Competition Act 1998

Decision of Director General of Fair Trading
No. CA98/3/03

Exclusionary behaviour by Genzyme Limited

27 March 2003
(Case CP/0488-01)

SUMMARY

The Director General of Fair Trading (the 'Director') has concluded that Genzyme Limited ('Genzyme') has abused its dominant position in the market for the supply of drugs for the treatment of Gaucher disease in the UK in breach of section 18 (the 'Chapter II prohibition') of the Competition Act 1998 (the 'Act').

Genzyme supplies the NHS with Cerezyme, a drug for the treatment of Gaucher disease. Gaucher disease is a rare inherited disorder. Genzyme has a dominant position in the market for the supply of drugs for the treatment of Gaucher disease.

Genzyme has abused its dominant position by making the NHS pay a price which includes home delivery of Cerezyme and provision of homecare services if the NHS wishes to purchase Cerezyme, and by adopting a pricing policy for Cerezyme which results in a margin squeeze. The first practice began in the early 1990s and it has constituted an infringement of the Act since the coming into force of the Chapter II prohibition on 1 March 2000. The second infringement began in May 2001 when Genzyme launched its own delivery and homecare services operation and continued until the date of this Decision.

Genzyme's behaviour has prevented any competition in home delivery of Cerezyme and provision of homecare services, thereby reserving this activity to Genzyme (or an undertaking acting under contract for it), and depriving the NHS and patients of a choice of delivery/homecare services provider. By preventing viable independent provision of delivery/homecare services for Cerezyme, Genzyme's behaviour has also raised barriers to entry into the market for the

supply of drugs for the treatment of Gaucher disease. The Director takes the view that this behaviour has affected trade within the UK and is in breach of the Chapter II prohibition.

The Director considers that Genzyme's behaviour constitutes a serious infringement of the Act. He is therefore imposing a financial penalty on Genzyme of £6.8 million.

TABLE OF CONTENTS

I. INTRODUCTION

1. This Decision arises from an investigation prompted by a complaint submitted by Heathcare at Home Limited ('HH') to the Director General of Fair Trading (the 'Director'), dated 23 March 2001. The complaint was accompanied by an application for interim measures under section 35 of the Competition Act 1998 (the 'Act'). HH alleged that Genzyme Limited ('Genzyme') had infringed the Chapter II prohibition imposed by section 18(1) of the Act[1].

2. On 11 June 2001, following representations made by HH and Genzyme, the Director exercised his discretion not to give directions for interim measures. However, the Director continued to have reasonable grounds for suspecting an infringement of the Chapter II prohibition and he informed Genzyme and HH of his intention to pursue an investigation into the matter.

3. On 11 October 2001, the Director issued to Genzyme a notice requesting information under section 26 of the Act. This was followed by a meeting with Genzyme at its offices in Oxford, on 18 December 2001. A subsequent section 26 notice was sent to Genzyme on 12 February 2002 followed by a number of informal requests for information and clarification. Information was also provided by HH, hospital consultants, a pharmacist, the Gaucher Association and other pharmaceutical companies.

4. On 31 July 2002, the Director issued to Genzyme Corporation (acting through its UK subsidiaries) a notice of a proposed infringement decision (the 'Rule 14 Notice') according to rule 14 of the Director's procedural rules (the 'Director's rules')[2]. Genzyme made written representations responding to the Rule 14 Notice on 25 October 2002 and oral representations on 6 November 2002. In response to matters put to it by the Director, Genzyme submitted supplementary written representations on 9 December 2002 (the 'first supplementary written representations'), on 10 January 2003 (the 'second supplementary written representations') and on 26 February 2003 (the 'third supplementary written representations'). Genzyme's written representations and its first, second and third supplementary written representations are jointly referred to in this Decision as the 'Response', unless otherwise stated.

[1] Letter from HH's then legal representatives, Ashurst Morris Crisp, to the OFT, dated 23 March 2001 enclosing HH's application for interim measures.

[2] The Competition Act 1998 (Director's rules) Order 2000, SI 2000 No.293.

II THE FACTS

1. The Complaint

5. HH's complaint stated that on 6 May 1998, Genzyme appointed HH as the sole and exclusive distributor and service provider for Cerezyme in the UK[3]. Cerezyme was, and arguably continues to be, the only effective[4] treatment currently available for Gaucher disease[5].

6. Under the terms of the distribution agreement HH agreed to buy Cerezyme exclusively from Genzyme for resale to 'Users'[6]. The distribution agreement was to remain in force until 5 May 2001 and to continue thereafter unless terminated by either party giving at least six months written notice[7]. HH was allowed to sell the drug to Users 'at any price up to the price shown in paragraph 5.2' (i.e. the price at which HH purchased the drug from

---

[3] During the period of their commercial relationship (from 1998 to 2001), Genzyme and HH had three different distribution agreements. Only one of those, however, took the form of a written and signed agreement (dated 1 February 2000). Any references made in this notice to a clause in the distribution agreement between Genzyme and HH are references to the 1 February 2000 agreement.

[4] On 20 November 2002, the European Commission granted marketing authorisation under exceptional circumstances to Zavesca, a new drug for the treatment of Gaucher disease. On 3 March 2003, Zavesca was launched in the UK. See document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003. See also Oxford Glycosciences ('OGS') Press Release entitled 'Actelion starts launch of Zavesca in the European Union' issued on 3 March 2003. As explained later in this Decision (see paragraphs 202 to 225), it does not appear at this stage that Zavesca is an 'effective' treatment for Gaucher disease and, indeed, cannot be used for patients for whom enzyme replacement therapy (Cerezyme) is suitable.

[5] Prior to the introduction of Cerezyme, Genzyme Corporation produced a similar treatment called Ceredase. As explained later in this Decision (see paragraph 26), Ceredase has now been replaced by Cerezyme and is only used where patients cannot tolerate Cerezyme. Contrary to Genzyme's initial submission before the Rule 14 Notice (letter from E. Perrott (TV) to the OFT dated 18 October 2001), Genzyme indicated in its Response that one patient is currently being treated with Ceredase in the UK, *[confidential]*. See Genzyme's written representations submitted on 25 October 2002, footnote 2 at page 46. See also Julie Kelly's statement in the Transcript of the oral hearing of 6 November 2002, page 70, lines 9-12. In this Decision, references to Cerezyme include references to Ceredase, unless the context indicates otherwise.

[6] Clause 2.2 of the distribution agreement. 'Users' was defined as any pharmacy, hospital or other person or body that is legally entitled to purchase the 'Product' (i.e. Cerezyme or Ceredase) for use in the 'Territory' (i.e. UK and Northern Ireland).

[7] Clause 12 of the distribution agreement.

Genzyme)[8]. HH also agreed to provide 'other services as may be requested by Genzyme'[9] and to provide services to patients as 'specified in the Distribution Procedures Agreement'[10].

7. Under these arrangements, the User (effectively the National Health Service ('NHS'), which was the only purchaser of Cerezyme in the UK) paid a single price to HH, which covered both the supply of the drug and the provision of services. HH's fees for the provision of services (which were to be specified in the Distribution Procedures Agreement) were paid by Genzyme[11]. HH therefore made its margin through the service fees received from Genzyme. HH made no margin on sales of Cerezyme to the NHS.

8. On 23 November 2000, Genzyme informed HH of its intention to terminate the distribution agreement on 5 May 2001 and to launch its own distribution and homecare services operation, Genzyme Homecare[12]. Termination of the distribution agreement would also mean that Genzyme would stop supplying HH with Cerezyme. On 23 March 2001, after a number of unsuccessful negotiations between HH and Genzyme, HH submitted a complaint to the Director alleging that Genzyme had abused its dominant position 'in relation to the treatment of Gaucher disease'[13] by giving HH notice of its intention to

---

[8] Clause 5.5 of the distribution agreement. HH has submitted that 'the words 'at any price up to the price shown in paragraph 5.2' were put in by Genzyme, as we understand, to avoid any accusation of price fixing, and it should not be assumed that HH had any freedom to set or vary prices.' (see HH submission entitled 'HH clarification of a factual document received from the OFT' dated 30 May 2002). It would indeed appear that, regardless of clause 5.5, HH would have had no incentive to sell the drug at a cheaper price than it paid for it, given that as the sole and exclusive distributor of Cerezyme, it faced no competition. Also, as Cerezyme is a 'zero discount' drug, the Prescription Pricing Authority would always reimburse HH the full amount of the drug (i.e. the National Health Service list price for Cerezyme) (see paragraph 85).

[9] Clause 2.1 of the distribution agreement.

[10] Clause 6.4 of the distribution agreement. Neither Genzyme nor HH have been able to submit a copy of the Distribution Procedures Agreement, as this was apparently never drafted.

[11] Clauses 6.7 and 6.8 of the distribution agreement.

[12] At the time of its launch, Genzyme Homecare offered distribution and homecare services in relation to Cerezyme only. In August 2001, Genzyme received marketing approval in Europe for a drug to treat Fabry disease (Fabrazyme). Genzyme Homecare also offers delivery and, if required, homecare services in relation to this drug and, according to Genzyme, it is envisaged that the same services will be offered for any other enzyme replacement therapies for the treatment of lysosomal storage disorders requiring such services, that Genzyme may develop in the future (see Genzyme's written submission dated 25 October 2002, paragraph 5.9 at page 84).

[13] HH's submission dated 23 March 2001, paragraph 1.2.

stop supplying it with Cerezyme and it requested that the Director adopt interim measures directions pending a full investigation of Genzyme's practices[14].

2. The Undertaking

(i) Genzyme

9. Genzyme Limited is a wholly owned subsidiary of the US company Genzyme Corporation of One Kendall Square, Cambridge, Massachusetts. Genzyme Limited therefore forms part of the single economic entity controlled by Genzyme Corporation.

10. Genzyme Corporation is a leading biotechnology company with three operating divisions: Genzyme General, Genzyme Biosurgery and Genzyme Molecular Oncology.

11. Genzyme General primarily consists of two business units: Therapeutics and Diagnostics. The Therapeutics business unit focuses on developing and marketing health care products for rare genetic diseases such as Gaucher disease.

12. Genzyme General manufactures and supplies Cerezyme[15].

13. Genzyme Corporation's worldwide turnover in 2002 was US$1,329 million, in 2001 US$1,224 million, in 2000 US$903 million and in 1999 US$772 million[16]. Sales of Cerezyme represented 51% (US$ 569.9 million)[17] of Genzyme's consolidated revenue in 2001, 66% in 2000 (US$ 536.9 million) and 70% (US$ 478.4 million) in 1999[18].

---

[14] HH's submission dated 23 March 2001.

[15] Prior to the introduction of Cerezyme, Genzyme Corporation produced a similar treatment called Ceredase. Ceredase has now been replaced by Cerezyme and is only used in a very limited number of cases worldwide *[confidential]*. In relation to the UK, contrary to Genzyme's initial submission before the Rule 14 Notice (letter from E. Perrott (TV) to the OFT dated 18 October 2001), Genzyme indicated in its Response that one patient is currently being treated with Ceredase (see footnote 5 above).

[16] See Form 10-K submitted by Genzyme Corporation to the US Securities and Exchange Commission for the fiscal year ended 31.12.01 (Exhibit 13.1 – Financial Statements). Genzyme's Form 10-K for 2002 will not be available until July 2003 and, therefore, it is not available at the date of this Decision.

[17] See Genzyme's Form 10-K for fiscal year ended 31.12.01.

[18] See Genzyme's Form 10-K for fiscal year ended 31.12.00.

14. Genzyme Limited was incorporated in the United Kingdom on 21 April 1981. Genzyme Limited is divided into three operating divisions: Genzyme Diagnostics, Genzyme Therapeutics, and Haverhill Operations.

15. Genzyme Diagnostics operates from 50 Gibson Drive, Kings Hill, West Malling, Kent, ME19 4AF. Genzyme Diagnostics includes manufacturing operations, R&D and a sales and marketing group which is responsible for the sales and marketing of the whole product line throughout the world outside North and South America[19].

16. Genzyme Therapeutics operates from 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford, OX4 2SU. Genzyme Therapeutics has two constituent parts: Speciality Therapeutics and Bio-Surgery. Speciality Therapeutics is responsible for the marketing and distribution of Cerezyme, through Genzyme Limited's new operation called Genzyme Homecare. Genzyme Homecare is a nursing and pharmacy service designed to support patients receiving enzyme replacement therapy (e.g. Cerezyme) in their homes. It has a licensed pharmacy which also manages the distribution of speciality therapeutics products to homes and hospitals in the UK[20]. It also has an NHS contract pharmacy at Rosehill, Oxford, UK[21]. This pharmacy dispenses Cerezyme against NHS prescriptions for home delivery by Genzyme Homecare. The nursing team covers the UK providing training and support to hospitals and patients in relation to rare diseases such as Gaucher disease[22].

17. Genzyme Haverhill Operations operates from 37 Hollands Road, Haverhill, Suffolk CB9 8PU. It is predominately a bulk pharmaceutical manufacturing facility[23].

18. Genzyme Limited has its registered UK office at 37 Hollands Road, Haverhill, Suffolk CB9 8PU. Sales of Cerezyme in the UK amounted to £*[confidential]*

---

[19] See document published on Genzyme's website, entitled 'Corporate Information – Genzyme in the UK – Kent', dated 2003 at http://www.genzyme.com.

[20] See document published on Genzyme's website, entitled 'Corporate Information – Genzyme in the UK – Oxford', dated 2003 at http://www.genzyme.com.

[21] Statement of Vivek Derodra dated 11 October 2002, paragraph 35 and 36, attached to Genzyme's written representations submitted on 25 October 2002.

[22] See document published on Genzyme's website, entitled 'Corporate Information – Genzyme in the UK – Oxford', dated 2003 at http://www.genzyme.com.

[23] See document published on Genzyme's website, entitled 'Corporate Information – Genzyme in the UK – Haverhill', dated 2003 at http://www.genzyme.com.

million in 2002[24], £*[confidential]* million in 2001[25], £*[confidential]* million in 2000[26] and £*[confidential]* million in 1999[27]. Genzyme Limited's UK turnover amounted to £*[confidential]* million (unaudited) in 2002, £53.8 million in 2001, £45.9 million in 2000 and £38.1 million in 1999.

3. The product and services concerned

(i) The Product

19. Cerezyme is an enzyme replacement therapy drug for the treatment of Gaucher disease.

20. Gaucher disease is a lysosomal storage disorder ('LSD'). LSDs are a form of metabolic disorder. There are many different LSDs, such as Fabry disease, Tay-Sachs disease, Sandhoff disease or Niemann-Pick disease.

21. Gaucher disease is an inherited enzyme deficiency disorder. Broadly, when waste material in the body is stored in certain white blood cells, the enzyme glucocerebrosidase is required to degrade that waste material. Sufferers of Gaucher disease lack the enzyme glucocerebrosidase, with the consequence that waste materials are not degraded and, therefore, remain stored in the body[28].

22. Gaucher disease can take three forms:

    (i) Type 1. This is the most common form of the disease. Symptoms may include an enlarged spleen and liver, bleeding and bruising problems, bone pain, demineralisation and fractures. These symptoms may vary from mild to severe and may appear at any age. Most sufferers can expect to reach old age with treatment. There are

[24] Letter from E.Perrott (TV) to the OFT dated 13 February 2003.

[25] Letter from E.Perrott (TV) to the OFT dated 13 February 2003.

[26] See Genzyme's response to the information request under section 26 of the Act submitted on 30 November 2001, page 7.

[27] See Genzyme's response to the information request under section 26 of the Act submitted on 30 November 2001, page 7.

[28] See HH's submission of 23 March 2001. For more information on Gaucher disease, see 'Improving health care together: Creating solutions for unmet medical needs' published by Genzyme; 'Living with Gaucher disease' published by Genzyme; the Gaucher's Association website www.gaucher.org.uk; the Addenbrooke's Hospital website www.addenbrokes.org.uk.

estimated to be approximately 180 patients receiving treatment for the Type 1 form of the disease in the UK[29];

(ii) Type 2. This occurs in infants. The sufferer is unlikely to survive for more than a few years. This is a rare form of the disease, affecting only one or two births a year in the UK; and

(iii) Type 3. This type shows the same symptoms as Type 1 at an early age and will progress to show neurological symptoms during childhood. These may include eye movement abnormality, unsteadiness and loss of skills. Some Type 3 sufferers have only slight brain impairment but develop severe disease in the liver, spleen and bone marrow. This is a rare form of the disease, affecting only two or three births a year in the UK.

23. Currently the only type of Gaucher disease that can be effectively treated is Type 1. All further references to 'Gaucher disease' in this Decision are references to Type 1 Gaucher disease, unless otherwise stated.

24. There are four potential methods of treatment for Gaucher disease:

(i) Enzyme Replacement Therapy ('ERT'). This is where a patient is administered replacement enzymes which degrade the stored waste material in white blood cells. ERT is the preferred standard of care for Gaucher patients[30]. Cerezyme is a type of ERT. Genzyme is currently the only supplier of ERT drugs for the treatment of Gaucher disease;

(ii) Gene Therapy. This aims to introduce copies of normal genes into patients, which will lead to the production of the normal enzyme and therefore correct the enzyme deficiency. As well as supplying the Cerezyme ERT, Genzyme is sponsoring trials in relation to a new gene therapy for Gaucher disease which is being undertaken at the

[29] See Genzyme's estimate of patients treated by Genzyme Homecare, submitted on 30 November 2001. See also HH's estimate of patients treated by HH submitted on 29 April 2002. Some patients with Gaucher disease do not receive enzyme replacement therapy, usually because their symptoms are not sufficiently severe to justify the inconvenience of regular infusions. In a small number of cases, however, the reason is that treatment with enzyme replacement therapy is not suitable for the patient.

[30] See document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, pages 23 and 27. See also note of meeting with Professor Cox dated 16 January 2003; see also document entitled 'Summary of Product Characteristics for Zavesca' published by OGS on 20 November 2002, at section 4.4.

University of Pittsburgh. This therapy is probably many years away from being marketed[31];

(iii) Substrate Balance Therapy. In contrast to ERT, this treatment partially inhibits the formation of waste material in the first place, resulting in less waste material being stored in white blood cells. Unlike ERT, however, it does not eliminate the waste material already stored. On 20 November 2002, four months after the Director issued the Rule 14 Notice, Oxford GlycoSciences Plc ('OGS') received marketing authorisation in Europe for the first substrate balance therapy for the treatment of Gaucher disease, 'Zavesca'. Zavesca was launched in the UK on 3 March 2003[32]. The marketing authorisation was granted under exceptional circumstances and Zavesca may be used only in the treatment of Gaucher patients for whom ERT is unsuitable[33]. Despite the authorisation granted to Zavesca, ERT continues to be the preferred standard of care for Gaucher patients in the UK[34] and Zavesca will be a second line treatment[35]; and

(iv) Other treatments. These include symptomatic treatments (such as splenectomy, hip replacement and/or pain medications) and bone marrow transplantation. Symptomatic treatments deal only with specific symptoms and do not deal directly with the cause of the disease. Bone marrow transplantation treats the cause of the disease and, if successful, may cure it. However, it is a highly complex and risky procedure associated with high mortality.

---

[31] See slides presented by Genzyme to the OFT's case team during the meeting of 18 December 2001.

[32] See OGS press release 'Actelion starts launch of Zavesca in the European Union', dated 3 March 2003.

[33] See 'Summary of Product Characteristics for Zavesca', published by OGS on 20 November 2002. See also Press Release issued by OGS on 26 November 2002 entitled 'European Commission approval for Zavesca'. See also document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, page 23.

[34] See document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, pages 23 and 27.

[35] See note of meeting with Professor Cox dated 16 January 2003. See also document entitled 'Summary of Product Characteristics for Zavesca' published by OGS on 20 November 2002, at section 4.4.

25. ERT is currently the treatment of choice and the preferred standard of care for the treatment of Gaucher disease[36]. According to Genzyme, ERT is the most direct therapeutic approach to the disease, as it supplements or replaces the enzyme missing in sufferers of Gaucher disease[37]. The only ERT currently available for the treatment of Gaucher disease is Cerezyme.

26. Prior to Cerezyme, Genzyme developed and marketed a similar drug called Ceredase. Ceredase is derived from very large quantities of human placenta, and involves a massive gathering operation. Production of Ceredase was discontinued in 1998 and replaced with Cerezyme, although small quantities may be produced for patients *[confidential]*[38]. A small quantity of Ceredase is currently being supplied in the UK for the treatment of *[confidential]*[39]. The reason for the discontinuation of Ceredase was partly the difficulty in obtaining sufficient amounts of the raw material, but also the reflection of a general move away from drugs derived from human material due to the risks of disease transmission[40]. In this Decision, references to Cerezyme include references to Ceredase, unless the context indicates otherwise.

27. Unlike Ceredase, Cerezyme is a 'recombinant', i.e. an artificially made version of glucocerebrosidase, which replaces the missing enzyme. Treatment with Cerezyme is ongoing during a patient's life. According to the Chief Scientific Officer of Genzyme Corporation, Dr Alan Smith, Cerezyme is spectacularly efficacious and works in essentially all patients[41].

28. There are currently approximately 180 Gaucher patients being treated with Cerezyme in the UK[42]. Treatment for each patient costs the NHS, on

---

[36] See document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, pages 23 and 27.

[37] 'Living with Gaucher disease' (undated) published by Genzyme, page 16.

[38] See Genzyme's Form 10-K for fiscal year ended 31.12.00.

[39] See Genzyme's written representations submitted on 25 October 2002, footnote 2 at page 46. See also statement by J.Kelly in the Transcript of the oral hearing of 6 November 2002, at page 70 lines 9-12.

[40] See, for instance, Dr Smith's statement in the Transcript of the oral hearing of 6 November 2002, at page 38, lines 20-33.

[41] Dr Smith's statement in the Transcript of the oral hearing of 6 November 2002, at page 39, lines 22-30.

[42] See Genzyme's estimate of patients treated by Genzyme Homecare, submitted on 30 November 2001. See also HH's estimate of patients treated by HH submitted on 29 April 2002. Some patients with Gaucher disease do not receive ERT, usually because their symptoms are not sufficiently severe to justify the inconvenience of regular

average, £100,000 a year[43]. Therefore, despite the relatively small number of Gaucher patients, Cerezyme is an exceptionally expensive drug, which represents a significant cost per patient for the NHS, particularly as the disease needs to be treated throughout the patient's life.

29. The only other drug authorised for the treatment of Gaucher disease is Zavesca. Zavesca was launched in the UK on 3 March 2003[44]. Zavesca is not an ERT, but a substrate balance therapy. Zavesca was granted authorisation for the treatment of patients with mild to moderate Gaucher disease for whom treatment with ERT (i.e. Cerezyme) is unsuitable[45].

(ii) The Services

30. Cerezyme is administered by intra-venous infusion.

31. In the UK, Genzyme distributes Cerezyme together with specialised homecare services[46]. Homecare services allow patients to receive infusions in their own homes saving the patients the inconvenience of attending hospital on a regular basis and giving them greater independence.

32. Patients infusing Cerezyme at home are usually prescribed the drug by hospital consultants at a centre specialised in treating Gaucher disease[47] and, occasionally, by GPs taking instructions from the specialist centre. The prescription is usually sent directly to the delivery/homecare services

---

infusions. In a small number of cases, however, the reason is that treatment with ERT is not suitable for the patient.

[43] See HH's submission of 23 March 2001.

[44] See OGS press release entitled 'Actelion starts launch of Zavesca in the European Union' issued on 3 March 2003.

[45] Ibid. See document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, pages 23 and 27.

[46] The way in which Genzyme distributes Cerezyme, varies from to country to country. Genzyme's system in the UK of appointing one distributor and homecare provider is unique. In most European countries, Genzyme supplies hospitals directly and takes no part in the provision of ancillary care services (e.g. Denmark, Belgium, Switzerland, Spain, France, Italy). In the United States, Genzyme supplies a number of independent healthcare companies who, in turn, distribute the drug and provide healthcare services. Unlike in the UK, however, US healthcare companies operate completely independently from Genzyme. See Genzyme's submission of 30 November 2001 under the section 'Information Request', Appendix 2.

[47] There are four Gaucher specialist centres in the UK, as set out in sub-section 'Specialised treatment of Gaucher disease in the UK' below.

provider[48] who arranges to deliver the drug to the patient's home and provides the required level of homecare services. The delivery/homecare services provider must be a licensed pharmacy in order to be able to dispense the drug against the prescription.

33. Currently community pharmacies do not stock Cerezyme, which is only available from HH and Genzyme Homecare, both of which have licensed pharmacies[49]. The delivery/homecare services provider also deals with any queries or emergencies a patient may have.

34. Therefore, when Cerezyme is for administration in the community, the delivery/homecare services provider delivers the Cerezyme to the patient's home and provides the homecare services. Depending on the patient, home delivery/homecare services can range from dispensing, home delivery, supply of accessories (e.g. fridges) and emergency help line only to full nursing support. The level of support needed by patients may vary over time and even self-administering patients may occasionally require some nursing support or respite care. In most cases, the delivery/homecare services provider delivers the Cerezyme to the patient's home and provides the level of care required by the particular patient. This may range from a basic stock check and waste removal service (where the patient self-infuses) to a higher level of service where training on how to infuse the drug is provided, or to an even higher level of service where the patient relies completely on the delivery/homecare services provider whose nurse routinely administers the drug[50]. In a small number of cases, the delivery/homecare services provider delivers the Cerezyme to patient's home, but a community nurse administers the Cerezyme and any other service required[51].

---

[48] In this Decision ,the term 'delivery/homecare services provider' refers to an undertaking whose business includes delivery of drugs to hospitals and delivery of drugs to patients' homes and provision of homecare services. Similarly, in this Decision 'delivery' of drugs should be interpreted as including both, delivery to hospitals and delivery to patients' homes, unless otherwise stated (i.e. unless it is stated that the delivery is delivery to hospitals or delivery to patients' homes).

[49] Since the launch of Ceredase in the UK in 1991, Genzyme has always distributed the drug through one appointed delivery/homecare services provider. First it was a company called Caremark Limited, then HH and now Genzyme Homecare. The fact that currently Cerezyme is distributed through HH as well as through Genzyme's appointed delivery/homecare services provider, Genzyme Homecare, is a result of HH's decision to continue to offer delivery of Cerezyme and homecare services to Gaucher patients even though it is currently doing so at a loss. See section 'The current position' below.

[50] See letter from P.Foster (Financial Controller, Genzyme) to R.Bratt (DoH, PPRS Branch) dated 22 March 2000.

[51] See paragraph 312.

35. When Cerezyme is sold for administration in hospitals, the delivery/homecare services provider delivers it to the hospital and it is dispensed by the hospital pharmacy. A hospital nurse administers the Cerezyme and provides any service required.

4. Specialised treatment of Gaucher disease in the UK

36. The treatment of Gaucher disease in the UK is covered by the National Specialist Commissioning Advisory Group (NSCAG)[52]. The aim of NSCAG is:

> 'to ensure the highest possible standard of care that can be delivered within available resources is available to all NHS patients requiring treatment or investigation of a very specialised nature, or for a very uncommon condition.'[53]

37. Since 1997, NSCAG has provided diagnosis and management advice for adults and children with Gaucher disease. This was felt necessary to ensure that all Gaucher patients had access to expert centres and it enabled the development of shared care arrangements between local clinicians, their patients and experts on Gaucher disease.

38. There are two units designated to run this service for adults and two for children. The table below lists the centres along with the name of the consultant responsible for Gaucher disease[54].

Hospital	**Consultant**	**Adults/Children**
Addenbrooke's	Professor Timothy Cox	Adults
Great Ormond Street	Dr Ashok Vellodi	Children
Royal Manchester Children's	Dr Ed Wraith	Children
Royal Free	Dr Atul Mehta	Adults

[52] The NSCAG is part of the NHS. The NSCAG was established in 1996 to advise Ministers on the identification and funding of services where central intervention into local commissioning of patient services was necessary for reasons of clinical effectiveness, equity of access and for economic viability. For more information see www.doh.gov.uk/nscag/whatis.htm.

[53] NSCAG Annual Report 1999-2000 published by the NHS, page 2.

[54] Ibid, page 31.

39. All patients newly diagnosed with Gaucher disease should be referred to one of the above hospitals to determine the correct treatment. Once treatment is established, however, it is carried out on a 'shared-care' basis with the patient's local doctor. Prescriptions can be written by the specialist centre or by the patient's local doctor. Regardless of who prescribes the drug, the funding comes from the patient's local Health Authority[55].

5. Regulatory Regime

(i) Legal requirements

40. Council Directive 2001/83/EC defines medicinal products as 'any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product'[56].

41. Cerezyme is a medicinal product as defined in Council Directive 2001/83/EC.

42. A medicinal product may only be placed on the market anywhere in the European Union when a marketing authorisation has been issued by the competent authority of a Member State for its own territory (national authorisation) or when an authorisation has been granted in accordance with Council Regulation 2309/93/EEC for the entire Community (a Community authorisation)[57]. Regulation 2309/93/EEC was implemented in the UK by the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994[58].

43. Where a national authorisation is sought, an application must be submitted to the competent authority of the Member State, which in the UK is the Medicines Control Agency ('MCA'). In cases where national authorisations

[55] See, for example, note of meeting with Dr Wraith dated 9 July 2002.

[56] Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use OJ (2001) L311/67.

[57] OJ (1993) L214/1. See also document published by the European Commission 'Notice to applicants: The rules governing medicinal products in the European Community; Volume 2A: Procedures for marketing authorisation; Chapter 1: Marketing authorisation', F2/AN D(2001). A copy can be found at http://pharmacos.eudra.org/F2/eudralex.

[58] Statutory Instrument 1994/3144.

are requested in more than one Member State, the so-called mutual recognition procedure can be used. Once the marketing authorisation has been granted in a Member State, the applicant submits applications in other Member States, requesting them to mutually recognise the marketing authorisation already granted.

44. In certain cases, it is possible to apply for a Community authorisation. The instances where this is possible are described in Regulation 2309/93/EEC. It is sufficient to say here that Cerezyme qualified for application of a Community authorisation[59]. In order to obtain a Community authorisation, an application must be submitted to the European Agency for Evaluation of Medicinal Products ('EMEA')[60]. The Committee for Proprietary Medicinal Products ('CPMP') carries out an evaluation of the application and it prepares a scientific opinion. The opinion is sent to the European Commission which grants the marketing authorisation after consultation with the Member States. The marketing authorisation is valid throughout the Community and confers the same rights and obligations in each of the Member States as a marketing authorisation granted by that Member State[61].

45. Council Directive 2001/83/EC[62] provides for marketing authorisations to be granted under 'exceptional circumstances'. This means the authorisation is subject to specific obligations which will be reviewed annually by the EMEA[63]. The Directive sets out when marketing authorisation is to be granted under 'exceptional circumstances':

> 'When, in respect of particular therapeutic indications, the applicant can show that he is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because:
>
> - the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or
> - in the present state of scientific knowledge, comprehensive information cannot be provided, or

[59] Cerezyme qualified for a Community authorisation as it is a medicinal product developed by means of one of the biotechnological processes referred to in Regulation 2309/93/EEC, Annex, Part A.

[60] 'Notice to Applicants: The rules governing medicinal products in the European Community' Volume 2A; Chapters 1 and 7.

[61] Ibid.

[62] Op. Cit, footnote 56 above.

[63] See Article 13 of Council Regulation 2309/93/EEC.

- it would be contrary to generally accepted principles of medical ethics to collect such information,

marketing authorisation may be granted on the following conditions:

(a) the applicant completes on identified programme of studies within a time period specified by the competent authority, the results of which shall form the basis of a reassessment of the benefit/risk profile.

(b) the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and for a radiopharmaceutical, by an authorised person,

(c) the package leaflet and any medical information shall draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.'[64]

46. Marketing authorisation under exceptional circumstances effectively means that a drug can be brought to the market more quickly. This is because the product is approved with additional requirements for post-marketing authorisation clinical studies, without having to supply the corresponding data at the time of approval[65]. This allows the drug to be placed on the market sooner, but the authorisation can be withdrawn in the event adverse effects occur[66].

47. Genzyme obtained individual marketing authorisations for Ceredase in various Member States.

48. Genzyme initiated the process of applying for a Community marketing authorisation for Cerezyme through the centralised procedure on 10 May 1996[67]. The authorisation was granted over a year later, on 18 November 1997.

49. While Cerezyme's marketing authorisation was not granted under exceptional circumstances, Zavesca's was. After over five years of clinical trials, OGS

[64] Council Directive 2001/83/EC, op. Cit., Annex 1 'Analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products', Part 4, Section G 'Documentation for applications in exceptional circumstances'.

[65] Further statement of Dr E.Tambuyzer (Senior Vice President of Genzyme Europe) dated 21 February 2003, attached to Genzyme's third supplementary written representations submitted on 26 February 2003.

[66] Ibid.

[67] Letter from J.M. Paardekooper (Associate Director Regulatory Affairs Europe, Genzyme B.V.) to the EMEA, dated 10 May 1996.

applied for a marketing authorisation in the EU on 29 June 2001 and it received it over a year later on 20 November 2002[68]. Zavesca's authorisation was granted under exceptional circumstances, as there are still questions over its safety and efficacy and it needs to be subjected to further clinical trials[69].

50. In addition to a marketing authorisation, medicinal products manufactured in the UK must be produced on a site that holds an appropriate manufacturer's licence. This could be a full manufacturer's licence (where the product is manufactured in the UK) or, as in the case of Genzyme, a manufacturer's (assembly only) licence (where the product is manufactured abroad, but packaged in the UK)[70].

51. Similarly, any company or individual wishing to wholesale deal (i.e. sell, supply or procure to anyone other than the end user) medicinal products within the EU must hold a wholesale dealer's licence or, where the medicines are imported from outside the EEA, a wholesale dealer's import licence[71]. Genzyme applied for an import licence to the MCA under the Medicines (Exemption from Licences) (Importation) Order, SI 673/1984 on 21 January 1997 and subsequently obtained it.

(ii) Orphan drugs

52. 'Orphan medicinal products' are for diagnosing, preventing or treating life-threatening or very serious conditions that are rare and affect not more than 5 in 10,000 persons in the EU. Pharmaceutical companies are unwilling to develop such medicinal products under normal market conditions, as the cost of bringing them to the market would not be recovered by the expected sales without incentives[72].

53. In order to encourage the development of drugs for rare conditions, the EC has adopted two regulations concerning so called 'orphan medicinal products'. A drug in development can be designated as an orphan medicinal

[68] See document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, page 1.

[69] Ibid, page 29.

[70] See http://www.mca.gov.uk/

[71] Ibid.

[72] See EMEA leaflet 'Orphan Medicinal Product Designation in the European Union'.

product under Council Regulation 141/00/EC[73]. This regulation concerns drugs developed for patients suffering from rare conditions such that the pharmaceutical industry might be unwilling to develop a medicinal product for their treatment under normal market conditions.

