discounts off trade prices (including retrospective discounts) given by Allergan to its various trade channels on a selection of its CLS products are shown in Table 4.41. The information is derived from sales in the year ended 30 November 1991. Total turnover in that year for the selected products was £9.2 million or 53 per cent of Allergan's turnover in CLS of £17.3 million.

TABLE 4.41 **Allergan: actual discounts by trade channel on selected products, 1991**

per cent

		Trade channels					
Product	*Total*	*Boots*	*D&A*	*Opticians*	*Pharmaceutical wholesalers*	*Optical wholesalers*	*Others*
Average discount for the selected products	25.6	33.8	30.4	20.4	15.8	17.3	16.2
Turnover at realized prices (£'000)	9,238	3,140	981	2,326	897	1,027	867

Source: Allergan.

Note: The selected products are LC-65, Hydrocare Fizzy, Solusal, Oxysept 1 and 2, Hydrocare Cleaning/Soaking and Clean-N-Soak.

The discounts shown represent the reductions from trade prices enjoyed by individual customers and customer groups. Trade prices are the prices at which, according to Allergan's price list, solutions would be sold by wholesalers to retailers. The average discounts on the products selected for the table vary between trade channels from 33.8 per cent (Boots) to 15.8 per cent (pharmaceutical wholesalers).

4.89. We asked Allergan to provide us with details of any savings below average costs, or additional costs above the average costs, arising from selling these products to each trade channel. By *deducting* savings and *adding* costs to the discount actually given we have calculated the relative cost to Allergan of doing business with each trade channel. This is shown in Table 4.42 as a percentage of the sales at trade price, and is the amount of the actual discount which is unsupported by cost savings below average costs or (when net additional costs arise) the actual discount given plus the additional net costs above average costs that are incurred. In this context, we have called this percentage 'the cost of doing business'. Allergan has said that the information on savings and additional costs has been extracted from its accounting records as a special exercise and the basis of allocation of savings/costs is somewhat arbitrary; for this reason Allergan believes that the results are not wholly reliable. The cost of starter packs, which is included in Allergan's promotion and marketing expenditure, has been wholly attributed to sales to opticians. As a result a relatively high percentage is shown against this trade channel. Notwithstanding these points the percentage shown against the opticians trade channel does, in part at least, indicate the emphasis placed by the company on giving favourable terms to the opticians trade channel compared with, say, optical wholesalers or pharmaceutical wholesalers.

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TABLE 4.42 **Allergan: cost of doing business with each trade channel as a percentage of sales at trade prices on selected products, 1991**

per cent

Product	*Average*	*Trade channels* *Boots*	*D&A*	*Opticians*	*Pharmaceutical wholesalers*	*Optical wholesalers*	*Others*
Average cost of doing business for the selected products	25.8	23.4	21.9	43.6	7.8	16.6	14.1
Average cost of doing business for the selected products with opticians = 100	59	54	50	100	18	38	32

Source: Allergan.

Note: The selected products are LC-65, Hydrocare Fizzy, Solusal, Oxysept 1 and 2, Hydrocare Cleaning/Soaking and Clean-N-Soak.

CV-UK

4.90. The actual discounts off trade prices given by CV-UK to its various trade channels on a selection of CV-UK's CLS products are given in Table 4.43. The information is derived from sales in the year ended 31 December 1991. Total turnover in that year for the selected products after discount was £8.0 million or 56 per cent of CV-UK turnover in CLS of £14.3 million. CIBA Vision told us that it had no information to quantify any cost savings supporting the levels of discounts.

TABLE 4.43 **CV-UK: actual discounts by trade channels on selected products, 1991**

Product	*Total*	*Trade channels* *Boots*	*D&A*	*Opticians**	*Pharmaceutical wholesalers*	*Optical wholesalers*	*Others*
Average discount for the selected products (%)	29.2	38.0	36.8	27.5	18.5	18.0	16.1
Turnover at realized prices (£'000)	8,058	2,268	391	3,185	1,416	678	120

Source: CIBA Vision.

*This is the average discount to all opticians dealt with other than BOL and D&A.
Note: The selected products are 10.10 Step 1 and 2, Solar Saline, Contactasoak, Hydrosoak and Miraflow.

4.91. The discounts include the standard 15 per cent trade discount given to all channels, together with other discounts, including retrospective discounts, which are separately negotiated. The discounts shown, therefore, represent the total reduction from list price enjoyed by individual customers and customer groups. Table 4.43 shows considerable variation—between 16 and 38 per cent—in the average discounts enjoyed by different trade channels, with Boots receiving the highest average discount and wholesalers the lowest.

Alcon

4.92. The actual average discounts off trade price given by Alcon to its various trade channels on a selection of CLS products are given in Table 4.44. The information is derived from sales in the year ended 31 December 1991. Total turnover in that year for the selected products was £2.5 million—56 per cent of the company's CLS turnover of £4.5 million.

TABLE 4.44 **Alcon: actual discounts by trade channel on selected products, 1991**

Product	Total	Trade channels: Boots	D&A	Opticians	Pharmaceutical wholesalers	Optical wholesalers
Average discount for the selected products (%)	30.6	43.8	34.6	22.9	13.5	25.3
Turnover at realized prices (£'000)	2,528	679	177	720	230	722

Source: Alcon.

Note: The selected products are Pliagel, Clen-zym, Alcon Aerosol Saline and Softab.

The discounts shown represent the reductions from trade prices enjoyed by individual customers and customer groups. Trade prices are those at which, according to Alcon's price list, solutions would be sold by wholesalers to retailers. The average discount on the selected products shown in the table varies between trade channels from 13.5 to 43.8 per cent.

4.93. Alcon told us that discounts are based on total purchase quantities, but that special discount rates may be individually negotiated by customers. Additional short-term promotional discounts can also be negotiated by customers. Alcon was asked to relate discounts to cost savings but the company was not able to calculate this. It said that in its view all its trade discounts are cost-related but could not be precisely defined.

B&L and M&L

4.94. The actual discounts on trade prices given by B&L and M&L to their various trade channels on a selection of CLS products are shown in Table 4.45. The information is derived from sales for the year ended 28 December 1991. Total turnover in that year for the selected products of B&L was £1.495 million or 84 per cent of B&L's turnover in CLS of £1.770 million. In the case of M&L, the selected products accounted for sales of £1.269 million or 83 per cent of M&L's CLS turnover of £1.522 million.

TABLE 4.45 **B&L and M&L: actual discounts by trade channel on selected products, 1991**

Product	Total	Trade channels: Boots*	D&A	Opticians	Pharmaceutical wholesalers*	Optical wholesalers
B&L products						
Average discount for the selected B&L products (%)	30.0	-	31.1	29.5	-	30.4
Turnover at realized prices (£'000)	1,495	-	166	859	-	470
M&L products						
Average discount for the selected M&L products (%)	26.1	34.0	28.0	5.9	26.2	28.2
Turnover at realized prices (£'000)	1,269	215	157	225	31	641

Source: B&L and M&L.

*B&L supplies only to the optical trade, hence no sales to Boots or pharmaceutical wholesalers are shown.
Note: The selected products are: B&L—Daily Cleaner, HGP Concentrated Cleaner, HGP Conditioning Solution, Aller Enzyme Tablets and Fizziclean Enzyme Tablets; and M&L—Boston Cleaner and Boston Wetting solution.

4.95. B&L average discounts on the selected products combined show only small differentials between trade channels. D&A discounts averaged 31.1 per cent, compared with opticians at 29.5 per cent and optical wholesalers at 30.4 per cent.

4.96. M&L discounts indicate somewhat bigger differentials between trade channels, ranging from 34.0 per cent for Boots and 28.0 per cent for D&A to 28.2 and 26.2 per cent for optical and pharmaceutical wholesalers respectively. M&L sales to opticians show a low discount primarily because no discount is given to opticians on Boston Cleaner.

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4.97. Neither B&L nor M&L allocates operating costs over products and trade channels, so it has not been possible to establish the extent to which discounts to trade channels are supported by net savings in costs. B&L has a retrospective discount scheme, but M&L does not.

Discount differentials off trade price on selected products within market segments

4.98. Table 4.46 compares the actual percentage discounts on trade price on selected products obtained by the three main trade channels, namely Boots, D&A and opticians. The products have been grouped into relevant market segments. The table shows that there are marked differences in the discounts off trade prices within given trade channels and for individual products/market segments. The most consistent discount structure is that of Allergan sales to Boots; in six out of the seven products selected the percentage discount is around 33 per cent. It should be noted that the table is derived from selected products of Allergan, CIBA Vision and Alcon and, although the selected products account for over 50 per cent of the turnover in each of the suppliers, the picture given is not complete. Moreover, the discount shown for opticians is the average discount given by each company. There may be significant variations in discounts given to individual opticians.

4.99. Table 4.46 also shows the percentage points difference in the discounts achieved by Boots and D&A compared with the opticians' discounts. For Boots the percentage points differential over opticians varies from just over five percentage points to some 23 percentage points on the product range reviewed. The comparable variation for D&A is from -1.3 percentage points to 16 percentage points.

TABLE 4.46 **Comparison of actual percentage discounts on trade price on selected products grouped in market segments**

	Pack size	*Boots discount % (1)*	*D&A discount % (2)*	*Opticians' discount* % (3)*	*Percentage points differential v opticians*	
					Boots (1)-(3)	*D&A (2)-(3)*
Surfactant cleaners						
LC-65 (A)	2 x 30ml	32.6	30.0	23.3	9.3	6.7
Miraflow (C)	35ml	39.2	36.7	24.1	15.1	12.6
Pliagel (Al)	25ml	42.0	34.0	18.6	23.4	15.4
Disinfectants						
Hydrogen peroxide systems						
Oxysept 1 (A)	250ml	33.4	30.7	20.6	12.8	10.1
10.10 Step 1 (C)	250ml	43.0	35.7	30.0	13.0	5.7
Oxysept 2 (A)	25 x 15ml	33.1	30.5	20.2	12.9	10.3
10.10 Step 2 (C)	25 x 15ml	32.9	37.8	26.3	6.6	11.5
Chlorine						
Softab (Al)	32 tabs	44.1	34.9	21.7	22.4	13.2
Soaking rinsing and disinfecting solutions						
Hydrocare Cleaning/Soaking (A)	240ml	33.3	30.0	19.5	13.8	10.5
Hydrosoak (C)	120ml	42.9	36.4	37.7	5.2	-1.3
Cold chemical						
Contactasoak (C)	120ml	42.9	36.2	25.7	17.2	10.5
Clean-N-Soak (A)	120ml	33.2	33.0	17.0	16.2	16.0
Saline solutions						
Solusal (A)	240ml	39.6	30.7	24.9	14.7	5.8
Solar Saline (C)	275ml	38.6	36.1	21.8	16.8	14.3
Alcon Aerosol Saline (Al)	240ml	45.2	34.5	31.5	13.7	3.0
Protein cleaners						
Hydrocare Fizzy (A)	24 tabs	33.1	30.2	19.0	14.1	11.2
Clen-zym (Al)	12 tabs	42.7	34.7	20.7	22.0	14.0

Source: MMC from data submitted by the companies.

*This is the average discount on each company's business with opticians other than BOL and D&A.
Note: (A) = Allergan; (C) = CIBA Vision; (Al) = Alcon.

Gross margin available to retailers

4.100. Table 4.47 compares the retail gross margin, expressed in £ per pack, for each of the selected products. The products are grouped in market segments. The gross margin represents the difference between the RRP and the supply cost over the three categories of retail outlets, namely Boots, D&A and opticians. The supply cost is the trade price less the relevant discount given to each of the trade channels and is therefore the net cost to each channel. We have been told that the retail price is normally very close to the RRP, although D&A appears to give, on average, a discount of 2 per cent off RRP. The gross margins set out in Table 4.47 show the relative advantage enjoyed by Boots and D&A over the opticians. It will be seen that both Boots and D&A have available higher gross margins, and in some cases significantly higher gross margins, than opticians. For Boots the lowest differential is on Hydrosoak, the margin being 8.5 per cent higher than that for opticians; the highest difference is that on Pliagel with a 46.4 per cent advantage. The differences available to D&A are lower and sometimes go the other way. To the extent that D&A sells branded CLS at less than RRP it is passing on some of its differential to its customers.

Costs associated with higher margins

4.101. Boots and D&A, because of their different methods of operation, may justify some additional gross margin. For example, Boots operates central warehousing and distribution facilities to its retail stores. We have been told that the same is true of D&A, whereas opticians generally enjoy direct delivery to each store. BTC has stated that its central warehousing stockroom and distribution costs expressed as a percentage of its turnover were 3.8 per cent in 1990, 3.7 per cent in 1991 and 3.8 per cent in 1992. D&A and some other opticians operate discount schemes which would be reflected in lower margins compared with those shown in Table 4.47.

Comparative profit margins on turnover and ROCE

4.102. In this section we compare the performance of the UK CLS business of the suppliers with various sectors of UK industry. We recognize that there are a number of measures available but in this case we have taken two of the more commonly used, namely:

(a) the percentage of PBIT to turnover; and

(b) the percentage of PBIT to tangible capital employed (ROCE). Where information has been made available, the capital employed used is the average of the opening and closing capital employed. Otherwise the closing capital employed has been used. Where capital employed is rising from one year's end to another, the use of the closing capital employed will give a lower ROCE than the figure based on average capital employed.

4.103. The MMC have, in recent years, taken comparative data on sectors of UK industry from an annual article in the Bank of England's Quarterly Review on the *Profitability of Large Companies*. However, from November 1991 the Bank has stopped publishing this article. The UK industry sector information used for comparison in this report has been calculated by the MMC using the MicroEXSTAT corporate financial database, the same database as that used by the Bank of England for its 1990 and 1991 articles. These aggregate sector results are drawn up on a basis consistent with that used for computing ROCE and PBIT/turnover ratios for the companies involved in this inquiry.

TABLE 4.47 **Comparison of retailers' gross margin £ per pack on selected products grouped in market segments—based on 1991 RRP (VAT excluded) and average supply cost for each trade channel for 1991**

PART A

	Pack size	*RRP £/pack*	*Boots margin £/pack (1)*	*D&A margin £/pack (2)*	*Opticians margin £/pack (3)*
Surfactant cleaners					
LC-65 (A)	2 x 30ml	6.35	3.21	2.99	2.75
Miraflow (C)	35ml	3.47	1.90	1.84	1.51
Pliagel (Al)	25ml	3.61	2.05	1.81	1.40
Disinfectants					
Hydrogen peroxide systems					
Oxysept 1 (A)	250ml	2.86	1.33	1.27	1.04
10.10 Step 1 (C)	250ml	3.05	1.66	1.18	1.34
Oxysept 2 (A)	25 x 15ml	4.25	1.98	1.88	1.54
10.10 Step 2 (C)	25 x 15ml	4.34	2.01	2.18	1.63
Chlorine					
Softab (Al)	32 tabs	3.34	1.90	1.65	1.33
Soaking, rinsing and disinfecting solutions					
Hydrocare Cleaning/Soaking (A)	240ml	6.13	3.12	2.94	2.44
Hydrosoak (C)	120ml	3.52	1.91	1.61	1.76
Cold chemical					
Contactasoak (C)	120ml	2.92	1.59	1.42	1.20
Clean-N-Soak (A)	120ml	3.15	1.60	-	1.21
Saline solutions					
Solusal (A)	240ml	1.85	0.96	0.83	0.73
Solar Saline (C)	275ml	2.31	1.17	1.13	0.86
Alcon Aerosol Saline (Al)	240ml	1.84	1.05	0.90	0.85
Protein cleaner					
Hydrocare Fizzy (A)	24 tabs	7.21	3.63	3.50	2.89
Clen-zym (Al)	12 tabs	3.30	1.89	1.69	1.33

PART B *Differential in margin £/pack against opticians*

	Boots		*D&A*	
	(1)-(3)=(4)	*(4)/(3)=(5)* %	*(2)-(3)=(6)*	*(6)/(3)=(7)* %
Surfactant cleaners				
LC 65 (A)	0.46	16.7	0.24	8.7
Miraflow (C)	0.39	25.8	0.33	21.9
Pliagel (Al)	0.65	46.4	0.41	29.3
Disinfectants				
Hydrogen peroxide systems				
Oxysept 1 (A)	0.29	27.9	0.23	22.1
10.10 Step 1 (C)	0.32	23.9	-0.16	-11.9
Oxyset 2 (A)	0.44	28.6	0.34	22.1
10.10 Step 2 (C)	0.38	23.3	0.55	33.7
Chlorine				
Softab (Al)	0.57	42.9	0.32	24.1
Soaking, rinsing and disinfecting solutions				
Hydrocare Cleaning/Soaking (A)	0.68	27.9	0.50	20.5
Hydrosoak (C)	0.15	8.5	-0.15	-8.5
Cold chemical				
Contactasoak (C)	0.39	32.5	0.22	18.3
Clean-N-Soak (A)	0.39	32.2	-	-
Saline solutions				
Solusal (A)	0.23	31.5	0.10	13.7
Solar Saline (C)	0.31	36.0	0.27	31.4
Alcon Aerosol Saline (Al)	0.20	23.5	0.05	5.9
Protein cleaner				
Hydrocare Fizzy (A)	0.74	25.6	0.61	21.1
Clen-zym (Al)	0.56	42.1	0.36	27.1

Source: MMC from data submitted by the companies.

Note: (A) = Allergan; (C) = CIBA Vision; (Al) = Alcon.

Manufacturers/suppliers

4.104. In Table 4.48 the PBIT/turnover and the ROCE of the UK CLS segments of the businesses which we have reviewed in this chapter are compared with those respectively of UK manufacturing industry, of the UK chemicals and pharmaceuticals sector, and of the combined results of the total businesses of three major specialized pharmaceutical companies (Glaxo, Wellcome and Fisons). It is recognized that the structure of the companies supplying CLS in the UK varies. Allergan obtains most of its solutions from API. CIBA Vision has only in the last year come into full operation with its new manufacturing facility. The other suppliers' products are either sourced from overseas or from UK subcontractors, with the exception of Sauflon which has its own manufacturing plant. Except for Alcon, the UK CLS business of the suppliers in the two years 1991 and 1992 earned margins on turnover at least equal to, and in some cases higher than, the UK manufacturing sector.

TABLE 4.48 **The CLS segment of the businesses of suppliers of CLS: net margin on turnover and ROCE comparisons**

per cent

	1988	*1989*	*1990*	*1991*	*1992**
Net margin on turnover					
Allergan†	18.1	10.8	10.4	18.2	21.0
CIBA Vision	6.8	12.1	9.8	9.2	12.9
Alcon	N/A	-7.8	10.9	6.9	N/A
B&L and M&L	N/A	19.8	17.2	14.1	N/A
Sauflon	N/A	-9.0	5.4	10.9	N/A
UK manufacturing sector‡	**9.2**	**9.9**	**9.8**	**9.1**	**8.4**
UK chemicals and pharmaceuticals sector‡	**12.7**	**13.5**	**13.2**	**12.3**	**13.0**
Glaxo, Wellcome and Fisons combined‡	**25.0**	**26.0**	**25.9**	**27.6**	**27.8**
ROCE					
Allergan	99.7	68.7	78.6	147.5	164.8
CIBA Vision	66.1	55.6	10.6	7.5	15.7
Alcon	N/A	-50.9	88.3	56.7	N/A
B&L and M&L	N/A	86.5	90.5	86.8	N/A
Sauflon	N/A	-25.9	16.1	28.8	N/A
UK manufacturing sector‡	**21.0**	**21.2**	**20.4**	**18.6**	**16.6**
UK chemicals and pharmaceuticals sector‡	**26.3**	**27.5**	**24.6**	**22.5**	**23.0**
Glaxo, Wellcome and Fisons combined‡	**45.1**	**44.5**	**41.0**	**39.6**	**42.7**

Source: The UK sector information—MMC from MicroEXSTAT. The CLS suppliers from the companies.

*Estimated.

†Allergan including API (SSAP basis)

Net margin on turnover	38.8	31.7	26.3	27.2	32.1
ROCE	100.0	92.7	86.7	109.3	120.0

‡The figures shown here include the UK and overseas subsidiaries results of those companies included in the sector analysis. The ROCE calculation is based on the year-end capital employed.

Note: N/A = either not requested by MMC or not available.

4.105. The ROCE earned by the UK CLS business generally show that the industry tends to have higher returns than both UK manufacturing as a whole and the chemicals and pharmaceutical sector but not as high as the average for the total businesses of Glaxo, Wellcome and Fisons. The CLS operations of Allergan, B&L (plus M&L) and in recent years Alcon have, however, earned higher ROCE than the average of the total businesses of Glaxo, Wellcome and Fisons combined. The results of CIBA Vision have been affected by the development of the new plant at Macclesfield. CIBA Vision told us that the 1992 estimate is reasonably indicative of the out-turn expected for future years.

ROCE for pharmaceutical manufacturers

4.106. Allergan has submitted to the MMC the results of a survey of the accounts of pharmaceutical manufacturers undertaken by a firm of consultants on its behalf. This is summarized

in Table 4.49. The survey covered the combined results of both UK-based pharmaceutical manufacturers and the UK subsidiaries of foreign groups for the two years 1989 and 1990. There is a significant difference in the ROCE of UK-based groups (1989—50 per cent, 1990—51.5 per cent), and those achieved by UK subsidiaries of foreign groups (1989—9.5 per cent, 1990—11.1 per cent). The UK-based groups' results of 50.0 per cent in 1989 and 51.5 per cent in 1990 and the combined results for 1989—42.4 per cent, and 1990—46.6 per cent compare with the ROCE for Glaxo, Wellcome and Fisons combined shown in Table 4.48 of 44.5 per cent and 41.0 per cent respectively for the two years.

TABLE 4.49 **ROCE—pharmaceutical manufacturers**

per cent

	1989	*1990*
UK-based groups	50.0	51.5
UK subsidiaries of overseas companies	9.5	11.1
Weighted average	42.4	46.6

Source: Allergan commissioned survey.

BTC

4.107. Table 4.50 compares, for BTC, its PBIT/turnover with the average achieved by the stores sector in each of the three years 1990 to 1992. BTC has outperformed the stores sector average, though other retailers have done likewise.

TABLE 4.50 **Net PBIT to turnover**

	Percentage PBIT to turnover		
	1990	*1991*	*1992*
BTC	8.4	9.7	10.0
UK stores sector average*	7.9	7.1	6.2

Source: The UK stores sector information—MMC from MicroEXSTAT. BTC.

*The figures shown here include the UK and overseas subsidiaries results of those companies included in the sector analysis.

4.108. Table 4.51 compares the BTC ROCE with the UK stores sector and the UK non-manufacturing sector. Only the two years to 31 March 1991 and 1992 have been made available by BTC which has told us that no balance sheet was prepared for the year ended 31 March 1990 for BTC division. The BTC ROCE shown in Table 4.51 differs from that shown in Table 4.32 because of an adjustment to capital employed to take account of the value of property used by BTC. BTC has stated that a more appropriate comparison is with figures adjusted to include the value of property used in its retail operations, assets which are currently held by a separate property company. BTC has supplied figures, adjusted to this basis, showing the ROCE at 23.5 per cent for 1991 and 25.4 per cent for 1992. The property values used in the computation are based on independent valuations up to 1989. BTC has told us that it has pursued a policy of owning freehold and long leaseholds for decades and the historic book values are not considered relevant.

TABLE 4.51 **BTC: ROCE comparison**

	Percentage ROCE	
	1991	*1992*
BTC*	23.5	25.4
Stores sector†	15.5	14.3
Non-manufacturing sector†	15.9	13.3

Source: The UK sector information—MMC from MicroEXSTAT BTC.

*The ROCE differs from that shown in Table 4.32 in that an adjustment has been made to include the value of property (which is held by a separate property subsidiary undertaking).

†The figures shown here include the UK and overseas subsidiaries' results of those companies included in the sector analysis.

PBIT/turnover and ROCE for retailers

4.109. BTC submitted to the MMC extracts from a report published by an investment management group giving the PBIT/turnover and ROCE figures for a number of retail companies. Details of those companies in the extract submitted by BTC for which information on both PBIT/turnover and ROCE were given are set out in Table 4.52.

TABLE 4.52 **PBIT/turnover and ROCE for a selection of retail companies**

per cent

	1991		*1992*	
	PBIT/ turnover	*ROCE*	*PBIT/ turnover*	*ROCE*
Boots	9.7	24.0*	10.0	24.7*
Body Shop	19.0	26.4	18.9	26.4
Marks & Spencer	11.6	22.6	12.3	22.4
N Brown	14.9	22.6	14.4	23.0
Sainsbury	8.3	25.4	8.7	23.4

Source: BTC.

*These are taken by BTC from an investment managers' report and differ marginally from the figures in Table 4.51.

Levels of expenditure on R&D in UK pharmaceutical companies

4.110. Table 4.53 sets out the expenditure on R&D reported by a selection of UK pharmaceutical companies. The expenditure is also expressed as a percentage of turnover. Similar information on R&D by some of the CLS manufacturers/importers discussed in this report is also given in the table. In general the CLS manufacturers/importers' levels of expenditure expressed as a percentage of turnover are approximately one-third of those of the selected UK pharmaceutical companies.

TABLE 4.53 **Expenditure on R&D by UK pharmaceutical companies and UK CLS companies**

£ million

	Years ending in				
	1988	*1989*	*1990*	*1991*	*1992*
UK pharmaceutical companies					
Turnover					
Glaxo	2,059	2,570	2,854	3,397	4,096
Wellcome	1,251	1,408	1,469	1,606	1,762
ICI*	1,172	1,334	1,415	1,588	N/A
SmithKline Beecham*	N/A	2,238	2,977	2,470	N/A
Expenditure on R&D					
Glaxo	230	323	399	475	595
Wellcome	164	189	221	230	255
ICI*	170	186	202	223	N/A
SmithKline Beecham*	N/A	N/A	339	370	N/A
					per cent
R&D—per cent of turnover					
Glaxo	11.2	12.6	14.0	14.0	14.5
Wellcome	13.1	13.4	15.0	14.3	14.5
ICI*	14.5	13.9	14.3	14.0	N/A
SmithKline Beecham*	N/A	N/A	11.4	15.0	N/A
					£'000
	1988	*1989*	*1990*	*1991*	*1992†*
UK CLS companies					
Turnover					
Allergan	7,973	12,023	14,839	17,269	18,742
CV-UK	12,022	11,653	13,530	14,297	16,986
Alcon	N/A	2,506	3,901	4,513	N/A
Sauflon	N/A	1,412	1,827	2,516	N/A
Expenditure on CLS R&D					
Allergan‡	372	578	722	853	1,003
CV-UK	N/A	796	875	701	529
Alcon	N/A	N/A	96	132	N/A
Sauflon	N/A	N/A	56	75	N/A
					per cent
R&D—per cent of turnover					
Allergan	4.7	4.8	4.9	4.9	5.4
CV-UK	N/A	6.8	6.5	4.9	3.1
Alcon	N/A	N/A	2.5	2.9	N/A
Sauflon	N/A	N/A	3.1	3.0	N/A

Source: MMC from both published company information and information provided by the CLS companies.

*Pharmaceutical business only.
†Estimated.
‡Actual charges plus unrecovered share of central group expenditure.

5 Views of third parties

5.1. We sought evidence from the DoH, consumer associations, ophthalmic experts, and other parties with an interest in solutions, including members of the public. This chapter summarizes the evidence we received from these parties.

Department of Health

5.2. The MCA and the MDD submitted written evidence and representatives attended two hearings at the MMC.

5.3. The current regulations governing the marketing and supply of solutions in the UK and the provisions of the EC Medical Devices Directive are summarized in paragraphs 2.19 to 2.42. During the course of the inquiry, we put to the MCA a number of issues in relation to the UK regulatory framework. These issues and the MCA's response are set out below.

The UK product licensing system

5.4. We asked the MCA whether the operation of the UK product licensing system had the effect of keeping out of the UK potential new suppliers of solutions or potentially useful new products, either through the stringency of its authorization requirements or because of the time and cost involved in obtaining a product licence.

5.5. The MCA said that it was theoretically possible that any licensing requirements could act as a deterrent to placing a product on the market. However, the MCA believed that the present licensing requirements were straightforward and easily interpretable via well publicized guidelines; did not involve a large R&D investment, by contrast with orthodox pharmaceuticals; had been readily explained to potential applicants who wished to meet with the MCA's professional assessors, either confidentially at the MCA (at no cost) or at public meetings; and were ultimately met by virtually all applicants, whether experienced in pharmaceutical regulation or not.

5.6. The MCA told us that in other European countries and the USA the systems for granting marketing approval to solutions varied considerably, and that there were marked differences both in the standards themselves and the stringency with which they were applied. So far as the EC was concerned, it was the purpose of the EC Directive on Medical Devices to harmonize such standards. The MCA said it accepted that the existing UK approach was more stringent than that in some other countries. There were good reasons for such stringency.

5.7. As to cost, the MCA said that it had to recover its costs from industry and this was the basis on which licence fees were calculated, together with factors such as inflation. Most solutions were classed as 'standard abridged' applications, attracting a fee of £7,385 (see paragraph 2.32).

5.8. The MCA was required to consult with industry when a fee increase or a change of fee classification was proposed, and due account was taken of the responses received.

5.9. The MCA said it recognized that applicants had to incur costs in generating data to meet the licensing requirements, as well as the fee for a product licence. These costs, however, had to be set

in the context of others incurred in marketing a product, including advertising, and of the potential profits to be gained. Possibly the perceived stringency of the licensing requirements was a greater potential deterrent than the costs involved.

5.10. Referring to the time taken to process applications for licences, the MCA said that the acknowledgement by Ministers that licensing delays had important repercussions for companies had led to the reorganization of the former Medicines Division in 1989 and the establishment of the MCA as an agency within the DoH. The MCA had clear time targets for processing applications and progress was reviewed frequently. Licence applications for solutions were now quickly picked up following validation (a procedure for checking the correctness and completeness of the submission) and processed within three months if no Committee advice was needed or around six months if Committee advice was required (see paragraph 2.31). The MCA contended that the processing of UK licence applications was now as fast as, if not faster than, in any EC member state, and faster than in the USA.

5.11. The MCA emphasized that UK requirements for solutions had been formulated on good scientific and clinical grounds and had been reviewed since their introduction (most recently in 1990). The initial imposition in the early 1980s of the quality, safety and efficacy requirements had removed inadequate or dangerous solutions from the market-place. Since then, the requirements had been met by applicants on all except very rare occasions.

Restriction on retail outlets

5.12. We asked the MCA whether the current restriction on retail outlets through which solutions might be sold in the UK restricted price competition and led to higher prices than would otherwise be the case. The MCA said that, since the terms of the Medicines Act 1968 did not permit considerations of cost, the MCA did not gather information on cost-related issues nor could it take cost into account in assessing product licence applications.

5.13. It was not uncommon for considerations of patient safety to dictate that the route of supply of a product should be restricted, for example to hospitals only; nor was it uncommon for a specialist product group to be the province of a small number of manufacturers. But because the legislative framework limited the Licensing Authority to concerns of safety, quality and efficacy on an individual case basis, overall market considerations could not be taken into account. Despite the restriction on the nature of retail outlets, the MCA believed that there was a sufficiently large number and variety of outlets, within the categories that were permitted, to allow ready patient access to a source of supply and, although it was not an MCA matter, to generate satisfactory price competition.

5.14. The MCA considered that there had been a change in the market for these products over the last three or four years due to the growth of 'own-label' distribution. The cost of own-label products tended to be lower than branded products and MCA officials suggested that this had demonstrated the potential for lower prices without a change in the route of supply. This was borne out by the MMC's survey which had found that own-label solutions were some 10 per cent cheaper than branded solutions. Even if wider retail distribution were allowed, in order to permit greater competition between suppliers, CLS retail prices would not fall unless distributors and manufacturers could lower their prices. The own-label solutions were generally the branded products under another label.

5.15. On the question whether wider retail distribution would threaten the safety of wearers, the MCA said that it (and previously the Medicines Division of the DoH) had based its policy on advice from the CDSM, whose expert advisers were appointed by the Secretary of State. Four important factors had to be taken into account:

(a) Whether the safety profile of the product in wide use over a reasonable period of time was acceptable.

(b) Whether the availability of professional advice at the point of sale was essential. The number of occasions on which customers took advantage of this advice was not necessarily a measure of its importance.

(c) Whether the potential for trivialization of the products in the customer's mind would pose a risk to correct use of the products or compliance with a care regime. Solutions were not ordinary items of commerce and should not be regarded as such. MCA noted that medicinal eye drops and eye ointments were not available through general sales outlets.

(d) Whether the recall procedures and storage measures which were routine in pharmacies were adequate in all proposed outlets. Major supermarket chains might have the facilities and resources to introduce these but it was questionable whether small outlets would. The GSL legal status did not differentiate between them.

5.16. The position in the rest of Europe was that GSL status did not exist, and to the best of the MCA's knowledge, solutions were not available from outlets other than those equivalent to UK opticians and pharmacies.

5.17. The MCA stressed that solutions were products which should not be used indiscriminately, on which patients required advice from time to time, and which should be kept under suitable conditions of storage. The present outlets were under the control of professional staff who understood that. Furthermore, registered pharmacies were regularly inspected by RPSGB inspectors. It was likely that advice would be needed more frequently if a wider distribution of outlets were permitted and the number of own-label products increased. Difficulties could arise in the absence of professional advice, for example if one solution was out of stock and the consumer was considering an alternative.

5.18. In recognition of the issues raised by the MMC, however, the MCA had now consulted the CDSM again on the route of sale or supply of solutions. The matter had been referred by the CDSM to a working party for further consideration. The recommendation of the working party was that the current restriction on sale and supply to pharmacies and opticians only should be maintained on grounds of safety. The working party also recommended that the Licensing Authority should begin a review of particular licensing requirements in the light of the EC Directive; in particular, disinfection standards, and the regulatory requirements for contact lens care products which had been pre-packed as complete systems. These recommendations were due for consideration, with a view to adoption, at the next meeting of the CDSM.

Modification of the product licensing requirements

5.19. Responding to the MMC's suggestion that the product licensing requirements might be modified, the MCA said that quality, safety and efficacy remained the only criteria which could be applied, so long as solutions fell within the scope of the Medicines Act 1968. Within the overall safety and efficacy considerations, a product's ease of use (and the consequent increased likelihood of patient compliance) could be taken into account as part of the risk:benefit analysis but considerations of cost were outside the scope of the Act.

5.20. Specific technical requirements might be modified in the light of scientific or regulatory developments. Such a development relevant to solutions was the recent *European Pharmacopoeia* guideline on preservative efficacy testing which had come into force on 1 January 1993 (see paragraph 2.42). A licence application to which this guideline was pertinent had yet to be considered by the CDSM.

5.21. The MCA said that, in 1990, an in-house review of the UK guidelines on applications for product licences for solutions had clarified assessors' current interpretation, but could not be formally published in view of the EC Commission's standstill arrangements barring changes to national requirements without EC consultation. Nevertheless, that review had ensured that the assessors' approach to applications, and their advice to companies, were up to date and consistent.

Consumer information

5.22. The MCA said that it would have no objection to product labelling being expanded to include the number of days' supply (or similar) of the solution, in addition to the current requirement to state

the volume of solution or number of tablets, if this would help consumers to calculate the relative costs of different solutions.

5.23. Labelling of, and leaflets accompanying, solutions were considered by the MCA to be part of its assessment process. Basic labelling requirements for CLS were laid down in the Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979 (see paragraph 2.33), but the content of the claims, warnings and advice on use was agreed with the MCA. All products had to state on the label the type of lenses with which the product could be used.

5.24. We asked the MCA what exactly was meant by the words 'Do not mix with other fluids except as directed' which it required to be displayed on the labels of solutions. The MCA said that the warning was intended to be interpreted as meaning that the solution in question should not be physically mixed together with other solutions except as directed. It agreed that the warning might, however, be taken to mean that the solutions of one brand should not be used with those of another brand in a lens care system.

5.25. With regard to switching brands, there was no reason to believe that switching between brands containing the same active constituent would pose any problems for the vast majority of patients. Inactive constituents varied between brands and these could sometimes lead consumers to prefer one rather than another, but usually no serious problems arose. All had been assessed as safe and efficacious and of satisfactory quality. Changing brands with different active constituents, however, could cause problems because of individual reactions to those constituents, many of which were intrinsically toxic and irritating.

5.26. The MCA said that opticians recommended a particular range of solutions to a patient on the basis of their professional judgment, probably taking account of a number of factors, for example previous patient experience, suitability for the lenses prescribed and suitability for the patient's wear regime and lifestyle. Economic factors might also have a bearing.

5.27. Commenting on periods of recommended use, the MCA said that these were not the same across all products and in many cases there were technical reasons for this. Historically the in-use period for solutions had been 28 days, in line with sterile ophthalmic products, but a number of companies had provided data to justify an extension of the in-use period to eight weeks or more. Some products did not need an in-use limit because of the type of packaging used. In all probability, more products could safely state an in-use period longer than 28 days, but the onus lay on the licence holder to present data justifying a licence variation for this. The MCA tried to ensure that the pack size was appropriate for the in-use period. This was not easy for some products such as cleaners where usage rates differed significantly between individuals.

Opticians' recommendations

5.28. The MCA considered that in general there was no scientific reason for an optician to recommend the use of one particular brand of products within a lens-type category. There might be differences in the relative efficacy and acceptability of different types of solutions designed for the same purpose but all licensed products had been assessed as safe and efficacious and of satisfactory quality. Under the Medicines Act, comparative efficacy could not be taken into account for licensing purposes (see paragraph 2.20).

5.29. Commenting on the MMC's survey of opticians, the MCA considered that the reasons given by opticians for making a recommendation were those which it would have expected (see also paragraph 5.26). The reason that 'less likely to cause irritation' appeared as a higher priority for soft rather than hard and GP lenses was that soft lenses absorbed the solutions more readily and were therefore more likely to cause irritation.

5.30. The change in advice in recent years regarding the care of soft lenses had coincided with the introduction of the peroxide disinfectants. After neutralization, there was virtually no peroxide left and the patient inserted the lenses from an effectively inert solution. The MCA said that, even though non-peroxide disinfection could be used by a number of soft lens wearers, it was not surprising that

the peroxide solutions were recommended since they were likely to be more acceptable to more patients.

Pharmacies

5.31. Commenting on the MMC's survey of pharmacists, the MCA said the survey showed that the vast majority of pharmacists were asked on a regular and frequent basis for advice on eye problems and on solutions. Examination of the detailed tables of data showed that, as expected, the frequency of requests for advice increased with the frequency of sales. This indicated that there was a consistent need for advice with these products.

Comment on companies' complaints

5.32. Commenting on complaints by various companies that they had been unable to obtain product licences for their solutions in the UK, the MCA said that in the UK solutions were treated as medicines and guidelines similar to those applying to medicines were used for applications in the lens care field. These were flexible guidelines and the method of use and the frequency and duration of exposure of the patient to the product were taken into account when considering the data presented in the form of a product licence application. Furthermore, clinical and market experience in other countries would be taken into consideration when submitted as part of the supporting data package. However, in the absence of a formal system of mutual recognition, market experience in another country could not replace a complete dossier. Such a system of mutual recognition did not operate within the EC for any pharmaceutical products, although the EC had developed common guidelines for medicinal products and had introduced a multi-state application procedure as a step in this direction.

5.33. Addressing the criticism that the UK guidelines on antimicrobial testing were stifling the introduction of new products, the MCA said that it had always emphasized that the 'requirements' were guidelines and that companies had the freedom to justify the provision of whatever information they considered appropriate to demonstrate the quality, safety and efficacy of their products. Representatives of the MCA had spoken publicly on suitable data packages, and product-specific guidance had been given to companies on many occasions.

5.34. The MCA observed that much had been said about the UK test for antimicrobial kill rates primarily in association with contact lens disinfectants: for example, that it was an unrealistic test and that the criteria were too tough. It was often argued that physical cleaning also removed microbial contamination and that disinfecting and cleaning products should be judged in combination. The MCA's view was that disinfection, even if viewed as but one element in a lens care system, was a critical step in the care regime and that it should be shown, by itself, to achieve a satisfactory kill in the minimum disinfection period recommended by the company. The MCA considered that, as had been shown in many surveys, compliance with lens care regimes was generally poor and it could not be assumed that both cleaning and disinfecting would be carried out, or carried out adequately. Furthermore, other than in the case of starter kits, lens care products were generally not sold as complete kits, and therefore it could not be argued that it was the whole regime which should be considered.

Summary of the MCA's regulatory position

5.35. In summary, the MCA said that the regulation of contact lens care products in the UK had been introduced on the advice of an independent committee of experts to remedy a risk to health due to ineffective and inadequately preserved products. Contact lens care products were sufficiently similar to ophthalmic pharmaceuticals in formulation and mode of use to have warranted medicines-type controls. Guidelines were not rigid requirements but were interpreted flexibly for each product, taking formulation and mode of use into account.

5.36. Licensing fees were the subject of consultation with industry, and the principle of primarily relating the fee charged to the cost of the work done in assessing applications was accepted by industry. The costs of adverse event monitoring and follow-up action, as well as the not insignificant resource involved in advising companies at the product development stage, were borne by the Licensing Authority. Furthermore, there was a concessionary fee for solutions containing a new active substance, which represented a considerable reduction compared with orthodox pharmaceuticals.

5.37. The restriction on route of sale and supply was based on expert advice to the Licensing Authority from both pharmacists and clinicians and its purpose was to safeguard the ocular health of those individuals who chose to wear contact lenses in preference to spectacles. The MCA considered that if the UK were to allow general sale of contact lens care products, it would depart from the understood practice in other member states. Within the category 'pharmacist and optician' was a large number and variety of outlets, particularly as many large supermarkets now contained a pharmacy.

5.38. Price was a matter which was outside the remit of the MCA under the terms of the Medicines Act 1968. However, the MCA observed that the lower prices seen when certain pharmacy chains introduced own-label brands demonstrated that prices could be reduced by means other than widening the route of sale.

Consumers' Association

5.39. The Consumers' Association (CA) gave written evidence and attended a hearing. It had carried out research into CLS in response to a number of complaints received from its members and other consumers about the high cost of solutions. Its report, entitled *Contact Lenses—the right solutions?* was published in the September 1991 issue of *Which?* magazine and revealed that solutions could cost users as much as £89 to £200 a year.

5.40. The research uncovered a number of issues relating to the market in solutions that caused CA concern and indicated a need for further investigation. CA's current view, however, was that there were at least three aspects of the market which might appear to restrict competition and help keep prices high. They were: insufficient information on which brands of solutions consumers could safely use; a lack of price transparency; and restrictions on the types of outlets that could sell solutions.

5.41. It was common practice, CA said, for consumers to be recommended a particular brand of care products by their optician when their contact lenses were first provided. Combined with a lack of information about the potential for switching brands, this could lead people to believe that it would be detrimental either to their eyes or to their lenses to use any alternative care products.

5.42. CA said that its research showed that as long as lens wearers took certain precautions and obtained their opticians' advice before they made the change, then switching from one brand of lens care product to another within the same type of system should not normally be a problem. CA suggested that one possible way of reducing consumer confusion would be for opticians to give consumers a full list of brands of lens care products they could use, with advice on precautions to take if they decided to switch brands.

5.43. CA also said that lack of information on which brands could be substituted for other brands might restrict competition in the market. During its investigation, the deeper it went into the research the more opposition it faced to the idea of consumers' switching brands at all, from opticians and manufacturers. It had been very difficult to get any information from the survey which would have allowed CA, and thereby consumers, to make meaningful comparisons between products. Opticians in particular did not seem to know which products were capable of being switched.

5.44. There were other problems that faced the consumer. One was the difficulty in calculating the cheapest care system. Solutions were sold in a variety of quantities and no information was given on the pack as to the number of 'daily doses' in the container. Therefore the consumer was at a disadvantage when calculating value for money. It would clearly help consumers to compare products if manufacturers were to be able to agree on a standard means of labelling their products, to allow direct comparison. For example, a standard daily dose and/or an annual estimated cost could be given

alongside the initial price quotation when lenses were prescribed, so that consumers could make better informed purchasing decisions from the outset.

5.45. At present contact lens cleaning products had to be licensed under the Medicines Act. Their sale was confined to pharmacies and opticians. CA said that it was time for a re-examination of this classification, because, once consumers had been recommended particular solutions, they should be able to buy them through other retail outlets. There was no reason why solutions should not be widely available and sold through drug-stores or in supermarkets. If consumers sought professional advice when they first had their contact lenses fitted, and if packs were clearly labelled, they would have maximum choice both of product and of the outlets where they could purchase solutions. CA said that during its research it felt that manufacturers had not seemed to welcome the idea of offering the consumer more choice, more transparency and more outlets. The results of its price survey had indicated that prices were similar across the 11 major chains it used to conduct the survey. The fact that prices differed very little might have been coincidence, but it might also have been a symptom of a resale price maintenance system.

5.46. CA also said that very little advertising was aimed at the final consumer of lens care products. It was clear that the promotional material by manufacturers was aimed at the optician or pharmacist and not at the consumer. This had an effect on inter-brand competition. The solutions market was very unusual, CA said, since it was the consumer who made the purchasing decisions and yet someone else had the marketing information about the products. Though the initial decision or recommendation was made by the optician in prescribing the lenses, from that point on it was the consumer who went to the pharmacist or optician requesting one product or another and yet that consumer had no information from the manufacturers to equip him or her to compare and contrast those products and the claims that were made for them.

5.47. CA said that this was a difficult market on which to get information about the comparability of products, both in terms of price and suitability for consumers. Some solutions were available from opticians only. Because of this apparently restrictive practice there was less competition in the marketplace. CA firmly believed that more information for consumers, greater price transparency and the lifting of restrictions on sales outlets would lead to increased competition and cheaper solutions.

Mr Buckley and Dr Stapleton, Moorfields Eye Hospital

5.48. Mr Buckley, a Consultant Ophthalmologist and Director of the Contact Lens and Prosthesis Department at Moorfields Eye Hospital (Moorfields) and a member of the CDSM, gave written evidence and attended a hearing together with Dr Stapleton, a Senior Optometrist at the hospital. The department handled approximately 18,000 patient visits and issued about 11,000 contact lenses and prostheses a year, 48 per cent of which were manufactured in-house. The patients seen were either in need of lenses for medical reasons, or (a much smaller group) had diseases related to the wearing of lenses. These patients would either have been referred to Moorfields by their doctors or other ophthalmologists, or were cases referred by other clinicians at Moorfields.

5.49. Mr Buckley's main clinical interests included contact lens medicine. He had taken part in research into all aspects of lenses from the materials and designs to the clinical effects of lens wear on ocular tissues. Corneal infection was the most severe complication that could arise in cosmetic contact lens wear, but it was relatively rare. Data obtained on risk factors in lens-related infections had shown the highest risk to occur with overnight use of soft lenses. Lens hygiene was only weakly associated with infection amongst daily-wear lens users, although lens storage cases were often found to be contaminated with the same organisms which had caused patients' infections.

5.50. Dr Stapleton told us that she had for some time been pursuing research into contact lens-related disease, particularly infection. She said that a recent study had looked at the risks associated with disposable lens wear. Patients had been asked about the advice they had received when being fitted with lenses and how long the instruction had taken. There had been some evidence that patients were not sufficiently aware of the reasons why they were carrying out care procedures. Dr Stapleton thought that even amongst lens wearers who followed the care procedures, compliance tended to decrease after about 18 months of wear and reinstruction then became necessary. Consumers were

inclined to skimp on care when they did not encounter problems. She emphasized that these were only the interim findings of an ongoing study. Some of the research work was funded by manufacturers, and projects could last from six months to two years. The final results would be published in appropriate ophthalmological and optometric journals.

5.51. Commenting on developments in contact lenses and lens care over the last ten or so years, Dr Stapleton said that an important development had been the move to new types of disinfecting systems which did not contain preservatives, particularly the peroxide systems. Such systems seemed to be very effective with soft lenses, probably more so than some of the other solutions which were available. Mr Buckley added that there had been a steady improvement in the quality of gas-permeable materials over this period; they had overtaken soft materials in their ability to transmit gases both to and from the cornea. The problem remained, however, that broadly speaking, although rigid lenses were safe, they were less comfortable to wear. Soft lenses, by contrast, were comfortable but less safe. That was a problem that had not been adequately addressed.

5.52. Both Mr Buckley and Dr Stapleton supported the stringency of the current UK product licensing system for solutions. Any relaxation of the criteria would be regrettable and would be likely to manifest itself in patterns of disease amongst wearers. The new one-step systems, which might well improve patient compliance, would be very difficult to perfect, since the inherently conflicting needs of adequate cleaning on the one hand and adequate disinfection on the other would be difficult to satisfy in one product. In particular, it would be hard to find an adequate substitute for the digital friction involved in cleaning the lenses with a traditional cleaner.

5.53. Mr Buckley and Dr Stapleton both believed that the retail sale of solutions should be limited to pharmacies and opticians, where professional staff were available to give advice when necessary. Extending their sale to supermarkets would bring the prices down but might increase the risk of damage to the eye. They expressed their concern that the existing high UK standards would not be maintained if solutions were brought under EC devices legislation. All solutions which entered the eye in or on contact lenses should be regarded as pharmaceutical agents.

Mr Meakin

5.54. Mr Meakin, who teaches at the University of Bath School of Pharmacy and Pharmacology, gave written evidence and attended a hearing. He said that he was also an administrative and scientific principal at the University's Centre for Drug Formulation Studies (CDFS), a consultancy research service for pharmaceutical and allied industries. He had worked for some time in the field of contact lenses and solutions. He was a member of the CDSM and had been involved in drawing up the regulations for licensing the supply of solutions. The CDFS also obtained contracts from the Government and industry and had carried out research for manufacturers of solutions. Its work was sometimes used in submissions to the MCA for product licences. With other colleagues Mr Meakin had developed the product OptimEyes, marketed by Bausch & Lomb.

5.55. Mr Meakin expressed concern about the EC Directive which would bring lens care products out of pharmaceutical control into medical devices control. He was in full agreement with the current UK product licensing regulations which, he said, embodied the highest standards in Europe in terms of the requirements for efficacy and safety. He thought, however, that the system might deter small companies from entering the market or introducing their own new products because of the costs involved in developing products which were able to meet the UK licensing standards. In the USA, the standards for solutions were different and, in particular, currently lower for microbiological efficacy. Referring to the 'one-step' solutions now being marketed in other countries, Mr Meakin said that they represented a compromise, so that neither the cleaning nor the disinfecting function was as efficacious as would be the case in single-function solutions. But the advantage of these systems was that wearers did find them simpler to use and for that reason they encouraged compliance.

5.56. Mr Meakin said that there should continue to be professional advice available at the point of sale of all CLS products and that opticians should give better advice to consumers who were obtaining contact lenses for the first time. Such advice needed to be reinforced on a regular basis in order to improve compliance with lens care regimes amongst consumers.

Professor Efron

5.57. Professor Efron is a professor of clinical optometry at the University of Manchester Institute of Science and Technology. He told us that he was also Director of the European Centre for Contact Lens Research, and that in this capacity he liaised closely with industry and the ophthalmic professions. He said that suppliers of solutions had complex technical issues to deal with because solutions had to be powerful enough to disinfect effectively and yet sufficiently weak to be non-toxic when entering the eye. Incompatibilities between lens materials and solutions could have serious consequences for the wearer. The formulation of solutions had to be modified as new materials and modes of wear were introduced, and this meant that manufacturers were constantly carrying out expensive R&D to ensure that their products were efficacious and safe. Professor Efron thought that it was not unreasonable that these costs should be reflected in the prices paid by consumers.

Optical Information Council

5.58. The Optical Information Council (OIC) is a public relations organization which advises on eye-care services and products. It told us that a large part of its work involved answering consumers' enquiries, a significant number of which related to contact lens wear and hygiene. The OIC said that it was clear that many contact lens wearers did not understand what was involved in caring for their lenses. For example, lens wearers would ask why certain solutions were necessary and even in what order they should be used. The OIC said that some lens wearers did not take the trouble to understand their care system and the importance of correct lens care, and it felt that the sale of solutions in outlets where professional advice was not available would not be in the interests of lens wearers as a whole. Unless properly advised, some wearers would misuse solutions and jeopardize their prospects of successful long-term wear.

Socialist Health Association

5.59. The Socialist Health Association told us that it was a voluntary organization which worked for a comprehensive health service, both preventive and curative, free at the time of use, and funded from general taxation. Membership was open to all health workers and anyone supporting the Association's aims, and currently comprised 1,500 individual and affiliated members. The Association thought that solutions should only be sold by pharmacists, optometrists and opticians, who could give professional advice. It did not think that this restriction was detrimental to competition.

Consumers

5.60. We received comments from 76 consumers in various regions of Great Britain but predominantly the South of England, the majority of whom complained about the high price of solutions. Other points raised included the short 'shelf-life' of products once opened, the size and type of packaging, the number of different solutions necessary to care for lenses, the limited number of outlets where solutions were sold and the lack of information given to consumers by manufacturers.

5.61. Eight of the 72 consumers who commented on high prices compared them with the lower prices in other countries, particularly the USA. Several consumers commented that the solutions, particularly saline, were relatively cheap to produce. Sixteen consumers complained about frequent price increases and some of these alleged that a cartel was operating. Several consumers said that the high prices forced them to ignore manufacturers' instructions and clean lenses infrequently, use out-of-date solutions or use tap water instead of saline.

5.62. Thirteen consumers complained about pack sizes and the short recommended periods of use. Several of these said that smaller quantities should be sold because the contents of the pack sizes available lasted longer than the period stated.

5.63. Five consumers questioned the need to follow the complex contact lens care programme. One of these said that people regarded opticians as 'theirs' and opticians traded on this loyalty by selling

the solutions at 'exorbitant' prices. Coupled with the loyalty factor was the fear factor. She knew of no readily available source of advice on the four-stage maintenance programme and said that whilst this programme gave manufacturers and retailers high profits there was no incentive for them to explore the possibility of producing a multi-purpose solution at a realistic price. Another consumer drew our attention to Renu, the Bausch & Lomb all-purpose disinfecting, storage, cleaning and rinsing solution, available in the USA but not the UK. He suggested that the high degree of competition in the USA had forced the introduction of such a product, whilst in the UK there appeared to be a cosy and overpriced market. He saw the decision not to introduce Renu here as a ploy to maximize profits and minimize competition.

5.64. Ten consumers complained that the products were not available in ordinary retail outlets. One of these said that the prices would remain high until they were.

5.65. Eight consumers complained about manufacturers' incomplete or misleading instructions. Some said that information about compatibility with other manufacturers' products should be given on containers. Three consumers criticized the lack of information available from assistants in opticians' or pharmacy outlets.

5.66. Four of the consumers who complained about the high price of solutions had to wear contact lenses for medical rather than cosmetic reasons and thought that in these circumstances the solutions should be available on prescription.

Superdrug

5.67. Superdrug, a member of the Kingfisher Group, gave written evidence and attended a hearing. It told us that it was the second largest personal healthcare retailer in the UK.

5.68. Superdrug complained that it was unable to obtain supplies of solutions, ostensibly because these products were licensed for retail sale on a 'pharmacy and optician only' basis. Superdrug said that it did not operate in-store pharmacies or opticians. It believed that the restriction on the distribution of these products was not an automatic result of the legal regime itself but was due to the manufacturers' manipulation of that regime. The manufacturers of solutions currently refused to supply Superdrug, because they claimed that the product licence for their solutions permitted them to supply only pharmacies and opticians. Superdrug said that the restriction of solutions to these outlets was not statutorily required by the regulatory regime governing the marketing of medicinal products, because sections 51 and 52 of the Medicines Act 1968 regulating the retail supply of medicinal products did not apply to lens fluids.

5.69. Superdrug said that it had asked the manufacturers whether they had actually applied for a broader retail licence for solutions and it appeared that they had not. The reaction of DoH to such an application had accordingly not been tested.

5.70. Superdrug was convinced that solutions could safely be sold by any retailer which was able to ensure correct storage conditions for the products. The presence of a pharmacist or optician did not assist the consumer any more than did clear labelling of the product. Superdrug agreed, however, that the MCA should have a role in regulating the retail sale of solutions, or imposing any appropriate conditions at the point of sale that would make it safe for solutions to have an extended distribution.

5.71. Products such as analgesics and certain feminine healthcare products which, Superdrug said, relied upon the consumers' good sense and adherence to instructions in order to avoid risks of damage to health, were already sold in its stores. Therefore Superdrug rejected the concern that the inherent danger posed by the active ingredients in properly labelled solutions made the solutions unsuitable for general retail sale. It firmly believed that the public also regarded solutions as a 'shelf' item not necessarily requiring professional supervision. This was because any advice the optician offered on the choice of CLS would already have been given to the consumer at the time he or she first took delivery of the lenses. Superdrug said that the sale of these products was unrestricted in other countries such as the USA. It stated that solutions were the most frequently requested product range that Superdrug did not stock.

5.72. Superdrug told us that this 'safety driven' restriction on the retail marketing of solutions reduced price competition. Nearly all retailers including Boots sold solutions at the RRP. There was therefore little or no effective price competition. It suspected that resale price maintenance existed in varying degrees throughout the retail sector for solutions. At the very least, it claimed, there was little incentive for the authorized outlets to engage in price competition given a relatively fixed level of demand and high margins. Superdrug believed that widening the distribution would result in fairer competition and lower prices.

5.73. Comparison between prices of different solutions was quite difficult, Superdrug said, because the dosages were not clearly indicated on the packs. It accepted that certain products should not be used with other products but thought that effective safety measures started and finished with product labelling and appropriate point of sale information.

5.74. If it were allowed to sell its own-label product, Superdrug said that it would probably offer it at a discount, eg 10 per cent off current recommended prices. It felt that Boots would not allow 600 Superdrug stores to sell at 10 per cent below the prices in its own outlets and was confident that Boots would match Superdrug's prices.

5.75. Superdrug said that advertising by the manufacturer was directed more at the retailer than the consumer; the relationship between manufacturers and retailers was very strong. The way in which solutions were currently promoted and sold at retail level tended to encourage users to adhere to one brand rather than looking for cheaper substitutes. This was done by warnings on most packs that one regime should be used and that users should be very careful about changing from one brand to another. Superdrug felt that the current system made people feel very uneasy about swapping brands.

5.76. Quite apart from the pricing aspect, Superdrug thought that solutions would gradually lose their mystique as very complicated products if they were available in its stores. Lens wear was considerable in the South-East and quite small in the rest of the country. If solutions were to be sold in Superdrug stores, a completely new market would be opened up and this would favour the manufacturers.

A supermarket

5.77. A large supermarket chain told us that it currently sold solutions through its pharmacy departments, which were part of its supermarkets and hence open for extended hours, ie until 8.00 pm on most days. The supermarket said that its customers appreciated the availability of these products during the evenings when traditional outlets selling solutions were closed.

5.78. The supermarket told us that margins on solutions were lower than on other healthcare products. It said that it would, however, like to see the current restriction on the distribution of solutions lifted. If they were sold in supermarkets, competition would increase and this would exert a downward pressure both on cost and retail prices. A widening of sales outlets would also lead to a growth in the solutions market because of increased availability and ease of access for the consumer.

6 Views of manufacturers and importers

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Allergan

Introduction

6.1. Allergan (by which term we mean Allergan Limited or the Allergan group as a whole, according to the context) said that it had made every effort to comply with the MMC's requests for information in an open and constructive manner. In meeting these requests, Allergan had naturally to consider carefully what public policy concerns might lie behind the current inquiry. In the process, it had identified the following questions:

— Were the restrictions on the products that were available for sale in the UK, and on where the consumer could purchase those products, necessary?

— Were the reference products too expensive?

— Did the dependence of the consumer (or 'patient') on optician recommendations mean that there was no effective consumer choice between products?

— Did the relatively high combined UK market share of Allergan and CIBA Vision imply any reduction in the effectiveness of competition?

— Were excessively high rates of return being earned on the reference business?

6.2. Allergan believed that a close examination of the highly competitive nature of the market more than adequately met any public policy concerns which might lie behind the above questions.

Restrictions on product availability

6.3. Allergan strongly supported strict regulation of the reference products, believing it to be firmly in the public interest (and also in the interests of the suppliers) that the consumer should continue to place a high degree of confidence in their safety. The regulatory hurdles were clear, approvals were efficiently handled by the regulatory authorities, and they applied in a non-discriminatory manner to all suppliers. If any relaxation of regulatory controls were to lead to unsafe products being launched in the UK, or to increase the risk of misuse of the reference products, this would have serious health and safety consequences for contact lens wearers.

Product prices

6.4. Allergan said that the ongoing cost of solutions to the contact lens wearer formed a substantial component of the total costs of his or her decision to wear lenses rather than spectacles. As the costs of lens manufacture had fallen in recent years, the component of total costs accounted for by care products had risen. Indeed, lens costs had fallen so far that the possibility of disposable lenses posed a real threat to the long-term existence of the reference business.

6.5. The following considerations should inform any assessment of reference product prices:

— prices for the reference products had fallen substantially in real terms over recent years;

— once any contact lens care product lost its innovative edge over the competition and became commonplace, price became the paramount competitive factor, with a consequent squeezing of margins and returns;

— at the same time, a constant stream of new products and processes had been introduced, on which successful suppliers were able to earn returns which reflected the benefits which they had brought to the lens wearer, and which compensated them for the risks they had taken and investments they had made; and

— where, as was typical, more than one generation of reference products competed side by side, the tendency was for the older (generally cheaper) products to decline in popularity as lens wearers and opticians opted in favour of the newer (generally more expensive) products in recognition of the benefits they brought.

6.6. Substantial R&D expenditures lay behind the reference products. In 1992 Allergan expected to reinvest some [*] per cent of its revenues from contact lens care activities into R&D on the next generation of products.

6.7. Finally, any considered analysis of price levels should have regard to the costs incurred by producers in meeting standards in manufacturing and packaging which formed part of the regulatory requirements.

The customer's dependence on the optician's advice

6.8. Allergan said that, having obtained their lenses from an optician, lens wearers also required advice as to how they should care for them. It had been Allergan's view that the optician's recommendation as to which reference products should be used was followed by the wearer throughout the life of the lenses, but Allergan noted that the MMC's survey of contact lens wearers had found a substantial degree of switching during that period.