54. Applications for orphan medicinal product designation are submitted by sponsors to the Committee for Orphan Medicinal Products ('COMP'). Such applications can be made at any time before applying for a marketing authorisation (i.e. they can be made at the early stages of research when it is still not certain whether the drug will be successful). There is no limit on the number of designations that will be granted for any therapeutic indication (e.g. for Gaucher disease).

55. Applications for Community marketing authorisation for orphan drugs are made, as with non-orphan drugs, to the EMEA.

56. Orphan medicinal products are eligible for a number of incentives[74] as outlined below:

- Marketing exclusivity - when a medicinal product which has received designated orphan status is granted a marketing authorisation pursuant to Regulation 2309/93/EEC (or if all the Member States have granted marketing authorisations in accordance with mutual recognition procedures), the drug benefits from marketing exclusivity for a period of 10 years. Marketing exclusivity, therefore, is not granted when the drug is designated an orphan drug, but when it is receives marketing authorisation. Marketing exclusivity means that during that time no authorisation will be given to any similar medicinal product for the same therapeutic indication. The period of exclusivity may be reduced to six years if, at the end of the fifth year, it established, inter alia, that the product is sufficiently profitable not to justify maintenance of market exclusivity. This exclusivity can be broken by a competitor which develops, for the same therapeutic indication, a product based on a different mechanism or technology, or by a competitor which develops a similar product for the same therapeutic indication, if that second product is clinically superior to the first product[75].

---

[73] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products OJ (2000) L18/1.

[74] See EMEA leaflet 'Orphan Medicinal Product Designation in the European Union'.

[75] Further statement by Dr E.Tambuyzer dated 21 February 2003, paragraph 9, attached to Genzyme's third supplementary written representations submitted on 26 February 2003.

- Protocol assistance – the EMEA provides assistance to sponsors of orphan drugs, which includes advice on the conduct of trials necessary to demonstrate quality, safety and efficacy of the product. For example, because the population affected by an orphan drug is necessarily small, the EMEA provides advice on clinical methodologies for small populations.
- Access to the centralised procedure – orphan drugs have direct access to the EMEA centralised procedure for the application for marketing authorisation.
- Fee exemptions – a special fund from the European Commission is used by the EMEA to grant total or partial fee exemption for all types of centralised activities including marketing authorisation and protocol assistance.
- EU-funded research – sponsors of orphan drugs may be eligible for special grants.

57. Prior to Regulation 141/00/EC, six medicinal products had been granted fee exemptions by the EMEA on the grounds that they were indicated for patients with rare diseases. These drugs, which include Cerezyme, continue to receive partial fee exemptions.

58. Drugs designated as orphan medicinal products must still demonstrate quality, safety and efficacy, in the same way as any other drug, before they will be granted marketing authorisation[76]. The EMEA has stated,

> 'Designation of orphan status is not an endorsement for the use of the product in the designated condition as it does not indicate that the product will satisfy the criteria for the grant of a marketing authorisation which is a separate step. The quality, safety and efficacy of the medicinal product in the proposed therapeutic indication can only be evaluated, as for any medicinal product, once the application for marketing authorisation has been submitted.'[77]

59. The European Commission has recently carried out a review of the legislation and procedures for medicinal products and has proposed amendments to Council Regulation 2390/93/EEC[78]. One of these proposals is for an

[76] See note of telephone conversation between the OFT and M.Harvey (EMEA) dated 22 January 2003.

[77] Ibid.

[78] See COM(2001) 606 23.10.2001 A report from the Commission on the experience acquired as a result of the operation of the procedures for granting marketing authorisations for medicinal products laid down in Regulation (EEC) no 2309/93. See

accelerated procedure for marketing approval for drugs which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Orphan drugs will not automatically qualify for the accelerated procedure and will have to satisfy the criteria in the same way as any other drug[79]. The accelerated procedure shortens the maximum time for receiving an opinion from the CPMP as to whether marketing authorisation should be granted from 210 to 150 days.

60. The Director has sought the views of the EMEA on the timescale for getting orphan drugs to the market and how this compares with non-orphan drugs. The EMEA's spokesman has told the Director that there is nothing inherent in the nature of orphan drugs that makes it quicker to get a drug to the market compared with non-orphan drugs. Small patient populations could make it harder to put a clinical trial together, as it may be more difficult to find sufficient patients with the right medical history[80].

61. It appears, therefore, that orphan drugs may or may not qualify for the proposed accelerated procedure and that, where they do, the effect will be that the time required for a CPMP opinion will be reduced from 210 to 150 days. It would also appear that, while there are clearly incentives for pharmaceutical companies to develop orphan drugs, there is nothing in EC Regulations or inherent in the nature of orphan drugs that means that they can be brought to the market more quickly than non-orphan drugs.

(iii) Pharmaceutical Price Regulation Scheme (PPRS)

62. The PPRS is a voluntary scheme agreed between the Secretary of State for Health and the Association of the British Pharmaceutical Industry (ABPI). It regulates the profit that companies may make from their sales of branded prescription medicines supplied to the NHS. Although participation in the scheme is voluntary, companies that do not participate in the scheme are subject to statutory regulation under sections 34 to 38 of the Health Act 1999. Genzyme is a member of the current PPRS.

---

also COM(2001) 404 26.11.2001 for an outline of the proposals and OJ (2002) C75E/189 for the proposed text of the new regulation.

[79] Genzyme has submitted that orphan drugs are 'by definition' the type of drug for which the fast track procedure is being designed. See Genzyme's third supplementary written representations submitted on 26 February 2003, paragraph 3.12, page 14.

[80] Note of telephone conversation between the OFT and M. Harvey (EMEA) dated 22 January 2003.

63. The current PPRS agreement will last for five years (1999-2004). It has the same objectives as the agreements which preceded it. These are:

(i) to secure the provision of safe and effective medicines for the NHS at reasonable prices;

(ii) to promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; and

(iii) to encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in the UK and other countries.

64. The PPRS sets a limit on the rate of return (measured as a percentage return on capital employed or sales) that a company can earn on its sales of branded prescription medicines to the NHS. The PPRS profit limit is applied across all the products that a company sells to the NHS and is not applied to each product individually. Under the terms of the current PPRS scheme, companies are set a target rate of return on capital ('ROC') of 21% with an upward margin of tolerance of 40% of the target. Companies exceeding the margin of tolerance (i.e. with an ROC over 29.4%) are required to repay any excess to the Department of Health ('DoH') or reduce prices.[81]

65. The profitability of companies is monitored through detailed annual returns submitted by the companies to the PPRS. However, companies whose sales to the NHS are below £25 million (*[confidential]*) do not have to submit detailed returns[82] and, therefore, their profitability is not closely monitored. The DoH can request such returns if circumstances demand it, for example, if a company wishes to increase prices.

66. Under the terms of the PPRS, companies are free to set the NHS list price of new products (introduced following the granting of an EU or UK new active substance marketing authorisation from the appropriate Licensing Authority) provided profits from NHS sales overall remain within the profit

[81] Report entitled 'Report on regulatory and structural issues in the publicly funded UK pharmaceutical sector relevant to the OFT Rule 14 notice in respect of Genzyme and Healthcare at Home' prepared by Translucency Ltd on 24 October 2002, section 2.5 at page 10 et seq. See also 'The Pharmaceutical Price Regulation Scheme', July 1999.

[82] Report entitled 'Report on regulatory and structural issues in the publicly funded UK pharmaceutical sector relevant to the OFT Rule 14 notice in respect of Genzyme and Healthcare at Home' prepared by Translucency Ltd on 24 October 2002, paragraph 2.2.4 at page 9. See also 'The Pharmaceutical Price Regulation Scheme', July 1999.

limit[83]. This flexibility is designed to allow companies to price new and innovative products so as to gain a return on that innovation during a period of patent protection. The PPRS is not a cost-plus system of pricing where the price of each individual drug is calculated by adding together its individual costs plus an element for profit. As explained by Genzyme, 'A company is free to price a product at launch as it sees fit, subject to the profit cap determined by the PPRS'[84].Once prices are set, however, the PPRS restricts any increase. Under the current PPRS, a company may only apply for a price increase if its profits fall short of 50% of an ROC target of 17% (i.e. 8.5%)[85].

67. In 1999 the DoH negotiated an across the board price cut on all branded medicines sold to the NHS of 4.5%. Companies were permitted to lower the prices of some products more than others provided the overall effect was that of a 4.5% price cut[86].

(iv) The NHS list price and the PPRS

68. The NHS list price and the PPRS are inextricably linked. This is illustrated by a report commissioned by Genzyme from the consultancy Translucency Ltd ('Translucency') (the 'Translucency Report')[87]. The Translucency Report contains a section on 'The relationship between PPRS and NHS list or basic price'[88]. This section explains that when a company within the PPRS

[83] See report commissioned by Genzyme, 'Report on regulatory and structural issues in the publicly funded UK pharmaceutical sector relevant to the OFT Rule 14 notice in respect of Genzyme and Healthcare at Home' prepared by Translucency Ltd on 24 October 2002.

[84] Ibid, paragraph 2.9.1, at page 13.

[85] Report entitled 'Report on regulatory and structural issues in the publicly funded UK pharmaceutical sector relevant to the OFT Rule 14 notice in respect of Genzyme and Healthcare at Home' prepared by Translucency Ltd on 24 October 2002, paragraph 2.6.2 at page 11. See also 'Pharmaceutical Price Regulation Scheme' July 1999, Chapter 20.

[86] Report entitled 'Report on regulatory and structural issues in the publicly funded UK pharmaceutical sector relevant to the OFT Rule 14 notice in respect of Genzyme and Healthcare at Home' prepared by Translucency Ltd on 24 October 2002, paragraph 2.6.1 at page 11. See also 'The Pharmaceutical Price Regulation Scheme', July 1999, Chapter 20.

[87] Report entitled 'Report on regulatory and structural issues in the publicly funded UK pharmaceutical sector relevant to the OFT Rule 14 notice in respect of Genzyme and Healthcare at Home' prepared by Translucency Ltd on 24 October 2002.

[88] Translucency Report, section 2.9 at page 13 et seq.

introduces a new drug (a new chemical entity), that company is free to set the price of the drug[89]. The Translucency Report explains that 'the prices permitted under the PPRS become the NHS list or basic price (as appropriate) listed in the Drug Tariff'[90]. 'A company cannot then increase its price without negotiations with the DoH'[91].

69. There is no legal instrument or NHS official document which provides a definition of 'NHS list price' or which prescribes how a pharmaceutical company determines the price of a drug that will become the 'NHS list price'.

70. The Director has consulted the head of the PPRS on the question of what the NHS list price covers. The head of the PPRS explained that[92],

> 'Under the Pharmaceutical Price Regulation Scheme (PPRS), companies have freedom of pricing when launching a major new product, defined as a new active substance. This price becomes the NHS list price on which the reimbursement price is based.
>
> Companies are required to provide annual financial information [to the PPRS] including a breakdown of costs. If a company's overall profit is assessed as exceeding their target profit (and a margin of tolerance), they are required to repay the excess profits to the Department or to reduce prices.
>
> Companies provide information on the following costs:
>
> 1. Costs of manufacturing
> 2. Distribution
> 3. Information (samples, data sheets, medical symposia (not organised by the company)
> 4. Sales promotion (literature, sales reps, advertising, other promotional activities and associated administration)
> 5. General and administrative expenses
> 6. Research and development expenditure including royalties.
>
> There may also be one-off expenses e.g. rationalisation and restructuring costs, redundancy costs, product withdrawals and legal costs.
>
> The scheme specifically states that expenditure on samples (other than for identification), gifts and hospitality are not allowed as a charge in NHS prices.

[89] Translucency Report, paragraph 2.9.1, at page 13.

[90] Translucency Report, paragraph 2.9.3, at page 13.

[91] Translucency Report, paragraph 2.9.2, at page 13.

[92] Email from M.Brownlee (Head of PPRS) to the OFT dated 13 December 2002.

> However, the scheme is not specific on what may or may not be included as part of distribution costs. Distribution normally covers the cost of delivering the product from the manufacturer to the wholesaler. If a company's distribution costs are high (e.g. as a result of including the cost of delivery to the patient), the level allowed might be restricted and might result in excess profits being repaid.
>
> It is important to note that the Department receives no information on the costs of individual products only in aggregate on a company's portfolio of products sold to the NHS.'

71. It appears therefore that the NHS list price is intended to cover the cost to the manufacturer of producing the drug and the cost of delivering the drug from the manufacturer to the wholesaler plus a reasonable profit on these activities. The PPRS also allows manufacturers to include a wholesaler margin within the NHS list price, which covers the cost of distributing the drug from the wholesaler to a pharmacy (either a hospital or a community pharmacy)[93].

72. Genzyme has contested this conclusion. Genzyme contends that, in addition to covering the cost of producing the drug and wholesale delivery, the NHS list price is also intended to cover the cost of delivering the drug to the patient's home[94]. In support of this statement, Genzyme referred to section 5.1.5 of the Translucency Report[95], which states

> 'The NHS list price is intended to cover the cost of the pharmaceutical, together with manufacturer's profit which is constrained to a maximum by the PPRS. The NHS list price also covers, de facto, the costs of delivering the medicine to the patient. In the case of most drugs, this is through a retail pharmacist with a pharmaceutical wholesaler as an intermediary.' [96]
> [Emphasis added]

73. In response to the Director's request for clarification on this subject, Genzyme stated that, although the Translucency Report only says that the

[93] Translucency Report, paragraph 5.1.14 at page 37. See also Pharmaceutical Price Regulation Scheme, July 1999, Chapter 28.

[94] Genzyme's written representations submitted on 25 October 2002, paragraphs 10.20 to 10.23 at pages 136 and 137.

[95] Genzyme's written representations submitted on 25 October 2002, paragraph 10.20 at page 136.

[96] Translucency Report at paragraph 5.1.5.

NHS list price 'de facto' covers the costs of delivering the medicine 'to the patient', this is intended to mean 'delivery to the patient's home'[97].

74. The Director has put this conclusion to the head of the PPRS for comment. The head of the PPRS explained that the NHS list price basically covers the cost of manufacture and the cost of distribution up to the point of delivery to the pharmacy where it is dispensed by the pharmacist and collected by the patient. In particular, referring to the statement made in the Translucency Report quoted above, the head of the PPRS stated that[98],

> 'We are not aware that the components of 'the NHS list' price have been defined. The last sentence of the above statement would be correct if understood in the following context. The operating assumption of the PPRS in primary care is that the supply to patients of medicines manufactured by scheme members is through wholesalers and community pharmacist that dispense the medicines to patients in the pharmacy.'

75. Therefore, while the NHS list price is intended to cover the cost of delivering the drug from the manufacturer to the pharmacy, it is not intended to cover the cost of delivering the drug from the pharmacy to the patient's home.

76. A full review of the Translucency Report would appear to support the above conclusion.

77. At paragraph 5.1.26 the Translucency Report states:

> 'The system by which the cost of drugs dispensed on FP10 prescription forms is reimbursed is as follows. The manufacturer's list price, notified to the Department of Health and constrained to a maximum determined by the PPRS formula, is the NHS list price, which in turn forms the basis on which reimbursement to the pharmacist is calculated. By custom and practice – and not by statutory definition – this price covers the ingredient cost, packaging, and distribution to the retail pharmacist for supply to the patient. In agreeing the NHS list price, these elements are not separately identified.' [Emphasis added]

78. The Translucency Report refers to 'distribution to the retail pharmacist for supply to the patient'. However, there is no mention of the cost of distribution from the pharmacy to the patient's home. This would suggest that, as explained by the head of the PPRS, the NHS list price covers the cost of distribution to the pharmacy where the drug is dispensed to the

[97] Genzyme's second supplementary written representations submitted on 10 January 2003, paragraph 2.5 at page 5.

[98] Email from M. Brownlee (PPRS) to the OFT dated 13 December 2002.

patient, but not the next step, namely, distribution from the pharmacy to the patient's home.

79. At paragraph 7.3.7 the Translucency Report states,

> '(...) With the exception of domicilliary oxygen services, no mechanism currently exists in the NHS reimbursement and remuneration system for pharmaceuticals for anyone in the supply chain to recover the costs of drug delivery and ancillary services. Recovery of such costs could only be achieved by persuading PCTs [Primary Care Trusts] (or an NHS Trust acting as the agent of a PCT) to make a contract for the provision of services.' [Emphasis added]

80. It is clear, therefore, that since there is no mechanism 'in the NHS reimbursement and remuneration system for pharmaceuticals for anyone in the supply chain to recover the costs of drug delivery and ancillary services', the NHS list price is not intended to be a mechanism designed to reimburse the cost of delivering a drug to a patient's home and/or providing 'ancillary services'.

81. Genzyme contends that the Director cannot rely on the evidence submitted by the head of the PPRS on this subject, as this is 'a matter which is not in his knowledge'[99]. According to Genzyme, the head of the PPRS simply 'give[s] his view as to the operating assumption of the PPRS which (...) is a separate matter to that of the NHS list price'[100].

82. It is clear, in particular from statements made in the Translucency Report commissioned by Genzyme, that the NHS list price and the PPRS are inextricably linked[101]. The Director considers the head of the PPRS a very reliable expert on matters related to the NHS list price and the PPRS. The statement that 'we [the PPRS] are not aware that the components of the 'NHS list price' have been defined' is a reference to the lack of legislation or official document setting out such components, and not a reference to his lack of knowledge of this subject as suggested by Genzyme. In fact, the Translucency Report commissioned by Genzyme refers to the lack of any

[99] Genzyme's second supplementary written representations submitted on 10 January 2003, paragraphs 2.13 to 2.18 at pages 7 and 8.

[100] Ibid.

[101] See the Translucency Report, paragraph 2.9.3 at page 13 ('the prices permitted under the PPRS become the NHS list or basic price') and 5.1.26 at page 40 ('the manufacturer's list price, notified to the Department of Health and constrained to a maximum determined by the PPRS formula, is the NHS list price').

statutory definition of the components of the NHS list price[102]. Furthermore, Genzyme has not submitted any evidence in support of its own interpretation of what the NHS list price is intended to cover, other than the relevant statement at paragraph 5.1.5 of the Translucency Report (quoted in paragraph 72 above), which is not supported by any piece of legislation or NHS official document. In fact, the Director is of the view that, as shown above, read in its entirety, the Translucency Report does not support Genzyme's position. In view of this, the Director considers the evidence given by the head of the PPRS, who through his work is intimately familiar with the working of the NHS list price, more reliable than any other evidence put to him on this matter.

83. The Director therefore concludes that the NHS list price is intended to cover the cost of the manufacturer of producing the drug and the cost of wholesale delivery of the drug to the pharmacy (plus a reasonable profit on these activities). However, it is not intended to cover the cost of delivering the drug from the pharmacy to the patient's home.

(v) Pharmacy reimbursment

84. Licensed pharmacists who dispense drugs against community prescriptions are reimbursed by the Prescription Pricing Authority (PPA). They receive two main types of payments: an amount to compensate them for the cost of the medicines they dispense and various professional fees to remunerate them for the dispensing and associated professional services they provide. The latter may include a 2% Expensive Prescription Fee payable on all prescriptions over £100.

85. Standard industry practice is for branded drug manufacturers to sell their products to pharmaceutical wholesalers at a 12.5% discount to the NHS list price. The wholesaler can then sell on to licensed pharmacies at any price up to the list price. In practice, many drugs are sold at a price below the NHS list price because of competition between wholesalers and parallel importing. To take account of this lower price, the DoH does not reimburse the full list price, but applies a 'clawback' percentage to the list price when reimbursing pharmacies. However, some drugs are designated as 'zero discount' which means they are reimbursed at the full NHS list price. Cerezyme is a zero discount drug.

[102] Translucency Report, paragraph 5.1.26 at page 40.

86. As licensed pharmacies, delivery/homecare service providers receive payment for dispensing prescriptions in the same way as a community pharmacy[103]. Payment for home delivery and homecare services is often under a contract between the delivery/homecare services provider and a local NHS trust and may involve a number of patients receiving a range of treatments. For some drugs, however, the price of home delivery and homecare services is included in the price of the drug. In these circumstances, a delivery/homecare services provider can be properly remunerated only by gaining access to the drug at a reasonable price or by receiving a separate payment from the drug supplier for the home delivery and homecare services.

5. Pricing[104]

(i) NHS list price and hospital price

87. Cerezyme is priced in units and is primarily supplied in 200 unit vials.

88. Cerezyme's NHS list price is currently £2.975 per unit (or £595 per 200 unit vial). This price includes the provision of delivery/homecare services provided by Genzyme Homecare (and previously by HH)[105].

89. Sales of Cerezyme to the community are zero rated for VAT purposes. However, sales of Cerezyme to hospitals are subject to VAT at the standard rate of 17.5%. As hospitals do not resell the drug, the NHS cannot recover the VAT and, if hospital and community prices (before VAT) were the same, the NHS would end up paying a higher price for hospital purchases than is paid for community purchases.

90. According to Genzyme, in order to reduce the difference in cost to the NHS between hospital and community purchases, in 1993 it introduced a concessionary price to hospitals. Genzyme Homecare indicated to the Royal Free Hospital that the concessionary price was introduced 'to assist hospitals meet the additional burden of VAT which is chargeable on supplies used in hospitals and not on dispensed supplies for self administration at home and

[103] In fact, in addition to the standard dispensing fee, both HH and Genzyme Homecare receive a 2% fee for dispensing Cerezyme, which is classed as an expensive drug.

[104] See document entitled 'Cerezyme/Ceredase Price History' produced by the OFT and agreed by Genzyme by letter of E. Perrott to the OFT, dated 8 May 2002. See also other relevant documents relating to pricing issues submitted by Genzyme and attached to the Rule 14 Notice.

[105] Note that Genzyme disputes that the NHS list price of Cerezyme covers not only the drug, but also the provision of delivery/homecare services (see section 'the NHS list price and the PPRS' above).

consequently is only available for supplies which are administered to patients in hospital. This price is not applicable for product which is to be resold or distributed by any other means. If the product is to be administered outside the hospital, then the actual price of £2.975 + VAT at the prevailing rate applies'[106]. Currently, the concessionary hospital price is £*[confidential]* per unit (plus VAT) which gives a total of £*[confidential]* per unit (i.e. still significantly higher than the £2.975 per unit charged for Cerezyme to be administered in the community)[107].

91. When Ceredase (the predecessor to Cerezyme) was first introduced in the UK in 1991, only a few patients were being treated with Ceredase and they all received treatment in hospital. Ceredase was imported from the US on a named patient basis and sold directly to hospitals, which were invoiced by Genzyme from the US at a price of US$*[confidential]* per unit (approximately £*[confidential]*).

92. By 1993 the number of patients prescribed with Ceredase increased and Genzyme decided to appoint a distributor to handle the distribution of the drug and to offer patients the possibility of receiving treatment at home. Genzyme appointed a company called Caremark Limited ('Caremark'). At this point, the price of Ceredase was increased to £2.97 per unit, which became the NHS list price. The hospital price was set at £*[confidential]* [108] (giving a unit price of £*[confidential]* plus VAT), but was subsequently reduced to £*[confidential]* per unit (plus VAT)[109].

---

[106] Letter from D.Moreland (Genzyme Homecare) to the Royal Free Hospital dated 25 June 2001.

[107] See document entitled 'Genzyme – Pricing Structure' submitted to the OFT on 5 March 2002 and amended on 22 March 2002; see also fax from M Cortvriend (Genzyme) to J. van Heek (Genzyme B.V.) dated 14 January 1997.

[108] *[confidential]* (see statement of M.Cortvried (Genzyme) dated 23 October 2002, attached to Genzyme's written response dated 25 October 2002.

[109] See fax from M.Cortvriend (Genzyme) to R.Dibblee (Unicare) dated 23 March 1993. See also document prepared by Genzyme for the purposes of this investigation, entitled 'Genzyme – Pricing Structure' submitted to the OFT on 5 March 2002 and amended on 22 March 2002. See also document entitled 'Cerezyme/Ceredase Price History' produced by the OFT and agreed by Genzyme by letter of E.Perrott (TV) to the OFT, dated 8 May 2002.

93. In February 1994, Genzyme increased the NHS list price of Ceredase to £3.09 per unit (£618 per vial) and the concessionary hospital price to £*[confidential]* plus VAT[110].

94. In 1997, Cerezyme was introduced in the UK and it soon replaced Ceredase. Cerezyme entered the market at the then prevailing price for Ceredase, namely, NHS list price of £3.09 per unit and the concessionary hospital price of £*[confidential]* plus VAT per unit. This price remained unchanged when Caremark was replaced by HH in 1998.

95. In 1999, Genzyme joined the PPRS. As a result, it had to implement a 4.5% price reduction imposed by the PPRS on branded medicines sold to the NHS[111]. Genzyme wrote to the PPRS explaining that the NHS list price of Cerezyme (at that time £3.09 per unit) included not only the drug, but also the provision of home delivery and homecare services.

96. In a letter to the DoH dated 7 September 1999, Genzyme stated[112]:

> 'You [DoH] commented that Cerezyme pricing may be unique. Our price of £618 per unit vial is the price which our home care provider, HealthCare at Home Limited [sic], supplies the product to the NHS. However, this, as I pointed out, does not just include the price of the drug. Healthcare at Home provide extensive nursing support to many patients, even to the extent of thrice weekly visits to patient's homes to administer two hour infusions. In addition, home delivery and ancillaries such as water for injection, infusion pumps and lines, needles, swabs, etc, are all provided as part of this service together with fridges for storage of drugs, etc.
>
> We discussed two issues for which we would like clarification. If Genzyme agrees to participate in the PPRS scheme as outlined in the letter, what opportunities are there for negotiation regarding the proposed 4.5% price decrease, based, in part, on the unique pricing as described above?' [Emphasis added]

97. It is the Director's understanding that the reference to Cerezyme possibly being 'unique' in its pricing reflects the rarity of the NHS list price of a drug including the cost of home delivery and homecare services.

---

[110] See letter from H.A.Termeer (Chairman and CEO of Genzyme) to J. Manuel (Gaucher Association) dated 2 February 1994. This price increase took place before Genzyme became part of the PPRS (which did not happen until 1999). Once a company is regulated by the PPRS, it is difficult to change the initial price notified to the PPA.

[111] Translucency Report, paragraph 2.6.1 at page 11. See also 'The Pharmaceutical Price Regulation Scheme', July 1999.

[112] See letter from M.Cortvriend (Genzyme) to R.Bratt (DoH – PPRS branch) dated 7 September 1999.

98. In response to Genzyme's letter, the DoH stated in a letter dated 14 September 1999[113]:

> 'In response to your letter of 7th September 1999, I can confirm that your company is subject to the PPRS and with sales of £*[confidential]*m you are also subject to the 4.5% price reduction. We have considered your submission regarding Cerezyme, and in the light of the pricing of this product I have the following proposal.
>
> You will be required to reduce that proportion of the list price representing the cost of the actual pharmaceutical by 4.5%. To ensure that we have evidence of this could you please provide a breakdown of the list price of Cerezyme? Given the Department's requirements to demonstrate an audit trail, the price breakdown will have to be subsequently endorsed by your auditors.'[Emphasis added]

99. On 22 March 2000, Genzyme responded as follows[114]:

> 'The list price for the NHS represents two elements, firstly, the cost of the pharmaceutical drug and secondly the costs of providing homecare assistance for patients whom have infusions in their home environment. The cost of homecare is dependent on the level of service provided, ranging from delivery of the drug and ancillaries and waste disposal to complete nursing assistance in the form of home visits.
>
> To compute the price of the drug (which solely attracts the 4.5% discount, as agreed in your letter of 14th September 1999) we have had to deduct the average cost of homecare.
>
> (...)
>
> Deliveries to hospitals are historically charged at a lower price to reflect the burden of VAT and we have excluded these deliveries (26% of sales in the first nine months of 1999) from our analysis and price reduction. The price charged to hospitals is *[confidential]* the new price after the 99PPRS reduction.
>
> **The calculation**
>
> The average healthcare cost for the first nine months of 1999 was *[confidential]*p. This represents the average of service levels from *[confidential]*p to £*[confidential]*. As the average is near the lower end of the scale, the Genzyme management has thought it appropriate to build in a contingency of *[confidential]*p to cover a likely shift of increased service levels

[113] See letter from R.Bratt (DoH, PPRS branch) to M.Cortvriend (Genzyme) dated 14 September 1999.

[114] See letter from P.Foster (Financial Controller, Genzyme) to R.Bratt (DoH, PPRS Branch) dated 22 March 2000.

for new patients. This gives a reduction of *[confidential]*p per unit and corresponds to a reduction of the price for the 200-unit vial from £618 to £595.' [Emphasis added]

100. Therefore, Genzyme applied the 4.5% reduction only to the drug element of Cerezyme's NHS list price.

101. The figures submitted by Genzyme in the letter of 22 March 2000, presented a calculation of the total amount paid to HH for home delivery and homecare services between January and September 1999 for non-hospital patients. Genzyme excluded hospital patients from the analysis on the basis that, as a result of the concession to take account of VAT, the hospital price was already more than 4.5% lower than the NHS list price.

102. Genzyme's calculation gave an average homecare cost per unit of *[confidential]*p. Homecare costs ranged from *[confidential]*p to £*[confidential]* per unit, so this average was at the lower end of the range (reflecting the fact that high cost patients were relatively small in number). However, Genzyme argued that it was likely that in the near future there would be a shift towards higher service levels because of new patients (on the basis that new patients require a high level of care when they first start receiving the treatment) and therefore added in a *[confidential]*p per unit contingency to take account of this. This gave an average home delivery and homecare services cost of *[confidential]*p or *[confidential]*% of the list price.

103. On the basis of the above calculation, Genzyme submitted that the drug element of the list price was £*[confidential]* per unit and it was this price (as opposed to £3.09) that was cut by 4.5% to give a new drug list price of £*[confidential]* (£*[confidential]*) giving an overall price of drug and home delivery and homecare services of £2.975 (£*[confidential]* for the drug plus £*[confidential]* for the home delivery and homecare services) per unit (£595 per vial)[115]. The DoH accepted this methodology and the proposed reduction in price[116].

[115] See letter from P.Foster (FC Genzyme) to R.Bratt (DoH, PPRS Branch) dated 22 March 2000.

[116] See letter from R.Bratt (DoH, PPRS branch) to M.Cortvriend (Genzyme) dated 30 September 1999.

(ii) Payment for delivery[117] and homecare services

104. When Ceredase was first introduced in the UK in 1991, Genzyme distributed the drug directly to hospitals. All patients were treated in hospital and any nursing service required was provided by hospital nurses[118].

105. In 1993, Genzyme identified a demand from patients in the community for home delivery and provision of specialised care services in the home setting, which would obviate the need for the patient to go to hospital every time an infusion of Ceredase was required[119]. Genzyme therefore appointed Caremark Limited[120], a company operating as a specialised provider of delivery/homecare services for complex conditions, as its sole distributor and service provider in the UK. At the time of the appointment, Caremark was a delivery/homecare services provider for treatments for a range of diseases including multiple sclerosis, cancer and cystic fibrosis.

106. Initially Caremark paid Genzyme £*[confidential]* per unit of Ceredase and, under instructions of Genzyme, Caremark charged the NHS the then list price of £2.97 per unit for delivering the drug to patients' homes and providing homecare services in the community. Caremark funded the cost of home delivery and homecare services from the *[confidential]*p per unit margin. These terms were set out in a letter from Genzyme to Caremark in 1993, which stated,

> 'With regard to the community pharmacy supply of Ceredase via FP10 prescriptions, we intend that the price be £2.97 per unit to the customer and that you be charged £*[confidential]* per unit. This difference will encompass your total distribution costs, together with the supply of ancillary items used in the non-hospital environment, the provision of nursing support by Caremark where deemed to be appropriate and other elements of service as discussed' [121] [Emphasis added]

---

[117] In this Decision, unless otherwise stated, references to 'delivery' of drugs should be interpreted as including both, delivery to hospitals and delivery to patients' homes. See footnote 48 above.

[118] See M. Cortvriend's note on the history of Cerezyme in the UK attached to Genzyme's submission of 5 March 2002.

[119] Ibid.

[120] Caremark Limited is the main company in a small UK group of companies owned by a US parent, Caremark International Inc. The business currently conducted by Caremark in the UK was originally part of Unicare Medical Services Limited, which was owned by Baxter International Inc. until 1992.

[121] Letter from M. Cortvriend (Genzyme) to R. Dibblee (Caremark) dated 26 March 1993.

107. At this initial stage, Genzyme continued to invoice hospitals directly from the US and Caremark agreed to deliver the drug to hospitals at no charge to Genzyme. Subsequently, Caremark took over the dealings with hospitals, charging the NHS for sales to hospitals a price of £*[confidential]* per unit plus VAT (see paragraph 92 above).

108. At some point[122] the arrangement with Caremark was changed, so that Caremark paid Genzyme £2.97 per unit for Ceredase and received a service charge from Genzyme of *[confidential]*p per unit.

109. When the NHS list price of Ceredase was increased to £3.09 (and the hospital price to £*[confidential]*) in 1994 (see paragraph 93 above), the service charge paid to Caremark also increased to *[confidential]*p per unit[123]. This arrangement continued when Ceredase was replaced by Cerezyme in 1997[124].

110. In 1998, Genzyme terminated its distribution and service agreement with Caremark and, following a review of delivery and homecare services providers, on 6 May 1998 it entered into a new agreement with HH.

111. Under the terms of the first agreement between HH and Genzyme[125], HH agreed to purchase Cerezyme at the list price of £3.09 per unit (plus VAT) and resell it to the community at £3.09 per unit and to hospitals at the concessionary price of £*[confidential]* per unit (plus VAT)[126].

112. HH was reimbursed by Genzyme for the delivery and homecare services provided to the NHS, according to a scale of charges per unit delivered which depended on the level of care required by the patient[127]. In addition, Genzyme paid HH a management fee of *[confidential]*% on its total

---

[122] Genzyme was unable to provide an exact date (see note of telephone conversation between the OFT and E.Perrott (TV) produced by TV on 20 March 2002 and letter from E.Perrott (TV) to the OFT dated 27 March 2002.

[123] See document entitled 'Genzyme – Pricing Structure' submitted by Genzyme to the OFT on 5 March 2002 and amended on 22 March 2002.

[124] See letter from P.J.Hastings (Vice President, Genzyme) to R. Dibblee (Caremark) dated 6 October 1995. Fax from M.Cortvriend (Genzyme) to M.Jenkins (PPA) dated 16 May 1997.

[125] The agreement between the parties at this stage was an oral one.

[126] See document entitled 'Cerezyme/Ceredase Price History' produced by the OFT and agreed by Genzyme by letter from E.Perrott (TV) to the OFT dated 8 May 2002.

[127] See document entitled 'Outline plan of the HH Genzyme service' submitted by HH, setting out the different categories of patient groups from A to E, depending on the demands and needs of the patient.

purchases of Cerezyme. Hospital sales attracted *[confidential]* unit charge to reflect the fact that HH had paid Genzyme the list price (£3.09 per unit) but HH charged the NHS the lower concessionary price of £*[confidential]* per unit. Genzyme also paid a fee of £*[confidential]* for each nurse visit to a patient's home and separately financed miscellaneous activities.

113. When the agreement between Genzyme and HH was revised in 2000, patient categories were reduced to two: 'A' category comprising deliveries of Cerezyme to hospitals and 'B' category comprising home delivery and homecare services provided at the patient's home (regardless of the level of service provided). The separate payment for nurse visits was abandoned[128].

[128] Distribution agreement between Genzyme and HH dated 1 February 2000.

114. The scale of payments made to HH before and after the change in February 2000 is given in Tables 1 and 2. The cost of HH's service for 'category B homebase' patients at the time its contract with Genzyme was terminated was *[confidential]*p per unit.

Table 1: Original payment structure before 01/02/00	
Patient category[129]	**Unit charge paid to HH by Genzyme in pence**
A	*[confidential]*
B	*[confidential]*
C	*[confidential]*
D	*[confidential]*
E	*[confidential]*
Nurse visit	*[confidential]*
Management fee	*[confidential]*

Table 2: Revised payment structure after 01/02/00	
Patient Category	**Unit charge paid to HH by Genzyme in pence**
A: Hospital	*[confidential]*
B: Home-based	*[confidential]*
Nurse visit	N/A
Management fee	*[confidential]*

Source:
Table 1: Draft agreement between HH and Genzyme dated 2/4/98
Table 2: Draft agreement between HH and Genzyme dated 6/12/99 and agreement between HH and Genzyme signed on1/2/00

115. On 5 May 2001, Genzyme terminated its agreement with HH and launched its own delivery and homecare services operation, Genzyme Homecare. Despite its original intention to cease supplying HH, Genzyme continued supplying Cerezyme to HH at the NHS list price of £2.975 per unit (plus

[129] For a description of each patient category, see document entitled 'Outline plan of the HH Genzyme service' submitted by HH setting out the different categories of patient groups from A to E, depending on the demands and needs of the patient.

VAT), but ceased to fund the delivery and homecare services provided by HH.

6. The current position

116. Contrary to its original decision to stop supplying Cerezyme to HH after the termination of the distribution agreement, Genzyme has continued to supply HH. The terms and conditions of sale are, however, different. Under the new terms and conditions, Genzyme continues to charge HH the same price as it did under the distribution agreement (i.e. the NHS list price of £2.975 (plus VAT) per unit, which is the price HH subsequently charges the NHS). However, HH does not receive any service or management fees from Genzyme, the NHS or any other source, in consideration for providing the delivery and homecare services. HH has sixty days from the day of the invoice to pay for the order, but it must issue Genzyme with an irrevocable letter of credit for the full amount of the order when each order is placed[130].

117. The launch of Genzyme Homecare as delivery/homecare services provider, had no impact on the price Genzyme charges the NHS for Cerezyme and any delivery and homecare services provided. This continues to be £2.975 per unit when Cerezyme is to be sold in the community and £*[confidential]* (plus VAT) per unit when Cerezyme is to be sold to hospitals for infusion within the hospital. Where Cerezyme is to be sold to hospitals for infusion outside the hospital, the price is £2.975 (plus VAT) per unit.

118. HH recently tried to purchase Cerezyme from the Royal Free Hospital which wished to continue to use HH to provide home delivery and homecare services to its Gaucher patients. The Royal Free attempted to purchase Cerezyme at the *[confidential]* price of £*[confidential]* per unit (plus VAT[131]) with a view to selling it on to HH, which would allow HH a margin to fund its home delivery and homecare services. This arrangement, however, was not accepted by Genzyme. As explained in a letter from Mr Moreland (Director, Genzyme Homecare) to the Royal Free Hospital, *[confidential]*[132].

119. HH is currently charging the NHS for the Cerezyme and the home delivery and homecare services, the same price it pays Genzyme for the Cerezyme only (i.e. £2.975 plus VAT). This only applies to NHS purchases for patients

---

[130] See letter from Genzyme to HH dated 25 April 2001.

[131] Note that HH would have been able to reclaim the VAT so the price would have effectively been £*[confidential]* per unit.

[132] Letter from D.Moreland (Director, Genzyme Homecare) to the Royal Free Hospital dated 25 June 2001.

who receive treatment at home, as HH cannot afford to offer the NHS the concessionary price for hospitals of £*[confidential]* (plus VAT) per unit while paying Genzyme £2.975 (plus VAT) per unit.

120. HH told the Director that, in order to remain a player in the provision of delivery of Cerezyme and provision of homecare services *[confidential]*, HH was prepared to run a loss making operation in the terms set out above. Should the current position continue, however, HH would cease providing delivery of Cerezyme and homecare services[133].

III. LEGAL AND ECONOMIC ASSESSMENT

121. Section 18(1) of the Act imposes the Chapter II prohibition which provides that any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the UK or any part of it[134]. 'Dominant position' in section 18 means a dominant position within the UK or any part of it[135].

122. To find an infringement of the Chapter II prohibition, the Director must establish:

(i) that Genzyme holds a dominant position within the UK or any part of it;

(ii) that Genzyme has abused this dominant position; and

(iii) that such abuse may affect trade within the UK or any part of it.

123. Section 60(1) of the Act sets out the principle that, so far as it is possible (having regard to any relevant differences between the provisions concerned), questions arising in relation to competition within the UK are dealt with in a manner which is consistent with the treatment of corresponding questions arising in European Community law in relation to competition within the Community. In particular, under section 60(2) of the Act, the Director must act (so far as it is compatible with the provisions of the Act) with a view to securing that there is no inconsistency with the principles laid down by the EC Treaty and the European Court and any

[133] See letter from C.Walsh (HH) to the OFT dated 26 November 2001. In fact, HH does not currently supply Cerezyme to hospitals, as it cannot afford to buy the Cerezyme at £2.975 (plus VAT) per unit and resell it to hospitals at the concessionary price charged by Genzyme of £*[confidential]* (plus VAT) per unit.

[134] The Chapter II prohibition does not apply in cases in which it is excluded pursuant to section 19 of the Act. None of the excluded cases are applicable in respect of the infringement that is the subject of this Decision.

[135] Section 18(3) of the Act.

relevant decision of the European Court. Under section 60(3) of the Act, the Director must, in addition, have regard to any relevant decision or statement of the European Commission.

A. Dominance

1. Definition of dominance

124. The European Court of Justice ('ECJ') has defined a dominant position as:

> 'a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers.'[136]

2. Market definition

125. For the purposes of the Chapter II prohibition, dominance is assessed within a relevant economic market[137]. The relevant market has two dimensions: the relevant goods or services (the product market) and the geographic extent of the market (the geographic market).

(i) Relevant product market

126. The Director considers that there are two distinct relevant product markets.

[136] Case 27/76 *United Brands v EC Commission* [1978] ECR, 207, paragraph 65.

[137] OFT 402, 'The Chapter II Prohibition', paragraph 3.3.

(a) The upstream market

127. The EC Commission[138] and the OFT[139] have noted in previous decisions that a starting point for defining the product market in the case of pharmaceutical products is the Anatomical Therapeutic Chemicals (ATC) classification. The ATC classification is recognised and used by the World Health Authorisation (WHO) and its purpose is to serve as a tool for drug utilisation research in order to improve quality of drug use. Registration with the ATC classification is voluntary. The ATC classification system divides pharmaceuticals into groups according to their composition and therapeutic properties. At the first level, the ATC classification system divides drugs into fourteen main groups. The second level divides drugs into pharmacological/therapeutic subgroups. The third and fourth levels divide drugs into chemical/pharamacological/therapeutic subgroups. The fifth level is the chemical substance[140].

128. The ATC classification was originally based on another classification system, namely the Anatomical Classification system. This was developed by the European Pharmaceutical Market Research Association (EPhMRA) and the Pharmaceutical Business Intelligence and Research Group. In the EPhMRA system, pharmaceutical products are classified in groups at three or four different levels. The ATC system modified and extended the EPhMRA system by the addition of a therapeutic/pharmacological/ chemical subgroup

---

[138] Commission Decision IV/M.737 *Ciba-Geigy/Sandoz* OJ (1997) L201/1; Commission Decision IV/M.950 *Hoffmann-La Roche/Boehringer Mannheim* OJ (1998) L234/14; Commission decision IV/M.1403 *Astra/Zeneca* OJ (1999) C335/3; Commission Decision IV/34.279/F3 *Adalat* OJ (1996) L201/1; Commission Decision IV/M.072 *Sanofi/Sterling Drug.*OJ (1991) C156/0; Commission Decision IV/M.323 *Procordia/Erbamont* OJ (1993) C128/0; Commission Decision *Rhone Poulenc/Cooper* OJ (1994) C113/0; Commission Decision IV/M.457 *La Roche/Syntex* OJ (1994) C278/3; Commission Decision IV/M.500 *AHP/Cyanamid* OJ (1994) C278/3; Commission Decision IV/M.555 *Glaxo/Wellcome* OJ (1995) C65/3; Commission Decision IV/M.495 *Behringwerke AG/Armour Pharmaceutical Co.* OJ (1995) C134/4; Commission Decision IV/M.587 *Hoechst/Marion Merrell Dow* OJ (1995) C193/5; Commission Decision IV/M.631 *Upjohn/Pharmacia* OJ (1995) C294/9; Commission Decision IV/M.1229 *American Home Products/Monsanto* CMLR 5 [1998] 664; Commission Decision IV/M2312 *Abbott/Basf* dated 28/02/01 OJ [2001] C149/23; Commission Decision IV/M.1878 *Pfizer/Warner-Lambert* dated 22 May 2000, OJ [2000] C210/9.

[139] DGFT Decision No. CA98/2/2001 *Napp Pharmaceutical Holdings Limited,* 30 March 2001.

[140] See letter from H.Strom (WHO Collaborating Centre for Drug Statistics Methodology) to E.Perrot (TV) dated 30 September 2002. More information about the ATC system can be found in the WHO Collaborating Centre for Drug Statistics Methodology website, http://www.whocc.no/atcddd/atcsystem.html

as the fourth level and a chemical substance subgroup as the fifth level. The EPhMRA classification system is used by the Intercontinental Medical Statistics (IMS) in producing marketing research statistics for the pharmaceutical industry[141].

129. The third level of the ATC classification (ATC 3) groups together pharmaceuticals by reference to their therapeutic indications, i.e. their intended use. On this basis, the ATC 3 can be used as a starting point for an operational market definition[142]. In some cases, the third level of the ATC may not be an appropriate basis for defining the relevant product market and it may be necessary to carry out the market analysis at other levels of the ATC classification. For example, it may be appropriate to apply a narrower market definition where the pharmaceuticals forming part of a certain ATC 3 class have clearly differing therapeutic indications[143].

130. In the ATC system, Cerezyme has been listed under the A16A class ('Other Alimentary Tract and Metabolism Products') in the third level of the classification under the main group 'Alimentary Tract and Metabolism'. This class comprises a number of miscellaneous products, such as amino acids and derivatives, which are used in the treatment of different blood related conditions (e.g. carnitine deficiency and cystinosis). This third level also includes OGS's new drug for the treatment of Gaucher disease, Zavesca[144].

131. The fourth level, A16AB ('Enzymes') includes enzyme replacement therapies. At the time the Rule 14 Notice was issued, the only pharmaceuticals listed under 'Enzymes' were Ceredase (A16AB01) and Cerezyme (A16AB02), as they were the only ERT drugs in existence. Since then, two new ERT drugs have been launched for the treatment of Fabry disease. These two ERT drugs have been classified as 'Enzymes', under the same fourth level as Cerezyme. However, as pointed out by the WHO, 'the substances classified under A16AB 'Enzymes' do have different indications for use (Gaucher's Disease, Fabry's Disease, treatment of mucopolysaccharide storage disease)'[145]. It is clear that an ERT drug indicated for the treatment for

---

[141] Ibid.

[142] See e.g. DGFT Decision No. CA98/2/2001 *Napp Pharmaceutical Holdings Limited*, 30 March 2001, paragraph 47.

[143] See, e.g. Case IV/M.1378, *Hoechst/Rhone-Poulenc* OJ (1999) C254/5.

[144] See letter from H.Strom (WHO Collaborating Centre for Drug Statistics Methodology) to E.Perrot (TV) dated 30 September 2002.

[145] See letter from H.Strom (WHO Collaborating Centre for Drug Statistics Methodology) to E.Perrot (TV) dated 30 September 2002.

Fabry's disease cannot be used for the treatment of Gaucher disease, as only an ERT drug which targets the correct enzyme can be an effective treatment for this disease.

132. In relation to Zavesca, the WHO has indicated that this drug will be classified in the same third level classification as Cerezyme, i.e. as a drug indicated for Gaucher disease. However, as it is not an ERT drug, it will not be classified under the fourth level 'Enzymes'. Instead, it will be classified at ATC fourth level 'Various Alimentary Tract Metabolism Products'[146].

133. The only treatments currently indicated for Gaucher disease under any level of the ATC classification are Cerezyme, Ceredase and Zavesca.

134. As stated above, however, the ATC classification has been used by competition authorities only as a starting point for defining pharmaceutical markets. In order to define the relevant product market, other elements have to be considered.

135. Market definition is primarily a question of interchangeability. In its judgment in *Continental Can*[147] the ECJ stated that in order to define the market it was necessary to consider

> '[those] characteristics of the products in question by virtue of which they are particularly apt to satisfy an inelastic demand and are only to a limited extent interchangeable with other products.'

136. The same concept is developed in the EC Commission's notice on market definition, where it is stated that 'a relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use.'[148]

137. The EC Commission's notice on market definition summarises the framework within which markets are defined for the purposes of enforcing competition law:

> '13. Firms are subject to three main sources of competitive constraints: demand substitutability, supply substitutability and potential competition. From an economic point of view, for the definition of the relevant market, demand substitution constitutes the most immediate and effective disciplinary

[146] Ibid.

[147] Case 6/72 [1973] ECR 215.

[148] Commission Notice on the definition of the relevant market for the purposes of Community competition law (OJ C372, 9.12.1997, p.5). This definition reflects the case law of the ECJ.

> force on the suppliers of a given product, in particular in relation to their pricing decisions. (...)
>
> 14. The competitive constraints arising from supply side substitutability (...) are in general less immediate and in any case require an analysis of additional factors. As a result such constraints are taken into account at the assessment stage of competition analysis.'

138. Similarly, the Director is of the view that 'the issue in market definition is usually to determine products to which *consumers* might switch'[149]. However, where relevant, the Director will also consider supply side substitution and in some circumstances he will define markets on the supply-side[150].

139. Demand-side substitutability is, therefore, the principal analytical tool for establishing the relevant market.

140. The process starts by looking at a relatively narrow potential product market. This is normally the product that is the subject of a complaint or investigation[151], in this case, Cerezyme. The Director then considers how customers would react if prices were raised a small but significant amount above competitive levels.

141. Cerezyme v symptomatic treatments: Although Gaucher patients can receive other treatments for specific symptoms or problems caused by the disease (e.g. pain medications, hip transplantation, splenectomy etc), these are not adequate substitutes to treating the underlying disease. Symptomatic treatments deal only with specific problems caused by the disease, but they do not attack the disease itself and they cannot completely alleviate all the symptoms and problems associated with Gaucher disease. Cerezyme, on the other hand, targets the disease directly and deals with all symptoms associated with it and, although it is a life-long treatment, it is highly efficacious[152]. There is, therefore, no question of these treatments being substitutes for Cerezyme in the face of a price rise. A clear indication of this is that the NHS currently uses Cerezyme, a drug which costs on average

[149] OFT 403, 'Market Definition', paragraph 2.11.

[150] Ibid, paragraph 3.18.

[151] Ibid, paragraph 3.1.

[152] See Dr Smith's statement in the Transcript of the oral hearing of 6 November 2002 at page 39, lines 22-30.

£100,000 a year per patient for the lifetime of the patient[153], in preference and, sometimes, in addition to these treatments.

142. Cerezyme v bone marrow transplantation: Bone marrow transplantation is a highly complex and risky procedure. Although, if successful, it may cure Gaucher disease, the difficulties associated with it discard it as a viable substitute for Cerezyme. Because of the risks involved, bone marrow transplantation has only been tried as a treatment for severely ill people with Gaucher disease. As explained by the Gaucher Association, because it is such a high-risk procedure, and it requires carefully matched donors, bone marrow transplantation is not performed often. The procedure is generally reserved as a treatment option for terminally ill patients[154]. There is, therefore, no question of bone marrow transplantation being a substitute for Cerezyme in the face of a price rise.

143. Cerezyme v other drugs for the treatment of Gaucher disease: For over ten years, the only drug available for the treatment of Gaucher disease was Cerezyme. On 20 November 2002, four months after the Director issued the Rule 14 Notice, Zavesca received marketing authorisation in Europe. Zavesca became available in the UK on 3 March 2003[155]. Zavesca is a new drug for the treatment of mild to moderate Gaucher disease[156]. Zavesca can only be used on patients for whom ERT (currently only Cerezyme) is not suitable[157]. ERT (i.e. Cerezyme) will continue to be the treatment of choice

[153] It is important to note that, in the UK, Cerezyme is given to every Gaucher patient who needs it and can tolerate it. See note of meeting with Professor Cox dated 16 January 2003.

[154] 'Living with Gaucher Disease: a guide for patients, parents, relatives and friends' published by the Gaucher Association in April 1999.

[155] OGS Press Release entitled 'Actelion starts launch of Zavesca in the European Union', dated 3 March 2003.

[156] See OGS Press Release entitled 'European Commission approval for Zavesca' dated 26 November 2002. See also EMEA document entitled 'EMEA Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca' published by the EMEA in 2003, page 23.

[157] Ibid.

and the preferred standard of care for Gaucher patients[158] and in the UK Zavesca is expected to be a 'second line treatment'[159].

144. Gaucher specialists across Europe have agreed a position statement setting out the circumstances in which Zavesca will be prescribed[160]. According to this statement, Zavesca will be prescribed in the following circumstances[161]:

(a) For patients naïve to treatment (i.e. patients who have never received any treatment before) with mild or moderate symptoms, who are unwilling or unable to receive ERT for medical or personal reasons;

(b) For patients unwilling or unable to continue receiving ERT, for example because of needle phobia, persistent difficulties, poor compliance, poor access to veins, religious reasons, particular occupations or travelling arrangements, patients with infusion reactions; and

(c) For patients with persistent signs of the disease where ERT has not been completely effective. In these cases, Zavesca would be used in combination with ERT. According to the statement, the product licence does not preclude this although such patients would require frequent monitoring.

145. Therefore, in relation to the limited categories of Gaucher patients described above (those for whom ERT is not suitable), Zavesca will be a substitute for treatment with Cerezyme.

146. The Director recognises that given the limited marketing authorisation granted to Zavesca and, in particular, the fact that it can only be used for treating Gaucher patients for whom ERT (i.e. Cerezyme) is not suitable, it is arguable that Zavesca is not a sufficiently close substitute for Cerezyme to be included in the same market. However, it is clear that for a few[162]

---

[158] EMEA document entitled 'EMEA Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca' published by the EMEA in 2003, pages 23 and 27.

[159] See note of meeting with Professor Cox dated 16 January 2003 and document entitled 'Summary of Product Characteristics for Zavesca' published by OGS on 20 November 2002, section 4.4.. See also email from Professor Cox to E. Perrott (TV) dated 21 February 2003 where Professor Cox clarifies that Zavesca has been licensed as a 'second round treatment for adults with mild to moderate type 1 Gaucher's disease'.

[160] See note of meeting with Professor Cox dated 16 January 2003.

[161] Ibid.

[162] Given that Zavesca has only recently received marketing authorisation, the relevant specialist consultants have not been able to give the Director an accurate indication of

Gaucher patients Zavesca will be a substitute for Cerezyme. Whether Zavesca is in the same market as Cerezyme or not does not alter the Director's conclusions on dominance (see paragraphs 202 to 286 below). Therefore, the Director does not need to reach a conclusion on this point and will proceed on the basis of a wider market, namely one in which these two drugs compete.

147. Cerezyme v drugs for the treatment of a disease other than Gaucher disease: The ability of Gaucher sufferers (or, in fact, of prescribing doctors) to substitute a treatment for Gaucher disease with a treatment for any other disease (even if it is another LSD[163]) is clearly determined by, and limited to, drugs which are indicated for the treatment of Gaucher disease. Contrary to Genzyme's arguments[164], drugs for the treatment of other LSDs which are not indicated for the treatment of Gaucher disease are not, therefore, substitutes for drugs for the treatment of Gaucher disease.

148. In *Ciba-Geigy/Sandoz*, when considering the demand side substitutability of medicines available only on prescription (such as Cerezyme), the EC Commission stated:

> '21. The interchangeability of products depends in principle not on their physical, technical or chemical properties but on their functional substitutability as viewed by those supervising their consumption. In the case of medicines available on prescription only, therefore, these would be established medical practitioners. (...) Factors militating against more far reaching market definition include different degrees of tolerance of medicines by the patient and differences in price. In the case of medicines available on prescription only, therefore, the market definition cannot be based simply on whether different medicines are prescribed for the same illness (i.e. in the same indication group). The criterion is that prescription is based on fundamentally the same medical grounds. For such prescription practice,

---

how many Gaucher patients will be prescribed Zavesca in the UK. There are two specialist consultants in the UK who must be involved in any decision to prescribe Zavesca: Professor Cox and Dr Mehta (see paragraph 217 below). Dr Mehta has told the Director that, as things currently stand, he does not expect to actively prescribe Zavesca (see note of telephone conversation between the OFT and Dr Mehta (Royal Free Hospital) dated 21 January 2003). Professor Cox has told the Director that he only expects to prescribe Zavesca to a small number of his patients (see note of meeting with Professor Cox, dated 16 January 2003).

[163] LSDs are a form of metabolic disease. Gaucher disease is a LSD. There are 40 LSDs. These include Fabry disease, Tay-Sachs disease, Sandhoff disease and Niemann-Pick disease.

[164] Genzyme's written representations submitted on 25 October 2002, paragraph 1.10, page 49.

account can be taken of whether the medicines correspond to each other, for example in terms of active principles, tolerance, toxicity, and side effects.'[165]

149. Demand-side substitution considerations, therefore, point to a considerably narrower product market than the third level of the ATC classification, including only drugs indicated for the treatment of Gaucher disease (currently only Cerezyme and Zavesca).

150. Supply-side substitutability is concerned with situations in which its effects are equivalent to those of demand substitution in terms of effectiveness and immediacy[166]. This requires that suppliers be able to switch production to the relevant products and market them in the short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices[167].

151. The nature of pharmaceutical markets is such that supply-side substitution is often limited. Manufacturers must obtain a licence before they can sell a product and usually need to carry out some (if not extensive) R&D and clinical trials before they can obtain one. This is true of all pharmaceuticals, including orphan drugs, which must demonstrate quality, safety and efficacy like any other drug before they can receive marketing authorisation[168]. For instance, the latest orphan drug authorised for the treatment of Gaucher disease, Zavesca, required over five years of clinical trials[169] and over seventeen months to obtain a marketing authorisation[170], which was granted on the condition that further tests and follow up studies be carried out for the next three years[171].

152. As a result of the above, even where a product has little patent protection, a pharmaceutical manufacturer cannot quickly and easily begin production of a different drug unless it already has a licence. Genzyme has two patents on

---

[165] Commission Decision IV/M.737 *Ciba-Geigy/Sandoz* OJ (1997) L201/1, at paragraph 21.

[166] See Bellamy & Child, European Community Law of Competition (5th ed), page 694.

[167] Commission Notice on the definition of the relevant market, op. Cit., paragraph 20. See also OFT 403 'Market Definition', at paragraphs 3.13, 3.15 and 3.21.

[168] See EMEA leaflet 'Orphan Medicinal Product Designation in the European Union'.

[169] See document entitled 'EMEA Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca' published by the EMEA in 2003, pages16 to 23.

[170] Ibid, page 1.

[171] See note of meeting with Professor Cox dated 16 January 2003. See also document entitled 'EMEA Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca' published by the EMEA in 2003, pages 29 and 30.

Cerezyme's production process. One is on the method for producing enzymatically active recombinant glucocerebrosidase, which expires on 22 December 2009 and the other is on the production of enzymatically active glucocerebrosidase from recombinant cells, which expires on 17 January 2012[172]. Once the patent protection has expired (i.e. in 2012), any pharmaceutical manufacturer wishing to produce a generic drug based on Cerezyme's formulation will need to carry out clinical trials (which could take any time between three and five years or possibly more) and obtain a marketing authorisation (which is likely to take well over a year[173]).

153. In view of the above, the Director considers that the relevant product market in which Cerezyme competes is no wider than a market for the supply of drugs for the treatment of Gaucher disease (the upstream market).

154. Genzyme has contested the Director's conclusions on market definition. According to Genzyme, the relevant market is the market for the research, development and supply of drugs to treat LSDs[174].

155. The main arguments put forward by Genzyme to support its market definition can be summarised as follows: (i) pharmaceutical companies that carry out research into treatments for orphan drugs do not confine themselves to developing treatments for just one type of LSD. One of the main reasons for this is that the risk of failure in drug research is so great that research necessarily covers a broad range of LSDs[175]; (ii) while the individual conditions may differ, essential elements of the underlying research, development, production and marketing are applicable across the field, as are methods of treatment[176]; (iii) LSD drug production methods and facilities are not necessarily disease specific. The same methods and facilities can be and are used for the production of ERTs for different LSDs such as Gaucher, Fabry, MPSI, MPSVI and Pompe diseases[177]; (iv) the academic and practical

[172] See 'IP Portfolio for Cerezyme' submitted by Genzyme to the OFT on 30 November 2001.

[173] Note that it took both Genzyme and OGS over a year simply to obtain marketing authorisation for Cerezyme and Zavesca, respectively, even after all the clinical trials were finalised. See paragraph 48 above.

[174] Genzyme's written representations submitted on 25 October 2002, paragraph 1.10, page 49.

[175] Ibid, paragraph 1.10, page 49. See also Genzyme's third supplementary written representations submitted on 26 February 2003, paragraphs 2.8 and 2.9, pages 6 and 7.

[176] Genzyme's written representations submitted on 25 October 2002, paragraph 1.10, page 49.

[177] Ibid, paragraph 3.10, page 69.

study of LSDs by consultants and physicians also takes place in relation to LSDs as a group and not in relation to each individual disease[178]; (v) Zavesca has the potential to be used for the treatment of other LSDs; (vi) if the Director's proposed market definition was correct (i.e. the supply of drugs for the treatment of Gaucher disease), there would potentially be some 5,000 separate markets in all the different conditions where a treatment could be designated as an 'orphan drug' and there could be some 40 separate markets for LSDs, which, according to Genzyme, would be ludicrous[179].

156. The Director is not persuaded by Genzyme's arguments on market definition. The Director does not dispute that pharmaceutical companies carry out research into a wide range of treatments, or that LSDs share some common elements, or that doctors specialise on a number of different conditions. However, these arguments, by themselves, have little bearing on the definition of the relevant market for the purposes of competition law. Genzyme's arguments do not address the question of the absolute lack of demand-side substitution between treatments for different LSDs. A patient suffering from Gaucher disease cannot be treated with a drug for any LSD other than Gaucher disease. Genzyme's argument that the relevant market is wider because Zavesca may be used for the treatment of a number of different LSDs is flawed. Although there are clinical trials underway for using Zavesca for treating other LSDs, none of these have been successful[180]. Even if clinical trials were successful in the future, OGS would need to obtain marketing authorisation to use Zavesca for a different indication. As explained by Professor Cox to Genzyme,

> 'OGT 918 Zavesca has been licensed only as a second round treatment for adults with mild to moderate type 1 Gaucher's disease, and therapeutic efficacy in the other conditions for which it has been considered applicable has in no way been demonstrated and to my knowledge no license has been granted for its application in these areas.'[181]

157. In view of this, the Director does not accept Genzyme's contention that the potential use of Zavesca for the treatment of different LSDs is evidence of a wider market, not least since the therapeutic efficacy of Zavesca in treating other LSDs is far from being demonstrated.

---

[178] Ibid, paragraph 3.12, page 69.

[179] Ibid.

[180] Email from Professor Cox to E.Perrott (TV) dated 21 February 2003, attached to Genzyme's third supplementary written representations dated 26 February 2003.

[181] Ibid.

158. Similarly, Genzyme's arguments do not address the question of whether a supplier of a drug for the treatment of a LSD other than Gaucher disease could, following a small but significant increase in the price of Cerezyme above competitive levels, begin supplying a treatment for Gaucher disease in the short term without incurring significant additional cost or risk. The Director's view on this point is set out in paragraphs 150 to 152 above. In relation to supply-side substitution, Genzyme has argued that some elements of the production methods and facilities may be shared between LSDs[182]. In support of this statement, Genzyme has indicated that one of the production lines used for producing Cerezyme has also been used for producing its drug for the treatment of Fabry disease, Fabrazyme. The Director does not accept that this statement, by itself, demonstrates supply-side substitutability between different LSD drugs. While it may indicate a degree of substitutability once the drug reaches the production stage, it ignores the fact that well before a company can switch to producing a LSD drug for the treatment of Gaucher disease, it needs to first carry out R&D and clinical trials and obtain a marketing authorisation, all of which would make switching in the short term virtually impossible.

(b) The downstream market

159. As explained in paragraphs 30 to 35 above, Cerezyme is administered by intra-venous infusion either in hospital or at a patient's home. In the UK, Genzyme delivers Cerezyme to patients' homes and provides the required level of homecare services. Genzyme also delivers Cerezyme to hospitals.

160. When Ceredase was first launched in the UK in 1991, all patients were treated in hospital and any nursing service was provided by hospital nurses. At this initial stage, Genzyme distributed the drug directly from the US to hospitals in the UK[183].

161. In 1993, Genzyme identified a demand by patients in the community for home delivery and provision of specialised care services in the home setting, which would obviate the need for the patient to go to hospital every time an infusion of Ceredase was required[184]. Genzyme appointed Caremark, a company operating as a specialised provider of delivery/homecare services

[182] Genzyme's written representations submitted on 25 October 2002, paragraph 3.10, page 69.

[183] See M.Cortvriend's note on the history of Cerezyme in the UK, attached to Genzyme's submission of 5 March 2002.

[184] See M. Cortvriend's note on the history of Cerezyme in the UK attached to Genzyme's submission of 5 March 2002.

for complex conditions, as its sole distributor and homecare services provider in the UK. HH replaced Caremark as Genzyme's sole and exclusive distributor and homecare services provider in May 1998. In May 2001, Genzyme began to distribute Cerezyme via its own delivery/homecare services operation, Genzyme Homecare.

162. In the UK, Genzyme's distribution of Cerezyme has two aspects:

(i) Sale by Genzyme to delivery/homecare services providers who buy Cerezyme for 'resale' to the NHS. Currently Genzyme has two 'customers' at this level: Genzyme Homecare[185] and HH. This activity comes within the market for the supply of drugs for the treatment of Gaucher disease, described above (the upstream market).

(ii) Sale of Cerezyme and provision of delivery and homecare services to the NHS. There are currently two players operating at this level: Genzyme Homecare and HH[186]. They sell the drug to the NHS. They deliver the drug to hospitals and patients' homes and provide the required level of homecare services to NHS patients. NHS patients fall broadly into two categories:

- Patients that receive infusions of Cerezyme in hospital. Cerezyme purchased for infusion in hospitals is delivered by the delivery/homecare services provider to the hospital against a pharmacy order. In this case, the service is limited to the delivery of Cerezyme to hospitals and sales support. No patient registrations are undertaken. HH does not currently have any patients in this category. The cost of delivering Cerezyme to a hospital is covered by Cerezyme's NHS list price (see paragraphs 68 to 83above). In this Decision, delivery of Cerezyme to hospitals and sales support will be referred to as 'Wholesale' or 'Wholesaling', and 'Wholesaler' should be construed accordingly.

[185] As part of the same legal entity as Genzyme, Genzyme Homecare does not actually 'purchase' the Cerezyme and is not, therefore, strictly speaking Genzyme's 'customer'. Genzyme purchases the Cerezyme from Genzyme B.V. (see Genzyme's submission of 5 March 2002 (response to request number 19) and Genzyme's submission of 1 May 2002 (response to question 2).

[186] There is another company, Central Homecare, who also operates at this level. However, it only purchases Cerezyme for the treatment of one patient. Before HH's agreement as exclusive distributor was terminated, Central Homecare purchased the Cerezyme from HH. Currently, Central Homecare sources its requirements from a hospital. In these special circumstances, the role played by Central Homecare is de minimis, and is not addressed further in this Decision.

- Patients that receive infusions of Cerezyme in their home. When the Cerezyme is purchased for infusion at the patient's home, the delivery/homecare services providers dispense the drug against a prescription and deliver it to the patient's home. In this case, the level of service may range from dispensing, home delivery, emergency help-line and provision of accessories (when the patient self-infuses) to comprehensive care, which might include any one or more of the following: taking complete charge of the infusion, training the patient to self-infuse, providing a 24-hour help line, supplying and monitoring the need for accessories (e.g. fridges, syringes, etc) and, among other things, advising on storage of the drug (see paragraphs 30 to 35 above). The NHS list price paid by the NHS for a drug is not intended to cover the cost of home delivery and provision of homecare services (see paragraphs 68 to 83 above).

163. Wholesaling could, in theory, be carried out by a company which does not operate as a delivery/homecare services provider. In fact, for some drugs, delivery to hospitals is undertaken directly by the manufacturer. However, in relation to Cerezyme, Wholesaling has always been undertaken by the delivery/homecare services provider appointed by Genzyme. The price charged for sales of Cerezyme to hospitals is the same price charged for sales of Cerezyme for use in the community (less a special concession to take account of the fact that the NHS pays VAT on sales of Cerezyme for use in hospitals but not on sales of Cerezyme for use in the community)[187].

164. Delivery of a drug to patients' homes is generally carried out by the same entity that provides the homecare services. In relation to Cerezyme, delivery to patients' homes has always been undertaken by Genzyme's appointed delivery/homecare services provider.