6.9. Any idea that optician recommendations reduced the effectiveness of competition between suppliers of the reference products would, however, be wholly misconceived. Suppliers had to sell their products primarily to opticians who were well informed of the alternatives available from competing suppliers, and who (through their recommendations to lens wearers) had the power to influence developments in the reference market. There was every indication that this bargaining power was used

*Figure omitted. See note on page iv.

to highly competitive effect, and that there was full and effective competition between suppliers in seeking to convince opticians, pharmacists and consumers of the benefits of their products.

6.10. At the retail level, there was also evidence of strong competition between optical outlets (many of which were now organized into retail chains), and a marked trend towards repeat sales of reference products being made via pharmacy outlets rather than opticians. The optician's recommendation of a particular lens care system did nothing to guarantee that future requirements of those products would be purchased from that practice.

The competitive relationship between the market leaders

6.11. Allergan said that about three-quarters of the reference market was served by two suppliers, itself and CIBA Vision. Both companies owed this strong position largely to their respective peroxide disinfection systems for soft lenses.

6.12. Any suggestion that these two market leaders enjoyed a comfortable co-existence was, however, immediately dispelled by an analysis of recent market developments. For its part, Allergan had aggressively marketed its peroxide system with the express intention of winning share from CIBA Vision, with the result that CIBA Vision's share of this segment of the market had declined from 87 per cent in 1986 to 47 per cent in 1991, whilst Allergan's share had risen from zero to 38 per cent, and was still growing. In other product areas CIBA Vision had won share from Allergan.

6.13. The market leaders also faced strong competition from the other UK CLS suppliers, and there were currently over 20 suppliers of ophthalmic pharmaceutical products to the UK market, many of which would have no difficulty in entering the market, using their existing expertise and resources as a basis to develop and manufacture a range of reference products.

Rates of return on the reference business

6.14. Allergan told us that it had enjoyed a strong profit performance in its reference market operations over recent years. Consolidated accounts prepared for the current inquiry showed that Allergan had earned a ROCE in the region of 40 per cent over the last five years if both tangible and intangible assets were included, and 65 per cent if only tangible assets were taken into consideration.

6.15. Allergan said that the MMC would wish to place these figures in the context of the returns earned by other suppliers in order to form a view on the general level of returns on the reference business. From Allergan's viewpoint, the returns achieved reflected the nature of the business, with high risks and a high orientation to research and new product development. The returns achieved by Allergan, and its position as a market leader, were also the result of actions—with respect to the successful introduction of innovative products, efficiency in manufacturing and distribution, and aggressive marketing and promotional efforts—in which Allergan had outperformed its main rivals.

Market risks

6.16. Allergan said that suppliers of solutions operated in a fast-changing market environment, and faced a number of market risks, including dependence on lens trends, technology risks, retailer pressure and regulatory risks.

Dependence on lens trends

6.17. Allergan said that solutions suppliers were completely at the mercy of trends in lens use, since demand for solutions only arose as a result of the consumer's decision to wear lenses rather than spectacles. Even after a consumer had decided to wear lenses, the choice of lens type and the replacement regime agreed between the wearer and the optician had a vital bearing on that consumer's demand for solutions. Since different lenses required different solutions systems, trends in lens use

affected the solutions market. For example, the shift from hard to soft lenses had led to the soft lens solutions systems gaining market share against those designed for hard lens care. More recently, the use of peroxide solutions systems had been threatened by the successful introduction of soft lenses with high water content, since some opticians were concerned about compatibility problems in this area.

6.18. Trends in lens replacement regimes increasingly affected the nature of demand for solutions, and this was now possibly the most significant threat facing solutions suppliers. Within the last ten years, the idea of regular replacement of lenses had become established as lens prices had fallen and opticians had become convinced of the improvements to patients' vision and ocular health that had resulted from regular replacement.

6.19. Allergan believed that around 45 per cent of all soft lens prescriptions were made as part of a planned replacement regime (for example, every six months) or disposable regime (defined as replacement within one month), and that 74 per cent of opticians offered a planned replacement scheme. The use of disposable lenses was believed currently to account for some 44 per cent of the value of the total lens market, compared with some 30 per cent in 1990. An estimated 15 per cent of new lens fits were disposable lenses.

6.20. In cases where extended wear regimes were used, the risk facing solutions suppliers was absolute; there was simply no need for care products. The same would hold true of the daily disposable lens which was being test-marketed in the USA.

6.21. Allergan said that the most popular mode for disposable lenses was currently the one-month replacement regime. Even at this level, disposable lenses represented a substantial competitive threat to Allergan's solutions sales. First, and most directly, a one-month cycle removed the need in many cases for the use of protein removal tablets, and the recommended use of surfactant cleaners was often reduced in a disposable lens regime. Secondly, there was a tendency for opticians to recommend the use of chlorine disinfecting systems rather than peroxide systems with disposable lenses. More generally, there was a greater threat to compliance in the case of disposable lenses. Consumers inevitably perceived that there was more scope to 'cut corners' in the care of their disposable lenses than with lenses on which they would be reliant for six months or more.

Technology risk

6.22. Allergan said that there was constant pressure for solutions suppliers to develop new products, both in response to changing trends in lens usage and to meet the demands of the optical profession (for better efficacy) and consumers (for greater convenience). The protection afforded to suppliers which were successful in this quest for new products was minimal, and the ease with which advances, once made, were matched and even superseded as a result of competitive reaction served to underline the transitory nature of competitive advantage in the solutions market. Patent protection was not a major barrier to new product development.

The influence of retailer pressure

6.23. Allergan said that the growing influence of optical chains and their use of own-label solutions acted in many ways as a catalyst to hasten change in the market and to magnify some of the risks facing solutions suppliers. There were two effects at work here.

6.24. The first derived from the sheer size of the own-label business of the major chains such as Boots and D&A. For the top five or six optical chains a decision to take an own-label product, which was accompanied within the chain by an instruction to opticians to recommend that product range to their patients, virtually guaranteed a certain sales volume for the solutions supplier that held the contract to supply own-label products, at the expense of other suppliers.

6.25. In different ways, CIBA Vision, B&L and specialist producers such as Sauflon and CCL (previously known as Minipak Aerosols Ltd) had all used the attractive volumes offered by own-label

supply contracts to enhance their positions in the market. Allergan said that it was increasingly looking to follow their example in this respect.

6.26. The second effect followed directly from this. The presence of retailer own-label products in so many of the key optical chains added to the pressure on proprietary suppliers such as Allergan to stay ahead of the field in terms of product development, since only by offering a product demonstrably superior to the own-label systems could a branded solutions supplier reasonably expect to continue to make sales through these key optical outlets. This phenomenon had been demonstrated in the case of sales of Allergan's Oxysept peroxide system through Boots. After CIBA Vision had commenced supplies of its peroxide system under a Boots own-label contract, it had become impossible for Allergan to achieve recommendations from Boots' opticians.

Regulatory risk

6.27. Allergan said that the requirement for regulatory approval introduced a further element of risk for new products, since the producer had to be in a position to predict at the outset of research on a new product whether it would obtain approval. For many solutions, the time taken to develop and test a new product could be five years or more. The eventual market for that product might also be affected by the outcome of parallel efforts by other suppliers to introduce directly competing new products into the market.

6.28. These comments applied with particular force because of the current debate on harmonization of regulatory standards within Europe. There was real uncertainty at present as to the standards for production and product approval that would determine whether the next generation of solutions would obtain access to the European market, and this in itself created additional uncertainty with respect to new product development.

Scale monopoly issues

The scale monopoly situation

6.29. Allergan told us that it accepted that a scale monopoly situation existed in its favour. Since, however, the only member of the Allergan group to supply solutions in the UK was Allergan Limited, it was the company's belief that the 'scale monopoly' existed in favour of Allergan Limited alone and not also in favour of overseas members of the group.

6.30. Allergan pointed out that neither API nor Allergan Inc supplied CLS in the UK or carried on business there at all. Allergan submitted that the person in whose favour a scale monopoly situation existed would normally be the supplier itself, and that other persons would be involved only in exceptional circumstances, such as where a quarter or more of the reference goods were supplied by an agent on behalf of a principal.

6.31. Allergan further argued that it was not open to the MMC to find that a scale monopoly existed in favour of overseas companies whenever they supplied goods to an interconnected body corporate which had a scale monopoly. Nor, it was suggested, would a finding that overseas companies were persons in whose favour a monopoly situation existed seem to serve any useful purpose, bearing in mind the limitation placed by section 90(3) of the Fair Trading Act on the order-making powers provided for in section 56. Neither API nor Allergan Inc was a person such as was described in section 90(3), and no act or omission of either of them within the UK had been called in issue in the present inquiry.

6.32. Moreover, Allergan observed that it was possible that in the MMC's eventual report, recommendations might be made by the MMC in relation to conduct outside the UK; while, by reason of section 90(3) of the Act, these could not be directly implemented by Order, they might form the basis for indirect pressure being put on an overseas company.

6.33. Allergan said it accepted that some previous MMC reports had found a monopoly situation in favour of shareholders in, and suppliers to, the monopoly supplier itself. Allergan did not regard

this consideration as convincing since none of those cases had been challenged by way of judicial review and hence tested in the courts, and it could discern no consistency in the MMC's treatment of the point. Some of the cases could, in any event, be distinguished from the present one on their facts.

6.34. Finally, Allergan argued that many companies could be said to benefit from a given scale monopoly situation. There was no satisfactory way to distinguish between them, for example by reference to the scale of their shareholding in, or their volume of trade with, the monopoly supplier.

Competition

6.35. Allergan said that in assessing the competitiveness of the reference market, the following had to be taken into account:

(a) The reference market was a dynamic market; suppliers' relative success or failure was dependent on continuing innovation; such innovation might come not only from existing suppliers of solutions but also from other companies operating in the ophthalmic pharmaceutical field. Opticians who influenced consumers' purchases were well-informed and this contributed to the competitiveness of the market.

(b) A number of Allergan's competitors in the UK reference market were parts of large multinational groups that had technically strong, well-endowed and successful solutions businesses. Some of those groups were substantially larger than Allergan. At the same time, UK experience confirmed that small companies could compete successfully in the reference market.

(c) No supplier in the reference market was dominant. None could disregard market forces. Suppliers' shares of the market as a whole and of segments of the market had been volatile and were precarious.

(d) Suppliers could command a price premium for new and innovative products but only for so long as those products had a competitive edge. As a result of competition, Allergan had made significant reductions in the average price of its reference products in real terms.

(e) Allergan's success had been attributable to performance-related competitive conduct. It had not restricted competition by others, nor could it do so.

6.36. Allergan said that out of its total market share of about 39 per cent, some 16 percentage points were attributable to its Oxysept 1 and 2 products. If Allergan did not have those products, then even if it sold all the remaining reference products in the quantities that it did, it would not even have a 'scale monopoly'. Yet Allergan had entered the oxidative disinfecting segment only five years before the present reference was made and, by competing successfully with CIBA Vision, had, according to its own estimates, contributed to the erosion of that company's share of the segment from 87 per cent in 1986 to 47 per cent in 1991.

6.37. Allergan said that, in January 1993, continuing the performance-related competitive strategy that it had consistently pursued, it had launched in the UK its Oxysept One-Step system which was intended to keep Oxysept as the disinfecting/storage system that was most frequently adopted by new users. Again, the company's spearheading of the use of economy packs had contributed to the 12 per cent reduction in the average price of Allergan reference products in real terms that had been made since 1988/89. Partly as a result of increases in turnover but also through use of innovative methods and rigorous price control, Allergan had also reduced promotional expenditure as a percentage of turnover.

6.38. Many factors contributed to the competitiveness of the market. One significant such factor was the influence of opticians who were well-informed and competitive *inter se*. Additionally, consumers were price-sensitive as was evidenced by the fact that 50 per cent of consumers sampled had changed their solutions. On the supply side of the market, patents were relatively insignificant as a barrier.

6.39. Allergan said that the extent to which suppliers were affected by those aspects of the reference market that generated and enhanced its competitiveness was well evidenced by the remarkable fluctuations in suppliers' shares of the market as a whole and of particular segments.

6.40. Allergan said that it was very important to note that many suppliers had fared quite differently in different segments. Allergan's overall success was almost entirely attributable to its gain of share in the oxidative disinfection segment; elsewhere, apart from the very small wetting solutions segment, it had lost share.

6.41. In the circumstances, Allergan believed that it had demonstrated beyond reasonable doubt that its own market share had not adversely affected the level of competition in relation to the supply of reference products generally or in any segment of the reference market.

Profitability

6.42. Allergan said it strongly believed that there was full and effective competition in the solutions market. Accordingly, it did not accept that the existence of a scale monopoly situation in its favour had resulted in any lack of effective competition with a resultant boost to its profitability.

6.43. Referring to the financial information which it had provided to the MMC, Allergan said that it had adjusted the amounts reported in its statutory accounts by capitalizing operating leases. Its main reasons for doing so were that:

(a) the UK Accounting Standards Board believed that the capitalization of operating leases was right in principle;

(b) the failure to capitalize operating leases produced financial results that were not in accordance with economic reality: this was particularly so in respect of ROCE which was the measure that was most relevant for the MMC's purposes;

(c) operating leases were much more significant in the case of Allergan than other similar companies; and

(d) Allergan's financial information was more comparable with that of other companies if operating leases were capitalized.

Allergan therefore believed that the financial information which it had submitted to the MMC, which included the capitalization of operating leases, gave a fairer presentation of the capital employed in, and the profitability of, its reference business, and was therefore more useful and relevant for the MMC's purposes, than would have been the case if operating leases had not been capitalized.

6.44. Allergan had presented the MMC with a summary of the returns on average tangible capital employed and on average total capital employed (covering both tangible and intangible assets) achieved by Allergan and API combined in respect of the supply of solutions in the UK for the years 1988 to 1992.

6.45. Allergan said that, at first sight, the overall return it had achieved on the reference business, which averaged 66 per cent over the period from 1988 to 1992, appeared to be significantly higher than the returns being achieved by other companies, particularly when the Bank of England survey *Profitability of Large Companies* was used for comparative purposes. The average ROCE of chemical and pharmaceutical manufacturers over the same period was 24.5 per cent. However, in Allergan's view there were a number of technical factors which meant that those returns were not, in fact, comparable.

6.46. Allergan said that in the first place, whilst the category 'chemicals and pharmaceuticals' in the Bank of England survey included the pharmaceutical companies with which Allergan's reference business was most comparable, it also included low value-added bulk chemicals businesses with which Allergan's reference business had little in common. Up to and including the 1989 Bank of England

issue, the categories used in the survey had included 'chemicals' and 'health and household products'. From 1990 the categories had been 'chemicals and pharmaceuticals' and 'household goods'. As the 1990 survey had included comparative data for prior years on the new basis, it was possible to make a comparison between these two bases.

6.47. The result was that the household goods companies were making much lower returns than the pharmaceutical companies. The average ROCE for the latter companies for 1988 must therefore have been in excess of the average of 32.6 per cent achieved by the category overall, probably by a significant amount. Given the relatively small increase (of about one percentage point) over the average ROCE for chemical companies of 24.4 per cent that resulted from the addition of the pharmaceutical companies, it was also clear that the new category was dominated by chemical companies. The 'chemicals and pharmaceuticals' category in the more recent Bank of England surveys was therefore not a good indicator of the performance of pharmaceutical companies.

6.48. Secondly, Allergan said that the Bank of England survey covered not only listed companies, for which the maximization of profitability was the primary objective, but also private companies, some of which might have different objectives or might adopt more conservative accounting practices that understated their true profitability; and UK subsidiaries of foreign groups, whose published returns might not be reflective of the overall returns being achieved by the groups concerned. Whilst Allergan was itself foreign-owned, it had made available to the MMC, for the purposes of the inquiry, information showing the overall ROCEs achieved by the Allergan group on the reference business. It was not possible to quantify exactly what effect the inclusion of unlisted and foreign-owned companies had had on the ROCE data shown in the Bank of England survey, although it appeared that the effect might be very significant in relation to pharmaceutical companies.

6.49. In the third place, Allergan said that the Bank of England's annual surveys of company profitability up to 1989, which were based on information provided by Datastream, had presented two measures of profitability—ROCE and return on trading assets (ROTA). The ROTA was the ROCE adjusted to exclude the effects of the non-trading assets held by many UK companies, such as surplus cash and bank balances, liquid investments and minority investments in other companies. Allergan's reference business did not have any such non-trading assets. Consequently, it would have been more meaningful to compare the reference business returns with the ROTA for other companies. However, the last two Bank of England surveys, which were based on information provided by Extel Financial, did not present ROTA data. It was clear from previous years' surveys, however, that ROTA for UK industry were always higher than ROCE. For example, the ROTA for the 'health and household products' category in 1987 and 1988 were 11.1 and 12.3 percentage points, respectively, higher than the ROCE.

6.50. Fourthly, Allergan said that the Bank of England surveys were based on the annual accounts published by the companies in the sample. The latest survey was based on the accounts of 1,400 of the largest UK companies. Most of these companies used the modified historical cost accounting convention. Under that convention, land and buildings, and occasionally other tangible fixed assets and investments, were revalued periodically from their original historical cost to their current value. (A small but increasing number of companies were also including intangible assets, such as brands, in their balance sheets at current valuations.) Because of the impact of inflation, the revaluations almost always had the effect of increasing the book value of the fixed assets and hence the capital employed. At the same time, they also increased the annual depreciation charged to the profit and loss account and hence decreased the profitability. Both of these effects decreased the ROCE. Consequently, the ROCEs shown in the Bank of England survey were lower than they would have been if all the companies had used pure historical cost accounting that did not reflect any asset revaluations. It was not possible to quantify what effect this would have had on the figures shown in the survey. As Allergan's fixed assets were all included in its accounts at original historical cost, however, it was clear, Allergan said, that its performance should be compared with adjusted, higher ROCE for other companies.

6.51. Finally, Allergan said that its ROCE had been calculated on the basis of average capital employed, as requested by the MMC. The ROCE in the Bank of England survey had been calculated on the basis of closing capital employed. For most companies, capital employed increased during the year, and closing capital employed was therefore higher than average capital employed. The use of closing capital employed in calculating ROCE therefore resulted in lower ROCE than the use of average capital employed.

6.52. Allergan said it was clear from the above that, if the Bank of England survey had had pharmaceutical manufacturers as a separate category and if it had calculated ROCE in the same way as the MMC had asked companies to do, then the returns shown would have been significantly higher, probably in the 50 to 60 per cent range, than the average of 24.5 per cent reported for the chemicals and pharmaceuticals category for the three years 1988 to 1990.

6.53. Allergan also submitted that for companies like itself with significant intangible assets, derived from R&D and advertising, promotion and marketing costs, the omission of those assets from their balance sheets resulted in the rates of return shown by their accounts being substantially overstated in relation to the economic returns actually being achieved. The accounting rates of return shown by such companies were therefore not comparable with the rates of return achieved by companies whose assets were mainly tangible. Allergan's results should therefore be compared with those of pharmaceutical companies, not with manufacturing companies in general or with chemical companies.

6.54. Allergan said that, in considering the overall returns achieved by the reference business, the following matters were especially relevant. First, Allergan had benefited in recent years from the fact that it had been a very successful competitor in the solutions market, the single most important determinant of success in which was the introduction of innovative products; Allergan had enjoyed a virtuous circle in which its sales had grown rapidly whilst its costs, particularly its manufacturing and promotion costs, had been tightly controlled. Secondly, the solutions market was, however, a high-risk one in which both the size of the total market and the shares of the companies competing in it were under considerable threat. Thirdly, the reference business was only one part of the Allergan group's total activities. That must be borne in mind in any comparison of the reference returns with either figures for companies as a whole (ie including the less successful as well as the more successful parts of their businesses) or figures for groups of companies (ie including unsuccessful as well as successful companies).

6.55. In support of its view that its profitability as a supplier of solutions in the UK was highly sensitive to possible developments in the market-place, Allergan had submitted to the MMC a sensitivity analysis paper which illustrated the consequences for the results of Allergan's reference business of four different factors, each of which had been selected as representing a realistic and immediate risk for its business. The four events illustrated were: a devaluation of sterling; a fall in Allergan's market share; a contraction in the overall value of the CLS market; and being forced by competitive pressures to continue to reduce real selling prices at the same rate as had occurred in recent years, whilst being unable to continue to reduce costs throughout the production and distribution chain as it had in recent years. Allergan said that its paper had demonstrated that each of those events could individually have a significant effect on the ROCE in its reference business and that various combinations of the effects acting together could result in Allergan clearly failing to achieve an adequate return on the tangible and intangible capital employed in the reference business.

Suggested remedies on profitability

6.56. Responding to the MMC's suggested remedy that, if Allergan were found to have been making excessive profits on the reference business, its profits might be regulated along the lines of the Pharmaceutical Price Regulations Scheme (PPRS), Allergan said that this would be wholly inappropriate in a fully competitive market. The PPRS was a necessary discipline in a captive market in which the state paid. By contrast, contact lens wearers could, and did, move in and out of wearing contact lenses, they switched between different after-care products and they paid for those products.

6.57. Allergan also rejected the suggestion that its prices should be regulated by way of restrictions on price increases, analogous to an RPI-X regime. Allergan said that there would be substantial practical problems in attempting to apply to solutions a method of price control normally used in industries where there was a standard unit, for example gas or electricity. To apply RPI-X to a substantially changing basket of products was very difficult.

6.58. More generally, Allergan said that the imposition of price controls would gravely distort competition and would do so in unforeseeable as well as predictable ways.

6.59. Allergan also commented on the MMC's suggested remedy that it should publish information showing the profitability of the Allergan group as a whole—ie taking account of R&D and manufacturing costs incurred outside the UK—on its solutions business in the UK. Allergan said that the issues arising from the suggested remedy were best considered under three headings, namely, subjectivity of information; usefulness of information; and extent of work involved.

6.60. On the subjectivity of the information, Allergan said that, while it did not believe that the allocations it had made in presenting financial information to the MMC were unreasonable, many of the allocations made were necessarily arbitrary and could have been done on alternative bases. There would be significant practical problems involved in specifying exactly how the companies which were to be subject to this remedy should calculate the information to be published, so as to ensure comparability both as between all companies in respect of particular years and from year to year in respect of individual companies.

6.61. Secondly, Allergan did not believe that the publication of financial information would be particularly useful to existing competitors or potential entrants. It was clear from Allergan's statutory accounts, which were publicly available, that it was making very good returns in the UK, where its principal business was solutions. What mattered to other companies, however, was what returns they could achieve from selling comparable products. This they could readily establish.

6.62. Thirdly, Allergan said that it ran a very efficient operation in the UK. It did not have the spare capacity in its finance function to produce the financial information requested by the MMC for the present inquiry and had had to hire consultants for the purpose. Allergan acknowledged that, once an agreed methodology had been adopted, less time would be required to do the calculation in future. Nevertheless, it considered that the amount of work which the companies in the industry would have to undertake and the bureaucracy required to administer the suggested remedy from the Government side would be out of all proportion to the size of the market in the UK.

Prices

6.63. Allergan maintained that any suggestion that it was market share that enabled a supplier to earn price premia was to put the cart before the horse. It was the supply of innovative products offering improved value for money that enabled suppliers to earn such premia and to gain market share.

6.64. Thus, when Allergan launched its Oxysept disinfection system in the UK in 1987, it had done so at a premium relative to the price of the established chemical disinfection products, albeit that its price was pitched slightly below that for CIBA Vision's peroxide-based system. On that basis, Allergan had continued to expand its UK reference sales and its share of the oxidative disinfection segment.

6.65. CIBA Vision was now supplying its peroxide-based disinfection system to Boots and D&A for own-label sale; and those retailers were selling their own-label products at a price below Allergan's RRP for the Oxysept system. As explained above, Allergan had just launched its Oxysept One-Step system in the UK. Its price for that system had been determined by reference to market conditions and not Allergan's pre-existing share either of the reference market or of the oxidative disinfection segment.

6.66. Allergan said that salines provided a good area for consideration in this context. There was little, if anything, to differentiate the various suppliers' products. Allergan's 'scale monopoly' in relation to the segment (where its share still exceeded 30 per cent) was irrelevant to the price that it could charge. Even if Allergan were to increase its share of the salines segment, that would not lead to any increase in the price that its product would command in the market-place.

6.67. Allergan said that, so far as it could tell, all suppliers appeared to be pursuing entirely independent pricing strategies, with no pattern of established relationships between prices to be discerned and with nothing in the nature of price leadership operating.

6.68. Allergan also drew attention to the reduction of 12 per cent in the average level of its prices of reference products in real terms over the five years 1987/88 to 1991/92 and to the fact that the prices of its reference products in the UK were not high by international standards. Out of 49 retail prices (exclusive of taxes) for Allergan products outside the UK that fell within the terms of the MMC's question about international price comparisons, only seven were lower than in the UK and four of the seven were US prices which were not entirely comparable since in the USA opticians were not remunerated in part out of the gross margin on sales of solutions as they were in Europe. Of the remaining 42 prices, nine were up to 20 per cent, and 33 were more than 20 per cent, higher than in the UK (all comparisons being made at the exchange rates ruling on 9 October 1992).

Allergan's margins in the specialist cleaner segment

6.69. Allergan said that its share of the protein removal segment of the UK reference market was, according to the MMC's figures, 70 per cent in 1991. Allergan estimated that its share had been 88 per cent in 1986. This implied a one-fifth reduction in Allergan's share in the period under review.

6.70. Allergan said that it had two products in the segment, namely Hydrocare Fizzy and Ultrazyme; the latter had been launched in the UK in May 1990. Allergan had been the first company to produce and market a protein removal product (Hydrocare Protein Removal Tablets) and thus to solve what had been a substantial problem for the contact lens user. Hydrocare Fizzy represented a further significant innovation by improving the solubility of the active ingredient. Ultrazyme was another 'first', in that it enabled the user to remove protein from his or her lenses at the same time as disinfecting them with the Oxysept system. In 1991, only a year after its launch, Ultrazyme had contributed about 21 of Allergan's 70 points share of the segment.

6.71. The other suppliers of protein removal products in the UK were B&L and Abatron, on the one hand, and Alcon, Sauflon and S&NP, on the other hand, the latter three supplying products not only under their own brand names but also as own-label products. B&L, which used to buy its protein removal products from Allergan, had in 1991 commenced marketing in the UK protein removal products of its own manufacture.

6.72. Allergan said there was no doubt that, but for the introduction of Ultrazyme and the 9 to 10 per cent reduction in the price in real terms of Hydrocare Fizzy, Allergan's share of the protein removal segment would have declined over the five-year period even more than it had done in the face of the vigorous competition from other suppliers, including two new entrants to the segment and the introduction of own-label products. The development of the market in this way clearly demonstrated that Allergan did not possess economic power such as to enable it to prevent effective competition in the protein removal segment of the reference market.

6.73. Allergan said that, in assessing the public interest in this connection, it should also be borne in mind that the entire protein removal segment had a value in 1991 of under £4 million and that the segment was the one most at risk from disposable and frequent replacement lens regimes, so that the products in the segment were especially liable to become commercially obsolescent as a result of changes in contact lens technology and wear regimes.

Discounts to optical wholesalers

6.74. In Allergan's view, optical wholesalers no more required a margin in excess of 15 per cent to handle reference products than did pharmaceutical wholesalers, who had never received a margin above that level, either for reference products or for the other products that they handled. Efficient optical wholesalers were today operating perfectly satisfactorily on the 15 per cent margin allowed to them by Allergan. Indeed, Allergan believed that optical wholesalers frequently passed on to their customers, in one way or another, part of their nominal margin, corroborating Allergan's view that its nominal margin of 15 per cent was fully sufficient.

6.75. Allergan said that if sales to Boots and to D&A were excluded, optical wholesalers handled 30 per cent of Allergan's total sales of reference products to opticians in 1991. Given the split in

Allergan's trade between optical multiples and other optical outlets specializing in contact lenses on the one hand, and optical outlets that handled relatively small quantities of reference products on the other hand, the proportion of the trade accounted for by wholesalers was what Allergan would in any event have expected.

6.76. Thus, the enjoyment by optical wholesalers of a 25 per cent margin was a historical anomaly and created a situation of unfairness between optical wholesalers and pharmaceutical wholesalers. As sales of reference products by pharmacies expanded, that unfairness would also have grown and competition would have been increasingly distorted if Allergan had maintained a differential in the trade margins that it allowed to optical and pharmaceutical wholesalers.

6.77. It was in those circumstances that in 1987 Allergan had reduced the discount from trade price that it allowed to optical wholesalers from 25 per cent to the 15 per cent that it already granted to pharmaceutical wholesalers. It had made the change having previously invited the other suppliers to a meeting to inform them of its intention and to explain its reasons, and following receipt by the company of legal advice. It had stated openly that it was relying on that legal advice and that had no doubt contributed to other suppliers of reference products examining their own position, with the result that CIBA Vision and S&NP shortly afterwards had also harmonized their wholesaler discounts at the pharmaceutical level.

6.78. Of the remainder, Abatron, B&L and Sauflon sold and continued to sell their reference products only through optical outlets and there was, therefore, no question for them of harmonizing their discounts to optical and pharmaceutical wholesalers: in the event, they had left their discounts to wholesalers, ie optical wholesalers, at their pre-existing level of 25 per cent. Alcon and PBH, although selling reference products through both optical and pharmaceutical outlets, decided to maintain the pre-existing differential in the discounts that they allowed to wholesalers in the one category and the other.

Discounts to retailers

6.79. So far as the discounts allowed by Allergan to Boots, D&A and other direct optical customers were concerned, Allergan said that it was not in a position to dictate trade terms to suit itself but had to take the market as it found it and offer what, in the exercise of its individual commercial judgment, it believed to be competitive terms. In so far as this led it to offer certain retailers discounts off trade price, those discounts came straight off Allergan's bottom line and the MMC could therefore be sure that the discounts reflected competitive pressures to which Allergan was subject.

6.80. The discounts available to a number of direct optical retailers other than Boots and D&A were attributable to a combination of, on the one hand, the services that the retailers in question provided in recommending and dispensing reference products and the value of those services to Allergan, and on the other hand the scale of the turnover in Allergan reference products in relation to which those services were provided.

6.81. Wholesalers of reference products, whether they were optical or pharmaceutical wholesalers, provided essentially a run-of-the-mill wholesaling service. It would, in Allergan's view, be quite extraordinary to prohibit a supplier from recognizing the value to it of the services provided by customers in circumstances such as those described, especially given the innovative and competitive nature of the market.

6.82. Allergan said that the position was rather different in respect of the discounts allowed by Allergan to Boots and D&A. It was true that Boots, in particular, placed very large orders for Allergan reference products for delivery to one or other of its two distribution warehouses. However, the primary reason for the size of the discounts allowed by Allergan to Boots and D&A was simply the magnitude of their overall purchases from Allergan. Neither of those retailers provided on any scale, in relation to Allergan reference products, services of the kind just described as being provided by other optical retailers.

6.83. This was not a situation that Allergan particularly liked. But it was not at all clear to Allergan what could sensibly be done by way of mandatory government measures to alter the pattern of trading thrown up by free market forces. It went without saying that Governmental regulation that was confined to the discounts allowed by the two suppliers which happened currently to offer the most competitive range of reference products and, therefore, for the time being enjoyed market shares in the UK in excess of 25 per cent would, in Allergan's belief, combine the practical disadvantages referred to above with a gross distortion of competition as between different suppliers of reference products. Any system of regulation would, therefore, have to operate across the board (especially as, in particular segments of the market, B&L, Alcon and S&NP enjoyed shares of the order of, or in excess of, 25 per cent), even though the more extensive the regulation, the more difficult it would be to administer it effectively and the greater the risk of conduct that was inconsistent with at least the spirit that lay behind the regulation, with another consequential distortion of competition.

Retrospective discounts

6.84. Allergan said that its use of retrospective discounts was of a commercially normal nature and on a scale which was much smaller than was common in many markets.

6.85. Allergan allowed retrospective rebates to two wholesalers, Mid-Optic and Martin, and one multiple optical retailer, Ronald Brown Group plc. In 1991 the sum of money or money's worth involved had been £41,283 or 0.24 per cent of Allergan's total turnover in reference products.

6.86. Allergan said that it was not aware, on the basis of any of the material furnished to it by the MMC in connection with the present inquiry or otherwise, of anything to suggest that the retrospective discounts had the effect of preventing, restricting or distorting competition, let alone of foreclosing any part of the market to competitors, a number of whom offered substantially larger discounts to optical wholesalers than did Allergan even after taking into account the retrospective discounts. Nor did the use of such discounts constitute recourse to methods other than those that conditioned normal competition. Allergan was, therefore, unable to see on what basis the discounts could be regarded as objectionable and, in particular, why they should be singled out for criticism as anti-competitive rather than pro-competitive.

6.87. In response to our suggested remedy that discounts should reflect the costs of supply of CLS, and that monitoring by the Office of Fair Trading (OFT) would be required to check that they did so, Allergan said that there would be immense practical difficulties in implementing any such requirement.

6.88. The practical problems fell into two categories. The first related to the degree of refinement of the calculation of costs deemed appropriate: thus each order would attract different 'costs of supply' according to the location of the point(s) at which the customer took delivery, the size (and, because of the different weight:value ratios of different products, the composition) of the order delivered to any one point and the use or otherwise by the customer of Electronic Data Interchange facilities.

6.89. The practical problems in the second category were likely to be even more troublesome: those problems would arise from the different costing systems likely to be in place in different CLS suppliers' organizations. In the absence of enforced standardization of costing systems, different suppliers might find themselves constrained, as a result of using different costing systems rather than differences in economic reality, to charge different net prices to different customers, with a consequential distortion of the pattern of trade.

Starter packs

6.90. Allergan told us that starter packs of reference products were provided free of charge (or, in the USA, at a nominal charge which could be waived) in every country in which Allergan operated. They were a form of promotional activity which was of direct and obvious benefit to consumers in that it relieved them of the need to purchase reference products, and in some cases lens cases and bags, which they would otherwise need to buy for use, during the trial period of wearing new lenses.

6.91. All suppliers of reference products were free to present patients with, and in fact did provide, starter packs; and retailers who marketed own-label reference products also did so. The ability to provide starter packs and the effects of so doing were, therefore, independent of the provider's position in the market. The offer of free or heavily discounted samples was a common commercial practice. Examples included a free packet of household detergent with a new washing machine; introductory offers by book clubs and record clubs; 'piggy-back' promotions; and a mass of other promotional offers of a wide range of consumer goods that were the subject of repeat purchases.

6.92. Responding to the MMC's proposed remedy that the issue of free starter packs should be prohibited, Allergan said that no useful purpose would be served in seeking to prohibit the practice of providing free starter packs generally, let alone on a discriminatory basis as between suppliers and retailers with own-label products or as between particular suppliers.

Resale of solutions by Allergan's customers

6.93. Allergan said that it was opposed to any of its optical retailers to whom it gave a 25 per cent discount in consideration of the functions performed and the services provided by that retailer, reselling the products to non-qualifying customers, whether those customers were optical wholesalers, pharmaceutical wholesalers or non-qualifying retailers. If Allergan were to acquiesce in a practice whereby a qualifying optical retailer who was in receipt of a 25 per cent discount resold to, for example, Aspect, the latter would be free to offer, and could be expected to offer, a substantial discount off Allergan's trade price to retailers who simply passively met repeat purchase orders for Allergan reference products placed by consumers in respect of whom all the initial work had been done by a 'qualifying retailer'.

6.94. Allergan said that, to date, it had not in fact prevented such resales. However, Allergan believed that it should be free to say to a '25 per cent discount retailer' who was passing on part of its purchases to a wholesaler that, on those particular orders, the retailer was acting as a wholesaler and should, therefore, receive a discount of 15 and not 25 per cent. Otherwise, wholesalers in the position of Aspect would be able to compete unfairly with other wholesalers and to pass on to retailers the benefit of a differential discount that was given specifically in consideration of functions and services that the retailers in question did not perform or provide.

Marketing solutions as parts of complex care systems

6.95. We put it to Allergan that by marketing CLS as parts of complex care systems, which should not be used with solutions from other suppliers' care systems, Allergan was restricting competition and consumer choice.

6.96. Allergan submitted that there was no foundation for this charge. It pointed to the legal requirement with which in all cases Allergan had to comply, namely stating the warning 'DO NOT MIX WITH OTHER FLUIDS, EXCEPT AS DIRECTED' on the labels of its solutions.

6.97. In the case of a product such as LC-65 surfactant cleaner, while the instructions contained the required warning, the container stated 'LC-65 solution is suitable for use with *all* types of contact lenses and is compatible for use with *all* contact lens disinfection systems' (original emphasis).

6.98. Allergan said that, apart from the statutorily required warning, *none* of Allergan's reference products was marketed subject to any instruction that implied that it should not be used as part of a care regime that included use of non-Allergan products.

6.99. So far as the Oxysept system was concerned the position was as follows. The Oxysept 1 and Oxysept 2 fluids had to be mixed in the lens case and if protein removal, as well as disinfection and storage, was required, an Ultrazyme tablet would be added to the Oxysept 1 solution. The MCA took the view that one could not be sure that, whatever might be the position when Allergan printed the instructions, other manufacturers' products would be compatible with Oxysept 1, Oxysept 2 and Ultrazyme at the time when the consumer used the products. Allergan, therefore, could not lawfully

qualify the statutorily required warning 'DO NOT MIX WITH OTHER FLUIDS, EXCEPT AS DIRECTED' by a statement that indicated that the products could be mixed with any other solutions.

Complex monopoly issues

6.100. We invited Allergan to comment on the practices listed in paragraph 8.53.

Packaging and labelling

6.101. Allergan said that the diversity of pack sizes of the reference products resulted from the independence of the decision-taking process on the supply side of the reference market: in other words, it was an aspect of competition and was the very antithesis of the taking by suppliers of steps to prevent, restrict or distort competition. It was also typical of consumer products such as were marketed through pharmaceutical retail outlets; for example, there were over 30 sizes of shampoo on the market. Like solutions, these varied in strength and consumers would use different quantities per operation.

6.102. Allergan said that consumers did cope with the diversity of products that were available to them; and it was counter-intuitive to suppose that the very considerable range of different sized containers of, for example, shampoo which were marketed in this country indicated the existence of lack of competition. In the case of Allergan, it marketed its reference products in the UK in sizes in which it also sold those products elsewhere and, in particular, in other EC member states. By standardizing pack sizes across the common market, it had achieved economies at the production level. When it had launched new sizes, they had often been introduced in order to provide economy packs, the availability of which had manifestly *enhanced* competition.

6.103. Allergan said that the size of container could be seen as a general parameter of competition in the reference market. This was well illustrated by the history of the development of the salines segment. When Hydron Europe Ltd (not then yet part of Allergan) introduced the first aerosol saline products, it had done so in 90ml and 240ml cans. Allergan had followed suit with Lens Plus packed in the same sized cans. When, however, CIBA Vision introduced its aerosol salines, it did so in 110ml and 275ml cans as part of a competitive move to offer a lower price per ml. Allergan subsequently introduced its 360ml aerosol saline that offered a further reduction in price per ml. Sauflon, when it entered the segment, did so with 120ml, 300ml and 420ml cans, thus offering more product per can than Allergan.

Recommended periods of use

6.104. Allergan said that the issue raised by the MMC, namely whether some solutions were marketed in quantities which could not be exhausted during the recommended period of use if the recommended daily dose were consumed, did not reflect the factual position accurately. First, more than one member of a household might wear contact lenses; secondly, users, especially myopic users, might use more than the recommended daily dose when cleaning their lenses; and thirdly, some users cleaned their lenses more than once a day. But, leaving those considerations aside, only packs of sizes approved by the MCA could lawfully be marketed. Any health risk (and Allergan believed that there was none) would be a matter for the MCA and not for the MMC.

Recommended retail prices

6.105. Allergan said that an examination of *Chemist & Druggist* suggested that there was a supplier's RRP for over half of all the products listed. There was nothing to suggest that the recommendation or listing of retail prices by suppliers of the reference products was attributable to anything peculiar to the reference market or to its structure.

6.106. As to the effects of the practice, Allergan said that, again so far as pharmacies were concerned, there was nothing to suggest that they earned a higher gross margin on reference products than on the other products that they handled, whether or not those other products had a supplier's retail price attached to them.

6.107. So far as opticians were concerned, Allergan said that there was evidence of considerable price competition in one form or another. It was as plausible to suggest that such competition was increased as a result of the existence of supplier's RRPs, which formed a bench-mark for price cutters, as to argue that the competition was diminished as a result of opticians simply adopting suppliers' listed retail prices instead of calculating their own. Moreover, in the absence of suppliers' listed retail prices, the retail prices calculated by opticians were as likely to be on average higher as they were to be lower than today.

6.108. Allergan said that it did not regard the listing or recommendation of retail prices as having any great commercial significance for the company itself. However, it believed that any case that might be made out against listed or recommended retail prices would be speculative and unsubstantiated and that, if action against the practice was desirable in the public interest, there was no valid basis on which to confine such action to the reference products. Moreover, since under the Fair Trading Act the MMC's remit was to report on practices which the MMC were satisfied operated against the public interest and there was no, or no sufficient, evidence to support a definite conclusion to that effect in the present case, there were juridical reasons why the MMC ought not so to conclude.

Extension of types of retail outlet in which solutions may be sold

6.109. Commenting on the proposed remedy that the range of retail outlets at which solutions might lawfully be sold should be extended to drug-stores and supermarkets, Allergan said that the availability of solutions in outlets where no professionally qualified person was at hand would give rise to an increased risk of corneal injury and consequential visual impairment. At present users had occasion to visit their local optician or pharmacy regularly to renew their supplies of solutions. Such visits provided a natural opportunity for mention by the user (or notice by a professional) of any problem and, thus, to the speedier identification of problems and their removal or treatment, as the case might be. Any shift away from the present pattern of professional distribution would create an added hazard, if only through diminution in the frequency of visits by users to professionally staffed retailers.

6.110. Additionally, Allergan believed that it was undesirable for users to switch from one solution to another without at least checking with a professional that such a switch would not be liable to raise problems (and, if so, what to look out for).

6.111. Again, it was not as though the present restriction of retail outlets had led, in Allergan's view, to any insufficiency of availability of solutions to the public. Allergan knew of no dissatisfaction on the part of consumers, so far as ready availability was concerned. In fact, widening the range of retail outlets offering solutions would fragment distribution and reduce the average rate of stockturn, thereby tending to increase, rather than to reduce, average distribution costs.

6.112. Lastly, the present system of distribution facilitated the marketing by Allergan of a full range of products, whereas experience indicated that supermarkets tended to be interested in stocking only the largest selling lines. Particularly in relation to the introduction of innovative products which characterized this market, the cause for concern was apparent. The optician, in particular, was capable of appraising the technical merits and advantages of new solutions, and reacted favourably to the introduction of new products with superior qualities or price performance. This was important to an innovative supplier such as Allergan.

6.113. In response to our inquiry whether Allergan knew of any evidence that unrestricted distribution of solutions in the USA had led to problems, Allergan sent us statements from two leading members of the optometry profession in the USA. The first, Professor Barr, Chief of Optometric Services at the College of Optometry, The Ohio State University, stated that:

> In my experience, the restricted distribution practices in the UK are preferable to those followed in the US. The UK system allows for a greater opportunity to prevent and detect possible lens care problems than does the US practice. Greater access to the professional allows for prevention of confusion, early detection of poor compliance and resolution of misuse issues which can lead to injury and added expense. Detection of these problems through regular supervision by a professional also minimizes the risk for the development of long-term habits of poor compliance or product misuse. Based on the increasing number of products and the increasing sophistication of the types of products available, the US consumer would, in my opinion, clearly benefit from the type of supervision and professional guidance afforded by the UK system.

Dr Ghormley, a practising contact lens consultant and President (1991/92) of the American Academy of Optometry, expressed essentially similar conclusions.

CV-UK

6.114. CV-UK agreed that a scale monopoly situation existed in its favour and that of CVLCP and CIBA-GEIGY. It said that this monopoly position had not given rise, however, to any adverse effects on the level of competition in the UK market as a whole or in any segment of it. CV-UK gave evidence jointly with CVLCP and we use the term 'CIBA Vision' to refer to the two companies together or the CIBA Vision group as a whole, according to the context.

6.115. CIBA Vision pointed to its level of profitability, which, it said, was reasonable; to the declining trend of its prices in respect of its main products, which had resulted from competitive pressures and the power of purchasers; and to the fall in the market share of its main product, 10.10, in response to the entry of competing products.

Scale monopoly issues

6.116. CIBA Vision responded in detail to a number of issues raised by the MMC in connection with the scale monopoly situation. These are set out below.

Profitability

6.117. CIBA Vision said that its ROCE figures demonstrated an unobjectionable level of profitability. As a result of the transfer of production to Macclesfield in 1991, 1992 was the first year in which the financial information provided to the MMC reflected the activities of the reorganized business.

6.118. Thus, the ROCE figures for 1988 and 1989 reflected not only the low level of capital employed by the manufacturing operation at Southampton, but also market conditions which no longer prevailed. Notably, since that time, CIBA Vision's market share and prices (measured in real terms) for its peroxide products had declined markedly and the volume of sales of some of its other branded products (the 'traditional' Hydro and Contacta ranges) had fallen dramatically.

6.119. On a consolidated basis (ie including the UK solutions business of CVLCP, as well as CV-UK), the negative ROCE and net margin figures for 1990 and 1991 reflected the costs associated with the start-up of operations at Macclesfield. The initial difficulties had now been to a large extent overcome, and CIBA Vision believed that the 1992 figures provided a more meaningful guide to the profitability of the restructured business.

6.120. On a disaggregated basis (ie covering CV-UK only), the 1990 and 1991 ROCE figures for Southampton were high. They reflected, in addition to the low level of capital employed, the fact that, in anticipation of the transfer of production to Macclesfield, the profitability of the Southampton operation had increased in 1990 to a level which would not be sustainable over the longer term, due to exceptional conditions which would not apply in future.

6.121. CIBA Vision believed that the consolidated figures for CV-UK and CVLCP provided a more appropriate guide to the profitability of CIBA Vision's lens care business in the UK than the figures for the individual companies. Although CV-UK and CVLCP were separate legal entities, they were part of the same division of CIBA-GEIGY, and were now both controlled by the UK holding company CIBA-GEIGY PLC. Their individual ROCE figures were influenced significantly by two factors: first, the recent cessation by CV-UK of manufacturing activity, the investment by CVLCP in new manufacturing plant, and the associated costs and savings, which had resulted in sharp fluctuations in the ROCE of the individual companies; and secondly, the level at which transfer prices between the companies were fixed by CIBA Vision management in Switzerland. No internal transfer price wholly corresponded to a free-market price, as the MMC had recognized in the past. The individual ROCE figures did not, therefore, provide a basis for comparison of the profitability of CV-UK and CVLCP with each other or with the profitability of the manufacturing or marketing operations of third companies.

Price trends

6.122. CIBA Vision said that its average realized price per litre of lens care products had declined in real terms over the period 1988 to 1992, the greatest pressure having been on CIBA Vision's principal products (10.10, Solar Saline and Miraflow). This was a reflection of the strength both of the competition between suppliers, and of the pressure exerted by the major retail chains and the opticians. The power of the opticians (exercised both individually, and through buying groups) was reinforced by their ability to generate new business by recommending or not recommending a product. D&A, for example, had 'delisted' a number of products.

Market shares

6.123. The impact of competition in the supply of solutions was, CIBA Vision said, vividly illustrated by the decline of the market share of 10.10 since its introduction: originally the only peroxide system, it now accounted for less than 50 per cent of all peroxide sales. CIBA Vision's share of the solutions market as a whole had declined from 38.3 to 33.5 per cent between 1988 and 1991. Its existing market position remained vulnerable both to competition from domestic and overseas suppliers, and to the development of new contact lens and lens care products: the volatility of the market was illustrated by the MMC's own survey of opticians, which showed that, within the space of five years, the proportion of opticians recommending the use of peroxides with soft lenses had increased from 12 to 75 per cent.

6.124. Commenting on the MMC's suggestion that a system of regulation of prices or profits might be introduced, possibly on the lines of the PPRS, CIBA Vision said that such a system would be both unnecessary and unhelpful as a means of protecting the public interest. This type of system involved determining a 'fair' rate of return for the firm in question and not allowing profits over and above that level. Regulation of this sort had many disadvantages, affecting consumers, producers and regulators. The main problem was that of inefficiency.

6.125. Rate of return regulation effectively broke the link between efficiency and profitability. The firm did not benefit from efficiency gains, and might escape the consequences of inefficiency; there was little incentive to cut costs since this would not increase profits, and higher costs could simply be passed on in the form of higher prices. This might mean that firms provided goods of too high a price and quality. 'Gold-plating,' where firms over-invested in capital, might also occur, since this enlarged the base on which the return was calculated, raising the allowed level of profits. Employment might be adversely affected and the firm might move into unprofitable areas of business. There had been experience of 'gold-plating' in the USA, particularly in the case of regulated private water utilities.

6.126. In addition, the administrative burden of profit control could be enormous, both for the firm involved and the regulatory authority. Decisions had to be made about the allowability of each item in calculating the capital base. The firm would always have more information than the regulator, and would have a much better idea of the impact of regulation and the ways in which to minimize that impact. If solutions were to be regulated, the number of firms involved would greatly multiply the administrative burden involved.

6.127. CIBA Vision said that the solutions market was a competitive one with a range of comparable products, and was quite different from the market for prescription drugs. The PPRS was devised to cope with a market where firms provided unique products to a monopsonistic buyer (the NHS). Such a scheme was necessary because there was currently no other possibility for competition. The companies affected by the scheme had learned to work within its boundaries, but this had led to some degree of overcapacity.

6.128. Prices were usually regulated only in markets with a homogeneous product and dominant supplier. Water, gas, telecommunications and airports had all been regulated through some form of price control. These were all markets with some claim to natural monopoly, where it was difficult to encourage sufficient competition in the short run, so that regulation could be dispensed with. Given these criteria for regulation, it would seem wholly inappropriate to control solutions prices.

6.129. Fixing one variable for the firm (ie price) would be bound to lead to distortions of one sort or another. In contrast with the encouragement of 'gold-plating' brought about by profit regulation, price control could result in under-investment by the firm, particularly in sunk-cost assets. For an industry like solutions, where technology changed quickly and much R&D was necessary, this would be against the interest of consumers in the long term. Price control could also lead to cost cutting that was detrimental to quality. Given the distortions that regulation could bring about and the difficulties of administering price control satisfactorily, the end result might be to stifle actual and potential competition.

6.130. Finally, operating a price control system in the solutions market would be fraught with practical difficulties. Would such a system be imposed on manufacturers, suppliers, or retailers, or some combination of these? If the prices of manufacturers were capped in some way, wholesalers or retailers would not necessarily pass these prices on to consumers. Capping the prices of manufacturers or suppliers might reduce the number of customers it was economic to supply (for example, optical wholesalers, whom CIBA Vision could currently afford to supply at the discount they now received, but might not be able to continue to supply at a lower price). Capping retailers' prices would be tantamount to resale price maintenance and would prevent the price competition at retail level that the MMC had been keen to stimulate. It would, for example, negate any benefit from broadening the range of retail outlets. It was clear that such a scheme would be complex to operate in this market, and that the outcome, while difficult to predict, would not necessarily be in the public interest.

6.131. CIBA Vision believed that efficiency should be rewarded and encouraged, and that free market competition was the best way to achieve this end. The solutions market was very different from those where price and profit control systems already operated. There was a much higher degree of competition, a far wider range of products, and a greater number of suppliers.

Pricing policies

6.132. CIBA Vision said it did not consider that the scale monopoly in its favour had resulted in pricing policies which were uncompetitive. Its level of profitability, as evidenced by ROCE and net margins, was not objectionable. Furthermore, the international price comparisons provided by CIBA Vision to the MMC showed that UK prices were low by comparison with those in the other countries on which the MMC had requested data. Again, the market was highly competitive, as was demonstrated, in particular, by the decline in CIBA Vision's real prices and market shares already mentioned. The existence of vigorous competition was also demonstrated by advertising campaigns, by which the suppliers responded to consumer demand.

6.133. CIBA Vision pointed, in addition, to a particularly significant feature of the market, namely the buying power of the larger retailers. [

Details omitted. See note on page iv.

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6.134. CIBA Vision maintained that its discount policy was based on objectively justifiable criteria. Volume discounts were generally available, while certain customers operating through buying groups or independently were able to insist on higher discounts as a result of the extent to which CIBA Vision depended on their business. This reflected their importance in generating new business and in recommending products, and was reinforced by their ability to 'delist' suppliers. In some cases, the retailers received larger discounts than wholesalers, but ordered a greater volume.

Boots' concern about D&A's pricing

6.135. We established at the public interest hearing that, from time to time since the launch just over three years ago of D&A's own-label products sourced from CIBA Vision, Boots had sought to communicate, in meetings with CIBA Vision, its wish to see D&A's own-label pricing brought into line with that of Boots.

6.136. In November 1990 Boots had informed CIBA Vision's National Account Manager that, unless D&A aligned its prices with Boots' own-label prices, Boots would price-match D&A as of January 1991 and expect CIBA Vision to pay the difference of any margin erosion. CIBA Vision had presented this scenario to D&A, which had realigned its pricing strategy from 5 per cent below Boots to 2.5 per cent below Boots.

6.137. During 1991 the subject was broached once again with CIBA Vision's Account Manager in a meeting about pricing, but no action was taken. The issue was last raised at a strategy meeting in March 1992, by Boots' senior managers with CIBA Vision's managers. CIBA Vision had explained to Boots that it was not in a position to cause D&A to bring its pricing into line with Boots. No further action had been agreed or taken. The issue had not been raised since.

Complex care systems

6.138. CIBA Vision said that, by its marketing of contact lens care systems, it neither restricted competition among manufacturers and importers of CLS, nor restricted consumer choice. Any recommendations as to use with other products were subject to approval by the MCA and were designed solely to ensure the safety of the user and the effectiveness of the product. CIBA Vision said that it had only marketed products in a way such that they should not be used with other products where such use was not permitted by the product licence and where to do otherwise would have exposed CIBA Vision to significant additional regulatory requirements and expense.

6.139. CIBA Vision emphasized that most of its lens care products (10.10, Saline, Miraflow, Clerz, Lensept/Lensrins, Complete Care, and O_2 Care) were not sold as, or as a part of, complex care systems. They were individual products, albeit in the case of 10.10 and Lensept/Lensrins comprising separate but interdependent components. The Hydro and Contacta ranges were sold as systems consisting of several compatible agents; the labelling of these made clear, however, that the cleaning agent need not be Hydroclean or Contactaclean respectively, and that the wetting drops were optional.

6.140. CIBA Vision pointed to the risks of mixing peroxide products, which could result in insufficient neutralization of the peroxide, causing severe pain on insertion of the lens. Although the components of 10.10 could at present be mixed with the components of the Boots own-label version which was the same product, this would not necessarily remain so. Boots, D&A and Specsavers were free to review the sources of their own-label solutions, and had recently done so. CIBA Vision considered that, given this possibility, users would be exposed to an unacceptable degree of risk, and in consequence CIBA Vision itself would be exposed to an unacceptable degree of potential liability, if it were to indicate that the components of its system were compatible with the elements of particular own-label systems. It was unlikely that, except in very exceptional circumstances, customers would have any interest in purchasing one component of a peroxide system in branded form and the other as an own-label product. CIBA Vision considered that any benefits which might be derived in such circumstances would be totally disproportionate to the risk of injury to customers and consequent potential liability of CIBA Vision.

6.141. As to its Hydro and Contacta ranges, CIBA Vision said that these were complex systems, the labelling of the products reflecting the fact that the different components had been licensed for use with each other. CIBA Vision was not aware of the compatibility of its disinfecting agents, cleaning and wetting solutions with preserved products of other manufacturers. It could only establish this by means of exhaustive tests on products, the formulations of which could change at any time. If there were no recommendation as to which cleaner and wetting agent to use with a preserved system, the possibility of use with incompatible products was a real one, and this could be risky. If the labelling of a particular product recommended or permitted the use of a solution of a competing manufacturer, difficulties would arise if that manufacturer changed the formulation of its solution to one which was no longer compatible with the first product. The current regulatory system operated by the MCA was designed to ensure that these risks did not arise and that the products in a system remained compatible, safe and effective.

6.142. CIBA Vision considered that it was only in exceptional circumstances that a user might wish to combine components of preserved systems of different manufacturers, and that, as with peroxides/oxidatives, the risks and costs of labelling products to provide for this would be disproportionate to any benefits.

Reducing discounts to wholesalers

6.143. CIBA Vision pointed out that, at the time of the reduction of discounts to optical wholesalers in 1987, the UK companies now forming part of CIBA Vision were not part of the CIBA-GEIGY group, with the exception of Titmus Eurocon, which had a negligible share of the UK solutions market. It understood, however, that steps were taken at that time to eliminate the disparity between discounts offered to optical wholesalers (previously at 25 per cent) and pharmaceutical wholesalers (15 per cent).

6.144. The decisions made by the various retailers as to whether to use a wholesaler or not would determine the extent of business available to the wholesalers. CIBA Vision was equally happy to supply its products through wholesalers or directly to retailers. It had no policy of reducing (or increasing) the market share of wholesalers. Nor had its pricing been used to target particular competitors or to create a barrier to entry.

6.145. Optical wholesalers in general did most of their business with the smaller independent opticians, the larger opticians using their negotiating power to obtain higher discounts from the manufacturer. Solutions sales through the smaller opticians had experienced a decline over recent years, as the optical chains had rapidly expanded. In 1991 optical wholesalers represented only a small proportion of CIBA Vision's business.

6.146. Optical wholesalers had little direct influence over the product choice of the opticians. Manufacturers created the demand through their marketing and sales activities, and wholesalers met that demand. Consequently, optical wholesalers had less negotiating power than retailers.

6.147. Pharmaceutical wholesalers had, on the other hand, increased their share of the supply of solutions as the sales of lens care products through pharmacies had grown. Like optical wholesalers, however, they had less negotiating power than large retailers, and had a lower level of influence on sales.

Relating discounts to costs

6.148. Commenting on the implications of having to relate the discounts it gave to customers to its costs, CIBA Vision said that, without a clear indication of how a cost-based discount system would be structured in terms of comparator costs, it was not possible to indicate whether CIBA Vision would be put at a particular advantage or disadvantage by such a requirement. If such restrictions were to relate only to scale monopolists, CIBA Vision would be at a significant competitive disadvantage. Many of its competitors would be able to undercut it in specific negotiations, secure in the knowledge that CIBA Vision could not respond. This in turn would create a disincentive for those suppliers to compete aggressively on price.

6.149. CIBA Vision said that it made no significant overall cost saving from dealing with certain customers other than the benefits which securing a large order gave it in terms of greater certainty and easier planning of production and distribution. Such cost savings as it had made could at least partly be attributed to the efficiency of its current distribution network. Yet the result of having to relate discounts to savings was that CIBA Vision would be able to provide only very low levels of discount to its customers.

6.150. As the customer's buying power would remain unchanged and significant discounts could not be provided, negotiations could be expected to move into other areas such as more promotional support, credit terms and payments in return for shelf space. Such moves would make the true profitability of dealing with a customer less transparent.

6.151. Artificial restrictions on the freedom to negotiate prices would have to be policed to avoid abuse. The difficulties experienced by CIBA Vision in providing certain of the financial data requested by the MMC in the course of the current inquiry (for example, relating to the allocation of costs and identification of savings) were indicative of the likely cost and complexity of the administration and enforcement of such a regime. CIBA Vision was doubtful whether many suppliers had a policy of monitoring costs in the necessary detail; in practice it was therefore likely to be hard to ascertain whether any individual complaint about a particular company's discount policy was justified. In particular, the base cost of supply would have to be established to ensure that like was compared with like; there might otherwise be a tendency, for example, to over-differentiate between products.

6.152. A rigid discount policy was likely to stifle innovation and lead to stagnation of the market, suppliers being deprived of the ability to use discounts to reduce the risks associated with the development of new products and activities. It would also reduce the flexibility of suppliers to use discounting to facilitate disposal of stocks when necessary.

6.153. There was no guarantee, moreover, that to require discounts to be related to cost savings would change the structure of the market. Even if a cost saving related to volume were established, the restriction of discounts to savings would present a barrier to entry for new suppliers and wholesalers. Neither would be able to provide a discount until a high volume had been established and it would be difficult to establish a high volume without providing the discount.

Retrospective discounts

6.154. CIBA Vision said that its current retrospective discounts had been introduced in January 1992 in response to pressure from buyers, and represented a small additional discount on total purchases, payable quarterly in arrears, on attainment of a turnover target. Information from CIBA Vision's sales force indicated that certain of its competitors also operated such schemes.

6.155. Retrospective discounts were at present granted to seven customers, who accounted for 12 per cent of CIBA Vision's business over the period January to August 1992. The retrospective discounts represented a small proportion of the total discounts available to these customers.

6.156. In respect of each of its principal products, CIBA Vision said that it faced competition from suppliers which were at least evenly matched with it. The period over which the target was to be attained (generally three months) was sufficiently short for customers to be able to switch frequently between suppliers. Customers were free to stock only part of CIBA Vision's product range, and to take competitors' products. These factors and the low level of retrospective discounts, together with the limited success of customers in achieving targets, indicated that these discounts did not involve any tie-in or full-line forcing effect. They were merely a response to, and evidence of, competitive pressures.

Starter packs

6.157. CIBA Vision said that the provision of starter packs was very widespread in the lens care sector. They were offered by all contact lens fitters in the UK, and supplied by all UK solutions

manufacturers. They were available in many markets world-wide, and in most were provided free of charge.

6.158. Starter packs were a valuable means of promotion, since the recommendation of a regime was an important source of new business for a supplier. Their issue did not appear to result in any significant foreclosure effect: the findings of the MMC's survey of consumers indicated that 50 per cent of the sample had changed solutions, two-thirds of these having done so since 1990.