165. In its Response, Genzyme challenged the assertion that delivery of Cerezyme to a patient's home is part of the homecare services offered by Genzyme Homecare. Genzyme stated that the term 'homecare' in its written

[187]The price of £*[confidential]* (plus VAT) offered by Genzyme to hospitals is not a 'wholesale price'. According to Genzyme, this price is lower than the NHS list price of £2.975 per unit to take account of the fact that sales to hospitals attract VAT, while sales to the community do not. See paragraph 90 above. The reduced price is not intended to reflect cost savings arising from bulk delivery or any other cost savings resulting from wholesaling. According to Genzyme, the reduced price is simply a concession to take account of the VAT issue and was calculated in 1993 using the NHS list price as a reference.

representations is intended 'to mean nursing services carried out at a patient's home, but not the delivery of a drug to a patient's home'[188]. However, in its letter to the DoH dated 7 September 1999, Genzyme stated[189]:

> 'Our price of £618 per unit vial is the price which our home care provider, HealthCare at Home Limited [sic], supplies the product to the NHS. However, this, as I pointed out, does not just include the price of the drug. Healthcare at Home provide extensive nursing support to many patients, even to the extent of thrice weekly visits to patient's homes to administer two hour infusions. In addition, home delivery and ancillaries such as water for injection, infusion pumps and lines, needles, swabs, etc, are all provided as part of this service together with fridges for storage of drugs, etc.'[Emphasis added]

166. Further, when discussing the Director's conclusions on market definition, Genzyme stated that[190]

> 'There are two principal elements to homecare: (i) delivery of the drug for administration to the patient at either hospital or via a pharmacy at home and (ii) nursing care for those relatively few number of patients who do not self-administer the drug. The extent of either depends upon the treatment concerned.' [Emphasis added]

167. During the same discussion, Genzyme went on to say that[191]

> 'The supply of homecare services – which in fact involves separate activities of cool-chain delivery and nursing – has to be seen separately [from the supply of Cerezyme].' [Emphasis added]

168. In parts of its Response, therefore, Genzyme appeared to admit that delivery of the drug to the patient's home is an element of the homecare services offered by Genzyme Homecare.

169. Genzyme's main argument to exclude home delivery of Cerezyme from the provision of homecare services is that there is nothing particular about the home delivery of Cerezyme which would make it part of the provision of homecare services. According to Genzyme, any entity providing a delivery

---

[188] Genzyme's written representations submitted on 25 October 2002, footnote 1 at page 45.

[189] See letter from M.Cortvriend (Genzyme Therapeutics) to R.Bratt (DoH) dated 7 September 1999. Full text quoted in the 'Pricing' section above.

[190] Genzyme's written representations submitted on 25 October 2002, paragraph 10.10 at page 133.

[191] Ibid, paragraph 10.16 at page 135.

service in any other industry would be capable of undertaking the specialised type of cold chain delivery carried out by Genzyme Homecare's drivers[192].

170. In the Director's view, Genzyme ignores the fact that its 'Homecare Service Drivers'[193] do not simply deliver the drug to the patient's doorstep and leave. They go into the patient's home to assist the patient in unpacking the product and the ancillaries, they check that the stock held by the patient in his or her fridge is not out of date and, if necessary, they rotate the stock, and they remove all packaging and waste[194]. This would appear to go well beyond a basic delivery service. Furthermore, Dominic Moreland (Director, Genzyme Homecare) submitted in a statement to the Director that,

> 'Our drivers are also sent on training courses; they have been given therapy training courses which, though less intensive than those undergone by our nurses, nonetheless give them a thorough grounding in field [sic] of Gaucher and Fabry Disease and their treatment. They also attend advanced driving courses and receive regular Health and Safety updates.'[195]

171. Similarly, Julie Kelly (Senior Director of LSDs at Genzyme) indicated in a statement submitted to the Director that,

> 'The delivery drivers are another important point of contact between the patient and the homecare service provider,as they may see a patient more regularly than a nurse does (for example, where the patient is independent and self caring). For this reason, Genzyme Homecare has chosen their delivery drivers for their care experience or for personal qualities which make them particularly well-suited to the role. The head delivery driver is a former paramedic/ambulance driver.'[196]

172. In view of the above, the Director concludes that delivery of Cerezyme to the patient's home is part of the homecare services offered to patients by Genzyme Homecare. Home delivery of Cerezyme and provision of homecare services are considered together in this Decision and will be jointly referred to as 'Homecare Services'.

---

[192] Ibid, paragraphs 10.11 and 10.12 at page 134.

[193] See Genzyme Homecare's Homepack, 'Patient's Diary', 'Delivery Service' section.

[194] Ibid.

[195] Statement by D.Moreland (Director, Genzyme Homecare) dated 24 October 2002, paragraph 14, attached to Genzyme's written representations submitted on 25 October 2002.

[196] Statement by J.Kelly (Genzyme) dated 23 October 2002, paragraph 70, attached to Genzyme's written representations submitted on 25 October 2002.

173. In defining the relevant market, the Director has again started by looking at a relatively narrow potential market, which in this case comprises Wholesaling and Homecare Services. The next step is to consider how customers would react if prices were raised a small but significant amount above competitive levels.

174. The demand-side substitution of Homecare Services is necessarily determined by the nature of the services relevant to the drug required by the patient. A Gaucher patient's demand for Homecare Services can only be met by a delivery/homecare services provider with access to the appropriate drug (i.e. Cerezyme). If a Homecare Services provider increased the price of its services, a Gaucher patient who requires treatment with Cerezyme could not switch to another delivery/homecare services provider who may be cheaper but has no access to Cerezyme.

175. Similarly, a hospital's demand for Cerezyme can only be met by a wholesaler with access to that particular drug (i.e. Cerezyme). If a Wholesaler increased the price of its services, a hospital which required Cerezyme could not switch to another wholesaler who may be cheaper, but has no access to Cerezyme.

176. In 1998, the Monopolies and Mergers Commission ('MMC') produced a report on the proposed merger between two specialised delivery/homecare services providers, Fresenius AG ('Fresenius') and Caremark[197]. In its report, the MMC considered the issue of market definition in specialised homecare services markets. The report distinguished between 'prescribed services' (the supply of services with a drug on a single prescription) and 'contracted services' (where the services are provided separately from the drug). It is important to note that the terms 'prescribed' and 'contracted' services are not terms used by the NHS, but they were used by the MMC for the specific purposes of its analysis of the merger between Fresenius and Caremark. The MMC defined Gaucher disease as a prescribed service. In its discussion of demand-side substitution, the MMC report found that:

> 'In the context of determining whether different high-tech homecare treatment areas belong to the same market, however, it is clear that demand-side substitution between treatment areas may be ruled out as a possibility: the category of treatment suitable for a patient is a result of his or her healthcare needs, and healthcare providers are not in a position to choose between different treatment categories when providing care to a particular patient.'[198]

[197] Monopolies and Mergers Commission 'A report on the proposed merger Fresenius AG and Caremark Limited', Cm 3925 (April 1998).

[198] Ibid, paragraph 4.125.

177. Supply-side substitution for Homecare Services is possible in theory. Delivery/homecare services providers that currently provide treatments for other serious conditions (e.g. HIV, cancer, diabetes, multiple sclerosis) could, with some training, switch to providing Homecare Services[199]. In practice, however, any potential for supply-side substitution is prevented by Genzyme's policy of making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, combined with the terms of supply offered to independent delivery/homecare services providers. The delivery/homecare services provider's ability to compete is dependent on having access to Cerezyme at a price which allows it to offer Homecare Services on a viable basis. Since the price at which Cerezyme is sold to independent delivery/homecare services providers is the same price at which Genzyme Homecare supplies Cerezyme and Homecare Services direct to the NHS, it is impossible for an independent delivery/homecare services provider to operate a viable business offering Homecare Services[200]. Furthermore, as the NHS automatically pays a price which includes Homecare Services when it purchases Cerezyme, it has no incentive to demand the Homecare Services from anyone other than the Homecare Services provider appointed by Genzyme, even where the NHS might prefer to use a different one.

178. In its discussion of supply-side substitution for prescribed services, the MMC report on the proposed merger between Fresenius and Caremark stated:

> 'We believe it is necessary, in the light of this evidence, to draw a distinction between contracted and prescribed services. In prescribed services the possibility of entry by service providers depends on their ability to establish a relationship with the product supplier, which is the sole source of remuneration, and in effect to sell their services to them. The product suppliers effectively, therefore, have the discretion, if they so choose, to foreclose the supply of homecare service, either by providing the services in-house (vertical integration) or by establishing preferential relationships with individual service providers (vertical agreements), and in practice [...] have done so. Such foreclosure clearly limits the scope for supply-side substitution.'[201]

179. At paragraph 2.78, the MMC concluded:

---

[199] See note of telephone conversation between Transkaryotic Therapies (TKT) and the OFT on 17 April 2002.

[200] This argument is not undermined by HH's continued existence in the downstream market. HH has decided to remain in the market *[confidential]* but its position is not sustainable at Genzyme's current price and terms for the supply of Cerezyme.

[201] Monopolies and Mergers Commission 'A report on the proposed merger Fresenius AG and Caremark Limited', Cm 3925 (April 1998), paragraph 2.75.

'In principle the five prescribed services could also be in the same market because of the similarities in the services supplied and the assets and skills required, but in practice this method of funding ensures that suppliers of drugs and feeds determine who will supply the services associated with each treatment. Accordingly we believe it is necessary to examine supply for each of the prescribed services separately, while taking account of the possibilities for cross entry between them and from suppliers in the contracted service market.'

180. Similarly, at paragraph 4.128 the MMC found that:

'It is notable that the examples of difficulties in obtaining drugs cited by HaH [Healthcare at Home] (...) (i.e. Gaucher disease (...)) were all in relation to prescribed services. As discussed in paragraph 4.97, the funding system for prescribed services implies that a homecare compay generally gains business in these areas only if the relevant pharmaceutical supplier either offers it the product at a suitable discount or, alternatively, makes the homecare company a payment to cover its services. To the extent that pharmaceutical companies are unwilling to make such arrangements with different homecare providers, the potential for supply-side substitution between treatments will be reduced.'

181. A similar argument applies to Wholesaling. Supply-side substitution is possible in theory since entities that currently deliver drugs to hospitals, could relatively easily start Wholesaling. In practice, however, it is not possible for anyone other than Genzyme (or an undertaking acting under contract for Genzyme) to Wholesale, as Genzyme supplies Cerezyme to independent wholesalers at the NHS list price of £2.975 (plus VAT) per unit (i.e. a price higher than that offered by Genzyme Homecare to hospitals, which is £*[confidential]* plus VAT) therefore preventing independent entities from Wholesaling viably.[202].

182. It is possible that Wholesaling could be a separate market from the provision of Homecare Services. However, the Director does not need to reach a conclusion in this case, as the analysis of Genzyme's behaviour is the same whether both activities are segments of the same market or are in separate markets.

[202] Note that the price of £*[confidential]* (plus VAT) offered by Genzyme to the NHS for Cerezyme to be used in hospitals is not a 'wholesale price'. According to Genzyme, this price is lower than the NHS list price of £2.975 per unit to take account of the fact that sales of Cerezyme for use in hospitals attract VAT, while sales of Cerezyme for use in the community do not (see paragraph 90 above). The reduced price is not intended to reflect cost savings arising from bulk delivery or any other cost savings resulting from wholesaling. According to Genzyme, the reduced price is simply a concession to take account of the VAT issue and was calculated using the NHS list price (at the time £3.09 per unit) as a reference (see paragraph 90 above).

183. In the circumstances, the Director is proceeding on the basis that there is a separate relevant downstream market which, at most, comprises delivery of Cerezyme to hospitals and sales support (i.e. Wholesaling[203]) and home delivery of Cerezyme and provision of homecare services (i.e. Homecare Services[204]). In this Decision, this market will hereinafter be referred to as the 'downstream market'. Wholesaling will be referred to as the 'Wholesale segment' of the downstream market and Homecare Services will be referred to as the 'Homecare Services segment' of the downstream market.

184. Genzyme has contested the Director's finding of a downstream market. According to Genzyme, there is only one market, namely the 'market for the supply of drugs for the treatment of LSDs, whether by ERT or any other method'[205]. Alternatively, in so far as there is a downstream market, this would include all homecare services in the UK[206]. In so far as this market exists, Genzyme argued that it does not compete in it[207].

185. Genzyme challenged the Director's conclusions on demand-side substitution. According to Genzyme, 'the Director's finding that the demand-side substitution of homecare services is necessarily determined by the nature of the services relevant to the drug required by the patient is not borne out by the evidence and is contradicted by the MMC report *Fresenius/Caremark*'[208]. In support of this, Genzyme stated that[209],

> 'As regards homecare services which may be provided for Gaucher disease patients being treated with Cerezyme, those services plainly do not constitute a market in their own right. (...) As the Monopolies and Mergers Commission ('MMC') said in its report into the proposed *Fresenius/Caremark* merger (volume 12, section 1), there are similarities in the homecare services themselves and in the assets and skills used to provide them.'

186. Genzyme's reference to 'Volume 12, section 1' is a reference to a copy of the MMC report and not to any particular section in the report. The Director

---

[203] See definition in paragraph 162 (ii) above.

[204] See definition in paragraph 172 above.

[205] Genzyme's written representations submitted on 25 October 2002, paragraph 9.5 at page 120.

[206] Genzyme's written representations submitted on 25 October 2002, paragraph10.25 at page 138.

[207] Ibid, paragraph 10.28 at page 138.

[208] Ibid, paragraph 10.9 at page 133.

[209] Ibid, paragraph 1.3 at page 46.

has reviewed the report carefully and has found several references to the fact that, contrary to Genzyme's contention, the demand-side substitution of homecare services is determined by the nature of the services relevant to the drug required by the patient. In fact, the wording referred to by Genzyme to support its conclusion, namely that 'there are similarities in the homecare services themselves and in the assets and skills used to provide them', can be found in a paragraph which, when read in its entirety, supports the Director's findings. Paragraph 2.78 of the MMC report, under the section 'Market Definition', states:

> 'In principle, the five prescribed services could also be in the same market because of the similarities in the services supplied and the assets and skills required, but in practice this method of funding ensures that suppliers of drugs and feeds determine who will supply the services associated with each treatment. Accordingly, we believe it is necessary to examine supply for each of the prescribed services separately.' [Emphasis added]

187. Paragraphs 2.70 and 2.71 set out the framework within which the MMC defined the relevant markets:

> 'In order to assess the merger's effects on competition we define first the scope of the market or markets within which the effects will be felt. This issue generally turns on whether services or products are substitutable, so that competition between them is sufficient to restrict a company's ability to raise its prices above competitive levels.
>
> In the case of the services considered in this inquiry, there is no substitutability on the demand side, in the usual sense, because each treatment is specific to a particular condition, although it is possible for purchasers to redefine the requirement, for example by hospitals providing compounding and nursing services and contracting out only the delivery element. The issue of market definition, therefore, depends principally on the extent of supply-side substitution, that is the ease and speed with which a producer of one product or service is able to offer another in response to a price rise or the opportunity to offer the service at a lower cost.'

188. The Director's downstream market definition is therefore in line with the MMC's findings in *Fresenius/Caremark*.

189. Another argument used by Genzyme to challenge the Director's market definition is that 'similar nursing services are required for many diseases other than LSDs. Nursing services in the case of ERTs for Gaucher disease and other LSDs are only required for those patients who do not self-administer. (...) Any reasonably competent nurse can be taught about the treatment of Gaucher or Fabry disease or with any other disease or condition

requiring infusion. There is nothing disease specific about the procedure that nurses are required to carry out.'[210]

190. The Director has dealt with this in paragraph 177 above. The Director acknowledges that supply-side substitution for Homecare Services is possible in theory. In practice, however, any potential for supply-side substitution is prevented by Genzyme's policy of making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, combined with the terms of supply offered to independent delivery/homecare services providers. The ability of delivery/homecare services providers to transfer skills and begin offering Homecare Services is in practice constrained because they are unable to obtain Cerezyme at a price which allows them to offer Homecare Services on a viable basis[211].

191. Genzyme denies that it has a policy of making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme. According to Genzyme, it provides the Homecare Services to the NHS for free. This point is discussed below under the 'Abuse' section of this Decision.

(ii) Relevant geographic market

(a) The upstream market

192. Cerezyme is manufactured in Boston, Massachusetts, USA[212]. The country of first import into the European Union is the UK. Cerezyme is sent to Genzyme's premises in Haverhill, Suffolk, UK where it is packaged and appropriately labelled for sale in Europe[213].

[210] Ibid, paragraph 10.16 at page 135.

[211] See in this respect, MMC report on *Fresenius/Caremark* at paragraph 2.73 where the MMC records the views of a number of service providers: 'Caremark told us that its staff were readily interchangeable between the different treatments, subject to receiving 'top up' training, where necessary, in relation to a particular treatment. Most of the drugs and equipment required, however were specific to individual treatments. Similar views were expressed by other service providers, although some said that their ability to transfer skills was in practice constrained because they were unable to offer homecare services on a viable basis. The examples given were (...) Gaucher's disease (...).' [Emphasis added]

[212] Genzyme Form 10-K (2000).

[213] Letter from J.M. Paardekooper (Associate Director Regulatory Affairs Europe, Genzyme B.V.) to the EMEA, dated 10 May 1996.

193. Zavesca will be manufactured by OGS and distributed throughout the EU by a Swiss company called Actelion Ltd[214].

194. As explained in paragraphs 40 to 51 above, in order to market a medicinal product in the UK, an undertaking must obtain marketing authorisation either at UK level (from the MCA) or at European level (from the EMEA). This is likely to take at least a year and could take two to three years[215]. Similarly, a company wishing to wholesale medicinal products within the EU, must hold a wholesale dealer's licence or, where the medicines are imported from outside the EEA, a wholesale dealer's import licence. Obtaining an import licence is also likely to take some time[216].

195. In *Napp,* in concluding that the geographic market in that case was national[217], the Director referred to the European Commission's decision in *Hoffmann-La Roche/Boehringer Mannheim*, where the Commission found that:

> 'The sale of medicines is influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in the Member States. Some countries exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social-security system for different categories of medicines. For this reason, the prices for medicinal products may differ from one Member State to another. In addition, there are far-reaching differences in terms of brand and pack-size strategies

[214] OGS press release entitled 'European Commission approval for Zavesca' dated 26 November 2002.

[215] Genzyme applied for marketing authorisation for Cerezyme to the EMEA on 10 May 1996 and obtained it over a year later on 18 November 1997. Zavesca applied for marketing authorisation on 29 June 2001 and obtained it over a year later on 20 November 2002.

[216] It is the MCA's view that it is difficult to estimate how long it takes to issue an import licence, given that there are a number of factors affecting the length of the procedure, which are beyond the MCA's control. For example, there is usually a need to wait for information from the regulatory authority in the member state concerned to ensure that the product to be imported has no differences, having a therapeutic effect, from the corresponding UK product. Also, there are often delays in the applicant responding to requested changes in their application, to the text of their proposed labelling and to the drafting of their patient information leaflet (see Decision of the Director General CA98/2/2001 *Napp Pharmaceutical Holdings Limited*, 30 March 2001, footnote 57).

[217] DGFT Decision No. CA98/2/2001 *Napp Pharmaceutical Holdings Limited*, 30 March 2002, paragraphs 89 to 93.

and in distribution systems. These differences lead to national market characteristics.'[218]

196. In view of all these factors, the Director considers that the relevant geographic market for the supply of drugs for the treatment of Gaucher disease (the upstream market) is the UK.

(b) The downstream market

197. An entity operating in the downstream market must be able to deliver the Cerezyme to hospitals (Wholesale) and to deliver the Cerezyme to individual patients' homes and provide the required level of homecare services (Homecare Services). The rarity of the disease means that the number of patients in any given area is unlikely to be sufficient to run a viable local business in the downstream market. This means that Wholesalers/Homecare Services providers need to access hospitals and patients across a relatively wide area so that they encompass a sufficient number of hospitals and patients.

198. Both Genzyme Homecare and HH provide or have provided Wholesale/Homecare Services across the UK. While it is possible to offer such services on a purely local basis, it seems unlikely that a hypothetical monopoly supplier in a locality would have the ability to charge a price significantly above the competitive level because of competition from other Wholesalers/Homecare Services providers in adjacent locations.

199. Genzyme Homecare and HH charge the NHS a uniform price across the UK.

200. The Director considers that the geographic dimension of the downstream market is not wider than the UK.

3. Assessment of Dominance

201. In assessing dominance, the Director considers whether and to what extent an undertaking faces constraints on its ability to behave independently. Those constraints may be:

(i) existing competitors, according to their strength in the market, which may be shown by market shares;

(ii) potential competitors, which may be shown by a lack of significant entry barriers and the existence of other undertakings which might easily enter the market; and

[218] Commission Decision IV/M.950, *Hoffmann-La Roche/Boehringer Mannheim* (1998) OJ L234/14, paragraphs 16 and 17.

(iii) other constraints, such as strong buyer power from the undertaking's customers[219].

(i) The upstream market

(a) Existing competitors

202. For over ten years, Cerezyme was the only drug developed specifically for the treatment of Gaucher disease[220]. According to Genzyme, the fact that Cerezyme was the only treatment available for Gaucher disease is well known and not disputed[221].

203. On 20 November 2002, four months after the Director issued the Rule 14 Notice, the European Commission granted marketing authorisation in the EU for Zavesca[222]. Zavesca is the only other drug, apart from Cerezyme, authorised for the treatment of Gaucher disease. Zavesca became available in the UK on 3 March 2003. Zavesca is an oral drug.

204. ERT is currently the treatment of choice and the preferred standard of care for Gaucher patients[223]. Cerezyme is the only ERT currently available for the treatment of Gaucher disease. Zavesca is not an ERT. It is expected that only a small number of Gaucher patients in the UK will be treated with Zavesca instead of ERT (i.e. Cerezyme)[224].

---

[219] OFT Guideline 402 'The Chapter II Prohibition', paragraph 3.11.

[220] 'Living with Gaucher disease', page16.

[221] See Genzyme's written representations submitted on 25 October 2002, paragraph 9.18 at page 124.

[222] Document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003.

[223] See note of meeting with Professor Cox, dated 16 January 2003. See also document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, pages 23 and 27.

[224] Zavesca's marketing authorisation states that Zavesca may only be used in the treatment of patients for whom ERT is unsuitable. Given that Zavesca has only recently received marketing authorisation, the relevant specialist consultants have not been able to give the Director an accurate indication of how many Gaucher patients will be prescribed Zavesca in the UK. There are two specialist consultants in the UK who must be involved in any decision to prescribe Zavesca: Professor Cox and Dr Mehta (see paragraph 217 below). Dr Mehta has told the Director that, as things currently stand, he does not expect to actively prescribe Zavesca (see note of telephone conversation between the OFT and Dr Mehta (Royal Free Hospital) dated 21 January 2003). Professor Cox has told the Director that he only expects to prescribe Zavesca to a small

205. ERT (i.e. Cerezyme) has significantly changed the treatment of Gaucher disease by safely and effectively arresting, decreasing or normalising many of its major signs and symptoms. This treatment has essentially obviated the need for other treatments, such as symptomatic treatments (which attack the symptoms, but not the disease) and bone marrow transplantation, which is a highly risky procedure associated with high mortality[225].

206. According to the Chief Scientific Officer of Genzyme Corporation, Dr Alan Smith, Cerezyme is spectacularly efficacious and works in essentially all patients[226]. This view is supported by a panel of European Gaucher expert consultants who have stated that ERT (i.e. Cerezyme) is the preferred standard of care for Gaucher patients[227]. Similarly, the EMEA has indicated that ERT (i.e. Cerezyme) is currently the treatment ofchoice in treatment-naïve patients with Gaucher disease[228].

207. The only other drug authorised for the treatment of Gaucher diease in Europe is Zavesca. Zavesca is manufactured by the UK pharmaceutical company, OGS and distributed by the Swiss company, Actelion Plc ('Actelion'). Zavesca became available for use in the UK on 3 March 2003[229].

208. Zavesca is not an ERT but a substrate balance therapy (see paragraph 24 above) aimed at inhibiting the formation of waste material, but (unlike Cerezyme) it does not eliminate the waste already stored.

209. Zavesca received marketing authorisation from the European Commission on 20 November 2002[230]. According to the marketing authorisation, Zavesca may be used only in the treatment of patients with mild to moderate Gaucher

---

number of his patients (see note of meeting with Professor Cox, dated 16 January 2003).

[225] Cerezyme Product Monograph published by Genzyme in 1998, page 8.

[226] Dr Smith's statement in the Transcript of the oral hearing of 6 November 2002, at page 39, lines 22-30.

[227] See note of meeting with Professor Cox, dated 16 January 2003.

[228] Document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, pages 23 and 27.

[229] See OGS press release 'Actelion starts launch of Zavesca in the European Union' dated 3 March 2003.

[230] Document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003.

disease for whom ERT is unsuitable[231]. ERT remains the preferred standard of care for patients who require treatment for Gaucher disease and, therefore, in the UK, Zavesca is expected to be a second line drug[232].

210. Zavesca can only be prescribed by physicians who are knowledgeable in the management of Gaucher disease and its use is not recommended for children and adolescents[233]. There are only two doctors in the UK who can decide to treat patients with Zavesca: Professor Cox and Dr Mehta (see paragraph 217 below). Dr Mehta has told the Director that, as things currently stand, he does not expect to actively prescribe Zavesca.[234] Professor Cox has told the Director that he only expects to prescribe Zavesca to a small number of his patients[235].

211. Further evidence of the limited application of Zavesca is provided by the EMEA, which has stated that

> 'In summary, defining an indication for Zavesca is difficult because of the limited trial data. The study in treatment naïve patients included only those with mild to moderated type 1 Gaucher disease AND who are unsuitable or unwilling to receive ERT. Therefore the potential target population is already limited. Enzyme replacement therapy is the current treatment of choice in treatment-naïve patients with type 1 Gaucher disease. Despite a lack of direct comparative studies, it appears that Zavesca does not offer any efficacy advantage over ERT.
>
> (...)
>
> Although no direct comparisons with Enzyme Replacement Therapy (ERT) have been performed in treatment naïve patients, it appears that it would take longer to achieve an effect with Zavesca and Zavesca does not offer any

[231] OGS Press Release, 'European Commission approval for Zavesca', dated 26 November 2002. See also document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, page 23.

[232] See note of meeting with Professor Cox dated 16 January 2002. See also email from Professor Cox to E. Perrott (TV) dated 21 February 2003. See also document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003.

[233] See document entitled 'Summary of Product Characteristics' for Zavesca, published by OGS on 20 November 2002. See also document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003.

[234] See note of telephone conversation between the OFT and Dr Mehta (Royal Free Hospital) dated 21 January 2003.

[235] See note of meeting with Professor Cox, dated 16 January 2003.

efficacy advantage over ERT. It is yet unknown if treatment with Zavesca would achieve the same object obtainable with ERT, the current standard of care for patients who require treatment for type 1 Gaucher disease.'[236]

212. And,

> '(...) the benefit/risk profile of Zavesca was acceptable only for a small subset of patients with type 1 Gaucher disease for whom enzyme replacement therapy was unsuitable as assessed by physicians knowledgeable in the treatment of patients with this disease. This assessment forms the basis of a restricted indication.'[237]

213. During the clinical trials for Zavesca (previously known as Vevesca), preliminary results suggested that, at least initially, it might be a partial substitute being used alongside reduced Cerezyme dosages and allowing patients to have 'enzyme holidays'. However, Zavesca has received marketing authorisation for use only in patients for whom ERT (i.e. Cerezyme) is unsuitable[238]. Where ERT is suitable, therefore, Zavesca will not be prescribed.

214. Zavesca's marketing authorisation was granted 'under exceptional circumstances'[239]. Therefore, Zavesca's marketing approval is subject to stringent conditions aimed at ensuring that the drug is safe[240]. For the first three years after the launch of Zavesca, OGS will have to carry out and submit to the EMEA the results of rigorous clinical tests and pre-clinical follow-up measures to enable the EMEA to monitor the safety of Zavesca[241].

---

[236] Document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, pages 23 and 27.

[237] Ibid, Abstract.

[238] OGS Press Release, 'European Commission approval for Zavesca', dated 26 November 2002.

[239] OGS Press Release, 'European Commission approval for Zavesca', dated 26 November 2002.

[240] Document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, page 23. See also note of meeting with Professor Cox, dated 16 January 2002.

[241] See note of meeting with Professor Cox, dated 16 January 2002. See also document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, page 29.

The Summary of Product Characteristics published by OGS for Zavesca[242] reveals the reason for such stringent conditions:

> **'4.4 Special warnings and special precautions**
>
> Although no direct comparisons with Enzyme Replacement Therapy (ERT) have been performed in treatment naïve patients, it appears that it would take longer to achieve an effect with Zavesca and there is no evidence of an efficacy or safety advantage over ERT. ERT is the standard of care for patients who require treatment for type I Gaucher disease (see section 5.1). The efficacy and safety of Zavesca has not been evaluated in patients with severe Gaucher disease, defined as a haemoglobin concentration below 9 g/dl or a placelet count below 50 x 10 9/l or active bone disease.
>
> Approximately 30% of patients have reported tremor or exacerbation of existing tremor on treatment. These tremors were described as an exaggerated physiological tremor of the hands. Tremor usually began within the first month and in many cases resolved between 1 to 3 months during treatment. Dose reduction may ameliorate the tremor usually within days, but discontinuation with treatment may sometimes be required.
>
> Cases of peripheral neuropathy have been reported in patients treated with Zavesca with or without concurrent conditions such as vitamin B12 deficiency and monoclonal gammapathy. (...)
>
> Isolated cases of cognitive dysfunction have been reported during clinical trials (...)
>
> Until further information is available, it is advised that before seeking to conceive, male patients should cease Zavesca and maintain reliable contraceptive methods for 3 months thereafter.
>
> Due to limited experience, Zavesca should be used with caution in patients with renal or hepatic impairment.
>
> (...)
>
> **4.8 Undesirable effects**
>
> Adverse events reported in clinical trials with Zavesca in 82 patients are listed in the table below by body system and frequency (very common: > 1/10, common: > 1/100, < 1/10). Most events were of mild to moderate severity.

Metabolism and Nutrition Disorders	
Very Common	Weight loss
Common	Decreased appetite, weight increase

[242] See 'Summary of Product Characteristics' for Zavesca, published by OGS on 20 November 2002.

Nervous System Disorders	
Very Common	Tremor, dizziness, headache, leg cramps
Common	Paraesthesia, peripheral neuropathy, cognitive dysfunction
Eye Disorders	
Very Common	Visual disturbance
Gastrointestinal Disorders	
Very Common	Diarrhoea, flatulence, abdominal pain, nausea, constipation, vomiting
Common	Dyspepsia, distension

(...)

5.3 Preclinical safety data

The main effects common to all species were weight loss and diarrhoea, and, at higher doses, damage to the gastrointestinal mucosa (erosions and ulceration). Further, effects seen in animals at doses that result in exposure levels moderately higher than the clinical exposure level were: changes in lymphoid organs in all species tested, transaminase changes, vacuolation of thyroid and pancreas, cataracts, nephropathy and myocardial changes in rats. These findings were considered to be secondary to debilitation.

Repeated dose toxicity studies in rats showed effects on the seminiferous epithelium of the testes. Other studies revealed changes in sperm parameters (motility and morphology) consistent with an observed reduction in fertility. These effects occurred at exposure levels similar to those in patients but showed reversibility. Miglustat affected embryo/foetal survival in rats and rabbits; dystocia was reported; postimplantation losses were increased and an increased incidence of vascular anomalies occurred in rabbits. These effects may be partly related to maternal toxicity.'

215. The list of Zavesca's potential adverse effects is, therefore, long. Professor Cox, UK expert in this field, explained that it is not usual that a drug with so many indicated adverse effects would be granted marketing authorisation and that this is in fact the reason why Zavesca has received marketing approval subject to a large number of conditions to ensure its safety[243]. Professor Cox explained that during its first three years, Zavesca will remain 'on trial' and

[243] See note of meeting with Professor Cox, dated 16 January 2002. See also Council Directive 2001/83/EC, Annex 1, Part 4, Section G.

OGS will need to submit a large amount of safety information to the EMEA[244].

216. Further, the EMEA has stated that

> 'There are unresolved safety concerns that need to be addressed. Therefore, follow-up studies should be considered. In view of the small number of patients, the preference for larger benefit achieved with ERT and the 'open' studies that will be conducted, any future studies would have difficulties in recruiting a sufficient number of patients.'[245]

217. Zavesca is only suitable for use in adults (approximately over 18 years old) and must be prescribed by an expert consultant. The Director has consulted the two doctors in charge of care of adult Gaucher patients in the UK (Professor Cox and Dr Mehta)[246] on the likely impact of Zavesca on the treatment of Gaucher disease in the UK. Zavesca will not be prescribed to any patient in the UK, without the involvement of Dr Mehta or Professor Cox. Both Professor Cox and Dr Mehta are experts in the field and have participated in drafting an agreed position statement on behalf of Gaucher specialists across Europe, setting out the circumstances in which Zavesca will be prescribed (the 'Position Statement'). In addition, Professor Cox was involved in Zavesca's clinical trials and the marketing authorisation procedure.

218. Professor Cox explained that according to the Position Statement ERT continues to be the preferred standard of care for Gaucher patients[247].

---

[244] Ibid.

[245] Document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, page 29.

[246] The patients treated by the other two expert consultants in the UK, Dr Vellodi (Great Ormond Street Hospital) and Dr Wraith (Royal Manchester Childrens' Hospital) are children, for whom the use of Zavesca is not recommended. Dr Wraith has approximately 10 adult patients (who he treated as children), but these are included in the patients treated by Professor Cox. Genzyme submitted that Dr Vellodi 'is about to commence treating a group of children suffering from Gaucher Disease with Zavesca' (see Genzyme's third written representations submitted on 26 February 2003). Genzyme submitted no supporting evidence for this assertion. The Director contacted Dr Vellodi who confirmed that Genzyme's assertion was incorrect. Dr Vellodi will be involved in a clinical trial to test OGT 918 in children with Type 3 Gaucher disease. The clinical trial is designed to test OGT 918 in combination with Cerezyme and the children involved will remain on the same dosage of Cerezyme (see note of telephone conversation between the OFT and Dr Vellodi dated 4 March 2003). It is therefore clear that Dr Vellodi is not, and will not be, involved in prescribing Zavesca under its current marketing authorisation.

[247] This is also acknowledged in Zavesca's Summary of Product Characteristics, published by OGS on 20 November 2002.

According to Professor Cox, Zavesca is likely to have significant impact in countries where patients do not currently receive ERT (i.e. Cerezyme) because of its cost. In contrast, in the UK, where ERT is given to all patients who need it and can tolerate it, Zavesca's impact is likely to be minimal. In the UK Zavesca will be a second line drug for the treatment of Gaucher disease and it is likely to be taken by a small minority of patients. Professor Cox also explained that during its first three years, Zavesca will remain 'on trial' and OGS will need to submit a large amount of safety information to the EMEA. While Professor Cox has identified a number of his patients who may be suitable for Zavesca, he said that the number is small[248].

219. Professor Cox explained that[249], according to the Position Statement, Zavesca will be prescribed in the following circumstances:

(a) For patients naïve to treatment (i.e. patients who have never received any treatment before) with mild or moderate symptoms, who are unwilling or unable to receive ERT for medical or personal reasons;

(b) For patients unwilling or unable to continue receiving ERT, for example because of needle phobia, persistent difficulties, poor compliance, poor access to veins, religious reasons, particular occupations or travelling arrangements, patients with infusion reactions; and

(c) For patients with persistent signs of the disease where ERT has not been completely effective. In these cases, Zavesca would be used in combination with ERT. According to the Position Statement, the product licence does not preclude this although such patients would require frequent monitoring. Professor Cox believes that very few patients would be in this category.

220. It is important to note that Genzyme is of the opinion that Zavesca should not be used in combination with Cerezyme (i.e. the last category of patients described above). Genzyme has told the Director that tests have shown that, used with Cerezyme, Zavesca may inhibit the effectiveness of Cerezyme in patients[250].

---

[248] See note of meeting with Professor Cox, dated 16 January 2003.

[249] Ibid.

[250] See Genzyme's written submissions dated 25 October 2002, Volume 3, Part 1, statement by E.Tambuyzer, Vice President of Corporate Affairs, Genzyme Europe BV, paragraph 10 at page 6.

221. Doctor Mehta told the Director that, in his view, Zavesca will not have a major impact in the UK and will be suitable for only a very small number of patients. In fact, Dr Mehta stated that, as things currently stand, he sees Zavesca being used more for research rather than as a medicine he would actively prescribe. Dr Mehta emphasised that more clinical trials are required to ensure the safety of Zavesca[251].

222. Professor Cox's and Dr Mehta's expert opinions on the limited impact that Zavesca will have in the UK, together with the limited marketing authorisation granted to Zavesca and the views expressed by the EMEA, all suggest that Zavesca will not, at least in the short to medium term, generate the movement of any significant number of Gaucher patients away from treatment with Cerezyme and onto treatment with Zavesca.

223. Moreover, the Director is of the view that prior to Zavesca receiving marketing authorisation in the EU, Genzyme did not consider it a significant competitive threat. Following a request from the Director to submit internal documents discussing the likely impact on the demand for Cerezyme of Zavesca's approval as a drug for the treatment of Gaucher disease, Genzyme was unable to produce any[252]. As a general proposition, the Director considers it unlikely that in the face of the imminent entry of a competitor potentially posing a significant competitive threat, a company would not produce any business/strategy documents or hold any discussions at company meetings.

224. In its Response to the Rule 14 Notice, Genzyme argued that Zavesca has the potential to take away much of Cerezyme's market share[253]. Genzyme itself accepts, however, that it is unclear to what extent Zavesca could be a total replacement for Cerezyme and that only if effective would it provide

---

[251] See note of telephone conversation between the OFT and Dr Mehta (Royal Free), dated 21 January 2003.

[252] In response to an information request under section 26 of the Act dated 30 November 2001, Genzyme submitted a manuscript note of a meeting with HH held on 29 July 1999. One of the annotations read 'E patients at risk to go to oral alternative (OGS)'. In a further information request under section 26 of the Act dated 12 February 2002, the Director asked Genzyme to provide any documents produced by or on behalf of Genzyme considering the effect that the availability of OGS's oral treatment may have on the supply of Cerezyme, and in particular, but not exclusively, on the physician's choice of, or the patients' preferences for, Cerezyme. Although Genzyme submitted in its response of 5 March 2002, that the context in which the annotation had been made at the meeting of 29 July 1999 was that it viewed the OGS oral alternative as a significant potential competitor, it did not submit any other documents on this point.

[253] Genzyme's written representations submitted on 25 October 2002, paragraph 9.30 at page 127.

significant competition to Cerezyme[254]. According to Genzyme 'If an orally administered drug to treat successfully Gaucher disease can be developed – as OGS believes is the case with Zavesca – then it has the potential to remove Cerezyme from the market or to reduce its position almost overnight'[255]. With regard to the limitation in Zavesca's marketing authorisation, namely, that it can only be used in patients for whom ERT is unsuitable, Genzyme submitted that 'we do not know what is meant by 'suitable'. (...) Zavesca may prove to be much more 'suitable' than ERT for many patients. At any rate, the Director has no evidence to conclude that it will not be more suitable'[256].

225. On the basis of the limited marketing authorisation granted to Zavesca, the views expressed by the EMEA and the expert opinions of Professor Cox and Dr Mehta, the Director is of the view that the introduction of Zavesca will not, in the short to medium term, remove Cerezyme from the upstream market or significantly reduce its position in such market.

(b) Market shares

226. The ECJ has stated that, save in exceptional circumstances, dominance can be presumed, in the absence of evidence to the contrary, if an undertaking has a market share persistently above 50%[257].

227. From 1991 until 3 March 2003, Genzyme was the only supplier of drugs for the treatment of Gaucher disease. Genzyme's share of the relevant market for the supply of drugs for the treatment of Gaucher disease was during this period of twelve years 100%. Such a share of a relevant market is, in itself, a clear indication of the existence of a dominant position in the relevant market[258].

228. Following the launch of Zavesca in the UK on 3 March 2003, OGS entered the upstream market. The Director is of the view that Zavesca will, at least

---

[254] Ibid, paragraph 4.31 at page 81.

[255] Ibid, paragraph 1.14 at page 50.

[256] Genzyme's supplementary written representations submitted on 9 December 2002, paragraph 2.4 at page 6.

[257] OFT Guideline 402 'The Chapter II Prohibition', paragraph 3.13. See also Case T-30/89 *Hilti AG v Commission* [1991] ECR II-1439, paragraph 92; Case 62/86 *AKZO Chemie BV v Commission* [1991] ECR I-3359, paragraph 60; Case T83/91 *Tetra Pak v Commission* [1994] ECR II-755, paragraph 109.

[258] Case T-30/89 *Hilti AG v Commission* [1991] ECR II-1439, paragraph 92; Case 62/86 *AKZO Chemie BV v Commission* [1991] ECR I-3359, paragraph 60; Case T83/91 *Tetra Pak v Commission* [1994] ECR II-755, paragraph 109.

in the short to medium term, have a minimal impact on Genzyme's share of the market for the supply of drugs for the treatment of Gaucher disease. This is mainly because of the limitation incorporated into Zavesca's marketing authorisation, which prevents its use on patients for whom ERT (i.e. Cerezyme) is suitable[259]. It is also based on the opinion of the two UK expert consultants who will be prescribing Cerezyme and Zavesca, that the impact of Zavesca in the treatment of Gaucher disease in the UK will be minimal (see paragraphs 215 to 222 above).

229. The Director is of the view, therefore, that following Zavesca's launch Genzyme's share of the relevant market for the supply of drugs for the treatment of Gaucher disease will continue to be significant and, probably above 90% in the short to medium term.

(c) Barriers to entry - General

230. The Director has also considered the existence of barriers to enter the upstream market. The lower the barriers to entry, the more likely it is that potential competition will prevent undertakings within the market from exerting market power[260].

231. Barriers to enter this market are high and include carrying out R&D, completing clinical trials, developing a manufacturing process, obtaining a manufacturing licence and obtaining a marketing authorisation. These barriers are not insurmountable, but do represent a significant hurdle for anyone trying to enter the market.

232. Ceredase was developed after significant investment by the United States government with much of the scientific research being sponsored or performed by the US National Institute of Health (NIH)[261]. Genzyme did not itself discover alglucerease (the generic name for Ceredase) and could not therefore obtain a patent on the drug. It did however obtain orphan drug status in the US for Ceredase[262]. Orphan drug status in the US means that a drug has marketing exclusivity within the US for seven years.

---

[259] Document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by the EMEA in 2003, page 23.

[260] See OFT Guideline 415 'Assessment of Market Power', Part 5.

[261] See 'Federal and Private Roles in the Development and Provision of Alglucerase Therapy for Gaucher Disease' A report by the US Government Office of Technology Assessment, October 1992.

[262] Ibid.

233. In relation to Cerezyme, Genzyme obtained a licence from the Scripps Institute in California in the early 1990s to use the gene necessary to develop the recombinant form of the enzyme. This resulted in the launch of Cerezyme in the US in 1995[263].

234. Genzyme obtained orphan drug status for Cerezyme in the US. Orphan drug status for Cerezyme (and Ceredase) in the US expired in 2001. Cerezyme has never had orphan drug status in the UK, as it was introduced in the UK before such status became available in Europe[264]. However, Cereyme was accepted by the EMEA as having the equivalent status to an orphan drug, as from 19 November 1997[265].

235. In Europe (and in the US) Cerezyme is protected by two patents on the production process. One is on the method for producing enzymatically active recombinant glucocerebrosidase, which expires on 22 December 2009 and the other is on the production of enzymatically active glucocerebrosidase from recombinant cells, which expires on 17 January 2012[266].

236. Genzyme enjoys a natural first-mover advantage which also makes it difficult for other companies to enter the market. The number of Gaucher patients receiving treatment is small (approximately 180 receiving treatment in the UK) and there are correspondingly relatively few new patients diagnosed each year. There may be sufferers who do not know they have the disease and some who have such mild symptoms that are not undergoing any treatment. In any case, the number of Gaucher patients receiving treatment at any one time is likely to remain constant with little or no room for overall expansion of demand. This impacts on a potential new entrant's ability to find patients on which to conduct clinical trials. As explained by Professor Cox during an interview with Genzyme,

> 'TC [Professor Cox] responding that new clinical trials will be difficult in the future as most patients are already on Cerezyme. Since most patients are now treated, there is only a very limited number of patients new to treatment who could be trialled. TC believes this figure to make up under 10% of the actual sufferers of Gaucher's Disease in his practice and in the UK. However,

[263] Goozener, M, 'The Price Isn't Right', The American Prospect Magazine, volume 11, no. 20, 11 September 2000.

[264] See letter from Taylor Vinters to the OFT dated 27 March 2002, page 3.

[265] Genzyme's written representations submitted on 25 October 2002, paragraph 2.8 at page 62.

[266] See 'IP Portfolio for Cerezyme' submitted by Genzyme to the OFT on 30 November 2001.

whilst new trials e.g. of other 'small molecules' such as Zavesca and Genzyme's agent, P4, would be difficult to conduct in previously tested patients, perfectly satisfactory data can be obtained for well-designed studies.'[267]

237. Genzyme has submitted that the fact that a significant proportion of LSD sufferers are known, means that they are readily available for clinical trials[268]. This is incorrect. As illustrated by Professor Cox's statement quoted above, whether or not patients are available for clinical trials depends mainly on finding treatment naïve patients (i.e. those who have not previously undergone any treatment), and not simply on whether the patients are identifiable. For instance, clinical trials for Zavesca were conducted only on treatment naïve Gaucher sufferers with mild to moderate Gaucher disease and who were unsuitable or unwilling to receive ERT[269]. Therefore, the potential target population in that case was already limited[270]. In fact, the EMEA has indicated that

> 'In view of the small number of patients, the preference for larger benefit achieved with ERT and the 'open' studies that will be conducted, any future studies would have difficulties in recruiting a sufficient number of patients.'[271]

238. The small number of patients also affects a potential new entrants' ability to sell a drug once it has been developed and trialled. Most of the existing Gaucher patients are being treated with Cerezyme, which until 3 March 2003, was the only drug for the treatment of Gaucher disease in the UK. This makes it difficult for newcomers to enter the market since, in order to sell their drug, they must either compete in the limited market for treating patients with such mild symptoms that they have not so far undergone treatment with ERT[272], or patients for whom ERT is not suitable, or persuade patients (through their doctors) to switch from Cerezyme to the new drug.

---

[267] Minutes of meeting between Professor Cox and Genzyme's legal representatives dated 30 August 2002, page 5.

[268] Genzyme's third supplementary written representations submitted on 26 February 2003, paragraph 3.8 at page 13.

[269] See document entitled 'EMEA – Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by EMEA in 2003, page 23.

[270] Ibid, page 23.

[271] Ibid, page 29.

[272] According to Dr. Mehta, there are approximately 5 to 10 such people in the UK each year. See note of meeting with Dr Mehta dated 10 July 2001.

239. Doctors (and, ultimately, patients) are generally reluctant to switch to a new treatment[273]. It can take some time to establish the optimal dosage of Cerezyme which will suit an individual patient. Once the initial settling period is over and patients are established with Cerezyme, it may be difficult to persuade patients (through their doctors) to move to a new drug unless significant therapeutic benefits can be shown, even if the alternative product is cheaper[274].

240. Barriers to entry into the market for the supply of drugs for the treatment of Gaucher disease are therefore high.

241. Genzyme has disputed that barriers to entry into the market for drugs for the treatment of Gaucher disease are high. Its position is that 'barriers to entry are indeed very low or non-existent'[275]. It argues that its own success, rather than creating a first mover advantage, has acted as an incentive for other firms to develop new drugs for orphan diseases[276]. It points particularly to the marketing authorisation of OGS's drug, Zavesca and, what it describes as, the 'promised' generic competitor from Transkaryotic Therapies Inc ('TKT') in *[confidential]*, as evidence that barriers to entry are low and that Genzyme is always under the threat of a new drug entering the market at any time[277].

242. The Director is of the opinion that Genzyme's argument in relation to OGS and TKT is incorrect. Genzyme's approach is to equate the existence of entry (OGS) or potential entry (TKT) as proof that barriers to entry are low. This analysis is incorrect. As pointed out in paragraph 231 above, the Director recognises that the barriers to entry into the market are not insurmountable and it is to be expected that occasionally entry will occur.

---

[273] The resistance of patients and doctors to change is demonstrated by the unwillingness of many to move from HH to Genzyme Homecare after the termination of HH's appointment (even though in this case, the change only involved the Homecare Services provider and not the actual treatment). According to the estimates of patients treated by HH and Genzyme Homecare submitted by those companies respectively, the number of patients treated by HH at their homes has only gone down by *[confidential]*% since Genzyme Homecare's entry (see Genzyme Homecare's estimate of patients treated by it, submitted on 30 November 2001 and HH's estimate of patients treated by it, submitted on 29 April 2002).

[274] See, for example, the Monopolies and Mergers Commission 'A report on the proposed merger Fresenius AG and Caremark Limited', Cm 3925 (April 1998).

[275] Genzyme's written representations submitted on 25 October 2002, paragraph 1.15 at page 51.

[276] Ibid, paragraph 11.12 at page 142.

[277] Ibid, paragraph 1.14 at page 50.

However, in the assessment of dominance, the issue is whether entry barriers are sufficiently low that the behaviour (and in particular, pricing) of a firm with a high market share is constrained by the threat of new entry[278]. The Director's view is that this is not the case in the upstream market. It is clear that a pharmaceutical company cannot simply start producing a drug for the treatment of Gaucher disease, even if it is prepared to spend large sums of money. On the contrary, the process of getting a drug to market involves many steps including identifying a potential treatment, carrying out R&D, completing clinical trials and obtaining marketing authorisation. There is no certainty of success and, in fact, there is risk of failure at each step. This point was emphasised by Dr Alan Smith in Genzyme's oral representations when he stated:

> 'It [this industry] is fragile because it is high risk. Most drugs fail. Most of the things we try to do fail (...) Most things do not work. A small number succeed.'[279]

243. R&D into new drugs is also expensive. As Genzyme notes in its Response:

> 'It should be borne in mind that the cost of developing a new medical product approaches EURO800 million and it has been estimated that only about one of every 5,000 products reaches the market.'[280]

244. Even when R&D is successful in developing a new treatment, getting a drug to the market can take some time. This is illustrated by the European Commission's recent review of pharmaceutical legislation, which found that:

> '(...) quite often it takes up to fifteen years to bring a new innovative product on the market.'[281]

245. When a drug is finally brought to the market, it may fail to obtain a marketing authorisation that allows it to be used for all patients and it may be unable to generate a significant level of sales. Genzyme stated in its Response that

> 'However, very few of those orphan drug products so approved have made any substantial return for the company that developed and marketed them.'[282]

---

[278] OFT 415 'Assessment of Market Power', paragraph 3.2.

[279] Transcript of the oral hearing held on 6 November 2002, page 49, .lines 2-11.

[280] Genzyme's written representations submitted on 25 October 2002, paragraph 2.1 at page 60.

[281] See COM(2001) 606 23.10.2001 A report from the Commission on the experience acquired as a result of the operation of the procedures for granting marketing authorisations for medicinal products laid down in Regulation (EEC) no 2309/93.

246. In assessing dominance in cases such as the present, therefore, the likely effectiveness of new entry is as important as the question of whether or not entry can occur.

247. The Director acknowledges that Genzyme's success with Cerezyme is likely to have encouraged others to research new drugs for rare diseases. However, Genzyme clearly has a first mover advantage in having the first drug on the market and in such a drug being highly successful and efficacious[283]. In the circumstances, the Director considers that Cerezyme is the standard against which all new drugs for the treatment of Gaucher disease will be assessed. The example of Zavesca illustrates this point. Zavesca has been authorised for use only in patients for whom ERT (Cerezyme) is unsuitable. It follows that if ERT did not exist, Zavesca would have received a different authorisation.

248. Genzyme has also argued that, given the small number of Gaucher patients, and the incentives offered for the development of orphan drugs, a new drug could take over from Cerezyme in a matter of months. In support of this statement, Genzyme gave the example of the way in which Cerezyme took over from Ceredase[284].

249. The Director does not accept that the example of Cerezyme almost completely replacing Ceredase is typical of what might be expected if a new drug entered the market. Cerezyme was a recombinant version of Ceredase, which worked in the same way as Ceredase and was equally effective. It was produced by the same company, was sold at the same price, in the same quantities and had the same recommended dosage. Homecare Services were provided by the same Homecare Services provider. Furthermore, it was Genzyme's decision to withdraw Ceredase from the market (except for those patients who cannot tolerate Cerezyme) and introduce Cerezyme. Therefore, Cerezyme's entry and Ceredase's exit from the market was not the result of the normal competitive process.

250. The Director does not dispute that orphan drug legislation has gone some way to reducing barriers to entry for drugs for the treatment of rare diseases. However, this was necessary because the barriers to entry for such drugs are

---

[282] Genzyme's written representations submitted on 25 October 2002, paragraph 2.5 at page 61.

[283] See Dr Alan Smith's statement in the Transcript of the oral hearing of 6 November 2002, at page 39, lines 22030.

[284] Genzyme's written representations submitted on 25 October 2002, paragraph 11.15 at page 51.

so high. As described in paragraphs 52 to 61 above, the measures introduced in the EU provide greater incentives for companies to engage in the development of orphan drugs but by no means do they guarantee success. The number of orphan drug designations does not give a reliable indication of the number of drugs that will eventually be successful. Orphan drug status is granted before a marketing authorisation is obtained and it does not guarantee that one will be granted. Orphan drugs must still demonstrate quality, safety and efficacy in the same way as any other drug[285]. These points were emphasised by Dr Tambuyzer during Genzyme's oral representations:

> 'The results of that [the European Orphan Drug Regulation] are remarkable because European applications for orphan medicines have sharply increased. There are now in two years over 210 submitted applications with 123 positive designations. Please remember that designations are at early stages in research. They have to be converted into products and if you look at the US experience about 20% of designated products really convert into commercially available products.'[286]

251. The above evidence shows that, even with orphan drug incentives, the prospects for a pharmaceutical company bringing a new product to market once it has orphan drug designation, are highly uncertain. This uncertainty means that the impact of threatened entry on Genzyme is greatly reduced.

252. Genzyme has also argued that the imminent introduction of fast-track procedures will significantly reduce the time taken to get an orphan drug to the market. The Director has investigated the accelerated procedures available for drugs seeking Community marketing authorisation. As outlined in paragraphs 59 to 61 above the proposed accelerated procedure is not for orphan drugs in particular (although orphan drugs are likely often to satisfy the criteria), but will apply to all drugs which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Orphan drugs will not automatically qualify for the accelerated procedure and will have to satisfy the criteria in the same way as any other drug. The accelerated procedure shortens the maximum time scale for receiving an opinion from the CPMP from 210 to 150 days. In the context of the overall time it can take to bring a drug to market, a reduction of 60 days in the maximum time taken to receive a marketing authorisation does not represent a significant reduction in barriers to entry.

---

[285] See 'Orphan drugs' section at paragraphs 52 to 61 above.

[286] Transcript of the oral hearing held on 6 November 2002, page 56, lines 8-16.

253. Similarly, Genzyme has argued that another way in which orphan drugs get priority review and therefore reach the market more quickly, is through the possibility of receiving marketing authorisation under 'exceptional circumstances'[287]. The Director acknowledges that this procedure may help a new drug to reach the market more quickly[288], but as explained in the context of fast track procedures, it does not shorten the time required to carry out R&D, nor does it provide any greater chance of success.

254. The experience of OGS with Zavesca supports the above. Even though it is an orphan drug and has received authorisation under exceptional circumstances, the clinical trials lasted over five years, it took seventeen months to obtain a marketing authorisation and even now, when it has received marketing authorisation, it has not been licensed for all Gaucher patients but only those for whom ERT is unsuitable[289].

255. The Director is not persuaded by Genzyme's arguments and therefore concludes that the upstream market is characterised by high barriers to entry.

(d) Barriers to entry - Potential entrants

256. Despite the existence of high barriers to entry into the market, the Director is aware of one other company in the process of researching a drug for the treatment of Gaucher disease. TKT is researching an ERT drug for the treatment of Gaucher disease, which is similar to Cerezyme. It is intended to be a fully human glucocerebrosidase to be administered intravenously.

257. The TKT report and accounts for 2001 showed that the 'GCB for Gaucher disease' is still at the research phase. There are five more stages the drug will need to go through before it can apply for marketing authorisation[290]. To the Director's knowledge, TKT has not yet started clinical trials for its drug. If successful trials are eventually completed, TKT will then need to apply for marketing approval. As indicated in paragraphs 40 to 51 above, marketing approval is likely to take at least a year. TKT has confirmed to the Director that it does not expect to be able to launch a treatment for Gaucher disease

[287] See paragraphs 45 and 46 above.

[288] See paragraphs 45 and 46 above.

[289] See document entitled 'EMEA - Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by EMEA in 2003. See also OGS press release 'European Commission approval for Zavesca' dated 26 November 2002.

[290] See TKT product pipeline from 2001 Report and Accounts.

in the UK in the near future[291]. TKT does not yet have an official estimated launch date, as it is still at the early stages of development (clinical trials have not yet started). However, in response to the Director's request for a best estimate, in April 2002 TKT indicated that, on a very preliminary estimate, the earliest possible date it would be able to launch its drug would be late *[confidential]*[292]. At the date of this Decision, however, TKT's website does not show its drug for the treatment of Gaucher disease as having begun any clinical trials[293]. This indicates that TKT has not yet initiated clinical trials and, therefore, the late *[confidential]* date may not be realistic. Furthermore, as part of a recent restructuring announced by TKT, the company has indicated that it will be 'reviewing the future of the gaceae [Gaucher] (...) programme'[294]. The discontinuation of TKT's research into a drug for the treatment of Gaucher disease has also been reported in a specialist pharmaceutical magazine[295]. In light of this evidence, the Director considers that the time lag before TKT is in a position to start selling a drug into the UK market is, therefore, at best some way off and, more importantly, it is by no means certain it will ever get to that stage.

258. In response to a request for information under section 26 of the Act dated 11 October 2001, Genzyme provided a list of products which have orphan status in Europe[296]. OGS is the only company listed with a drug for the treatment of Gaucher disease[297].

259. *[confidential]*[298]. *[confidential]*.

---

[291] Note of telephone conference between the OFT and TKT dated 17 April 2002.

[292] Note of telephone conference with TKT dated 17 April 2002.

[293] See the 'Products in the Pipeline' section on TKT's website (www.tktx.com). This list shows the status of TKT's drug for Gaucher disease as 'Preclinical'.

[294] See document entitled 'Event Transcript' dated 12 February 2003, page3 and 7, attached to Genzyme's third supplementary written representations submitted on 26 February 2003.

[295] SCRIP Magazine No.2825 'CEO resigns as TKT cuts back', 19 February 2003, page 8.

[296] See list of drugs with orphan drug status in Europe.

[297] When Ceredase and Cerezyme were launched in the Europe, the orphan drug legislation had not yet been passed in Europe and so there was no such thing as 'orphan drug' status. According to Genzyme, however, Cerezyme has been accepted by the EMEA as having equivalent status to an orphan drug as from 19 November 1997 (see Genzyme's written representations submitted on 25 October 2002, paragraph 2.8 at page 62).

[298] See document entitled '*[confidential]*' dated October 2001.

260. *[confidential]*[299]. *[confidential]*.

261. *[confidential]*.

262. The evidence shows that although Gaucher disease is the subject of research by a number of companies, only one, OGS, has been successful in developing a drug for the treatment of Gaucher disease (although with all the limitations described above) since Cerezyme was launched more than ten years ago. The rest are either at pre-clinical trial stage (e.g. TKT's drug) or 'unknown'. This fact, combined with Genzyme's strong first-mover advantage, means that the potential for new effective entry is not sufficiently certain and/or imminent to act as an effective constraint on Genzyme's market power in the short to medium term.

263. Genzyme has disputed the Director's view on potential entry. In particular, Genzyme has made several references to the immediacy of TKT's entry in its Response, including: 'TKT expects to introduce a generic competitor to Cerezyme some time in *[confidential]*'[300]; 'TKT's anticipated generic product for the treatment of Gaucher disease which apparently is due to come on stream in *[confidential]*'[301]; 'TKT expect very soon to have their products on the market'[302]. Genzyme has not submitted any evidence to support these statements. The Director therefore assumes that Genzyme bases these statements on the note of the Director's telephone conversation with TKT[303]. It is clear from this note that TKT did not say with any certainty that it would be launching a competing product to Cerezyme in late *[confidential]*. Rather, in response to a question regarding the earliest date on which it might be able to launch a product in the UK, TKT responded that the earliest possible date would be late *[confidential]*. TKT indicated that this estimate was extremely confidential, as it was not an official estimate of the company, but the 'best estimate' of TKT's representative in response to the Director's

---

[299] Subsequent evidence submitted by Genzyme suggests that the 'OGT 923' drug is in fact being trialled for Sandhoff and Niemann Pick Type C diseases (see Genzyme's third supplementary written representations submitted on 26 February 2003, Annex 1, page 5.

[300] Genzyme's written representations submitted on 25 October 2002, paragraph 3.8 at page 68.

[301] Ibid, paragraph 4.16 at page 78.

[302] Ibid, paragraph 9.25 at page 126. See also paragraph 1.14 at page 50 and paragraph 9.31 at page 127.

[303] Note of telephone conversation between the OFT and TKT dated 17 April 2002.

specific question[304]. As stated above, it is now unlikely that TKT will launch a product within this timescale, particularly as it has not yet begun clinical trials and given its recent statements regarding the possibility of discontinuing its research into a drug for the treatment of Gaucher disease. It is, therefore, not at all certain that TKT will launch a product at all.

264. Genzyme also points to the fierce competition between itself and TKT with their respective ERT drugs for Fabry disease (another LSD), which received dual marketing authorisation in Europe, as evidence that TKT would be a significant competitor in the treatment of Gaucher disease[305].

265. The Director considers the experience of Genzyme and TKT with their respective treatments for Fabry disease to be of limited relevance to the threat posed to Cerezyme by TKT's potential future drug for the treatment of Gaucher disease. First, the supply of drugs for the treatment of Gaucher disease is a different product market for the purposes of the Act. Secondly, the ERT drugs for Fabry disease both entered the market at the same time. Therefore, Genzyme and TKT are, in the context of Fabry disease, actively competing for new patients who, up to now, have not had the option of treatment with an ERT drug. This is very different from the situation that might arise in the future with Gaucher disease, should TKT succeed in developing a drug. In this case, TKT would need to persuade patients to switch from Cerezyme, an established, highly efficacious product, to a new drug.

266. Genzyme's Response also identifies two other potential competitors who are developing drugs for the treatment of LSDs[306]. These are BioMarin Pharmaceutical Inc., which is developing a drug for the treatment of MPS VI and is involved in a joint venture with Genzyme to develop an ERT for MPS1, and Large Scale Biology Corp. which Genzyme believes is researching an ERT drug for the treatment of Gaucher disease[307].

267. BioMarin is not researching a product for Gaucher disease[308]. Genzyme has not been able to submit firm information about Large Scale Biology, other than to say that it believes that Large Scale Biology is researching an ERT

---

[304] See letter from the OFT to E. Perrot (TV) dated 10 September 2002.

[305] Genzyme's written representations submitted on 25 October 2002, paragraphs 2.7 and 11.13 at pages 62 and 143.

[306] Ibid, paragraph 4.34 at page 82.

[307] Ibid.

[308] Ibid, paragraph 4.34 (a) at page 82.

drug for the treatment of Gaucher disease. The Director assumes that even if Genzyme is correct in its belief, the lack of firm evidence as to whether or not Large Scale Biology is indeed researching an ERT drug for the treatment of Gaucher disease, must mean that any such research is a the very early stages. Therefore, the Director does not consider these companies to be potential entrants into the upstream market in the short to medium term.

(e) Buyer power

268. Another factor to consider when assessing dominance is the buyer power of customers. All the Cerezyme prescribed in the UK is purchased by the NHS (for infusion in hospitals or in the community). The NHS is therefore Genzyme's only UK customer and, given its size, it might be able to exert some pressure to counteract Genzyme's market power. However, the evidence does not support this view. The lack of effective substitute products makes it difficult for buyer power to have any real effect. In deciding how best to treat Gaucher patients, doctors have had for over ten years a stark choice of ERT using Cerezyme, or no drug treatment at all. Even with Zavesca's recent entry on 3 March 2003, this will not change significantly. This is because ERT is currently the treatment of choice and the preferred standard of care for the treatment of Gaucher disease[309]. Further, in the UK Gaucher disease is always treated with ERT where the patient can tolerate it[310]. As ERT (i.e. Cerezyme) is the preferred standard of treatment for Gaucher disease, it is expected that in the UK Zavesca will be a 'second line treatment' which will only be an alternative where ERT (i.e. Cerezyme) is not suitable[311]. Therefore, under the terms of its current marketing authorisation, Zavesca will not represent a viable alternative to Cerezyme for the majority of Gaucher patients and will not, therefore, offer the NHS a significantly wider choice than it previously had.

269. Since the launch of Ceredase (the predecessor of Cerezyme) in 1991, there have been a number of occasions when doctors, the Gaucher Association and other delivery/homecare services providers have shown an interest in purchasing or allowing others to purchase the drug separately from the

[309] See document entitled 'EMEA - Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by EMEA in 2003, pages 23 and 27.

[310] See note of meeting with Professor Cox dated 16 January 2003.

[311] See note of meeting with Professor Cox dated 16 January 2003 and note of telephone conversation between the OFT and Dr Mehta (Royal Free) dated 21 January 2003. See also email from Professor Cox to E. Perrott (TV) dated 21 February 2003.

Homecare Services[312]. Genzyme rejected these requests and simply stated that its chosen method of distribution was in 'everybody's best interest'[313], although it has not been able to submit any evidence to support this[314]. This suggests that the NHS does not have strong buyer power.

270. Another indication of the NHS's lack of buyer power is illustrated by the NHS's inability to achieve price reductions following a fall in Genzyme's manufacturing costs. In February 1994, Genzyme increased the list price of Ceredase from £2.97 per unit to £3.09 per unit. *[confidential]*[315]. *[confidential]* it is acknowledged that producing a recombinant form of the molecule (i.e. Cerezyme) is cheaper than producing the human form of it (i.e. Ceredase)[316]. However, no cost reduction was reflected in the price of Cerezyme, which was introduced in the UK at the higher price of £3.09 per unit[317].

271. Evidence of the ability of Genzyme to act independently of its customers is also shown by the fact that, despite the choice of many doctors (and, therefore, patients) to continue to obtain Homecare Services from HH[318],

---

[312] Letter from Professor Cox to M.Cortvriend (Genzyme Corporation) dated 11 June 1996. Letter from Professor Cox to M. Cortvriend dated 19 September 1996. Letter from M. Cortvriend to Professor Cox dated 21 June 1996. Letter from M. Cortvriend to Professor Cox dated 24 September 1996. Letter from H.Termeer to J. Manuel dated 12 December 1996 regarding pricing. Letter from M. Cortvriend to J. Manuel dated 12 November 1996. Letter from A.Scrivener (Fresenius Limited) to M. Cortvried (Genzyme) dated 28 August 1996.

[313] Fax from M. Cortvriend (Genzyme) to J. van Heek (Genzyme B.V.) dated 14 January 1997.

[314] Note prepared by Taylor Vinters of telephone conversation between the OFT and Genzyme on 20 March 2002. Also letter from Taylor Vinters to the OFT dated 27 March 2002 at point 4.

[315] See letter from H. Termeer (Genzyme) to J. Manuel (Gaucher Association) dated 2 February 1994.

[316] Goozner, M, 'The Price Isn't Right', The American Prospect Magazine, volume 11, no.20, 11 September 2000. Genzyme has challenged the authority of Mr Goozner as a scientific expert, but it has not challenged the accuracy of the statement that it is cheaper to produce Cerezyme than Ceredase. This point is also stated in a report produced by Bearn Stearns International Limited 'The Value is in Proteomics' dated 6 September 2001, at page 13.

[317] Fax from M. Cortvriend (Genzyme) to M. Jenkins (PPA) dated 16 May 1997.

[318] Since the launch of Genzyme Homecare, *[confidential]*% of the patients treated by HH at home have chosen to stay with HH and not switch to Genzyme Homecare. This calculation is based on the number of patients HH currently supplies with Cerezyme. See Genzyme Homecare's estimate of patients treated by it, submitted on 30 November 2001. See also HH's estimate of patients treated by it, submitted on 29 April 2002.

Genzyme has continued to pursue a policy which would eventually force HH out of the Homecare Services segment of the downstream market, thereby depriving them of this option.

272. The above suggests that the NHS does not have strong buyer power in relation to purchases of Cerezyme.

273. Genzyme contested the Director's conclusion that the NHS has no significant buyer power. In support of its position, Genzyme listed five factors that, according to Genzyme, show that the NHS has buyer power. The first factor was the DoH has the power 'to set the original price with the manufacturer'[319]. As set out in paragraph 66 above and, indeed, as stated in the Translucency Report submitted by Genzyme[320], this is incorrect. A pharmaceutical company launching a new product is free to set the price of that product as it sees fit, subject to the profit cap determined by the PPRS.

274. The remaining four factors listed by Genzyme are as follows. The DoH and the NHS have power[321],

> '(b) to address the cost-effectiveness of products (NICE [National Institute of Clinical Excellence]);
>
> (c) in central purchasing (PASA [Purchasing and Supply Agency]);
>
> (d) use of specialist centers (NSGAG);
>
> (e) local tendering (PCT [Primary Care Trust]).'

275. Genzyme submitted no explanation as to how these factors give the DoH and the NHS buyer power in its purchases of Cerezyme.

(d) Pharmaceutical Price Regulation Scheme (PPRS)

276. The PPRS regulates the profit that pharmaceutical companies may make from their sales of branded prescription medicines supplied to the NHS. Pharmaceutical companies whose UK turnover is below £25 million do not have to submit detailed returns to the PPRS. The DoH can request such returns if circumstances demand it, for example, if a company wishes to increase prices[322].