6.159. In addition, starter packs constituted an excellent aid to compliance: the optician's advice on care of the lenses was thereby reinforced over a period of several days, the starter pack also providing a visual reminder of the brand or type of solutions recommended by the optician as suitable. The importance of this was demonstrated, CIBA Vision said, by the MMC's finding that one-third of the consumer sample, when asked to name the brand of solution they used, were unable to do so without fetching the solutions. Starter kits were often provided on the occasion of a refit; this offered an additional opportunity to reinforce compliance.

6.160. CIBA Vision said that a requirement to charge for starter packs would result in difficulties in determining the basis for such charge, and in policing implementation. Retailers welcomed the ability to provide incentives to new patients: charging for starter packs would merely result in the competitive pressures being expressed by other means, for example in the contents of the kit, or by the provision of free gifts such as travel bags.

6.161. Although the cost of providing starter packs was a significant element in a supplier's marketing and advertising expenditure, such packs were a valuable means of promotion, particularly suited by reason of their educational properties to the products in question: they did not, by their effects or the amount of expenditure involved, result in any barriers to entry or other adverse effects on competition. If the full costs of starter kits were passed on to opticians, the real loser would be the patient. The response from the industry would possibly be to produce cheaper kits which only included the basic disinfecting product. As a result, compliance with cleaners and protein removal tablets would be expected to fall further, with a resulting increased risk to ocular health.

Complex monopoly issues

6.162. We invited CIBA Vision to comment on the issues listed in paragraph 8.53.

Packaging and labelling

6.163. CIBA Vision said that it did not believe the packaging and labelling of its solutions distorted competition by making it difficult for consumers to make price comparisons between different brands. Packs came in different sizes as a result in particular of the following factors: usage rates, discard dates, consumer preferences and the conditions of competition, and technical considerations.

6.164. CIBA Vision said that usage rates varied markedly, for a variety of reasons. The usage rate was determined by the instructions, the patient's needs, the optician's recommendation, how frequently the lenses were worn, and, for disinfectants, the size of the lens case.

6.165. For example, the instructions for Hydrosoak recommended two good rinses of Hydrosoak to remove the Miraflow or Hydroclean used to clean the lens. In most cases, patients would now instead use a saline solution to perform this function as it was cheaper. A patient using Hydrosoak according to the instructions would therefore need significantly more of the product than one using saline. The position was the same in the case of Contactasoak.

6.166. The usage rate of any cleaning agent was difficult to assess. Solutions were no exception, the amount required depending upon personal preference and how dirty the lens was. Again, the usage rate for wetting drops was totally dependent upon the level of wetting a patient needed to make a lens comfortable: a patient with dry eyes, wearing high water content or highly gas-permeable lenses and working in a dry, dusty or smoky environment would have a considerably greater need for comfort

and wetting drops than the average wearer. For these reasons, both cleaners and wetting drops were produced in a variety of sizes to meet the patient's requirements.

6.167. Saline solutions were subject to the greatest variation in usage rates as they might be used simply for rinsing the lens or for dissolving chlorine tablets and protein removal tablets. As a result, CIBA Vision again produced a variety of sizes to suit the individual patient's needs. In the case of preserved disinfectants, the usage rate varied from product to product as a result of the variety of lens cases available and their different volumes.

6.168. Responding to the suggestion that suppliers should be required to indicate daily doses on the labels of their solutions, CIBA Vision said that while it saw considerable difficulty in the case of some products, as a result of the variation in usage rates described above, for products where the rate of use was clearly defined there should be no difficulty.

6.169. As for discard dates, these were determined by the MCA, in the light of the stability and antimicrobial properties of the product once opened.

6.170. The size of the bottle reflected the supplier's perception of consumer preferences and the conditions of competition, taking into account affordability and convenience, and the possibility of competing not just on price but on other factors, including volume. The supplier's choice of bottle size would also be influenced by the technical possibilities open to it, in particular the availability of bottle sizes.

6.171. Referring to the issue of the ease of making price comparisons between products, CIBA Vision said that the largest element of the cost of lens care for the patient was the cost of the disinfectant. CIBA Vision's most popular product was 10.10, for which there was no difficulty in calculating the daily cost of use. The lens case for use with 10.10 required 10ml of the Step 1 solution for disinfection of the lenses; this was shown on the lens case. A 250ml bottle would therefore last 25 days. Step 2 was sold in 25-unit dose packs, lasting for the same period.

6.172. CIBA Vision believed that, in the case of other lens care products, any differences in pack sizes were not so great as to cause significant problems in comparing prices. Comparison of the prices of cleaning products supplied in 25, 30 and 35ml packs and of preserved disinfectants in 120, 175 and 240ml sizes was not difficult for the average purchaser. The variety of sizes of saline, which was a commodity product, illustrated the degree of competition between manufacturers, and resulted in increased consumer choice.

6.173. CIBA Vision considered that, if suppliers were to agree among themselves, directly or through a trade association, to supply products only in certain sizes, or if suppliers were to agree only to stock certain sizes, such an agreement would restrict competition. It would limit the ability of suppliers to compete by marketing their products in sizes which they considered best responded to the needs of customers and to the conditions of competition in the market-place. Any attempt to extend the application of the agreement to new suppliers would represent a barrier to entry.

6.174. Governmental controls on pack sizes would restrict the free movement of goods within the EC, and represent a significant barrier to entry with regard to third country suppliers. CIBA Vision believed that such measures would be disproportionate to any benefits to be achieved by standardizing pack sizes. CIBA Vision pointed to the proposed EC Medical Devices Directive, which was to apply to contact lens care products (see Appendix 2.4). It provided in Article 4 that: 'Member States shall not create any obstacles to the placing on the market or the putting into service within their territory of devices bearing the CE marking.' CIBA Vision was not aware of any national market in which standardization of the pack sizes of solutions had been required.

6.175. An obligation to change pack sizes would result in the imposition of very significant costs on suppliers, and would take considerable time to complete. For each change in fill volume, new stability data would have to be prepared in respect of three batches of the product for six months, and then submitted to the DoH for approval of the variations. These stability trials would then have to be continued for one year after the proposed shelf life. For products the packs of which were to become smaller, with a consequently larger surface area to volume ratio, a change might have adverse

effects on the stability of the formulation. The same adverse effects might occur if bottles were only partially filled.

Recommended periods of use

6.176. CIBA Vision said that only one of its products, Miraflow, might not be exhausted by the average user by the expiry date. CIBA Vision calculated that a patient removing and cleaning his or her lenses once a day would use a 35ml bottle of Miraflow in 58 days, whereas patients were recommended to discard the solution after 28 days.

6.177. Usage rates varied markedly between consumers, for a variety of reasons, and were very difficult to calculate with any degree of accuracy. However, CIBA Vision pointed out that Miraflow was available in a smaller size. Patients who found that their usage pattern prevented use of the product by the discard date could always purchase the smaller size, or a product from a different manufacturer, as there were a variety of sizes of cleaning agents available.

6.178. The larger sizes were more economical for CIBA Vision to produce, and this saving was passed on to the patient in a lower price per ml. Any patient using more than 25ml of Miraflow by the discard date would find it more economical to purchase the larger size and discard any unused solution, as instructed. Patient preference for the larger size was considerable, with 89 per cent of Miraflow sales being of the larger pack size.

Recommended retail prices

6.179. CIBA Vision said that the Resale Prices Act expressly permitted the recommendation of resale prices. It provided that the prohibition on resale price maintenance 'is not to be construed as precluding a supplier (or an association or person acting on behalf of a supplier) from notifying to dealers or otherwise publishing prices recommended as appropriate for the resale of goods supplied or to be supplied by the supplier' (section 9(2)). It was in exercise of this legal right that CIBA Vision published a list of recommended resale prices.

6.180. CIBA Vision believed that the setting of RRPs did not discourage price competition at the retail level, and that, although solutions might be sold only in certain types of retail outlets, there was a sufficient number of such outlets to ensure that competition could take place.

6.181. CIBA Vision's RRP was just that: a recommendation. There was no coercion involved, and retailers were free to sell CIBA Vision products at a different price. In fact, many opticians did offer a discount on the RRP, through their loyalty programmes.

6.182. Most pharmacies and opticians actually sold at the RRP, other than through the schemes mentioned above, but they did so through choice. Given that there were a large number of retail outlets, rather than just two or three large chains, it would be impossible for CIBA Vision to ensure that they were all charging the RRP even if it wished to do so. If retailers wanted to compete more vigorously on price, CIBA Vision's RRP would not stop them. Likewise, removing that price would not encourage them to compete in this way.

6.183. CIBA Vision said that the RRP actually served the purpose of holding down the price the consumer had to pay. Between 1988 and 1992, prices on several products (the 10.10 products, Miraflow and Solar Saline) had fallen in real terms. It was in CIBA Vision's best interest to keep prices as low as possible. Given the discounts that it was forced to concede in negotiation with many of its customers, CIBA Vision's interest lay in those customers passing as much of the discount on to consumers as possible; CIBA Vision then benefited from the extra volume sold.

6.184. The practice of setting RRP was a widespread one in many sectors. There were recent cases where the MMC had not found this practice to be against the public interest. CIBA Vision said it was convinced that the practice of suggesting RRPs to retailers did not prevent or distort competition, and was in fact beneficial to consumers.

6.185. Commenting on the MMC's suggestion that the retail outlets at which solutions could legally be sold should be widened in order to stimulate more price competition, CIBA Vision said that a reason which was often given as to why solutions should only be available through opticians and pharmacies was that consumers might need advice as to which brand was appropriate for their lenses. CIBA Vision said that, in view of the fact that lens care products were increasingly being displayed for self-selection, well away from the pharmacist's or optician's counter—and indeed the pharmacist or optician did not need to be present when these products were sold—it was increasingly hard to oppose suggestions that there would be no additional risk to the public if these products were available through supermarkets and drug-stores.

6.186. However, CIBA Vision thought that difficulties would result if no control was exerted over the conditions of supply in retail outlets. Contact lens products were like pharmaceuticals in terms of their formulation. Their storage therefore needed to be controlled to ensure patient safety. In addition, product recall procedures needed to be in place in the event of a quality problem being identified with a batch. Moreover, as CLS represented a relatively low-value market with a diverse range of products, there were disadvantages in dispersing this market to more outlets. Supermarkets and drug-stores were likely only to stock brand-leading products, with the lower-value, speciality products becoming unavailable except through specialist suppliers.

6.187. CIBA Vision considered that, if supermarkets or drug-stores were able to sell solutions, the impact on pricing would be determined by how these products fitted into the store's portfolio of goods. If lens care products were regarded as a convenience purchase, price competition would be low. If stores felt that they could gain an overall advantage through operating consumer promotions, this would provide for greater price competition.

The UK product licensing system

6.188. CIBA Vision said that the UK was widely acknowledged to have the strictest licensing system in Europe, probably in the world, although the Food and Drug Administration, which was responsible for the pre-market authorization of contact lenses in the USA, was now becoming comparable. In the UK, contact lens care products were not medicines; they were substances which had been brought under the control of the Medicines Act, and were treated as medicines for the purpose of licensing. Lens care products most closely resembled sterile ophthalmic pharmaceuticals. Relying on the sparse guidelines for ophthalmic preparations, it was the responsibility of the individual company to provide the data it considered appropriate to demonstrate the quality, safety and efficacy of the product in question.

6.189. This could result in considerable problems when companies were required to provide additional data to reassure the UK regulatory body of the product's quality, safety and efficacy, particularly when the product had already been registered or marketed in other countries for a period of time.
[*Details omitted. See note on page iv.*
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6.190. CIBA Vision told us that it welcomed the EC Directive on Medical Devices which would introduce a common system of standards for solutions in Europe. CIBA Vision took the view that, since the UK licensing system was as strict as any in the world, some relaxation of standards under the EC regime was likely, and that would allow products which did not currently qualify for a licence to do so.

Alcon

6.191. Alcon is owned by Alcon Universal Ltd and Alcon Canada Inc, subsidiaries of Nestlé SA. Alcon gave written evidence and attended a hearing. It said that it had three business divisions: contact lens care, ophthalmic pharmaceuticals and surgical eye products. It was primarily a distributor of solutions, rather than a manufacturer (although it did some packing).

Profitability

6.192. We invited Alcon to comment on the MMC's comparison of the net margin on turnover and ROCE of solutions suppliers with those of Glaxo, Wellcome and Fisons and with the figures for the UK manufacturing sector (see paragraphs 4.104 and 4.105). It said that these three companies were not comparable with solutions suppliers because of their size and the complexity of their operations; also, being manufacturers, they and the UK manufacturing sector as a whole were not appropriate comparators for Alcon's business as a distributor. Alcon also argued that ROCE was not a proper measure of its profitability because it leased the vast majority of its fixed assets and, as a distributor, had no manufacturing plant or machinery. Its capital employed was therefore disproportionately low. In commenting on the comparisons in Table 4.48, Alcon said that in 1989 its net margin on turnover had been lower than the average of the three companies combined, and of the UK chemicals and pharmaceuticals sector, and that its ROCE had been less than that of the three companies combined, and of this sector. It also said that figures for two years could not be used to establish a trend, in particular where the figures for the third year showed a great disparity.

Product licensing

6.193. Alcon said that the UK system of product licensing was different from that in most other countries. One feature was that while licences were required for lens care products there was no licensing for contact lenses themselves. Alcon was unaware of any data which showed that the safety and effectiveness of lens care products in the UK were better than in countries where either no licensing requirements applied (eg Germany) or there were very different licensing requirements (eg the USA).

6.194. In Alcon's view the highly-regulated UK environment for solutions deterred new entry and hindered the introduction of new products which were already supplied safely and successfully in other parts of the world. The requirement to obtain product licences caused Alcon's product range in the UK to be typically a couple of years behind other countries. The system resulted in anomalies: for example, contact lenses which were applied directly into the eye did not require a product licence whereas the solutions used to care for those lenses did. On the other hand, in response to the MMC's suggested remedy that solutions should be sold freely in retail outlets, Alcon pointed out that all eye drops and eye ointments were excluded from the GSL regardless of their intended purpose or their ingredients. Alcon did not disagree with the suggestion that the supply of lens care products without professional supervision was undesirable and would not benefit the consumer. It thought that concerns over the potential risks associated with these products which had the potential to produce serious adverse health effects must have led to the original regulation of lens care products.

The complex monopoly

6.195. Alcon repudiated the provisional finding of a complex monopoly. It said that in making such a finding, the MMC had to establish both that the practices they identified were engaged in by a sufficiently large proportion of suppliers of solutions; and that the practices prevented, restricted or distorted competition in the supply of solutions. In Alcon's view the first part of the test was satisfied; but the second was not. It commented as follows on our provisional findings.

Packaging and labelling

6.196. In Alcon's view the fact that individual producers developed a varied product range showed that there was inter-brand competition. The implementation of uniform pack sizes across brands would in all likelihood have to be effected by way of Order rather than undertakings since any arrangement among suppliers to standardize pack sizes would in principle be likely to contravene Article 85(1) of the EC Treaty. Alcon said that its parent company might not feel it economically worthwhile to produce special UK pack sizes. It was possible that a remedy of this kind would result in a less competitive rather than a more competitive market.

6.197. Alcon did not believe that the imposition of a requirement to supply products in smaller pack sizes would result in a cost saving to consumers as the high costs of production were largely attributable to the sterile nature and high quality of the products. Alcon thought that it was fairly easy, where the solutions themselves were comparable, for a consumer to make price comparisons between different suppliers' products. All packaging indicated the contents, for instance liquid volumes were shown in mls, and this meant that it was also relatively easy to compare products within a particular type.

6.198. Alcon observed that the UK was already fairly highly regulated in this respect. It considered its own labels to be clear and sufficiently informative to allow consumers to have a good basis for comparative shopping. The labels on some Alcon products, eg Clen-zym, already stated that they could be used with all lens care systems. More extensive labelling requirements would increase manufacturers' costs (particularly in terms of additional testing if it were necessary for labels to state which other products the CLS concerned could be used with) and would not, in Alcon's view, significantly benefit consumers.

Marketing solutions in quantities which cannot be exhausted within the recommended period

6.199. Alcon said that it did not engage in such a practice. It aimed to market solutions in quantities which would be used by the majority of users within 28 days (as indicated in the relevant licensing guidelines). In this case the majority was represented by the daily lens wearer using lenses in both eyes. Infrequent lens wearers, those wearing only one lens or those who did not follow the instructions might find solution left at the end of the 28-day period. The only products it supplied where the full amount might not be used within the recommended period were daily cleaners. Given that some people would use more cleaner than others, Alcon believed that any reduction below a 25ml size bottle for a 28-day period would encourage users to skimp on lens cleaning and use too small an amount of solution.

Recommended retail prices

6.200. Alcon said that the unilateral recommendation by a supplier of a minimum resale price was not prohibited under UK competition law (Resale Prices Act 1976) or under EC law (Article 85(1)). Although Alcon recommended a retail price it made no attempt to enforce that price. It said that, if unilateral recommendation of a resale price was not in itself anti-competitive, the fact that a number of suppliers in a market engaged in that practice could not result in an anti-competitive effect. The removal of such a guide price would be as likely to result in higher retail prices as the reverse.

Differential discounts

6.201. Whilst Alcon's trade discounts could not be precisely and individually justified on the basis of direct cost savings, Alcon told us that they were all cost-related. It would be unrealistic and unreasonable to expect a greater degree of demonstrable cost relationship from any supplier of goods of this kind. Discounts reflected the customer's value to the seller in terms not only of direct and indirect cost savings (such as order processing and transportation costs arising from the volume ordered or the ability to take central delivery) but also of the customer's status as a regular, financially-reliable buyer. That aspect of discount setting was a commercial reality and not anti-competitive. Above all, discounts were a response to market conditions, not a consequence of any lack of competition. For example, in response to a question on its discounts, Alcon told us that Boots required a discount of 50 to 57 per cent off RRP. Alcon acknowledged the advantages in dealing with Boots, including its financial reliability.

6.202. Alcon referred to the theory that the differential pricing that commonly resulted from a system of negotiated prices was not inherently anti-competitive although, where associated with a degree of market power, it could be used in an anti-competitive way—eg to impose purchasing exclusivity or as a vehicle for predatory pricing. Alcon said that it accepted this analysis and pointed out

that it did not use its discount system to promote any system or to operate full-range tie-ins or in any other respect for an anti-competitive purpose.

6.203. Alcon considered its system of discounts wholly unexceptionable on competition grounds and regarded regulatory intervention in such circumstances as contrary to the public interest in maintaining a competitive free market system.

Extension of types of retail outlet in which solutions may be sold

6.204. Alcon suggested that this was a remedy which the MCA could already implement if it was considered to be in the interests of public safety to do so—for example, by declining to grant product licences on an outlet-restricted basis. Since that was not the MCA's policy at present, it presumably considered that such an approach would not be in the public interest. The MCA's present policy, Alcon noted, was consistent with the approach of several other overseas jurisdictions (eg Germany).

B&L

6.205. B&L, an importer of solutions, related accessories and sunglasses, is a subsidiary of the US company Bausch & Lomb Inc. B&L's subsidiary, M&L, which it acquired in 1989, distributes solutions and also manufactures contact lenses. B&L gave written evidence on behalf of the two companies and attended a hearing. It told us that the B&L group supplied a wide range of healthcare and medical and optical products and was the leading supplier of solutions to the US market. B&L and M&L were managed as separate businesses.

Product licensing

6.206. B&L submitted that the current system of licensing of solutions in the UK was seriously out of step with the system followed in most other countries. It further submitted that the current licensing system in the UK inhibited competition and increased the barriers to market entry of products which had been on the market in other countries for some time. B&L said that it was aware of a number of products which were awaiting approval from the UK regulatory authorities and had been available in most other markets for up to ten years.

6.207. Whilst B&L accepted that regulatory controls of solutions for lens care were justified, the level of control in the UK was greater than elsewhere. The UK regulatory authorities treated solutions as proprietary medicinal products within the Medicines Act 1968. Consequently the UK Licensing Authorities required a full marketing authorization procedure before granting a licence application, and for new products they did not take into account experience of usage outside the UK. By contrast, other countries accepted that these products did not contain conventional pharmacologically active ingredients and that the potential health risk was low. Many regulatory authorities treated eyecare products under the regulatory system applicable to medical devices rather than medicinal products.

6.208. B&L cited its own experience with the product Renu, otherwise known as its multipurpose solution. In all markets other than the UK the product was a major source of competition to other solutions and was probably the leading product world-wide measured by opticians' recommendations to new lens wearers. In Australia, for example, where Renu had been marketed since 1985/86, a lens care system based on Renu was significantly lower in price than other systems and had made significant inroads against Allergan which had been the market leader with its peroxide system. Although Renu had also been available in the US market since 1986, it had been the subject of an application for a product licence in the UK for some three and a half years. B&L had been required to submit further data to the MCA to support its application for a product licence. This data had not been required in any other jurisdiction and was extremely expensive and scientifically difficult to collate.

6.209. B&L pointed out that the EC Directive on Medical Devices would require significant changes in the UK regulatory system. Under the Directive solutions were treated as accessories to

medical devices and not as proprietary medicinal products. Member states would be required to incorporate this Directive in their respective legal systems in the near future. B&L emphasized the importance of this Directive in changing the regulatory regime in the UK and submitted that the UK would be in breach of its obligations under EC law if it continued to insist upon the current licensing system once the Directive came into force. Additionally there was the danger of another European country adopting the Directive ahead of the UK. This would give competitors based in the EC countries an unfair advantage in the UK market by enabling them legally to import CLS into the UK whilst domestic companies would still be significantly handicapped by the regulatory system in this country. B&L expressed the hope that the DoH would implement the Directive at the earliest possible opportunity.

The complex monopoly

6.210. B&L said that in their provisional findings on the complex monopoly the MMC had not taken account of the fundamental changes in the regulation of contact lens care products just referred to. B&L commented as follows on our provisional findings.

Packaging and labelling

6.211. The solutions which B&L sold in the UK were manufactured on a world-wide basis by Bausch & Lomb Inc. In adapting its plant in Italy, where most products for the EC market were made, B&L had mirrored the operations which had already been established in the USA. It had instituted a uniform production system which included the packaging of solutions in the same sized bottles in each of the two plants. The bottle sizes, which met US market requirements, were similar in most other parts of the world. It would be both costly and inefficient for B&L to be required to change these standard bottle sizes solely for the UK market.

6.212. There were important consumer and other benefits resulting from selling a uniform bottle size world-wide. If supply problems arose B&L could obtain a product from one of its alternative plants. In certain cases, it established stocks of unlabelled bottles of solutions which could then be supplied to a variety of locations by attaching the appropriate labels. Consumers were thus guaranteed consistency of supply world-wide. This efficiency and safeguard would not be available if different bottle sizes were used for the UK market. Moreover, it would be contrary to the objectives of the EC Directive for manufacturers to be *required* to market their solutions in different sized bottles in different member states.

6.213. B&L considered that in some cases its products could technically be used with those of other manufacturers. However, to ensure that users avoided eye damage, B&L advised them to consult their optician before experimenting with different types of solution. Opticians were better placed to assess compatibility of products than consumers, who might be unaware of the type of lenses they wore or the reasons why they had been recommended a particular solution in the first place. B&L said that MCA regulations required it to state on its products that they could not be mixed with other fluids unless otherwise directed. If a list of compatible products were to be produced manufacturers would have to update it continually. Each supplier would have to inform competitors of the formulation of its solutions and notify them of changes, agreeing with competing manufacturers whether solutions were indeed compatible. In addition there might be possible patent infringement proceedings in circumstances where one party positively affirmed a claim that one product could be substituted for another in a patented system. For these reasons B&L believed that opticians and possibly also pharmacists were best qualified to provide consumers with appropriate advice on solution compatibility.

Marketing solutions in quantities which cannot be exhausted within the recommended period

6.214. B&L said that it was not necessarily the case that its 30ml bottle of daily cleaner would be fully used by the 28-day discard date, since this would depend on usage during the period. In common with all other suppliers it was required by the terms of its licence to label surfactant cleaners with a

28-day discard date from the time of opening. This practice was peculiar to the UK licensing system. Although it was possible to obtain a variation of the 28-day period, detailed evidence had to be provided to the DoH to show that in normal circumstances the solution would not become infected after such date. B&L understood that generally the MCA had shown itself reluctant to grant such a variation. B&L said that standard usage was difficult to determine. It did not market a 30ml bottle to encourage patients to ignore the 28-day discard date. This was the size of the daily cleaner that Bausch & Lomb supplied to all its other markets, without the discard date. To produce a separate and smaller bottle exclusively for the UK market would result in additional costs which would almost certainly counterbalance the savings that would be achieved by supplying less solution.

6.215. B&L did not consider that UK consumers were being unfairly treated by any supply of larger bottles than might be necessary for 28 days' use. Many variables had to be taken into account including the following:

(a) differences in the volume of solution that could be contained in the contact lens cases presently available;

(b) whether consumers used the soaking solution, for example, for rinsing purposes as opposed to overnight disinfection only;

(c) whether they cleaned their lenses more than once a day;

(d) whether they used lenses for recreational activities and therefore removed them more often than average;

(e) whether the solution was used by more than one person in a household; and

(f) the need to supply enough daily cleaner to last for 28 days plus a margin for additional wastage (eg spillage when filling lens cases).

6.216. Marketing solutions in quantities which might not be exhausted if only the recommended daily dose was used did not restrict competition among suppliers. It was a direct result of regulatory requirements which might offer a number of advantages to consumers. Although it thought that the current position was justified, B&L said that it would support any review to establish whether a standardized dosage system could be defined so that consumers might make informed choices. This might prove to be a difficult exercise and might not ultimately have any great effect on competition.

6.217. If the MMC were to identify this practice as one which operated against the public interest, retailers could provide on their display shelving the price per ml of competing solutions. B&L believed that such a system worked satisfactorily in the USA. This type of price information service had been instituted by a number of UK supermarket chains in respect of other products; B&L believed that it was open to retailers to provide similar price information for solutions. Such a system would be appropriate only in respect of homogeneous products (eg peroxides), where price per unit was an appropriate basis for comparison. In the main, however, consumers did not purchase on price but on other factors such as previous experience of a product, ease of use, efficacy and recommendation from an optician.

Recommended retail prices

6.218. B&L regarded the setting of RRPs as a service which was provided to, and valued by, its retail customers. It indicated B&L's perception of the value of the goods at retail level and provided retailers with a nominal bench-mark against which they were entirely free to set their own prices. B&L said that it had never acted to maintain its RRP and had never tried to limit or penalize discounts which were given by its retailers.

6.219. B&L said that, in the knowledge that it could not influence its customers' prices, it had not conducted any formal research into prices of its solutions at retail level. It noted that the MMC's own market research data showed that 41 per cent of opticians in the survey sold solutions at discounted

prices and that this was a considerably higher percentage than was found in a large number of other retail sales by pharmacists. B&L tried to concentrate sales of its solutions through opticians, and the MMC's statistics showed that this sector was the more willing to offer discounts from RRPs. B&L did not consider that there was any justification for excluding opticians' own discount schemes when analyzing price competition in the retail market. It said that such schemes formed a significant element of price competition in the solutions market and created additional competition between pharmaceutical and optical outlets. B&L considered that in all areas of retail sales, and in particular those through opticians, there was evidence of widespread discounting which contradicted the provisional finding that the setting of RRPs discouraged price competition.

Differential discounts

6.220. B&L said that since 1988 it had offered a graded volume-related discount on purchases of solutions. Optical wholesalers who would normally make bulk orders on a monthly basis received a 25 per cent discount from list price. B&L believed its discount structure to be consistent, transparent and non-discriminatory. It accorded with normal commercial practice and could not be said to affect competition in the solutions market adversely.

Extension of types of retail outlet in which solutions may be sold

6.221. B&L said that selling solutions in supermarkets in the UK would be inconsistent with the current UK regulations which required a licensed pharmacist to be on site. B&L said that it would not support the selling of solutions in UK supermarkets unless there were changes in regulations and safeguards for consumers, particularly relating to qualified advice being available. B&L believed that the sale of solutions in supermarkets might deprive the consumer of the choice currently available, as after an initial reduction in price due to product promotion, there would be pressures to increase prices by supermarkets keen to maintain margins on products with low throughput. There was the additional danger of further polarization in the market-place, should the supermarkets take only the top-selling brands, leaving B&L at a serious disadvantage, especially as Renu, which it considered to be highly competitive, was unlicensed in the UK.

PBH

6.222. PBH, a wholly-owned subsidiary of Pilkington, gave written evidence. PBH told us that in the UK it manufactured and distributed contact lenses and distributed solutions made for it by third parties.

Product licensing

6.223. PBH said that the MCA granted product licences for contact lens care products only if quality, safety and efficacy were adequately demonstrated. The strict rules were necessary because of the risk to contact lens wearers of using preparations which might contain potentially harmful substances. The degree of control of the products varied throughout Europe, from strict control in France to light control in Spain. Attempts were being made to standardize a form of licensing for EC member states.

The complex monopoly

6.224. PBH said that it was not clear why the MMC had made a provisional finding of a complex monopoly. Two market participants—Allergan and CIBA Vision—each had a market share of about 40 per cent. Scale monopolies existed in favour of both. PBH's share of the market was 1 per cent based on sales of its branded products and 3 per cent if sales manufactured under licence from it, but

over which it had no control, were included. It was unrealistic to call PBH a monopolist with so small a market share—the more so when together the two market leaders controlled 80 per cent of the market. The finding of a complex monopoly implicitly suggested a degree of criticism of the market behaviour of those involved. PBH suggested that the explanation for any parallel conduct was not the existence of a complex monopoly but rather the power of the market leaders: the conduct did not constitute a complex monopoly but was a consequence of the way in which the scale monopoly was operating. PBH made the following comments on our provisional findings on behalf of itself and Pilkington.

Packaging and labelling

6.225. The main element of this alleged practice was that there was no consistency between the sizes of containers. In the case of daily cleaners and salines PBH's pack sizes were also sizes supplied by Allergan and CIBA Vision. It was only in the case of disinfectant and storage solutions that PBH supplied a different size to that of the market leaders; this was a conscious decision aimed at product differentiation. PBH said that each product size required a separate approval and for a company with a small market share it was inevitable that only a limited range of sizes would be offered.

6.226. The second element of this practice—recommended period of usage—was a matter which was beyond PBH's control; it was determined by the product authorization. Finally, PBH said, there was no indication on its products as to the number of daily doses because there were practical difficulties in calculating this figure. Nevertheless it had taken note of the evidence the MMC had obtained and would be considering whether there was a marketing advantage to be gained from showing the average number of doses.

Marketing solutions in quantities which cannot be exhausted within the recommended period

6.227. PBH said that it did not carry out this practice and offered to provide evidence to refute any allegations that it did so; for a company with such a small market share to do this would risk the alienation of its already small client base. It made the following comments:

(a) PBH had no control over the discard date.

(b) The amount of solution used inevitably varied from person to person, particularly in soaking and cleaning. There was therefore considerable practical difficulty in estimating what was both an average usage and the usage which would achieve the relevant medical purpose.

(c) PBH was concerned that to understate the amount could leave it open to criticism and vulnerable to complaints under the Trade Descriptions Act.

6.228. PBH said that it would have no objection to a move which assisted customer comparison. There were, however, two practical problems. The first was that the amount of dosage might not be standard because of different product formulations. Secondly, co-operation and agreement between the parties as to what was an average dosage might give rise to a registrable agreement under the Restrictive Trade Practices Act 1976.

Recommended retail prices

6.229. PBH found it difficult to understand why there was a complaint about setting RRPs. First, RRPs were permitted under current legislation. Secondly, PBH was almost entirely reliant upon its sales to opticians. It provided RRPs in response to customer demand. Thirdly, PBH said that this was not a form of resale price maintenance since its customers sold above and below its RRPs. PBH had no interest in seeking to enforce what were intended to be no more than helpful guidelines. These prices had no effect on the final price paid by consumers and PBH did not discuss with opticians the retail prices they charged; that was their decision. The practice was, in any event, one which was widespread throughout a whole range of industries.

Differential discounts

6.230. PBH denied that it applied different levels of discounts to different types of trade channel; its discount structure was based solely on the quantity purchased.

Sauflon

6.231. Sauflon is an independent UK-registered company, formed in 1985, whose principal activity is the manufacture and distribution of contact lens care products. Sauflon gave written evidence and attended a hearing.

Product licensing

6.232. Sauflon said that as contact lens care products were applied to the eye, safety, quality and effectiveness were essential. If licensing achieved this in the UK then it was justified. Within Europe, only France and Italy classified solutions as medicines. In the Netherlands they were controlled under cosmetics regulations. Other European countries tended to operate on an assurance system, ie products imported had to be manufactured in accordance with recognized standards. Sauflon noted that the prices of solutions at producer and distributor level in the less regulated markets like the Netherlands and Germany were no lower than in the UK.

The complex monopoly

6.233. Sauflon did not accept that it operated in a manner conforming with the existence of a complex monopoly. It said that the solutions market was highly competitive, and most of the practices the MMC had named as distorting competition to Sauflon's advantage were common in all competitive markets. The only unusual distortion to this market was the treatment of solutions as medicines. The companies themselves had not sought this legal status for their products. While being prepared to face the competition in the market Sauflon took the public health implications of the sale of solutions seriously, and believed that categorizing these products as medicines was essential. It understood that the changes in rules associated with EC harmonization would largely bring all other member states into line with UK standards. Sauflon commented as follows on our provisional findings.

Packaging and labelling

6.234. The existing pack sizes were historical and largely based on the types which companies had been marketing when they first registered with the MCA in 1983. Bottled solutions, in particular, were required to be used within one month of opening for licences to be granted. Wherever possible, Sauflon had moved to larger pack sizes to offer consumers a better deal. As well as new pack designs and alterations to machinery, these changes involved preparing and submitting product licence variations. Limited resources imposed some constraints on the speed with which Sauflon could implement changes. As regarded the quality of the instructions on daily dosages, Sauflon believed that in the case of daily cleaners it was ahead of other manufacturers. Some products, such as aerosol saline, might be used in a range of different sized storage cases and to place 'volume fill' instructions on the product label might result in consumers not properly soaking their lenses.

Marketing solutions in quantities which cannot be exhausted within the recommended period

6.235. Sauflon said that if consumers followed the recommended dosage on its solutions they would use all the solution within the recommended period. Sauflon's daily cleaners had instructions on the labels which advised applying a few drops in the palm of the hand on each contact lens daily (the label

stated that this was about 1ml per lens). Without very expensive metering it would be impossible to be certain of the amount a particular patient would use. The 60ml size bottle should provide an adequate amount of solution for one month's use for any patient but the 20ml Soft Lens daily cleaner was also available for the patient with a more economical usage.

Recommended retail prices

6.236. The setting of RRPs was common practice in companies supplying the general retail sector and Sauflon did not believe that it restricted competition. Opticians were free to set their retail prices in accordance with their own cost structures and what they thought the market would bear. Sauflon's recommended prices were merely a guide. Its publicity literature to opticians detailed the comparative monthly costs to consumers of the care systems of its competitors, and it used RRPs as the basis for this exercise. If Sauflon did not use RRPs it would have to use some other prices. In a market without manufacturers' direct marketing of their products and prices to the consumer Sauflon believed that manufacturers could not be accused of retail price setting.

Differential discounts

6.237. Sauflon's standard price structure was based on volume purchases which reflected savings in shipping costs. It did not charge its UK customers packing and freight costs. Special terms were negotiated with high-volume retailers reflecting order processing and freight savings and the competitive nature of the market. It was also common practice in the drug-store and, Sauflon believed, the food retail market for larger retailers to enjoy better terms of supply than small traders. This reflected bargaining strength relative to other buyers and competition on the part of the suppliers.

Extension of types of retail outlet in which solutions may be sold

6.238. Sauflon considered that the present medicinal status of solutions was correct and that they should not be sold in drug-stores or supermarkets. It criticized the way in which some pharmacies sold solutions at present and said that it was quite common for patients to be switched to different brands if they bought from a pharmacy rather than an optician. This was dangerous because:

(a) the chemist was not aware of the patient's history, ie the patient might react to certain solutions;

(b) the chemist was not aware of the exact type of lenses worn, and therefore could not be sure of compatibility;

(c) the shop assistant might be inexperienced and without the necessary knowledge to advise a patient; and

(d) patients might be given wholly inappropriate solutions by a chemist, which could be highly dangerous.

Sauflon said that these problems already occurred and extension of sale to less qualified outlets would make matters very much worse. When it came to brand switching, the ophthalmologist was the only person who should advise a patient. It noted that no Western European state had followed the USA in permitting the sale of solutions through supermarkets.

6.239. Sauflon did not think that there would be any change in CLS prices if they were more widely available. There was already little profit in the production of solutions, offering insufficient encouragement to new entrants. Multiple chains of opticians commanded considerable purchasing power and in the current distribution channels new major outlets would be unable to obtain lower prices. Should such a process be attempted, companies such as Sauflon would be unable to operate, and competition in the industry would be reduced until it was entirely in the hands of foreign-owned multinational companies with enough financial power from income in other markets to survive a period of severe

price cutting. Once competition had been eliminated the remaining producers (probably all overseas-based) would either use their power to drive prices up again or alternatively treat the UK as a small unprofitable market with insufficient rewards to justify product innovation. This would be detrimental to contact lens wearers.

Complex care systems

6.240. Sauflon also commented on the issue of complex care systems. It said that manufacturers marketed complex care systems in the UK not for the purpose of restricting competition, but because each product in the system was required for it to be effective and to ensure minimum discomfort to the patient. The MMC's consumer survey did not show complexity to be a significant issue. Sauflon emphasized that there was a continued drive by manufacturers and suppliers to simplify systems. The microbiological considerations of the *British Pharmacopoeia* had so far prevented the introduction of one-step systems in the UK. The introduction of the 'Phar Eur' rules in place of the *British Pharmacopoeia*, expected during 1993 as part of European harmonization measures, would probably mean that these solutions would be available on the UK market.

S&NP

6.241. S&NP, a subsidiary of Smith & Nephew plc, is primarily engaged in the manufacture and marketing of ethical pharmaceuticals. It gave written evidence and attended a hearing. S&NP told us that it had started manufacturing solutions in 1965. In 1992 solutions represented less than 9 per cent of its total turnover.

Product licensing

6.242. S&NP said that there was at present no unified licensing system in Europe, and data required on products in other countries, such as the USA, differed from those required in the UK. In the Netherlands and Belgium there was no licensing of solutions whereas in France, Italy and Germany licences were needed. It thought that within Europe, at least, the regulatory control of contact lens care products should be uniform. This matter was at present under consideration by the EC Commission.

The complex monopoly

6.243. S&NP accepted that technically a complex monopoly might exist in the UK in relation to the supply of solutions. However, it believed that the scale monopolies which existed in favour of Allergan and CIBA Vision gave these companies the ability to act independently of their smaller competitors. Opticians usually recommended Allergan and CIBA Vision products and, because of the nature of the products, consumers were reluctant to ignore their opticians' advice. [

Details omitted. See note on page iv.

] It believed that, in order to encourage more competition, appropriate remedies needed to be directed at opticians and other CLS retailers, as well as at Allergan and CIBA Vision. S&NP emphasized that it had not colluded with its competitors or participated in any practices which were against the public interest. It gave the following comments on our provisional findings.

Packaging and labelling

6.244. S&NP's packaging had not varied significantly over the last ten years. It could therefore not be said deliberately to market products in sizes different from those of its competitors. S&NP's small market share would make it unprofitable to produce solutions in the wider range of container sizes supplied by larger manufacturers. It believed that the larger manufacturers probably could economically change their pack sizes if they wished.

6.245. S&NP said that elements of its cold chemical system could be used with other manufacturers' systems to perform discrete functions such as cleaning, disinfecting or protein removal. Although in theory it would be possible to mix different manufacturers' products, in sensitive lens wearers this might cause irritation or injury. Given the possibility of product liability claims in such circumstances, it was likely that manufacturers would be reluctant to advise lens wearers that they could mix products. Moreover, products would have to be tested to establish which were compatible. It would be unlikely that major manufacturers would wish to pay for these tests when the main beneficiaries would be their smaller competitors. Small companies like S&NP which might benefit would probably be unable to justify the cost.

6.246. S&NP thought that consumers were unaware of how the price of the products they used compared with the price of other manufacturers' products, and that its interests would be served if consumers were able to make comparisons. There was no reason why manufacturers should not publish details of the cost per year at the RRP for the average user or why retailers should not be required to display similar information. In addition opticians should be prevented from recommending particular brands of solutions and should be allowed to recommend only a particular type of system. To address the practice whereby manufacturers of both lenses and solutions linked the two together and recommended that wearers of their lenses use their solutions, S&NP said that manufacturers should be required to publish, and retailers to display, information indicating the type of lens material for which their products were suitable. This had been, but was no longer, a requirement in the USA.

Marketing solutions in quantities which cannot be exhausted within the recommended period

6.247. S&NP said that it was difficult for manufacturers to specify precisely the number of daily doses in a particular size of container, except possibly on the basis of an 'average' consumer. For example, consumers were advised to fill their storage case with Transoak 'to the recommended level' and the number of doses would depend on the size of the case. The differences in the recommended 'use-by' dates had arisen for historical and regulatory reasons. When product licences for solutions had first been issued, a standard limit of 28 days (the limit for all optical application medicines) had been imposed. S&NP had had to carry out extensive testing to justify an extension to 60 days for its Transol and Transoak solutions. It disagreed with the MMC's provisional view that 50ml containers of Transol could not be used at 'average' daily doses within the 60 days use-by period. It said that if the solution were used regularly it would be exhausted within 50 to 60 days.

6.248. With regard to the practice generally, S&NP said that if a consumer once bought a product and did not use it within the time stated a smaller size should be purchased next time. However, the fact that smaller containers might not have proportionately lower prices might dissuade consumers from doing this.

Recommended retail prices

6.249. S&NP thought that the practice of recommending retail prices, which occurred in most consumer goods markets, in reality did not affect retail competition. Retail prices were determined by the conditions of retail competition that existed. In the CLS market RRPs tended to act as a price ceiling rather than a price floor and if they were abandoned the retail price of solutions, particularly those sold by opticians, would tend to rise. Once the initial choice as to type of solution had been made consumers were relatively insensitive to price and in certain local retail markets would, in any case, have little choice of retail outlet from which to purchase solutions.

Differential discounts

6.250. S&NP said that major customers were generally able to demand larger discounts from suppliers than those available to wholesalers and independent opticians and pharmacies. Obtaining larger discounts encouraged such retailers to display these products with a view to obtaining market share. Reducing the price of S&NP's products would be unlikely to increase its sales, as opticians were generally committed to two or three main players.

6.251. Small manufacturers must retain some freedom of pricing and the opportunity to offer discounts which were not wholly volume-related if they were able to compete with Allergan and CIBA Vision. If differential discounting were not permitted it was likely that some suppliers would find it difficult to remain in the market.

Extension of types of retail outlet in which solutions may be sold

6.252. S&NP thought that although in the short term this might reduce prices, it would also result in less consumer choice. Retail outlets which had limited shelf space and high turnover criteria would be likely to offer only the leading brands, which were the ones most likely to be recommended by opticians. So whilst solutions would overall be more generally stocked, smaller manufacturers' products would become increasingly less widely available. Moreover, as advice from a pharmacist or optician on alternative products would not be on hand in the new outlets, it would be even less likely than at present that a consumer would consider switching brands.

Aspect

6.253. Aspect, a subsidiary of New Focus Health Care Ltd, gave written evidence and attended a hearing. It told us that the main part of its business, in value terms, was the supply of contact lenses. It also marketed its own-brand solutions and, since 1990, had supplied own-label solutions to Specialeyes. Its trading division, Kelvin, was a wholesaler of solutions for all the solutions manufacturers.

6.254. Aspect said that the proportion of total market sales of solutions through pharmacies was increasing and that through opticians was decreasing, with about two-thirds of solutions now being sold through pharmacies and one-third through opticians. Pharmacies relied upon pharmaceutical wholesalers, which were often part of the same group, and which gave them better discounts than optical wholesalers such as Aspect. Another increasing trend was the direct sale by manufacturers to retailers, which had led to a further reduction in the sales of solutions through wholesalers.

The complex monopoly

6.255. Aspect disagreed with our provisional finding that it was a member of the complex monopoly group and commented as follows on the issues which arose.

Packaging and labelling

6.256. Aspect said that its packaging of solutions was consistent both within and across brands. There was complete consistency between size of container and recommended period of use. There were also clear instructions as to daily dosage. Specific instructions in each of its monthly-care packs indicated the exact method and amount of usage. Its solutions were marketed in quantities which, if used as recommended, would be exhausted during one month, with a small amount over as spare.

Recommended retail prices

6.257. Aspect said that it set RRPs but, in common with the rest of the industry, did not enforce them. It applied clear, published levels of discount, related to volume of purchase and therefore to cost, to all its customers.

Differential discounts

6.258. Aspect said that in March 1987 Allergan, Coopervision and S&NP had simultaneously announced a reduction in their discount to optical wholesalers from 25 to 15 per cent. The OFT had been informed of the meetings which had taken place between these companies prior to the reductions taking place. This action had reduced business for the optical wholesalers and, in Aspect's view, in discriminating against them it distorted competition between types of customer. Aspect said that the same manufacturers had then gone on to offer higher discounts, of 25 or 30 per cent, to retail opticians some of whom purchased relatively small quantities, certainly smaller than those which wholesalers routinely purchased. As a result, Aspect had found it impossible to sell to those outlets. It had been forced to discount its prices and seek improved margins by purchasing Allergan and CIBA Vision products through retail outlets. Aspect said that Allergan had tried to dissuade those retail outlets (largely opticians groups with considerable buying power) from selling on to Aspect but, so far as Aspect was aware, Allergan had never carried out any threat either to cut off the supply or reduce the discount to those retailers. So far as CIBA Vision was concerned, Aspect was aware of no action on its part to prevent retailers from selling its products to Aspect although Aspect thought that CIBA Vision must be aware of the situation.

Extension of types of retail outlet in which solutions may be sold

6.259. Aspect believed it essential that qualified advice should be available at the point of retail sale of solutions. If they were sold in outlets where this was not available, consumers could be given the wrong advice, purchase the wrong solutions and possibly endanger their eyes.

Waverley

6.260. Waverley told us that it was a contract manufacturer and did not market its own products. The products it supplied were of two kinds. First, it manufactured solutions for brand owners under their own licences and supplied these products as bulk-filled, labelled or cartoned products ready for final sale. The companies concerned were responsible for the products' sale into the market. Secondly, Waverley manufactured own-label [*Details omitted. See note on page iv.*].

6.261. Waverley said that other companies had shown an interest in introducing own-label solutions into the market-place. This could increase competition and ensure price competitiveness for the benefit of the consumer. Waverley had been approached by some supermarket chains and said that both they and it believed that the MCA would allow at least unpreserved solutions to go on sale through supermarkets, provided that they were adequately labelled. This would benefit the consumer by increasing both availability and competition. Waverley thought that the cost of solutions might contribute to drop-out rates among lens wearers. Because some wearers were not given sufficient advice about the costs of lens care, they stopped wearing their lenses after two or three months because they found they could not afford the maintenance. Others skimped on lens care to make their solutions go further and this led to dirty, uncomfortable lenses and eye problems which also made them stop wearing lenses.

7 Views of opticians, pharmacists and wholesalers

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7.1. This chapter summarizes the views of opticians and pharmacists, of their related trade associations and professional bodies, and of wholesalers of solutions. We begin with Boots, which operates both opticians and pharmacies.

The Boots Company PLC

7.2. The Boots Company PLC gave written evidence and attended a hearing. It said that the company was not engaged in the supply by retail of the reference goods because all sales to customers were made by BTC and BOL. Accordingly, it was not appropriate to include The Boots Company PLC in the provisional 'scale monopoly', or any of the provisional complex monopoly findings set out in the MMC's letter of 23 October 1992. (We use the term 'Boots' to refer to the Boots group as a whole or to BTC and BOL together, according to the context.)

Scale monopoly

7.3. Boots said it did not believe that the fact that BTC and BOL might have a scale monopoly adversely affected the level of competition in the retail sale of solutions. The MMC's own findings disclosed that almost all pharmacies and opticians' practices stocked and sold solutions. BTC operated only 8.9 per cent of the total number of pharmacies in the UK, and BOL accounted for approximately 4 per cent of the total number of opticians' practices. Moreover, of the 287 opticians' outlets currently operated by BOL, 111 were located in retail stores of BTC and accordingly the Boots group companies accounted for only 6.6 per cent of the retail outlets offering solutions for sale. In almost every locality the consumer would have a genuine choice of pharmacy or optician outlets in close proximity.

7.4. Boots said that its share of the solutions market had only exceeded 25 per cent in the last three years, but that the characteristics of the market and the nature of Boots' activity in it had been constant for a considerably longer period. It was Boots' submission that the existence of the 'scale monopoly' had not affected the market at all; the level and nature of competition remained the same. Before Boots had acquired a 'scale monopoly' position most retailers had sold solutions at, or close to, manufacturers' RRP, and they continued to do so. Boots had always competed in the retail market for solutions using a mix of tools in which rivalry over price was not the key component, and that remained the case now. Boots' pricing policies before and after its market share had exceeded 25 per cent had continued to be the same in respect of both proprietary and own-label solutions. Boots had provided details of 'margins' from suppliers for the last four years; the margins achieved from suppliers both before and after it had acquired a 'scale monopoly' were broadly the same. Indeed, the only real change in margins during this period had been a worsening of Boots' margin in respect of its own-label solutions. Qualification as a 'scale monopolist' had not affected the way in which Boots competed, had not allowed Boots to charge higher prices and achieve higher margins on own-label solutions, had not enabled Boots to extract larger discounts from suppliers, and had not put Boots in a position to sell branded solutions at higher prices and to obtain higher margins than would otherwise have been the case.

7.5. Boots had achieved its market share by offering a wide selection of solutions, and by providing a high level of service and advice to customers. Both BTC and BOL employed large numbers of highly qualified and professional staff, at considerable expense. Both companies also expended considerable time, effort and resources in training the high quality staff they employed, particularly in areas such as the provision of advice on solutions. Those staff provided advice and assistance to customers and Boots believed service to be the principal reason why customers chose to purchase solutions from it. The companies also mainly traded from expensive, high street locations. The provision of those staff, their training, and the cost of well presented high street premises were significant expenses. Moreover, the healthcare business (of which solutions formed part) had a disproportionately high staff cost.

7.6. There had been, and continued to be, price competition in the retailing of solutions, but Boots understood that many sales of solutions were at or about RRP. It believed, however, that selling at or close to RRP was evidence of the fact that competition on price was not the principal component in the competitive mix in this market. BTC and BOL between them had only a very small percentage of the total number of outlets that sold the products, and many of the other outlets were operated by companies with significant numbers of stores. By way of example, Lloyds operated over 850 pharmacies, and D&A approximately 470 opticians' practices. If Boots had achieved a greater share of the market than its proportion of retail outlets then that must be because customers preferred to buy from it. This, Boots believed, was because it offered a comprehensive range of solutions (including Boots' own-label at a lower price), and a high standard of service, both in respect of solutions specifically and in respect of its healthcare business generally.

7.7. Boots said that its own-label goods (including solutions) that were based on proprietary products were usually sold at a discount to those proprietary products, and provided the customer with a cheaper alternative. Boots emphasized that whilst own-label goods might earn a higher gross profit margin than the branded product, the goods were not in themselves more profitable, as the retailer had to finance from the gross margin those overheads and costs (especially the marketing costs, for example the provision of free starter kits) that proprietary manufacturers bore themselves in respect of their branded goods.

7.8. Boots said that, notwithstanding the popularity of the Boots own-label, Boots provided significantly more consumer choice of branded solutions than other major retailers. BTC stocked 60 solutions lines, and BOL slightly more, as a limited number of solutions were available only in opticians. The range of products carried by Boots' stores was understood to be almost half as large again as that carried by D&A practices (which, of course, had their own-label solutions), and nearly twice the size of the range carried by Lloyds. Two-thirds of the solutions sold by Boots were proprietary brands.

7.9. Boots said that it was important to take account of the fact that the Boots group acted as its own wholesaler and distributor and took central delivery of goods, and that it was reasonable for its gross profit margin to reflect the cost necessarily incurred in performing this function. Boots said that it did not know whether it secured larger discounts from manufacturers than wholesalers did but there were two major pharmacy wholesalers whose purchasing power matched its own, and which serviced significantly more outlets than BTC and BOL together.

7.10. Boots told us that it did not have formal contractual arrangements with either of its own-label suppliers, Allergan or CIBA Vision, although it did have basic terms and conditions which applied to all its suppliers. Rather, a commercial negotiation took place in which Boots sought to achieve a price which would safeguard its margins against its proposed retail price. The supply price was not fixed for any agreed period although in practice it was reviewed on an annual basis.

7.11. Boots said that it was surprised at the suggestion that the availability of a Boots own-label product could be interpreted as restricting customer choice. The majority of solutions sales in Boots' stores and practices were of proprietary branded solutions; only one-third of its sales were of Boots' own-label solutions. It was not correct to suggest that a Boots own-label product was recommended 'as a matter of course' in BTC. Pharmacy staff were trained to know which proprietary and own-label lines were equivalent and could indicate equivalence when asked.

CIBA Vision's pricing to D&A in summer 1990

7.12. Boots told us that in the summer of 1990 D&A's own-label pricing had moved from around 5 per cent below Boots' own-label to around 10 per cent below. This had suggested to Boots that CIBA Vision, which supplied own-label products to both retailers, might have been offering D&A a lower price than Boots. Boots had accordingly raised the matter with CIBA Vision. CIBA Vision had told Boots that D&A's input price was not lower than Boots', although Boots had no way of knowing whether this was true or not. In the event, within around two months, D&A's prices had returned to the level of 5 per cent or so below Boots', and as far as Boots was aware the issue was not thereafter debated further. Boots had assumed that D&A's price reduction had been a promotional activity over a specified period.

7.13. Boots said that, had a pricing differential of 10 per cent continued, it would have reviewed the competitive strategy for its product, and might have concluded that a price reduction was necessary. Had that been the case, Boots would have sought to protect its margin. Boots said that CIBA Vision would have expected it to do so, as CIBA Vision was aware of the importance that Boots attached to maintaining margins. However, doing so would have required additional negotiation with CIBA Vision, which would not necessarily have agreed to reduce its input price, given the limited alternative for Boots' own-label supply and the importance to Boots of CIBA Vision's proprietary range.

7.14. Boots said that it was not aware of any other similar incidents with CIBA Vision or any other supplier. It did not think that any of its suppliers could believe that it was actively pursuing any course of action with them to force other retailers to increase their prices. Boots said that it had not put pressure on CIBA Vision in this instance.

Retailers complex monopoly

7.15. Responding to the issues raised by the MMC in connection with their provisional finding of a retailers complex monopoly situation (see paragraph 8.76), Boots said that no company in the Boots

group had any agreements or understandings with any other company cited or any other retailer concerning the price at which solutions were sold. In addition it did not believe that the fact that a number of retailers sold at or close to RRP was a course of conduct that 'prevented, restricted or distorted competition'. There was substantial competition between brands on price. Any of the many thousands of retailers stocking solutions were able to compete on price if they wanted to do so, and some did. They could if they wished aggressively advertise the competitive price at which they sold solutions, and seek custom on that basis. BTC would be likely to respond to aggressive price competition, but the fact that it had achieved a high market share without engaging in aggressive pricing indicated that customers believed that the current price levels in Boots stores represented good value for money and regarded professional advice and service as the most influential determinants of purchase decisions. It was also Boots' view, confirmed by the MMC's own research, that 'availability' was not an important issue for customers, as solutions were widely on offer.

7.16. Boots said it believed that the extension of distribution to outlets where professional advice was not available if required would be against the public interest. The MMC's survey had indicated approximately 2 million enquiries of pharmacists in a year in respect of solutions, roughly equivalent to one enquiry per contact lens wearer in the UK each year. Quite a high proportion of customer complaints received by Boots was attributable to customers' switching products unsupervised or using incompatible products. Boots' own in-house market research into the extent and nature of the advice sought by customers of its pharmacists showed that, even in a situation where advice was available and frequently provided, the area of problems related to eyes, contact lenses and solutions was the fourth most frequently asked-about category of queries by customers of pharmacists after cough medicines, children's medicines and pain relief. The importance of professional advice and support was, Boots believed, one of the most important reasons for the restrictions imposed by the MCA. It was in the public interest to err on the side of caution in a market where there was substantial evidence of non-compliance with care regimes.

7.17. Boots believed that there was a substantial risk that the extension of distribution of solutions to outlets where no advice was available could result in some customers purchasing incompatible products from different care systems, leading to damaged contact lenses, and, more importantly, temporary or even permanent damage to the eye. If restrictions were completely removed, any retailer could stock the products; many might stock only a limited range of solutions rather than the wide range currently carried by stores such as BTC, and some could even at some times not stock complete systems. Without the safety net of staff advice, solutions-related eye problems would almost certainly rise dramatically. It was not sufficient to expect customers to make the right purchase decisions based solely upon pack information, as of necessity the amount of information that could be given on a pack was severely limited. Moreover, the purchaser might not be the end user.

7.18. Boots also said that it supported the continuation of the licensing system which ensured that products of the highest quality were supplied in the UK. Solutions were complex products, quite unlike some analgesics and other medicines that were available for sale in outlets other than pharmacies.

7.19. Boots told us that in 1989 the RPSGB had agreed its proposals to display GSL medicines and CLS on open display in its pharmacy outlets. Boots said that it had no record of any increase in the proportion of customers who had both bought solutions from those pharmacies and had experienced problems with their solutions following that move. Certainly there had been no marked increase, or Boots would have moved to remedy the situation. Boots said that open selection of solutions in outlets where professional advice was on hand represented an efficient and speedy method of purchase for the customer while ensuring that advice was available if needed.

7.20. Boots also commented on the restrictions on the opening of new pharmacies. In theory, any pharmacist or company employing a pharmacist could open a pharmacy, so long as his premises were registered with the RPSGB, but in practice the control of entry into NHS dispensing contracts greatly restricted the ability of persons to open new pharmacies. Boots was strongly in favour of the removal of this restriction, and of NHS contractors being reimbursed a flat fee for every prescription they dispensed; this was not because of any particular self-interest on Boots' part, but because it believed that the abolition of controls on entry and the introduction of a single tier of remuneration would introduce competition into retail pharmacy, reduce bureaucracy and cost, improve the service to the community and be of great benefit to the Government and consumers.

Own-label suppliers complex monopoly

7.21. Again, Boots said it wished to emphasize that no company in the Boots group had any agreements or undertakings with any other company cited with regard to the practices referred to in the MMC's issues letter. Moreover, Boots' policy for its own-label solutions across the entire range was to offer products comparable in quality to manufacturers' brands at a value-for-money price. It priced Boots' own-label CLS products at around 5 per cent on average less than the corresponding proprietary products, taking account of price points. On the ten (of the eleven) Boots own-label lines sold in the healthcare business where there was a direct proprietary equivalent, the non-weighted price saving in 1991/92 was 6 per cent, but the weighted saving, based on mix, was 12 per cent. Boots considered this to be a substantial saving.

7.22. Boots said that it noted the MMC's concern that own-label goods were not available in every comparable size to that of every manufacturers' brand. However, Boots' own-label goods were manufactured by the suppliers of proprietary goods, which held the necessary MCA licence, and its own-label goods were simply differently packaged versions of branded products. Accordingly, own-label solutions could only be packed in the sizes in which the corresponding proprietary product was available, as the suppliers' product licence determined what could be sold. Boots' own-label solutions of necessity corresponded to the proprietary equivalents.

7.23. It was not Boots' policy, however, to offer own-label solutions in every size that the proprietary manufacturer offered. Boots would not market such solutions in sizes which were likely to generate very little demand from customers (eg a 10ml Wetting Solution or 15ml Preservative-Free Daily Cleaner). However, whilst it might not stock every size specified on its various suppliers' licences, it did sell complete systems as required by the MCA.

7.24. Boots could not see, therefore, how the selling of solutions in sizes dictated by manufacturers could be a course of conduct adopted by retailers constituting a complex monopoly.

7.25. Boots also stressed that it did not market own-label solutions in quantities which could not be exhausted in the recommended use period, given proper compliance. Boots' assumptions and calculations, made independently, tallied closely with those of CA's *Which?* report in September 1991. Boots therefore rejected a suggestion that it carried out the practice which the MMC believed could constitute a complex monopoly.

7.26. Boots said that it understood the MCA only licensed complete systems and not isolated products. The labelling regulations (SI 1979/1759—see Appendix 2.1) required the form of warning which appeared on all packs advising against mixing with other fluids without advice. That warning was, Boots believed, in the public interest and helped to prevent the purchase of incompatible products in error. Use of incompatible products could lead to eye problems, lens damage or both. In addition, Boots' staff were trained to advise which proprietary brand systems were compatible with each other and could safely be interchanged. It was this licensing requirement which dictated that solutions were marketed only as part of a complex care programme.

Proposed remedy that Boots' ability to increase prices of solutions should be limited by some formula such as RPI-X

7.27. Boots emphasized the fact that solutions were not commodities, or the sort of product (like paracetamol) where retailers had a wide range of manufacturers to choose between when they decided which products to stock. There were two strong suppliers in this market whose products were 'must stock' items, and those manufacturers were well aware of that fact. These manufacturers had considerable muscle in any negotiation, and it would be quite inequitable to restrict the price that Boots could charge to its customers whilst leaving the manufacturers free to determine the price that they charged to Boots. It would also be inequitable to control the price that Boots could charge whilst not restricting other retailers in the same way.

7.28. The proposed remedy was unnecessary in Boots' view. The market was one where retailers competed using a number of ingredients, with price generally not being a significant component,

although price competition existed both between brands and between retailers. Retailers were free to seek a competitive advantage by cutting retail prices, and many already did so. It was Boots' view that a small adjustment in Boots' prices would not result in any adjustment in prices in the market generally; only if Boots significantly reduced its prices would there be any real impact on the competitive strategies adopted by other retailers, which might then be compelled to match Boots' prices or lose market share. Many of those retailers might be unable to match Boots' prices while maintaining other standards of service as a part of their competitive mix, and might therefore withdraw from the market.