---

[319] Genzyme's written representations submitted on 25 October 2002, paragraph 11.19 at pages 144 and 145.

[320] Translucency Report, paragraph 2.9.1 at page 13.

[321] Genzyme's written representations submitted on 25 October 2002, paragraph 11.19 at pages 144 and 145.

[322] See paragraphs 62 to 67 above.

277. *[confidential]*[323]. *[confidential]*.

278. In any case, the profitability of Cerezyme is highly dependent on the price at which the drug is purchased by Genzyme from Genzyme Corporation[324]. This price is currently £*[confidential]*, making Cerezyme marginally profitable in the UK in accounting terms. However, this is a transfer price and does not provide a true indication of the profitability of Genzyme[325].

279. Genzyme has argued that the ability of the DoH to impose a 4.5% price reduction on Genzyme through the PPRS in 1999 demonstrates that buyer power exists. In the Director's view the 4.5% price reduction was a requirement placed on all pharmaceutical companies supplying branded drugs the NHS and it applied to their total product portfolio, as opposed to individual drugs. Although it shows that the DoH is able to extract an across-the-board price reduction as part of the negotiations for agreeing the PPRS, it does not demonstrate that the NHS has strong buyer power with regard to any particular drug supplier or for any individual drug. This is particularly the case where a company has a monopoly or a near monopoly position on the market.

280. It seems, therefore, clear that the PPRS does not constrain Genzyme's market power in the supply of drugs for the treatment of Gaucher disease. A similar point was considered and supported by the Competition Commission Appeal Tribunal in Napp, where it stated:

> 'In our view nothing in the PPRS affects Napp's autonomous conduct in such a way as to deprive Napp of its dominant position, as the Director found in paragraphs 122 to 136 of the Decision. Moreover, on Napp's argument virtually the entire pharmaceutical industry of the United Kingdom would be outside not only the scope of the Chapter II prohibition but also Article 82 of the Treaty. The decisions of the Commission cited by the Director at paragraph 137 of the Decision are contrary to that point of view.'[326]

---

[323] Confirmed by D.Kullman, Principle Policy Manager of the PPRS branch of the DoH.

[324] Genzyme purchases Cerezyme from Genzyme B.V. which imports it from the US parent. See Genzyme's submission of 5 March 2002 (response to request number 19) and Genzyme's submission of 1 May 2002 (response to question 2).

[325] This is reflected in an internal Genzyme memo regarding the implications of the 1999 PPRS, which states: '*[confidential]*. See memo from P.Foster (Financial Controller of Genzyme) to M. Cortvriend dated 28 July 1999.

[326] Case 1001/1/101 *Napp Pharmaceutical Holdings Limited and Subsidiaries v DGFT* [2002] CAT 1 at [168], [2002] CompAR 13.

281. The Director therefore concludes that the PPRS does not constrain Genzyme's market power in the supply of drugs for the treatment of Gaucher disease (the upstream market).

(ii) The downstream market

(a) Market shares

282. Before the termination of HH as Genzyme's Wholesaler and Homecare Services provider, HH was the only undertaking that could Wholesale and provide Homecare Services, as it was the only delivery/homecare services provider with access to Cerezyme. HH was, by virtue of its exclusive agreement with Genzyme and, effectively on Genzyme's behalf, the monopolist Wholesaler/Homecare Services provider[327].

283. Since the agreement between HH and Genzyme was terminated and Genzyme Homecare launched in May 2001, there have been two entities operating in the downstream market, namely, Genzyme Homecare and HH[328]. HH's market share has come down from 100% to approximately *[confidential]*%[329]. However, as explained in paragraphs 119 and 120 above, HH will have to exit the market in the short term[330] if Genzyme's pricing policy does not change[331]. This would leave Genzyme (via Genzyme Homecare), which currently has *[confidential]*% market share, with a 100% market share in the downstream market.

---

[327] With the exception of one patient treated by Central Homecare, as explained in footnote 186 above.

[328] Note that HH is not currently Wholesaling, as it cannot afford to purchase Cerezyme at the NHS list price of £2.975 (plus VAT) per unit and sell it to hospitals at the concessionary price offered by Genzyme of £*[confidential]* (plus VAT) per unit.

[329] This is based on the number of patients HH currently supplies with Cerezyme. This has been calculated on the basis of Genzyme Homecare's estimate of patients treated by it, submitted on 30 November 2001 and HH's estimate of patients treated by it, submitted on 29 April 2002.

[330] HH has indicated that, although it is currently running a loss making operation, it is prepared to remain in the downstream market *[confidential]* in the hope that it will then be able to obtain supplies of Cerezyme on terms which allow it to compete viably (see letter from C.Walsh (HH) to the OFT dated 26 November 2001). In fact, HH has effectively already exited the Wholesale segment of the market. This is because following the termination of HH as Genzyme's Homecare Services provider and the launch of Genzyme Homecare, HH cannot compete with Genzyme Homecare's concessionary price to hospitals of £*[confidential]* (plus VAT) per unit, when HH purchases the drug from Genzyme at £2.975 (plus VAT) per unit).

[331] See letter from Dr Norfolk (The Leeds Teaching Hospitals) to Dr. Jones (HH) dated 6 September 2001.

(b) Barriers to entry

284. In the absence of Genzyme's policy of making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme and the terms of supply currently offered by Genzyme to independent delivery/homecare services providers, there would be no significant barriers to entry for undertakings already in the business of providing services for the treatment of complex diseases[332]. Indeed, wholesaling of drugs to hospitals and the provision of home delivery/homecare services are not characterised by high barriers to entry. However, as a result of Genzyme's pricing policy, in combination with the terms of supply offered to independent delivery/homecare services providers, the market for Wholesaling and Homecare Services is effectively foreclosed[333].

4. Conclusion on dominance

(i) The upstream market

285. Genzyme's market share combined with the lack of effective competition, the existence of significant barriers to entry, the uncertainty surrounding potential new drugs for the treatment of Gaucher disease and the lack of buyer power through the NHS, collectively show that Genzyme enjoys a dominant position in the upstream market. The market power enjoyed by Genzyme enables it to act independently of its competitors (OGS), potential competitors (TKT), customers (NHS and delivery/homecare services providers) and, ultimately, consumers (the patients).

286. The Director considers that Genzyme is therefore dominant on the market for the supply of drugs for the treatment of Gaucher disease (the upstream market) in the UK.

(ii) The downstream market

287. Genzyme's policy of making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme and the terms of supply applied by Genzyme to independent delivery/homecare services providers, have the effect of completely foreclosing the downstream market to any

[332] See note of telephone conversation between the OFT and TKT on 17 April 2002.

[333] This statement is not undermined by HH's continued existence in the market. As explained previously in this document, HH has indicated that, although it is currently running a loss making operation, it is prepared to remain in the market *[confidential]* in the hope that it will then be able to obtain supplies of Cerezyme on terms which allow it to compete viably.

delivery/homecare services provider other than the one appointed and reimbursed by Genzyme[334].

288. Given that HH is currently running a loss making operation and it will eventually have to leave the market if the status quo is maintained, it is arguable that Genzyme (through Genzyme Homecare) has potential market power in the downstream market[335]. However, on the basis of Genzyme's (through Genzyme Homecare) current market share of *[confidential]*%, it is unlikely that Genzyme Homecare could currently hold a dominant position in the downstream market.

289. The Director therefore considers that Genzyme Homecare is not currently dominant in the downstream market.

B. Assessment of abuse of dominance

290. The holding of a dominant position is not in itself prohibited under section 18(1) of the Act. As pointed out by the ECJ in *Michelin v Commission*,

> 'A finding that an undertaking has a dominant position is not in itself a recrimination but simply means that, irrespective of the reasons for which it has such a dominant position, the undertaking concerned has a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market.'[336]

291. The ECJ has also indicated that the degree of special responsibility imposed on a dominant company is to be considered in the light of the specific circumstances of each case, reflecting a weakened competitive situation[337].

292. The concept of 'abuse' is an objective one. As the ECJ stated in *Hoffmann-La Roche v Commission*,

---

[334] Ibid.

[335] In fact, HH has already left the Wholesale segment of the downstream market (leaving Genzyme, through Genzyme Homecare, as the only player in this segment), as it cannot afford to buy the Cerezyme at £2.975 (plus VAT) per unit and resell it to hospitals at the concessionary price charged by Genzyme of £*[confidential]* (plus VAT) per unit.

[336] Case 322/81 *Michelin v Commission* [1983] ECR 3451, paragraph 57.

[337] Case T-83/91 *Tetra Pak International SA v Commission* [1994] ECR II-755, paragraph 115; upheld on appeal to the ECJ on Case C-333/94 *Tetra Pak v Commission* [1996] ECR I-5951, paragraph 24.

> 'The concept of an abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.'[338]

293. The Director considers that Genzyme has abused its dominant position in the upstream market by, without objective justification,

(i) making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, thereby reserving to itself (or to an undertaking acting under contract for Genzyme) the ancillary but separate activity of providing Homecare Services; and

(ii) adopting a pricing policy following the launch of Genzyme Homecare which results in a margin squeeze;

with the effect of

(i) foreclosing the Homecare Services segment of the downstream market; and

(ii) raising barriers to entry to the upstream market.

1. Genzyme is making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, thereby reserving to itself (or to an undertaking acting under contract for Genzyme) the ancillary but separate activity of providing Homecare Services

294. Section 18(2)(d) of the Act gives as an example of an abuse:

> 'making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of the contracts.'

295. The European Commission and the European Courts have found on numerous occasions that, absent an objective justification, behaviour by a dominant company causing its customers to purchase a product or service as a

[338] Case 85/76 *Hoffmann-La Roche v Commission* [1979] ECR 46, paragraph 91.

condition of purchasing another one, constitutes an abuse of Article 82[339]. This behaviour is often referred to as a tie-in[340].

296. An undertaking that is dominant in one market may infringe section 18(1) of the Act by committing an abuse in a different but closely associated market. This principle was set out by the ECJ in the case of *Tetra Pak II*[341] and is recognised by the Director in a number of his Guidelines[342]. The process of extending market power in one market into another can be achieved in a number of ways, one of which is through the use of a tie-in[343].

297. In *Napier Brown/British Sugar*[344] the European Commission found that British Sugar's policy of including in the price of the sugar the cost of its transport to the customer's site (whether British Sugar delivered the sugar itself or did so through third parties acting under contract for it), was abusive. The Commission found that

> '(...) BS [British Sugar] has abused its dominant position on the sugar market by refusing to grant to its customers an option between purchasing sugar on an ex-factory or delivered price basis, thereby reserving for itself the ancillary

---

[339] See, for example, Commission Decision IV/30.787 *Eurofix-Bauco - Hilti* OJ (1988) L65/19; Commission Decision IV/30.178 *Napier Brown – British Sugar* OJ (1988) L284/41; Case 311/84 *Centre belge d'etudes de marche – Telemarketing (CBEM) v SA Compagnie luxembourgeoise de telediffusion (CLT) and Information publicite Benelux (IPB)* [1985] ECR 3261; Commission Decision IV/32.318 *London European – Sabena* OJ (1988) L317/47; Case C-333/94P *Tetra Pak II* [1996] ECR 5951; Commission Decision *Flughafen Frankfurt/ Main AG* OJ (1998) L72/30. See also OFT Guideline 402 'The Chapter II Prohibition', paragraphs 4.31 et seq.; OFT Guideline 414 'Assessment of Individual Agreements and Conduct', sections 6 and 8.

[340] See, for example OFT Guideline 414 'Assessment of Individual Agreements and Conduct', section 9 where a tie-in is defined as 'Where the manufacturer makes purchase of one product (the tying product) conditional on the purchase of a second (tied) product.'

[341] Case C-333/94P *Tetra Pak II* [1996] ECR 5951. In this case, the ECJ referring to *Commercial Solvents* (Cases 6/73 and 7/73 [1974] ECR 223) and *Telemarketing* (Case 311/84 [1985] ECR 3261), confirmed that there can be an abuse of a dominant position where conduct on a market distinct from the dominated market produces effects on that distinct market.

[342] OFT Guideline 414 'Assessment of Individual Agreements and Conduct', section 8. OFT Guideline 402 'The Chapter II Prohibition', paragraph 4.50.

[343] OFT Guideline 414 'Assessment of Individual Agreements and Conduct', section 8.

[344] Commission Decision IV/30.178 *Napier Brown – British Sugar* OJ (1988) L284/41, paragraph 69.

activity of the delivery of that sugar, thus eliminating all competition in relation to the delivery of the products.'[345]

298. In reaching the above conclusion, the Commission referred to the judgment of the ECJ in *Telemarketing*[346]. Here, a television station was making the sale of broadcasting time for any telemarketing operation subject to the use of the telephone number of an exclusive advertising agent belonging to its group. The ECJ found this conduct in breach of Article 82(d) of the EC Treaty and stated that:

> '(...) an abuse within the meaning of Article [82] is committed where, without any objective necessity, an undertaking holding a dominant position on a particular market reserves to itself or to an undertaking belonging to the same group an ancillary activity which might be carried out by another undertaking as part of its activities on a neighbouring but separate market, with the possibility of eliminating all competition from such undertaking.'[347]

299. Similarly, in *Tetra Pak II*[348], the Commission condemned as a serious infringement of Article 82, Tetra Pak's practice of tying the supply of its filling machines to the supply of its cartons. The Commission found that Tetra Pak's policy had the effect of limiting outlets and making contracts subject to acceptance of conditions which had no connection with their purpose[349]. The effects of this practice were further strengthened by Tetra Pak's integrated distribution system and patents policy. In particular, the Commission found that Tetra Pak's system of tied sales enabled competition to be limited to the market in which Tetra Pak enjoyed a virtual monopoly and where technological entry barriers were very high (the sale of machines) while preventing the emergence of any competition in the separate but

---

[345] Ibid, paragraph 71. See also Commission Decision IV/30.787 and IV/31.488 *Eurofix-Bauco/ Hilti* OJ (1988) L65/19, paragraph 75; Commission Decision IV/34.801 *Flughafen Frankfurt/ Main AG* OJ (1998) L72/30, paragraph 72.

[346] Case 311/84 *Centre belge d'etudes de marche – Telemarketing (CBEM) v SA Compagnie luxembourgeoise de telediffusion (CLT) and Information publicite Benelux (IPB)* [1985] ECR 3261.

[347] Ibid, paragraph 27.

[348] Commission Decision IV/31043 *Tetra Pak II* OJ (1992) L72/1.

[349] Similarly, in Commission Decision *Van den Bergh Foods* OJ (1988) L246/1, the Commission condemned Unilever's policy of 'inclusive pricing' whereby Unilever charged all retailers a single price which included the cost of the ice cream products and the cost of providing a freezer cabinet whether the freezer cabinet was taken or not. Unilever terminated the alleged abuse upon receiving the Commission's statement of objections, and so no formal finding was made on this point.

related market (the sale of cartons), where the technological barriers were much lower[350].

300. The Court of First Instance upheld the Commission's Decision on appeal and when considering Tetra Pak's submission that its behaviour was objectively justifiable, it held that:

> '(...) the tied sale of filling machines and cartons cannot be considered to be in accordance with commercial usage. Moreover and in any event, even if such a usage were shown to exist, it would not be sufficient to justify recourse to a system of tied sales by an undertaking in a dominant position. Even a usage which is acceptable in a normal situation, on a competitive market, cannot be accepted in the case of a market where competition is already restricted. The Court of Justice has in particular ruled that, where an undertaking in a dominant position directly or indirectly ties its customers by an exclusive supply obligation, that constitutes an abuse since it deprives the customer of the ability to choose his sources of supply and denies other producers access to the market.'[351]

(i) Foreclosure of the Homecare Services segment of the downstream market

301. As Genzyme submitted to the PPRS in 1999, the NHS list price charged for Cerezyme includes not only the drug, but also the Homecare Services[352]. According to Genzyme's own calculations, *[confidential]*% of the NHS list price represents the price of Cerezyme, while *[confidential]*% represents the price of Homecare Services[353].

302. As a result of this pricing policy, when the NHS purchases Cerezyme (for use in the community or in hospitals), it automatically pays for the Homecare Services. Therefore, if the NHS wished to purchase Homecare Services from anyone other than Genzyme (or an undertaking acting under contract for Genzyme) it would have to pay for the Homecare Services twice[354]: first to

---

[350] Ibid, paragraph 120.

[351] Case T-83/91 *Tetra Pak International SA v Commission* [1994] ECR II-775, paragraph 137.

[352] Ibid. In particular, see letter from M.Cortvriend (Genzyme) to R.Bratt (DoH - PPRS branch) dated 7 September 1999; letter from R.Bratt (DoH – PPRS branch) to M.Cortvriend (Genzyme) dated 14 September 1999; letter from P.Foster (Financial Controller, Genzyme) to R.Bratt (DoH – PPRS branch) dated 22 March 2000.

[353] See section on 'Pricing' at paragraphs 87 to 115 above.

[354] This is effectively already happening in a few cases where the NHS, through community nurses, provides the Homecare Services itself.

Genzyme, as part of the inclusive price of the drug and Homecare Services, and then to the independent delivery/homecare services provider, as reimbursement for the Homecare Services. It is, therefore, of no interest to the NHS to purchase the Homecare Services from anyone other than Genzyme [355].

303. The fact that currently the NHS can purchase the Homecare Services not only from Genzyme, but also from HH, does not alter the conclusion set out in the previous paragraph. This is because, while currently the NHS has a choice between receiving Homecare Services from Genzyme Homecare or from HH[356], this choice is only available as a result of HH's temporary decision not to charge the NHS for the Homecare Services and to operate at a loss[357]. It is clearly not economic to operate a loss-making business indefinitely. According to HH, the only reason it continues to offer Homecare Services is to retain its contacts with the NHS and its Gaucher patients, *[confidential]*. In the absence of *[confidential]*, HH would not currently be providing Homecare Services[358] and, therefore, the only choice for the NHS would be Genzyme Homecare (unless the NHS were willing to pay for the Homecare Services twice).

---

[355] Similar behaviour was found to be abusive by the Commission in Case COMP D3/34493 *Duales System Deutschland AG* OJ [2001] L166/1. DSD was the only company running a countrywide system for the recovery and recycling of sales packaging in Germany. According to DSD's payment system, DSD customers had to pay fees corresponding to the volume of packaging bearing DSD's Green Dot trademark rather than fees corresponding to the volume of packaging for which DSD was actually providing a take-back and recycling service. The Commission found, inter alia, that this payment system led to '*its being of no interest to undertakings subject to the take-back and recovery obligation to take part in a competing exemption system or a competing self-management solution because either a licence fee must be paid to DSD in addition to the remuneration made to the competitor or separate packaging and distribution channels would be necessary. In their actual effect, these terms are very close to being an exclusivity requirement. They thereby make it much more difficult for competitors to enter the market, strengthen DSD's dominant position and further weaken competition. There is thus no equality of opportunity for competition.*' (paragraph 115).

[356] This choice only applies to Homecare Services purchased by the NHS for patients that receive treatment at home (i.e. the Homecare Services segment). Where the Cerezyme is for administration within the hospital, the only Wholesaler is currently Genzyme Homecare, as HH cannot afford to offer the NHS the concessionary price offered by Genzyme to hospitals of £*[confidential]* (plus VAT) per unit, while paying Genzyme £2.975 (plus VAT) per unit.

[357] See section, 'The current position', at paragraphs 116 to 120.

[358] See, for instance, letter from C.Walsh (HH) to the OFT dated 26 November 2001.

304. As stated above, an undertaking with a dominant position in a market may abuse such a position if it leverages its market power from a market in which it is dominant into a separate but related market, with the effect of foreclosing the related market to other competitors[359]. This can be achieved where an undertaking which is dominant in one market (here, the supply of drugs for the treatment of Gaucher disease) makes customers pay for a product or service in a separate but related market (here, the provision of Homecare Services in the Homecare Services segment of the downstream market) in which the undertaking does not have market power or where it is more vulnerable to competition.

305. Genzyme's practice of including Homecare Services in the price of the drug, effectively deprives the NHS of the option to purchase Cerezyme independently from the Homecare Services in normal competitive conditions. This enables Genzyme to reserve to itself (or to an undertaking acting under contract for Genzyme) the separate but ancillary activity of providing Homecare Services (i.e. the Homecare Services segment of the downstream market). This ancillary activity could, under normal competitive circumstances, be undertaken by an independent third party acting alone (e.g. a delivery/homecare services provider which provides specialised home delivery and homecare services for a range of complex conditions).

306. Genzyme's policy, which is a form of tying, effectively makes Genzyme a compulsory trading partner (i.e. Homecare Services provider) for the NHS[360] in the Homecare Services segment of the downstream market. In addition, it prevents competition in that segment where entry would otherwise be relatively easy and where Genzyme is trying to establish its position (Genzyme only entered this segment itself in May 2001).

307. Genzyme's tying policy ultimately leaves the NHS with no real choice of Homecare Services provider and, as such, abusively exploits the NHS, and through it, the patients[361]. The fact that the Homecare Services are provided

[359] OFT Guideline 402 'The Chapter II Prohibition', paragraph 4.50. See also OFT Guideline 414 'Assessment of Individual Agreements and Conduct', section 8.

[360] This argument is not undermined by the fact that HH is currently also trading with the NHS. As explained previously in this Decision, HH has indicated that, although it is currently running a loss making operation, it is prepared to remain in the downstream market *[confidential]* in the hope that it will then be able to obtain supplies of Cerezyme on terms which allow it to compete viably.

[361] Commission Decision IV/30.787 *Eurofix-Bauco - Hilti* OJ (1988) L65/19; Case T-83/91 *Tetra Pak International SA v Commission* [1994] ECR II-775.

by Genzyme itself (through Genzyme Homecare) or through a third party acting under contract for Genzyme (e.g. Caremark or HH until 5 May 2001), is irrelevant[362]. In either case, the customer (the NHS) and the consumer (the patients) are deprived of choice over the source of supply from other parties because the NHS is effectively tied (through Genzyme's pricing policy) to receive the Homecare Services from Genzyme or an undertaking acting under contract for Genzyme[363].

308. There can be no doubt that the NHS wants to have such a choice, as illustrated by the following:

(i) In a letter to D.Moreland and L.Burnett (Genzyme Homecare), Gaucher specialist, Professor Timothy Cox stated that,

> 'I would wish that the patients under my care should be supplied under the current arrangements by Healthcare at Home or, if necessary, by another free-standing agency, rather than supplied by Genzyme or an affiliated division thereof.'[364]

(ii) During a meeting between the OFT and Gaucher specialist Dr Wraith on 9 July 2001, Dr Wraith expressed a similar view to Professor Cox's. Dr Wraith indicated that he would like to have a choice over who provides Homecare Services to his patients[365];

(iii) The Royal Free Hospital has indicated that, given the option, its preferred method of purchasing delivery/homecare services would be to have one delivery/homecare services provider to treat a whole

---

[362] Commission Decision IV/30.178 *Napier Brown – British Sugar* OJ (1988) L284/41, paragraph 69.

[363] As explained previously in this Decision, the fact that since the termination of the HH distribution agreement and the creation of Genzyme Homecare (i.e. May 2001), the NHS has a choice of Homecare Services providers (HH or Genzyme Homecare) does not change this argument. The current choice only exists because HH is providing the Homecare Services for no charge. HH has indicated that it has remained in the downstream market with a loss making operation, *[confidential]*. In the absence of *[confidential]*, HH would not compete with Genzyme Homecare in the Homecare Services segment of the downstream market and the choice currently available to the NHS would not exist.

[364] See letter from Professor Cox (Addenbrooke's Hospital) to D. Moreland and L.Burnett (Genzyme) dated 10 May 2001. See also letter from Professor Cox to the OFT dated 10 May 2001.

[365] Note of meeting with Dr Wraith, Royal Manchester Childrens Hospital, dated 9 July 2001.

range of complex conditions (i.e. Gaucher disease, Fabry disease, HIV, cancer, multiple sclerosis, etc), as opposed to one Homecare Services provider for Gaucher patients which require treatment with Cerezyme and another one for the rest of the conditions[366];

(iv) In 1996, the specialised delivery/homecare services provider Fresenius Limited ('Fresenius') was contacted by a hospital in Northern England which wanted to obtain a quote from Fresenius for providing Homecare Services. The hospital was already using Fresenius to provide services in the home setting to patients suffering from complex conditions other than Gaucher disease and was satisfied with its service. The hospital was unhappy with the service provided by the Homecare Services provider appointed by Genzyme (Caremark Limited) and wanted to consider the possibility of switching to Fresenius to treat Gaucher patients at home. Fresenius approached Genzyme to enquire about the possibility of providing Homecare Services, but Genzyme refused to allow this[367].

309. In its Response, Genzyme argued that the Director is mistaken in his finding that Genzyme makes the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme. Genzyme explained that the price it charges the NHS for Cerezyme cannot be a 'bundled price', as it is the NHS list price, which

> 'is for the supply of the drug and its delivery to patients. It does not include any price for homecare, which is supplied free of charge by Genzyme. There is therefore no price for homecare to be unbundled.'[368]

310. Genzyme clarified that the term 'homecare' in its Response means 'nursing activities carried out at a patient's home, but not the delivery of a drug to a patient's home'[369].

---

[366] Note of meeting between J.Farrell, Chief Pharmacist at the Royal Free Hospital, dated 17 December 2001.

[367] See letter from A.Scrivener (Fresenius Limited) to M. Cortvriend (Genzyme) dated 28 August 1996. See also explanation provided by Genzyme of its response to Fresenius in Genzyme's submission to the OFT of 5 March 2002.

[368] Genzyme's written representations submitted on 25 October 2002, paragraph 12.20 at page 152.

[369] Ibid, footnote 1 at page 45. See also paragraphs 165 to 172 above.

311. Genzyme contended, therefore, that the cost of delivering Cerezyme to a patient's home is included in the NHS list price (and, therefore, cannot be a 'bundled price') and the cost of providing 'homecare' services is born by Genzyme, as such services are supplied to the NHS free of charge (and, therefore, they cannot be 'bundled' either).

312. Genzyme's argument that the NHS list price is intended to cover the cost of delivering a drug to a patient's home has been thoroughly discussed in paragraphs 68 to 83 above, under the section 'The NHS list price and the PPRS'. As set out in that section, the evidence does not support Genzyme's allegation. Instead, the evidence available to the Director indicates that the NHS list price is intended to cover the cost of producing a drug and the cost of delivering it from the manufacturer to the pharmacy (whether this is a hospital or community pharmacy), plus a reasonable profit on those activities. It is not intended to cover the cost of delivering the drug from the pharmacy to a patient's home.

313. Genzyme also stated that it supplies 'homecare' services (but not home delivery) to the NHS free of charge. In order to support this allegation, Genzyme submitted that the following matters illustrate the fact that 'homecare' services are not included in the price of Cerezyme[370]:

> 'First, there are a number of patients, currently *[confidential]*, who receive treatment in hospital (where Genzyme Homecare delivers Cerezyme to the hospital). Second, relatively few patients actually require nursing services at home. Most patients (*[confidential]*) taking Cerezyme at home administer it themselves (or in the case of children have their parents do so) so there is no nursing cost. Third, NHS community nurses look after many of those patients (*[confidential]*) that do require homecare which is paid for by the NHS budget (see volume 5 section 3.5). Fourth, the NHS is entirely free to outsource that nursing by contract to a third party other than Genzyme. Genzyme is in no position to prevent that happening. Fifth, those patients who receive Genzyme homecare treatment do so at no cost to the NHS.'[371]

314. Genzyme sets out five arguments in support of its statement that 'homecare' services (but not home delivery) are provided for free. The first three arguments aim to show that there are very few patients actually receiving 'nursing services' (i.e. 'homecare' services). The Director considers that this argument does not support Genzyme's position, flatly contradicting

[370] Ibid, paragraph 12.16 at page 151.

[371] Ibid, paragraph 12.20 at page 152.

Genzyme's statement to the DoH that 'Healthcare at Home provide extensive nursing support to many patients...'[372]. Even if, as Genzyme now maintains, it provides 'homecare' services to a few patients, the fact that few patients receive 'homecare' services can only mean that the NHS is paying for a service which is not provided in the majority of cases, although the NHS pays for it every time it purchases Cerezyme.

315. In any case, Genzyme's estimate of the number of patients receiving 'homecare' services is based on patients who receive 'nursing services' only, i.e. it excludes home delivery services (taking the drug to the patient's home, assisting with unpacking the product and the ancillaries, checking the stock, rotating the stock, removing all packaging and waste)[373]. When home delivery services are included as part of Homecare Services (see paragraph 172 above), the number of patients receiving Homecare Services is estimated to be *[confidential]*[374].

316. Further, the Director does not accept Genzyme's statement that *[confidential]* patients receive 'homecare' services from NHS community nurses. Genzyme refers to Volume 5 section 3.5 of its written representations in support of this statement, which contains an attachment to the statement of Dominic Moreland, Director of Genzyme Homecare. In his statement, Mr Moreland explains that he estimates that around *[confidential]* Gaucher patients in the UK may receive community nursing support from various NHS organisations[375]. Genzyme quotes the figure of *[confidential]* patients four times in its Response[376] but at no point makes it clear that this figure is an estimate, nor does it explain the basis on which this estimate is calculated. Having examined the source of this figure, the Director does not accept that it provides a reliable indication of the number of patients receiving

---

[372] See letter from M.Cortvriend (Genzyme) to R.Bratt (DoH – PPRS branch) dated 7 September 1999.

[373] It is not clear whether Genzyme's definition of 'homecare' services includes the provision of accessories, such as fridges and syringes which are supplied to all patients, or whether Genzyme considers this to be part of home delivery of Cerezyme.

[374] See Genzyme's estimate of patients treated by Genzyme Homecare, submitted on 30 November 2001. See also HH's estimate of patients treated by HH submitted on 29 April 2002.

[375] See statement of D.Moreland, attached to Genzyme's written representations submitted on 25 October 2002, paragraph 53.

[376] Genzyme's written representations submitted on 25 October 2002, paragraphs 10.8 at page 133, 10.17 at page 135, 11.20(b) at page 145 and 12.20 at page 152.

'homecare' services from NHS community nurses[377]. Further, it is in stark contrast with the much lower figure estimated by July Kelly that

> 'I believe that there are currently around *[confidential]* patients in this situation [receiving 'homecare' services from NHS community nurses].'[378]

317. Genzyme's fourth argument is that the NHS is free to outsource the 'homecare' services by contract to a third party other than Genzyme. As explained in paragraphs 301 and 302 above, as a result of Genzyme's pricing policy, when the NHS purchases Cerezyme (for use in the community or in hospitals), it automatically pays a price which includes Homecare Services. Therefore, if the NHS wished to purchase Homecare Services from anyone other than Genzyme (or an undertaking acting under contract for Genzyme) it

---

[377] The table attached to D.Moreland's statement shows numbers of Homecare Services patients, for both HH and Genzyme, receiving different types of infusion: those receiving 'nurse assisted home infusion' from Genzyme Homecare or HH, those receiving 'NHS-assisted home infusion' from the NHS and 'independent home infusion'. The table shows the number of patients receiving 'NHS-assisted home infusions' as *[confidential]*, but it does not indicate that this figure is an estimate. Further down in the table, however, it shows the number of patients 'Delivered to Home by HH for independent infusion or NHS/GP infusion' as *[confidential]*. A footnote next to this number states:

> 'Patients independent or receiving community NHS support (District Nurses/GP surgery). Exact data not available but based on Genzyme Homecare small UK population – could be as high as *[confidential]*% or *[confidential]* patients of the *[confidential]*.'

The Director assumes that the *[confidential]* patients referred to are those served by HH but not receiving regular nursing visits from HH. Genzyme does not know how many of these patients receive NHS/GP infusions so has assumed that the proportion who do so is *[confidential]*%. This percentage is based on 'Genzyme Homecare small UK population'' but the table does not give an explanation of how the percentage has been calculated. There are *[confidential]* Genzyme Homecare patients who receive infusions at home: *[confidential]* receive nurse-assisted home infusion from Genzyme Homecare, *[confidential]* receive NHS-assisted home infusion from the NHS and *[confidential]* independently infuse. The proportion of these patients receiving NHS-assisted home infusions is therefore *[confidential]* out of *[confidential]*, or 33%. Genzyme appears to have taken this percentage and applied it to the *[confidential]* HH patients who do not receive nurse-assisted home infusions from HH, to arrive at a figure of *[confidential]* HH patients receiving NHS-assisted home infusions. Adding these to the *[confidential]* Genzyme Homecare patients receiving NHS-assisted home infusions gives the total figure of *[confidential]*.

Genzyme's estimate is therefore based on the assumption that the proportion of patients receiving NHS-assisted home infusions will be the same for Genzyme Homecare and HH. There is no compelling reason for these proportions to be the same, particularly when only *[confidential]* patients have switched to Genzyme Homecare, and an estimate based on this assumption is therefore unreliable.

[378] Statement by J.Kelly dated 23 October 2002, paragraph 37, attached to Genzyme's written representations submitted on 25 October 2002.

would have to pay for the Homecare Services twice: first to Genzyme, as part of the inclusive price of the drug and the Homecare Services, and then to the independent delivery/homecare services provider, as reimbursement for the Homecare Services. Therefore, the NHS is not effectively free to outsource the Homecare Services to a third party other than Genzyme or an undertaking acting under contract for Genzyme (unless it is willing to pay twice for the Homecare Services).

318. Finally, Genzyme argues that the NHS patients who receive 'homecare' services from Genzyme do so at no cost to the NHS; in other words, 'homecare' services (but not home delivery) are provided for free. This statement appears to be entirely inconsistent with the statements made by Genzyme to the DoH in 1999 during the PPRS price reduction negotiations[379]. At that time Genzyme told the DoH:

> 'You [DoH] commented that Cerezyme pricing may be unique. Our price of £618 per unit vial is the price which our home care provider, HealthCare at Home Limited [sic], supplies the product to the NHS. However, this, as I pointed out, does not just include the price of the drug. Healthcare at Home provide extensive nursing support to many patients, even to the extent of thrice weekly visits to patient's homes to administer two hour infusions. In addition, home delivery and ancillaries such as water for injection, infusion pumps and lines, needles, swabs, etc, are all provided as part of this service together with fridges for storage of drugs, etc.
>
> We discussed two issues for which we would like clarification. If Genzyme agrees to participate in the PPRS scheme as outlined in the letter, what opportunities are there for negotiation regarding the proposed 4.5% price decrease, based, in part, on the unique pricing as described above?' [380]
> [Emphasis added]

319. Genzyme also told the DoH[381]:

> 'The list price for the NHS represents two elements, firstly, the cost of the pharmaceutical drug and secondly the costs of providing homecare assistance

[379] See 'Pricing' section at paragraphs 87 to 115 above. In particular, see letter from M.Cortvriend (Genzyme) to R.Bratt (DoH - PPRS branch) dated 7 September 1999; letter from R.Bratt (DoH – PPRS branch) to M.Cortvriend (Genzyme) dated 14 September 1999; letter from P.Foster (Financial Controller, Genzyme) to R.Bratt (DoH – PPRS branch) dated 22 March 2000.

[380] See letter from M.Cortvriend (Genzyme) to R.Bratt (DoH – PPRS branch) dated 7 September 1999.

[381] See letter from P.Foster (Financial Controller, Genzyme) to R.Bratt (DoH, PPRS Branch) dated 22 March 2000.

for patients whom have infusions in their home environment. The cost of homecare is dependent on the level of service provided, ranging from delivery of the drug and ancillaries and waste disposal to complete nursing assistance in the form of home visits.

To compute the price of the drug (which solely attracts the 4.5% discount, as agreed in your letter of 14th September 1999) we have had to deduct the average cost of homecare.' [Emphasis added]

320. The only explanation provided by Genzyme in its written representations of 25 October 2002 in response to the Rule 14 Notice about the statements made to the DoH in 1999 was as follows:

> 'Genzyme did seek to assess its homecare costs (which then included the payments made to HH under its agreement) in response to the Department of Health's imposition of a reduction in its list price (see volume 5 section 2), but the price that has been charged following that price reduction remains a price for the supply of the drug and its delivery to the patient alone.'[382]

321. And,

> 'The Director seeks to rely in this regard on the 1999 price reduction negotiations with the Department of Health (i.e. the same negotiations he chooses to disregard in assessing NHS buyer power). Genzyme accepts that it argued in 1999 in price reduction negotiations with the Department of Health that the cost of homecare at a time when it was contracted to HH should be taken into account in fixing the price of Cerezyme under the PPRS. The Department of Health agreed with Genzyme's representations (see witness statement of Malcolm Johnson at volume 5 section 2). Equally,there is no question (for the reasons set out above) of the NHS authority paying for homecare or paying for homecare twice ([Rule 14] Notice §182) and there is no evidence to support that factual allegation in the [Rule 14] Notice, §183.'[383]

322. Genzyme's explanation was inadequate. It accepted that the cost of Homecare Services had been taken into account to fix the price of Cerezyme under the current PPRS (which runs from 1999 to 2004), but at the same time stated that the price charged to the NHS does not include the 'homecare' services (although it includes home delivery).

---

[382] Genzyme's written representations submitted on 25 October 2002, paragraph 1.22 at page 53.

[383] Ibid, paragraph 12.22 at page 153.

323. In view of Genzyme's confusing and extremely brief explanation of this central question in its written representations, the Director asked Genzyme during its oral representations to reconcile the statements made to the DoH in 1999 to the statement that Genzyme provides 'homecare' services (but not home delivery) free of charge. Genzyme declined to respond at that time and agreed to provide a written answer to the question[384]. Following the oral representations, the Director put the question in writing to Genzyme[385]. Genzyme responded that,

> '1.1 There is no inconsistency between the statements made to the Department of Health and the position that Genzyme has at all times provided homecare services free of charge. (...) the Director does not appreciate that there is a fundamental difference between the PPRS (which is an exercise to determine overall profitability) and the NHS Drug Tariff (which concerns pricing of individual products).
>
> (...)
>
> 1.6 What the Director appears to be confusing is the cost of homecare services to Genzyme – a relevant matter in determining profitability under the PPRS (...) – with whether Genzyme is paid by the NHS for supplying homecare services – which it is clear it is not.'

324. Genzyme then referred to the head of PPRS's statement that 'The operating assumption of the PPRS in primary care is that the supply to patients of medicines manufactured by scheme members is through wholesalers and community pharmacists that dispense the medicines to patients in the pharmacy'. Genzyme argued that it was precisely because distribution of Cerezyme involved costs which departed from the operating assumptions of the PPRS that Genzyme made representations to the DoH as to distribution costs in 1999.

325. As explained in detail in paragraphs 68 to 83 above, under the section 'The NHS list price and the PPRS', the NHS list price and the PPRS are inextricably linked. This conclusion is supported by the Translucency Report submitted by Genzyme[386].

---

[384] See Transcript of the oral hearing held on 6 November 2002; in particular, question put by the OFT to M.Johnson (Vice President & General Manager, Genzyme Therapeutics) at page 86, lines 2 to 19; and Mr Johnson's response at page 86, lines 20-24.

[385] See letter from the OFT to E.Perrott (TV) dated 13 December 2002.

[386] See, in particular, Translucency Report paragraphs 2.9.3 at page 13 and 5.1.26 at page 40.

326. In any case, none of Genzyme's arguments explain its submissions to the DoH that

> 'the list price [of Cerezyme] for the NHS represents two elements, firstly, the cost of the pharmaceutical drug and secondly the costs of providing homecare.'[387]

327. Similarly, Genzyme has not explained why, if 'homecare' services (but not home delivery) are provided for free, it told the DoH in 1999 that in order

> 'to compute the price of the drug (which solely attracts the 4.5% discount…) we have had to deduct the average cost of homecare.'[388]

328. Furthermore, in a statement attached to Genzyme's Response, M.Cortvriend (Vice President at Genzyme), who was involved in the 1999 negotiations with DoH, stated,

> 'The NHS was aware that this single price covered both supply of the drug and provision of homecare.
>
> (…)
>
> It has always been Genzyme's policy that there is a single inclusive price payable by the NHS for the supply of Cerezyme and the provision of homecare.'[389]

329. In view of the above, the Director rejects Genzyme's contention and concludes that Genzyme makes the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme.

330. Genzyme also argued that 'it is not an abuse for the supplier of a product to choose to supply it to the market directly rather than through wholesalers, distributors or other third parties'[390]. This is an argument that Genzyme has made throughout its Response. However, this argument has no bearing on the abuse, as set out in the Rule 14 Notice and in this Decision. The abuse, as set out in those two documents, is making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, thereby

---

[387] Letter from P.Foster (Financial Controller, Genzyme) to R.Bratt (DoH, PPRS branch) dated 22 March 2000.

[388] Ibid.

[389] Statement by M.Cortvriend (Genzyme) dated 23 October 2002, attached to Genzyme's written representations submitted on 25 October 2002.

[390] Genzyme's written representations submitted on 25 October 2002, paragraph 12.23 at page 153.

reserving to itself (or to an undertaking acting under contract for Genzyme) the ancillary but separate activity of providing Homecare Services. The abuse, as set out in the Rule 14 Notice and in this Decision, is not Genzyme's decision to supply Cerezyme directly and not through HH or any other third party. In view of this, there is no need for the Director to address Genzyme's representations in this respect.

(ii) Raising barriers to entry to the upstream market

331. Genzyme's policy of making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, has the effect of raising the already high barriers to enter the upstream market for suppliers of new drugs for the treatment of Gaucher disease requiring home delivery and homecare services.

332. As explained in paragraphs 230 to 255 above, barriers to entry into the upstream market are already high. Genzyme's first mover advantage in a market with a small number of patients, combined with its patent protection and the regulatory barriers faced by suppliers of new drugs, make it difficult for a new treatment to gain a foothold in the market. An example of this is that since Cerezyme was first launched in the UK in 1991, there has been only one entry, Zavesca (which entered on 3 March 2003), and it is questionable whether this is an 'effective' entrant[391].

333. In addition, a supplier of a new drug for the treatment of Gaucher disease needs to have access to existing Gaucher patients if it is to be successful in launching its drug. Access to patients is obtained through their doctors, following the advice of specialist physicians[392]. Where the number of patients suffering from a disease is so small as it is the case with Gaucher, finding patients willing to try a new treatment can prove very difficult.

334. Access to patients is made even more difficult for drugs for the treatment of Gaucher disease requiring home delivery and homecare services if Cerezyme, the only currently available ERT (the preferred standard of care for Gaucher patients) and the Homecare Services are effectively tied together and are supplied by the drug manufacturer (or an undertaking acting under contract for it). This is because patients would be required not only to switch to the

[391] See paragraphs 202 to 225 above.

[392] The importance of accessing patients in order to successfully launch a new drug was confirmed by TKT, which has recently launched its new treatment for Fabry disease in the UK. See note of telephone conversation dated 29 April 2002.

new drug, but also to a new delivery/homecare services provider. This difficulty is illustrated by the statement made by Professor Cox in an interview with Genzyme,

> 'EFVP [Genzyme's external solicitor] asking whether TC [Professor Cox] would personally be influenced by the identity of the homecare provider in changing from one medication to another. (...). TC responding that this is genuinely difficult. When a patient receives nursing support and delivery of medication from a particular homecare service provider, a close relationship can build up, a relationship of reassurance. This can be very important to certain types of patient. In relation to TC's disagreement with Genzyme in 2001, this initially arose when a local physician changed the homecare service provider for three of his patients. This caused anxiety and dislocation for vulnerable and sensitive patients, and was, overall, negative for them. This illustrates that there can be genuine difficulties in changing homecare service providers, and if the service provider 'comes with' the drug, this then becomes a factor when seeking to change the drug.'[393]

335. The need to change delivery/homecare services provider if the drug is changed, assumes that the Homecare Services provider (whether it is Genzyme or a third party acting under contract for it) is prevented from, or considers that it has a conflict of interest in, offering home delivery and homecare services for a competing drug. While there is no direct evidence of this (as there is no such competing drug yet in existence), on the evidence available it is reasonable to assume that Genzyme would not be prepared to distribute a drug that would compete directly with its own[394]. Genzyme will have an inherent conflict of interest in the home delivery/homecare services function. This is evidenced from the fact that although Genzyme's distribution agreement with HH did not contain a clause preventing HH from distributing a Gaucher drug that competed with Cerezyme, Genzyme has indicated that such a non-compete clause 'must have been implied into the Agreement'[395]. Similarly, during an interview with Professor Cox where this subject was discussed, Genzyme's legal representative questioned 'whether TC would genuinely expect a drug company to use the same homecare

[393] Minutes of meeting between Professor Cox and Genzyme's legal representatives dated 30 August 2002, page 4.

[394] One of the Gaucher specialists, Dr Mehta, expressed this concern during a meeting on 10 July 2001.

[395] Genzyme's submission to the OFT dated 2 May 2001.

provider as its direct commercial competitor'[396]. Further, Genzyme's negative reaction when it discovered that HH was considering distributing TKT's Fabry disease drug (which competes with Genzyme's own Fabryzyme), indicates a general policy of not allowing HH to distribute drugs that compete with Genzyme's[397]. There is no reason to believe that Genzyme's policy in this respect changed with the launch of its own home delivery/homecare services operation.

336. Doctors and patients are generally reluctant to switch to a new drug. Furthermore, once the treatment routine and a strong patient relationship has been established, Gaucher patients are extremely reluctant to change the Homecare Services provider because of the relationship built between homecare staff and the patient. Although it is ultimately the doctor's decision to choose a patient's treatment, the patient will influence this decision. This is illustrated by the statements made by Professor Cox and Keith Davis (Administrator at Addenbrooke's Hospital) during an interview with Genzyme,

> 'KD [Keith Davis] responding that patients do, of course, have their own views on treatment and may be swayed by non-clinical considerations such as liking a particular homecare service provider. This can then influence the clinician, in that he can only treat a patient with consent. TC [Professor Cox] stating that, while he does have some influence over patients, he does also fail to convince them on occasion. KD adding that this is a problem facing the NHS as a whole since the service is increasingly forced to focus on patients and their wishes.
>
> (...)

[396] Minutes of meeting between Professor Cox and Genzyme's legal representatives dated 30 August 2002, page 5. Professor Cox responded that he could not see a real reason why not, if the Homecare Services provider was independent.

[397] Note prepared by M. Johnson (Vice President & General Manager, Genzyme Therapeutics) as part of Genzyme's response of 30 November 2001 to the section 26 Notice dated 11 October 2001 (see response to request for information, appendix 1, section entitled 'Terminating the Healthcare at Home contract'). In his note, Mr Johnson stated 'During my discussions with Charles Walsh, I became suspicious he was dealing with TKT (a rival US biotech company who have a competing ERT for Fabry disease). I asked him directly if he had agreed a distribution contract with TKT for their competing product to Fabrazyme, Replegal. He said there was not a signed contract in place at that time. Subsequent to this, we now know that Healthcare at Home is the distributor for TKT's Replegal in the UK. In light of this information and market intelligence regarding TKT's plans to announce in the near future the start of a generic imiglucerase (Cerezyme) trial in the UK, Genzyme is actively considering its position and what, if any, action to take.'.

> TC summarising – any person can influence a patient's request for treatment and the patient can then influence TC. TC is a 'modern doctor' in that he tries to agree treatment with the patient.'[398]

337. Similarly, Dr Waldek (a Fabry specialist asked by Genzyme to comment on this point) stated that

> 'the idea that it is the physician who prescribes a drug entirely independent of the patient is no longer true. Physicians now work in consultation with the patients, which I believe to be of great benefit for the patients.'[399]

338. Similarly, Dr Lee (a Fabry specialist asked by Genzyme to comment on this point) in response to Genzyme's question as to whether Genzyme's decision to distribute Cerezyme directly would affect a physician's decision as to whether to prescribe Cerezyme or a competing drug if there was one, stated

> 'Dr Lee responding that, on the basis that Healthcare at Home were there to deliver the drug, it would really make no difference at all. A physician would decide which drug to prescribe in consultation with the patient, and according to the characteristics of the drug and the patient's needs.'[400]

339. The reaction of patients and doctors to Genzyme's termination of the HH contract demonstrates the importance given to the Homecare Services element of their treatment and the doctors' (and, ultimately, patients') reluctance to change. As Genzyme's drug was the first in the market and has been, for over ten years, safe and effective, doctors and patients will understandably resist change to a new drug, unless they can see significant benefits in it. If switching to a new drug also involves changing the delivery/homecare services provider, this resistance will increase and the need to change both the drug and the delivery/homecare services provider will become a factor in doctors' (and patients') decision to change a patient's treatment, which may ultimately mean that change is rejected in favour of remaining with Cerezyme. This is supported by the evidence gathered by the MMC during its inquiry into the merger between Fresenius and Caremark Limited, where it observed that:

---

[398] Minutes of meeting between Professor Cox and Genzyme's legal representatives dated 30 August 2002, pages 3 and 4.

[399] Statement of Dr Stephen Waldek given to Genzyme on 18 October 2002.

[400] File note of telephone conversation between E.Perrott (TV) and Dr Philip Lee (Royal National Hospital) dated 8 August 2002.

'In addition, clinicians are often opposed to the switching of existing patients between [homecare services] suppliers because of the disturbance to patients, many of whom may not be happy with changes in the treatment they are receiving.'[401]

340. Another factor is the fact that some patients react better to one drug than to another one. Doctors may need to try the various available treatments on a particular patient before being able to determine which one is the most effective and best suited in that case. If this involves changing delivery/homecare services provider every time a different drug is tested, doctors (and patients) are likely to be less willing to try alternative drugs.

341. The ease with which patients can be switched to a new drug requiring home delivery and homecare services would be much greater if the supplier of the drug did not determine, directly or indirectly, the identity of the delivery/homecare services provider. This would also mean that one undertaking could offer a choice of treatments for Gaucher disease rather than just one.

342. A further consideration is the possibility that some new drugs for the treatment of Gaucher disease may be complementary to (i.e. a partial substitute for) Cerezyme and, therefore, need to be administered alongside Cerezyme. Given Genzyme Homecare's inherent conflict of interest regarding the provision of home delivery and homecare services for competing drugs highlighted in paragraph 335 above, if the only Homecare Services operator providing Homecare Services is Genzyme Homecare, it is likely that the same patient would have to receive home delivery and homecare services from two different companies (Genzyme Homecare and the new supplier(s)'s delivery/homecare services provider(s)). This would create difficulties for doctors in ensuring that treatment is monitored properly and is more likely to make patients unwilling to try the new treatment.

343. Genzyme's policy of making the NHS pay a price which includes Homecare Services if it wishes to buy Cerezyme therefore has the effect of raising barriers to entry to the upstream market for suppliers of new drugs for the treatment of Gaucher disease, requiring home delivery and homecare services (e.g. new ERTs such as the one TKT is developing). Raising barriers to entry when they are already high is of particular concern as the Competition Commission Appeals Tribunal recognised in its judgement in *Napp*:

[401] Monopolies and Mergers Commission 'A report on the proposed merger Fresenius AG and Caremark Limited', Cm 3925 (April 1998).

'In a situation where the barriers to entry protecting an incumbent monopolist are already high, even a modest raising of further barriers by the pricing actions of that monopolist is potentially a serious matter.'[402]

344. Furthermore, Genzyme, as the dominant supplier of the drug of choice in the UK for treating Gaucher disease, which faces competition only from one other drug which is effectively still 'on trial' for the next three years and will only be suitable for a limited number of patients[403], must ensure that its behaviour does not hinder the maintenance of the degree of competition still in the market or the growth of that competition[404].

345. As highlighted by the European Commission in *Tetra Pak (BTG licence)*[405], the effect of blocking or delaying entry of a new competitor is all the more serious in a market (such as the present one) where the incumbent has a monopoly position and new entry is the only way its market power could be challenged. Genzyme has had a monopoly position in the upstream market for over ten years. Although Zavesca has now entered the market, the limitations in its marketing authorisation[406] and the status of ERT (i.e. Cerezyme) as the preferred standard of care for Gaucher disease[407], mean that Genzyme will, in the short to medium term, continue to hold a near monopoly position.

346. Genzyme argued that the Director is mistaken in his conclusion that Genzyme's policy to make the NHS pay a price which includes Homecare Services if it wishes to buy Cerezyme creates an additional barrier to enter the upstream market.

---

[402] Case No.1001/1/1/01 *Napp Pharmaceutical Holdings Limited and Subsidiaries v DGFT*, [2001] CAT1 at [286], [2001] CompAR 13.

[403] See note of meeting with Professor Cox dated 16 January 2003. See also OGS press release 'European Commission approval for Zavesca' dated 26 November 2002.

[404] Case 85/76 *Hoffmann-La Roche v Commission* [1979] ECR 46, paragraph 91.

[405] Commission Decision IV/31.043 *Tetra Pak (BTG licence)* OJ (1988) L272/46, paragraph 47. Decision upheld on appeal to the CFI on case T-51/89 *Tetra Pak Rausing SA v Commission* [1990] ECR II-309.

[406] See note of meeting with Professor Cox dated 16 January 2003. See also OGS press release 'European Commission approval for Zavesca' dated 26 November 2002. See also document entitled 'Summary of Product Characteristics for Zavesca', published by OGS on 20 November 2002. See also document entitled 'EMEA - Committee for Proprietary Medicinal Products European Public Assessment Report – Zavesca', published by EMEA in 2003.

[407] Ibid.

347. In support of this argument Genzyme referred to OGS's statement that 'the way in which Genzyme distributes Cerezyme does not have a direct impact on OGS's ability to launch a product like Vevesca [now called Zavesca]'[408]. When OGS made this statement, Zavesca had not yet received marketing authorisation and was, therefore, a potential (as opposed to an actual) competitor of Cerezyme. Genzyme argued that the Director must be mistaken in his conclusion that Genzyme's pricing policy raises barriers to enter the upstream market, since one of the only two potential competitors of Cerezyme (OGS) did not view it as a barrier to entry.

348. The Director does not accept this argument. The reason why OGS did not view Genzyme's policy of making the NHS pay a price which includes Homecare Services if it wishes to buy Cerezyme as a barrier to enter the upstream market, is because its own drug, Zavesca, is an oral drug which does not require the provision of home delivery and homecare services. The channels of distribution for Zavesca are, therefore, likely to be different from those of Cerezyme and Genzyme's policy regarding the pricing of Homecare Services does not affect OGS.

349. Genzyme also argued in this context that the identity of the delivery/homecare services provider would not affect a doctor's decision as to the treatment to be prescribed. In support of this statement, Genzyme referred to evidence provided by Dr Waldek, Dr Lee and Dr Wraith[409]. Genzyme did not explain in its Response, how this evidence supported its allegation; it simply referred to the witness statements made by the doctors. On examining these witness statements, the Director found that none of the doctors were asked the question whether the identity of the delivery/homecare services provider could affect their choice of treatment if they were considering switching from an established drug to a new entrant, where such a switch would involve changing the patient's delivery/homecare services provider[410].

---

[408] Genzyme supplementary written representations submitted on 9 December 2002. See also note of telephone conversation between the OFT and M.Kranda (OGS) dated 10 May 2002.

[409] Genzyme's written representations submitted on 25 October 2002, paragraph 12.35 at page 155.

[410] Dr Waldek was asked 'whether the identity of the homecare provider may in any way restrict the access of a new or competing therapy producer to the upstream market' (Statement of Dr Stephen Waldek given to Genzyme on 18 October 2002). Dr Lee was asked whether 'if Genzyme took the distribution of Cerezyme completely in-house (i.e. if HH were not distributing Cerezyme at all) was there any likelihood that that would affect

350. The Director does not dispute the statement that, all things being equal, it is ultimately the doctor's choice to determine the best treatment for a patient, regardless of the identity of the delivery/homecare services provider. However, the Director's argument is based on the scenario where the supplier of an existing drug determines, directly or indirectly, the identity of the delivery/homecare services provider (as it is the case with Cerezyme)[411]. In this context, patients could be switched to a new treatment more easily if the supplier of the drug did not determine, directly or indirectly, the identity of the delivery/homecare services provider.

(iii) No objective justification

351. In its written representations Genzyme referred to the judgments of Laddie J in *Getmapping plc v Ordnance Survey*[412] and *Suretrack Rail Services Ltd v Infraco JNP Ltd* [413]. Genzyme submitted that the burden of proof was on the Director to prove, to the requisite high standard, that Genzyme's distribution policy was incapable of objective justification in the sense that it was a policy which no rational and fair person could justify[414].

352. The Director notes that both of these judgments concerned the special circumstances of a court deciding on whether a claimant had satisfied the high hurdle required for interim relief[415] where the claimant was alleging an

---

the decision of physicians in whether to prescribe Cerezyme or a competing drug if there was one' (file note of telephone conversation between E.Perrott (TV) and Dr Philip Lee (Royal National Hospital) dated 8 August 2002); and Dr Wraith was asked whether 'by restricting the homecare provider to Genzyme, it inhibits any other product coming in and the freedom for you, as the physician caring for the patient to have the autonomy to use whatever product you wish, just because the homecare service is provided by us [Genzyme]. I would guess that this would not be the case, because you have the latitude to use whatever you decide is best. Am I right?' (email from J.Kelly (Genzyme) to E.Wraith (Manchester Children's Hospital) dated 8 August 2002).

[411] This is not undermined by the fact that HH is currently also offering Homecare Services. As explained previously in this Decision, HH has indicated that, although it is currently running a loss making operation, it is prepared to remain in the downstream market *[confidential]* in the hope that it will then be able to obtain supplies of Cerezyme on terms which allow it to compete viably.

[412] *Getmapping plc v Ordnance Survey* [2002] UKCLR 410.

[413] *Suretrack Rail Services Ltd v Infraco JNP Ltd* [2002] EWHC 1316 (CH).

[414] Genzyme's written representations submitted on 25 October 2002, paragraphs 13.5 and 13.6.

[415] Laddie J stated that '…in simple terms, applications for interlocutory relief, whether mandatory or prohibitory, should not be seen as a means by which a court can be

abuse of a dominant position in the course of private litigation in respect of a commercial dispute.

353. In accordance with section 60 of the Act, the Director does not consider that when making a decision at the culmination of the administrative procedure under the Act that the Chapter II prohibition has been infringed by Genzyme, he must demonstrate that Genzyme's behaviour is incapable of objective justification.

354. In any event, for the reasons given below (paragraphs 355 to 363), the Director considers that there is no objective justification for Genzyme's conduct that is the subject of this Decision.

355. Genzyme does not accept that the price it charges the NHS for Cerezyme, includes Homecare Services. According to Genzyme, the 'homecare' services (but not the home delivery) are provided free of charge. Therefore, Genzyme has not submitted any justification for the fact that it charges the NHS a price for Cerezyme which includes Homecare Services.

356. Genzyme's pricing policy has been questioned on a number of occasions by doctors and by the Gaucher Association. In 1996, Gaucher specialist Professor Timothy Cox wrote two letters to Genzyme asking for clarification on pricing and enquiring about the possibility of purchasing Ceredase directly from Genzyme. On 11 June 1996, Professor Cox asked 'Can you tell me what the unit cost is when Caremark trains patients and provides home care assistance? Finally, would it not be possible for hospital pharmacies to import this licenced agent independently?'[416]. On 19 September 1996, Professor Cox asked 'what the cost of the drug is if purchased directly from Genzyme compared with that from Caremark'[417]. In response to these queries Genzyme offered the following explanations.

357. Response to the June 1996 letter :

> 'At present we are convinced that Caremark, by virtue of their unique position in wholesaling, dispensing and providing home care, are offering the best

---

persuaded to grant relief on the basis of a claim to rights which it is fairly confident would not be upheld at the trial. The more confident it is that the claimant will fail at the trial, the less likely it is that an interlocutory injunction will be appropriate' (at paragraph 28 of *Getmapping* and paragraph 14 of *Suretrack*).

[416] Letter from Professor Cox to M.Cortvriend (Genzyme) dated 11 June 1996.

[417] Letter from Professor Cox to M.Cortvriend (Genzyme) dated 19 September 1996.

possible deal to all concerned. If you feel that there is another way that this could be done which would free up more money to be spent on the active treatment itself, I would be very interested to hear about it. I do realise that in many areas of business competition can often help to bring prices down, but for Ceredase I do not feel that this would happen and the price to the patients during the learning curve if new suppliers are involved, could be considerable.

Your question regarding the possibility of a hospital pharmacy acting as an importer of a licenced medicine is an interesting one. In order to do this an individual pharmacy would have to, among other things, set itself up as a registered wholesaler and apply for a wholesaler dealer's licence to the MCA. This process of parallel importing is not uncommon within the EC where there are large price differentials between prices and countries, however this is not the case with Ceredase and in fact the UK price is at the lower end of the scale of prices across the EC and I do not see that it would be a worthwhile exercise for a pharmacy to undertake as far as Ceredase is concerned.'[418]

358. Response to the September 1996 letter:

'There is no new price for Ceredase and the £3.09 per unit to which you refer is the 'List Price' which Caremark charge when they dispense Ceredase on a prescription. The price of £*[confidential]* per unit is the *[confidential]* 'Hospital Price' which has remained unchanged for several years although of course with VAT this comes to £*[confidential]* per unit. If we were to revert to a system where customers were to purchase Ceredase directly from Genzyme the resultant price would inevitably be somewhat higher than the above.'[419]

359. Similarly, Jeremy Manuel, chairman of the Gaucher Association, questioned the high price charged for Genzyme's drugs (first Ceredase and, later, Cerezyme) and the home delivery and homecare services on a number of occasions[420]. In a fax from M. Cortvriend (Genzyme) to J. van Heek (Genzyme B.V), Mr Cortvriend referred to the ongoing discussions with J.

[418] Letter from M. Cortvriend (Genzyme) to Professor Cox, dated 21 June 1996.

[419] Letter from M. Cortvriend (Genzyme) to Professor Cox, dated 24 September 1996.

[420] Letter from H.Termeer (Genzyme) to J.Manuel (Gaucher Association) dated 12 December 1996 which refers to the extensive correspondence between Genzyme and Mr Manuel regarding the price of Ceredase and the price charged by the service provider, Caremark. See also letter from M. Cortvriend (Genzyme Corporation) to J. Manuel (Gaucher Association) dated 12 November 1996, fax from M. Cortvriend (Genzyme) to J. van Heek (Genzyme B.V.) dated 14 January 1997 suggesting wording to be included in future correspondence with J. Manuel; fax from M. Cortvriend (Genzyme) to J. van Heek (Genzyme B.V.) dated 2 June 1997 referring to discussions and correspondence with J. Manuel.

Manuel about prices and suggested that the following wording should be included in any future letter to Mr Manuel:

> 'Our goal is to act in the best interests of both patients and physicians with respect to the provision of treatment for Gaucher Disease. Our initial responsibility is to market the product for which we make a charge. In other areas of the pharmaceutical industry that is as far as it goes and other costs are charged separately by third parties. However, given that Ceredase is a particularly expensive product to manufacture, we felt that we had a duty to ensure that there was a certain degree of control over the subsequent management of the product, as we too were concerned that some patients would not be able to obtain reimbursement due to the high cost to the Health Authorities. In fact prior to Caremark's involvement, community pharmacies dispensing Ceredase were charging an additional 10%. By dealing with one organisation who could manage every aspect of Ceredase provision we felt we were acting in everybody's best interest.
>
> As you know we are currently working with Caremark who act as a specialist 'Home Care' provider, a wholesaler and distributor, and a dispensing pharmacy. Caremark are currently the only company in the UK who are able to manage all these services without having to contract entire components of this to a third party. Putting two or three separate organisations together into the business of bringing Ceredase to the patient would, in our estimation, add to the cost to the health service. As an example of the costs which might be charged, just for pharmaceutical wholesaling and distributing, we were recently quoted 5-6% by the UK biggest pharmaceutical distributor.'[421]

360. None of the letters quoted above or any other document submitted by Genzyme provides evidence to support Genzyme's statement that its method of distribution is the most cost effective and, therefore, the best option for the NHS. In fact, when asked by the Director for evidence supporting Genzyme's statement that 'By dealing with one organisation (...) we felt we were acting in everybody's best interest' and 'Putting two or three separate organisations together (...) would, in our estimation, add to the cost to the health service', Genzyme admitted that it had not carried out any market analysis or reports which led it to reach those conclusions[422]. Instead, Genzyme submitted that given the limited numbers of patients receiving

[421] Fax from M. Cortvriend (Genzyme) to J. van Heek (Genzyme B.V.) dated 14 January 1997.

[422] Note prepared by Taylor Vinters of telephone conversation between the OFT and Genzyme on 20 March 2002. Also Letter from Taylor Vinters to the OFT dated 27 March 2002 at point 4.

Ceredase initially and the very nature of the introduction of Ceredase to the UK (responding initially to specific requests) it is very unlikely that Genzyme would have carried out any such market analysis[423]. It seems, therefore, that Genzyme's statements that its method of distributing Cerezyme (namely through a Homecare Services provider which charges a single price for the drug and the Homecare Services) is the most cost effective for the NHS are not substantiated.

361. In any case, it is not for Genzyme to determine what is in the best interest of the NHS (or any other purchaser of Cerezyme), while effectively denying the customer the option of obtaining a better deal through competition. Whether or not it would be more cost effective for the NHS to purchase the drug and Homecare Services together as a package or separately, should be a decision for the NHS itself and not for a monopolist supplier of the only available drug.

362. Genzyme has argued that the Director cannot rely on correspondence going back to 1996 and 1997 to support his finding that there is no objective justification for Genzyme's current distribution policy, as this is old correspondence which does not address Genzyme's current distribution policy[424]. The Director is of the view, however, that the relevant correspondence represents valuable evidence of Genzyme's pricing policy then, and, in the absence of convincing evidence to the contrary, now. The price charged by Genzyme for Ceredase in 1996 (£3.09 per unit) remained unchanged when Cerezyme was introduced in 1997 and it has remained unchanged to this date, other than to apply the 4.5% compulsory PPRS reduction to the proportion of the price that represented the cost of the drug. The correspondence is, therefore, highly relevant.

363. Genzyme also argues that its decision to bring the provision of Homecare Services in-house is a rational decision and, therefore, is objectively justified. As explained in paragraph 330 above, the abuse, as set out in the Rule 14 Notice and in this Decision, is not Genzyme's decision to supply Cerezyme directly and not through HH or any other third party. In view of this, there is no need for the Director to address Genzyme's representations in this respect.

[423] Letter from Taylor Vinters to the OFT dated 27 March 2002 at point 4.

[424] Genzyme's written representations submitted on 25 October 2002. paragraph 13.9 at page 162.

2. Genzyme's pricing policy regarding the sale of Cerezyme to delivery/homecare services providers since the launch of Genzyme Homecare results in a margin squeeze

364. A pricing policy operated by a vertically integrated dominant undertaking may infringe section 18 of the Act. This might occur where a vertically integrated undertaking which is dominant in the upstream market operates a pricing policy which does not allow reasonably efficient competitors in the downstream market a margin sufficient to enable them to survive in the long term[425]. This pricing behaviour is known as 'margin squeeze'[426].

365. In the Director's view, a margin squeeze may give rise to an abuse

> 'Where a vertically integrated undertaking is dominant in an upstream market and supplies a key input to undertakings that compete with it in a downstream market, there is scope for it to abuse its dominance in the upstream market. The vertically integrated undertaking could subject its competitors in the downstream market to a price or a margin squeeze by raising the cost of the key inputs and/or by lowering its prices in the downstream market. The integrated undertaking's total revenue may remain unchanged. The effect would be to reduce the gross margin available to its competitors, which might well make them unprofitable.'[427]

366. In considering whether an undertaking is engaging in margin squeezing in breach of the Act, the Director will consider whether the dominant undertaking would be profitable in the relevant downstream market if it had to pay the same input prices as its competitors[428].

367. The European Commission's Telecommunications Access Notice[429] sets out two alternative methods of demonstrating a margin squeeze:

---

[425] Commission Decision 76/185/ECSC *National Carbonizing Company Limited* OJ [1976] L35/6.

[426] See Oftel Guideline OFT 417 'The Application in the Telecommunications Sector', paragraph 7.26; the European Commission Notice on the Application of Competition Rules to Access Agreements in the Telecommunications Sector OJ [1998] C/265/02.

[427] Oftel Guideline OFT 417 'The Application in the Telecommunications Sector', paragraph 7.26.

[428] Ibid.

[429] European Commission Notice on the Application of Competition Rules to Access Agreements in the Telecommunications Sector OJ [1998] C/265/02. Although primarily concerned with the application of competition law in the telecommunications sector, the Notice points out (at paragraph 6) that the principles set out in the Notice will, to the

'117. (...) A price squeeze could be demonstrated by showing that the dominant company's own downstream operations could not trade profitably on the basis of the upstream price charged to its competitors by the upstream operating arm of the dominant company.

118. (...) A price squeeze could also be demonstrated by showing that the margin between the price charged to competitors on the downstream market (including the dominant company's own downstream operations, if any) for access and the price which the network operator charges in the downstream market is insufficient to allow a reasonably efficient service provider in the downstream market to obtain a normal profit (unless the dominant company can show that its downstream operation is exceptionally efficient).'

368. In its decision in *Napier Brown/ British Sugar*[430] the Commission found British Sugar's pricing policy to be an abuse and stated that[431]

'The maintaining by a dominant company, which is dominant in the markets for both a raw material and a corresponding derived product, of a margin between the price which it charges for a raw material to the companies which compete with the dominant company in the production of the derived product and the price which it charges for the derived product, which is insufficient to reflect that dominant company's own costs of transformation (in this case the margin maintained by BS [British Sugar] between its industrial and retail sugar prices compared to its own repackaging costs) with the result that competition in the derived product is restricted, is an abuse of dominant position.