7.29. A restriction on Boots' ability to increase its prices could be anti-competitive. It could also threaten the position of those retailers of solutions which currently competed on price.

Proposed remedy of an enforced 15 per cent price differential between Boots' own-label and branded solutions

7.30. Boots said that in its view the prospective remedy was not only undesirable (for all the reasons stated in reply to the first proposed remedy) but also in this case impracticable.

7.31. The prices of Boots' own-label solutions were to a large extent dependent upon the price charged to Boots for them by manufacturers. There were presently only two manufacturers which could offer technologically advanced solutions, and if Boots wished to offer high-quality own-label solutions then it had no choice but to deal with them. Those manufacturers' principal interest was in their proprietary solutions, which Boots also stocked. Proprietary manufacturers would almost certainly be reluctant to supply own-label solutions if they saw a pricing differential between products sitting side by side on the shelf of a magnitude that would lead to the wider use of own-label at the expense of their proprietary products. Even if they could be persuaded to continue to supply existing lines they would almost certainly prevent the development of the range. Boots understood that there was likely to be little organic growth in the solutions market.

Opticians complex monopoly

7.32. Responding to the issues raised by the MMC in connection with their provisional finding of an opticians complex monopoly situation (see paragraph 8.86), Boots made the following comments.

7.33. Boots said that BOL was registered as an Ophthalmic Opticians' Corporate Body with the GOC. It was a part of a separate division of The Boots Company PLC (the Retail Division) and was managed quite separately from the business of BTC. It did not have any agreements or understandings concerning the selling prices of solutions with any of the listed companies (apart from BTC) or with any other retailers of solutions.

7.34. Boots said that, in determining the market share of prospective participants in this proposed complex monopoly, only the share of BOL (not of any other Boots group company) should be considered. It pointed out that BOL's own share of the total solutions market was around 5 per cent and falling. It had no precise figure for the share held by D&A but was confident that the combined share of BOL and D&A would be substantially below 25 per cent. Therefore it suggested that the existence of any monopoly in this group depended entirely upon proving the existence of sufficient other retailing opticians whose market share was large enough to bring the total market share to a clear 25 per cent.

Opticians' recommendations

7.35. Boots said it rejected the suggestion that the opticians working for BOL gave insufficient weight to the cost of particular types and brands of solutions when making their recommendations to patients. All professional opticians were under a legal and professional duty (enforceable by law and by professional discipline) to give first priority to the clinical needs and the safety and comfort of each patient. In recommending a type of contact lens and a care system to accompany it, priority

had always to be given to ensuring a safe and comfortable regime for the patient, and in so doing the cost could not be the sole criterion. For the vast majority of contact lens patients lenses were an optional purchase, as only a very small percentage of patients had a clinical need for contact lenses instead of spectacles. The choice of contact lenses was thus normally a voluntary one taken by a patient in the knowledge that it was unlikely to be less costly than the alternative of spectacles. Contact lenses were not recommended to patients who were known to have a lack of disposable income.

7.36. BOL's practices had available starter kits from almost all proprietary manufacturers, and when they recommended Boots' own-label solutions to new lens wearers they did so on the basis that the solutions they were recommending were those that would, firstly, be most efficacious and, secondly, give best value for money to the customer. Peroxide systems, for example, were licensed to be used for GP lenses but BOL did not recommend their use with those lenses, because other solutions were less costly but just as efficacious.

7.37. Boots said that the MMC's survey of opticians had asked for a ranking of reasons for recommending a disinfecting system and the responses to that survey (see Appendix 3.8) had shown that the majority of opticians placed effectiveness, the possibility of eye irritation and ease of use as the three most important factors. This result was exactly what would have been expected from opticians who were carrying out their professional duties to their patients. The fact that the cost of solutions to the patient had emerged as a slightly lower factor did not indicate that 'little weight' was given to it, because it would always be in the patients' best interest to afford priority to the other clinical factors.

7.38. It might well be substantially more costly for the individual patient to choose solutions solely on the basis of cost if, as a result, an adverse reaction was experienced. This particularly applied to soft lenses where cold chemical disinfecting solutions were far more likely to cause irritation to the eye. It was impossible to identify in advance whether new patients were likely to suffer irritation from a particular solution and there was no particular time-scale within which the problem might arise. Even after six months or more of regular use, it was quite possible for a patient suddenly to experience severe irritation. If this happened, the patient was likely to require at least a four-week gap in the use of contact lenses and would subsequently need to purchase a new pair of lenses because the original pair of soft lenses would have absorbed the substance which had caused the problem. The patient might also need to obtain a new pair of spectacles to cover the interim period and might well have lost time at work. In economic terms, this turn of events could present a sudden bill to the patient of between £100 and £180 for a pair of lenses alone. Against this was set the additional cost of using a peroxide system for soft lenses which in the case of Boots' own-label was approximately £72 per year. For each individual patient using a peroxide system, this cost was in effect an insurance against the higher risk of suffering irritation by using the cheaper system.

7.39. Boots said that BOL opticians always advised new patients to use Boots' own-label solutions (whatever type of solution might be recommended) unless there were clinical reasons to the contrary. The MMC's own survey had shown that Boots' own-label prices were in all cases lower than the RRP of the equivalent branded product and therefore, in making a recommendation to use own-label, BOL would be advising the use of products which were less expensive than the normal cost of the branded alternative, thereby automatically having regard to consumer cost. For this reason also it could not be said that the opticians were 'giving little weight to the cost', and BOL was accordingly not involved in the practice cited.

7.40. Boots said that the MMC's survey of opticians had confirmed that BOL opticians and opticians generally said that they always, nearly always or mostly advised patients on the likely cost of solutions. BOL's own internal survey of 15 per cent of its practices had disclosed that in all cases the opticians stated that they always explained the cost of solutions to patients. The MMC's consumer survey had shown a different result. Boots suggested that there might be at least two reasons for this. The first was that the question put to consumers referred to the point at which they were first considering wearing contact lenses. It might well be that this was not the point at which a full consultation with an optician took place, because patients would frequently need to discuss the options, and a good deal of explanation had to be given to the patient. The first trial lens fitting might take place at the same time. Secondly, patients were more likely to remember the detailed instructions and advice given, and their first trial fitting, in relation to physical aspects rather than to the cost aspects.

7.41. Boots therefore rejected the suggestion that BOL opticians were failing to make sufficiently clear to patients all relevant information about the prices of solutions which they recommended.

7.42. Boots commented on the suggestion in the MMC's provisional summary of its findings on the survey of opticians that 'a number of opticians are recommending the more expensive peroxide system when they believe that many wearers of soft lenses could satisfactorily use the cheaper cold chemical system'. Boots said that it was impossible to predict which patients were likely to suffer irritation, and the MMC's suggestion could only be justified if *(a)* patients were wholly unconcerned about increasing the risk of irritation together with the unpleasant and potentially expensive result, or *(b)* it was possible to determine in advance which patients were more at risk of suffering irritation.

7.43. With regard to the MMC's suggestion in the same provisional summary that 'as many as 85 to 90 per cent of soft lens wearers could use the cheaper cold chemical systems', Boots said that this was not justified from the statistics quoted. Only 6 per cent of the responding opticians recommended cold chemical disinfection systems for use with soft lenses, and the same respondents reported a 10 per cent experience of eye soreness or similar problems. If 94 per cent of the respondents were not recommending cold chemical disinfection systems, the percentage of soreness would not reflect a neutral sample of patients using cold chemical systems. A statistical conclusion about the percentage of soft lens wearers who could use the cold chemical system without experiencing any difficulty could not be based upon this survey. BOL was confident that substantially more than 10 to 15 per cent of soft lens wearers would get an adverse reaction from the use of cold chemical systems.

Opticians

Dollond & Aitchison

7.44. D&A gave written evidence and attended a hearing. It told us that it was the oldest established and, in terms of outlets, the largest opticians' chain in the UK. It was primarily involved in the provision of spectacles and contact lenses. D&A saw the supply of solutions as an integral part of the supply of contact lenses and had started to sell branded solutions in 1967. It said that its reputation in the market had enabled it to introduce own-label solutions in 1990. This had been D&A's response to a very competitive market. CLS nevertheless accounted for a relatively small part of D&A's business.

7.45. The majority of D&A's branches employed an ophthalmic optician and the remainder operated with either a locum ophthalmic optician or a self-employed ophthalmologist who might also operate elsewhere. Most of the ophthalmic opticians in D&A's practices also fitted contact lenses although in the bigger branches this was usually undertaken by qualified dispensing opticians. In most branches the dispensing optician was the manager of the outlet. D&A said that in all cases the professional staff would be unaware of the discounts which D&A received from its suppliers and there were no instructions to staff to recommend particular branded or own-label solutions. Practitioners used their professional judgment as to which solutions to recommend, taking account of the clinical needs and the suitability of the patient and of what would offer the best economic deal.

7.46. D&A told us that before stocking a branded solution it had to be sure that the product would be safe and effective for its patients and that there was public demand for it. It liked to assess a newly introduced product's performance in the UK market before offering it in D&A outlets, and would rarely stock a product immediately it was launched, even if it had been successful in other countries. D&A would have lengthy discussions with the manufacturer before accepting any new product. The technical advances in contact lenses and solutions had been rapid and D&A took a cautious approach.

Retailers complex monopoly

7.47. D&A said that the MMC had not indicated what was meant by 'only just below' in their statement that retailers of CLS sold at, or only just below, the RRP. D&A's general policy was to

price branded (as opposed to own-label) CLS at prices based on a percentage reduction of the manufacturer's RRP. D&A's prices were also influenced by regular surveys of its competitors' prices. D&A said that it therefore assessed the market situation and aimed to gain an edge over its competitors on price. Although the RRP was a factor in D&A's calculation, it was only the starting point in the setting of the final retail prices which ranged from between 2 and 15 per cent below RRP. D&A did not accept that pricing in the market for CLS generally was rigidly tied to the RRP.

7.48. D&A thought that the MMC's suggested remedy of requiring retailers not to adhere to RRP was unworkable. This proposal would not in itself eliminate any perceived rigidity in price structures in the market and would appear to be directed towards the wrong target. D&A assumed that the MMC were also considering a remedy requiring manufacturers not to recommend RRPs. It said that it was not aware how the manufacturers arrived at their recommendations for retail prices. Many small retailers operated only one or two outlets, in which solutions represented a small part of their businesses, and they might find it convenient to set their retail prices for CLS products solely by reference to RRPs. However, as a multiple operator, D&A was quite able to determine its retail prices without any recommendation from the manufacturers.

7.49. D&A did not regard the alleged adherence to RRP as a reason for widening the range of retail outlets at which CLS might be sold. It assumed that the MMC envisaged the removal of the restriction in the product licences of CLS, which specified sale by pharmacies and opticians. The regulatory control of the route of sale was a matter affected by medical and scientific issues and was not simply a matter of economic expedience. The MCA had taken the view that professional advice should be available to customers at the point of sale of CLS. D&A regarded its reputation as a provider of such services as valuable in ensuring the safety of patients. It wished to make certain that patients who had been fitted with lenses at a D&A outlet did not experience difficulties with solutions and it could be more confident if professional advice was available at the point of sale.

7.50. D&A said that it had an interest from an economic, as well as a professional or ethical, point of view in ensuring that advice was available to patients when they purchased CLS. To some extent opticians were already bearing the costs of advising on the adverse consequences of using unsuitable solutions where the profit on the sale of those solutions had gone to another operator, such as a pharmacist. However, pharmacists were obliged to have a professional adviser available to answer questions about solutions.

Own-label suppliers complex monopoly

Packaging and labelling

7.51. D&A said that the own-label retailer was dependent on MCA approval granted to the manufacturer for the specification of package size and style. Generally D&A own-label solutions were sold in the same pack sizes as the nearest equivalent branded products. It was easier and cheaper for the manufacturer to obtain licensing approval for a pack which was similar to its branded counterpart because fewer test data were required. Apart from the ease of obtaining a licence, the own-label retailer's main concern as to the size of pack was the safety and convenience of the patient. The regulatory regime required CLS labels to indicate the volume contained in the pack. The size of packs for equivalent branded and own-label CLS products was the same and the consumer seeking to check the prices of identical systems could compare volumes and prices as easily as with any other consumer product. In D&A's view consumers generally preferred to buy most types of product in larger packs which were usually more economical because of savings in packaging costs. Consumers were likely therefore to purchase the largest size of CLS pack available, consistent with the requirement to use the product within the 28-day period where applicable.

7.52. D&A thought that the MMC's suggested remedy that own-label CLS labelling should be made more informative on matters such as daily doses would be difficult to implement, as it was hard to assess precisely how much solution a particular patient would use per day. This point was particularly important when considering the issue of whether consumers were being encouraged to buy certain sized containers of CLS which could not be used up in the recommended period of use. The MMC had stated that D&A's 25ml container of One-2-One RGP cleaner would not be exhausted

before the discard date. D&A said that this statement distorted the situation. The minimum amount of that product which D&A would regard as necessary to clean the lens effectively each day was 0.7ml. However, as the product was poured into the palm of the hand in order to clean the lens, it was unlikely that patients would measure out 0.7ml accurately each day. The amount actually used would vary depending on the size of the patient's hand, how thorough they were and the amount of spillage. When dealing with such small amounts it was possible that patients would use more than 0.7ml; if a patient used only 0.2ml over the required amount each day the pack would last less than 28 days.

7.53. D&A did not accept, either, that its One-2-One Universal Cleaner would not be exhausted within the 28-day period as the MMC had suggested. This cleaner was most commonly used for soft lenses which had a larger surface area than RGP lenses and were harder to clean. A patient might well clean soft lenses more than once a day. The figure of 2.5ml a day was D&A's best guess as to the minimum daily requirement for this solution for the type of lens for which it was most suitable. D&A also noted that the required dosage of a solution, particularly a soaking and wetting solution, often depended on the size of the patient's lens container, and sizes varied considerably. Furthermore, some patients preferred to rinse more thoroughly than others and their consumption would be greater.

Marketing own-label CLS as parts of complex care systems

7.54. D&A said that the MMC had suggested that by marketing own-label CLS as parts of complex systems the own-label retailers restricted competition and consumer choice. This restriction was said to result from marketing solutions which 'should not be used' with CLS from other systems. D&A thought that the marketing of own-label CLS as part of care systems was attributable to the MCA's product licence requirements which were beyond the retailer's control. It understood that if it wished to recommend another supplier's product for use within D&A's own system, its own-label manufacturer would have to obtain MCA approval for this. Product licences were awarded to each solution following regulatory testing by the approved authorities. Solutions could be purchased as individual items. However, D&A said, the product licence stipulated via the packaging instructions that the solution was only to be used as part of that particular system.

7.55. D&A believed that there would be no problem in interchanging the elements of identical systems (eg own-label to branded product and vice versa). There were, however, serious limitations when switching between *similar* products which were widely available, and some CLS systems could not be used with all lenses. Solutions underwent a number of tests in order to satisfy the requirements of the product licensing system; for example, they were tested for their reaction to other solutions in the system of which they formed a part. In order properly to assess the compatibility of a product with other products from a different system, extensive further testing of all possible solution combinations would be required.

7.56. If products were to be labelled in a more informative way, as the MMC had suggested, it would be necessary to consider who should be responsible for, and bear the cost of, such testing. Even if appropriate testing could be done without undue expense to the consumer and compatibility between different systems could be established, D&A doubted that information on the labels would be a practical method of informing patients about substitutability. Professional advice would still be important when a patient was considering switching brands. D&A said it would resist strongly any requirement that the labelling of its own-label products should list all other systems with which they might be compatible, as new products were frequently being introduced and such a requirement would force D&A to change its packaging each time a new product came on to the market. This in turn would require fresh product licence approval and would in the end be disproportionately costly to the patient. In any case, D&A believed that it could not refer to the brands of other companies on its packaging without risking trade-mark infringement proceedings. It also doubted the practicability of requiring compatible solutions to be described generically on product labels. For example, even if it were ascertained that existing solutions containing a particular preservative were generally compatible with other solutions using the same preservative, a new product containing that preservative might have an additional ingredient which would react with the other products. This was quite likely in a market in which manufacturers were seeking to develop products which would enable patients to wear lenses safely and with greater comfort for longer periods.

7.57. D&A noted CA's suggestion that opticians should give consumers a list of compatible products. It believed that this course of action would have the same difficulties as the labelling suggestion discussed above. Whether information was given by way of a list or by way of labelling on the package, D&A would be particularly concerned that the supplier should not incur liability for any statement as to compatibility made on its own-label products or by way of a list of products when there was even a small risk of any damage to the patient being caused by use of the products together.

Opticians complex monopoly

Cost considerations

7.58. D&A said that the MMC had suggested that opticians did not give sufficient weight to the relative costs of different CLS products when advising patients. So far as its own opticians were concerned, D&A said that they regarded safety and efficacy as their prime concerns when recommending products. No medical professional should prescribe or recommend products primarily on commercial grounds. Where there was more than one product which was equally safe and effective for the particular patient's needs, D&A believed that its staff would recommend the cheaper alternative. This would very often be D&A's own-label product, which was always cheaper than the branded equivalent. D&A suggested that the questions in the MMC's opticians survey which related to the reasons for recommending particular brands of solutions had been inappropriate. Opticians had been asked to select three important reasons for suggesting particular systems out of a series of eight options. As D&A's main concern was for patient safety, the most important reasons would inevitably be safety and effectiveness (which it thought were inextricably linked) leaving in reality a choice of one in six options. It said that the cost of solutions might, therefore, have been the second most important factor considered if a true choice had been available.

7.59. D&A said that it operated a scheme under which patients could make regular monthly repayments covering all their CLS requirements for soft lenses (the most common type prescribed). This scheme had been actively promoted in D&A outlets and in the national media. All patients enquiring about soft lenses in recent months had been advised of the monthly cost of the scheme. This was an example of full cost information being given to patients. D&A thought it possible that although patients were informed about CLS costs, they did not retain this information.

7.60. D&A had no information about the extent to which patients failed to comply with their prescribed lens care regimes. Even if this occurred on a widespread basis D&A did not believe that it was because patients had insufficient information about the costs of solutions. Non-compliance could be linked to the fact that the proper procedures could be time-consuming and required care. It might also be because patients, although fully aware of the costs of using solutions properly, might try to save money by not doing so. D&A did not know how the optician could control this, other than by continuing to recommend proper procedures.

D&A's own-label pricing in 1990

7.61. We asked D&A about the information we had received from Boots that in the summer of 1990 D&A's own-label pricing had moved from around 5 per cent below Boots' own-label to around 10 per cent below (see paragraphs 7.12 to 7.14). D&A told us that the Group Contact Lens Director at the relevant time was no longer employed by D&A and the company was therefore not in a position to give a full account of what had occurred. At our request D&A contacted the individual concerned who said that during 1990 a number of meetings had been held with CIBA Vision, the supplier. This had been normal practice for D&A as it kept in close touch with its CLS suppliers. The former director said that at one such meeting the CIBA Vision representative had commented to the effect that D&A should be mindful of its discounting policy for own-label products as Boots would react in a competitive manner. D&A said it was confident that such a comment would not have been taken into account when considering its pricing for own-label products. Indeed the price of D&A's One-2-One range (which was compatible with, and competed with, Boots' own-label products and which was on sale in July/August 1990) was not altered between the date of its introduction in February 1990 and October 1991. D&A therefore disagreed with the account we had been given.

D&A emphasized that it competed strongly with Boots across the range of its business and it did not allow its competitors or its suppliers to dictate its decisions on resale prices.

Specsavers

7.62. Specsavers, which gave written evidence and attended a hearing, said that it was an optical franchise group owned by the Guernsey-based Visionplus Ltd. It had started trading in 1984 and by mid-1992 had 180 outlets in the UK, each with a resident ophthalmic optician. Specsavers had introduced two own-label CLS systems in 1989, one chlorine-based, the other peroxide-based. It had marketed these as complete regimes and had found that the incidence of contact lens-related problems had dropped dramatically as a result. Customers were less likely to make the mistakes they had done when using a combination of different suppliers' products.

7.63. Specsavers said it advised its practitioners that it was in their interest to recommend own-label products. Apart from that it had no influence on which solutions were recommended; the practitioners would suggest what they considered to be best for the patient. Two-thirds of the CLS systems sold by Specsavers were chlorine-based and Specsavers thought that these were just as effective as peroxide-based systems. As they were also more economical for the patient and simpler to follow, the recommendation of a chlorine-based system was more likely to result in patient compliance.

7.64. In responding to our provisional findings, Specsavers said that it did not agree that any form of monopoly existed in the UK retail side of the CLS market, either with branded products or specifically with Specsavers' own-label range of products. It fully accepted that there were controls on the channels of distribution which were part of the intention and result of the Medicines Act 1968. It was sure that these controls were in the public interest and of themselves had not created a monopoly of any kind. Specsavers believed that extending the availability of solutions to other outlets would increase contact lens-related eye problems, and thereby the demand on the time and resources of general practitioners and hospitals, because of the lack of advice available to contact lens wearers at the point of sale.

Retailers complex monopoly

7.65. Specsavers said that its pricing policy gave the customer the best value for money. It was predominantly a franchise business with each franchisee deciding its own pricing policy and special offer strategy. The recommended price structures were used for guidance only. In all Specsavers' locations there was vigorous local competition from both optical and pharmaceutical retailers. Specsavers was strongly of the view that the combined total of 17,000 retail pharmacies and opticians ensured that there was both comprehensive and widespread distribution of solutions throughout the UK. So far as Specsavers was concerned, there was no evidence whatsoever of price fixing between competing retailers.

Own-label suppliers complex monopoly

Packaging, labelling and use-by dates

7.66. Specsavers said that container sizes were specified in the product licences, the originals of which were held by the product manufacturers, and Specsavers was unable to market alternative sizes unless approved by the MCA. Where more than one size of container was allowed for a particular product (such as with aerosol saline) it had taken the opportunity to provide the user with both the convenience of smaller containers and the economy of large containers. It was invariably less expensive per unit of volume to supply in larger containers.

7.67. Commenting on the MMC's suggestion that the recommended number of daily dosages should be stated on product labels, Specsavers suggested that this might be appropriate for medicinal products, but even there it was quite usual to find the instructions 'take as directed' or similar wording. It said that there was no such thing as an 'average' patient in terms of cleaning. The

frequency of use for a particular solution depended on a number of factors, both technical and practical, for example the size of contact lens container that would be used; the length of time the wearer intended to wear lenses; the type of lenses, which might be made from any one of many different materials; and the particular contact lens wearer's experience and the advice of the prescribing optician.

7.68. Specsavers said that the question of product labelling and container sizes had been thoroughly examined by the Licensing Authority following the 1976 legislation on contact lenses and solutions and before any licences were issued. It understood that these rules had been reviewed in 1986. Specsavers said that it could do no more than comply with the requirements of the product licences and found it difficult to conclude how such compliance could be construed as maintaining any kind of monopoly situation.

Marketing own-label CLS as parts of a complex care systems

7.69. Specsavers did not accept that its CLS systems were in any way complex and said that the products which made up the Specsavers 'own-label' regimes were selected for their effectiveness and simplicity of use. It thought that, ideally, the number of steps required in the routine of lens cleaning and storage should be reduced, but this would have to be done without diminishing the effectiveness of the care regime. The matter wholly depended on R&D into new products and the licensing of such products. Specsavers said that it would be delighted to have new solutions available to customers and did not believe that any product, eg a single-step system, had been kept out of the UK market for any reason other than the fact that it had not yet been granted a product licence. Specsavers noted that there was a single-step system for soft lenses available in the USA. As far as it was aware this product was not licensed in the UK.

Opticians complex monopoly

7.70. Specsavers said that its policy was to recommend whichever regime was most appropriate for each individual user. This was initially a professional judgment on the part of the optician but might later be changed in the light of the experience of the particular patient. It knew from experience that compliance with a recommended CLS regime was more likely to be maintained when a complete regime was used and less likely when a combination of different manufacturers' products was purchased. Specsavers' recommendation of a complete regime was entirely in the interests of the contact lens wearer and not in any way designed to create a form of discreet monopoly, either of own-label or branded products.

7.71. Specsavers said that there was ample clinical evidence to show that failure to comply with the recommended CLS regime was a major cause of contact lens-related problems, such as bacterial keratitis. The need therefore for opticians and pharmacists to do all they could to ensure continued compliance on the part of the contact lens wearer was essential, and failure in this respect would be reflected in an increase in the number of lens-related eye problems. Specsavers acknowledged that there were instances where some opticians and pharmacists had failed to give adequate advice to consumers at the point of sale. But rather than widening the type of retail outlets permitted to sell solutions, it thought that this indicated a need to emphasize to all opticians and pharmacists the importance of giving individual advice to contact lens wearers.

Vision Express

7.72. Vision Express, a multiple optician with 47 outlets in the UK, said that it was primarily engaged in the supply of spectacles. Contact lenses and associated solutions represented approximately 7 per cent of its turnover, with solutions accounting for less than 1 per cent. Vision Express stocked solutions because it believed that as a supplier and fitter of lenses it should provide everything its patients needed to maintain their lenses in good condition. In all aspects of its business it aimed to offer value for money and quality service.

7.73. Vision Express said that it was widely reported that more than 60 per cent of solutions sales were through pharmacies, rather than through optical outlets. It pointed out, however, that many of the problems associated with the wearing of contact lenses were induced by non-adherence to the disinfecting and cleansing regimes advised by optical practitioners. Ultimately it was the optical practitioner/contact lens fitter who was expected to diagnose and correct whatever problems arose. Vision Express said that practitioners sometimes found during routine after-care that patients had changed a solution regime to a cheaper alternative (obtained through a pharmacist) only to find that that regime was causing an adverse allergic reaction. An incorrect CLS system could cause ocular problems which might result in prolonged visual disturbances due to corneal tissue swelling and oedema. Vision Express said that it was for this reason that it would object to the wider availability of CLS through other retailers. A shop assistant in a general store without any optical, or even pharmaceutical, training could not be expected to advise correctly upon what was best when it came to inserting chemicals into the eye. The systems had to be efficacious in neutralizing and killing bacteria and Vision Express said that a degree of professional knowledge and expertise was accordingly a prerequisite to advising on their use.

Price competitiveness

7.74. Vision Express said that any claim that its products were disadvantageously priced to consumers was unfounded. On the contrary, it could keep its prices at lower levels than other retailers for a number of reasons. It entered into a forward contract with a manufacturer on a fixed price basis and was therefore able substantially to control price increases to consumers. This contract provided the manufacturer with a predictable production level which eliminated wastage and thus kept prices under control. Packaging and distribution costs were reduced and this also contained price levels. Vision Express offered the consumer 'packages' in the same way as other general retailers. For example, it had recently offered a third bottle of solution free with the first two purchased. It sold two- and four-month CLS packs and such combinations greatly reduced the cost compared with single item purchases. Vision Express had negotiated with the manufacturer of one popular CLS system a deal enabling it to sell a four-month pack for the same price as a three-month pack was sold in other outlets.

7.75. In conclusion, Vision Express said that from a commercial point of view it was not concerned at how widespread the availability of solutions became, through normal retailing channels. It was happy to compete with anybody. However, it was concerned about the problems which might arise from system misuse by patients when ill-advised by unqualified staff.

General Optical Council

7.76. The GOC is the statutory body responsible for safeguarding the public interest in all aspects of eye care, and the registering body for practising opticians. The GOC said that although solutions appeared expensive this was mainly due to the essential cost of the high standards of production and licensing controls. Many different types of lenses were available and it was important that the solutions used were both appropriate for the type of lens material and sterile. Solutions were more than simply healthcare products. Contaminated solutions could cause grave eye disorders and even loss of vision. Their proper use was critical to the ocular integrity and health of all contact lens wearers. The incidence of CLS-related medical problems was well documented. The clinical importance of solutions was highlighted by the fact that there had recently been a steady increase in the number of cases of microbial keratitis amongst contact lens wearers. It was a problem directly related to the efficacy of disinfecting systems in terms of their antimicrobial activity. The GOC commented as follows on the MMC's provisional findings.

Widening the range of retail outlets selling solutions

7.77. In the GOC's view the potential consequences of CLS-related problems were so grave that there should be no question of allowing their sale other than on premises where expert advice was available from registered opticians or pharmacists. The GOC accepted that, in order to reduce

CLS-related problems, steps should be taken urgently to ensure that opticians gave the best possible advice to patients on the use and care of lenses, and that they provided effective public information to convince patients of the importance of following this advice. It was the GOC's intention to ask the optical professional bodies to initiate such steps without delay.

Advice by opticians on costs of solutions

7.78. The GOC said that it was pleased to note from the MMC opticians survey that participating opticians followed correct professional practice and recommended disinfecting systems primarily on the basis of each patient's ocular health needs. The GOC believed that a more extensive survey would show that in this respect the best interests of the public in terms of ocular health were being served by current practice. It thought, nevertheless, that practitioners should take particular care to inform patients fully of the ongoing costs of solutions. Again, the GOC said that it would bring this matter to the attention of the optical professional bodies with a request that they should issue detailed guidance to their members on this matter.

7.79. The GOC said that it had noted the various comments made to the MMC about CLS pack sizes and the possibility that all the contents might not be used up by the end of the in-use period. The risks of not discarding the disinfecting solution on a daily basis could not be overemphasized. Where patients 'topped up' their solutions, their cases were invariably heavily contaminated with pathogenic micro-organisms. Lens cases should be emptied and cleaned every morning and left open and dry during the day.

British College of Optometrists

7.80. The BCO, which gave written evidence and attended a hearing, told us that it was the learned, professional and examining body for optometrists and that the objects laid down in its Memorandum of Association required it to work exclusively for the public benefit. It had 7,054 members, which accounted for 94 per cent of practising optometrists in the UK.

7.81. The BCO said that, in the public interest, it would be most concerned at any outcome of the MMC's inquiry which might result in a relaxation of the control on these products, in terms of their safety, quality and efficacy. The majority of solutions came into contact with the surface of the eye and in that sense were no different from any other 'eye drops'. The BCO said that specific products had to be used with specific lens materials and the use of unsuitable solutions could cause ocular complications, including eye infections.

7.82. In commenting on our provisional findings the BCO said that the practice of selling solutions at, or just below, RRP was a commercial decision and it was not within the BCO's remit to comment on that aspect. Responding to the MMC's provisional finding that practitioners did not take sufficient account of costs to wearers in recommending solutions, the BCO said that the effectiveness and efficacy of a particular disinfecting system was the optometrist's prime consideration in recommending that system, in order to minimize any risk to ocular integrity. Although cost was a lesser consideration, however, the optometrist should still make the ongoing costs absolutely clear to the patient. The BCO's Guidelines for Professional Conduct clearly stated that before patients were asked to commit themselves to being supplied with contact lenses, they must understand exactly what costs and fees would be involved, both initially and on a continuing basis.

7.83. The BCO said that there was known to be a steady increase in the incidence of microbial keratitis amongst contact lens wearers, and as a result the DoH had set up a working party to look at the use of extended wear lenses, including any possible connection with such infection. It also said that complications arising from daily wear lenses were frequently due to non-compliance with the recommended hygiene regime. One issue that the working party had already considered was how information might be given to patients, prior to lens fitting, and the implications of maintaining lenses in a safe condition both in terms of costs and time required. The working party was currently formulating several documents on this matter.

7.84. As to the current regulation of solutions, the BCO said that in the interests of public safety there should be no reduction in the standard of quality or the stringency of the licensing procedure. The BCO also took the view that solutions could safely be sold only through outlets such as optometric practices or pharmacies, where professional advice was available on their use and where the correct storage conditions could be ensured. Patients should be warned about changing brands of solution without professional advice. There were many instances of patients tolerating one brand of peroxide but not another. Again, although solutions might have identical active ingredients, they might vary in 'Ph' or tonicity and this information was not available in a comprehensible form to the average patient. There were even more cases of severe ocular reactions in patients who had changed from one preserved solution to another; patients could not be expected to understand the difference between, say, chlorhexidine and thiomersal.

Federation of Ophthalmic and Dispensing Opticians

7.85. FODO supplemented its written evidence at two hearings. It told us that it had just over 130 members who employed about 3,000 full-time opticians. About 40 per cent of total UK optical activities were carried out by practitioners employed by its members, who ranged from the large chains, eg D&A and Boots, to individual practitioners. FODO said that it did not tell its members how to run their businesses, nor did it issue any advice or recommendations with regard to the pricing of solutions.

7.86. FODO said that the highest possible standard in solutions was essential. It did not believe that the stringency of licensing requirements in the UK restricted the choice of solutions available to consumers, and thought it important that they were sold in premises where professional advice was available. It said that the complexity of the systems, and in particular the 'hassle' of using CLS, rather than the cost caused users not to comply with after-care regimes.

Complex monopoly

7.87. In responding to the MMC's provisional finding that an opticians complex monopoly situation existed, FODO said that, according to the ACLM, 40 per cent of solutions were sold through opticians and 60 per cent through pharmacies. On this basis, if a complex monopoly were to exist in respect of opticians, then two-thirds of all the reference goods supplied within the UK would have to be supplied by opticians engaging in one or other of the practices we had identified. FODO was unable to find any evidence that a complex monopoly existed. Moreover, the MMC had not, FODO said, identified all the opticians alleged to be part of the complex monopoly situation. FODO commented as follows on our provisional findings.

7.88. On the question of opticians giving little weight to the cost of solutions when recommending them to patients, FODO said that when opticians were advising on the type of solutions, the most important consideration was that they should be safe, effective and easy to use. Price should not be the overriding factor. The MMC survey of opticians had shown that almost one-third of opticians gave reasonable cost to the consumer as one of the most important reasons for recommending solutions. In FODO's view, this figure did not support the MMC's provisional finding that little weight was given to cost when advising patients. Practitioners had to take a balanced view of what was in the patient's best interests and the reasons given by opticians in the MMC's survey—'technically less likely to cause irritation to the eye', 'solution effectiveness' and 'easy to use'—all seemed to FODO to be vital considerations in a practitioner's balanced decision.

7.89. On the issue whether opticians gave information about the ongoing costs of solutions, FODO said that our opticians survey showed that 71 per cent of opticians had replied 'yes, always or nearly always' and 23 per cent had replied 'yes, mostly', making a total of 94 per cent who did give advice on the likely future monthly or annual costs of solutions. It believed that the discrepancy between this figure and the 71 per cent of consumers who said that they had not been told about the costs of solutions when first fitted with lenses was likely to be due to consumers having forgotten that this advice had been given, rather than to lack of advice. It pointed out that the sample covered patients who had been fitted with lenses over a period of 16 years, 70 per cent of them over four years ago. It was

significant that almost half of those who had had lenses fitted in the previous year did remember that the optician had discussed the cost of solutions. When obtaining lenses they would have had to absorb a considerable amount of information about handling, cleaning and wearing lenses. FODO added that the introduction of contact lens replacement schemes over recent years, many of which included the supply of solutions, would themselves provide patients with full details of the annual cost of being a contact lens wearer. FODO said that it was in favour of opticians giving patients the fullest possible information on all aspects of optical services, including the costs of lenses and solutions.

7.90. Turning to RRPs, FODO said that the MMC survey had shown that over 40 per cent of opticians were giving discounts below RRP to all comers—ie including consumers not in specific discount schemes. Almost half of all opticians selling lenses gave discounts under their own lens discount schemes. FODO did not regard 15 per cent discount as insignificant in relation to the margin on these products. It thought that this evidence did not support the MMC's provisional finding of a complex monopoly situation with respect to the RRP.

7.91. There was a low margin on CLS sales even for those opticians who sold at manufacturers' RRP. Nevertheless, solutions significantly contributed to opticians' profitability. Any reduction in their supply through opticians would be likely to cause financial difficulties and could lead to the closure of some outlets. As contact lens business became less profitable, this reduction in outlets could be compounded by fewer opticians offering a full contact lens service.

Widening the range of retail outlets selling solutions

7.92. FODO thought that any widening of the range of retail outlets could be disadvantageous to consumers. It could reduce the range of products and the overall number of outlets because new entrants would be likely to concentrate only on fast-moving lines. With loss of sales to new outlets, some existing outlets would find it no longer economic to stock a range of CLS which had a limited shelf life. Consumers would have to make decisions about changing brands without the benefit of professional advice. The majority of eye problems found during routine after-care examinations were solution- rather than lens-related. Patients might experience difficulties by using less effective, unsuitable or incompatible solutions and this could result in considerable 'costs' in terms of time, inconvenience and discomfort. Therefore FODO believed that it would be detrimental to patients and against the public interest to widen the range of retail outlets.

Association of Optometrists

7.93. AOp gave written evidence and attended a hearing. It told us that it had about 5,000 members, representing 90 per cent of practising optometrists and a small number of dispensing opticians. AOp said that there were already cases of consumers using the wrong types of solution, eg hydrogen peroxide as a soft lens soaking solution. It thought that these mistakes could be due to deficiencies in supervision at point of sale, particularly in pharmacies, and emphasized how important it was that solutions were only sold where advice as to their proper use could be given. AOp was therefore against extending their sale beyond pharmacies or opticians.

7.94. In responding to our provisional findings that retailers sold solutions at, or only just below, RRP, AOp said that most sole optical practitioners sold at or just below RRP because the volume of their sales, coupled with the low profit margins, made any other course of action economically unviable. AOp found it difficult to see how this provisional monopoly finding existed in favour of opticians. The price of solutions to consumers was determined by external factors, not by the way in which opticians conducted their businesses.

7.95. AOp thought that, in finding that an opticians monopoly situation existed, the MMC had not taken account of the clinical and professional judgment which was essential in recommending solutions. On the other hand, AOp said, the MMC opticians survey had shown that 30 per cent of respondents saw cost as one of the most significant factors in recommending solutions.

7.96. AOp noted that the opticians survey had indicated the almost universal view of practitioners that they gave sufficient information to patients about costs. It also noted that the majority of participants in the consumers survey had little recollection of being given information on costs. AOp said that, although it believed that most practitioners conscientiously informed their patients of the ongoing cost of wearing contact lenses, it would be drawing the MMC's finding to its members' attention, and advising them again to make certain, perhaps by means of written information to patients, that their patients understood the likely overall annual cost of solutions.

Association of British Dispensing Opticians

7.97. ABDO gave written evidence and attended a hearing. It told us that it had a membership of about 3,500 dispensing opticians in practices throughout the UK. About 1,000 of these were qualified to fit contact lenses. ABDO supported the current control of solutions in the UK and expressed concern at the possibility of their becoming more widely available at retail level. It had consistently emphasized that the lack of professional advice available at point of sale would increase the risk to consumers.

7.98. ABDO was concerned that the MMC's provisional findings had focused on what it considered to be the relatively minor issue of price. Although costs were important, the optician's main concern was that patients bought the solutions most appropriate for them, even if they were not the least expensive available. Patients should be given a good indication of the costs at an early stage. Whilst there might be some who complained that they were not told, there were many others who were content. Two million lenses were sold to thousands of wearers every year and with the lenses came a large quantity of solutions. The MMC consumer survey had indicated that about 4 per cent of those surveyed had complained that solutions were too expensive which would indicate that 96 per cent were content with the costs. Nevertheless ABDO said that it welcomed lower prices, provided the quality was maintained.

7.99. ABDO confirmed that most of its members sold solutions at manufacturers' recommended prices. Profit margins on solutions were small and there was therefore little point in selling them for less than the RRP. It did not believe that this prevented, restricted or distorted competition. Whatever the RRP, solutions would be sold at about the present price level. If the RRPs were higher, more discounts would be available and a wider spread of prices would result. ABDO's members had indicated that the present RRPs gave little scope for discounting.

7.100. ABDO said that provided standards were maintained it would welcome a reduction in the costs of licensing and, possibly, a lowering of the licensing category. Savings could then be passed on to consumers and this might lead to better compliance with after-care procedures. ABDO conjectured that, whilst wider availability of solutions might induce a slight price change, it would increase complications caused by inappropriate use by consumers. Recent press reports concerning non-compliance with after-care procedures appeared to argue for tighter controls, rather than a relaxation.

Federation of Independent British Optometrists

7.101. The Federation of Independent British Optometrists (FIBO) is a federation for groups which hold similar views with regard to the advancement of the optometric profession in a clinical direction for the public benefit.

7.102. Commenting on the MMC's provisional finding that opticians did not give sufficient weight to the cost of solutions when recommending after-care for patients, FIBO said that the decision as to which solutions would be prescribed was dependent on the clinical assessment of each particular case and, to a certain extent, on the practitioner's own experience. It was difficult to predict accurately the cost of care for a particular patient, as patients' usage varied as did their adherence to the discard dates; patients also sometimes needed to switch solutions on the advice of their practitioner once they were using contact lenses.

7.103. FIBO said that the use of appropriate solutions and the maintenance of their high standard was very important to the successful and safe use of contact lenses. It had no evidence to suggest that independent optometric practices charged more for solutions than other suppliers.

Bowden & Lowe

7.104. Mr Bowden, of Bowden & Lowe, an independent optician in South-East England, said that he took time to ensure that his patients understood the uses and limitations of their selected lens type and the purpose of the type of care system he had recommended. He said that at subsequent appointments he would check and reinforce patients' compliance with the use of both lenses and solutions. This minimized the risk to the patient. In his experience, compliance was much better in the care of disposable lenses where either a very simple system was necessary or solutions could be dispensed with altogether. Mr Bowden said that it was essential, when suggesting an alternative solution, that it was compatible was with the lens type and the patient, and that the patient understood the system. He supported the current basis on which CLS were sold at retail level, ie that professional advice was available.

Pharmacists

Royal Pharmaceutical Society of Great Britain

7.105. The RPSGB, which gave written evidence and attended a hearing, told us that it had about 38,500 members, of whom about 34,500 were resident in Great Britain.

7.106. The RPSGB told us that the questions that pharmacists were asked about contact lenses fell into two main categories. The first related to the solutions which could be used with contact lenses and the most common enquiry was whether it was safe to switch from one brand of solution (cleaner/disinfectant or rinse/neutralizer) to another. Here, pharmacists were reluctant to offer advice which might contradict that given by the optician who had supplied the lenses. The RPSGB said that pharmacists would, however, be keen to provide advice if the necessary information were available to them. They were used to dealing with requests for advice on alternatives to specific medicinal products and were able to give that advice because they had the required information. The RPSGB said that it would, therefore, support wholeheartedly a proposal that much more information about solutions should be made available to pharmacists to enable them to offer sound advice to consumers.

7.107. The second main area on which pharmacists were asked for advice related to whether it was safe or appropriate to take or use specific medicines while wearing contact lenses. Pharmacists, from their own knowledge or from relevant reference sources held in the pharmacy, were able to provide that advice.

7.108. The RPSGB said that these comments were borne out by the MMC's survey of pharmacists. It was clear also from the results of that survey that pharmacists were regularly asked for advice about soreness or other problems with the eyes when either the contact lenses themselves or solutions used in association with the lenses appeared to be causing problems.

7.109. The RPSGB said it had noticed that in the MMC's consumer survey a much more limited question had been included, and that it was reported that 90 per cent of the sample had never asked a pharmacist for advice about solutions. The RPSGB said that these consumers had apparently not been asked about whether they had sought advice from a pharmacist about soreness of the eyes which might be associated in some way with the wearing of contact lenses, or advice about taking or using medicines while wearing contact lenses.

7.110. Nevertheless, the MMC's surveys had confirmed that advice was sought from pharmacists and although the incidence of consultation might be relatively low, the potential harm which could result from inappropriate use of lenses or solutions was considerable. The RPSGB therefore believed that it was important that informed advice should be available at outlets where solutions were sold. The fact that advice was not required on every occasion, or even on most occasions when solutions were purchased did not of itself support a decision to widen distribution. The RPSGB noted that when

the CDSM had been consulted in 1981 and again in 1986, its expert opinion was that professional advice should be available at the point of sale of solutions.

7.111. Another strong reason for limiting distribution was to ensure that there were effective recall procedures in the event of a defect being found in any product or any batch of products. In the RPSGB's experience, where a product was in wide circulation, recall procedures were relatively ineffective. The RPSGB thought that the Yellow Card Scheme for reporting adverse reactions to lenses or care products should be extended to pharmacies.

7.112. The RPSGB said it had noted that over 60 per cent of those participating in the MMC's consumer survey had said that they did not find it inconvenient that they could not buy solutions in a wider variety of retail outlets. A decision to require a widening of distribution would therefore not be justified on the grounds of public demand or convenience. On the other hand, for the reasons set out above, there were sound grounds for limiting the distribution of solutions to pharmacies and opticians.

7.113. Consumer organizations in the USA had expressed concern that some medicines were available for sale in outlets where no professional advice was available and had lobbied the US Congress for the introduction of an intermediate category of medicines to be available only from pharmacies.

7.114. The main concern of the MMC, the RPSGB said, appeared to relate to the fact that most pharmacies and opticians sold solutions at or about the manufacturers' RRP. The RPSGB submitted that if more information were available to pharmacists about the interchangeability of solutions, this, of itself, would create competition among various brands and would lead to more price competition and promotions, either manufacturer-led or at the retail level. The present situation under which contact lens wearers were unable to change brands, mainly because of the lack of adequate information about interchangeability, was bound to stifle competition.

7.115. In conclusion, the RPSGB urged the MMC to keep the question of safety for the contact lens user as the first priority in any decision on action to be recommended. The present distribution presented no inconvenience to the public, it provided an assurance that advice was available if needed wherever the solutions were purchased, and it offered a guarantee of effective withdrawal from the market of any batch of product should this be necessary.

Pharmaceutical Society of Northern Ireland

7.116. The Pharmaceutical Society of Northern Ireland (PSNI) said that consumers buying solutions frequently needed advice on which solutions to choose and on their use, as they did with medicines. Retailers of solutions should therefore be able to offer this advice and deal with queries on any eye problems associated with lenses or solutions that might have arisen. Pharmacists and opticians were able to give this service. As healthcare advisers, pharmacists were the first call for many people suffering from minor ailments, and pharmacists frequently referred patients with eye problems to their optical or general practitioners. The PSNI said that restricting distribution to opticians and pharmacies also ensured that, if necessary, faulty solutions could be recalled; an effective system of recall could only operate where the distributors could be identified. The PSNI believed that the present method of distribution ensured a more than adequate availability of choice of solutions to the public. The efficient wholesale supply arrangements enjoyed by pharmacists enabled them to obtain any solution not held in stock within 24 hours.

National Pharmaceutical Association

7.117. The NPA told us that it represented the vast majority of community pharmacies—ie about 10,000—in the UK. BTC and Lloyds were not members; between them they owned rather fewer than 2,000 pharmacies. The NPA thought that the supply of solutions should be restricted to pharmacies and opticians who were able to offer advice on the choice of product, correct usage and any associated eye problems. The NPA said that there was a sufficient number of pharmacies and at least one

optician in most towns and the range of outlets selling solutions did not need to be widened on the grounds of consumer convenience.

7.118. The NPA noted that the MMC's survey of pharmacists had shown that the average pharmacy received between 14 and 47 queries about solutions every year. That indicated that between 150,000 and 500,000 customers were able to obtain advice that would not easily be available to them if CLS were available through non-professional bodies. Very often, the advice sought related not to the use of solutions but to the use of other eye preparations, including prescription eye drops and systemic medicines, by contact lens wearers. Solutions were not, in the NPA's view, ordinary items of commerce and contact lens wearers needed to be aware that care of their lenses and of their eyes often necessitated advice from healthcare professionals.

7.119. We invited the NPA to comment on our provisional finding that most pharmacists sold solutions at, or only just below, RRP. The NPA said that informal soundings of its members had indicated that the maintenance of RRP existed for two reasons:

(a) some pharmacists thought that because solutions were licensed products they were proprietary medicines and hence subject to resale price maintenance; and

(b) because of the relatively high professional input in supplying advice with these products, NPA members felt that selling solutions at RRP ensured that the time spent providing professional advice was, at least to some extent, financially rewarded.

7.120. The NPA said that if the existing controls on outlets were removed, although wider distribution might reduce prices, customers would ultimately be disadvantaged because of the lack of availability of professional advice. It was not enough to hope that if consumers were professionally advised when lenses were fitted then future supplies could be purchased from other outlets. Opticians often stocked a limited range of solutions and many consumers would not have sufficient knowledge to purchase equivalent products made by other manufacturers. The NPA said that it provided to its members, on request, information leaflets detailing products available through pharmacies to enable pharmacists to give advice to customers wishing to change brands.

College of Pharmacy Practice

7.121. The College of Pharmacy Practice said that it was a registered charity concerned with post-qualification education, practice research in the profession and the setting of practice standards. Membership was by examination and was open to individual practising pharmacists. It was the College's view that solutions should be manufactured to the highest hygienic and microbiological standards and that to achieve this the products must continue to be licensed under the Medicines Act. The College said that the public should be given access to professional advice where this was necessary and desirable and this advice was not available in outlets where staff did not have the required professional qualifications and experience.

7.122. The College supported competition in the sale of solutions, provided the outlets where they were sold achieved and demonstrated the required standards of service. It also supported price competition where appropriate. It believed that in the interest of public health, solutions should only be sold in pharmacies and opticians where professional advice was available.

Company Chemists' Association

7.123. The Company Chemists' Association Limited (CCA) said that it represented those companies which operated a significant number of retail pharmacies in the UK, including all the major chains. Between them the CCA members operated over 2,000 community pharmacies (approximately one-fifth of the national total).

7.124. In commenting on our provisional findings, the CCA said that most, if not all, of its members tended to sell solutions at, or just below, RRP, although there was no agreement between

them to do so. However, the CCA rejected the suggestion that this practice prevented, restricted or distorted competition. All retailers of solutions were free to compete on price and many did so.

7.125. Price was only one element of competition in the sale of solutions. The fact that many retailers sold them at or close to the RRP was not in itself an anti-competitive practice, but evidence of the fact that, in the sale of solutions by pharmacies, price was not the major method of competition between retailers. Whilst consumers expected value for money in the products they purchased from pharmacies, pharmacies competed on product ranges and service, as well as price. Competition on price did exist in the sale of solutions; this was both intra-brand and between retailers. Customers sought value for money but, in the CCA's view, other elements of competition, particularly service and the provision of advice, were more important to customers than price.

7.126. The CCA said that nearly all its members supported the present system of licensing solutions and believed that an extension of availability to outlets where professional advice was not available would not be in the public interest. The CCA understood that the MMC had heard extensive evidence on the medical problems that could result from incorrect use of solutions; those problems justified the current restrictions on outlets.

Lloyds Chemists

7.127. Lloyds told us that it sold solutions in all its pharmacies and eyecare centres, which together accounted for about 900 outlets. It had started to sell CLS in 1972 in order to meet consumer demand and was now considering selling own-label solutions. Lloyds said that all its pharmacies were staffed by a pharmacist manager, a senior assistant and sufficient staff to ensure adequate provision of pharmaceutical services. The pharmacist manager was responsible for monitoring and supervising all questions from the public and advice sought on medical matters. Pharmacists would automatically intervene if they thought that a question directed at a member of staff required answering by a pharmacist.

7.128. In responding to our provisional findings, Lloyds said that in its view the current restriction on retail outlets should remain in place. Opticians and pharmacies were able to assist with care and maintenance questions and recognize potential eye health problems, and Lloyds thought that this professional advice at point of sale was essential so far as solutions were concerned. If the MMC were to take a different view, then any alternative retail arrangements should operate within a regulatory framework which ensured that trained assistance was given at point of sale and consumers were not encouraged to use excessive amounts or inappropriate types of CLS.

7.129. Lloyds said that there was no monopoly situation in the supply of CLS, nor were any uncompetitive practices undertaken. If there was a monopoly situation, it did not work in Lloyds' favour. Lloyds said that it sold solutions at or near RRP but there was no co-ordinated action with other retailers. Lloyds treated CLS as medical products and consequently they were not price-promoted. Price-cutting would encourage excessive use of solutions and although this might be in the interest of retailers and manufacturers it would not be in the interest of consumers. Lloyds thought that availability of solutions was more important than price, and it stocked a range of solutions as a service to its customers. Other retailers, notably opticians' chains, operated promotional plans which kept potential customers away from Lloyds' stores by operating customer-loyalty schemes. It said that if price was the main consideration such retailers would have captured all the business long ago and other retailers, such as Lloyds, would have been forced to stop stocking solutions.

Wholesalers

7.130. Details of our survey of optical wholesalers are given in Appendix 3.6. The views of two of the largest solutions wholesalers are summarized here.

Martin Optical

7.131. Martin, which gave written evidence, said that its main customers were opticians. Its only other sales, which accounted for about 1 per cent of its business, were to hospital pharmacies. Martin stocked the full range of all the major suppliers' solutions. It thought that the solutions market was very competitive at every level and saw solutions wholesalers and suppliers as its main rivals. In response to competitive pressures within the last five years, Martin had introduced a next-day delivery service to all customers and had lowered its threshold on solutions qualifying for discounts. Martin said that margins were low on solutions and a wholesaler had to generate a considerable turnover for its business to be viable. It considered this to be a barrier to entry to new wholesalers but did not think that there were any barriers to existing solutions wholesalers who wished to expand their business.

7.132. With the exception of aerosol salines which might safely be made available from any retailer, Martin thought that the sale of solutions should not be extended to other outlets. The diversity of systems and their potential for misuse made it essential that they should be sold only where professional advice was available. Prices of solutions were likely to fall if they were sold through supermarkets, as this would encourage manufacturers to offer increased discounts in order to maintain their market shares. As supermarkets could handle volume goods more efficiently than other retail outlets they would be able to pass these on to customers. Conversely, small retail outlets did not have the efficiency or the buying power of major chains and would be less likely to reduce retail prices.

Mid-Optic

7.133. Mid-Optic, a family business, gave written evidence and attended a hearing. It said that it delivered to the whole of the UK, concentrating its supplies almost wholly on opticians, with only 8 per cent of its business directed towards pharmacies. It could supply the complete range of solutions for all suppliers apart from Sauflon. Mid-Optic said that, as a general rule, the main customers of CLS wholesalers were opticians whilst pharmaceutical wholesalers' main customers were pharmacists, and it accordingly competed against other wholesalers of solutions and not pharmaceutical wholesalers. Mid-Optic told us that Sauflon and B&L had asked it to stop selling their solutions to pharmacies. It said that the number of CLS wholesalers had fallen from 40 in 1980 to 10 in 1993.

7.134. Mid-Optic said that until 1987 the standard discounts given by most suppliers had been 25 per cent off the trade price to solutions wholesalers, and 15 per cent off the trade price to pharmaceutical wholesalers. Larger discounts were granted by some suppliers. In March 1987, on the same day, some of the leading four suppliers had changed their discount policies and had reduced the discounts to solutions wholesalers from 25 to 15 per cent, making Mid-Optic's discounts the same as those given to pharmaceutical wholesalers. Mid-Optic was unable to compete with manufacturers which were now encouraging opticians to order direct from them. Mid-Optic felt that, to promote fair competition, manufacturers should offer discounts according to the size of the purchase by the optical wholesaler, pharmaceutical wholesaler or optician.

7.135. Mid-Optic said that both the retail price list and the trade price list were set by the manufacturers and Mid-Optic's price list was compiled from these two lists. Mid-Optic did not think that solutions should be sold in supermarkets or drug-stores because professional guidance was not available in those premises.

8 Conclusions

8.1. This chapter includes the following sections:

Paragraph

Background 8.2
The monopoly situations 8.28
The operation of the market 8.98
Public interest issues 8.127
Allergan scale monopoly situation 8.128
CIBA Vision (UK) scale monopoly situation 8.153
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Background

8.2. Our terms of reference (see Appendix 1.1) require us to investigate and report whether a monopoly situation exists in relation to the supply within the UK of contact lens solutions (CLS). If we find that such a monopoly situation does exist, various other questions then follow.

8.3. In his press release announcing the setting up of the inquiry the Director General of Fair Trading said that the reference had been 'prompted primarily by concerns that suppliers of CLS may be enjoying high rates of return, suggesting that price competition in this market is not as effective as it might be'. The reference, however, covers all levels of supply: manufacturers and importers (whom we refer to as 'suppliers'), wholesalers and retailers.

The products

8.4. Contact lenses need to be kept in good condition in order to maintain quality of vision and comfort and avoid the risk of ocular infection. CLS achieve these aims by cleaning the lens, preventing the accumulation of deposits on its surface and keeping it free from contamination. Depending on lens type (see paragraphs 2.1 to 2.8), solutions are needed for the following functions:

- surfactant cleaning, which involves physical rubbing of the lens to remove surface deposits;
- disinfecting, by means of immersing the lens in solution for a specified period;
- neutralizing: some disinfectants require neutralizing as a separate step before the lens can be used again;
- rinsing: typically a saline solution is used to rinse off the lens after surfactant cleaning;

— soaking/storage: lenses are kept immersed while not in use in order to keep them disinfected and, in the case of soft lenses, to prevent dehydration (in most cases the disinfecting or neutralizing solution is also used as the storage medium);

— wetting and comfort: solutions used mainly with hard lenses to aid insertion and lubricate the lens during wear; and

— the periodic removal of protein deposits, particularly from soft lenses, by means of specialist cleaners, also known as protein removers.

8.5. Among disinfectants, the largest category by value, there are three distinct types:

— traditional cold chemical disinfectants, consisting of a single disinfecting/soaking solution which contains preservatives in order to perform the disinfection function and to keep the solution itself free from contamination;

— hydrogen peroxide products, used mostly for soft lenses, consisting of a disinfecting solution and a neutralizing solution; and

— chlorine disinfectants, which require a chlorine disinfectant tablet to be dissolved in saline solution.

Peroxide and chlorine systems, which are also referred to collectively as oxidatives, are preservative-free.

8.6. Solutions are generally marketed as parts of lens care systems, consisting of a range of products required to perform the various functions described above. Particular systems are intended primarily for use with either hard or soft lenses but this separation is not total: some products can be used for both hard and soft lenses while others cannot. Moreover even among products designed for, say, soft lenses, some products from one system can be interchanged with products from another system but some cannot. These and other factors limit the extent to which consumers can switch between products and create a need for information, sometimes involving professional advice, on the opportunities for and implications of doing so.

The regulatory framework

8.7. The incidence of eye infections among contact lens wearers in the UK prompted the Government to commission a study in the mid-1970s into the effectiveness of the CLS then on the market. A high proportion were found to be unsatisfactory and the Government decided to bring CLS within regulatory control under the Medicines Act 1968. With effect from 1983, suppliers were required to hold a product licence before a CLS product could be marketed in the UK. Licensing is also applied to the importation, manufacture and wholesaling of solutions. In addition, product licences for CLS are not granted unless the applicant specifies that the retail distribution of the product will be restricted to opticians and/or pharmacists so that professional advice can be available at the point of sale. The Medicines Control Agency (MCA) of the Department of Health is responsible for administering the regulations with the advice of the Committee on Dental and Surgical Materials (CDSM) consisting of independent experts. The MCA is required by the Medicines Act to determine applications for product licences on the basis of the quality, safety and efficacy of the products in relation to their intended purpose.

8.8. Health Ministers have also issued specific regulations governing the labelling of solutions and the information which must be given to opticians and pharmacists on such matters as the product's active ingredients and its compatibility with different types of lenses. Among other provisions these regulations require that labels should state the recommended period within which the solution should be used once the container has been opened. The MCA's guidelines for applicants state that 'the container of a product intended for use on more than one occasion shall normally be sufficient for not more than 28 days' use' (see paragraph 2.35). Labels must also carry a warning in capital letters: 'Do not mix with other fluids except as directed'.

8.9. Near the end of our inquiry the Council of Ministers of the EC adopted a Directive on Medical Devices which will govern the regulation of the vast majority of CLS (among many other products) in the future: see paragraphs 2.36 to 2.42. The UK authorities will have to decide the precise means of implementing the Directive with respect to CLS within the framework which the Directive has established. There will be a choice of routes for suppliers to satisfy a 'notified body'—which each member state will be entitled to nominate—that they conform to the essential requirements laid down in the Directive. This system will replace the present MCA product licensing requirements. Specific standards for CLS have yet to be agreed among the EC member states but the end result will be that once a product has gained the approval of a notified body it can be sold anywhere in the EC. The Directive's provisions take effect in January 1995 but may be implemented by member states at any time between then and 1998. Assuming standards for CLS are agreed by January 1995, companies wishing to market solutions in the UK may then choose whether to follow the existing Medicines Act procedures or—as soon as notified bodies are set up in any member state—to opt for one of the routes laid down under the Directive. Meanwhile, however, we have to address the situation as it exists under present UK regulations.

The role of opticians and pharmacists

8.10. Opticians crucially affect the CLS market because of their role in promoting, prescribing and fitting contact lenses and in recommending lens care systems to consumers. At the first lens fitting opticians normally demonstrate the use of solutions and give customers a free pack consisting of small quantities of the care system they recommend (the 'starter pack'), sufficient for perhaps two weeks' use. The customer returns for a further consultation at the end of that period. If all is well the optician confirms the recommendation of a care system and the customer thereafter purchases the necessary solutions. Allergan Limited (Allergan), the leading supplier of CLS in the UK, told us that typically the optician's recommendation as to which solutions should be used was followed by the wearer throughout the life of the lenses (though our survey of consumers showed a significant degree of switching). Because of the importance of this role in recommending CLS, the suppliers concentrate their marketing efforts on opticians.

8.11. In considering how products are sold it is instructive to compare solutions with prescription drugs. In both cases the person who chooses the product is generally not the user but the professional adviser, although in the case of solutions it is the user who pays. But whereas doctors prescribe but do not (with minor exceptions) sell drugs, opticians both recommend and sell solutions and therefore have both a professional and a commercial interest in the products.

8.12. Solutions are also sold through pharmacies. The MCA, on the advice of the CDSM, permits this on the grounds that pharmacists are expected to be able to advise customers as necessary about the solutions they may wish to buy, or at least recommend that customers seek the advice of their optician. Pharmacists should also be able to answer questions, for example, about the compatibility of solutions with any medicines which the customer might be taking.

8.13. Both opticians and pharmacists are subject to specific systems of regulation as described in Chapter 2. In particular the British College of Optometrists has issued guidelines on contact lens practice (see paragraphs 2.50 to 2.53).

Users

8.14. It is estimated that there are currently over 2 million contact lens wearers in the UK, about 4 per cent of the population. The proportion of lens wearers is greater among women than men and much greater among people under the age of 45. Lens wearers also tend to come from the higher socio-economic groups.

8.15. The annual costs of CLS to wearers vary considerably depending on the type of lens and the particular care system adopted. A comparison of systems for soft lenses—comprising surfactant cleaner, saline and disinfectant—shows that a system based on a cold chemical disinfectant costs around £120 a year, a system based on chlorine tablets around £140 a year, and one based on a

peroxide disinfectant around £170 a year (assuming the purchase of monthly pack sizes and full compliance with the instructions). Protein removal would add some £35 to the annual costs in each case. On the same basis a cold chemical system for hard lenses costs around £110. Protein removal is less likely to be necessary for hard lens wearers.

8.16. There is evidence indicating that a sizeable proportion of lens wearers fail to comply properly with lens care regimes. Many wearers use solutions after the date by which they should be discarded, do not clean their lenses every time they use them, or do not always use fresh solution. These failings in compliance appear to be due to a variety of reasons, notably inertia, lack of time, lack of understanding and unwillingness to bear the full costs of proper lens care. Some wearers seem not to experience any ill effects as a result of their non-compliance but others suffer adverse consequences ranging from irritation and discomfort to serious eye infections in a small proportion of cases, even loss of sight at the extreme.

The market and its definition

8.17. The main suppliers of CLS in the UK are as follows:

(a) Allergan, which is owned by a US company Allergan Inc and obtains most of its solutions from a sister company, Allergan Pharmaceuticals (Ireland) Limited Inc (API) which manufactures in Ireland;

(b) CIBA Vision (UK) Ltd (CV-UK), which is part of the CIBA Vision division (CIBA Vision) of the Swiss company CIBA-GEIGY AG (CIBA-GEIGY) and sources most of its solutions from a fellow UK subsidiary CIBA Vision Lens Care Production Ltd (CVLCP) which has a new factory at Macclesfield; we use the name 'CIBA Vision' to refer to CV-UK and CVLCP together, or to the CIBA Vision division as a whole, according to the context;

(c) Alcon Laboratories (UK) Ltd (Alcon), part of the US-based Alcon group but ultimately owned by Nestlé SA of Switzerland;

(d) Bausch & Lomb UK Limited (B&L) together with its subsidiary Madden & Layman Ltd (M&L), both owned by a US company Bausch & Lomb Inc;

(e) Sauflon Pharmaceuticals Ltd (Sauflon), a small independent UK company;

(f) Smith & Nephew Pharmaceuticals Ltd (S&NP), a subsidiary of the UK company Smith & Nephew plc; and

(g) Pilkington Barnes-Hind Limited (PBH), a subsidiary of the UK company Pilkington plc.

8.18. The estimated total value of CLS sales by suppliers in 1992 was £50 million, of which disinfectants represented about 61 per cent, salines 13 per cent, surfactant cleaners 12 per cent, protein removers 8 per cent and other products 6 per cent (see Table 3.2). Suppliers' estimated shares of this overall CLS market were as follows:

TABLE 8.1 **Suppliers' shares of the total CLS market, 1992**

	%
Allergan	38
CV-UK	34
Alcon	9
B&L/M&L	8
Sauflon	6
S&NP	2
PBH	1
Others	2

Source: MMC, based on data provided by the suppliers.

8.19. As explained in Chapter 3 (paragraphs 3.40 to 3.50), there are differences of view about the definition of the market for the purposes of economic analysis. CIBA Vision argued that CLS were part of a wider market in sterile ophthalmic solutions. Allergan said that it saw CLS as part of a market for vision products, which included spectacles, and that there were close associations on the supply side between CLS and ophthalmic pharmaceuticals.

8.20. In our view there are barriers to entry, resulting in particular from the operation of the regulatory controls (see paragraphs 8.115 to 8.126), which prevent companies which do not currently supply CLS, albeit they may have expertise in other ophthalmic products, from posing a credible threat to the existing suppliers. As to 'vision products', there may be some consumers who choose between wearing spectacles and contact lenses because of the cost of solutions, but the weight of evidence we received was that any such trade-off was marginal. A further possibility is to see lenses and solutions together as a single market since there is a range of lenses available varying in their requirements for solutions and including, in particular, disposable lenses which may occasion little use of solutions. However, the use of disposable lenses is very limited at present (though we consider in paragraph 8.100 their likely impact on the CLS market in future), and most recommendations made by opticians involve a combination of lenses with a range of solutions. We do not therefore consider that the market should be defined more widely than solutions alone.

8.21. Indeed, there is a case for considering solutions as divisible into four product markets, namely surfactant cleaners, disinfectants, salines, and protein removers. Most solutions can be allocated to one of those four categories, and for the majority of wearers the uses of the solutions in these categories are distinct. In other words, the extent to which the consumer can substitute a product from one of these categories by a product from another category is for the most part severely limited. Moreover, although the production facilities required may often be similar, the absence of appropriate product licences may well impede 'supply side substitution'. The argument for looking at different product markets is clearest in the case of protein removers, where a consumer needing to remove protein deposits has a choice only among the products made specifically for that purpose.

8.22. At the same time, there is a case also for thinking of CLS as representing a single market. Some products can be used for more than one function; in particular, some products are designed to serve as both disinfectants and cleaners, and salines are not only used for rinsing, but are also necessary for dissolving chlorine tablets (ie in the disinfection process) and protein removal tablets. Furthermore, a consumer will require products for the various stages of the treatment of lenses—which in turn results in solutions being sold as part of systems.

8.23. We have adopted both the approaches described in paragraphs 8.21 and 8.22 although for the most part we take solutions as a single market.

8.24. We consider that the UK is, at present, a separate market for solutions because the regulatory system causes the range of products which are on offer in this country to be significantly different from that in most other markets and presents a barrier to entry both for new suppliers and new products.

8.25. The suppliers' shares of the four product markets identified in paragraph 8.21 and the two sectors of the disinfectant market (oxidatives and cold chemical) are shown in Tables 3.3 to 3.8. Among the main features are the all-round strength of Allergan, its very high share in protein removers, and the dominance of the oxidative sector by CV-UK and Allergan.

8.26. Table 3.11 shows the breakdown of suppliers' sales to wholesalers and retailers. In 1992 34 per cent of suppliers' sales in aggregate went direct to opticians other than the Dollond & Aitchison Group plc (D&A) and Boots Opticians Ltd (BOL), the two biggest optician chains; 28 per cent to Boots, including supplies both for BOL and Boots' pharmacies which are operated by Boots The Chemists Ltd (BTC); 13 per cent to optical wholesalers; 11 per cent to D&A; 10 per cent to pharmaceutical wholesalers; and 4 per cent to others such as individual pharmacists and buying groups. At retail level we estimate that just under 60 per cent of CLS are sold by opticians and just over 40 per cent by pharmacists, measured by value at retail prices. Boots alone has about 36 per cent

of the total, made up of 31 per cent through BTC and 5 per cent through BOL.[1] (We use the name 'Boots' to refer to the Boots group as a whole or to BTC and BOL together, according to the context.)

8.27. Some of the leading retailers, notably Boots, D&A and Specsavers Optical Group Ltd (Specsavers, a group of franchised opticians outlets), sell CLS under their own labels, most of them sourced from the leading suppliers listed in paragraph 8.17. In 1992 own-label sales (which are included in the figures given in Table 8.1 and in paragraph 8.26) accounted for around 17 per cent of suppliers' sales and between 20 and 25 per cent of total sales at retail prices.

The monopoly situations

8.28. Our terms of reference (Appendix 1.1) require us to investigate and report on whether a monopoly situation exists in relation to the supply within the UK of CLS, and if so by virtue of which provisions of sections 6 to 8 of the Fair Trading Act 1973 (the Act) the monopoly situation may be taken to exist, and in whose favour the situation exists. As noted in paragraph 8.3, the terms of reference do not specify any particular level of supply (manufacture/import, wholesale, retail): we have therefore investigated the possible existence of monopoly situations at each level.

8.29. Section 6 of the Act deals with monopoly situations in the supply of goods and is therefore the relevant section for our inquiry (section 7 deals with services and section 8 with exports). It envisages two different kinds of monopoly situation, usually referred to as 'scale' and 'complex'.

Findings on scale monopoly situations

Suppliers

8.30. A scale monopoly situation under section 6(1)*(a)* or *(b)* is taken to exist when at least one-quarter of all the goods of a particular description which are supplied in the UK are supplied by or to the same person, or by or to members of the same group of interconnected bodies corporate. Table 3.9 shows that in 1992 Allergan accounted for 38 per cent and CV-UK for 34 per cent of the CLS sold by suppliers, measured by value at suppliers' realized prices, to wholesalers and retailers in the UK. The supply data for 1992 are estimates but the position was not substantially different in 1991, when Allergan's share was 39 per cent and CV-UK's was 32 per cent. In October 1992 we informed Allergan and CV-UK, separately, of our provisional findings that scale monopoly situations existed in that they each supplied at least one-quarter of the reference goods supplied in the UK. Each company told us it agreed, or had no reason to doubt, that the provisional finding made in respect of it was correct.

8.31. We conclude:

(a) that a monopoly situation exists by virtue of section 6(1)*(a)* of the Act (a scale monopoly) in that Allergan supplies at least one-quarter of the CLS which are supplied in the UK; and

(b) that a monopoly situation exists by virtue of section 6(1)*(a)* of the Act (a scale monopoly) in that CV-UK supplies at least one-quarter of the CLS which are supplied in the UK.

8.32. Our terms of reference also require us to report in whose favour the monopoly situations exist. We informed Allergan of our provisional conclusion that the monopoly situation existing by virtue of its supplies of CLS existed in favour of Allergan itself and of API and Allergan Inc (see paragraph 8.17*(a)*).

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[1]For comments on the difference between Boots' share of suppliers' sales and its share of retail sales see paragraph 8.168.

8.33. Allergan advanced a number of arguments against this finding in relation to API and Allergan Inc. It pointed out, as we accept, that Allergan was conducting its own business and that neither API nor Allergan Inc supplied CLS in the UK or carried on business there at all. Allergan submitted that the person in whose favour a scale monopoly situation existed would normally be the supplier itself, and that other persons would be involved only in exceptional circumstances, such as where a quarter or more of the reference goods were supplied by an agent on behalf of a principal.

8.34. Allergan further argued that it was not open to the MMC to find that a scale monopoly existed in favour of foreign companies whenever they supplied goods to an interconnected body corporate which had a scale monopoly. Nor, it suggested, would a finding that foreign companies were persons in whose favour a monopoly situation existed seem to serve any useful purpose, bearing in mind the limitation placed, by section 90(3) of the Act, on the order-making powers provided for in section 56. Neither API nor Allergan Inc was a person such as was described in section 90(3) and no action or omission of either of them within the UK had been called in issue in the present inquiry. The finding was therefore of theoretical and not practical interest.

8.35. Moreover, Allergan observed that it was possible that in the MMC's eventual report recommendations might be made in relation to conduct outside the UK; while, by reason of section 90(3) of the Act, these could not be directly implemented by order, they might form the basis for the placing of indirect pressure on a foreign company.

8.36. Allergan accepted that some previous MMC reports had found a monopoly situation in favour of shareholders in, and suppliers to, the monopoly supplier itself. Allergan did not find this consideration convincing since none of those cases had been challenged by way of judicial review and hence tested in the courts, and it could discern no consistency in the MMC's treatment of the point. Some of the cases could in any event be distinguished from the present one on their facts.

8.37. Allergan further argued that many companies could be said to benefit from a given scale monopoly situation. There was no satisfactory way to distinguish between them, for example by reference to the scale of their shareholding in, or their volume of trade with, the monopoly supplier.

8.38. We have taken careful account of these arguments and have had regard to recent cases in which questions relating to 'persons in whose favour' have been judicially considered, albeit in relation to complex monopoly situations. While it is likely that the supplier will normally be a person in whose favour a scale monopoly situation exists, the Act appears to us to provide no impediment to a finding that there are other such persons too. The question necessarily involves a factual element and section 48*(b)* of the Act, which relates to this question, contains neither an express nor an implied limitation.

8.39. It appears to us implicit in the outcome of the Visa case[1] that a finding may properly be made that a foreign company is a person in whose favour a monopoly situation (scale or complex) exists. We consider that it is open to us to find that a foreign company is such a person whether or not it is carrying on business in the UK within the meaning of section 90(3)*(c)* of the Act. As regards the argument advanced by Allergan that foreign companies might be exposed to indirect pressure by reason of possible MMC recommendations, and presumably by reason of their ability to give undertakings, we find it impossible to speculate on what might be the result of hypothetical recommendations which, it must be assumed, would be properly made. The point, however, does not seem to us to bear on the interpretation of the expression 'persons in whose favour' in section 48*(b)*.

8.40. We do not consider that it would be consistent with our statutory duties to attempt to define all the circumstances in which persons, not themselves suppliers of the goods or services concerned, would be persons in whose favour a monopoly situation existed. The facts of a particular case are necessarily of particular relevance and we see no reason to accept any limitation such as that in Allergan's example of principal and agent. As Allergan has recognized, in a number of previous reports which concerned a variety of circumstances, the MMC have found that the persons in whose favour a scale monopoly situation existed were not confined to the monopoly supplier itself. These conclusions were not challenged and we have no reason to doubt their correctness.

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[1] *R v Monopolies and Mergers Commission and others ex parte Visa International Service Association*: judgments of Mr Justice Hodgson given on 15 June 1990 and of the Court of Appeal given on 4 October 1990.

8.41. As noted in paragraph 8.34, Allergan has suggested that no action or omission on the part of API and Allergan Inc has been called into question. In the result this is correct. However, we do not believe that this result means that they cannot be persons in whose favour the monopoly situation exists, which is a separate question.

8.42. In the present case API is the source of some 90 per cent of Allergan's supplies of CLS. Because of the system used to determine the transfer prices which Allergan pays to API, API's income from these sales depends on the selling prices and costs of Allergan's operations in the UK (see paragraph 4.15). Therefore the more profitable Allergan becomes, the more profit will accrue to API. Allergan Inc is the parent company, holding indirectly 100 per cent of the shares in both Allergan and API, and is therefore the ultimate beneficiary of the results of both companies. While, therefore, we take Allergan's point that many persons could be said to benefit in one way or another from the scale monopoly situation, we believe there are sufficient grounds for regarding these two companies as persons in whose favour the scale monopoly situation exists.

8.43. We therefore conclude that the scale monopoly situation which we have identified exists in favour of the supplier, Allergan—and, for the reasons which we have set out above, in favour also of API and Allergan Inc.

8.44. In the case of CV-UK we informed the company of our provisional conclusion that the monopoly situation existed in favour of CV-UK, and also CVLCP and CIBA-GEIGY.

8.45. CIBA Vision did not question our provisional finding on this point. Its response to our issues letter was made expressly on behalf of both CV-UK and CVLCP. Moreover, CIBA Vision argued that the profitability of its UK CLS business should be judged by reference to the consolidated figures for CV-UK and CVLCP, which were both controlled by the same UK holding company, CIBA-GEIGY PLC.

8.46. CV-UK now sources the great majority of the CLS which it sells in the UK from CVLCP, which benefits directly from CV-UK's performance through the transfer prices paid for those goods. CIBA-GEIGY, as the parent company owning 100 per cent of the shares in both the UK companies concerned, is the ultimate beneficiary of their results from CLS business in the UK. We therefore confirm our provisional finding that the monopoly situation exists in favour of the supplier, CV-UK, and also CVLCP and CIBA-GEIGY.

Wholesalers

8.47. In both 1991 and 1992 23 per cent of suppliers' total sales of CLS were made to wholesalers and the rest direct to retailers (see Table 3.11). We have already dealt with the question of scale monopoly situations among suppliers. Leaving them aside it is clear that no wholesaler or group of wholesalers supplies, or buys, as much as one-quarter of the CLS supplied in the UK. We therefore conclude that no monopoly situation exists at the wholesale level separate from those which we have found at the supplier level.

Retailers

8.48. Table 3.15 shows that in 1992 the Boots group accounted for 36 per cent of the CLS supplied by retailers (opticians and pharmacists) in the UK, measured at retail prices. In October 1992 we informed Boots of our provisional finding that a scale monopoly situation existed in that The Boots Company PLC, BTC and BOL together supplied at least one-quarter of the reference goods supplied in the UK at retail level and that the monopoly situation existed in favour of the same three companies.

8.49. Boots did not dispute that group companies accounted for over 25 per cent of the CLS sold at retail level in the UK. It pointed out, however, that the parent company, The Boots Company PLC, was not directly involved in this supply. It was responsible for the procurement of solutions but then transferred them to BTC and BOL which supplied them to customers. We accept that this is the case.

8.50. We therefore conclude that a monopoly situation exists by virtue of section 6(1)*(b)* of the Act (a scale monopoly) in that BTC and BOL, being members of the same group of interconnected bodies corporate, together supply at least one-quarter of the CLS which are supplied at retail level in the UK.

8.51. Although not a supplier of CLS to third parties, The Boots Company PLC benefits financially from that business as the group's ultimate holding company, holding 100 per cent of the shares in both BTC and BOL, and is involved in the purchasing of solutions. Boots did not dispute that The Boots Company PLC was a person in whose favour the monopoly situation existed. We conclude that the monopoly situation exists in favour of BTC and BOL, and also in favour of The Boots Company PLC.

Findings on complex monopoly situations

8.52. A complex monopoly situation under section 6(1)*(c)* and (2) of the Act is taken to exist when at least one-quarter of all the goods of a particular description which are supplied in the UK are supplied by or to members of the same group consisting of two or more persons (not being a group of interconnected bodies corporate) who, whether voluntarily or not and whether by agreement or not, so conduct their respective affairs as in any way to prevent, restrict or distort competition in connection with the production or supply of goods of that description.

The suppliers complex monopoly situation

8.53. In October and November 1992 we informed the suppliers listed in paragraph 1 of Appendix 8.1 of our provisional finding that a complex monopoly situation existed in respect of the supply of CLS in the UK, in that they engaged in one or more of the following practices:

(a) packaging CLS in a range of different sized containers such that there is no consistency of size within or across brands, no consistent relationship between size of container and recommended period of use and no indication on the label as to numbers of daily doses;

(b) marketing some CLS in quantities which cannot be exhausted during the recommended period of use if the recommended daily dose is consumed;

(c) setting recommended prices for solutions; and

(d) applying different levels of discounts unrelated to cost differences respectively to independent opticians, optical groups and large independent opticians, multiple opticians, and optical and pharmaceutical wholesalers.

We invited the suppliers concerned to comment on our provisional finding and on the issues which appeared to us to arise from it.

8.54. The suppliers responded in writing and most of them also attended hearings. The following paragraphs summarize their views on the four practices listed above.

8.55. On the variability of pack size, suppliers argued that this was an aspect of competition among them, as they sought to differentiate their products. The introduction of large, economy packs had been a particular feature in recent years. The variation was no greater than with many other products. The volume of the pack's contents was always stated on the label and there was no great difficulty for consumers in making price comparisons. Some suppliers said that they marketed the same pack sizes in the UK as their sister companies did in the rest of the world: any requirement to adopt special sizes for the UK alone would raise costs and reduce security of supply.

8.56. We raised with the suppliers the possibility of a requirement that packs might have to state the number of doses contained, as an aid to price comparisons. Suppliers said that while such statements could readily be made for some products, eg those where a specified amount had to be poured into a particular sized lens case, difficulties arose with daily cleaners, where the instructions typically

stated that a few drops should be sprinkled into the palm of the hand, or for products used for more than one function, eg salines and certain multi-purpose solutions. A requirement that labels should state the number of doses, based on some kind of average use, would be misleading given also the variety in users' patterns of lens wear, reactions to lenses, wearing conditions and hence usage of solutions. As with changing pack sizes, the imposition of new labelling requirements would entail regulatory costs.

8.57. On the marketing of pack sizes such that the contents could not be exhausted during the recommended period of use, some suppliers denied that they engaged in this practice. Others agreed that they did market 'over-size' containers but justified this on various grounds: that the products in question were low sellers; that large pack sizes were offered in order to give better value for heavy users or for families with more than one lens wearer; and that the 28-day period of recommended use laid down by the MCA was unreasonably short for some products, notably daily cleaners. Allergan argued that if there was a problem here it was a matter for the MCA, as the authority responsible for product licensing, not the MMC.

8.58. On the setting of recommended retail prices (RRPs), suppliers said that this practice was very widespread in UK markets for consumer products. Suppliers made no attempt to impose their recommendations. There were enough retailers handling CLS to ensure price competition. The MMC's own survey had revealed considerable discounting of branded products by opticians, and the availability of cheaper own-label products represented another form of price competition.

8.59. With regard to differential discounting (point *(d)* in paragraph 8.53), Alcon said that while its discounts could not be precisely justified by cost savings, they were all cost-related. Discounts reflected the customer's value to the seller, not only because of direct and indirect cost savings resulting from large orders or taking central delivery but also from factors such as the customer's status as a regular, financially reliable buyer. Alcon did not use its discount system for any anti-competitive purpose. B&L said that it offered a graded, volume-related discount on purchases of solutions. It believed its discount structure to be consistent, transparent and non-discriminatory. Sauflon told us that its discount structure was based on the volume of purchases and reflected savings in shipping costs. In addition it negotiated special terms with high-volume retailers which reflected *inter alia* the competitive nature of the market. For large retailers to enjoy better terms of supply than small traders was normal practice, resulting from their bargaining strength and competition among suppliers. S&NP also put forward this argument. It submitted that small manufacturers must retain some freedom of pricing, including the ability to offer discounts which were not wholly volume-related, if they were to compete with the two large suppliers.

8.60. We deal with the positions of Allergan and CV-UK on discounting in the context of our consideration of the scale monopoly situations (see paragraphs 8.148 to 8.151 and 8.160 to 8.162).

8.61. In considering our conclusions on the existence of a complex monopoly situation we have taken account of the suppliers' views as summarized above, as well as all the other evidence bearing on the findings. We believe the wide variation in pack sizes does create difficulties for the consumer wishing to choose between different products and brands. Such a choice involves a number of considerations, for example how each product would fit in with the rest of a lens care system, the fact that different dosages are needed for different products, and the different possible effects on the eye, as well as the relationship between price and volume. The inclusion on the label of information about the number of dosages would ease the difficulties and we return to this issue later (see paragraph 8.227). But we accept that, in the circumstances of this market, differentiation of pack size does not in itself prevent, restrict or distort competition.

8.62. The marketing of solutions in over-size containers is a matter which causes us some concern and we return to this matter too in the context of the regulatory regime (paragraph 8.227). But if this practice has an effect on competition, it lies in the marketing of large pack sizes as an attempt to secure a competitive advantage by offering greater convenience and lower unit price, actions which are a manifestation of competition. We have therefore concluded that this practice, too, should not be regarded as conduct which could form the basis of a complex monopoly group.

8.63. The setting of RRPs is a different matter. Although the practice is widespread, its effect has to be considered in the context of the market or markets in question. One of the conclusions of the 1969 MMC report on *Recommended Resale Prices*[1] was that the recommendation of resale prices in conjunction with factors such as restriction of outlets and monopoly in the supplying industry may prevent price competition in retailing, and that in such cases prices were likely to be higher than they otherwise would be. The report found that the effects of the practice differed in different trades and that the balance of the effect on the public interest differed accordingly. It concluded that it would not be possible to define the circumstances in which the listing of RRPs should be prohibited and that any such prohibition should be made only after an investigation of the relevant markets.

8.64. In the present case there are two factors which seem to us important. First, CLS are seen by many people as akin to medicines. They are regulated under the Medicines Act and their retail sale is confined to opticians and pharmacists. Medicines are one of the few categories of products which have been exempted from the prohibition of individual resale price maintenance (RPM) in the Resale Prices Act 1976. We received evidence that some pharmacists believe CLS themselves to be subject to RPM. Secondly, our surveys found that over 90 per cent of pharmacists sell all branded CLS products at the RRP (see paragraph 3.203). The position of opticians is complicated by the prevalence of discount schemes but leaving these schemes aside the majority of opticians also sell all branded solutions at the recommended price. In these circumstances it seems to us that the setting of RRPs by suppliers restricts price competition among retailers of CLS because retailers' prices would be likely to show greater variation if the practice were not followed. As recorded in paragraph 3.177, the evidence is clear that all the suppliers engage in this practice.

8.65. Differential discounting can be seen as a form of competition or an attempt to distort competition depending on the circumstances. In the CLS market we have found that, while there are similarities in the pattern of discounts given to the various trade channels, there are differences in the practices of individual suppliers. We attach weight to the contention of some of the smaller suppliers that their discounting behaviour is conditioned by, and to some extent responds to, the strength of Allergan and CV-UK, which between them have over 70 per cent of the total market. While there are aspects of the discounting behaviour of Allergan and CV-UK which fall to be considered in the context of the scale monopoly situations in favour of those companies, we do not believe that the practices of the other suppliers are forms of conduct which prevent, restrict or distort competition in these markets.

8.66. Taking account of the views we have set out in paragraphs 8.61 to 8.65 and the evidence recorded in paragraph 3.177, we conclude that a monopoly situation exists by virtue of sections 6(1)*(c)* and (2) of the Act (a complex monopoly) in that the suppliers listed in paragraph 1 of Appendix 8.1 (being members of one and the same group for the purpose of these provisions) supply at least one-quarter of the CLS which are supplied in the UK and engage in the following practice, namely the setting of RRPs.

8.67. We also conclude that this monopoly situation exists in favour of the persons referred to in paragraph 2 of Appendix 8.1. These persons comprise the members of the complex monopoly group itself; their ultimate holding companies (where such exist); API; and CVLCP. Our reasoning for this conclusion is the same, *mutatis mutandis*, as applied in the context of the scale monopoly situations involving Allergan and CV-UK: see paragraphs 8.38 to 8.42 and 8.46.

Own-label suppliers

8.68. In October and November 1992 we informed the retailers listed in paragraph 3 of Appendix 8.1 of our provisional finding that a complex monopoly situation existed in that they engaged in one or more of the following practices:

(a) packaging own-label CLS in a range of different-sized containers such that there is no consistency of size within or across brands, no consistent relationship between size of container and recommended period of use and no indication on the label as to numbers of daily doses;

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[1] *Recommended Resale Prices: a report on the general effect on the public interest of the practice of recommending or otherwise suggesting prices to be charged on the resale of goods*, HC 100, 10 February 1969.

(b) marketing some own-label CLS in quantities which cannot be exhausted during the recommended period of use if the recommended daily dose is consumed; and

(c) marketing own-label CLS as parts of complex care systems which should not be used with CLS from other brands of care systems.

We invited the retailers concerned to comment on our provisional finding and on the issues which we put to them in connection with it.

8.69. The retailers responded in writing and most of them also attended hearings. The following paragraphs summarize their views on the practices listed in paragraph 8.68.

8.70. The retailers said that their own-label products were virtually always 'resleeved' versions of proprietary branded products, ie they were the same products in different packaging. Licensing approval was needed from the MCA before solutions could be marketed in this way and it was easier and cheaper to obtain approval for pack sizes which were the same as those already approved for the branded version. The selling of pack sizes which were determined by the suppliers and the MCA could not be regarded as a course of conduct adopted by retailers. On the related question of labelling products with the number of doses contained as well as the volume, the retailers put forward arguments similar to those advanced by the suppliers (see paragraph 8.56).

8.71. With regard to the marketing of solutions in 'over-size' containers, too, the retailers' responses were similar to the suppliers' (see paragraph 8.57). Boots and D&A maintained that the pack sizes they sold would normally be used up by the discard date if users complied fully with the recommended regimes of lens care. Specsavers commented that the pack sizes which it sold had been approved by the MCA.

8.72. On the marketing of own-label CLS as part of complex care systems, the retailers said that this practice was attributable to the product licensing regime. There were serious limitations to the possibilities for users to switch from one product to another even where the products were of the same type (eg peroxide disinfectants). Specsavers told us that it had found that user compliance was much better when opticians recommended a complete lens care system. D&A said that although own-label retailers recommended complete systems, their ability to draw on different suppliers in making up those systems provided an entry route for suppliers with individual products, rather than a complete range.

8.73. Our view of the first two practices listed in paragraph 8.68 has been set out in the context of the suppliers' complex monopoly situation where the same points arose (see paragraphs 8.61 and 8.62): in brief we have decided that these are not practices which prevent, restrict or distort competition.

8.74. As regards the marketing of CLS as parts of complex care systems, our concern had been that the marketing of complete systems might be used to shut out other products which, on their individual merits, offered good value for money. But we received no complaints about such consequences, and it became clear during the inquiry that the marketing of systems is an aspect of inter-brand competition. We therefore do not believe that the practice forms the basis of a complex monopoly situation among own-label retailers.

8.75. Given the views we have now reached on these matters, as recorded in paragraphs 8.73 and 8.74, we conclude that there is no complex monopoly situation among own-label suppliers of CLS.

The retailers complex monopoly situation

8.76. In October and November 1992 we informed the retailers listed in paragraph 5 of Appendix 8.1 of our provisional finding that a complex monopoly situation existed in that they and others sold CLS at, or only just below, RRP. We also wrote to bodies representing opticians and pharmacists inviting them to comment on this finding and the issues which appeared to us to arise as a result. These bodies are listed in paragraph 7 of Appendix 8.1 and their membership and role are set out in Chapter 7.

8.77. The retailers argued that there was substantial price competition between brands. There was also considerable discounting of CLS by opticians. Moreover CLS were available at prices below the level recommended by suppliers via retailers' own-label products. Those retailers who sold own-label solutions preferred to concentrate their price competitiveness on their own products.

8.78. Boots said that the market in CLS was not price-sensitive. It chose to compete primarily on other factors (see paragraph 8.172). It had no fixed policy always to price at the recommended levels but had seen no sufficient reason to depart from them. D&A told us that its chosen strategy was to set the prices of branded solutions at 2 per cent below the suppliers' recommended levels in order to give itself an edge over its competitors. In addition it offered prices up to 15 per cent below recommended levels via its contact lens care scheme. Lloyds Chemists plc (Lloyds), which had told us that all the solutions it sold were at the recommended price, said that price-cutting would encourage excessive use of CLS, which was not in the interest of the consumer.

8.79. Two of the opticians' representative bodies commented that the low margins available to opticians left little room for discounting.

8.80. The National Pharmaceutical Association said that soundings of its members suggested two reasons for pharmacists selling at recommended prices: first that some believed that CLS were proprietary medicines and hence subject to RPM; and second that the professional input in supplying advice with CLS products needed to be financially rewarded.

8.81. In considering these arguments we note that nearly two-thirds of CLS are sold by retailers who sell all branded solutions at the recommended price. This calculation is heavily influenced by the position of Boots, which alone has 36 per cent of the market. But in addition D&A, which has around 10 per cent, sells branded solutions at only just below recommended price except for those customers who are prepared to join its discount scheme, and according to our survey other opticians with over 11 per cent of the market between them sell branded solutions at the full recommended price except under their discount schemes.

8.82. We do not ignore the existence of discount schemes offered by a significant number of opticians but we do regard them as an imperfect form of price competition since the price benefit is only available to customers who are prepared to be tied to buying solutions from the optician in question. For other customers, branded solutions are only available at or close to the recommended price in a very high proportion of outlets. In this respect CLS differ from many other consumer products for which there are RRPs. In the light of these considerations we believe that the selling of CLS at, or only just below, recommended prices is a practice which restricts competition at retail level.

8.83. The evidence for the existence of this practice comes from two sources. First, as recorded in paragraph 8.78, the four retailers named in paragraph 5 of Appendix 8.1 (BTC, BOL, D&A and Lloyds) told us that they charged prices at—or, in the case of D&A, 2 per cent below—the suppliers' RRPs. Secondly, since it was impracticable to get similar direct evidence from all retailers, we carried out surveys of opticians and pharmacies. These surveys are described in Appendix 3.7 and the results are summarized in Appendices 3.8 and 3.9. We are satisfied that the results of these surveys may be relied on, as orders of magnitude though not as precise percentages, as evidence of opticians' and pharmacists' pricing behaviour.

8.84. Paragraph 3.204 shows that the four named retailers have about 47 per cent of the retail market, while the other, unnamed retailers engaging in the practice account for about a further 35 per cent.

8.85. We therefore conclude that a monopoly situation exists by virtue of sections 6(1)*(c)* and (2) of the Act (a complex monopoly) in that the retailers referred to in paragraph 5 of Appendix 8.1 (being members of one and the same group for the purpose of these provisions) supply at least one-quarter of the CLS which are supplied in the UK and engage in the following practice, namely selling CLS at, or only just below, RRP. We further conclude that this situation exists in favour of those same retailers and, for the reasons given in paragraph 8.51, in favour also of The Boots Company PLC.

The opticians complex monopoly situations

8.86. In October and November 1992 we informed the opticians listed in paragraph 8 of Appendix 8.1 of our provisional finding that a complex monopoly situation existed in that they engaged in one or both of the following practices:

(a) giving little weight to the cost of particular types and brands of CLS when making their recommendations to patients; and

(b) failing to make sufficiently clear to patients, before they purchase contact lenses, all relevant information about the prices of the CLS they recommend, in particular the likely overall annual cost to the patient of complying with the recommended regime.

We also wrote to opticians' representative bodies inviting them to comment on this provisional finding and the issues which we had identified as arising from it. These bodies are listed in paragraph 10 of Appendix 8.1 and their membership and role are described in Chapter 7.

8.87. The evidence underlying our provisional conclusion was based on our surveys of opticians and consumers. With regard to the first practice our survey of opticians (see Appendix 3.8) showed that nearly three-quarters of opticians in the sample did not give 'reasonable cost to the customer' as one of the three main reasons for recommending a particular disinfecting system. Three-quarters of opticians said that they normally recommended a peroxide system for wearers of soft lenses while 13 per cent recommended a chlorine system and 5 per cent a cold chemical system. At the same time 79 per cent said that most wearers could satisfactorily use a chlorine system and 50 per cent said the same for cold chemical systems, compared with 93 per cent for peroxide systems. Chlorine systems are significantly cheaper than peroxides, and cold chemical systems are cheaper again (see paragraph 8.15).

8.88. The evidence concerning the second practice comes from our survey of consumers (see Appendix 3.10). Approaching three-quarters of the sample said that when they were first considering wearing contact lenses the optician did not discuss with them the likely future costs of buying solutions, while nearly 30 per cent of those who were told about this said that they were informed after they had made their decision to wear lenses.

8.89. On the first point opticians submitted that they were under a professional duty to give first priority to clinical considerations, not cost. It was therefore correct for opticians to have said, in reply to our survey, that the three most important reasons for recommending particular solutions were concerned with effectiveness, comfort and ease of use. The survey results were consistent with opticians having regard to cost factors once these primary considerations had been satisfied. As to the recommendations of particular systems, there were sound clinical reasons for the pattern which the survey had found.

8.90. Concerning the second point, opticians' representatives said that opticians had a duty to make clear to customers, before the customers committed themselves to buying lenses, what costs would be involved both on supply and on a continuing basis. This duty was specifically stated in the guidelines issued by the British College of Optometrists (see paragraphs 2.50 to 2.53). Opticians' representatives maintained that the costs of lens care were explained to new customers and cited the results of our opticians survey in support of this contention (see paragraph 19 of Appendix 3.8). They attributed the results of our consumer survey to forgetfulness on the part of consumers, pointing out that nearly half of wearers fitted in the year immediately before the survey was conducted said the optician had discussed the cost of solutions. Such forgetfulness was not surprising since opticians had to put across a good deal of information all at once to people contemplating wearing contact lenses for the first time. Some opticians pointed to the growing use of regular payment schemes which showed customers very clearly what the monthly cost of solutions was.

8.91. We have carefully considered the evidence and views put forward on these points. On the first practice the opticians survey provides clear evidence that a substantial majority of opticians normally recommend peroxide disinfectants (see paragraph 8.87) and this is supported by other information, notably the rapid growth in the proportion of the disinfectant market taken by peroxides (see

Table 3.2). Equally the survey shows that a substantial majority of opticians believe that chlorine systems could be satisfactorily used by most lens wearers. It appears to be the case that most opticians recommend peroxides in order to avoid the risk of adverse reactions which would affect a relatively small proportion of people. Optician witnesses told us that it was normal practice for opticians to recommend a particular lens care regime to a customer and not to discuss alternative possibilities (see Chapter 7). We consider that it would be quite feasible, however, for opticians to explain the options to customers, bringing out the cost as well as other implications, and not simply make a single recommendation. We believe that their failure to do so limits the effectiveness of price competition among suppliers and therefore restricts and distorts competition.

8.92. On the second practice the position is less clear because there is a conflict of evidence between the optician and consumer surveys. However, even if we give greater weight to the replies from consumers who were first fitted with lenses in the 12 months before the survey, the proportion saying that the overall costs of lens care were not discussed with them by the optician is still around half, while about a third of the remainder were informed after making their decision to buy lenses (see paragraph 3.148).

8.93. On balance we rely on the evidence of the consumer survey on this practice because the consumers had no reason to claim that the subject of cost had not been discussed if in reality it had been. Even if, in some cases, the consumers forgot what the optician had said about costs, this suggests that the subject may have been given insufficient emphasis. We have in mind that over time the costs of solutions are likely to exceed the cost of lenses, both those originally supplied and any subsequent replacements, possibly by a considerable margin, a fact of which many consumers are probably unaware. We consider that this conduct limits the ability of consumers to make well-informed choices based on an accurate knowledge of costs, and hence distorts competition.

8.94. As in the case of the retailers complex monopoly situation (see paragraph 8.83) we have perforce to rely largely on survey evidence in arriving at a picture of the conduct of opticians in advising their customers. The evidence concerning the first practice listed in paragraph 8.86 comes from our survey of opticians and is set out in paragraphs 3.141 to 3.146. This shows that about three-quarters of opticians did not give 'reasonable cost to the customer' as one of the three most important reasons for recommending solutions to customers. The survey indicates that most of the opticians working for BOL and D&A were among these three-quarters. We have shown in Chapter 3 that opticians account for nearly 60 per cent of the CLS market at retail level. It follows that three-quarters of all opticians account for about 45 per cent of total retail sales of CLS. Even allowing for the possible imprecision of survey evidence, the proportion of opticians engaging in the practice is clearly well above 25 per cent. BOL and D&A, the two named members of the group, have about 15 per cent of the retail market between them.

8.95. We conclude that a monopoly situation exists by virtue of section 6(1)*(c)* and (2) of the Act (a complex monopoly) in that BOL, D&A and other opticians engaging in the practice referred to below (being members of one and the same group for the purpose of these provisions) supply at least one-quarter of the CLS which are supplied in the UK and engage in the following practice, namely giving little weight to the cost of particular types and brands of CLS when making their recommendations to patients. We further conclude that the monopoly situation exists in favour of those same opticians and, for the reasons given in paragraph 8.51, in favour also of The Boots Company PLC.

8.96. As mentioned above, the evidence for the second practice comes from our survey of consumers, the findings of which are summarized in Appendix 3.10. We agree that more weight should be placed on the evidence of consumers who had been fitted with lenses in the 12 months preceding the survey. On this basis, as noted in paragraph 8.92, around half of opticians fail to discuss the costs of lens care with new customers, while about a third of the remainder do so after the customer has taken the decision to wear lenses. As a proportion of total retail sales of CLS, therefore, the two-thirds of opticians engaging in this practice account for about 40 per cent—again, well over the 25 per cent threshold. In this case, however, the evidence is not specific to any named persons.

8.97. We therefore conclude that a monopoly situation exists by virtue of section 6(1)*(c)* and (2) of the Act (a complex monopoly) in that the opticians engaging in the practice referred to below (being members of one and the same group for the purpose of these provisions) supply at least

one-quarter of the CLS which are supplied in the UK and engage in the following practice, namely failing to make sufficiently clear to patients, before they purchase contact lenses, all relevant information about the prices of the CLS they recommend, in particular the likely overall annual cost to the patient of complying with the recommended regime. We further conclude that the monopoly situation exists in favour of those same opticians.

The operation of the market

8.98. Before we turn to the issues arising from the monopoly situations it is necessary to highlight the key features of the market's evolution in the last few years and of its current operation.

Demand

8.99. Table 3.2 shows that at current prices sales of CLS in the UK more than doubled in the period 1988 to 1992, though the growth rate has slowed in the last two years. CLS sales have recently tended to increase more rapidly than lens sales. This appears to be due to the shift to soft lenses, which require greater use of solutions to keep them in good condition, and to the growth in popularity of peroxide disinfectants which are more expensive than other systems.

8.100. The prospects for demand are difficult to assess. Penetration of contact lens wear in the UK is far below the USA but the industry does not appear confident that rapid growth in lens wear will resume. Nor will demand for solutions necessarily grow as rapidly as lens wear if disposable lenses take an increasing share of the market. The concept of lenses being worn continuously (ie day and night) for periods of a week or two and then discarded has been introduced to the market. This mode of lens wear requires little or no use of solutions. Serious doubt has, however, been cast on the safety of wearing lenses day and night and it appears likely that daily wear will continue to predominate. The possibility that disposable lenses might be made so cheaply that they could be worn for a day and then discarded also remains uncertain. We do not believe therefore that the market for solutions will collapse. There are nevertheless major uncertainties about demand prospects, and we received evidence that suppliers' strategies for the future were affected by this. The uncertainty may also discourage new entry.

8.101. The importance of disinfectants has increased so that they now represent over 60 per cent of the total value of solutions sold, the bulk of it in the form of peroxides. Cold chemical preserved disinfectants have declined in popularity. Peroxides are the prime source of the high market shares held by Allergan and CV-UK.

Suppliers

8.102. The pattern of suppliers' shares in the overall CLS market has not changed fundamentally over the last five years (see Table 3.9). CV-UK had a clear lead in 1988 but lost ground steadily until 1992, when it appears to have achieved a modest recovery. Allergan's share increased between 1988 and 1989 at CV-UK's expense but has since remained broadly constant. The combined share of these two leading suppliers declined from 77 to 72 per cent between 1988 and 1990 but has since held steady. Among the other suppliers Alcon has seen little change in its share, Sauflon and B&L/M&L have increased theirs and S&NP has lost ground.

8.103. Positions in the individual product markets and sectors have been more volatile. For example, Allergan, having introduced a peroxide product later than CV-UK, doubled its share of sales in the oxidative sector of the disinfectant market at CV-UK's expense, the combined shares of these two companies falling only from 89 to 85 per cent between 1988 and 1992 (see Table 3.5). In surfactant cleaners the combined share of the three original leaders (Allergan, CV-UK and Alcon) fell from 85 per cent in 1988 to 64 per cent in 1992 while the share of B&L/M&L rose from 16 per cent in 1989 to 27 per cent in 1992 (see Table 3.3). In salines CV-UK's share fell from 36 to 21 per cent while Sauflon's rose from 12 to 23 per cent over the period 1988 to 1992 (see Table 3.7).

Allergan's position in protein removers has remained very strong: its share fell from 74 to 66 per cent between 1988 and 1989 but then stabilized and in 1992 recovered to 70 per cent (see Table 3.8).

8.104. No new suppliers have entered the market in the last five years. Sauflon acquired the solutions part of an optical business in 1985 and has increased its CLS sales fivefold since 1987. CIBA Vision entered the UK CLS market in 1983 and greatly increased the size of its operations in 1988 by acquiring the lens care business of The Cooper Industries Inc. Other significant acquisitions were those of Hydron International by Allergan in 1987, of Barnes-Hind Ltd by Pilkington plc also in 1987, and of M&L by B&L in 1989.

8.105. In the second half of the 1980s the main area of product innovation was the introduction of preservative-free solutions. This began with disinfectants where CV-UK's 10.10 (introduced in 1985) and Allergan's Oxysept (1987) are now the top-selling CLS products. Alcon and Sauflon introduced their chlorine tablets around the same time. The move to preservative-free products continued with surfactant cleaners and salines. Relatively few new products have been introduced since 1988. The only one to make a significant impact on the market so far is a protein remover, Ultrazyme, which Allergan launched in 1990: Ultrazyme enables protein cleaning to be carried out at the same time as disinfection but is licensed for use only with Allergan's Oxysept. At the beginning of 1993 Allergan launched Oxysept One-Step which allows the disinfecting and neutralizing processes to be carried out in a single operation.

8.106. The introduction of own-label solutions by some of the biggest retailers (but largely sourced from the suppliers listed in paragraph 8.17) has been an important feature of the market in the last five years. The market share figures cited earlier in this chapter include the suppliers' sales for retailers' own-labels as well as branded sales. The share taken by all own-label sales seen as a separate category has risen from 3 per cent in 1988 to 17 per cent in 1992, measured at suppliers' prices, and between 20 and 25 per cent at retail prices (see Table 3.9 and paragraph 3.163). Since prices for own-label products are below those for branded products, the share of suppliers' own-label sales measured by volume must be higher, but no statistics are available on that basis. CV-UK is the leading supplier of own-label solutions with 53 per cent of the total in 1992, the other main suppliers being Sauflon with 21 per cent and Alcon with 11 per cent. Allergan was a late entrant to this business and had only 4 per cent of the total in 1992.

8.107. The breakdown between trade channels (see paragraph 8.26) was little changed between 1991 and 1992 but over a longer period there has been a substantial shift towards sales through pharmacists. The pattern varies considerably among the different suppliers. In particular some companies (B&L, Sauflon, PBH) choose to sell only to opticians or optical wholesalers. Of the two leading suppliers, CV-UK is more dependent on sales to Boots and D&A (50 per cent of its total business) than Allergan (37 per cent): see Table 3.11.

8.108. In money terms RRPs of solutions have risen in almost all cases over the period 1988 to 1992 but by widely varying amounts: see Tables 3.17 to 3.20. Adjusted for changes in the Retail Price Index (RPI), prices of preservative-free products have generally fallen. Thus the inflation-adjusted prices of Allergan's Oxysept and CV-UK's 10.10 peroxide disinfectants declined by about 6 per cent over the period (taking the standard pack size as the measure). Real prices of older-generation preserved products, on the other hand, have tended to increase, despite their declining popularity, although cold chemical disinfectants are still substantially cheaper than peroxides (see paragraph 3.192). Of the four product markets identified in paragraph 8.21, only in salines have real prices fallen across the board.

Retailers

8.109. Since the introduction of the current regulatory regime governing the supply of CLS in 1983, the retail sale of solutions has been restricted to opticians and pharmacists. Allergan told us that in the early 1970s almost all sales of solutions were via opticians. Since then the share of pharmacists has grown to reach an estimated level of just over 40 per cent of total CLS sales at retail level in 1992. The bulk of this consists of sales by Boots pharmacies, which alone accounted for 31 per cent of the total market in that year. Lloyds, the second biggest chain of pharmacies after Boots, has only 1 per cent of the market.

8.110. The other notable trend in the retail market has been the growth of own-label sales (see paragraph 8.106). In 1988 these sales, at suppliers' prices, totalled £0.7 million, but by 1992 they had grown to £8.4 million (Table 3.9). Nearly all these sales were made to three retailers: Boots, D&A and Specsavers. Boots told us that own-label products accounted for 35 per cent of its total turnover of solutions in 1992. D&A, which introduced own-label solutions only in 1990, stated that they accounted for about 65 per cent by volume of its CLS sales in 1992. UniChem PLC (UniChem), which is one of the two leading pharmaceutical wholesalers and also owns a chain of pharmacies, told us that it planned to launch a small range of own-label solutions in March 1993. We also heard of other retailers who have been considering such a step, including some who are not currently permitted to do so by the regulatory regime but who hoped that the restrictions on distribution channels would be eased.

8.111. As in many other consumer product markets, own-label solutions allow retailers to enhance their reputation for giving good value for money, by making available sound quality products at prices below those of equivalent branded products, and to encourage customers to come back specifically in order to buy those products in future. There is an additional factor in the CLS market because of the opticians' role in recommending products to customers: Boots, D&A and Specsavers all told us that their opticians recommended their own-label products wherever it was appropriate to do so in an individual case.

8.112. Retailers are able to negotiate lower prices from suppliers for own-label products because of the value of the business on offer and because retailers do not contribute to suppliers' marketing costs. As a result, despite lower selling prices both Boots and D&A achieve gross margins on own-label products which are significantly higher than on the equivalent branded products. Boots submitted that this differential was necessary to cover its higher costs in marketing own-label products (see paragraph 8.177).

Competition

8.113. Competition among suppliers takes various forms:

(a) *Product innovation*. Suppliers have sought to introduce products which would reduce the incidence of adverse reactions, in particular by dispensing with the use of preservatives. The two-step peroxides have established themselves as the leading disinfectants despite being more expensive and more complicated to use than chlorine tablets and cold chemical preserved products. The current focus appears to be on the introduction of products which combine convenience with comfort: one-step peroxide disinfectants, and so-called 'all-in-one' solutions which carry out all necessary functions except protein removal. We were told of a variety of approaches being pursued by suppliers. The need to obtain a product licence from the MCA appears, however, to have substantially slowed the introduction of new products to the UK market compared with other countries (see paragraphs 8.116 to 8.118).

(b) *Setting recommended prices*. As discussed further in paragraph 8.193, suppliers frequently pitch the recommended prices of individual products at levels designed to give them an edge over competing products.

(c) *Discounts to retailers*. Most suppliers offer discounts for volume orders but also negotiate individually with specific customers. All the major suppliers give their biggest discounts to Boots and the second-biggest to D&A. Allergan and CV-UK offer bigger average discounts to opticians than to wholesalers. At our request Allergan calculated its relative costs and savings in supplying different trade channels. The results showed that after taking account of the relative discounts, Allergan's costs of doing business with opticians are on average greater than with Boots, which orders in large volumes and takes delivery at a central warehouse. CV-UK was unable to make a comparable calculation but its pattern of average discounts is similar to Allergan's. Both companies said that they gave opticians favourable prices because of the importance of opticians as advisers to lens wearers; Allergan referred to this as the 'gatekeeper role' in relation to the marketing of CLS (see paragraphs 8.10 and 8.11). By contrast in 1987 Allergan took the lead in cutting discounts to optical wholesalers from the

traditional level of 25 per cent to 15 per cent, the same as for pharmaceutical wholesalers, and was followed by CV-UK's predecessor company and S&NP. Allergan told us that in its view optical wholesalers performed a largely passive role and had little ability to influence the market. Most other suppliers still give 25 per cent discounts to optical wholesalers.

(d) Starter packs. The free issue of starter packs to consumers (see paragraph 8.10) enables them to try out the lens care regime for perhaps two weeks before returning to the optician for a further consultation. From the supplier's standpoint the aim is that the consumer, having thus had a free trial, will thereafter continue to use the same system. (Some opticians, however, told us that they may recommend a system made up of different suppliers' products, in which case they will change the contents of the starter pack.) The supply of starter packs is the largest element in suppliers' marketing and promotion budgets.

(e) Other aspects of suppliers' promotional activities are also focused primarily on opticians. For example, suppliers produce literature for opticians giving technical information about their products and comparing them with competing products as regards effectiveness, RRP and margin available for the optician. Allergan told us that it had run television advertising campaigns in South-East England but in general there is little advertising aimed at consumers.

(f) Suppliers' ability to provide an efficient distribution service and to give technical advice to opticians whenever it is needed are important factors in influencing opticians' perceptions.

8.114. At retail level the principal features of competition are as follows:

(a) Prices of branded products. As described in Chapter 3 (see paragraphs 3.201 to 3.205), opticians do to some extent engage in price competition in selling branded products, though pharmacists generally do not. Some retailers, such as D&A, follow a policy of always pricing below recommended levels; others do so as part of temporary promotions.

(b) Discount schemes. Nearly half of opticians offer schemes which enable regular customers to buy solutions at less than the recommended price. Such schemes are sometimes linked with the replacement of lenses and periodic consultations with the optician (see paragraphs 3.199 and 3.200).

(c) Own-label products. As described in paragraphs 8.110 to 8.112, the leading retailers have introduced own-label solutions priced below the equivalent branded products.

(d) Advice. Opticians advise customers on all aspects of lens care, including the implications of switching between different types and brands of solutions. Pharmacists provide more limited advice.

(e) Ranges stocked. Boots told us that one aspect of its competitive stance was the number of CLS lines which it stocked, which it said was much higher than those of other leading retailers.

(f) Convenience and service. Pharmacists offer a much wider range of other products than opticians, thus enabling customers to combine the buying of solutions with other purchases in one visit.

In considering the relative importance of opticians and pharmacists in this market it is relevant to note that there are some 6,000 optician outlets and 11,000 pharmacies in the UK, most of which sell solutions. As mentioned in paragraph 8.26, we estimate that opticians have nearly 60 per cent of the retail CLS market and pharmacists just over 40 per cent.

The effect of MCA regulations

8.115. MCA regulations (see paragraph 8.7) affect the CLS market in two main ways: by the impact of product licensing on the introduction of new products, and by the restriction of retail distribution to opticians and pharmacists.

8.116. Among the suppliers, Alcon and B&L, big players in the USA and certain other major CLS markets, have a significantly weaker presence in the UK. This is primarily a consequence of their inability to secure MCA approval for the main products which they have introduced in recent years to compete in the disinfectant market.

8.117. B&L told us that its 'all-in-one' solution, Renu, had been on the market in most other advanced countries for some years and was probably the leading product world-wide measured by opticians' recommendations to new lens wearers. B&L cited the example of Australia, where Renu had been marketed since 1985/86. According to B&L, both Renu and Alcon's soft lens disinfectant Optifree, which was similarly not available in the UK, had made significant inroads against Allergan which had been the market leader with its peroxide system. Alcon told us that the UK system of product licensing was different from that in most other countries. In Alcon's view the UK regulatory regime deterred new entry and hindered the introduction of products which were already being safely and successfully marketed elsewhere. Alcon's product range in the UK was typically a couple of years behind other countries (see paragraphs 6.193 and 6.194).

8.118. CIBA Vision, despite its high market share, was also critical of the UK licensing system which it said was widely acknowledged to be the strictest in Europe and probably in the world. Companies faced considerable problems in deciding what data would be required to satisfy the licensing authority of the product's quality, safety and efficacy even when the product had been marketed in other countries for a period. CIBA Vision said that the UK market was probably two generations of product behind many other markets which had moved on from two-step non-preserved systems through single-step non-preserved systems to products (such as Renu and Optifree) based upon new preservatives which appeared to cause less irritation to the eye. [

Details omitted. See note on page iv.

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8.119. Allergan, on the other hand, said that it strongly supported strict regulation of solutions. It believed this was in the interests both of the public and of suppliers, in that it was important for consumers to have confidence in the safety of the products. Allergan said that the regulatory hurdles were clear and were applied in an efficient and non-discriminatory way (see paragraph 6.3). It did not consider them to be barriers to entry to the UK CLS market. Allergan launched its one-step peroxide, Oxysept One-Step, early in 1993 having applied for the necessary product licence during 1992.

8.120. The MCA itself said that the product licensing system was straightforward and easily interpretable via well-publicized guidelines. The MCA's assessors were willing to explain the system to potential applicants and had frequently given advice to companies about specific products. The guidelines were interpreted flexibly and it was open to applicants to make a case for whatever information they considered would demonstrate that their products satisfied the criteria. Ultimately the requirements were met by virtually all applicants.

8.121. The MCA accepted that UK standards were more stringent than those in some other countries but maintained that there were good reasons for this. The MCA took account of clinical and market experience in other countries when considering applications for products which were already marketed elsewhere, but in the absence of a system of mutual recognition such experience could not remove the need for a complete dossier to be submitted to meet UK requirements.

8.122. The MCA pointed out that under the Medicines Act the only criteria for deciding applications were quality, safety and efficacy. Within this constraint it was able to take account of a product's ease of use, which might make for better user compliance. But it could not take account of cost factors, for example that cheaper products might lead to improvement in compliance.

8.123. The MCA acknowledged that there had in the past been excessive delays in processing applications but this had greatly improved since 1989. UK processing times were now at least as fast as any EC member state and faster than the USA.

8.124. We have thus been presented with conflicting accounts and opinions. Our considered view of the evidence presented to us is that the effect of the product licensing system has been seriously to inhibit competition in the supply of CLS in the UK. Apart from the direct impact on suppliers who

have not been able to obtain licences for particular products, the system evidently causes substantial uncertainties—as to the time and costs involved, as well as the outcome—which are likely to influence suppliers' approach to the UK market. These effects may be at least partly a consequence of the original decision that CLS should be controlled under the Medicines Act, which imposes certain constraints on the regulatory authority. Most of the suppliers told us that they expected some relaxation of standards as a result of the decision that solutions should in future be regulated under the EC Directive on Medical Devices. The Directive may not be fully implemented for five years, however, and we believe that earlier action should be taken to remedy the situation (see paragraph 8.218).

8.125. In the course of the inquiry we noticed two detailed aspects of the product licensing regime which seemed to us unsatisfactory:

(a) The warning 'Do not mix with other fluids except as directed' (see paragraph 8.8) is capable of two quite different interpretations. The MCA told us that the intention was to warn against the physical mixing together of different solutions, but some other witnesses (including suppliers) interpreted it as a warning against combining different solutions in the same lens care system. The latter interpretation may reinforce users' reluctance to switch between products in order to get better value for money.

(b) We found that some products, particularly surfactant cleaners, were sold in amounts which would not normally be used up within the period of recommended use (see paragraphs 3.29 and 3.30). We received letters from members of the public complaining that they either had to waste money by discarding unused amounts or to use the solution beyond the discard date. The MCA told us that more products could probably be used for longer than the normal 28-day period but the onus lay with the licence holder to make out a case for a licence variation allowing a longer period of recommended use to be stated on the container (see paragraph 5.27). Allergan said that it regarded a 28-day recommended use period for its surfactant cleaner LC-65 as unrealistically short but that to support an application for a longer period would have required lengthy and expensive clinical trials which it believed would have been a waste of time and money. It may be true, as Allergan said, that no health risk results directly from this situation. The danger is that if users find that this aspect of the instructions is not to be taken seriously, they will adopt a more casual attitude to other aspects which do matter.

8.126. A further element in the regulatory regime is to restrict the retail outlets for CLS to opticians and pharmacists. As noted in paragraph 8.64, a substantial majority of retailers sell all branded CLS at RRP. CLS are available at prices below the recommended level via retailers' own-label sales but the extent of the reductions is not large compared with other product markets: Boots in particular sells its own-label solutions at a weighted average of about 6 per cent below the recommended price for the equivalent branded products, which is at the low end of the range of discounts at which it sells own-label products generally. We believe that this lack of price competition would not be possible without the restriction on outlets. This situation is exacerbated by the fact that there are also restrictions on the opening of new pharmacies: see paragraph 2.55.

Public interest issues

8.127. We now address the remaining questions in our terms of reference (see Appendix 1.1) and in particular whether any of the monopoly situations gives rise to facts which are against the public interest.

Allergan

8.128. Allergan is the market leader in terms of share of CLS sales overall, having held about 38 per cent of the total since 1989. It is the leading supplier of surfactant cleaners (35 per cent), cold chemical disinfectants (38 per cent) and most notably protein removers (70 per cent), and is very well

represented in every type of solution. Although its advantage over CV-UK in the overall CLS market is only a few percentage points, it is the stronger company in several respects. Its product strength is more broadly based than CV-UK's, whose position depends heavily on its 10.10 peroxide disinfectant. It is less dependent on sales to Boots and D&A, the two most powerful retailers. Nearly all its sales are of branded products whereas over a quarter of CV-UK's sales are for retailers' own-labels. Its average discount off trade prices is lower than CV-UK's. It does not appear to have experienced the production difficulties from which CIBA Vision has suffered in the start-up of production at the Macclesfield plant. Above all it is far more profitable: the net margin on turnover achieved by Allergan and API on UK CLS business has averaged 31 per cent over the last three years compared with 10 per cent for CV-UK and CVLCP.

Prices and profits

8.129. The assessment of Allergan's profitability has been an important element in our inquiry. (As mentioned in paragraph 8.3, the apparent earning of high rates of return was one of the principal reasons for the inquiry being set up.) Allergan itself is purely a distribution company and as such has relatively little by way of physical assets. It obtains all its supplies of CLS from other companies in the Allergan group, around 90 per cent coming from API. Allergan provided us with the information necessary to combine its results with API's in such a way as to show the profitability of the two companies jointly on UK CLS business. Table 8.2 sets out these combined figures, which allow for Allergan's full share of group royalties, research and development (R&D) and central overheads (only a small proportion of these costs are included in Allergan's statutory accounts).

TABLE 8.2 **Allergan and API: results on UK CLS business**

£ million

	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992 (est)*
Turnover	8.0	12.0	14.8	17.3	18.7
Operating profit	3.1	3.8	3.9	4.7	6.0
Average capital employed	3.1	4.1	4.5	4.3	5.0
Return on turnover (%)	38.8	31.7	26.3	27.2	32.1
Return on capital employed (%)	100.0	92.7	86.7	109.3	120.0

Source: Allergan.

8.130. Allergan argued that two further adjustments were needed to the figures in its statutory accounts:

(a) It said that its practice until 1991 was to lease most of its assets rather than purchase them. Most of the leases were operating rather than finance leases, hence following standard accounting practice the assets were not capitalized in its statutory accounts. Allergan submitted that in order to show a true return on capital employed (ROCE) figure for the business these assets should be treated as capitalized.

(b) Allergan also urged that, given the importance to its business of R&D and product promotion, expenditure under these headings should be capitalized as intangible assets rather than written off in the year it was incurred. It presented figures for its results adjusted in line with this proposal.

Table 8.3 shows the effect of both these sets of changes on the ROCE figures set out in Table 8.2: fuller details of the adjustments made are given in paragraphs 4.7 and 4.14.

TABLE 8.3 **Allergan and API: results on UK CLS business on different accounting bases**

£ million

	Years ended 30 November				
	1988	*1989*	*1990*	*1991*	*1992 (est)*
ROCE as in Table 8.2	100.0	92.7	86.7	109.3	120.0
ROCE with operating leases capitalized	67.4	61.2	56.9	67.6	74.7
ROCE with operating leases and intangible assets capitalized	49.3	42.8	35.4	37.3	41.7

Source: Allergan.

Even after making every adjustment proposed by Allergan we note that its ROCE figures in this period have been around twice the average achieved by UK manufacturing companies measured according to standard accounting practice (see Table 4.48).