(...) It is clear from the facts as set out above that should BS have maintained this margin in the long term, NB [Napier Brown], or any company equally efficient in repackaging as BS without a self-produced source of industrial sugar, would have been obliged to leave the United Kingdom retail sugar market.'

369. The Director considers that there is no need for a company to be dominant in both the raw material and derived product markets to operate a margin squeeze. If the company is dominant in the raw material market it can

---

extent that comparable problems arise, be equally applicable in other areas, such as access in digital communications sectors generally. Similarly, several of the principles will be of relevance to any company occupying a dominant position, including those in fields other than telecommunications.

[430] Case IV/30.178 OJ [1988] L284/41. See also Case T-5/97 *Industrie des Poudres Spheriques v Commission* [2001] 4 CMLR 1020.

[431] Case IV/30.178 OJ [1988] L284/41, paragraph 66.

exercise a margin squeeze, distorting competition in the derived product market, as long as it is active in that market[432].

(i) Foreclosure of the Homecare Services segment of the downstream market

370. Genzyme terminated its exclusive distribution and service agreement with HH on 5 May 2001. On the same date, Genzyme launched its own delivery/homecare services operation, Genzyme Homecare, and began to operate in the downstream market. Following this change, Genzyme's pricing policy[433] with regard to its competitors in the Homecare Services segment of the downstream market has had an anti-competitive effect on competition in this segment of the market[434]. The only independent delivery/homecare services provider currently purchasing Cerezyme from Genzyme is HH. Genzyme has indicated that the price currently offered to HH would apply to any independent undertaking wishing to purchase the drug for distribution[435].

371. Genzyme's current pricing policy for Cerezyme in the UK can be summarised as follows: Genzyme (in its capacity as supplier of Cerezyme) has only one category of customers, namely Wholesalers/Homecare Services providers. There are currently two entities in this category: (i) Genzyme Homecare, which pays the transfer price of £*[confidential]* per unit[436]; and (ii) HH, which

[432] The OFT has also made this point of principle in its recent case No. CA98/20/2002 *BSkyB investigation: alleged infringement of the Chapter II prohibition,* 17 December 2002, at footnote 306.

[433] See letter from Genzyme to HH dated 25 April 2001. See also Genzyme's current pricing structure provided by Genzyme on 30 November 2001 in its response to question 5.3 of the section 26 Notice dated 11 October 2001.

[434] The Wholesale segment of the downstream market is not considered further in this section, as the margin squeeze applied by Genzyme has a direct anti-competitive impact only on the margin of delivery/homecare services providers when providing Homecare Services.

[435] This was stated by Genzyme in its description of its current pricing structure provided by Genzyme on 30 November 2001 in its response to question 5.3 of the section 26 Notice dated 11 October 2001. In this description, Genzyme sets out the price offered to 'other distributors' and gives as an example the price offered to HH.

[436] Genzyme Homecare is a division of Genzyme Limited. Genzyme Limited purchases Cerezyme from Genzyme *[confidential]* at the transfer price of £*[confidential]* per unit. According to Genzyme, no consideration is paid by Genzyme Homecare to Genzyme Limited for Cerezyme, as Genzyme Homecare is a division of Genzyme Limited and not a separate trading entity. Genzyme has *[confidential]* days to pay for the order. (See Genzyme's submission of 5 March 2002 (response to request number 19) and Genzyme's submission of 1 May 2002 (response to question 2).

pays £2.975 (plus VAT) per unit[437]. These two entities compete in the Homecare Services segment of the downstream market[438]. They only have one customer, namely, the NHS. The prices charged by Genzyme Homecare to the NHS (which HH has to match in order to compete) are as follows:

- £2.975 per unit when the product is to be sold in the community;
- £*[confidential]* (plus VAT) per unit when the product is to be sold to hospitals for infusion within the hospital; and
- £2.975 (plus VAT) per unit when the product is to be sold to hospitals for infusion outside the hospital.

372. As a result of this price structure, HH (or any other delivery/homecare services provider wishing to offer Homecare Services) cannot obtain Cerezyme from any source at any price other than £2.975 (plus VAT)[439].

373. In order to be able to compete with Genzyme Homecare, HH is currently charging the NHS £2.975 per unit of Cerezyme for community sales (including Homecare Services), that is, the same price HH pays Genzyme for the Cerezyme alone[440]. This arrangement does not allow HH a margin on the sale of the drug and it forces it to provide Homecare Services for free if it is to compete with Genzyme Homecare in the Homecare Services segment of the downstream market. This is because the price HH pays Genzyme for Cerezyme (£2.975 plus VAT per unit) is the same price at which Genzyme Homecare sells Cerezyme, together with Homecare Services, to the NHS.

---

[437] HH pays Genzyme £2.975 (plus VAT) per unit of Cerezyme. HH has 60 days from the day of the invoice to pay for the order (although it must issue Genzyme with an irrevocable letter of credit for the full amount when each order is placed, which, in effect, requires HH to have sufficient money in the bank to pay for the order at the time the order is placed).

[438] Following the termination of HH's distribution agreement, HH stopped Wholesaling, as it cannot afford to buy the Cerezyme at £2.975 (plus VAT) per unit and resell it to hospitals at the concessionary price charged by Genzyme of £*[confidential]* (plus VAT) per unit.

[439] For example, if a hospital purchases Cerezyme from Genzyme with the intention of reselling it to HH, the lower price of £*[confidential]* does not apply, as the drug will not be infused in the hospital. According to Genzyme, this is because the lower price offered to hospitals is a concession to take account of the fact that hospitals have to pay VAT on drugs (see paragraph 90 above).

[440] In fact, HH pays Genzyme (either when it purchases the Cerezyme directly or through hospitals) £2.975 plus VAT. For sales into the community HH can, however, reclaim the VAT.

374. Dispensing the drug is an integral part of the Homecare Services segment of the downstream market and, in order to dispense the drug, the Homecare Services provider must first purchase it.

375. In assessing whether the pricing policy of a vertically integrated dominant undertaking results in a margin squeeze, the Director considers whether the dominant undertaking would be profitable in the downstream market if it had to pay the same input prices as its competitors[441] (this is the same as the first test set out in the European Commission's Telecommunications Access Notice[442]). The price at which Genzyme sells Cerezyme to HH (£2.975 plus VAT) is the same price at which Genzyme Homecare sells Cerezyme and Homecare Services to the NHS. If Genzyme Homecare was required to pay £2.975 (plus VAT) for Cerezyme and it continued to sell it to the NHS, together with Homecare Services, at its current price of £2.975, it would make no margin on the drug and it would make a loss on the provision of the Homecare Services. Regardless of how efficient Genzyme Homecare might be, it is clear that it could not trade profitably on these terms.

376. The European Commission's Telecommunications Access Notice[443] sets out a second, alternative, test. Given that the first test is clearly met in the present case, there is no need to consider this second test. However, to illustrate the extreme nature of the margin squeeze applied by Genzyme in this case, the Director has also considered the second test. The margin between the price charged for Cerezyme to competitors (here HH) on the Homecare Services segment of the downstream market and the price which Genzyme Homecare charges in this segment (i.e. the list price charged to the NHS) is insufficient to allow a reasonably efficient Homecare Services provider to obtain any, let alone a normal profit. In fact, even an exceptionally efficient undertaking would not be able to obtain any kind of profit, as the pricing structure applied by Genzyme does not allow any margin at all. The price charged by Genzyme to HH for the drug is the same price charged by Genzyme to the NHS, not only for the drug, but also for the Homecare Services. This allows HH no profit; in fact, it forces HH to sustain a loss in the provision of Homecare Services. No undertaking, regardless of

[441] Oftel Guideline OFT 417 'The Application in the Telecommunications Sector', paragraph 7.26.

[442] European Commission Notice on the Application of Competition Rules to Access Agreements in the Telecommunications Sector OJ [1998] C/265/02, paragraph 117.

[443] Ibid, paragraph 118.

how efficient it may be, could trade profitably in the Homecare Services segment of the downstream market under these terms.

377. The Director therefore considers that Genzyme's pricing policy prevents independent delivery/homecare services providers, no matter how efficient, from operating in the Homecare Services segment of the downstream market. HH will eventually be forced to leave this segment of the market, as it cannot continue to sustain losses indefinitely. The effects of this will be particularly serious, as HH's exit will leave Genzyme Homecare as the monopoly supplier of Homecare Services, in a segment of the downstream market which is completely closed to competition.

378. Genzyme is aware that the current conditions under which it is supplying Cerezyme to HH will have the effect of forcing HH out of the Homecare Services segment of the downstream market. Genzyme has sent letters to a number of doctors responsible for Gaucher patients advising them to switch their patients to Genzyme Homecare, as HH will not be able to provide the Homecare Services at a competitive price in the long term. According to Dr Norfolk, a consultant at The Leeds Teaching Hospital, in September 2001 Genzyme indicated to him that 'if we [the hospital] stayed with Healthcare at Home, the Health Authorities would have to pick up a much bigger bill, as your organisation [HH] obviously couldn't continue to subsidise the service'[444]. This statement suggests that the price charged by Genzyme to HH is intended to force HH's exit from the Homecare Services segment of the downstream market, thus reserving it to its own operation, Genzyme Homecare.

379. Genzyme has argued that there cannot be a margin squeeze, as Genzyme does not charge for the provision of 'homecare' services (although it does for home delivery)[445]. The Director's findings on this point are set out in paragraphs 309 to 329 above.

380. Genzyme also contends that the Director's case on margin squeeze 'is a blatant attempt to avoid confronting the reality of HH's complaint, which is

[444] Letter from the Dr Norfolk (The Leeds Teaching Hospitals) to G.Jones (HH) dated 6 September 2001. See also, letter from D. Moreland (Genzyme Homecare) to the Cornwall and Isles of Scilly Health Authority dated 12 July 200). Letter from D. Moreland (Genzyme Homecare) to the Cornwall and Isles of Scilly Health Authority dated September 2001.

[445] Genzyme's written representations dated 25 October 2002, paragraph 12.27 at page 153.

that of a refusal to supply'[446]. Genzyme has argued throughout its Response that the Director's case is about Genzyme's initial decision to stop supplying HH with Cerezyme.

381. This view is misconceived. The case was clearly set out in the Rule 14 Notice and none of the abuses alleged in that Notice referred to Genzyme's refusal to supply HH with Cerezyme. The Director put this to Genzyme during its oral representations, and Genzyme responded that 'there seems to be a sub-text in the [Rule 14] Notice that bringing it [the Homecare Services] in-house was not correct because it is tied in'[447]. This is mistaken. The case put to Genzyme was clearly set out in the Rule 14 Notice. The case set out in the Rule 14 Notice and in this Decision, is not one of refusal to supply. In view of this, there is no need for the Director to address Genzyme's representations in this respect.

(ii) Raising barriers to entry to the upstream market

382. By selling Cerezyme to delivery/homecare services providers at the same price at which Genzyme Homecare sells Cerezyme and Homecare Services to the NHS, Genzyme ensures that HH cannot operate viably in the short to medium term, or at all in the long term, in the Homecare Services segment of the downstream market and that no independent delivery/homecare services provider can enter such segment. Consequently, Genzyme, the dominant supplier of drugs for the treatment of Gaucher disease (the upstream market), will become the only Homecare Services provider in the Homecare Services segment of the downstream market where entry is completely foreclosed. This will have the effect of further raising barriers to enter the upstream market for the supply of drugs for the treatment of Gaucher disease for suppliers of new drugs for the treatment of Gaucher disease requiring home delivery and homecare services, for the reasons set out in paragraphs 331 to 350 above.

(iii) No objective justification

383. In its written representations Genzyme referred to the judgments of Laddie J in *Getmapping plc v Ordnance Survey*[448] and *Suretrack Rail Services Ltd v*

[446] Ibid, paragraph 12.27 at page 153.

[447] See Transcript of the oral hearing of 6 November 2002, in particular, question put by the OFT, page 101, lines 25 to 38; and response by David Vaughan, QC at page 102, lines 1 to 9.

[448] *Getmapping plc v Ordnance Survey* [2002] UKCLR 410.

Infraco JNP Ltd [449]. Genzyme submitted that the burden of proof was on the Director to prove, to the requisite high standard, that Genzyme's distribution policy was incapable of objective justification in the sense that it was a policy which no rational and fair person could justify[450]. The Director's view in respect of this argument has been set out in paragraphs 351 to 353.

384. Genzyme has also submitted that the justification for the price charged to independent delivery/homecare services providers is the fact that such a price is the NHS list price

> 'The objective justification for the price of Cerezyme to a pharmacy, including HH's pharmacy, is that it is the NHS Drug Tariff price.'[451]

385. The Director does not accept Genzyme's argument. Genzyme merely reiterates that in supplying Cerezyme to pharmacies (HH and Genzyme Homecare) it charges the NHS list price for the drug. It does not justify why it supplies Cerezyme to HH at the same price as Genzyme Homecare sells the drug *and* the Homecare Services to the NHS.

3. Conclusion on abuse of dominance

386. The Director concludes that Genzyme has abused its dominant position in the upstream market by, without objective justification

(i) making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, thereby reserving to itself (or to an undertaking acting under contract for Genzyme) the ancillary but separate activity of providing Homecare Services; and

(ii) adopting a pricing policy following the launch of Genzyme Homecare which results in a margin squeeze;

with the effect of

(i) foreclosing the Homecare Services segment of the downstream market; and

---

[449] *Suretrack Rail Services Ltd v Infraco JNP Ltd* [2002] EWHC 1316 (CH).

[450] Genzyme's written representations submitted on 25 October 2002, paragraphs 13.5 and 13.6.

[451] Genzyme's written representations dated 25 October 2002, paragraph 13.15 page 164.

(ii) raising barriers to entry to the upstream market.

C. Effect on trade within the UK

387. Genzyme is the dominant supplier in the UK of drugs for the treatment of Gaucher disease (the upstream market). The geographic dimension of the relevant markets is the UK. Genzyme's policy that is the subject of this Decision has the effect of completely foreclosing entry into the Homecare Services segment of the downstream market, as well as raising barriers to entry into the upstream market. Ultimately, this policy restricts or will restrict the UK customer's (NHS) and consumers' (patients') choice of Homecare Services provider and is liable to delay the introduction of new competing drugs for the treatment of Gaucher disease, requiring home delivery and homecare services, in the UK. Consequently, it affects or may affect trade within the UK.

IV. THE DIRECTOR'S PROPOSED ACTIONS

388. This section sets out the action which the Director proposes to take and his reasons for it.

389. All terms defined in earlier parts of this Decision continue to have the same meaning when used in this section, unless otherwise stated. In particular, references to Cerezyme include references to Ceredase, unless otherwise stated.

A. Directions

390. Section 33(1) of the Act provides that if the Director has made a decision that conduct infringes the Chapter II prohibition, he may give to such person or persons as he considers appropriate such directions as he considers appropriate to bring the infringement to an end.

391. Genzyme is dominant in the market for the supply of drugs for the treatment of Gaucher disease and it has abused this position in the manner set out in paragraph 386 above. Genzyme has therefore infringed the Chapter II prohibition.

392. The Director proposed in the Rule 14 Notice, to make a direction that the price at which Genzyme supplies Cerezyme to the NHS shall be a stand-alone price for the drug only, that is, exclusive of any Homecare Services that may be provided, thereby giving the NHS the option to purchase the drug alone or as part of a package including Homecare Services.

393. In 1999, in the context of a price reduction imposed by the PPRS (for the PPRS period of 1999-2004), Genzyme submitted to the DoH that the NHS list price of Cerezyme covered two elements: the drug (representing *[confidential]*% of the list price of Cerezyme) and the Homecare Services (representing *[confidential]*% of the list price of Cerezyme). Accordingly, following the implementation of the PPRS price reduction, the implied stand-alone drug-only price charged by Genzyme to the NHS for Cerezyme was and remains £*[confidential]*[452] per unit for the 1999-2004 PPRS.

394. The price of £*[confidential]* per unit of Cerezyme is a price agreed between the DoH and Genzyme. The Director acknowledges that any future alteration to this price is entirely a matter for negotiation between Genzyme and the DoH.

395. The Director also proposed to make a direction that the price at which Genzyme supplies Cerezyme to third parties should not be higher than the stand-alone drug-only price as agreed between Genzyme and DoH with respect to Cerezyme.

396. The Director accordingly gives to Genzyme Limited ('Genzyme') the following direction:

1. Genzyme shall

   1.1 within fifteen working days from the date of this Decision bring to an end the infringement referred to at paragraph 386 above;

   1.2 thereafter, refrain from repeating the infringement referred to at paragraph 386 above and

   1.3 with effect from the date of this Decision, refrain from adopting any measures having an equivalent effect.

2. In particular, within fifteen working days from the date of this Decision

   2.1 the price at which Genzyme supplies Cerezyme and Ceredase to the National Health Service shall be, in respect of each drug, a stand-alone price for the drug only that is exclusive of any Homecare Services that may be provided; and

   2.2 the price at which Genzyme supplies Cerezyme and Ceredase to third parties shall be, in respect of each drug, no higher than the

[452] See paragraphs 99 to 103 above.

stand-alone price for the drug only as agreed between Genzyme and the Department of Health.

3. The term 'Homecare Services' in paragraph 2.1 means, in respect of each of Cerezyme and Ceredase, the delivery of the drug to a patient's home and the provision of homecare services (including, but not limited to, basic stock check, supply of and monitoring of the need for accessories such as fridges and syringes, waste removal, dispensing the drug, training on how to infuse the drug, infusing the drug, providing an emergency help line, respite care and full nursing support).

B. Penalties

397. Section 36(2) of the Act provides that on making a decision that conduct has infringed the Chapter II prohibition, the Director may require the undertaking concerned to pay him a penalty in respect of the infringement. No penalty which has been fixed by the Director may exceed 10 per cent of the turnover of the undertaking determined in accordance with the provisions of the Competition Act 1998 (Determination of Turnover for Penalties) Order 2000[453].

398. Section 40(3) of the Act provides that a person is immune from the effect of section 36(2) if his conduct is 'conduct of minor significance'. This is defined, pursuant to section 40(1) and the Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations 2000[454], as conduct by an undertaking, the applicable woldwide turnover of which for the business year ending in the calendar year preceding the one during which the infringement occurred does not exceed £50 million. In accordance with paragraphs 3 and 4 of the Schedule to these Regulations and through section 60 of the Act which imports the meaning of the term 'undertaking' under EC law, the annual worldwide turnover of Genzyme Corporation is in excess of £50 million. Accordingly, Genzyme cannot benefit from the provisions of section 40(3) of the Act relating to immunity from payment of a penalty.

1. Intentional or negligent

399. The Director may impose a penalty on an undertaking which has infringed the Chapter II prohibition only if he is satisfied that the infringement has been

[453]Section 36(8) of the Act and SI 2000/309.

[454]SI 2000/262.

committed intentionally or negligently, but is under no obligation to determine specifically whether there was intention or negligence[455].

400. The Director is satisfied that Genzyme has intentionally or negligently engaged in the conduct and practices described, which infringe the Chapter II prohibition.

401. Genzyme cannot have been unaware during the period of the infringement of the very strong position it held and continues to hold in the market for the supply of drugs for the treatment of Gaucher disease, in terms of its very high market share, the reputation of Cerezyme as a highly efficacious and safe drug and the high barriers to entry facing rivals.

402. Genzyme is aware that its policy of making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme and of adopting a pricing policy which results in a margin squeeze, has the effect of preventing price competition in the Homecare Services segment of the downstream market. This is illustrated by the statement made by Genzyme's legal representative during an interview with Professor Cox that,

> 'EFVP [Genzyme's legal representative] suggesting that if the OFT's direction takes effect, various companies will be able to provide homecare in relation to Cerezyme and service providers will therefore have to compete on price.'[456]

(i) Genzyme is making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, thereby reserving to itself (or to an undertaking acting under contract for Genzyme) the ancillary but separate activity of providing Homecare Services

403. The Director is satisfied that the infringement in relation to making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, has been committed intentionally or, at the very least, negligently.

404. Contrary to Genzyme's representations, Genzyme cannot have been unaware that the price it charged the NHS for Cerezyme included Homecare Services, as explained by Genzyme to the DoH in 1999. Genzyme therefore knew (in

[455]Section 36(3) of the Act. Case No.1001/1/1/01 *Napp Pharmaceutical Holdings Limited and Subsidiaries and Director General of Fair Trading* [2002] CAT 1 at [455], [2002] CompAR 13.

[456] Note of meeting between Genzyme and Professor Cox, dated 30 August 2002, page 5.

the sense that it could not have been unaware) or ought to have known[457] that its conduct, without objective justification, would restrict competition by completely foreclosing the Homecare Services segment of the downstream market, therefore reserving such segment to Genzyme (or to an undertaking acting under contract for Genzyme) (see paragraphs 301 to 330 above).

405. Genzyme must have been aware that entry to the upstream market depends on access to patients and prescribing doctors who are prepared to try a new Gaucher drug coming into the market. Genzyme must have known that access to patients would be made even more difficult for suppliers of new drugs for the treatment of Gaucher disease requiring home delivery and homecare services, if it supplied Cerezyme (currently the preferred standard of care for Gaucher patients), at a price that effectively tied the Homecare Services, as patients would then be required not only to switch to a new drug, but also to a new delivery/homecare services provider. Genzyme must therefore have been aware that making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme would have the effect of raising barriers to enter the upstream market.

406. The Director takes the view that Genzyme's infringement in respect of its policy of making the NHS pay a price which includes Homecare Services it if wishes to purchase Cerezyme, was, for the purposes of section 36 of the Act, intentional or, at the very least, negligent.

(ii) Adopting a pricing policy following the launch of Genzyme Homecare which results in a margin squeeze

407. The Director is satisfied that the infringement in relation to Genzyme's adoption of a pricing policy following the launch of Genzyme Homecare which resulted in a margin squeeze, has been committed intentionally or, at the very least, negligently.

408. Genzyme knew (in the sense that it could not have been unaware) or ought to have known[458] that charging the same price for Cerezyme to its competitors in the downstream market, as that charged for Cerezyme and

[457] Case No.1001/1/1/01 *Napp Pharmaceutical Holdings Limited and Subsidiaries v DGFT* [2002] CAT 1 at [466], [2002] CompAR 13. See also OFT 407 'Enforcement', at paragraphs 4.6 and 4.9.

[458] Case No.1001/1/1/01 *Napp Pharmaceutical Holdings Limited and Subsidiaries v DGFT* [2002] CAT 1 at [466], [2002] CompAR 13. See also OFT 407 'Enforcement', at paragraphs 4.6 and 4.9.

Homecare Services to the NHS, would prevent any other potential provider of Homecare Services from viably offering such Homecare Services to the NHS. As pointed out in paragraph 378 above, the statement from The Leeds Teaching Hospital clearly shows that Genzyme was aware that its pricing policy would result in squeezing HH, its only competitor, out of the Homecare Services segment of the downstream market.

409. Genzyme, therefore, knew that its anti-competitive pricing policy would ensure that its only competitor, HH, would not be able to operate in the Homecare Services segment of the downstream market and that no independent delivery/homecare services provider could enter such segment. Consequently, Genzyme, the dominant supplier of drugs for the treatment of Gaucher disease, would become the only Homecare Services provider in the Homecare Services segment of the downstream market where entry is completely foreclosed. Genzyme, in addition, must have been aware that this would have the effect of further raising barriers to enter the upstream market for the supply of drugs for the treatment of Gaucher disease for suppliers of new drugs for the treatment of Gaucher disease requiring home delivery and homecare services, for the reasons set out in paragraph 382 above.

410. The Director takes the view that Genzyme's infringement in respect of its pricing policy following the launch of Genzyme Homecare, was, for the purposes of section 36 of the Act, intentional or, at the very least, negligent.

2. Calculation of Penalty

411. The Director is imposing a penalty on Genzyme. In accordance with section 38(8) of the Act, the Director must have regard to the guidance on penalties issued under section 38(1) of the Act when setting the amount of the penalty (the 'Guidance on Penalties')[459].

412. The Guidance on Penalties sets out a five-step approach that the Director will follow to calculate the amount of a penalty.

[459]OFT 423 'The Director General of Fair Trading's Guidance as to the Appropriate Amount of a Penalty', March 2000.

Step 1: Starting point

413. The starting point for determining the level of penalty is calculated by applying a percentage rate to the 'relevant turnover' of the undertaking, up to a maximum of 10%. The 'relevant turnover' is the turnover of the undertaking in the relevant product market and relevant geographic market affected by the infringement in the last financial year[460].

414. Genzyme's turnover in the 'relevant market', namely its turnover in the upstream and downstream markets for the financial year to 31 December 2002, was £*[confidential]*.

415. The actual percentage rate which will be applied to the 'relevant turnover' will depend upon the nature of the infringement[461]. It is the Director's assessment of the seriousness of the infringement which will determine the percentage of 'relevant turnover' which is chosen as the starting point for the penalty[462]. The more serious the infringement, the higher the percentage rate is likely to be[463]. When making his assessment, the Director will also consider a number of other factors, including the nature of the product, the structure of the market, the market share(s) of the undertaking(s) involved in the infringement, entry conditions and the effect on competitors and third parties. The damage caused to consumers whether directly or indirectly will also be an important consideration[464].

416. Genzyme was for over ten years the monopolist supplier of the only drug then available for the treatment of Gaucher disease. Even after Zavesca's recent entry its numerous limitations make it highly unlikely that it will take more than an insignificant share of the market in the short to medium term, therefore leaving Genzyme to continue to enjoy a near monopolist position. The market for the supply of drugs for the treatment of Gaucher disease is characterised by high barriers to entry. From its position as monopolist supplier, Genzyme has adopted a policy which, not only excluded all competition from the Homecare Services segment of the downstream market, but also reinforced its own monopoly position in the upstream

[460] Ibid, paragraph 2.3.

[461] Ibid, paragraph 2.4.

[462] Ibid, paragraph 2.5.

[463] Ibid, paragraph 2.4.

[464] Ibid, paragraph 2.5.

market by raising barriers to entry into a market which is already characterised by high entry barriers. The result, both in the Homecare Services segment of the downstream market and through the consequential effects of this, in the upstream market, operates to the detriment of customers (i.e. the NHS) and consumers (i.e. patients).

417. Genzyme's policy deprives the NHS (and, therefore, patients) of a choice of Homecare Services provider. The NHS has made it clear to Genzyme that it would like to have such a choice (see paragraph 308 above). Genzyme's policy clearly results in a lack of competition in the Homecare Services segment of the downstream market, and through the consequential effects of this it raises barriers to entry in the upstream market, to the detriment of customers (i.e. the NHS) and consumers (i.e. patients).

418. The Director regards it as an important feature of this case that it concerns a pharmaceutical product and ancillary services for the treatment of patients suffering from a potentially life-threatening disease that requires treatment throughout the patient's life. Genzyme's conduct has limited the choice of Homecare Services providers available to Gaucher patients and it has raised barriers to entry to the upstream market for new drugs for the treatment of Gaucher disease, requiring home delivery and homecare services.

419. The Director therefore concludes that Genzyme has committed a serious infringement of the Chapter II prohibition and has taken as a starting point for determining the penalty 7% of its turnover.

420. The fact that Genzyme has engaged in two types of anti-competitive conduct in breach of the Chapter II prohibition has not been taken into account in determining the starting point of the penalty. This is because this fact has been considered under step 4.

421. The starting point for determining the penalty is in this case, £*[confidential]*.

Step 2: Adjustment for duration

422. The starting point may be increased to take into account the duration of the infringement.

423. Genzyme's policy of making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme (the first infringement) has been implemented since Cerezyme's introduction into the UK in 1991. This has constituted an infringement of the Act since the coming into force of the

Chapter II prohibition on 1 March 2000 to date (i.e. a period of three years) and is continuing.

424. Genzyme's introduction of a pricing policy following the launch of Genzyme Homecare which results in a margin squeeze (the second infringement) started with the launch of Genzyme Homecare in May 2001. Therefore, this has constituted an infringement of the Act for a period of one year and ten months to date and is continuing.

425. The second infringement ran concurrently with the first infringement. The duration of the infringement for the purposes of calculating the penalty in this case is, therefore, three years.

426. Penalties for infringements which last more than one year may be multiplied by not more than the number of years of the infringement[465]. The Director has accordingly decided to increase the starting point of the penalty by a factor of 3, giving a figure of £*[confidential]*.

Step 3: Adjustment for other factors

427. The principles underlying the adjustment in Step 3 are set out in paragraphs 2.8 and 2.9 of the Guidance on Penalties[466]

> '2.8 The penalty figure reached after the calculations in steps 1 and 2 may be adjusted as appropriate to achieve the policy objectives …in particular, of imposing penalties on infringing undertakings in order to deter undertakings from engaging in anti-competitive practices. The deterrent is not aimed solely at the undertakings which are subject to the decision, but also at other undertakings which might be considering activities which are contrary to the Chapter I and Chapter II prohibitions. Considerations at this stage may include, for example, the Director's estimate of the gain made or likely to be made by the infringing undertaking from the infringement.
>
> 2.9 This step may result in a substantial adjustment of the financial penalty calculated at the earlier steps. The consequence may be that the penalty which is imposed is much larger than would otherwise have been imposed…'

428. The adjustment (if any) for deterrence should, therefore, be applied on a case by case basis, in the light of the relevant circumstances in each case.

[465] OFT Guideline 423, op. Cit., paragraph 2.7.

[466] Ibid.

429. Nevertheless, the Director notes that the Competition Commission Appeal Tribunal's judgment in *Napp*[467] considered that there were difficulties with the approach of attempting to estimate the gain made by Napp from its infringement of the Chapter II prohibition in order to determine an appropriate adjustment to the level of the penalty to achieve a deterrent effect. The Tribunal did not think that the calculation of a 'gain' should necessarily form the sole, or even the main, means of marking, for deterrent purposes, the seriousness of an infringement in the context of Step 3 except perhaps in the clearest cases.[468] However, it went on to state:

> 'The real 'gain' is the long-term advantage of protecting a monopoly market share and the profits that flow from that for as many years as possible.'[469]

430. The Director does not regard the present case as one where the amount of gain is clear, and so has not attempted to calculate it. However, he considers that the exclusionary effect of Genzyme's behaviour does indeed result in a substantial gain to Genzyme.

431. In addition, the Director has had regard to the Competition Commission Appeal Tribunal's general approach in *Napp* to the assessment of the appropriate amount of a penalty.

432. In order to ensure that the penalty acts as an effective deterrent to Genzyme, the Director has taken into account the size of both Genzyme and of its parent company, Genzyme Corporation. In 2002, Genzyme's turnover amounted to £*[confidential]* million (unaudited)[470] and Genzyme Corporation's worldwide turnover amounted to US$1.3 billion (approximately £830 million).

433. The penalty should also act as a deterrent to other undertakings which may be considering activities of the kind covered by this Decision, by sending an appropriate signal to the business community of the seriousness of infringements of the Act[471].

434. Therefore, to ensure that the penalty reached following steps 1 and 2 sends an appropriate signal to Genzyme and other undertakings which may be

---

[467] Case No.1001/1/1/01 *Napp Pharmaceutical Holdings Limited and Subsidiaries v DGFT* [2002] CAT 1, [2002] CompAR 13.

[468] Ibid paragraphs 507-509.

[469] Ibid, paragraph 510.

[470] This is Genzyme's section 36(8) turnover for 2002.

[471] Case No.1001/1/1/01 *Napp Pharmaceutical Holdings Limited and Subsidiaries v DGFT* [2002] CAT 1 at [541], [2002] CompAR 13.

considering similar activities, the Director has increased the penalty at Step 3 by £*[confidential]*, giving a figure of £ *[confidential]*.

Step 4: Adjustment for further aggravating and mitigating factors

435. The basic amount of the penalty, adjusted as appropriate at steps 2 and 3, may be increased where there are aggravating factors, or decreased where there are mitigating factors.

436. Following the date when Genzyme became aware of the Director's investigation, Genzyme engaged in a new form of abusive conduct related to the conduct subject to the investigation and consisting of adopting a pricing policy, following the launch of Genzyme Homecare, which results in a margin squeeze. The Director considers this to be an aggravating factor and, consequently, an increase of 10% is appropriate, giving a figure of £6.8 million.

437. Genzyme has argued that there are three factors (set out below) which should be taken into account in mitigation in this case. Having given careful consideration to Genzyme's representations, the Director has concluded that there are no mitigating factors in this case.

438. In particular, Genzyme contends that its continuing to supply HH is a substantial mitigating factor[472]. The Director considers that supply on the terms offered by Genzyme, which result in a margin squeeze, cannot be a mitigating factor.

439. Genzyme has also argued that the conduct objected to by the Director, falls into the category identified in the Guidelines on Penalties as conduct in relation to which there is 'genuine uncertainty as to whether the (…) conduct constituted an infringement'[473]. In view of the body of EC case law relied upon by the Director in the Rule 14 Notice and this Decision, the Director does not consider that there is any uncertainty that Genzyme's conduct constituted an infringement.

440. Finally, Genzyme has submitted that it has fully co-operated with the Director's investigation in a manner that goes beyond what can be expected

[472] Genzyme's written representations submitted on 25 October 2002, paragraph 14.12, at page 169.

[473] Ibid, paragraph14.14, at page 170.

from any undertaking[474]. The Director does not consider that Genzyme's cooperation has been over and above that expected of any undertaking.

Step 5: Adjustment to prevent maximum penalty being exceeded and to avoid double jeopardy

441. The final amount of any penalty imposed under section 36 of the Act may not exceed ten per cent of the turnover of the undertaking calculated in accordance with Competition Act 1998 (Determination of Turnover for Penalties) Order[475]. The section 36(8) turnover of an undertaking is not restricted to the turnover in the relevant product market and relevant geographic market[476].

442. The amount of the penalty calculated under steps 1 to 4 does not exceed the section 36(8) turnover of Genzyme and, therefore, no further adjustments are necessary.

3. Level of penalty

443. The Director requires Genzyme to pay him a penalty of £6.8 million in respect of the infringements set out in paragraph 386 above. The penalty must be paid by 27 June 2003 into the Consolidated Fund.

4 Payment of penalty

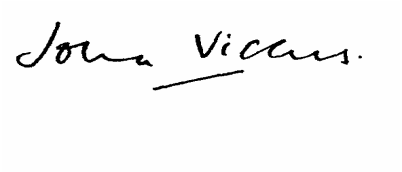
444. If Genzyme fails to pay the penalty within the deadline specified above, and has not brought an appeal against the imposition or amount of the penalty within the time allowed or such an appeal has been made and determined, the Director can commence proceedings to recover the required outstanding amount as a civil debt[477].

[474] Ibid, paragraph 14.16-14.17, at page 170.

[475] Section 36(8) of the Act and SI 2000/309.

[476] OFT 423, op. Cit., footnote 6.

[477] Section 37 of the Act.



John Vickers
Director General of Fair Trading
27 March 2003