8.131. In putting to Allergan our provisional findings we invited it to comment on whether the existence of a scale monopoly situation in its favour had enabled it to make higher ROCE and to charge higher prices in respect of CLS than would otherwise have been possible. Allergan agreed that it had made good profits on this business in recent years but regarded these as an appropriate, not an excessive, reward for its performance.

8.132. In amplification of this view, Allergan submitted that the UK CLS market was highly competitive. The other large multinational groups which were prominent in the CLS business world-wide were all active in the UK, and the success of Sauflon showed that small firms could also compete in this market. The suppliers found themselves dealing with increasingly powerful retailers. Product development was dynamic and market shares of the different product types were volatile. This competition had led to real reductions in prices: Allergan said that the recommended prices of its own solutions had fallen by an average of 12 per cent in real terms over the past five years.

8.133. Allergan said that the market was also risky. Technological change was rapid. Suppliers had to invest continuously in R&D with no assurance that marketable products would result. Because of developments in the lens market there was considerable uncertainty over demand prospects for CLS.

8.134. Allergan argued that its good results were due to its success in developing and marketing products which met customers' needs and gained the support of opticians. This had led to a virtuous circle of rising sales and falling unit costs as API had been able to load its production facilities fully. Allergan's prices were attributable, not to its monopoly position, but to the quality of its products. Peroxide disinfectants commanded premium prices because they had brought a breakthrough in comfort for wearers of soft lenses. Yet Allergan had had to pitch the recommended prices of its Oxysept disinfectant below CV-UK's 10.10 in order to make inroads into the latter's entrenched position. Allergan had also been the first to introduce a larger pack size at a lower unit price. Competitive pressures had obliged Allergan to cut the real prices of its products. Even in protein removers, where it had been the first in the field, it faced competition from five other suppliers and had seen its share fall despite real reductions in price and the introduction of an innovative new product, Ultrazyme. Allergan said that it had also kept a tight rein on its overhead costs.

8.135. Allergan presented figures, collected at our request, which it said showed that its recommended prices in the UK were generally below those of Allergan group products in other countries, apart from the USA.

8.136. Allergan said that seen in this context its profits were not excessive. Its high accounting returns did not reflect the true position, hence the adjustments which it submitted should be made to its statutory accounts. Its profitability was comparable with that of pharmaceutical companies, with which Allergan's CLS business had much in common.

8.137. We have noted these arguments carefully. But there is another side to the story. Of the two leading suppliers, Allergan has been significantly the stronger in recent years, as noted in paragraph 8.128. Although Alcon and B&L also operate in the UK, their impact on competition in key parts of

the market has been adversely affected by UK product licensing requirements (see paragraphs 8.116 and 8.117).

8.138. In disinfectants, which account for over 60 per cent of the overall total, Allergan and CV-UK have nearly 80 per cent of the market between them and about 95 per cent of sales of peroxides, which are currently by far the most popular product type. There is rivalry between Allergan and CV-UK but, considering the extent of the price difference between a peroxide system and a chlorine system (see paragraph 8.15), we do not regard the movements in RRPs for peroxides over the last five years as evidence of strong price competition (see paragraphs 3.187, 3.198 and Table 3.18).

8.139. We cannot attach much weight to the comparisons of retail prices of Allergan group products in different countries, since (as Allergan itself argued) such comparisons may be affected by a wide variety of factors, and we have not been able to carry out a study in the depth which would be required if firm judgments were to be based on the results. We accept that the figures presented by Allergan and other suppliers give no ground for believing that prices in the UK are above average among European countries, though we note that, as with many other products, prices in the more competitive environment of the USA appear to be significantly lower.

8.140. The weakness in competition at retail level which we discuss later in this chapter has benefited Allergan, in common with other suppliers, in as much as retailers are less likely to put pressure on the suppliers to cut prices than they would in a more competitive market where retailers themselves were under pressure.

8.141. As to the level of Allergan profits, we note Allergan's arguments about the treatment of operating leases. Other CLS suppliers also make substantial use of operating leases, however. To the extent that we need to assess the profitability of Allergan against that of its competitors and of other companies, this has to be done on the basis of standard accounting practice. Similarly as regards R&D and promotional expenditure, since these are not capitalized in Allergan's statutory accounts we see no sufficient reason to depart from the company's own practice in making our calculations of ROCE. We consider that the way to meet Allergan's point is to assess the company's profitability by reference to the results of other companies for which similar considerations arise.

8.142. It follows that the profitability figures which we consider appropriate as the basis for assessing Allergan's results are those in Table 8.2. These show ROCE averaging 102 per cent over the last five years, with the highest level of 120 per cent resulting from the estimated results for 1992.

8.143. Comparing these figures with the results of pharmaceutical companies, we find that the Allergan ROCE far exceeds the average of three major UK companies specializing in pharmaceuticals, namely Glaxo, Wellcome and Fisons: see Table 4.48. Allergan submitted to us the results of a consultants' survey of the accounts of pharmaceutical manufacturers (see paragraph 4.106). These showed that the ROCE of UK-based groups had averaged about 50 per cent in 1989 and 1990: about half the level achieved by Allergan and API on their UK CLS business.

8.144. The usual argument for high profits in the pharmaceutical industry is that the business is R&D-intensive and high risk. We consider that this argument is less valid for CLS since the products are less complex and the suppliers' level of spending on R&D, an average of about 5 per cent of turnover, is about a third of the norm for pharmaceutical companies (see paragraph 4.110).

8.145. We have also compared Allergan's profitability with that of the other CLS suppliers (see Appendix 4.1). Such comparisons have to be treated with caution because of differences in the operations of the companies concerned. The most appropriate comparisons are with CV-UK and CVLCP combined and with Sauflon, since in each case the figures encompass manufacturing as well as distribution. Allergan's net margin on turnover was far above that achieved by the other two suppliers (and indeed all the others active in the UK) in the period 1989 to 1991. The picture as regards ROCE is more varied but the only companies to have achieved returns as high as Allergan in any year are Alcon and B&L/M&L which are distributors only and therefore have a low capital base.

8.146. We asked Allergan to allocate its costs to individual products in order that we might examine the profitability of its leading solutions in the individual product markets which we identified (see

paragraph 8.21). The results, for 1991, are set out in Table 1 of Appendix 4.2. These figures too must be treated with caution because of the assumptions underlying the cost allocations, but we note that Allergan's net profit margin on Hydrocare Fizzy, its leading protein remover, was 50 per cent higher than the average for seven of its main products. We regard the size of this differential as evidence that Allergan has made particularly high profits in the protein removal market where its share is 70 per cent.

Finding on Allergan's prices and profits

8.147. Allergan has achieved high levels of profitability in each of the last five years, well above the average even for pharmaceutical companies. This may have been partly the result of Allergan's success in product innovation, its efficiency in production and marketing, and its low overheads. But we consider that Allergan has also been able to charge higher prices than would have been the case in a more competitive market and we conclude that this is contrary to the public interest.

Discounts

8.148. In 1987 Allergan cut its normal discount to optical wholesalers from 25 to 15 per cent, having previously invited the other suppliers to a meeting to inform them of its intention and to explain its reasons (see paragraphs 6.74 to 6.78). Two of the other suppliers followed suit. We make no public interest finding about this action, although we consider that it indicates an unhealthy lack of competition in the market at that time.

8.149. Allergan now gives discounts to opticians which are on average higher than its discounts to wholesalers, even though opticians frequently place smaller orders than wholesalers (see Table 4.41). Allergan said that this was in recognition of the importance of the services which opticians were able to provide to it. It told us that it gave 25 per cent discounts to opticians who agreed to recommend Allergan products to customers wherever it was professionally appropriate. The opticians who gave oral evidence told us that they never entered into such agreements, which they would regard as cutting across the optician's duty to recommend whatever products were judged most suitable for the individual customer. We have considered whether this practice distorts competition in a way which might be contrary to the public interest. We have concluded that its effects on competition are unlikely to differ significantly from other practices—such as the linking of discounts to size of order, the offering of retrospective discounts, and indeed simply selling CLS to opticians at a price which gives the retailer a bigger margin than competing products—all of which give the optician a financial incentive to recommend one product in preference to another. This is inherent in a situation where opticians act both as retailers of CLS and as professional advisers to customers (see paragraph 8.11). Overall we find that Allergan's discounting practices are not contrary to the public interest.

Resale of Allergan products

8.150. One optical wholesaler told us that it had found it impossible to deal profitably in Allergan products after the discount which it received from Allergan was cut from 25 to 15 per cent. It had been able to obtain supplies at a lower price from opticians, who were buying from Allergan at a 25 per cent discount and reselling to the wholesaler. Allergan told us that it was opposed to any of its optical retailers, to whom it gave a 25 per cent discount in consideration of services provided, reselling the products to customers who did not provide these services. Such action enabled the wholesaler in question to compete unfairly with other wholesalers and to give the benefit of a differential discount to retailers who did not provide the services. Allergan had not so far prevented such resales but believed it should be free to say to retailers that the discount on any products which they were reselling would be 15 per cent, as befitted a wholesaler.

8.151. This situation has arisen because of Allergan's segmentation of the market by giving bigger discounts to some customers than others unrelated to cost savings or size of order. For Allergan to cut its discount to certain opticians in the circumstances described might constitute a refusal to supply, in the terms of the Resale Prices Act 1976, and would be tantamount to its exercising control over

the resale of its products with the purpose of preserving this market segmentation. Given Allergan's market power and the weaknesses which we have identified in the competitiveness of the CLS market, we believe that such action could further restrict competition in a way which might be contrary to the public interest. The relevant authorities might also need to consider how the action stood under the Resale Prices Act 1976.

Conclusion on Allergan

8.152. In response to the questions in our terms of reference (see Appendix 1.1) we have concluded that Allergan's pricing policy constitutes a step taken for the purpose of exploiting the monopoly situation in its favour and that this is a fact which operates against the public interest, with the specific adverse effect that it has caused prices of CLS to be higher than they otherwise would have been.

CIBA Vision (UK)

8.153. CV-UK was the market leader in 1988, the year in which CIBA Vision acquired the UK CLS business of The Cooper Industries Inc, with 43 per cent of the overall market. It owed this position mainly to its dominance of peroxide disinfectants—The Cooper Industries Inc had been the first company to introduce a peroxide product into the UK market in 1985, and CV-UK still had nearly 70 per cent of the total sales in 1988. As we have seen (see paragraph 8.102), CV-UK's position was steadily eroded over the following few years until 1992 when it appears to have staged a modest recovery, taking its overall share from 32 to 34 per cent. Its main strength still lies in peroxide disinfectants, where its 10.10 solution (including supplies to Boots and D&A for sale under their own labels) is the top-selling product in the CLS market. CV-UK's position in the other product markets is much less prominent: compared with its 42 per cent share of the disinfecting market in 1992 it had 17 per cent of the surfactant cleaner market and 21 per cent of the saline market, and it has no protein removal product. [

Details omitted. See note on page iv.

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8.154. CV-UK along with S&NP was one of the first suppliers to sell solutions to retailers for resale under their own labels. Estimates for 1992 indicate that it still made more than half of all such sales of CLS by suppliers in that year, and these sales represented over a quarter of its total turnover in solutions. For the reason given in paragraph 8.106, the proportion by volume must be higher. Clearly CV-UK, unlike Allergan, espoused own-label business at an early stage as a means of protecting and enhancing its position in the market. One consequence of this policy is that 50 per cent of its total CLS sales in 1992 were to the two leading retailers, Boots and D&A, which are also the leading own-label retailers.

8.155. Following its acquisition of the UK CLS business of The Cooper Industries Inc, CIBA Vision decided to build a new manufacturing plant in Macclesfield as the main European production source for the CIBA Vision group. It has invested over £20 million in this plant, which is operated by CVLCP and now supplies the great majority of CV-UK's requirements for solutions. Previously CV-UK had its own, much smaller manufacturing unit at Southampton which closed in May 1991, following the commencement of production at Macclesfield in late 1990. CIBA Vision told us that it had encountered considerable production problems with the new plant as a result of which CV-UK had had to obtain supplies from other sources including subcontractors. The production problems had now been largely overcome but they had caused both supply shortages and extra costs for CV-UK in 1990 and 1991.

Profits

8.156. The effect of these problems can be seen in the group's financial results which are set out in Tables 4.10 to 4.13. CIBA Vision represented to us that the best way to assess its profitability was to look at the combined figures for CV-UK and CVLCP since they embraced the CLS manufacturing as well as distribution activities. On this basis Table 4.13 shows that on UK CLS business the CIBA Vision group earned a margin on turnover averaging 10 per cent over the five years, fluctuating in a

fairly narrow band from 7 to 13 per cent. ROCE, however, fell from 66 and 56 per cent in 1988 and 1989 respectively (the years before CVLCP existed) to 11 per cent in 1990 and 8 per cent in 1991 before recovering to an estimated 16 per cent in 1992.

8.157. This sharp fall in ROCE is due to a big increase in capital employed as a result of the investment in the Macclesfield factory and to losses being incurred by CVLCP in its first two years. Production from the plant was initially devoted mainly to the UK and so CIBA Vision has attributed the bulk of the losses and capital employed to the UK, though less so in 1991 than 1990 as production and export sales built up. We consider that these attributions have depressed the profitability of the CIBA Vision UK CLS business below what would reasonably be expected, in that the Macclesfield plant was designed to serve many other markets besides the UK. CIBA Vision told us, however, that it regarded the estimated results for 1992 as reasonably indicative of the results they expected to achieve over the next few years. For our part we would expect some further growth in output by CVLCP in view of the amount invested in the Macclesfield plant and the fact that the production problems were still being overcome in the course of 1992. This may lead to higher levels of profitability.

8.158. CV-UK was highly profitable in terms of ROCE in 1988 and 1989, although margin on turnover in those years was modest at 7 and 12 per cent respectively. CIBA Vision told us that the high ROCE was largely due to the fact that the assets in CV-UK's production plant at Southampton had been substantially written down. The separate figures for CV-UK in 1990 (see Table 4.11) show ROCE even higher at nearly 100 per cent and margin on turnover rising to 22.5 per cent. According to CV-UK these levels of profitability were the result of running the Southampton plant at a high level of output in anticipation of its closure and the transfer of production to Macclesfield. The company therefore achieved high output and low unit costs from equipment with a low capital value. This was a temporary state of affairs pending the full coming on stream of the Macclesfield plant.

8.159. Because of these changes in operations, it has not been possible to arrive at a complete picture of the underlying profitability of CIBA Vision's UK CLS business over recent years. The information given to us, however, indicates that it is unlikely that profits have been particularly high during the five years 1988 to 1992 taken as a whole. For some products, notably 10.10, CV-UK's RRPs have been a little higher than Allergan's competing products. But CV-UK has been obliged to concede higher discounts on branded products (see Tables 4.41 and 4.43) and a much higher proportion of its sales are for retailers' own labels and command lower prices than branded products. The evidence we obtained, including that relating to profits, is that CV-UK's prices have not been contrary to the public interest.

Discounts

8.160. In common with other suppliers, CV-UK gives its highest discounts off trade price to Boots and its second highest to D&A. Like Allergan its standard discount to wholesalers is 15 per cent (though the average given in practice is a little higher) and it grants considerably higher discounts to opticians than to wholesalers (see Table 4.43). (Coopervision Ltd, The Cooper Industries Inc's UK CLS subsidiary, was one of the suppliers which joined Allergan in 1987 in cutting the standard discount to wholesalers from 25 to 15 per cent: see paragraph 8.148.) We regard CV-UK's discounting policy in general as a response to market conditions and as a means by which it seeks to compete with Allergan and the other suppliers.

8.161. Unlike Allergan, CV-UK makes significant use of retrospective discounts which customers can earn by achieving sales targets in quarterly periods. CV-UK has such agreements with seven customers (three optical wholesalers and four chains of retail opticians) together representing 12 per cent of its sales in 1992. The value of the retrospective discounts is, however, a small proportion of the total discount offered to these customers. CV-UK told us that it introduced these arrangements at the beginning of 1992 because it understood that similar arrangements were being used by some of its competitors. Experience with these discounts had so far been mixed, in that some customers had hit their targets in one or both of the periods elapsed to date while others had not.

8.162. Retrospective discounts can be anti-competitive in some circumstances, particularly if used by a company with market power seeking to shut out smaller suppliers. We do not believe that this is currently the situation with CV-UK.

Negotiations with major retailers

8.163. CV-UK told us that in late 1990 Boots observed that D&A was selling CV-UK products to consumers under its own label at prices below those which Boots was charging for the same products under the Boots brand. According to CV-UK, Boots informed it that unless D&A brought its prices in line with Boots', Boots would match D&A prices and expect CV-UK to pay the difference of any erosion in Boots' margins. CV-UK said that it presented this scenario to D&A which realigned its prices from being 5 per cent below Boots' to 2.5 per cent below. CV-UK said that although Boots had raised the matter with it on two further occasions, it had taken no further action, explaining to Boots that it was not in a position to cause D&A to bring its pricing into line with Boots (see paragraphs 6.135 to 6.137).

8.164. Boots confirmed to us that it had raised with CV-UK the prices at which D&A was selling CV-UK products though its account of the episode differed in some respects from CV-UK's. In particular it denied that it had put pressure on CV-UK, though it said that CV-UK was aware of the importance which Boots attached to maintaining its margins (see paragraphs 7.12 to 7.14).

8.165. D&A told us that CV-UK had said D&A should be mindful of its discounting policy for own-label solutions as Boots would react in a competitive manner. D&A said that this comment was never taken into account when pricing discount decisions were made in respect of its own-label products. Changes in D&A's own-label prices had not been effected until October 1991 (see paragraph 7.61).

8.166. Although there are discrepancies between these statements it is clear to us that Boots attempted to use its power over CV-UK to influence D&A into increasing its prices for own-label solutions. We return to this matter in the context of our consideration of Boots' scale monopoly situation. As far as CV-UK is concerned we consider that its statement to D&A might be construed as an attempt to take advantage of its strength as a supplier to avoid pressure being brought on it by Boots to increase its discounts to Boots. But CV-UK does not appear to have tried very hard to influence D&A, according to D&A did not succeed in doing so, and did not take any further action in response to subsequent promptings from Boots. We conclude that CV-UK's action did not amount to an action attributable to its monopoly situation.

Conclusion on CV-UK

8.167. Having considered the evidence we conclude, in the terms of the Act, that CV-UK is not taking any steps for the purpose of exploiting or maintaining the monopoly situation in its favour, and that there are currently no actions or omissions on its part which are attributable to the monopoly situation. We have found no facts, in the course of our inquiries into this monopoly situation, which operate or may be expected to operate against the public interest.

Boots

8.168. Boots has rapidly increased its share of retail sales of CLS, measured at retail prices, from 29 per cent in 1989 to 36 per cent in 1992. (Information on suppliers' sales shows only 28 per cent going to Boots in 1992. The explanation for this difference is that Boots buys at lower prices than any other retailer but sells all branded solutions at the RRP and sells own-label solutions at an average of only 6 per cent below the recommended prices of the equivalent branded products. In addition BOL sources some branded solutions through optical wholesalers.) All the increase in Boots' sales between 1989 and 1992 came from its pharmacies, which by 1992 accounted for some 85 per cent of the Boots total. Boots is the only retailer which is well represented among both opticians and pharmacies and is therefore in a uniquely advantageous position in the CLS market. Unlike many other

large opticians BOL has no discount scheme for CLS: it sells them on the same terms as BTC. Boots is also the only pharmacist to sell own-label solutions although we were told of plans by UniChem and by another pharmacist to launch own-label products during 1993 (see paragraph 8.110).

8.169. We invited Boots to comment on whether the scale monopoly situation:

— had adversely affected competition in the supply of CLS at retail level;

— enabled Boots to charge higher prices and achieve higher margins on own-label CLS, by not passing on to customers the benefits of the lower prices which it secured from suppliers, than would otherwise have been possible;

— enabled Boots to extract larger discounts from suppliers than would otherwise be possible; and

— enabled Boots to sell branded CLS at RRP rather than passing on to customers the benefits of the larger discounts which Boots received from suppliers, thus achieving higher margins than would otherwise be the case.

8.170. Boots said that it did not believe the monopoly situation adversely affected competition in the retailing of CLS. BTC had only 9 per cent of pharmacies and BOL only 4 per cent of opticians' practices in the UK; overall Boots operated about 6.6 per cent of all retail outlets selling CLS. The consumer had a choice of outlet almost everywhere.

8.171. Boots said that its share of CLS sales had exceeded 25 per cent only in the last three years but the characteristics of the market and Boots' activity in it had been constant for much longer. Boots therefore submitted that the existence of the monopoly situation had not affected the market at all. For example, Boots' pricing policies were the same, and its margins on CLS broadly the same, as before the monopoly situation existed.

8.172. In response to our questions Boots said that it had a unique competitive mix among CLS retailers which was based on the provision of advice and service, the range of products stocked, and value for money, all provided in convenient high street locations in which it had invested heavily. Boots did not regard CLS as a price-sensitive market. The fact that it had rapidly increased its sales and market share without engaging in aggressive pricing showed that it was giving customers what they wanted. There was price competition and Boots was ready to respond if necessary but in view of the success of its present strategy it had seen no good reason to cut prices.

8.173. Boots told us that it needed good gross margins in order to cover the costs of its highly qualified staff and its expensive high street locations. At the net level its profits were not out of line with other retailers. Since it took central delivery of bought-in goods and acted as its own wholesaler, it needed bigger margins than retailers who enjoyed delivery direct to store. Healthcare products such as CLS were particularly staff-intensive. Boots also needed bigger gross margins on own-label than on branded products in order to cover the extra marketing costs involved, particularly on the provision of free starter packs.

8.174. Boots said that its general policy in selling own-label products was to price them in the range 5 to 15 per cent lower than the equivalent branded products. It told us that its prices for own-label CLS were about 5 per cent below the equivalent branded products. The prices of its own-label solutions were largely dependent on the price charged by the manufacturers, only two of which could offer the technologically advanced products which Boots wanted. The manufacturers would be reluctant to supply for own-label sale if the price differential on the shelves was such as to undermine their proprietary products. Boots also argued, however, that the weighted average price of its own-label solutions was 12 per cent below that of the branded products.

8.175. The information we have collected shows that Boots' share of the CLS market has exceeded 25 per cent at least since 1989 and probably earlier: see Table 3.15. We therefore do not accept that the monopoly situation has existed for only three years, as Boots contended (see paragraph 8.171). In any case the question whether Boots' behaviour changed after it attained a 25 per cent share of the market is not relevant to our analysis: 25 per cent is the level used in the Act for the purpose of

defining whether a scale monopoly situation exists, but that does not preclude the possibility that a firm with a market share somewhat below that level may behave in an anti-competitive way.

8.176. Information we received from Boots showed that BTC's gross margins on CLS have averaged 53 to 54 per cent in the three years to March 1992. This compares with 50 to 51 per cent for the rest of BTC's non-dispensing healthcare business (of which CLS form part) and a 41 to 43 per cent average for BTC as a whole: see Table 4.33. (These figures are based on Boots' supplies to retail stores—see paragraph 4.67—and are a little higher than gross margins on actual sales would be, but comparisons with other figures on the same basis may properly be made.)

8.177. BTC's gross margin on own-label CLS has averaged 61 per cent in the last two years compared with 50 per cent for branded CLS. Boots told us that a similar pattern could be observed for its business in own-label and branded over-the-counter medicines. When allowance is made for the extra costs incurred in marketing the own-label solutions (see paragraph 4.74) the difference in gross margin falls to two percentage points according to figures Boots gave us for 1991/92. Boots added that because of the lower prices at which it sold own-label solutions, its average gross margin on their sale was slightly lower, in cash terms, than the average margin on branded solutions. The gross margins on BOL's sales of own-label and branded CLS are similar to BTC's.

8.178. Boots does not calculate net profit margins or ROCE at product level. BTC as a whole earned net profits before interest and tax rising from 8.4 per cent of turnover in 1990 to 10 per cent in 1992, years in which the average for the UK stores sector as a whole fell from 7.9 to 6.2 per cent (Table 4.50). BTC's ROCE in 1992 was 25.4 per cent after adding to capital employed the value of properties (which are owned by a different group company), compared with 14.3 per cent for the stores sector (Table 4.51).

8.179. It will be seen that CLS gross margins are well above the average for BTC, and that BTC's overall net profit is well above average for the stores sector. It is against this background that we examine Boots' behaviour in the market.

8.180. It appears to us that, aided by the number, location, size and quality of its stores, Boots exercises substantial market power, in that it has room to make its own decisions without regard to the reactions of other players in the CLS retail market. Its position is also strong in relation to the large suppliers, all of whom are dependent on Boots for a big proportion of their sales. In 1992 Boots took 37 per cent of CV-UK's sales of CLS, 31 per cent of Allergan's and 28 per cent of Alcon's (Table 3.11). Most of the smaller suppliers who deal exclusively or mainly with opticians do not sell to Boots at present but they will find it difficult to raise their market shares very far without being obliged to trade with Boots.

8.181. The main suppliers told us that the big discounts which they accorded to Boots were attributable to Boots' negotiating strength. Allergan said that both Boots and D&A required high discounts as a pre-condition of listing a supplier (see paragraph 3.217). CV-UK said that Boots insisted on a minimum level of profit before it would stock a product (see paragraph 6.133) and gave us an example of a solution which Boots had refused to take because this profit could not be achieved. Alcon said that Boots required a 50 to 57 per cent discount off RRP (see paragraph 6.201).

8.182. Boots argued that there were only two strong suppliers: their products were 'must stock' items and Boots was therefore obliged to deal with them. On the other hand Boots is the only scale monopolist at retail level, with a share of the retail market far greater than the next biggest retailer. It therefore has the ability to play off Allergan and CV-UK against each other. Boots' position *vis-à-vis* smaller suppliers is stronger again.

8.183. Figures given to us by the suppliers show that Boots receives the biggest discounts off trade price in its purchases of solutions (see paragraphs 4.88 to 4.99). In 1991 Allergan's average discount to Boots was 34 per cent compared with 30 per cent to D&A, 20 per cent to opticians and 16 to 17 per cent to wholesalers. CV-UK's discounts showed a broadly similar pattern, the corresponding figures being 38, 37, 27.5 and 18 per cent. Alcon's figures indicate a much higher average discount for Boots, at 44 per cent, and a bigger differential over D&A (35 per cent), opticians (23 per cent) and pharmaceutical wholesalers (13.5 per cent). Our analysis of differences in the gross margins earned

by retailers on CLS shows that, among 17 major products, Boots' margin exceeded the average for opticians by more than 20 per cent on all but two (see Table 4.47).

8.184. Allergan drew our attention to the significance of the own-label business of major optical chains such as Boots and D&A. It said that the introduction of an own-label product, accompanied by an instruction to opticians to recommend that product to their customers, virtually guaranteed a certain sales volume for the supplier at the expense of its competitors. Allergan cited the example of its Oxysept peroxide system: once CV-UK commenced supplies of 10.10 for Boots' sale under its own label it had become very difficult for Allergan to achieve recommendations from Boots' opticians (see paragraphs 6.23 to 6.26). (Although the RRP for the standard size of Oxysept packs is a little below 10.10's, it is a little above the Boots own-label version.)

8.185. Boots said that its opticians always advised new patients to use Boots' own-label solutions unless there were clinical reasons to the contrary. They did so because they regarded those products as the best available on the UK market and because, being priced below the recommended price of the equivalent branded products, they offered the best value for money.

8.186. In 1992 own-label solutions accounted for 35 per cent of Boots' total sales of CLS, and 45 per cent of its sales through BOL. This is well below the equivalent proportion for D&A (an estimated 65 per cent by volume in 1992). But we note that between 1989 and 1992 sales of Boots' own-label solutions grew much faster than sales of branded solutions; indeed in the case of BOL, own-label sales nearly quadrupled whilst branded sales fell (see Table 3.16).

8.187. Boots told us that it had no contracts for its supplies of own-label solutions because it preferred to retain flexibility to respond to events. [

Details omitted. See note on page iv.

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8.188. Boots' ability to exercise market power in relation to other retailers puts it in a strong position to retaliate against any perceived threat to its business. It is worth noting also that overall demand for CLS probably does not respond much to changes in price. Few of our witnesses thought that a reduction in the price of solutions would stimulate an increase in the number of lens wearers and hence boost demand for solutions. Retailers collectively therefore cannot greatly expand the volume of CLS sold and to that extent have less motivation for cutting prices than is the case for many other products.

8.189. We observe that Boots buys at the lowest prices and yet sells all branded CLS at the recommended price and gives only a small reduction on its own-label products, thus failing to pass on the benefits of its aggressive purchasing to its customers. (For some non-CLS products, such as paracetamol, the difference between Boots' own-label price and the branded equivalent is much greater than the 5 to 15 per cent range which Boots cited to us (see paragraphs 3.206 to 3.211).) As a result it enjoys the substantial margins referred to in paragraph 8.176. Boots' evidence indicates that this is due to a lack of sufficient competition in the retail market. This is partly the result of the regulatory controls which not only restrict outlets to opticians and pharmacies but also have the effect of weakening competition among suppliers and hence reducing retailers' ability to negotiate terms. But we believe the competitive weakness is also due to the position and behaviour of Boots, which exercises price leadership. The MMC's 1981 report on *Discounts to Retailers*[1] found that the granting of discounts to large buyers had tended to increase concentration in retailing but that the benefits of lower buying prices had been substantially passed on to consumers. This is not the case as far as Boots' operations in the CLS market are concerned. Boots' conduct towards CV-UK, described in paragraphs 8.163 to 8.166, indicates that when it felt threatened by price competition from another major retailer Boots' reaction was not to cut prices in response but to apply pressure with a view to persuading the other retailer to raise its prices.

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[1] *Discounts to Retailers: a report on the general effect on the public interest of the practice of charging some retailers lower prices than others or providing special benefits to some retailers where the difference cannot be attributed to savings in the supplier's costs*, HC 311, May 1981.

8.190. We also note that BOL, unlike other major chains of opticians, has no discount scheme covering CLS. Uniquely it is able to recommend its own-label products without having to attract customers back to its own outlets. Instead customers can buy the products from BTC which relies on the convenience factor and on the other elements in Boots' 'competitive mix' to generate trade, not on price.

Conclusion on Boots

8.191. We conclude that Boots' pricing policy in relation to CLS is a step taken to exploit its monopoly situation and is a fact which operates against the public interest, with the particular adverse effect that it causes prices for CLS to be higher than they otherwise would be.

Suppliers complex monopoly situation

8.192. The practice which we consider in this section is the setting by suppliers of RRPs (see paragraph 8.66).

8.193. The views which the suppliers put forward in arguing that setting recommended prices did not amount to 'complex monopoly' behaviour are relevant here also (see paragraph 8.58). In addition suppliers argued that recommended prices were helpful to retailers, giving them a bench-mark against which to reach their own pricing decisions; and to suppliers who wanted to compete on price, by enabling them to demonstrate how their recommended prices compared with those of rival products. Examples of such behaviour were Allergan, which set its recommended prices for Oxysept below CV-UK's 10.10 in order to attack the latter's entrenched position; and Sauflon and PBH which said that their publicity material used recommended prices in order to highlight the value for money offered by their own systems compared with those of the market leaders. In the absence of price recommendations, suppliers said that retailers would rely on traditional mark-ups and independently published price guides. There was no reason to think that retail prices would be lower, rather than higher, if recommended prices were not set by suppliers, nor that competition would increase.

8.194. In assessing the effect of this practice it is important to draw a distinction between the conduct of suppliers in listing recommended prices and that of retailers in responding to those recommendations: consideration of the latter belongs to the next section (paragraphs 8.198 to 8.203). In paragraph 8.63 we noted that the recommendation of retail prices in conjunction with the restriction of outlets was among the circumstances identified in the MMC's 1969 report as possibly causing prices to be higher than they otherwise would be. Since outlets are indeed restricted in the CLS market, we have to examine the effect of suppliers' price recommendations with particular care.

8.195. Some of the smaller suppliers choose to sell only through opticians but the leading players supply pharmacies as well. As a result most of the 17,000 outlets of opticians and pharmacists combined sell solutions. All the suppliers also make a significant proportion of their sales through wholesalers. In these circumstances it would be impossible for the suppliers to control the pricing behaviour of all retailers of solutions. They could attempt to influence the market by seeking to enforce their price recommendations on the leading retailers but we received no evidence that they did so. A significant proportion of opticians do sell branded solutions at a discount from the RRP, although this is often done only in the context of discount schemes for regular customers, which have disadvantages as a form of price competition (see paragraph 8.82).

8.196. We have attempted to judge whether prices would be likely to be higher or lower if suppliers were banned from publishing recommended prices. We believe that many pharmacists would continue to look to a source of external guidance, such as the *Chemist & Druggist* which publishes a great deal of price information, and would simply attempt to follow the market. To the extent that they took their own decisions, we cannot exclude the possibility that some of them would choose to increase prices particularly in areas where there is little competition, having regard to the fact that for many pharmacists, particularly small, independent outlets, CLS are probably slow-moving and not particularly profitable products. The same might well be the case with some of the smaller opticians. For such retailers, recommended prices effectively set a maximum price: the evidence we received

suggested that very few retailers charge prices above the recommended level. A prohibition on the setting of recommended prices would therefore be likely to lead to a wider dispersion in retail prices, with some being lower but also some higher than would be the case if recommended prices continued.

8.197. Taking account of these factors we have concluded that the setting by suppliers of RRPs is not a practice which in this market operates against the public interest.

Retailers complex monopoly situation

8.198. We next consider the other side of this coin, namely the practice by a substantial majority of retailers of selling branded CLS at, or only just below, RRP (see paragraph 8.85).

8.199. Again the views expressed by retailers and their representative bodies which we summarized in the section on the existence of the complex monopoly situation (paragraphs 8.77 to 8.80) are also relevant to the consideration of the public interest.

8.200. We have considered why such a high proportion of retailers observe the suppliers' recommendations on retail prices. There appear to be three reasons. First, we judge that many retailers share the view of Boots that consumers are not price-sensitive. We received evidence that lens wearers tend to follow their opticians' advice as to choice of lens care system. Our survey of consumers found that only 12.5 per cent of the sample had changed solutions for reasons of price. Neither suppliers nor retailers thought that overall demand for solutions would increase if prices were lower. On the other hand retailers still have the motive of pricing keenly in order to take a greater share of the available market.

8.201. Secondly we accept that for many small retailers, particularly independent opticians and pharmacists who obtain their supplies through wholesalers, the margin between the price they pay their supplier and the RRP may not leave much room for discounting. This is not the case for the optical chains, however, still less for Boots; and the evidence on discounts suggests that even quite modest-sized opticians (eg independents with a few outlets) will enjoy terms a good deal better than the normal retail margin.

8.202. Thirdly we believe the structure of the market weakens retailers' motivation to compete on price. Several factors are at work here. The MCA prohibition on the sale of solutions other than by opticians and pharmacists prevents the entry of other types of retailer, notably supermarkets and drug-stores, which would be more likely to price competitively. Boots' practice of selling all branded CLS at recommended price provides a shelter for other retailers to do the same, while its powerful position deters others from risking retaliation if they were to cut prices significantly. Boots' own-label products are priced at only a modest discount to the recommended prices of the equivalent branded products. Finally, as noted in paragraph 8.64, there is a tendency among pharmacists to treat CLS as if they were proprietary medicines and hence subject to resale price maintenance.

8.203. While some of the factors set out above are not attributable to retailers (and we address those elsewhere in this report), we believe that many more retailers could sell branded CLS at less than the recommended price while still making a sufficient return, thus offering consumers better value for money. Moreover if there were more price competition, retailers would be likely to put more pressure on suppliers to cut the prices at which they sell to retailers and this would act as a stimulus to efficiency among suppliers. We conclude that the observance of recommended prices by a substantial majority of retailers is a step taken for the exploitation of the monopoly situation and operates against the public interest, with the effect that it causes prices of solutions at retail level to be higher than they otherwise would be.

Opticians complex monopoly situations

8.204. These situations arise from the two practices listed in paragraph 8.86, both of which concern the advice and information given by opticians to patients. Paragraphs 8.89 and 8.90 set out the views of opticians and their representative bodies on how widespread these practices were and whether they constituted 'complex monopoly' behaviour.

8.205. Opticians further argued that, in respect of opticians' recommendations of particular lens care systems to patients (the first practice), there were very good clinical reasons for not recommending cold chemical disinfecting solutions for soft lens wearers. The majority said that there were also good grounds for recommending peroxide disinfectants in preference to chlorine tablets for soft lenses, although one major optical chain told us it considered that chlorine systems were just as effective as peroxides and were easier to use, as well as cheaper.

8.206. We cannot comment on the respective merits of different solutions. Our concern is that opticians should tell customers about the alternative systems available and the advantages and disadvantages of each, including relative costs. Opticians could still make clear which system or combination of products they favoured. We cannot accept that this approach would conflict with an optician's duty to give the best advice. Because of the potential conflict of interest inherent in the dual role of opticians (see paragraphs 8.11 and 8.149), it is important that opticians should not put themselves in the position of appearing to favour solutions which are more expensive for consumers and bring higher cash margins for opticians. We regard the failure of most opticians to put a range of options to patients, and thus enable them to take account of relative costs in choosing solutions, as an omission attributable to the existence of the monopoly situation and we conclude that this omission is a fact which operates against the public interest, with the specific adverse effect that it restricts consumers' ability to exercise informed choice in purchasing solutions.

8.207. As regards the second practice, opticians have a duty, which is laid down in the guidelines of their regulatory bodies, to make clear to customers what the continuing costs of wearing contact lenses will be (see paragraph 8.90). We believe the evidence of our consumer survey shows that many opticians are failing to observe this duty so far as solutions are concerned. As a result customers may take on a financial burden which they had not expected, with various further possible consequences, including weaknesses in compliance with lens care regimes (see paragraph 8.16). We conclude that this practice is an omission attributable to the existence of the monopoly situation and that it operates against the public interest because it deprives customers of information they need in order to make soundly-based decisions about contact lens wear and care.

Summary of conclusions

8.208. Whilst there is evidence of—sometimes quite keen—competition in various parts of the CLS market, there are also important weaknesses in the competitive process and in the way the market operates. We have found a number of features which in our view operate against the public interest.

8.209. We have concluded that three scale monopoly situations exist in relation to the supply within the UK of CLS by virtue of sections 6(1)(*a*) and (*b*) of the Act (see paragraphs 8.31 and 8.50). We have concluded that these monopoly situations exist respectively in favour of Allergan, API and Allergan Inc; CV-UK, CVLCP and CIBA-GEIGY; and BTC, BOL and The Boots Company PLC (see paragraphs 8.43, 8.46 and 8.51).

8.210. We have also concluded that four complex monopoly situations exist by virtue of sections 6(1)(*c*) and (2) of the Act. These concern suppliers (paragraph 8.66), retailers (paragraph 8.85) and opticians (paragraphs 8.95 and 8.97). Paragraphs 8.67, 8.85, 8.95 and 8.97 set out our conclusions as to the persons in whose favour these monopoly situations exist.

8.211. We have carefully considered the facts found in the course of our inquiry, including those which flow from the monopoly situations which we have identified. We have concluded that there are facts arising from the scale monopoly situations in favour of Allergan and Boots, and from the complex monopoly situations in favour of retailers and opticians, which operate against the public interest. These facts are set out in paragraphs 8.152 (Allergan), 8.191 (Boots), 8.203 (retailers) and 8.206 and 8.207 (opticians). We have specified in those paragraphs the particular adverse effects which those facts have or may be expected to have.

8.212. We are required by section 54(3) of the Act to consider what action (if any) should be taken for the purpose of remedying or preventing the adverse effects we have identified, and we may if we think fit make recommendations as to such actions.

Recommendations

8.213. As described in our report (paragraphs 6.56 to 6.58 and 7.27 to 7.31), we explored in general terms with Allergan and Boots the implications of direct remedies for the adverse effects which we have found to result from the scale monopoly situations in their favour. Essentially these remedies would entail the imposition of controls on prices and/or profits. Such controls would have serious disadvantages, in particular by causing further distortions in the market, and we see them very much as second-best to measures which would introduce new competition and enable the market to work better.

8.214. We have remarked at various points on the influence on the market of the regulatory regime operated by the MCA. While there are other imperfections in the market, our judgment is that the adverse effects we have identified would not exist, or would exist to a much lesser extent, if it were not for this influence. Our preferred remedies therefore concern changes in the regulatory framework. These would address the adverse effects arising from the retailers complex monopoly situation as well as from the scale monopoly situations in favour of Allergan and Boots.

8.215. As far as product licensing is concerned, we have carefully considered the arguments put forward by the MCA and others (see Chapter 5) to justify the stringency of the current regime. In our view, however, there is a lack of balance in the assessment of applications in that too little weight is placed on considerations of ease of use and none at all on considerations of cost to the consumer. The MCA told us that it did have regard to ease of use in considering applications for product licences since decisions were ultimately a judgment of the balance between risk and benefit. We attach importance, however, to the evidence of Alcon, B&L and CIBA Vision to the effect that the UK market has so far effectively been closed to a number of products which are available in most other developed countries (see paragraphs 8.116 to 8.118). We received no evidence that in those countries the use of these products had given rise to any serious worries about safety. The 'all-in-one' solution marketed by B&L and the new generation disinfectant products of CIBA Vision and Alcon are designed for ease of use, and we consider that this factor should weigh more heavily in the appraisal process. Moreover the availability of such products could be expected to enhance the overall competitiveness of the market and bring down prices, with a further beneficial effect on users' compliance with lens care regimes.

8.216. The MCA told us that the terms of the Medicines Act prevented it from taking any account of price considerations, whether affecting particular products or the overall state of the market. This appears to be a consequence, therefore, of the original decision that solutions should be regulated as medicines: we note that under the agreement recently reached on the scope of the EC Directive on Medical Devices the great majority of CLS will be regulated as devices (being ancillary to contact lenses), not as medicines.

8.217. The implementation of the EC Directive on Medical Devices will bring major changes in the system. The expectation of most of our witnesses was that these changes would enable a wider range of products to be marketed in the UK. Such a development would foster competition among suppliers and widen choice for consumers.

8.218. The Directive, however, may not come fully into force until 1998. We therefore recommend that:

(a) The present regulatory authorities (the MCA, CDSM and the Secretary of State for Health) should take note of the adverse consequences of the present system, as identified in our report, and consider what changes should be made, consistent with safeguarding the health of contact lens wearers, to improve the situation. The changes should be designed to give greater weight to factors, including convenience and price/cost to consumers, which influence users' compliance with lens care regimes. In this respect the interpretation of the Medicines Act should be re-examined. We would expect such a change of approach to lead to the speedier availability of products which have been approved for use in other countries.

(b) The Government should give priority to the implementation of the EC Directive so that UK requirements may be brought closer into line with those in other EC member states well

before 1998. In this regard we have noted the view of one supplier that implementation of the Directive by other member states ahead of the UK would give companies based in those countries an unfair advantage, since they would be able to import into the UK products which had been approved elsewhere while domestic companies were still handicapped by the UK regulatory system.

We suggest that the Government's Deregulation Unit in the Department of Trade and Industry should be fully consulted about the health authorities' response to this recommendation.

8.219. With regard to retail outlets, we have carefully considered the arguments put to us by many parties—though not everyone in the CLS business shares this view—in favour of the current restrictions (see Chapters 5 to 7). These arguments are essentially threefold: that expert advice should always be available at the point of sale; that widening the range of permitted outlets would lead to a deterioration in compliance with lens care regimes; and that such widening would lead to a 'trivialization' of the products, particularly since removal of the restrictions would have to be complete, with the result that solutions, like GSL medicines, could be sold from all kinds of retail outlets.

8.220. On the first point we could see an argument for confining the sale of solutions to opticians, so that consumers would typically buy solutions from the optician who had fitted them with lenses and held the records of their optical history. In our view the drawbacks of such a restriction, in terms of loss of competition, choice and convenience for consumers, would clearly outweigh the advantages. What we consider unsustainable is the present arrangement whereby solutions can be bought off the shelf in pharmacies but not in other types of retail outlets such as drug-stores and supermarkets. Pharmacies have been permitted to sell solutions from open shelves since 1989 and Boots told us that it was not aware of any increase in customer problems, such as use of the wrong solutions, as a result of that change. In this respect solutions are treated like GSL medicines. Although a distinction can be drawn between solutions, which are usually required for everyday use, and GSL medicines which are in principle to be taken only at times of need, solutions generally pose less of a risk than certain GSL medicines (such as paracetamol) if misused.

8.221. It was put to us that customers did not always know they needed advice before going to buy solutions: for example, if a product was out of stock, customers would require advice on what alternatives would be suitable. We believe that in the great majority of cases customers would either know they needed advice, in which case they would probably contact their optician, or would definitely not require it. To deal with the small minority of customers who found they needed advice once they arrived at a retail outlet, it could be made a condition that retailers other than opticians and pharmacies should display notices telling customers to seek advice from opticians if they were in any doubt about the use of solutions or about the products they should buy. Moreover, any retailer who failed to stock complete ranges of products, or who allowed particular lines frequently to go out of stock, would be unlikely to attract customers for long.

8.222. The second argument—that widening the range of outlets would worsen the compliance problem—is linked to the first, since the availability of advice is thought to reduce the risk of lens wearers making mistakes. But it appears to us that the main causes of poor compliance (see paragraph 8.16 and Appendix 3.10) are not related to the availability or otherwise of advice when solutions are purchased. Indeed the restrictions on outlets may worsen the compliance problem since the weakness in competition which results from them keeps CLS prices high. Moreover the wider availability of solutions, particularly in supermarkets, would be likely to lead to some consumers buying them more regularly.

8.223. We do not attach much weight to the third argument, that wider availability of solutions would lead to their trivialization in the eyes of consumers. Again the comparison with GSL medicines is relevant: if the authorities deem it safe for those products to be on general sale, solutions could be treated in the same way. Indeed because the retailing of solutions is restricted via the product licences (see paragraph 8.7), it would be possible to widen the range of permitted outlets in a more controlled way than for products whose distribution is regulated according to routes laid down in the Medicines Act. This point also deals with concerns expressed to us about the conditions in which solutions were stored and the need to be able to recall faulty products.

8.224. We have also had regard to the situation in other countries. Although the pattern of retail distribution in the rest of Western Europe appears to be generally similar to that in the UK, solutions are sold without restriction as to range of outlet in other parts of the world, notably the USA and Canada. The USA alone accounts for about half the world's contact lens wearers. Despite our specific requests, no witness presented any evidence that this situation had led to a higher incidence of contact lens-related problems among wearers. In our view what has proved satisfactory for the world's largest contact lens market should be satisfactory for the UK.

8.225. In the light of the considerations set out above, we recommend that the retailing of CLS should be opened up to all retailers who wish to sell them and can satisfy reasonable and objective standards as to their arrangements for storage and product recall.

8.226. As long as the present restrictions remain, the existence of controls on the opening of new pharmacies (see paragraph 2.55) exacerbates the detriment to competition at retail level. While we recognize that any decision to ease or remove those controls will not be taken on the grounds of the effect on a small market such as CLS, we wish to reinforce the comments made in the MMC's February 1992 report on mergers in the pharmacy trade[1] to the effect that the controls have an adverse effect on competition.

8.227. There are three other points concerning the regulation of CLS which have caught our attention (as recorded in paragraphs 8.61, 8.62 and 8.125) and on which we make the following suggestions:

(a) the MCA should take the initiative to resolve the present unsatisfactory situation as regards the stated periods of recommended use for certain products: since this has implications for the general credibility of instructions to wearers, it should not be left to suppliers;

(b) the standard warning against the mixing of solutions without advice should be clarified; and

(c) the MCA should discuss with the suppliers the possibility of including statements of the number of doses, or the number of days' use, on the labels of all solutions as an aid to price comparisons.

Since these suggestions do not flow from the adverse effects which we have identified as attributable to the monopoly situations, they cannot be formal recommendations. We hope that the MCA nevertheless chooses to implement them.

Fall-back remedies

8.228. As stated in paragraph 8.214, we consider that the changes we have recommended in the regulatory system are the appropriate remedies for the adverse effects we have found to result from the scale monopoly situations in favour of Allergan and Boots and from the pricing behaviour of retailers generally. If for any reason they were not to be implemented in full, the question would arise whether direct action should be taken to address those adverse effects, which in each case essentially concern prices being too high. We discussed such possibilities with Allergan and Boots only in general terms, since they are not our preferred remedies.

8.229. As far as Allergan is concerned we recommend as a fall-back position that the weighted average of the RRPs which Allergan sets for its solutions should not be allowed to increase by more than the RPI less a specified factor (a formula commonly known as RPI minus X). Such a formula would be applied to an average of Allergan's prices weighted by each product's current or forecast contribution to Allergan's total revenue from sales of solutions. As to the level of 'X', Allergan told us (see paragraph 8.132) that its average price had fallen by 12 per cent over five years against the RPI, or about 3 per cent a year. We consider that the formula would need to bring a sharper real

[1] *UniChem PLC/Macarthy PLC and Lloyds Chemists plc/Macarthy PLC: a report on the proposed mergers*, Cm 1845, February 1992.

reduction in prices than has occurred in the recent past, bearing in mind our findings about Allergan's profits, and that 'X' should therefore be at least five. Any attempt by Allergan to pass on the impact of this remedy to its customers, by increasing the level of its trade prices relative to the RRPs or by cutting discounts, would be constrained by the remedy we propose for Boots and its wider effect on competition in the retail sector, and by Allergan's need to continue offering favourable terms to opticians.

8.230. In the case of Boots our fall-back recommendation is that Boots should be required to set its prices for all branded solutions at least 10 per cent below the RRP. Boots too might try to pass on the impact of such action to its suppliers by pressing them to grant even bigger discounts than those which Boots already receives, and the suppliers might react by putting up RRPs in order to restore the previous position. But if Allergan was subject to price control on the lines proposed above it would not be able to increase its recommended prices and the other suppliers would lose business if they did so while Allergan did not. A reduction of 10 per cent on recommended prices would have the effect of reducing Boots' average gross margin on CLS by about five percentage points but it would still be well in line with the average for BTC's non-dispensing healthcare business and well above the overall BTC average (see paragraph 8.176).

8.231. We cannot specify the precise circumstances in which these fall-back remedies would be appropriate or for how long they might prove to be necessary. That will be a matter for the Secretary of State to judge in the light of the action taken on our principal recommendations and in response to the EC Directive on Medical Devices. If fall-back action proves to be necessary, the Secretary of State will also have to consider in the case of Allergan whether, taking account of any price changes which it may introduce following publication of our report, an initial cut in recommended prices should be made before the programme of annual control begins.

8.232. The wider impact of these fall-back remedies, particularly in the case of Boots, would also address the adverse effect which we have found to result from the retailers complex monopoly situation.

8.233. Apart from the central problem that these fall-back remedies would further distort the market, however, we suspect their value might erode over time as the parties adapted their behaviour to the new situation. It is for these reasons that the regulatory changes we have identified, whether resulting from the EC Directive or otherwise, are the only satisfactory way of dealing with the adverse effects we have found.

Opticians

8.234. Finally as regards the opticians complex monopoly situation we recommend that the relevant regulatory or representative bodies should strengthen the guidelines for opticians to take account of the deficiencies which we have identified. We were glad to note that two of the bodies which responded to our Issues Letter (the General Optical Council and the Association of Optometrists) said that they intended to pursue the point that opticians should take care to inform patients fully about the prices of CLS and the likely overall annual costs of lens care.

8.235. The guidelines issued by the British College of Optometrists, which we take as an example, already address this latter issue, stating that 'it is essential ... that before patients are asked to commit themselves to being supplied with contact lenses, they understand precisely what costs and fees will be involved both on supply and on a continuing basis' (see paragraph 2.53). The guidelines do not, however, specifically refer to solutions, nor do they address the need for patients to be given information about costs of alternative lens care systems. We recommend therefore that these guidelines, and their equivalents in other opticians' bodies, should be amplified to provide that opticians should give clear information to patients, before they commit themselves (implicitly as well as contractually) to buying contact lenses, about:

(a) all the costs, both initial and ongoing, involved in wearing lenses, including specifically the costs of solutions; and

(b) the alternative types of lens care products available, together with the relative annual costs of the different systems. In this respect we suggest that opticians be required to prepare an information sheet containing information about the monthly or annual costs of lens care, and the costs of the various systems which they sell. The opticians' organizations might devise a standard format for these sheets to ensure that they satisfy the need which we have identified.

8.236. The opticians' bodies should put in place arrangements for monitoring the implementation of these guidelines. One possibility would be for them to carry out periodic surveys of customers recently fitted with lenses to find out what their experience had been.

H H LIESNER *(Chairman)*

C M BLIGHT

G C S MATHER

D MILLER

J F PICKERING

S N BURBRIDGE *(Secretary)*

26 February 1993

Glossary

ABDO — Association of British Dispensing Opticians. The professional and examining body for **dispensing opticians.**

ACLM — Association of Contact Lens Manufacturers. A UK body representing manufacturers and importers of contact lenses, **contact lens solutions** and related products.

BCO — British College of Optometrists. The professional and examining body for **optometrists.**

BMRB — British Market Research Bureau. A market research organization.

British Pharmacopoeia — A publicly available official publication prepared by the British Pharmacopoeia Commission in accordance with section 99(6) of the Medicines Act 1968. It includes mandatory standards for pharmaceutical raw materials and specific formulated products together with prescribed test methods. It also contains guidelines on pharmaceutical matters such as containers, methods of sterilization and antimicrobial **preservative** efficacy. It is updated regularly and it is published by HMSO.

CDSM — Committee on Dental and Surgical Materials. One of the statutory advisory committees to the **Licensing Authority,** under section 4 of the Medicines Act. Its remit includes **contact lens solutions.**

Chlorhexidine — An antimicrobial agent used in **cold chemical disinfection** of contact lenses and as a **preservative** in some other **solutions.**

Chlorine system — A method of disinfecting **soft lenses** using a chlorine releasing agent, usually in the form of a tablet which is dissolved in a saline solution.

Cleaner — See **surfactant cleaner.**

CLS — See **contact lens solutions.**

Cold chemical disinfection — A method of disinfecting lenses at room temperature which consists of a single disinfecting/soaking solution. It contains antimicrobial agents which serve the dual purpose of disinfecting the lenses and preventing contamination of the **solution** itself.

Contact lens solutions — Solutions (and tablets designed to be made up into solutions) for use in connection with the cleansing, disinfecting, rinsing, lubricating, storage or wearing of contact lenses. We use the terms 'contact lens solutions', 'solutions', 'CLS' and the more general expression 'contact lens care products' interchangeably throughout this report.

CSM — Committee on Safety of Medicines. One of the statutory advisory committees to the **Licensing Authority.**

Discard date — The date by which any remaining **solution** in a multi-dose container of a **CLS** product should be discarded, according to the instructions on the label (see also **recommended period of use**). Also referred to as the **'use-by date'.**

Dispensing optician — An optician qualified to dispense, fit and supply spectacles but not to test eyesight. Dispensing opticians must be specially certified before they are entitled to fit contact lenses. They must be registered with the **GOC.**

Disposable lenses — **Soft lenses** designed to be worn for periods of up to a month and then discarded.

DoH — Department of Health. The Government department responsible for regulating **contact lens solutions.**

EC Directive — The EC Directive on Medical Devices, in respect of which a 'Common Position' was reached by the EC Council in February 1993; the products it covers include contact lenses and **contact lens solutions.**

European Pharmacopoeia — A publicly available official publication of the Council of Europe in accordance with the International Treaty known as the Convention on the Elaboration of a European Pharmacopoeia (Treaty Series No 32 (1974) Command 5763). It includes mandatory standards on pharmaceutical raw materials together with mandatory test methods and generally applicable standards for types of dosage forms. In accordance with the International Treaty, monographs and standards published in the *European Pharmacopoeia* supersede those relating to the same subject in the ***British Pharmacopoeia.*** For example, in January 1993, the test on Efficacy of Antimicrobial Preservation superseded a similar test guideline in the ***British Pharmacopoeia.***

Extended-wear lenses — Lenses intended to be worn continuously (including while the wearer is asleep) for more than 24 hours, without removal.

FODO — Federation of Ophthalmic and Dispensing Opticians. A trade association representing optical employers.

Gas-permeable lenses — **Rigid (PMMA) lenses** made oxygen-permeable by the addition to the **PMMA** of various substances such as fluorocarbons or materials containing silicone. Generally referred to as **RGP** or simply **GP lenses.**

General Optical Council — The statutory body which regulates the optical profession and with which opticians must be registered in order to practise in the UK.

GOC — See **General Optical Council.**

GP lenses — See **gas-permeable lenses.**

GSL medicines — General sales list medicines. A category of medicines designated for supply purposes under the Medicines Act 1968. They may be sold in any retail outlet and are typically available in drug-stores and supermarkets as well as in retail pharmacies.

Hard lenses — **Rigid lenses** made of **PMMA.**

Hydrogels — See **soft lenses.**

Hydrogen peroxide system — A method of disinfecting contact lenses using hydrogen peroxide. The hydrogen peroxide must be broken down or neutralized before the lens can safely be inserted into the eye.

In-use period — See **recommended period of use.**

Licensing Authority — The UK Health Ministers responsible for administration of the Medicines Act. In practice the MCA acts as their agent.

MCA — The Medicines Control Agency, part of the **DoH.** The regulatory body which operates as the agent for the **Licensing Authority** responsible for administering the Medicines Act 1968. The MCA's responsibility is to ensure that all

	medicines sold or supplied for human use in the UK meet acceptable standards of safety, quality and efficacy. These standards are determined by the Medicines Act together with an increasing number of regulations and directives laid down by the EC.
MDD	Medical Devices Directorate, part of the **DoH**. The MDD is responsible for ensuring that devices and equipment used in the diagnostic and therapeutic environment of health care in the UK meet appropriate standards of safety, quality and effectiveness. It is responsible also for negotiating, on behalf of the UK Government, EC directives on medical devices and for putting in place the necessary statutory instruments to give effect to those directives in the UK.
Medicines Commission	Body set up under section 2 of the Medicines Act 1968 to advise Ministers on matters relating to the execution of the Act, including the establishment of committees under section 4, their functions and membership (see **CDSM**).
NPA	National Pharmaceutical Association. A body representing community pharmacists in the UK.
Ophthalmic medical practitioner	A fully qualified doctor specializing in eyes and eyecare and registered with the General Medical Council.
Ophthalmic optician	An ophthalmic optician (also known as an **optometrist**) is qualified to test sight and to prescribe and dispense spectacles, contact lenses and other optical appliances. Practising optometrists must be registered with the **GOC**.
Optometrist	See **ophthalmic optician**.
OTC	Over the counter. Refers to medicines which may be sold without a doctor's prescription, ie **P medicines** and **GSL medicines**.
P medicines	Pharmacy-only medicines. A category of medicines designated for supply purposes under the Medicines Act 1968. They may be sold only in a retail pharmacy under the supervision of a pharmacist.
Peroxide	See **hydrogen peroxide**.
PMMA	Polymethyl-methacrylate. The material from which **rigid lenses** are made.
POM medicines	Prescription-only medicines. A category of medicines designated for supply purposes under the Medicines Act 1968. These medicines may be obtained only on a doctor's prescription.
PPRS	Pharmaceutical Price Regulation Scheme. A joint Government and pharmaceutical industry scheme aimed at indirectly controlling the price of pharmaceutical products through regulation of the overall profitability of pharmaceutical companies from their sales to the UK National Health Service. The scheme originated in 1957.
Preservative	An antimicrobial agent present in multi-dose **contact lens solutions**, the purpose of which is to prevent significant microbial contamination of the solution during its **in-use period**. In **cold chemical disinfectants** the disinfectant also acts as the preservative for the lens **solution**.
Protein remover	See **specialist cleaner**.
PVP	Polyvinyl pyrollidone. A copolymer that is sometimes used to produce medium and high water content **soft lenses**.

Recommended period of use — The period of time over which, in respect of a multi-dose container of a **CLS** product, the **solution** can safely be used (see also **discard date**). Also referred to as the **in-use period.**

RGP lenses — Rigid gas permeable lenses. See **gas-permeable lenses.**

Rigid lenses — A term used to denote **gas-permeable** and **hard lenses**, as distinct from **soft lenses.**

RPSGB — Royal Pharmaceutical Society of Great Britain. The professional organization for pharmacy with which all pharmacists in Great Britain must be registered. It has a separate Scottish department.

RRP — (Manufacturers') recommended retail price.

RSGB — Research Surveys of Great Britain. A market research organization.

Soft lenses — Also referred to as **hydrogels.** They are made from polymers which are oxygen-permeable due to their water content, which may be low (<40 per cent), medium (>40 per cent, <60 per cent) or high (>60 per cent).

Solutions — See **contact lens solutions.**

Specialist cleaner — A **solution** the purpose of which is to remove specific deposits from the contact lens surface. The most common such deposits are proteins, whose build-up is caused by tears in the natural lubrication of the eye.

Surfactant cleaner — A **solution** the purpose of which is to remove superficial dirt, lipids and other contaminants from the contact lens surface.

Thiomersal — A **preservative** used in **cold chemical disinfecting,** and some other, **solutions.** Often used in combination with other **preservatives.**

Use-by date — See **discard date.**

APPENDIX 1.1
(referred to in paragraphs 1.1, 8.2, 8.28, 8.127 and 8.152)

The reference and conduct of the inquiry

1. On 30 April 1992 the Director General of Fair Trading sent to the MMC the following reference:

> The Director General of Fair Trading in exercise of his powers under sections 47(1), 49(1) and 50(1) of the Fair Trading Act 1973 ('the Act') hereby refers to the Monopolies and Mergers Commission the matter of the existence or possible existence of a monopoly situation in relation to the supply within the United Kingdom of contact lens solutions.
>
> The Commission shall investigate and report on the questions whether a monopoly situation exists in relation to such supply and, if so:
>
> *(a)* by virtue of which provisions of sections 6 to 8 of the Act that monopoly situation is to be taken to exist;
>
> *(b)* in favour of what person or persons that monopoly situation exists;
>
> *(c)* whether any steps (by way of uncompetitive practices or otherwise) are being taken by that person or those persons for the purpose of exploiting or maintaining the monopoly situation and, if so, by what uncompetitive practices or in what other way;
>
> *(d)* whether any action or omission on the part of that person or those persons is attributable to the existence of the monopoly situation and, if so, what action or omission and in what way it is so attributable; and
>
> *(e)* whether any facts found by the Commission in pursuance of their investigations under the preceding provisions of this paragraph operate, or may be expected to operate, against the public interest.
>
> For the purposes of this reference:
>
> 'contact lens solutions' means solutions (and tablets designed to be made up into solutions) for use in connection with the cleansing, disinfecting, rinsing, lubricating, storage or wearing of contact lenses.
>
> The Commission shall report on this reference within a period of ten months from the date hereof.
>
> *(signed)* GORDON BORRIE
> 30 April 1992 *Director General of Fair Trading*

2. The questions in the reference are answered in the following paragraphs of the report:

whether a monopoly situation exists: paragraphs 8.31, 8.50, 8.66, 8.85, 8.95, 8.97;

(a) paragraphs 8.31, 8.50, 8.66, 8.85, 8.95, 8.97;

(b) paragraphs 8.43, 8.46, 8.51, 8.67, 8.85, 8.95, 9.97;

(c) paragraphs 8.152, 8.167, 8.191, 8.203;

(d) paragraphs 8.167, 8.206, 8.207; and

(e) paragraphs 8.152, 8.167, 8.191, 8.197, 8.203, 8.206, 8.207.

3. The composition of the group of members responsible for the present investigation and report is indicated in the list of members which prefaces this report.

4. Notices inviting interested parties to submit evidence to the MMC were placed in the *Financial Times, Daily Telegraph, Daily Mail, Optometry Today, The Pharmaceutical Journal, Chemist & Druggist* and *Optician*. In addition we sought information and views from suppliers, wholesalers and retailers of contact lens solutions, trade associations, bodies representing opticians and pharmacists, academic and practising ophthalmic experts, the DoH (MCA and MDD) and the Consumers' Association. Written evidence was received from all these and from members of the public and is summarized in Chapters 5, 6 and 7. Twenty-five hearings were held of which two were with the MCA and two with FODO. We carried out a survey of optical and pharmaceutical wholesalers and commissioned three other surveys: the first, of practising opticians; the second, of practising pharmacists (both by way of a questionnaire); and the third, of contact lens wearers, a telephone survey. The results of the surveys are given in Chapter 3.

5. Members and staff of the MMC visited CIBA Vision's plant in Macclesfield and an optician's practice in Holborn, London. Staff visits were also made to the offices of CV-UK, Allergan, Alcon, Boots, B&L, D&A and Sauflon.

6. Some of the evidence received during the course of our inquiry was of a commercially confidential nature and our report contains only such information as we consider necessary for a proper understanding of our conclusions.

7. We thank all those who helped with our inquiry, particularly the companies principally involved.

APPENDIX 2.1
(referred to in paragraphs 2.33 and 7.26)

The Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979

Made	21st December 1979
Laid before Parliament	9th January 1980
Coming into Operation	1st February 1980

The Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred by sections 85(1), 86(1), 91(2) and (3) and 129(5) of the Medicines Act 1968(a) and now vested in them (b) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations—

Citation and commencement

1. These regulations may be cited as the Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979 and shall come into operation on 1st February 1980.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires—

'the Act' means the Medicines Act 1968;

'administer' has the same meaning as in section 130(9) of the Act as modified by Article 2 of, and paragraph 9 of Part II of Schedule 2 to, the Medicines (Specified Articles and Substances) Order 1976(c);

'contact lens substance' means any substance or fluid described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976;

'description' has the same meaning as in section 130(8) of the Act;

'selling by retail' has the same meaning as in section 131(3) of the Act;

'selling by way of wholesale dealing' has the same meaning as in section 131(1) and (2) of the Act; and

'supplying in circumstances corresponding to retail sale' has the same meaning as in section 131(4) of the Act.

(2) In these regulations, a reference to a numbered regulation is a reference to the regulation of these regulations bearing that number and a reference in a regulation to a numbered paragraph is a reference to the paragraph of that regulation bearing that number.

(a) 1968 c. 67, as applied by the Medicines (Specified Articles and Substances) Order 1976 (S.I. 1976/968).
(b) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule I to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388) and in the case of the Department of Health and Social Services for Northern Ireland by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(*b*) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).
(c) S.I. 1976/968.

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Application

3. Subject to the provisions of regulation 7, the requirements imposed by these regulations shall apply to any contact lens substance which, in the course of a business carried on by a person, is sold or supplied or is in his possession for the purpose of sale or supply.

Particulars required on labels or in leaflets

4.—(1) Subject to the provisions of paragraphs (2) and (3) and of regulation 7, the particulars specified in regulation 5 shall be shown on a label on the container containing any contact lens substance.

(2) Where the container containing any contact lens substance is too small for it to be reasonably practicable to show all the particulars specified in regulation 5 on the label thereon, such of those particulars as there is space for shall be shown on that label, precedence being given to them in accordance with the order in which they appear in regulation 5, and the other particulars so specified shall be shown on a label on the package in which the container is immediately enclosed or in a leaflet which is supplied or intended to be supplied with the contact lens substance.

(3) Where the size or nature of the container containing any contact lens substance is such that it is not reasonably practicable to show any of the particulars specified in regulation 5 on a label thereon, those particulars shall be shown on a label on the package in which the container is immediately enclosed or in a leaflet which is supplied or intended to be supplied with the contact lens substance.

5.—(1) Subject to the provisions of paragraph (2), the particulars specified for the purposes of regulation 4 in relation to any contact lens substance are—

(*a*) the number of any product licence which relates to such substance;

(*b*) the batch reference given by the person who manufactured such substance to the batch of which it forms a part;

(*c*) the name of such substance or an appropriate description thereof;

(*d*) the purpose or purposes for which such substance is to be used and in particular, if it is to be used for cleaning, disinfecting, irrigating, lubricating, wetting, soaking or rinsing a contact lens or blank or as a barrier between such lens or blank and the human eyeball, for which of those purposes it is to be used;

(*e*) the name and address of the holder of any product licence which relates to such substance;

(*f*) where it is recommended that the substance should not be applied directly to the eye, a warning to that effect; and

(*g*) the name of any antimicrobial agent which is an ingredient of such substance and the percentage of that substance which that agent comprises, calculated in terms of weight in weight (w/w), weight in volume (w/v), or volume in volume (v/v) as appropriate.

(2) The particulars specified in paragraph (1)(*f*) shall be shown in capital letters and where the substance is or is to be sold or supplied in solid form as a powder or tablet those particulars shall be so expressed as to relate to the substance in the liquid form in which it is to be administered.

(3) In this regulation, the expression 'contact lens' refers only to a contact lens which consists of a thin curved shell of glass, plastic or other hard or soft material intended for use by being applied to the human eyeball and the word 'blank' refers only to a blank from which a contact lens is to be prepared.

Additional particulars required for contact lens substances

6.—(1) Subject to the provisions of paragraph (3) and of regulation 7, in addition to the particulars specified in regulation 5, the particulars specified in paragraph (2) shall be shown either on a label on the container in which any contact lens substance is contained or on a label on the package in which the container is immediately enclosed or in a leaflet which is supplied or intended to be supplied with such substance.

(2) The particulars specified for the purposes of paragraph (1) in relation to any contact lens substance are—

(a) the date after which it is recommended that the substance should no longer be used;

(b) a recommended period within which the substance should be used after the container containing it has first been opened;

(c) directions as to how the substance is to be used;

(d) a warning in capital letters, 'DO NOT MIX WITH OTHER FLUIDS EXCEPT AS DIRECTED'; and

(e) a warning that the substance should not be administered to the eye concurrently with any eye medicament except on the advice of a doctor.

(3) Where any contact lens substance is or is to be sold or supplied in solid form as a powder or tablets—

(*a*) instructions as to how it is to be prepared for use, including a warning that only recommended fluids should be used for dissolving the substance for administration, shall be included in the particulars;

(*b*) the particulars specified in paragraph (2)(*c*) and (*e*) shall be so expressed as to relate to the substance in the liquid form in which it is to be administered; and

(*c*) an explanation shall accompany the warning set out in paragraph (2)(*d*) that the warning relates to the substance in the liquid form in which it is to be administered.

Temporary and transitional provisions

7.—(1) The requirements imposed by these regulations shall not apply until 1st January 1982 to a contact lens substance when it is sold or supplied by, or so long as it is in the possession of, a person who, on 1st January 1980 is exempt—

(*a*) by virtue of section 16(2) or (3) of the Act from the requirement to hold a product licence relating to that substance, or

(*b*) by virtue of section 16(4) of the Act from the requirement to hold a manufacturer's licence relating to that substance.

(2) Subject to paragraph (3), the requirements imposed by these regulations shall not apply to a contact lens substance—

(*a*) until 1st July 1982, when it is sold or supplied by way of wholesale dealing or so long as it is in the possession of a person for the purpose of such sale or supply, and

(*b*) until 1st January 1983, when it is sold by retail or supplied in circumstances corresponding to retail sale or so long as it is in the possession of a person for the purpose of such sale or supply.

(3) The provisions of paragraph (2) shall not apply to a contact lens substance when it is sold or supplied by, or so long as it is in the possession of, a person who—

(*a*) has manufactured or assembled it, or

(*b*) in the case of an imported contact lens substance, has imported it or procured its importation, or

(*c*) in the case of a contact lens substance which has not been imported, is responsible for its composition.

(4) For the purposes of paragraph (3)(*c*) the responsibility of a person for the composition of a contact lens substance shall be determined by the application of section 7(6) of the Act to that substance as though it were a medicinal product the responsibility for the composition of which was being determined for the purposes of section 7(5) of the Act.

Offences

8. Any person who contravenes the provisions of these regulations or contravenes the provisions of sections 85(3) or 86(2) of the Act shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £400 and shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

Patrick Jenkin,
20th December 1979. Secretary of State for Social Services.

Nicholas Edwards,
21st December 1979. Secretary of State for Wales.

George Younger,
20th December 1979. Secretary of State for Scotland.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 20th day of December 1979.

(L.S.) *N. Dugdale*,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations lay down special requirements as to the particulars to be furnished with certain substances and fluids for use with contact lenses or blanks which are for sale or supply, either on a label on the container or package or in an accompanying leaflet. They also contain transitional provisions. The substances and fluids concerned are those described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976.

Source: SI 1979/1759.

APPENDIX 2.2
(referred to in paragraph 2.34)

The Medicines (Contact Lens Fluids and Other Substances) (Advertising and Miscellaneous Amendments) Regulations 1979

Made	*28th December 1979*
Laid before Parliament	*9th January 1980*
Coming into Operation	*1st February 1980*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 18, 36, 95, 96(6) and 129(1) and (5) of the Medicines Act 1968(a) and now vested in them (b) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations:—

Citation and commencement

1. These regulations may be cited as the Medicines (Contact Lens Fluids and Other Substances) (Advertising and Miscellaneous Amendments) Regulations 1979 and shall come into operation on 1st February 1980.

Interpretation

2.—(1) In these regulations—

'the Act' means the Medicines Act 1968;

'contact lens substance' means any substance for use in cleaning, disinfecting, irrigating, lubricating, wetting or storing any contact lens or blank or any fluid in which such lens or blank is soaked or rinsed or any fluid used as a barrier between such lens or blank and the human eyeball or any other substance used in connection with the use of such lens or blank;

'data sheet' has the same meaning as in section 96(6) of the Act;

'description' has the same meaning as in section 130(8) of the Act;

'information sheet' means an advertisement, other than a data sheet, in the form of a leaflet relating to a contact lens substance;

'optician' means a person who is registered in any register established and maintained under section 2 of the Opticians Act 1958(a) either as an ophthalmic optician or as a dispensing optician; and

'the Schedule' means the Schedule to these regulations.

(a) 1968 c. 67, as applied by the Medicines (Specified Articles and Substances) Order 1976 (S.I. 1976/968).

(b) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388), in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Northern Ireland Departments, by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)*(b)* of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(2) In these regulations, unless the context otherwise requires, a reference to a numbered regulation is a reference to the regulation of these regulations bearing that number.

(3) In this regulation and in the Schedule, the expression 'contact lens' refers only to a contact lens which consists of a thin curved shell of glass, plastic or other hard or soft material intended for use by being applied to the human eyeball and the word 'blank' refers only to a blank from which a contact lens is to be prepared.

Particulars required in information sheets

3. Subject to the provisions of regulation 8, any information sheet which is sent or delivered to a pharmacist or optician must contain the particulars set out in paragraphs 1 to 13 of the Schedule and, where such substance is for use by being directly administered to the human eyeball, the particulars set out in paragraph 14 of the Schedule.

Particulars required in data sheets

4. Subject to the provisions of regulation 8, the particulars prescribed for the purposes of section 96(6) of the Act as the particulars required to be contained in a data sheet which relates to a contact lens substance of any description and is sent or delivered to a doctor shall be the particulars set out in paragraphs 1 to 13 of the Schedule and in addition, where such substance is for use by being directly administered to the human eyeball, the particulars set out in paragraph 14 of the Schedule.

Amendment to the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971

5. In regulation 2(1) of the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971(b) immediately after the definition of 'clinical trial certificate' there shall be inserted the following definition—

> '"medicinal product" includes the substances and fluids described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976;(c)'.

Amendment to the Medicines (Data Sheet) Regulations 1972

6. In regulation 1(2) of the Medicines (Data Sheet) Regulations 1972(a) in the definition of 'medicinal product' there shall be inserted between the word 'includes' and the word 'articles', where that word first appears, the following words—

> ', except for the substances and fluids described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976,'.

Amendment to the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975

7. In regulation 1(2) of the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975(b) in the definition of 'medicinal product' there shall be inserted between the word 'article' and the word 'specified' the words ', except for the substances and fluids described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976, which is'.

(a) 1958 c. 32.
(b) S.I. 1971/973, amended by S.I. 1972/1201, 1975/681, 1977/1051.
(c) S.I. 1976/968.
(a) S.I. 1972/2076.
(b) S.I. 1975/1326.

Temporary and transitional provisions

8. The requirements of regulation 3 shall not apply to an information sheet and the requirements of regulation 4 shall not apply to a data sheet where such information sheet or data sheet—

(a) relates to a contact lens substance in respect of which the restrictions imposed by section 7(2) of the Act (product licences) do not apply on 1st January 1980(c) by reason of section 16(2) of the Act (transitional exemption for products then on the market), and

(b) is sent or delivered, to a pharmacist or optician if it is an information sheet or to a doctor if it is a data sheet, within 6 months after such day as may be appointed by an order made under section 17 of the Act which provides that section 16(2) of the Act shall cease to have effect on or after that day in relation to contact lens substances of the description to which the information sheet or data sheet relates.

Offences

9. Any person who contravenes the provisions of regulation 3 shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £400.

Patrick Jenkin,
20th December 1979. Secretary of State for Social Services.

Nicholas Edwards,
21st December 1979. Secretary of State for Wales.

George Younger,
20th December 1979. Secretary of State for Scotland.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 28th December 1979.

(L.S.)

Peter Walker,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 20th day of December 1979.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 21st day of December 1979.

(L.S.)

J. A. Young,
Permanent Secretary.

(c) The day appointed under section 16, as applied, by the Medicines (Contact Lens Fluids and Other Substances) (Appointed Day) Order 1979, S.I. 1979/1539.

SCHEDULE Regulations 3 and 4

PARTICULARS REQUIRED IN INFORMATION SHEETS AND DATA SHEETS

1. Each purpose for which the contact lens substance is to be used and in particular, if it is to be used for cleaning, disinfecting, irrigating, lubricating, wetting, soaking or rinsing a contact lens or blank or as a barrier between a contact lens or blank and the human eyeball, for which of those purposes it is to be used.

2. A description of the pharmaceutical form of the contact lens substance.

3. The active ingredients of the contact lens substance and its quantitative composition.

4. The name of any antimicrobial agent which is an ingredient of the contact lens substance and the percentage of that substance which that agent comprises, calculated in terms of weight in weight (w/w), weight in volume (w/v), or volume in volume (v/v) as appropriate.

5. The quantity or amount of the contact lens substance in each size of package or container in which it is available for retail sale.

6. The compatibility and incompatibility of the contact lens substance for use with different types of contact lenses and blanks, other contact lens substances and any other substance commonly applied to the human eyeball.

7. Possibilities of interaction between the contact lens substance and any other contact lens substance or any other substance commonly applied to the human eyeball.

8. The shelf-life of the contact lens substance.

9. A recommended period within which the contact lens substance should be used after the container containing it has first been opened.

10. Any special requirements for the storage of the contact lens substance and where appropriate, pharmaceutical precautions including recommendations as to excipients and diluents.

11. Those adverse reactions to the contact lens substance which, if experienced, should be reported to a doctor, or to the pharmacist or optician who administered that substance or who sold or supplied it for administration.

12. Appropriate remedial measures in response to any adverse reaction to the contact lens substance which may be taken by the person to whom the substance was administered, sold or supplied.

13. Recommendations as to the antidote to be administered or other action to be taken by a doctor, pharmacist or optician on his becoming aware of any adverse reaction having occurred in connection with the use of the contact lens substance.

14. Any precautions required to be observed in the use of a contact lens substance which is intended to be administered directly to the human eyeball and any warnings relating to its use, either alone or in conjunction with any other substance, which should be given to any person to whom the substance may be sold or supplied.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations lay down requirements as to the particulars which must be contained in advertisements in the form of information sheets sent or delivered to pharmacists and ophthalmic and dispensing opticians relating to certain substances and fluids for use with contact lenses or blanks. They amend the Medicines (Data Sheet) Regulations 1972 so that those Regulations do not apply to data sheets which relate to such substances and fluids, and prescribe special particulars for such data sheets sent or delivered to doctors. They also contain certain transitional provisions.

Source: SI 1979/1760.

APPENDIX 2.3
(referred to in paragraph 2.35)

UK guidance notes on applications for product licences (MAL2)

ANNEX VII

GUIDANCE NOTES ON APPLICATIONS FOR PRODUCT LICENCES AND CLINICAL TRIAL CERTIFICATES FOR PRODUCTS USED IN ASSOCIATION WITH CONTACT LENSES

I—INTRODUCTION

1. The provisions of the Medicines Act 1968 were with minor modifications applied to contact lens fluids and other products in the Medicines (Specified Articles and Substances) Order (SI 1976 No 968). Contact lens fluids are defined as:

"Any substance for use in cleaning, disinfecting, irrigating, lubricating, wetting or storing any contact lens ... or blank from which the contact lens is to be prepared or any fluid in which such lens or blank is soaked or rinsed or any fluid used as a barrier between such lens or blank and the human eyeball or any other substance used in connection with the use of such lens or blank"

2. a) Subject to the exceptions and modifications specified in part II of Schedule 2 to SI 1976 No 968, the provisions of the Act set out in part I of the said Schedule 2 have effect in relation to contact lens fluids.

b) Regarding efficacy and quality the Order provides that consideration of efficacy and quality may be left out of account by the Medicines Control Agency if it is satisfied that it is reasonable to do so in the circumstances. Applicants should generally expect however to provide data on efficacy and quality in the normal way.

3. The **scope of licensing** is discussed in Section 1 of the main Guidelines.

4. **Standard provisions** applying to product licences for this class of products differ in certain respects from those applying to others.

5. **Documentation.** Although this class of product does not presently fall within the definitions of relevant EC medicines directives, applications should be made in the format used for products so covered. The general format of applications is discussed at Section 2 of the main Guidelines. The data requirements are discussed later in this Annex.

II—INFORMATION TO BE INCLUDED IN PRODUCT LICENCE APPLICATIONS

1. PART 1: GENERAL INFORMATION

Application form MLA 201 should be used. This should incorporate:

i. Administrative data, and
ii. Summary of product characteristics

as prescribed on the application form. It should be indicated that the application is for a 'contact lens substance'.

The information supplied on form MLA 201 will be used to prepare the schedule to the Product Licence and will be entered on the computer record held by the Medicines Control Agency.

2. PART 2: PHARMACEUTICAL DATA

See Part III of this Annex.

3. PART 3: EXPERIMENTAL AND BIOLOGICAL STUDIES

See Part IV of this Annex.

4. PART 4: STUDIES IN HUMANS.

See Part V of this Annex.

5. EXPERT SUMMARY REPORTS

An expert summary report is always required on the pharmaceutical aspects of the application. The format outlined in the main Guidelines is preferred. Expert summary reports may be required for the experimental and biological studies and studies in humans sections of the application: See below.

III—CHEMICAL AND PHARMACEUTICAL DOCUMENTATION

The general requirements described in Sections 2 and 3 of the main Guidelines apply. The following are areas to which special attention should be paid.

1. Microbiological Studies

Data should be provided to demonstrate that the antimicrobial activity of products should be adequate in relation to the method of use requested. For products intended for instillation into the eyes (eg. comfort drops) or for entering onto the eye on lenses (wetting products) a level of antimicrobial activity similar to that suggested by the BP for ophthalmic products is normally expected. Cold disinfection products are also expected to demonstrate good antimicrobial activity. Products (such as cleaners) which are intended to be used before disinfection procedures may have a lesser antimicrobial activity. Data should include kill curves on at least two fresh and aged samples of the formulation it is intended to market over a suitable period of time. (The sample times should be related to the intended use of the product but should normally extend to at least 28 days after inoculation). Full details of experimental technique and validation should be included; details of the recovery procedure (including media and preservative inactivation procedures) should be given, including a demonstration of the ability to recover small numbers of micro-organisms. The organisms suggested for use in the test procedure described in the BP should be used; additional organisms may also be used. Depending on their method of use it may be pertinent to provide information on anti-Acanthamoeba activity for some disinfection/storage systems. Other clinically significant organisms may also be used.

2. Compatibility Studies

2.1 Product—lens Compatibility

In-vitro lens compatibility data should be submitted. The extent of such data will depend on the claims made for the product's use.

Preservative, etc, uptake and physical parameters of lenses should be reported. A sufficient number of lenses of a range of prescription powers including high + and high - should be used. The types of lenses to be included should, depending on the intended use of the product, include:

PMMA

gas permeable

hydrogel lens: low and high water content (ie below and above 55% water content) materials including both ionic and non-ionic types.

At least one typical representative of each type of rigid gas permeable lens should be included.

2.2 Product—Container Compatibility

Suitable data should be presented.

3. Container Size

3.1 The volume in the container of a product intended for use on more than one occasion should normally be sufficient for not more than 28 days' use. Data should be provided to show the average rate of use of the product. If a period of use in excess of 28 days is proposed additional data will be required to show the suitability of the product for that longer period of use, unless a suitable pressurised delivery system is used.

3.2 The volume in the container of a product intended for use on one occasion should be sufficient for the intended purpose but should not include a surplus volume.

IV—EXPERIMENTAL AND BIOLOGICAL STUDIES

1. General Considerations

All tests must reflect the conditions of usage and be carried out on the full formulation as presented to the user.

Tests for local toxicity are required for all ophthalmic preparations.

Systemic effects following absorption should be investigated for new chemical entities following ophthalmic administration.

Dosage should be carried out seven days per week.

In tests of preparations in the presence of a contact lens, a lens of the same material and design should be worn in control eyes.

Tests should be performed on lens materials used in the preparation to be tested, to determine the qualitative and quantitative nature of extractables using validated methods.

Consideration should be given to the use of non-animal test systems which are validated as reliable methods.

Consideration should be given to the possibility of interaction with other ophthalmic preparations.

The lens should be observed for possible changes, including parameter power etc.

2. Sensitisation

A test for allergic sensitisation should be carried out or its omission justified.

3. Eye Irritation

Eye irritation studies must be carried out in the presence of lens types other than hard lenses and intended for use with the product.

Single dose eye irritation studies are considered inadequate for any contact lens preparation as sole evidence of safety.

In the case of hard lens preparations the duration of study should be appropriate to the type of preparation and likely clinical usage. Tests of say, 4 weeks, in the case of new formulations of known ingredients, and up to, say, 6 months in other cases, should mimic clinical usage. If a 'system' is being tested, the whole system should be used.

Disinfecting agents and other preparations for soft lenses which would come into daily contact with the eye should be tested for not less than 6 months.

4. Toxicological Observations

The following should be performed:

i. Daily examination by naked eye.

ii. Frequent slit-lamp microscope examination, with and without staining.

iii. Sacrifice and histology of eyes and eyelids.

It may be advisable to take major body organs and preserve them in case histological examination should become necessary as a result of early clinical findings.

It is advisable in long term studies that corneal thickness be monitored throughout the study and that special attention is paid to the corneal endothelium by specular microscopy and finally by flat mount preparations for microscopy.

5. Number of Animals

The number of animals remaining at the end of the study should be sufficient to validate the results.

6. Duration of Daily Lens Wear

The lens should be worn for not less than 6 hours per day.

7. Preparations Not Intended to Enter the Eye

A study should be performed to show that if accidentally introduced into the eye, there should be no irreversible damage.

V—STUDIES IN HUMANS

1. Clinical Trials

Statistically valid evidence of efficacy and safety is required. Testimonials without scientific substantiation are not acceptable.

The data should be presented with expert reports if appropriate as described in Section 2.7.

Evidence of efficacy will be drawn principally from comparative randomised trials.

For novel preparations for regular long-term use at least 100 patients should be exposed for one year.

2. Adverse Reactions

All information available worldwide on adverse reactions reported during the clinical use of the preparation should be included.

Source: MCA.

APPENDIX 2.4
(referred to in paragraphs 2.36 and 6.174)

EC Directive on Medical Devices

[*MMC note:* This text was adopted as representing the Common Position of the EC member states on 8 February 1993. It has not yet been published in the Official Journal of the EC. The annexes to the Directive are not included in this appendix.]

COUNCIL DIRECTIVE 93/.../EEC

of .....

concerning medical devices

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission[1],

In co-operation with the European Parliament[2],

Having regard to the Opinion of the Economic and Social Committee[3],

Whereas measures should be adopted in the context of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community;

Whereas the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonized in order to guarantee the free movement of such devices within the internal market;

Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, these provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;

Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;

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[1]OJ No C 237, 12.9.1991 and OJ No C 251, 28.9.1992, p 40.

[2]Opinion delivered on 13 May 1992 (not yet published in the Official Journal).

[3]OJ No C 79, 30.3.1992, p 1.

Whereas certain medical devices are intended to administer medicinal products within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products[1]; whereas, in such cases the placing on the market of the medical device as a general rule is governed by the present Directive and the placing on the market of the medicinal product is governed by Directive 65/65/EEC; if, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single-unit product shall be governed by Directive 65/65/EEC; whereas a distinction must be drawn between the abovementioned devices and medical devices incorporating, inter alia, substances which, if used separately, may be considered to be a medicinal substance within the meaning of Directive 65/65/EEC; in such cases, if the substances incorporated in the medical devices are liable to act upon the body with action ancillary to that of the device, the placing of the devices on the market is governed by this Directive; whereas, in this context, the safety, quality and usefulness of the substances must be verified by analogy with the appropriate methods specified in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products[2];

Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety;

Whereas, in accordance with the principles set out in the Council Resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization[3], rules regarding the design and manufacture of medical devices must be confined to the provisions required to meet the essential requirements; whereas, because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements should be applied with discrimination to take account of the technological level existing at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;

Whereas Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[4] is the first case of application of the new approach to the field of medical devices; whereas in the interest of uniform Community rules applicable to all medical devices, this Directive is based largely on the provisions of Directive 90/385/EEC; whereas for the same reasons Directive 90/385/EEC must be amended to insert the general provisions laid down in this Directive;

Whereas the electromagnetic compatibility aspects form an integral part of the safety of medical devices; whereas this Directive should contain specific rules on this subject with regard to Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility[5];

Whereas this Directive should include requirements regarding the design and manufacture of devices emitting ionizing radiation; whereas this Directive does not affect the authorization required by Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation[6], nor application of Council Directive 84/466/EURATOM of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination

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[1]OJ No L 22, 9.6.1965, p 369/65. Directive as last amended by Directive 92/27/EEC, (OJ No L 113, 30.4.1992, p 8).

[2]OJ No L 147, 9.6.1975, p 1. Directive as last amended by Directive 91/507/EEC, (OJ No L 270, 26.1.1991, p 32).

[3]OJ No C 136, 4.6.1985, p 1.

[4]OJ No L 189, 20.7.1990, p 17.

[5]OJ No L 139, 23.5.1989, p 19. Directive as last amended by Directive 92/31/EEC (OJ No L 126, 23.5.1991, p 1).

[6]OJ No L 246, 17.9.1980, p 1. Directive as last amended by Directive 84/467/EURATOM (OJ No L 265, 5.10.1984, p 4).

or treatment[1]; whereas Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[2] and the specific directives on the same subject should continue to apply;

Whereas, in order to demonstrate conformity with these essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices; whereas such harmonized European standards are drawn up by private-law bodies and should retain their status as non-mandatory texts; whereas, to this end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines on co-operation between the Commission and these two bodies signed on 13 November 1984;

Whereas, for the purpose of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted, on a mandate from the Commission, by either or both of these bodies in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations[3], and pursuant to the abovementioned general guidelines; whereas with regard to possible amendment of the harmonized standards, the Commission should be assisted by the Committee set up under Directive 83/189/EEC; whereas the measures to be taken must be defined in line with procedure I, as laid down in Council Decision 87/373/EEC[4]; whereas, for specific fields, what already exists in the form of European Pharmacopoeia monographs should be incorporated within the framework of this Directive; whereas, therefore, several European Pharmacopoeia monographs may be considered equal to the abovementioned harmonized standards;

Whereas, in Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives[5], the Council has laid down harmonized conformity assessment procedures; whereas the application of these modules to medical devices enables the responsibility of manufacturers and notified bodies to be determined during conformity assessment procedures on the basis of the type of devices concerned; whereas the details added to these modules are justified by the nature of the verification required for medical devices;

Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes; whereas the classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices; whereas the conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products; whereas, for Class IIa devices, the intervention of a notified body should be compulsory at the production stage; whereas, for devices falling within Classes IIb and III which constitute a high risk potential, inspection by a notified body is required with regard to the design and manufacture of the devices; whereas Class III is set aside for the most critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market;

Whereas in cases where the conformity of the devices can be assessed under the responsibility of the manufacturer the competent authorities must be able, particularly in emergencies, to contact a person responsible for placing the device on the market and established in the Community, whether the manufacturer or another person established in the Community and designated by the manufacturer for the purpose;

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[1]OJ No L 265, 5.10.1984, p 1.

[2]OJ No L 183, 29.6.1989, p 1.

[3]OJ No L 109, 26.4.1983, p 8. Directive as last amended by Commission Directive 92/400/EEC (OJ No L 221, 6.8.1992, p 55).

[4]OJ No L 197, 18.7.1987, p 33.

[5]OJ No L 380, 31.12.1990, p 13.

Whereas medical devices should, as a general rule, bear the EC mark to indicate their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose;

Whereas, in the fight against AIDS and in the light of the conclusions of the Council adopted on 16 May 1989 regarding future activities on AIDS prevention and control at Community level[1], medical devices used for protection against the HIV virus must afford a high level of protection; whereas the design and manufacture of such products should be verified by a notified body;

Whereas the classification rules generally enable medical devices to be appropriately classified; whereas, in view of the diverse nature of the devices and technological progress in this field, steps must be taken to include amongst the implementing powers conferred on the Commission the decisions to be taken with regard to the proper classification or reclassification of the devices or, where appropriate, the adjustment of the classification rules themselves; whereas since these issues are closely connected with the protection of health, it is appropriate that these decisions should come under procedure IIIa, as provided for in Decision 87/373/EEC;

Whereas the confirmation of compliance with the essential requirements may mean that clinical investigations have to be carried out under the responsibility of the manufacturer; whereas, for the purpose of carrying out the clinical investigations, appropriate means have to be specified for the protection of public health and public order;

Whereas the protection of health and the associated controls may be made more effective by means of medical device vigilance systems which are integrated at Community level;

Whereas this Directive covers the medical devices referred to in Council Directive 76/764/EEC of 27 July 1976 on the approximation of the laws of the Member States on clinical mercury-in-glass, maximum reading thermometers[2], whereas the abovementioned Directive must therefore be repealed; whereas for the same reasons Council Directive 84/539/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to electro-medical equipment used in human or veterinary medicine[3] must be amended,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions, scope

1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

2. For the purposes of this Directive, the following definitions shall apply:

(a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,

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[1]OJ No C 185, 22.7.1989, p 8.

[2]OJ No L 262, 27.9.1976, p 139. Directive as last amended by Directive 84/414/EEC (OJ No L 228, 25.8.1984, p 25).

[3]OJ No L 300, 19.11.1984, p 179. Directive as amended by the Act of Accession of Spain and Portugal (OJ No L 302, 15.11.1985, p 1).

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

(c) 'device used for in vitro diagnosis' means any device which is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of samples derived from the human body with a view to providing information on the physiological state, state of health or disease, or congenital abnormality thereof;

(d) 'custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices;

(e) 'device intended for clinical investigation' means any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in section 2.1 of Annex X in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

(f) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

(g) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

(h) 'placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(i) 'putting into service' means the stage at which a device is ready for use on the Community market for the first time for its intended purpose;

3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 65/65/EEC, that device shall be governed by the present directive, without prejudice to the provisions of Directive 65/65/EEC with regard to the medicinal product.

If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single unit product shall be governed by Directive 65/65/EEC. The relevant essential requirements of Annex I of the present directive shall apply as far as safety and performance related device features are concerned.

4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorized in accordance with this Directive.

5. This Directive does not apply to:

(a) in-vitro diagnostic devices;

(b) active implantable devices covered by Directive 90/385/EEC;

(c) medicinal products covered by Directive 65/65/EEC;

(d) cosmetic products covered by Directive 76/768/EEC[1];

(e) human blood, human blood products, human plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;

(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;

(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

6. This Directive does not apply to personal protective equipment covered by Directive 89/686/EEC. In deciding whether a product falls under that Directive or the present Directive, particular account shall be taken of the principal intended purpose of the product.

7. This Directive is a specific Directive within the meaning of Article 2(2) of Directive 89/336/EEC.

8. This Directive does not affect the application of Directive 80/836/EURATOM, nor of Directive 84/466/EURATOM.

Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.

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[1]OJ No L 262, 27.9.1976, p 169. Directive as last amended by Commission Directive 92/86/EEC (OJ No L 325, 11.11.1992, p 18).

Article 3

Essential requirements

The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.

Article 4

Free movement, devices intended for special purposes

1. Member States shall not create any obstacles to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11.

2. Member States shall not create any obstacles to:

— devices intended for clinical investigation being made available to medical practitioners or authorized persons for that purpose if they meet the conditions laid down in Article 15 and in Annex VIII;

— custom-made devices being placed on the market and put into service if they meet the conditions laid down in Article 11 in combination with Annex VIII; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex VIII.

These devices shall not bear the CE marking.

3. At trade fairs, exhibitions, demonstrations, etc Member States shall not create any obstacles to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply.

4. Member States may require the information, which must be made available to the user and the patient in accordance with Annex I, point 13, to be in their national language(s) or in another Community language, when a device reaches the final user, regardless of whether it is for professional or other use.

5. Where the devices are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the devices also fulfil the provisions of the other Directives.

However, should one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the devices fulfil the provisions only of those directives applied by the manufacturer. In this case, the particulars of these directives, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the directives and accompanying such devices.

Article 5

Reference to standards

1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been published in the Official Journal of the European Communities; Member States shall publish the references of such national standards.

2. For the purposes of this Directive, reference to harmonized standards also includes the monographs of the European Pharmacopoeia notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the Official Journal of the European Communities.

3. If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6(2).

Article 6

Committee on Standards and Technical Regulations

1. The Commission shall be assisted by the committee set up by Article 5 of Directive 83/189/EEC.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Article 7

Committee on Medical Devices

1. The Commission shall be assisted by the committee set up by Article 6(2) of Directive 90/385/EEC.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

3. The committee may examine any question connected with implementation of this Directive.

Article 8

Safeguard clause

1. Where a Member State ascertains that the devices referred to in Article 4(1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether noncompliance with this Directive is due to:

(a) failure to meet the essential requirements referred to in Article 3;

(b) incorrect application of the standards referred to in Article 5, insofar as it is claimed that the standards have been applied;

(c) shortcomings in the standards themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

— the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6;

— the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community.

3. Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Article 9

Classification

1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX.

2. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the competent authority to which the notified body is subject.

3. The classification rules set out in Annex IX may be adapted in accordance with the procedure referred to in Article 7(2) in the light of technical progress and any information which becomes available under the information system provided for in Article 10.

Article 10

Information on incidents occurring

following placing of devices on the market

1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving a Class I, IIa, IIb or III device is recorded and evaluated centrally:

(a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inaccuracies in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

2. Where a Member State requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorized representative established in the Community, is also informed of the incident.

3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.

Article 11

Conformity assessment procedures

1. In the case of devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance), or

(b) follow the procedure relating to EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to EC verification set out in Annex IV,

or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).

2. In the case of devices falling within Class IIa, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure relating to the EC declaration of conformity set out in Annex VII, coupled with either:

(a) the procedure relating to EC verification set out in Annex IV,

or

(b) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance),

or

(c) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

Instead of applying these procedures, the manufacturer may also follow the procedure referred to in paragraph 3(a).

3. In the case of devices falling within Class IIb, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); in this case, point 4 of Annex II is not applicable, or

(b) follow the procedure relating to EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to EC verification set out in Annex IV,

or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance),

or

(iii) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

4. The Commission shall, no later than five years from the date of implementation of this Directive, submit a report to the Council on the operation of the provisions referred to in Article 10(1), Article 15(1), in particular in respect of class I and class IIa devices, and on the operation of the provisions referred to in Annex II section 4.3 second and third subparagraphs and in Annex III section 5 second and third subparagraphs of this Directive, accompanied, if necessary, by appropriate proposals.

5. In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.

6. In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.

Member States may require that the manufacturer shall submit to the competent authority a list of such devices which have been put into service in their territory.

7. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.

8. The manufacturer may instruct his authorized representative established in the Community to initiate the procedures provided for in Annexes III, IV, VII and VIII.

9. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative established in the Community, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

10. The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

11. Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of five years.

12. The records and correspondence relating to the procedures referred to in paragraphs 1 to 6 shall be in an official language of the Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body.

13. By derogation from paragraphs 1 to 6, the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 6 have not been carried out and the use of which is in the interest of protection of health.

Article 12

Particular procedure for Systems and procedure packs

1. By way of derogation from Article 11 this Article shall apply to systems and procedure packs.

2. Any natural or legal person who puts devices bearing the CE marking together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:

(a) he has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions, and

(b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and

(c) the whole activity is subjected to appropriate methods of internal control and inspection.

Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a CE-marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant procedure under Article 11.

3. Any natural or legal person who sterilizes, for the purpose of placing on the market, systems or procedure packs referred to in paragraph 2 or other CE-marked medical devices designed by their manufacturers to be sterilized before use, shall, at his choice, follow one of the procedures referred to in Annexes IV, V or VI. The application of the above mentioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility. The person shall draw up a declaration stating that sterilization has been carried out in accordance with the manufacturer's instructions.

4. The products referred to in paragraphs 2 and 3 themselves shall not bear an additional CE-marking. They shall be accompanied by the information referred to in point 13 of Annex I which includes, where appropriate, the information supplied by the manufacturers of the devices which have been put together. The declaration referred to in paragraphs 2 and 3 above shall be kept at the disposal of competent authorities for a period of five years.

Article 13

Decisions with regard to classification, derogation clause

1. Where a Member State considers that:

(a) application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices,

or

(b) a given device or family of devices should be classified, by way of derogation from the provisions of Annex IX, in another class,

or

(c) the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 11, by applying solely one of the given procedures chosen from among those referred to in Article 11,

it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. These measures shall be adopted in accordance with the procedure referred to in Article 7(2).

2. The Commission shall inform the Member States of the measures taken and, where appropriate, publish the relevant parts of these measures in the Official Journal of the European Communities.

Article 14

Registration of persons responsible for placing devices on the market

1. Any manufacturer who, under his own name, places devices on the market in accordance with the procedures referred to in Article 11(5) and (6) and any other natural or legal person engaged in the activities referred to in Article 12 shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned.

2. Where a manufacturer who places devices referred to in paragraph 1 on the market under his own name does not have a registered place of business in a Member State, he shall designate the person(s) responsible for marketing them who is (are) established in the Community. These persons shall inform the competent authorities of the Member State in which they have their registered place of business of the address of the registered place of business and the category of devices concerned.

3. The Member States shall on request inform the other Member States and the Commission of the details referred to in paragraphs 1 and 2.

Article 15

Clinical investigation

1. In the case of devices intended for clinical investigations, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the Member States in which the investigations are to be conducted.

2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of sixty days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy.

Member States may however authorize manufacturers to commence the relevant clinical investigations before the expiry of the period of 60 days, insofar as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question.

3. In the case of devices other than those referred to in the second paragraph, Member States may authorize manufacturers to commence clinical investigations, immediately after the date of notification, provided that the ethics committee concerned has delivered a favourable opinion with regard to the investigational plan.

4. The authorization referred to in paragraph 2 second subparagraph and paragraph 3 above, may be made subject to authorization from the competent authority.

5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The provisions of Annex X may be adjusted in accordance with the procedure laid down in Article 7(2).

6. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy.

7. The manufacturer or his authorized representative established in the Community shall keep the report referred to in point 2.3.7 of Annex X at the disposal of the competent authorities.

8. The provisions of paragraphs 1 and 2 do not apply where the clinical investigations are conducted using devices which are authorized in accordance with Article 11 to bear the EC marking unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The relevant provisions of Annex X remain applicable.

Article 16

Notified bodies

1. The Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Articles 11 and 18 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as 'notified bodies'.

The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the Official Journal of the European Communities. It shall ensure that the list is kept up to date.

2. Member States shall apply the criteria set out in Annex XI for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonized standards shall be presumed to meet the relevant criteria.

3. A Member State that has notified a body shall withdraw that notification if it finds that the body no longer meets the criteria referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof.

4. The notified body and the manufacturer, or his authorized representative established in the Community, shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes II to VI.

Article 17

CE marking

1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the EC marking of conformity when they are placed on the market.

2. The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable the EC mark of conformity must also appear on the sales packaging.

It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI.

3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.

Article 18

Wrongly affixed CE marking

Without prejudice to Article 8:

(a) Where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State.

(b) Where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8.

Article 19

Decisions in respect of refusal or restriction

1. Any decision taken pursuant to this Directive:

(a) to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations,

or

(b) to withdraw devices from the market,

shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time limits to which such remedies are subject.

2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.

Article 20

Confidentiality

Without prejudice to the existing national provisions and practices on medical secrets, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

Article 21

Repeal and amendment of Directives

1. Directive 76/764/EEC is hereby repealed with effect from 1 January 1995.

2. In the title and Article 1 of Directive 84/539/EEC, the words 'human or' are deleted.

In Article 2 of Directive 84/539/EEC, the following subparagraph is added to paragraph 1:

'If the appliance is at the same time a medical device within the meaning of Directive.../.../EEC and if it satisfies the Essential Requirements laid down therein for that device, the device shall be deemed to be in conformity with the requirements of this Directive.'

3. Directive 90/385/EEC is hereby amended as follows:

1) In Article 1(2) the following two subparagraphs are added:

(h) 'placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(i) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

2) In Article 9 the following paragraphs are added:

'5. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.

6. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative established in the Community, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

7. The notified body may require, where duly justified, any information or data which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

8. Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of five years.

9. By derogation from paragraphs 1 and 2 the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 and 2 have not been carried out and the use of which is in the interest of protection of health.'

3) The following Article 9a is inserted after Article 9;

'**Article 9a**

1. Where a Member State considers that the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 9, by applying solely one of the given procedures chosen from among those referred to in Article 9, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. These measures shall be adopted in accordance with the procedure referred to in Article 7(2) of Directive 93/.../EEC.

2. The Commission shall inform the Member States of the measures taken and, where appropriate, publish the relevant parts of these measures in the Official Journal of the European Communities.'

4) The following is added to Article 14:

'In the event of a decision as referred to in the previous paragraph the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measures to be taken.'

Article 22

Implementation, transitional provisions

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1994. They shall immediately inform the Commission thereof.

The Standing Committee referred to in Article 7 may assume its tasks from the date of notification[1] of this Directive. The Member States may take the measures referred to in Article 16 on notification of this Directive.

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[1]This Directive was notified to the Member States on .....

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Member States shall apply these provisions with effect from 1 January 1995.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

3. Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 11(1) to (5) for conformity assessment take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant tests and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices.

4. Member States shall accept the placing on the market and putting into service of devices which conform to the rules in force in their territory on 31 December 1994 during a period of five years following adoption of this Directive.

In the case of devices which have been subjected to EEC pattern approval in accordance with Directive 76/764/EEC, Member States shall accept their being placed on the market and put into service during the period up to 30 June 2004.

Article 23

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

The President

APPENDIX 2.5
(referred to in paragraph 2.50)

BCO Code of Ethics and Guidelines for Professional Conduct

CHAPTER 5—CONTACT LENS PRACTICE

5.1: GENERAL

5.1.1 Contact lens practice is a field where developments occur rapidly. Practitioners should therefore make every effort to keep abreast of these changes and, if they do not possess the right qualifications, give priority to achieving them. This is especially important because contact lenses, unlike spectacles, can induce changes which may have deleterious effects on vision and eye health.

5.1.2 The professional responsibilities set out in these Guidelines apply to contact lenses supplied to correct defects of sight or for any other reason, including cosmetic.

5.1.3 Practitioners must comply in every respect with the requirements of the General Optical Council's Contact Lens (Qualifications) Rules 1988, Contact Lens (Specification) Rules 1989 and with any guidance issued by the General Optical Council on the subject (see paragraph 1.13.2: fitting of contact lenses by unqualified persons under supervision).

5.2: EQUIPMENT

5.2.1 All practitioners engaged in contact lens practice should possess the equipment necessary for such practice and be fully competent in its use. The equipment should include specifically a good quality slit-lamp microscope, a keratometer, verification equipment and appropriate drugs.

5.3: THE NATURE OF CONTACT LENS PRACTICE

5.3.1 For new contact lens patients the following procedures are usual:

(i) assessment of suitability (including diagnostic and tolerance tests);

(ii) issue of directions to fit, where appropriate;

(iii) fitting lenses;

(iv) dispensing lenses (including instruction on the safe insertion and removal of the lenses from the eyes together with an explanation of hygiene regimes); and

(v) aftercare.

5.3.2 For patients who are already wearing contact lenses, the practitioner may need to undertake all or some of the above, with appropriate advice.

5.4: ASSESSMENT

5.4.1 A full eye examination must always precede initial contact lens assessment, fitting and supply (see paragraph 1.5 The Eye Examination). In carrying out eye examinations practitioners must recall their obligations:

(i) to carry out all such tests as may be necessary in their clinical judgement to identify signs of injury, disease or abnormality; and

(ii) to refer the patient for medical investigation if any such signs are observed.

5.4.2 These obligations apply whether the eye examination is carried out within the General Ophthalmic Service or on a private basis.

5.4.3 The assessment of a patient's suitability to wear contact lenses should include, in addition to information gathered from a full eye examination, the physical assessment of the patient's ocular health, including those structures and tissues which can be affected by contact lens wear, for example cornea, the conjunctiva, limbus, lids and tears.

5.4.4 Besides the health of the ocular tissues being established, the suitability of the patient may well depend upon other factors, ie. wearing time required, standard of vision needed, working conditions (such as any exposure to noxious gases or substances, abnormal humidity or temperature), leisure or vocational activities, personal and domestic hygiene, manual dexterity, etc. It may be necessary for tolerance or diagnostic tests to be conducted with various forms of contact lens before any final advice on suitability is given.

5.5: DIRECTIONS TO FIT

5.5.1 When an optometrist intends to issue a 'direction to fit', he or she should carry out the assessment set out in paragraph 5.4 above, subject to having, or having access to, the necessary equipment. If the ocular tissues so examined are deemed suitable for contact lens wear, then a detailed statement should be made to this effect, not simply that the patient is 'suitable for contact lenses'. The items learned in 5.4.4 above will have to be discussed with the person intending to carry out the fitting before such opinions can be given. It may well be that the optometrist is of the opinion that certain types of contact lens might be suitable or unsuitable or that some form of continuing responsibility is required. If the direction to fit includes such a reference, it is essential that the reasons justifying it are carefully recorded in the optometrist's records. If a dispensing optician is to undertake the fitting, the clinical information given by the optometrist with the direction to fit should be only such as is necessary to enable the fitting to be carried out. ...

5.6: FITTING AND SUPPLY

5.6.1 In this stage of the procedure it is important to establish for each individual patient:

(i) the best possible vision;

(ii) maximum comfort and appropriate wearing times;

(iii) his or her minimal ocular response to contact lens wear; and

(iv) an appropriate hygiene regime.

5.6.2 It is the practitioner's responsibility to advise the patient in his or her best interests of any required changes in lens design, lens wearing pattern, or hygiene regime. Such advice should be recorded clearly in the patient's records.

5.6.3 The practitioner must ensure that every patient supplied with contact lenses has received and has understood full instructions on the insertion and removal of lenses, the care, storage and disinfection of lenses, the initial programme of aftercare, and the need for regular aftercare thereafter and, above all, on the importance of seeking professional advice immediately any problem or discomfort is experienced. ***Practitioners must check lenses on patients' eyes before they leave the practice.***

5.6.4 The practitioner should take care to include written instructions where necessary. These may be a supplement or an alternative to other information relating to, for example, insurance schemes or emergency procedures.

5.6.5 When the practitioner and the patient are satisfied that an acceptable fit has been achieved, the specifications for the lenses must be given to the patient (see paragraph 5.8 below).

5.7: AFTERCARE

5.7.1 Contact lens aftercare relates to the physical condition of the lenses themselves and the health of the tissues of the eye affected by the lenses. It does not in itself, therefore, constitute a primary health care measure; nevertheless, when, in providing aftercare, a practitioner observes signs of injury, disease or abnormality in the eye, the patient must still be referred for medical investigation. Particular circumstances may indicate that the practitioner should carry out an eye examination in the course of providing adequate contact lens aftercare, but in any event practitioners must ensure that all contact lens wearers under their care receive a full eye examination at regular intervals. In all cases the fees and the extent of the services to be provided should be made clear to the patient in advance. ...

5.7.2 The practitioner carrying out the fitting and supply of contact lenses is responsible for the continuing aftercare of the patient. Either this may be done personally or the patient may be referred to another qualified practitioner.

5.7.3 The responsibility described in paragraph 5.6.2 above also applies to aftercare.

5.7.4 In all cases the general eye care of a contact lens wearer must be in the hands of an optometrist, ophthalmologist or registered medical practitioner who must make every effort to ensure that the wearer receives regular full eye examinations.

5.7.4.1 Where adverse reactions to contact lenses or to disinfecting or cleansing solutions are observed in a patient's eyes, these should be reported through the Yellow and Green Card Schemes. ...

5.7.4.2 An optometrist in whose hands is the general eye care of a contact lens wearer has a duty to ensure that the wearer knows where emergency treatment is available at all times.

5.8: ADVICE RELATING TO THE APPLICATION OF THE CONTACT LENS (SPECIFICATIONS) RULES

5.8.1 The purpose of the advice which follows is to enable optometrists to apply the General Optical Council's Contact Lens (Specifications) Rules in such a way as to serve the interests of their patients in the best possible way.

5.8.2 Rule 3 states:
'It shall be the duty of an optician to give the person whom he has fitted with a contact lens, on completion of that fitting, such information as is necessary to describe fully the lens so as to permit its replication'.

5.8.3 'On completion of that fitting': this should, in the College's view, mean the point at which a final fit is achieved, to the practitioner's and the patient's satisfaction.

5.8.4 'Such information as is necessary to describe the lens so as to permit its replication': this information—the 'specification'—should be sufficiently comprehensive to permit an exact replica to be supplied, and might include, for example, material, water content, design etc. It is not in the patient's best interests that a specification should be issued that is incomplete in any way.

5.8.5 Practitioners must include in the specification

(i) their own name and practice address;

(ii) the date of the issue of the specification;

(iii) a note that replacement lenses should be supplied to the specification only after consultation with a contact lens practitioner;

(iv) a note that lenses should not be supplied to the specification beyond a period of twelve months from its date of issue, or such shorter period as may be considered by the issuing practitioner to be clinically necessary.

The inclusion of the above information will benefit the patient in that it will both indicate to any other practitioner where clinical information about the patient may be obtained, and encourage the patient to have regular ocular health checks.

5.8.6 Intermediate specification: where a final fit has not yet been achieved, the patient's circumstances may make it appropriate for the practitioner to issue an 'intermediate specification'; such circumstances might arise, for example, when the patient is due to go abroad on holiday. An intermediate specification should be marked as such, and should contain no less information than a specification issued after completion of the fitting; it must, however, specify a reassessment date.

5.8.7 Changes in fitting: if at any time it becomes necessary to change the fit of a patient's lenses, the practitioner should advise the patient that the original specification is no longer valid. When a 'final fit' has again been achieved in terms of paragraph 5.8.3 above, a fresh specification should be given to the patient.

5.8.8 Checking replacement lenses: again it is in the best interests of patients for every specification issued, whether intermediate or otherwise, to carry advice to the effect that any lens supplied to the specification should, before being worn, be checked by a qualified practitioner for quality and prescription, and for fit on the patient's eye.

5.8.9 Practitioner records must be carefully and clearly annotated when different lens dimensions and parameters have been substituted for the originals. The current lens specification should always be obvious in the contact lens record.

5.8.10 Specifications issued by another practitioner: It must always be seen as unethical, and could well raise serious legal problems, for an optometrist to accept a specification for contact lenses issued by another practitioner which is not drawn up in accordance with the requirements of paragraph 5.8.5. Optometrists have legal and ethical duties to meet in supplying replacement contact lenses to a specification issued by another practitioner. The extent of the duties will depend largely on the optometrist's professional judgement in each case. Where, however, it is clear that the patient is no longer effectively under the care of the practitioner who issued the specification, the legal and ethical duties of the supplying optometrist will be virtually the same as if he or she was starting the process of supplying contact lenses from the beginning.

5.8.11 Where the supplying optometrist is satisfied that the patient is still under the care of his or her original practitioner, it would be wise to ask the patient to read and sign an undertaking on the lines of the note attached as Annexure D to the Guidelines. [*Note:* Not attached.]

5.9: REPLACEMENT LENSES

5.9.1 When a contact lens has been lost, broken or in general needs replacement, every care should be taken to ensure that a duplicate lens meets the ordered specification and has

been verified by a registered person. A registered practitioner must also take responsibility for the fit of the lens and the vision with it.

5.9.2 A practitioner may well be held to have been negligent if he encourages his patients to use a system of direct supply and does not at the same time warn them fully of the risk of deterioration in their eyesight and of the necessity for regular checks. The College deprecates the concept of contact lens manufacturers supplying patients directly.

5.10: CONTACT LENS INSURANCE AND REPLACEMENT SCHEMES

5.10.1 Schemes are deprecated which enable a patient to order and receive a lens from a manufacturer without the relevant practitioner's knowledge. Apart from lenses not being checked on eyes there is a danger that the manufacturer may not have the latest specification. It is therefore advisable for practitioners to establish their own contact lens replacement schemes to avoid problems.

5.11: DISPOSABLE LENSES

5.11.1 Although this type of contact lens could broadly come under the heading of replacement lenses, their supply is generally different. New lenses may not always be checked on each eye, but before prescribing this type of lens the practitioner must satisfy himself that the reproducibility and behaviour of these lenses are clinically adequate, and ensure that the patient complies with an aftercare regime.

5.12 DELEGATION OF FUNCTIONS

5.12.1 Where practitioners wish to delegate any part of the contact lens procedure to a person, registered or unregistered, it is their ethical duty to be satisfied, prior to delegation, that the person to whom delegation is made is adequately trained and competent to perform the delegated function. In any case the delegating practitioner must be present on the premises at all times when an unregistered person is carrying out a delegated function. ...

5.13: PUBLICITY AND USE OF TITLES AND DESCRIPTIONS

5.13.1 The general principles of publicity and the use of titles and descriptions in connection with optometric practice ... apply equally to contact lens practice.

5.13.2 Optometrists whose qualifications are approved by the General Optical Council as entitling them to fit contact lenses, may use the title 'contact lens practitioner': the use of no other title or description is permissible. Any title suggesting 'specialist' knowledge and skill is particularly to be avoided. The holders of the Fellowship by Examination in the contact lens module may announce the fact on their practice stationery etc; similarly holders of the DCLP may announce that they are Diplomates in Contact Lens Practice.

5.13.3 Special care should be taken in the choice of business names for practices concentrating on contact lens work, since a name such as 'contact lens clinic' or 'contact lens centre' can imply wrongly that other optometric practices do not or cannot provide contact lens services.

5.13.4 In publicising contact lens services great care should be taken to avoid claims to superiority, both direct and indirect. While contact lens practice is a specialised area of optometry it does not constitute a 'speciality' in the medical sense of the word. Publicity other than the details of the practitioner(s) concerned should, therefore, be restricted to announcement of the nature and availability of the services.

5.14: CONTACT LENS FEES AND CHARGES

5.14.1 Contact lens services to the public involve a range of essential functions, all of which, in the patients' best interests, must be carried out, but not all of which can be carried out in a single transaction, as in the supply of spectacles. It is essential, therefore, that before patients are asked to commit themselves to being supplied with contact lenses, they understand precisely what costs and fees will be involved both on supply and on a continuing basis. Where a single fee is charged it should be made clear what services will be covered by that fee, with particular reference to the length and nature of aftercare to be provided. It is professionally unacceptable to seek to attract patients by publicising a single fee for the supply of contact lenses when that fee does not cover all the services necessary to the supply. ...

5.15: PRODUCT LIABILITY

5.15.1 *Drugs and Solutions:* Advice given by the Department of Health to Local Optical Committees indicates that optometrists fall into the same category as any other user/supplier of drugs and solutions so far as liability for negligence is concerned. Where a patient is supplied with a product which is later shown to have been defective and to have caused injury or damage, the supplying practitioner may incur liability for that defective product unless either the manufacturer or the supplier can be identified. This will require the keeping of records to show clearly from whom and when it was supplied. For this purpose it would seem necessary to record such details as the manufacturer/supplier, serial or batch number and the date of issue of the product to the patient and to be able to show that any instructions or warnings in relation to use, maintenance, storage, expiry dates etc., are observed and/or passed on to the patient. There will be practical limitations to such record keeping, but in the field of medical products practitioners should review their record systems to determine the extent to which products can be linked to potential claimants. ...

5.15.2 *Lenses:* In supplying contact lenses, whether at the time of the original fitting or as replacements, practitioners bear full personal responsibility for the quality of the lenses supplied as well as for their clinical suitability. If harm to a patient's eyes results from the supply of defective lenses, it is no defence to a claim of negligence that the fault was due to manufacturing error. This means that optometrists are personally responsible for ensuring that the lenses are verified and their quality is checked, before the lenses are checked for vision and fit on the patient's eyes and supplied to the patient. They have a clear legal and ethical duty to their patients that this essential checking process is carried out *whenever* contact lenses are supplied to a patient; lenses have, therefore, always to be supplied through the practice, and never direct from the manufacturer to patients; if lenses were to be supplied direct in that way, and were found subsequently to be defective, the practitioner concerned could still be held liable for the defect.

Source: BCO.

APPENDIX 2.6

(referred to in paragraphs 2.84, 3.78 and 3.122)

Identical solutions

Surfactant cleaners

Allergan LC-65	=	Boots Daily Cleaner		
[¤]	=	D&A Universal Cleaner		
B&L RGP Cleaner	=	Boston RGP Cleaner	=	D&A Daily Cleaner
CV-UK Contactaclean	=	Boots Hard Lens Cleaner		
CV-UK Hydroclean	=	Boots Soft Lens Cleaner		
Sauflon Soft Lens Daily Cleaner	=	Specsavers Daily Cleaner*	=	Vision Express Daily Cleaner
PBH Cleaner No 4†	=	Specsavers Daily Cleaner†‡	=	Prosol Daily Cleaner†

Disinfectants

[¤]	=	D&A Freshtab		
[¤]	=	D&A Soak and Wet		
Allergan Total	=	Boots All-in-one		
Allergan's Hydrocare Cleaning/Soaking	=	B&L Soaking		
B&L RGP Wetting and Soaking	=	Boston RGP Wetting and Soaking	=	D&A RGP Wetting and Soaking
CV-UK 10.10 Step 1	=	Boots Cleaning and Disinfecting	=	D&A Rapide Cleaning and Disinfecting
CV-UK 10.10 Step 2	=	Boots Rinsing and Neutralising	=	D&A Rapide Rinsing and Neutralising
CV-UK Contactasoak	=	Boots Hard Lens Soaking		
CV-UK Hydrosoak	=	Boots Soft Lens Soaking		
PBH Perform Step 1†	=	Specsavers Step A†	=	Prosept Step 1†
PBH Perform Step 2†	=	Specsavers Step B†	=	Prosept Step 2†
Sauflon Aerotab	=	Specsavers Disinfecting tablet	=	Vision Express Disinfecting tablet

Salines

[¤]	=	D&A Saline§		
Sauflon Saline	=	Specsavers Saline	=	Vision Express Saline
			=	D&A Saline¶

Specialist cleaner

[¤]	=	D&A Polyzyme		
Allergan Hydrocare Fizzy	=	Boots Effervescent Protein Remover		
S&NP Protein Cleaner	=	Sauflon Protein Cleaner	=	Specsavers Protein Cleaner
			=	Vision Express Protein Cleaner

Others

CV-UK Contactasol	=	Boots Hard Lens Wetting
CV-UK Hydrosol	=	Boots Soft Lens Comfort

Source: MMC from data provided by the suppliers.

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*20ml and 60ml containers.
†Manufactured by Waverley.
‡35ml.
§125ml and 240ml containers.
¶420ml container.

Note: All D&A solutions are sold under the brand name of One-2-One.

¤Details omitted. See note on page iv.

APPENDIX 3.1
(referred to in paragraph 3.20)

List of solutions marketed in the UK

Supplier	*Brand name*	*Lens type*
Surfactant cleaners		
CV-UK	Miraflow	All
	Hydroclean	Soft
	Contactaclean	Hard/GP
Allergan	LC-65	All
Alcon	Pliagel	All
	Preflex	Soft
	Clens	Hard/GP
S&NP	Transclean	Hard/GP
	Prymeclean	Soft
B&L	RGP Cleaner	Hard/GP
	Daily Cleaner	Soft
M&L	Boston Cleaner	Hard/GP
Boots	Boots Soft Lens Cleaner	Soft
	Boots Hard Lens Cleaner	Hard/GP
	Daily Cleaner	All
PBH	Cleaner No 4	Soft
Sauflon	Soft Lens Daily Cleaner	Soft
	SteriClens	Hard/GP
D&A	One-2-One Universal Cleaner	All
	One-2-One GP Cleaner	Hard/GP
Specsavers	Daily Cleaner	Soft
Vision Express	Daily Cleaner	Soft
Aspect	Prosol Daily Cleaner	Hard/GP
	Prosol Daily Cleaner	Soft
Disinfectants		
Peroxides		
CV-UK	10.10 Cleaning and Disinfecting Step 1	All
	10.10 Rinsing and Neutralising Step 2	All
	Lensept (Cleaning and Disinfecting)	Soft
	Lensrins (Rinsing and Storage)	Soft
Allergan	Oxysept 1 Disinfecting	Soft
	Oxysept 2 Neutralising	Soft
PBH	Perform 1 Cleaning and Disinfecting	Soft
	Perform 2 Rinsing and Neutralising	Soft
D&A	One-2-One Rapide Step 1	All
	One-2-One Rapide Step 2	All
Boots	Boots Cleaning and Disinfecting 1	All
	Boots Rinsing and Neutralising 2	All

Supplier	*Brand name*	*Lens type*
Specsavers	Disinfecting Step A	Soft
	Rinsing and Neutralising Step B	Soft
Aspect	Prosept Step 1	Soft
	Prosept Step 2	Soft
Chlorine tablets		
D&A	One-2-One Freshtab	Soft
Specsavers	Disinfecting tablets	Soft
Vision Express	Disinfecting tablets	Soft
Sauflon	Aerotab	Soft
Alcon	Softab	Soft
Cold chemical		
CV-UK	Hydrosoak	Soft
	Contactasoak	Hard/GP
	Complete Care	Hard/GP
	O2 Care	GP only
Allergan	Hydrocare Cleaning/Soaking	Soft
	Total	Hard/GP
	Clean-N-Soak	Hard/GP
PBH	Hexidin	Soft
D&A	One-2-One Soaking and Wetting	Hard/GP
	One-2-One Wetting and Soaking	Hard/GP
Boots	Boots Soft Lens Soaking	Soft
	Boots Hard Lens Soaking	Hard/GP
	All-in-One Solution	Hard/GP
Sauflon	Sterisoak	Hard/GP
	Steri-sal2	Soft
Alcon	Soaclens	Hard/GP
	Flexcare Hard/GP	Soft
	Flexsol	Soft
S&NP	Transoak	Hard/GP
	Prymesoak	Soft
B&L	Soflens Soak	Soft
	OptimEyes*	Soft
	RGP Wetting & Soaking	Hard/GP
M&L	Boston Wetting and Soaking	Hard/GP
Aspect	Prosol Soaking and Wetting	Hard/GP
Salines		
CV-UK	Solar Saline	All
	CIBA Saline	All
Allergan	Lens Plus	All
	Solusal	All
	CDP Saline	All

Supplier	*Brand name*	*Lens type*
Alcon	Salette	All
Aerosol Saline	All	
Normol	All	
B&L	Saline	All
Sauflon	Saline	All
Abatron	Amidose	All
PBH	Softmate Saline	All
D&A	One-2-One Saline	All
Boots	Saline	All
Specsavers	Saline	All
Vision Express	Saline	All
Protein cleaners		
Allergan	Hydrocare Fizzy	All
Ultrazyme	All	
Boots	Protein Removal Tablets	All
S&NP	Prymecare	All
Alcon	Clen-zym	All
Abatron	Amiclair	All
B&L	Fizziclean	All
Sauflon	Protein Removal Tablets	All
D&A	One-2-One Polyzyme	All
Aspect	Prosol Intensive Cleaner	All
Specsavers	Protein Removal Tablets	All
Vision Express	Protein Remover Tablets	All
PBH	Intensive Cleaner	All
Others		
CV-UK	Clerz	All
Contactasol	Hard/GP	
Hydrosol	Soft	
Allergan	Lens Fresh	All
Liquifilm	Hard/GP	
Boots	Boots Soft Lens Comfort	Soft
Boots Hard Lens Wetting	Hard/GP	
S&NP	Transol	Hard/GP
Transdrop	Hard/GP	

APPENDIX 3.2
(referred to in paragraph 3.29)

Discard dates

1. CV-UK estimated that if a consumer followed its recommendations and cleaned his or her lenses once a day, the contents of Miraflow in its 35ml container would only be used up in 58 days (compared with the discard date of 28 days). CV-UK pointed out that Miraflow is also sold in a 10ml bottle and that it was in the process of replacing its 35ml bottle with a 25ml one.

2. Allergan told us that it supplies four solutions which would not be used up by the discard date if the consumer were to follow the recommended dosage. It said that these solutions were of two types. The first type comprised Hydrocare Cleaning/Soaking in a 240ml bottle, Hydrocare Preserved saline, also in a 240ml bottle, and Liquifilm in a 30ml bottle. Allergan told us that each of these three solutions had low sales and were not being promoted. The second type covers just one solution, the surfactant cleaner LC-65. For this solution, Allergan said that it regarded the '28 days after opening discard date that the MCA requires to be recommended as quite simply unrealistically short'. Allergan believed that LC-65 in a 30ml container, when used at a standard rate by a single user, could safely be used for the three months that would be required to use up the solution. Allergan told us that to reduce the maximum size of the LC-65 container to that required for 28 days' standard use by a single user would mean a maximum size of container of about 8ml. It said that this would be 'ridiculous' and if it were to attempt unilaterally to make such a move, it would probably render the product commercially unviable.

3. Alcon said that, of its three daily cleaners (Pliagel, Clens, and Preflex) and the own-label daily cleaner it supplies to D&A, at most about 17ml would be needed for a 28-day discard date if the solutions were used as directed. Alcon told us that it supplied these solutions in 25ml bottles to accommodate a 'spillage allowance'. It said that this allowance for wastage was common in the case of cleaning solutions. Alcon also said that the 25ml bottle it used for these solutions in the UK was the Alcon group's smallest standard international size for this type of product.

4. B&L told us that all of its solutions were sold in pack sizes such that if customers followed the recommended dosage they would use all of the solution by the discard date. We found that the daily cleaner which is part of B&L's Freshvision system and is packaged in 10ml containers appears to be the same solution as the daily cleaner used in B&L's Soflens system which is packaged in 30ml containers. Both have a discard date of 28 days. B&L states on the packets of Freshvision that the amount of daily cleaner (10ml) in the pack 'is sufficient to care for your lenses for one month'. The instructions for using the daily cleaner as part of the Soflens and Freshvision systems are similar: the instructions in the Freshvision system state that 'a few drops of B&L Daily Cleaner are to be applied to each surface' compared with the instructions in the 30ml container which state that 'three drops of B&L Daily Cleaner are to be applied to each surface'.

5. B&L's Soflens is sold in a 240ml container. The instructions in a pack of Soflens tell the user to 'fill the storage case'. B&L's storage cases, for soft lenses, hold about 7ml of liquid (without lenses). A 240ml container of Soflens, used as recommended, would therefore be exhausted after 34 days (without allowing for spillage), 6 days after the discard date of 28 days. The instructions inside the lens storage case, however, tell the user to 'fill each side of the B&L case two-thirds full'. Following these instructions, a 240ml container of Soflens would be exhausted after 48 days (without allowing for spillage), 20 days after the discard date.

6. Sauflon's daily cleaners, Soft Lens Daily Cleaner and Steri-clens, which are sold in 20ml and 60ml bottles, also have a discard date of 28 days. Sauflon told us that customers should use 1 to 2ml of its daily cleaners for each day's wear. Sauflon said that it supplies these larger containers as it has found that customers use more than the recommended dosage. S&NP sells its daily cleaner only in 10ml containers. PBH told us that its pack sizes are designed so that the minimum amount of solution is wasted.

7. Allergan, which supplies Boots own-label daily cleaner, has accepted that its equivalent branded solution does suffer from this problem (see paragraph 3.30). But Boots told us that all of its own-label solutions would be exhausted if the customer wears the lenses every day and follows the recommended dosage. Boots told us that it was only able to sell the same sized packs as those which were registered on the licence by the supplier, the pack size being agreed between the supplier and the DoH. Boots' previous own-label protein removers, which it discontinued in October 1991, were sold in packs containing 24 tablets. S&NP, which supplied Boots with these tablets and sells its equivalent branded protein removers in packs containing eight or sixteen tablets, told us that Boots had requested the larger pack size.

8. D&A told us that it adopts the manufacturer's recommendations for its own-label solutions; it said that it does not assess or monitor individual solution usage with regard to the size of the containers supplied.

9. Specsavers' own-label Daily Cleaner is sold in three different sized containers (20ml, 35ml and 60ml); whilst Vision Express sells its own-label Daily Cleaner in 20ml and 60ml bottles.

APPENDIX 3.3
(referred to in paragaraph 3.31)

Pack sizes available in the UK

Supplier	*Solution*	*Pack size*
Surfactant cleaners		
Allergan	LC-65	15ml, 30ml
CV-UK	Miraflow	10ml, 35ml
	Hydroclean	35ml
	Contactaclean	35ml
Alcon	Pliagel	25ml
	Prefiex	25ml
	Clens	25ml
B&L	Daily Cleaner	30ml
	RGP Cleaner	30ml
M&L	Boston Cleaner	30ml
S&NP	Transclean	10ml
	Prymeclean	10ml
PBH	Cleaner No 4	35ml
Sauflon	Soft Lens Daily Cleaner	20ml
	Soft Lens Daily Cleaner	60ml
	Steri-clens	60ml
Aspect	Prosol Daily Cleaner	30ml
Salines		
Allergan	Lens Plus	90ml, 240ml, 360ml
	Solusal	240ml
	CDP saline	240ml
CV-UK	Solar Saline	115ml, 275ml
	CIBA Saline	360ml
Alcon	Aerosol Saline	125ml, 240ml
	Salette	125ml,240ml,360ml,30x15ml
	Normol	250ml
B&L	Saline	90ml, 240ml
PBH	Softmate Saline	360ml
Sauflon	Saline	120ml, 300ml, 420ml
Disinfectants		
Allergan	Hydrocare Cleaning/Soaking	120ml, 240ml
	Total	60ml, 120ml, 3x120ml
	Clean-N-Soak	120ml
CV-UK	Hydrosoak	120ml
	Contactasoak	120ml
	Complete Care	120ml
Alcon	Soaclens	120ml
	Flexsol	175ml
	Flexcare	250ml

Supplier	*Solution*	*Pack size*
B&L	Soaking Solution	240ml
	RGP Wetting and Soaking	120ml
M&L	Boston Wetting and Soaking	120ml
S&NP	Transoak	120ml
	Prymesoak	120ml
PBH	Hexidin	250ml
Sauflon	Steri-sal2	110ml
	Steri-soak	110ml
Aspect	Prosol Soak & Wetting	120ml
Protein cleaners		
Allergan	Hydrocare Fizzy	12, 24 and 48 tablets
	Ultrazyme	5 and 10 tablets
Alcon	Clen-zym	12 tablets
B&L	Fizziclean	12 and 24 tablets
Sauflon	Protein Tablets	8, 12 and 24 tablets
S&NP	Prymecare	8 and 16 tablets
PBH	Intensive Cleaner	90ml
Aspect	Intensive Cleaner	35ml

Source: Price lists provided by the suppliers.

APPENDIX 3.4
(referred to in paragraphs 3.33 and 3.96)

Suppliers' systems

1. Allergan markets its cold chemical solution for soft lenses, Hydrocare Cleaning/Soaking, as part of the Hydrocare system which also includes LC-65 (Daily Cleaner), Lens Plus (Saline) and Hydrocare Fizzy (Protein Remover tablets). It similarly markets its all-in-one solution for hard/GP lenses, Total, as being part of the Total system which includes LC-65 and Hydrocare Fizzy.

2. CV-UK offers its Hydro (for soft lenses) and Contacta (for hard lenses) systems which include a daily cleaner, a disinfectant and wetting solution/comfort drops (CV-UK has no protein remover).

3. Alcon told us that it had three lens care systems for soft lenses and one for hard/GP lenses. One example of its soft lens care systems is the Softab system which includes Pliagel (daily cleaner), Salette (saline), Softab (chlorine disinfectant tablet), and Clen-zym (protein remover). Alcon's hard lens care system includes Pliagel (daily cleaner), and Soaclens (disinfecting and wetting solution).

4. Alcon told us that Flexsol (disinfectant solution), which is part of another of its soft lens care systems, must be marketed and sold in conjunction with Preflex (daily cleaner) and Normol (rinsing solution) because of the specifications in the product licence.

5. B&L has three care systems, two for soft lenses and the other for hard/GP lenses. Its more established system for soft lenses is its Soflens system which includes a daily cleaner, a soaking solution, saline and a protein remover. Its second care system for soft lenses, Freshvision, was introduced in May 1990 and is used as part of a frequent replacement scheme for contact lenses. Freshvision contains a daily cleaner and disinfecting tablets, Optimeyes. B&L's care system for hard/GP lenses contains a daily cleaner and a wetting and soaking solution. M&L has one care system, Boston, which is used for hard/GP lenses and contains a daily cleaner and a wetting and soaking solution.

6. Sauflon has three systems, its main one being its Aerotab system which includes Aerotab chlorine tablets, Sauflon Saline, Sauflon Soft Lens Daily Cleaner, and Sauflon Protein Remover tablets.

7. S&NP has two systems which are both cold chemical in nature. For hard/GP lenses S&NP's system contains Transclean (daily cleaner), Transoak (disinfectant), Transol (wetting solution), Transdrop (in-eye comfort), and for GP lenses Prymecare (protein removers). S&NP offers its Pryme system for soft lenses which includes Prymeclean (daily cleaner), Prymesoak (disinfectant), and Prymecare (protein removers). S&NP does not offer a saline solution.

8. PBH has two systems, both for soft lenses. The main one is its peroxide system which includes Perform 1, Perform 2, Cleaner No 4, Softmate Saline and Intensive Cleaner. At the beginning of 1991 PBH withdrew its system for hard/GP lenses (Titan—daily cleaner—and Wetting & Soaking).

9. Aspect has two care systems, a peroxide system, Prosept, for soft lenses and a cold chemical system, Prosol, for hard/GP lenses. Unlike any other supplier, Aspect's solutions can only be bought in either monthly or three-monthly self-contained packs where Prosol Daily Cleaner and Prosol Intensive Cleaner (protein remover) are added to the packs. Aspect told us that it began this policy as a marketing tool and to aid compliance. It said that it was about to end the policy as it had not proved to be a success.

10. Boots markets its own-label cold chemical system for GP lenses which includes Boots All-in-one solution, Boots Daily Cleaner, Boots Saline solution, and Boots Protein Remover tablets. The same applies to its cold chemical systems for hard and soft lenses.

11. All the own-label solutions of D&A have the brand name One-2-One. D&A has five care systems, two of which use the same disinfecting solution. For all types of lenses D&A has its peroxide

system known as One-2-One Rapide; for soft lenses only it has a chlorine system known as One-2-One Freshtab; and for hard/GP lenses only it has three cold chemical disinfecting systems. Two of these disinfecting systems contain One-2-One Soaking & Wetting solution, one being used with One-2-One Universal Cleaner (daily cleaner for soft and hard/GP lenses), the other with One-2-One GP Cleaner. The remaining disinfecting system includes One-2-One Wetting & Soaking solution (for GP lenses only) which is used with One-2-One GP Cleaner.

12. Specsavers has two care systems, both of which are preservative-free. It has a peroxide and a chlorine system, both of which are used with its own-label Daily Cleaner, Saline and Protein Remover tablets.

13. Vision Express offers its patients its own-label chlorine system which, as well as chlorine tablets, includes its own-label Daily Cleaner, Saline and Protein Remover tablets.

APPENDIX 3.5

(referred to in paragraphs 3.86, 3.87 and 3.88)

Solutions which are sold in countries other than the UK and which would be sold in the UK if regulatory approval was granted

Supplier	*Solution*	*Type*
Allergan	None	
CIBA Vision	AOSept	One-step peroxide disinfectant for soft lenses
Alcon	Opti-free	Disinfectant for soft lenses
	Opti-free Daily cleaner	Surfactant cleaner for soft lenses daily cleaner
	Opti-free Enzymatic cleaner	Protein remover
	Opti-free Wetting drops	Wetting solution
	Opti-Clean II	Surfactant cleaner
	Opti-Tears	In-eye comfort drop
	Opti-Soak	Disinfectant for GP lenses
B&L	Renu	Multi-purpose solution for soft lenses
	Advance	RGP soaking solution
	Advance	RGP surfactant cleaner
Sauflon	Lobob	Surfactant cleaner
	Sauflon Peroxide	Peroxide disinfectant for soft lenses
	Sauflon Neutraliser	Aerosol neutraliser
	Sauflon DSW	Soaking and wetting solution for hard/GP lenses
	Sterifresh	In-eye comfort
S&NP	None	
PBH	Actizyme	Protein cleaner
	Consept	Peroxide disinfectant for soft lenses

Source: The suppliers.

APPENDIX 3.6
(referred to in paragraphs 3.131 and 7.130)

Survey of optical and pharmaceutical wholesalers

1. We sent out 49 questionnaires, and received 23 completed questionnaires, 8 from optical wholesalers, 14 from pharmaceutical wholesalers and 1 from a pharmaceutical wholesaler (Intercare) which only delivers Allergan's solutions.

2. Of the optical wholesalers, two had annual sales of solutions of less than £200,000; three at between £200,000 and £500,000; one at just over £1 million; and two at just under £3 million each. Nine of the pharmaceutical wholesalers had annual sales of solutions of less than £100,000; two at between £100,000 and £150,000; one at £2 million; and one at £3 million.

3. Four of the optical wholesalers delivered all their solutions to opticians. The two largest optical wholesalers (Martin and Mid-Optic) each delivered less than 5 per cent of their sales of solutions to pharmacies. The largest proportion of sales to pharmacies by an optical wholesaler was 19 per cent by Aspect (the third largest optical wholesaler). All but one pharmaceutical wholesaler delivered all their solutions to pharmacies.

4. We asked wholesalers for their assessment of competition in the solutions market at the three levels of: manufacturer/importer, wholesaler and retailer. Table 1 shows the results.

TABLE 1 **Wholesalers' view of the state of competition in the solutions market**

		Number of wholesalers	
Nature of business	*State of competition*	*Optical wholesalers*	*Pharmaceutical wholesalers*
Manufacturer/ importer	Very competitive	4	2
	Moderately competitive	2	8
	Uncompetitive	0	1
Wholesaler	Very competitive	7	7
	Moderately competitive	1	5
	Uncompetitive	0	2
Retailer	Very competitive	3	2
	Moderately competitive	3	6
	Uncompetitive	0	5

Source: MMC survey of wholesalers.

5. We asked wholesalers whom they regarded as their main competitors. Table 2 shows the results.

TABLE 2 **Wholesalers' view of whom they regard as their main competitors**

	Number of wholesalers	
Main competitors	*Optical wholesalers**	*Pharmaceutical wholesalers**
Optical wholesalers	8	7
Pharmaceutical wholesalers	1	14
Manufacturers/importers	6	3

Source: MMC survey of wholesalers.

*Most respondents gave more than one answer.

6. Both optical and pharmaceutical wholesalers told us that they competed mainly on price and delivery.

7. Five optical and six pharmaceutical wholesalers told us that they had changed their prices in the last five years in response to competitive pressures. Three optical and nine pharmaceutical wholesalers said that they had not responded by changing prices.

8. Five optical and five pharmaceutical wholesalers stated that there were barriers to entering the market at the distribution level. Three wholesalers said that the barriers were the cost of the regulatory licence and two gave low profitability as a barrier. Five optical and three pharmaceutical wholesalers said that there were barriers to expanding their business.

9. Five optical and three pharmaceutical wholesales said that in the last five years they had experienced difficulties in obtaining solutions.

10. All optical wholesalers and virtually all pharmaceutical wholesalers said that they did not favour solutions being sold in supermarkets. All optical and pharmaceutical wholesalers said that they did not favour solutions being sold in other kinds of retail outlets (other than opticians, pharmacies and supermarkets).

11. We asked wholesalers what the effect on retail prices would be if there was a widening of the type of retail outlets allowed to sell solutions. Five optical wholesalers said that prices would not change if solutions were on offer in supermarkets, and three said that they would fall, whereas seven pharmaceutical wholesalers said that prices would fall and seven said that they would not change. Six optical wholesalers said that prices would not change if other types of retail outlets were allowed to sell solutions, one said that prices would increase, whereas 11 pharmaceutical wholesalers said that there would be no change in prices whilst three said that prices would fall.

APPENDIX 3.7
(referred to in paragraphs 3.135 and 8.83)

Introduction to the surveys covering the retailers and contact lens wearers

1. The MMC arranged for Research Surveys of Great Britain (RSGB) to carry out two postal surveys on their behalf in order to obtain up-to-date information on the contact lens activities of opticians and pharmacists respectively. One major aim was to collect information on recommendation practices for new wearers (opticians' advice) and for wearers who were considering a switch of brands, or who had been advised to switch brands (opticians' or pharmacists' advice). In view of the large numbers of both optician and pharmacist outlets in the UK (over 6,200 opticians and over 11,000 pharmacists), it was decided not to write to all of these as potential main parties in a particular tier of supply in the reference, as is normally done where the numbers involved are small, but rather (following a number of MMC precedents, eg petrol retailers, new car retailers), to survey a representative cross-section in each group, selected on a random basis.

2. In the case of opticians RSGB sent out questionnaires to 776 outlets (a 1 in 8 sample), and in the case of pharmacists 1,153 outlets (a 1 in 10 sample). Addresses in the base population were stratified to ensure proportional representation of major multiples, such as Boots and D&A. Again in accordance with the MMC's normal practice, the form of questions used in the surveys were subject to amendment and clearance by experts in the appropriate field, in this case opticians and pharmacists.

3. While it was put to us that responses to the opticians survey covered only 5 per cent of opticians, this was because we chose to carry out a sample survey, as noted above. As is common with such surveys, we did not receive replies from all of those contacted. Stratified sampling was used, rather than a full census, in order to obtain information at reasonable cost and to minimize the form-filling burden on the industry. Sampling of this type is a normal procedure in inquiries of this sort, and enables the MMC to obtain an overview of the practices which are the subjects of the surveys. The MMC have received no evidence from any of those in the industry, to whom the results of the surveys were shown, to suggest that the results of either the opticians or pharmacists surveys were subject to response bias.

4. The MMC also conducted a survey of contact lens wearers in order to obtain information on the use of CLS by consumers. This survey was carried out by British Market Research Bureau (BMRB) using its Target Samples service to select a sample of known contact lens wearers in the UK. Out of a sample of 2,316 contact lens wearers, that is individuals who during the two-year period up to April 1992 had told BMRB that they were contact lens wearers, a group of 1,407 were identified as potential respondents to the MMC's consumer survey. Telephone interviews were carried out by BMRB with 792 of these over the period 1 to 13 September 1992, following a pilot consisting of 15 interviews carried out on 24 August. As in the case of the opticians and pharmacists surveys, the form of questioning was the subject of consultation with industry specialists.

APPENDIX 3.8
(referred to in paragraphs 2.66, 3.135, 7.37, 8.83, 8.87 and 8.90)

Survey of opticians

1. In order to collect up-to-date information on opticians' solutions activities, a postal questionnaire was sent to 776 opticians outlets in August 1992, using a 1 in 8 random sample of all outlets in the UK. The survey was undertaken by the market research company RSGB. RSGB carried out tabulations on 324 replies, giving a response rate of 48 per cent after allowing for 97 replies outside the scope of the survey, ie they did not fit or sell lenses or solutions, or had ceased trading.

2. The questionnaire addressed the following areas: turnover, both relating to solutions and to the overall business; whether the business formed part of a group under common ownership; the number of people buying contact lenses in the latest month, covering both existing and new wearers; stocking policy in relation to solutions; recommendations of solutions; the extent of eye problems related to lenses and solutions; and prices. The main area covered concerned the recommendations by the opticians and their reasons for such recommendations.

General

3. 68 per cent of opticians in the survey had been practising for 15 years or less; this proportion was fairly evenly divided between those who had been practising between one and five years (20 per cent), six to ten years (27 per cent) and 11 to 15 years (20 per cent).

4. 27 per cent of opticians covered had a total turnover in their latest trading year of up to £100,000, and 46 per cent had a total turnover of between £100,000 and £300,000. 51 per cent of opticians had a turnover relating to solutions of between £1,000 and £10,000 in their latest trading year.

5. 47 per cent of opticians were not part of a multiple group, and a further 16 per cent were part of a group with between two and ten outlets. A further 31 per cent were part of groups that had over 50 outlets.

6. Just under half the opticians in the survey sold lenses to between one and twenty customers in their latest month, whilst 83 per cent sold lenses to the same number of first-time wearers.

7. The great majority of opticians had all the leading brands of solutions available to them through their chosen supply route. Of these opticians, between 36 and 61 per cent stocked only part of the suppliers' ranges of solutions, and a lower proportion, between 8 and 35 per cent, took the full range of the suppliers' solutions. Just under half the opticians told us that the most important reason for not stocking a wider range of suppliers' solutions was that 'there was no significant demand for the solutions'. Three-quarters of opticians in the survey did not have a policy of excluding solutions on the grounds of effectiveness/quality.

Recommendations

8. Virtually all opticians in the sample recommended particular brands of solutions. We asked opticians to give us up to three reasons which they regarded as the most important when recommending a disinfecting system to their last three customers wearing hard/GP lenses and also to their last three customers wearing soft lenses. Table 1 shows the results.

TABLE 1 **Reasons that were most important to opticians in recommending a disinfecting system***

	Types of lenses	
	Hard/GP	*Soft*
(Base)	(299)	(296)
	Percentage of opticians	
Technically less likely to cause irritation to the eye	34	61
Solution effectiveness	78	78
Easy to use	61	45
Reasonable cost to the customer	28	25
Widely available	20	18
Few complaints from existing customers	25	20
Profitable to sell	2	4
Other	5	4

Source: MMC calculations.

*Averaged for the last three customers.

9. Table 1 shows that 78 per cent of opticians gave 'solution effectiveness' as one of the most important reasons for their recommendation of solutions for both hard/GP and soft lenses. The second most popular category differed by type of lens. 61 per cent of opticians gave 'less likely to cause irritation' as one of the most important reasons for their recommendation of solutions for soft lenses compared with 34 per cent for hard/GP lenses. 61 per cent of opticians selected 'easy to use' as one of the most important reasons for their recommendation of solutions for hard/GP lenses compared with 45 per cent for soft lenses.

10. About one-quarter of opticians cited 'reasonable cost to the customer' as one of the most important reasons for their recommendation of solutions for both hard/GP and soft lenses.

11. 67 per cent of opticians in the survey told us that in the last five years they had changed their advice as to the type of disinfecting system they normally recommend for soft lenses compared with 21 per cent for hard/GP lenses. 83 per cent of opticians advise a cold chemical disinfecting solution for hard/GP lenses compared with 5 per cent for soft lenses, down from 47 per cent during the last five years. Three-quarters of opticians recommended a peroxide system for wearers of soft contact lenses, while 13 per cent recommended a chlorine system.

12. When asked whether most wearers of soft lenses could satisfactorily use certain systems, 93 per cent of opticians said that this was the case for peroxide systems, 79 per cent told us that this was the case for chlorine systems, and 50 per cent said the same for cold chemical systems.

Eye problems

13. Between 65 and 75 per cent of opticians in the survey told us that 10 per cent or less of their customers had suffered eye soreness or similar problems as a result of using lenses and/or solutions.

14. 68 per cent of opticians in the sample stated that peroxide systems had caused their customers fewest problems. 21 per cent of opticians said the same of chlorine systems while only 4 per cent said this of cold chemical systems.

Prices

15. D&A, the largest optical group, operates a discount scheme; BOL, the second largest group of opticians, does not. 49 per cent of opticians (including D&A) in the survey offer a customer discount scheme.

16. 40 per cent of opticians, including BOL, did not operate a customer discount scheme and sold all branded solutions at RRP. Excluding sales through discount schemes, 19 per cent of opticians sold all branded solutions at RRP. 80 per cent of opticians who did not adopt suppliers' RRP chose a standard price difference from the RRP. Excluding sales through discount schemes, 19 per cent of opticians, including D&A, charged retail prices for branded solutions which were up to 5 per cent less than the suppliers' RRP and 13 per cent charged retail prices which were between 5 and 15 per cent below suppliers' RRP.

17. D&A operates a frequent replacement scheme for lenses which includes solutions; BOL does not. 49 per cent of opticians, including D&A, operate a frequent replacement scheme.

18. Virtually all opticians offer starter packs free to customers.

19. Virtually all opticians told us that they always, or nearly always, or mostly gave advice to their customers on the likely future costs to them of buying solutions.

APPENDIX 3.9
(referred to in paragraphs 3.135, 3.152 and 8.83)

Survey of pharmacies

1. In order to collect up-to-date information on pharmacies' solutions activities, a postal questionnaire was sent to 1,153 pharmacies in August 1992, using a 1 in 10 random sample of all outlets in the UK. The survey was undertaken by the market research company RSGB. RSGB carried out tabulations on 427 replies, giving a response rate of 39 per cent after allowing for 67 replies outside the scope of the survey, ie they did not fit or sell lenses or solutions, or had ceased trading.

2. The questionnaire addressed the following areas: turnover, both relating to solutions and to the overall business; whether the business formed part of a group under common ownership; the number of people buying solutions and the number of solutions bought in the week before receiving our questionnaire; stocking policy; prices; and finally the main area, advice on solutions sought by customers and given by pharmacists.

General

3. Virtually all pharmacies in the sample sold solutions. 7 per cent of pharmacies covered had a total turnover in their latest trading year of up to £100,000. The total turnover of a further 42 per cent fell between £100,000 and £400,000. Just under two-thirds of pharmacies had a turnover relating to solutions of £5,000 or less in their latest trading year.

4. Just over half the pharmacies in the survey were not part of a multiple group, with a further 21 per cent being part of a group with between two and ten outlets. A further 22 per cent were part of groups that had over 50 outlets.

5. One-third of pharmacies in the survey sold between one and five items of solutions in the last full week before they received our questionnaire. A further 31 per cent sold between 6 and 20 items of solutions in this same period.

6. 44 per cent of pharmacies said that they had sold solutions to between one and five customers in the last full week before receiving our questionnaire. A further 26 per cent reported that they had sold solutions to between 6 and 20 customers in this same period.

7. Pharmacies tend to stock part of the range of a supplier's solutions as opposed to the full range.

8. Just over half the pharmacies in the survey told us that the most important reason for their not stocking a wider range of suppliers' solutions was that 'there was no significant demand for the solutions'. Virtually all pharmacies covered do not have a policy of excluding solutions on the grounds of effectiveness/quality.

Prices

9. 97 per cent of the pharmacies in the survey did not operate a customer discount scheme. 92 per cent of pharmacies sell all branded solutions at the RRP.

Advice

10. We asked pharmacies how often in the week after they received our questionnaire their pharmacist(s) had been asked for advice in connection with eye problems and also specifically for advice in connection with solutions. Table 1 shows the main findings.

TABLE 1 **Number of times the pharmacists were asked for advice on eye problems and solutions***

(Base)	(427)	(427)
*Number of times asked for advice**	*Type of advice*	
	Eye problems	*Solutions*
	Percentage of pharmacies	
None	29	36
1 to 5	37	39
6 to 10	10	7
More than 11	12	5
Not answered	12	13
Mean	5.2	2.9

Source: RSGB.

*In the week after receiving our questionnaire.

11. These findings suggest that about 60 per cent of pharmacists explicity reported that they had been asked about eye problems in the relevant week; the equivalent proportion for advice about solutions was about 50 per cent. In the average pharmacy the pharmacist(s) will be consulted about eye problems by about five consumers per week and about solutions by about three consumers per week.

12. We asked pharmacies how often in the week after they received our questionnaire their pharmacist(s) had been asked for particular advice in connection with solutions. Table 2 summarizes the findings and Annex 1 contains the more detailed responses.

13. Table 2 shows that, in the week of the survey, the proportion of pharmacists who were asked for advice by consumers on specific areas of solutions (column *(a)*) ranged from 34 per cent ('use of solutions with particular types of lenses') to 11 per cent ('likely reaction to particular solutions'). Column *(b)* shows that in a year a pharmacist in an average pharmacy receives between 14 enquiries ('likely reaction to particular solutions') and 47 enquiries ('use of solutions with particular types of lenses').

14. Column *(e)* of Table 2 shows the percentage of pharmacists who said they answered consumers' questions on particular subjects without referring them to an optician, ranging from 77 per cent ('possibility of switching') to 43 per cent ('use of solutions within the same brand range').

TABLE 2 **Number of times the pharmacists were asked for particular advice on solutions***

	Advice sought (percentage of pharmacies) (a)	*Advice sought (implied average annual number of queries per pharmacy†) (b)*	*Advice sought and given with no referral to optician (percentage of pharmacies) (c)*	*Advice sought and given with no referral to optician (implied average no per pharmacy*) (d)*	*(d) as a percentage of (b)‡ (e)*
(Base)	(427)	(427)	(427)	(427)	
Soreness or other problems where solutions were thought to be the cause	22	27	11	13	48
Likely reaction to particular solutions	11	14	7	7	48
Use of solutions with particular types of lenses	34	47	26	32	68
Use of solutions within the same brand range	15	28	10	12	43
Use of solutions with those of a different brand	23	39	18	27	69
Possibility of switching	29	36	19	28	77
Other specified areas	20	37	7	13	35

Source: MMC calculations.

*Based on the week after receiving our questionnaire.
†Weekly mean multiplied by 52.
‡Refers to unrounded data.

Advice sought from pharmacists

Area	Advice sought	Advice given by pharmacist and no referral to an optician	Advice given by pharmacist and referral to an optician	Referral to optician only
A. Soreness or other problems with the eyes where solutions are thought by you to be the cause				
Base	427	95	95	95
None	332	13	9	14
Some	95	48	48	11
N/A	0	34	38	70
B. Likely reaction to particular solutions				
Base	427	47	47	47
None	380	4	5	8
Some	47	29	18	6
N/A	0	14	24	33
C. Use of solutions with particular types of lenses				
Base	427	47	146	146
None	281	5	17	20
Some	146	109	28	9
N/A	0	32	101	117
D. Use of solutions within the same brands				
Base	427	62	62	62
None	365	2	8	8
Some	62	44	8	2
N/A	0	16	46	52
E. Use of solutions within different brands				
Base	427	99	99	99
None	328	4	14	17
Some	99	77	23	8
N/A	0	18	62	74
F. Possibility of switching				
Base	427	122	122	122
None	305	7	11	17
Some	122	82	31	11
N/A	0	33	80	94
G. Other queries				
Base	427	86	86	86
None	341	34	37	37
Some	86	30	13	10
N/A	0	22	36	39

Source: MMC survey of pharmacists.

APPENDIX 3.10
(referred to in paragraphs 2.61, 2.68, 2.72, 3.33, 3.135, 8.88, 8.96 and 8.222)

Survey of contact lens wearers

1. In order to collect up-to-date information on people who use solutions, we commissioned a telephone survey from the market research company British Market Research Bureau (BMRB). BMRB used the Target Group Index (TGI) and related databases which contain information on about 2,500 individuals known to have been wearing contact lenses in the last 2½ years. The survey carried out by BMRB comprised a sample of 792 current contact lens wearers.

2. The questionnaire addressed the following areas: contact lenses; brands of solutions and reasons for using them; switching of solutions; compliance; costs and retail outlets; problems; and advice sought from pharmacies.

Contact lenses

3. 53 per cent of the sample wore only soft lenses, 32 per cent used GP lenses only, 9 per cent used only hard lenses, and the remainder used more than one lens type. 70 per cent of the sample wore lenses seven days a week, and 61 per cent of the sample used their lenses for 12 hours or more on each day they wore them.

Solutions

General

4. When asked to name the brands of the solutions they used, 65 per cent of the sample knew the name without having to fetch their solutions.

5. 70 per cent of the sample said that the optician had recommended the type or brand of solutions they used, 59 per cent being recommended a particular brand and 11 per cent being recommended a particular type of solution. 13 per cent decided to use their solutions on the basis of cost, 1 per cent on the recommendation of a doctor and less than half of 1 per cent on the recommendation of a pharmacist. 63 per cent of wearers said that the solutions they used belonged to a single brand.

6. 50 per cent of the sample had changed solutions. We asked consumers to tell us the year in which they had last changed their solutions. Over two-thirds of those who had switched did so after 1989, with 15 per cent last changing before 1988. The extent of switching differed by the length of time lenses had been worn. For those wearing lenses for one year or less 29 per cent had switched, compared with 38 per cent for those wearing lenses between two and five years and 62 per cent for those wearing them for six years and over. Two-thirds of those who had switched solutions changed their brand of disinfectant.

7. Of those consumers who had changed solutions, the most popular reason for changing, given by 25 per cent (12.5 per cent of the sample), was that the 'new solution was cheaper/old solution was expensive'. 45 per cent of those who had switched did so for reasons where the wearer may not have taken the initiative (15 per cent because an optician recommended a new solution, 15 per cent changed from one type of lens to another, 13 per cent because of sore eyes and 2 per cent because they changed opticians). Excluding these wearers reduces the extent of switching from 50 to 27 per cent.

8. 16 per cent of the sample said that there had been occasions when they had considered changing solutions but decided not to do so. The most popular reason was the cost of solutions which was given by 54 per cent of those that had considered changing but had not done so.

Compliance

9. We asked consumers about the extent to which they complied with various instructions and recommendations. We received the following replies:

(a) 82 per cent of the sample cleaned their lenses every day they used them. 30 per cent who did not said that their reason was 'laziness/can't be bothered/too busy' and 23 per cent said that they found 'the procedure too time-consuming'.

(b) 82 per cent of the sample said that they always used fresh solution for disinfecting and storing their lenses. 27 per cent of those who did not told us that their reason was that 'solutions are too expensive'.

(c) 61 per cent of the consumers who used a protein remover did so in the way recommended.

(d) Two-thirds of the sample told us that they never used solutions after their use-by date, 19 per cent occasionally did so and 11 per cent often did so. 40 per cent of those who often or occasionally used solutions after their use-by date said that their reason was that 'it was wasteful to throw solutions away'.

(e) 84 per cent of the sample said that they always used the recommended amount of solution. 21 per cent of those who do not told us that their reason is that 'solutions are too expensive'.

(f) Virtually no one in the sample used solutions in other ways to make them last longer.

10. We asked consumers how long the solutions they used normally lasted. Table 1 shows the combined results for Allergan, CV-UK and Boots solutions classified into peroxides, surfactant cleaner and cold chemical solutions.

TABLE 1 **Percentage of consumers who use solutions* beyond their use-by date**

Type of solution	*(Base)*	*Percentage of consumers who use their solutions beyond use-by date*
Surfactant cleaner†	(273)	61
Peroxides—cleaning and disinfecting (Step 1)‡	(225)	38
Preserved disinfecting/soaking§	(330)	59

Source: MMC calculations.

*Average for solutions of Allergan, CV-UK and Boots.

†Assumes a use-by date of 60 days unless otherwise specified. Includes Boots hard lens surfactant cleaner, Boots soft lens surfactant cleaner, Boots non-preserved surfactant cleaner (use-by date of 28 days), CV-UK Contactaclean, CV-UK Hydroclean, CV-UK Miraflow (use-by date of 28 days), and Allergan LC-65 (use-by date of 28 days).

‡Assumes a use-by date of 28 days unless otherwise specified. Includes Boots Cleaning and Disinfecting, CV-UK 10.10 Cleaning and Disinfecting, and Allergan Oxysept 1 (use-by date of six weeks).

§Assumes a use-by date of 28 days unless otherwise specified. Includes Boots Hard Lens Soaking solution, Boots Soft Lens Soaking solution (use-by date of 60 days), Boots All-in-One solution, CV-UK Contactasoak, CV-UK Hydrosoak (use-by date of 60 days), CV-UK Complete Care, Allergan Cleaning/Soaking, Allergan Clean-N-Soak and Allergan Total.

11. Table 1 shows that 38 per cent of consumers using step one of those brands of peroxides covered exceeded the discard dates. For the same brands of surfactant cleaners, 61 per cent exceeded the discard date, whilst for cold chemical solutions the proportion was 59 per cent.

Eye problems

12. 12 per cent of the sample had experienced sore eyes or similar problems as a result of using solutions with soft lenses and 6 per cent as a result of using solutions with hard/GP lenses. These findings are lower than the problem of sore eyes associated with lenses themselves—24 per cent in the case of hard/GP lenses and 20 per cent for soft lenses. Over 80 per cent of those who had experienced sore eyes as a result of using solutions with hard/GP lenses said that this was not because the solutions had been used incorrectly compared with 62 per cent of those who had experienced sore eyes as a result of using solutions with soft lenses.

Instructions provided with the solutions

13. Virtually all consumers in the sample found the instructions provided with solutions easy to understand.

Price information

14. 71 per cent of the sample told us that when they were first considering wearing contact lenses, the optician did not discuss with them the likely future costs of buying solutions. 53 per cent of those users who had been wearing lenses for one year or less told us that opticians did not discuss the likely future cost compared with 64 per cent for those wearing lenses between two and five years and 79 per cent for those of six years and over. 71 per cent of consumers in the sample who were advised about likely future costs of solutions were told before they had made their decision to wear lenses.

15. The average actual cost of solutions for the sample was just over £103 per year. The average for those wearing hard lenses was £68 compared with £92 for those using GP lenses and £118 for soft lens wearers. For those wearing lenses seven days a week, the average actual cost of solutions ranged from under £50 a year for some wearers to over £200 for others.

16. 74 per cent of the sample did not buy their solutions as part of a discount scheme, and 80 per cent did not buy their solutions as part of a frequent replacement scheme.

Retail outlets

17. 50 per cent of the sample normally bought their solutions from opticians, 40 per cent normally from pharmacies and 10 per cent told us that they bought solutions from opticians and pharmacies. Over 60 per cent of the sample said that they did not find it inconvenient that they could not buy solutions in a wider variety of retail outlets, but 79 per cent of the sample stated that they would like to see solutions sold in a wider variety of retail outlet. 90 per cent of the sample had never asked a pharmacist for advice about solutions.

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APPENDIX 3.11

(referred to in paragraphs 3.177, 3.179, 3.181, 3.183, 3.185, 3.196 and 3.209)

The dates at which the suppliers changed their RRP, 1988 to 1992

Allergan	*CV-UK*	*Alcon*	*Sauflon*	*S&NP*	*PBH*	*Aspect*	*B&L*
1.2.88	5.88	2.88	1.1.88	4.1.88	N/A	N/A	No increase
1.3.89	4.89	2.89	1.1.89	17.7.89, 2.1.89	1.89	N/A	5.89
29.1.90	2.90	2.90	1.1.90	13.8.90, 1.2.90	1.90	N/A	No increase
1.1.91	1.91	2.91	2.1.91	2.4.91	1.91	10.90	4.91
1.1.92	2.92	2.92	1.1.92	30.3.92	11.91	6.92	3.92

Source: Price lists provided by the suppliers.

APPENDIX 3.12
(referred to in paragraphs 3.97 and 3.216)

Discounts

1. Suppliers have a standard discount which they give on orders above a certain minimum level, with certain customers receiving additional discounts. Unless otherwise stated, the discounts below refer to reductions to the suppliers' trade prices.

2. In 1992 Allergan gave the following discounts to particular trade channels: 15 per cent to small independent opticians for all orders over £750; 15 per cent to both optical and pharmaceutical wholesalers; a range of between 15 and 25 per cent on all orders for optical groups and large independent opticians; 30 per cent to D&A; 32.5 per cent to Boots.

3. Allergan's minimum order levels for pharmaceutical wholesalers are currently £250 for solutions and £250 for pharmaceutical products, the latter receiving a discount of 12.5 per cent.

4. Allergan told us that it had increased the minimum order level at which it gives a discount to small independent opticians. In 1988 and 1989, the minimum order level was £300, in 1990 it was £450, and in 1991 it was £550. Allergan told us that it had raised the limits in order to discourage small orders which it believed were better handled by the wholesaler.

5. Alcon told us that it currently offers the following discounts to direct retail customers other than Boots and D&A: 10 per cent when between 10 and 24 dozen units are bought; 15 per cent for between 25 and 99 dozen units; 20 per cent for between 100 and 149 dozen units; and 25 per cent when 150 or more dozen units are bought. Discounts to other trade channels are: 12.5 per cent to pharmaceutical wholesalers; 23.5 per to optical wholesalers; 34 per cent to D&A (on Alcon brands); and between 33 and 46 per cent to Boots.[1] Alcon told us that between 1988 and 1992 there has been no change in its discounts apart from those to Boots.

6. B&L said that its discount structure was as follows: 15 per cent on solutions orders of £300 or more; 20 per cent on solutions orders of £500 or more (and key accounts); 25 per cent on solutions orders to wholesalers; and 30 per cent on solutions orders to D&A. B&L told us that its policy on discounts had not changed since 1988.

7. M&L's discounts are: 10 per cent on solutions orders of between 6 and 15 dozen units; 15 per cent on solutions orders of between 18 and 27 dozen units; 20 per cent on solutions orders of between 30 and 39 dozen units; and 25 per cent on solutions orders of 42 dozen units or more.

8. Sauflon told us that in general its four discount bands are based on total purchases. These are: 6 per cent when between 8 and 12 dozen units are bought; 16 per cent when between 13 and 17 dozen units are bought; and 22 per cent when 18 or more dozen units are purchased.[2] Sauflon also said that it negotiates special terms with multiple outlets which are capable of buying in much greater volumes. For these customers Sauflon gives discounts of between 28 and 44 per cent.[3] Sauflon told us that there had been no change in the size of its discounts between 1988 and 1992.

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[1]Alcon told us that discounts to Boots range from 50 to 57 per cent off RRP, and that this is graduated depending on the product range being supplied. Alcon said that the 57 per cent discount (first introduced in September 1990) is given if a full range of major products (Softab, Pliagel, Salette, Clen-zym, and Soaclens) is taken. We have recalculated these discounts as a percentage of Alcon's trade prices in order to make them consistent with the other information given to us by Alcon.

[2]Sauflon told us that it has four buying bands which give practitioners certain percentage gross margins. These percentage gross margins are: 20 per cent when less than 8 dozen units are bought; 25 per cent for between 8 and 12 dozen units; 33 per cent when between 13 and 17 dozen units are bought; and 38 per cent for 18 or more dozen units. We have recalculated these gross margins as discounts to ensure consistency with the information given to us by other suppliers.

[3]Sauflon told us that it gives gross margins of between 42.5 and 55 per cent to multiple outlets which are capable of buying much greater volumes. We have again recalculated these gross margins as discounts to make them consistent with the information given to us by other suppliers.

9. Table 1 shows the change in S&NP's discounts to opticians and pharmacies and their minimum order requirement between 1988 and 1992.

TABLE 1 **S&NP's discounts and their minimum order requirement between 1988 and 1992**

per cent

Minimum order requirements	*January 1988*	*August 1990*	*April 1991*
Dozens			
24–47	5		
24–59		7.5	5
48–71	7.5		
60–119		10	7.5
72–143	10		
120–287		12.5	
120–299			10
144–287	12.5		
288 and over	15	15	
300 and over			15

Source: S&NP.

10. S&NP gives a discount of 15 per cent to optical and pharmaceutical wholesalers, 30 per cent to D&A, and between 36 and 40 per cent to Boots. Discounts to Boots have increased by between six and ten percentage points between 1988 and 1992 whereas the discounts to D&A and wholesalers have remained unchanged.

11. PBH has the following standard discount structure for opticians: 7.5 per cent when between 6 and 19 dozen units are bought; and 15 per cent when 20 dozen units or more are bought. Pilkington told us that it does occasionally offer discounts of up to 25 per cent for customers who wish to purchase a substantial quantity of solutions. It said that it offers large optical wholesalers like Mid-Optic and Martin approximately 25 per cent discounts so they can offer volume discounts to opticians. It also said that there had been no change to its discount policy since 1988.

12. Aspect told us that it gives a discount on its branded solutions of 15 per cent when 36 or more of its one-month packs, or 12 or more of its three-month packs, are bought. It said that it had not changed its discounts since it introduced its branded solutions.

APPENDIX 4.1
(referred to in paragraphs 4.53 and 8.145)

CLS: summary of results of suppliers, 1989 to 1991

			£'000
	*1989**	*1990**	*1991**
Turnover in CLS—UK			
Allergan and API	12,023	14,839	17,269
CV-UK and CVLCP	11,653	13,530	14,297
Alcon	2,506	3,901	4,513
B&L and M&L	1,746†	2,766	3,292
Sauflon	1,412	1,827	2,516
PBH	316	423	639
S&NP	1,696	1,544	1,596
Net operating profit before interest and tax on CLS—UK			
Allergan and API	3,800	3,900	4,700
CV-UK and CVLCP	1,412	1,329	1,310
Alcon	-195	425	314
B&L and M&L	346†	475	465
Sauflon	-127	99	274
PBH	-43	-14	-6
S&NP	185	27	-37
Average capital employed in CLS—UK			
Allergan and API	4,100	4,500	4,300
CV-UK and CVLCP	2,540	12,532	17,553
Alcon	383	481	554
B&L and M&L	400†	525	536
Sauflon	491	615	950
PBH	Not available for CLS separately		
S&NP	Not available for CLS separately		
			per cent
Net margin on turnover			
Allergan and API	31.7	26.3	27.2
CV-UK and CVLCP	12.1	9.8	9.2
Alcon	-7.8	10.9	6.9
B&L and CVLCP	19.8†	17.2	14.1
Sauflon	-9.0	5.4	10.9
PBH	-13.6	-3.3	-0.9
S&NP	10.9	1.7	-2.3
ROCE			
Allergan and API	92.7	86.7	109.3
CV-UK and CVLCP	55.6	10.6	7.5
Alcon	-50.9	88.3	56.7
B&L and M&L	86.5	90.5	86.8
Sauflon	-25.9	16.1	28.8
PBH	N/A	N/A	N/A
S&NP	N/A	N/A	N/A

Source: Information supplied by the companies.

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*The relevant year-end dates are set out overleaf.
†M&L nine-month period only in 1989.

	Abbreviated name	*Date*
Alcon Laboratories (UK) Ltd	Alcon	31 December 1991
Allergan Ltd	Allergan	30 November 1991
Allergan Pharmaceuticals (Ireland) Limited Inc	API	30 November 1991
Bausch & Lomb UK Ltd	B&L	28 December 1991*
CIBA Vision Lens Care Production Ltd	CVLCP	31 December 1991
CIBA Vision (UK) Ltd	CV-UK	31 December 1991
Madden & Layman Ltd	M&L	28 December 1991*
Pilkington Barnes-Hind Ltd	PBH	31 March 1992
Sauflon Pharmaceuticals Ltd	Sauflon	2 November 1991†
Smith & Nephew Pharmaceuticals Ltd	S&NP	28 December 1991*

*Last Saturday in December.
†Nearest Saturday to end October.

APPENDIX 4.2
(referred to in paragraphs 4.54 and 8.146)

Product cost and profit profiles

1. Table 1 shows the turnover costs and net profit earned by Allergan on selected products. The information covers Allergan Limited only; the profit earned by API is not shown other than being included in the cost of sales figure. Allergan has said that where possible costs have been directly allocated to the product; otherwise they have been attributed pro rata to turnover. The gross profit to turnover ranges from 19.8 per cent for Solusal to 72.7 per cent for Oxysept 1. The combined gross margin for Oxysept 1 and 2 is 63.6 per cent. Hydrocare Fizzy tablets show the highest net profit margin on turnover at 35.6 per cent.

2. Table 2 shows the cost, gross margin and supplier's operating profit make-up of the price paid by the user for selected Allergan products, split by two trade channels, namely Boots and opticians. The final price taken is the RRP.

3. Table 3 sets out details, similar to those in Table 2, of selected CV-UK products. CV-UK told us that costs other than discounts cannot be attributed to sales by trade channels.

TABLE 1 **Allergan: product cost and profit profiles, 1991**

	LC-65		*Hydrocare Fizzy*		*Solusal*		*Oxysept 1*		*Oxysept 2*		*Oxysept 1&2 combined*		*Hydrocare C/S*		*Clean-N-Soak*		*Total*	
	£'000	*% of turnover*	*£'000*	*% of turnover*	*£'000*	*% of turnover*	*£'000*	*% of turnover*	*£'000*	*% of turnover*	*£'000*	*% of turnover*	*£'000*	*% of turnover*	*£'000*	*% of turnover*	*£'000*	*% of turnover*
Turnover	407	100.0	1,274	100.0	525	100.0	2,258	100.0	3,890	100.0	6,148	100.0	735	100.0	149	100.0	9,238	100.0
Cost of sales	-191	-46.9	-532	-41.8	-421	-80.2	-616	-27.3	-1,622	-41.7	-2,238	-36.4	-300	-40.8	-67	-45.0	-3,749	-40.6
Gross profit	216	53.1	742	58.2	104	19.8	1,642	72.7	2,268	58.3	3,910	63.6	435	59.2	82	55.0	5,489	59.4
Operating costs	-79	-19.4	-142	-11.1	-60	-11.4	-655	-29.0	-1,129	-29.0	-1,784	-29.0	-198	-26.9	-40	-26.8	-2,303	-24.9
Other costs of operations	-48	-11.8	-147	-11.5	-61	-11.6	-262	-11.6	-451	11.6	-713	-11.6	-86	-11.7	-17	-11.4	-1,072	-11.6
Net profit	89	21.9	453	35.6	-17	-3.2	725	32.1	688	17.7	1,413	23.0	151	20.6	25	16.8	2,114	22.9

Source: Allergan.

Note: The item 'operating costs' includes costs of promotion, marketing and advertising and administration. Other costs of operations include corporate headquarters charges.

TABLE 2 **Allergan: cost and profit profiles of selected products through main trade channels**

	Hydrocare Fizzy (24 tablets)				*Oxysept 1 (250 ml)*				*Oxysept 2 (25 x 15 ml)*			
	Boots		*Opticians*		*Boots*		*Opticians*		*Boots*		*Opticians*	
	£/pack	*% of RRP*	*£/pack*	*% of RRP*	*£/pack*	*% of RRP*	*£/pack*	*% of RRP*	*£/pack*	*% of RRP*	*£/pack*	*% of RRP*
Suppliers' costs and profit												
Cost of sales from connected companies	1.51	20.9	1.51	20.9	0.40	14.0	0.40	14.0	0.95	22.4	0.95	22.4
Other cost of sales	0.09	1.3	0.17	2.4	0.07	2.4	0.10	3.5	0.07	1.6	0.12	2.8
Operating costs*	0.79	11.0	1.30	18.0	0.37	12.9	1.22	42.6	0.65	15.2	1.91	45.0
Total cost to Allergan	2.39	33.2	2.98	41.3	0.84	29.3	1.72	60.1	1.67	39.2	2.98	70.2
Operating profit	1.19	16.5	1.34	18.6	0.69	24.2	0.10	3.5	0.60	14.2	-0.27	-6.4
Price paid by retailer to Allergan	3.58	49.7	4.32	59.9	1.53	53.5	1.82	63.6	2.27	53.4	2.71	63.8
Retailers' gross margin	3.63	50.3	2.89	40.1	1.33	46.5	1.04	36.4	1.98	46.6	1.54	36.2
Retailers' revenue at RRP	7.21	100.0	7.21	100.0	2.86	100.0	2.86	100.0	4.25	100.0	4.25	100.0
VAT @ 17.5%	1.26	17.5	1.26	17.5	0.50	17.5	0.50	17.5	0.74	17.5	0.74	17.5
Price paid by customer	8.47	117.5	8.47	117.5	3.36	117.5	3.36	117.5	4.99	117.5	4.99	117.5

Source: Allergan.

*In this table the term 'operating costs' combines both 'operating costs' and 'other costs of operations' shown separately in Table 1.

Note: The RRP excludes VAT.

TABLE 3 **CV-UK: cost and profit profiles of selected products through main trade channels**

	10.10 Step 1 (250 ml)				*10.10 Step 2 (25 x 15 ml)*			
	Boots		*Opticians*		*Boots*		*Opticians*	
	£/pack	*% of VAT excl RRP*	*£/pack*	*% of VAT excl RRP*	*£/pack*	*% of VAT excl RRP*	*£/pack*	*% of VAT excl RRP*
Suppliers' costs and profit								
Cost of sales	0.64	21.0	0.64	21.0	1.65	38.0	1.65	38.0
Operating costs	0.52	17.0	0.52	17.0	0.77	17.8	0.77	17.8
Total cost to CV-UK	1.16	38.0	1.16	38.0	2.42	55.8	2.42	55.8
Operating profit	0.23	7.5	0.55	18.1	-0.09	-2.1	0.13	3.0
Price paid by retailer to CV-UK	1.39	45.6	1.71	56.1	2.33	53.7	2.55	58.8
Retailers' gross margin	1.66	54.4	1.34	43.9	2.01	46.3	1.79	41.2
Retailers' revenue at recommended retail price	3.05	100.0	3.05	100.0	4.34	100.0	4.34	100.0
VAT @ 17.5%	0.53	17.5	0.53	17.5	0.76	17.5	0.76	17.5
Price paid by customer	3.58	117.5	3.58	117.5	5.10	117.5	5.10	117.5

Source: CV-UK.

APPENDIX 4.3

(referred to in paragraphs 4.71, 4.72, 4.73 and 4.74)

BTC and BOL: summary of BTC-sourced supplies to retail stores (SRS) and related gross profit (GP)

£'000

	Years ended 31 March								
	1990			1991			1992		
	SRS	GP	GP %	SRS	GP	GP %	SRS	GP	GP %
Branded CLS									
SRS–BTC	9,593	4,746	49.5	12,145	6,048	49.8	16,202	8,211	50.7
SRS to BOL by BTC	1,928	946	49.1	2,412	1,180	48.9	1,941	984	50.7
Total	11,521	5,692	49.4	14,557	7,228	49.7	18,143	9,195	50.7
Own-label CLS									
SRS–BTC	2,879	1,847	64.2	4,869	2,987	61.3	7,317	4,431	60.6
SRS to BOL by BTC	509	315	61.9	1,421	820	57.7	2,009	1,184	58.9
Total	3,388	2,162	63.8	6,290	3,807	60.5	9,326	5,615	60.2

Source: BTC.

APPENDIX 8.1
(referred to in paragraphs 8.53, 8.66 to 8.68, 8.76, 8.83, 8.85 and 8.86)

MMC's provisional findings

PART I

The suppliers complex monopoly situation (paragraph 8.53)

1. The provisional finding concerned the following suppliers:

Alcon Laboratories (UK) Limited
Allergan Limited
Aspect Vision Care Ltd
Bausch & Lomb UK Limited
CIBA Vision (UK) Limited
CIBA Vision Lens Care Production Ltd
Madden & Layman Ltd
Pilkington Barnes-Hind Limited
Sauflon Pharmaceuticals Limited
Smith & Nephew Pharmaceuticals Limited

2. The MMC also provisionally concluded that the monopoly situation existed in favour of the companies listed in paragraph 1 above, together with Allergan Pharmaceuticals (Ireland) Limited Inc, Allergan Inc, CIBA-GEIGY AG, New Focus Health Care Ltd, Nestlé SA, Bausch & Lomb Inc, Pilkington plc and Smith & Nephew plc.

PART II

The own-label suppliers complex monopoly situation (paragraph 8.68)

3. The provisional finding concerned the following own-label suppliers:

Boots The Chemists Ltd
Boots Opticians Limited
The Dollond & Aitchison Group plc
Specsavers Optical Superstores Limited
Vision Express UK Ltd

4. The MMC also provisionally concluded that the monopoly situation existed in favour of the companies listed in paragraph 3 above and The Boots Company PLC.

PART III

The retailers complex monopoly situation (paragraph 8.76)

5. The provisional finding concerned the following retailers:

Boots The Chemists Ltd
Boots Opticians Limited
The Dollond & Aitchison Group plc
Lloyds Chemists plc
Other retailers who sell CLS at, or only just below, recommended retail price

6. The MMC also provisionally concluded that the monopoly situation existed in favour of the persons referred to in paragraph 5 above and The Boots Company PLC.

7. The bodies representing opticians and pharmacists referred to in paragraph 8.76 are as follows:

Royal Pharmaceutical Society of Great Britain
National Pharmaceutical Association
Pharmaceutical Services Negotiating Committee
College of Pharmacy Practice
Scottish Office of the Royal Pharmaceutical Society
Company Chemists' Association Ltd
Royal Pharmaceutical Society of Northern Ireland
General Optical Council
Association of Optometrists
British College of Optometrists
Federation of Ophthalmic and Dispensing Opticians
Association of British Dispensing Opticians
Federation of Independent British Optometrists

PART IV

The opticians complex monopoly situation (paragraph 8.86)

8. The provisional finding concerned the following opticians:

Boots Opticians Ltd
The Dollond & Aitchison Group plc
Other retailing opticians who engage in the practices set out in paragraph 8.86

9. The MMC also provisionally concluded that the monopoly situation existed in favour of the persons referred to in paragraph 8 above and The Boots Company PLC.

10. The bodies representing opticians referred to in paragraph 8.86 are as follows:

General Optical Council
Association of Optometrists
British College of Optometrists
Federation of Ophthalmic and Dispensing Opticians
Association of British Dispensing Opticians
Federation of Independent British Optometrists

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