Title: Implementing the Health Act 2006: Fees for NHS pharmaceutical services: UPDATED **IA No:** 5098 **Lead department or agency:** Department of Health **Other departments or agencies:**	Impact Assessment (IA) **Date:** 23/07/2012 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Catriona Patterson - 0113 2545780

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
-£3.96m	-£7.3m	£0.85m	No	NA

What is the problem under consideration? Why is government intervention necessary?

This initiative introduced in 2008, through Directions to NHS Primary Care Trusts (PCTs), a charging regime for applicants applying to provide NHS pharmaceutical services as a contribution towards the costs the NHS incurs in dealing with such applications. This IA updates the previous 2008 impact assessment to take account of a review of that original initiative in 2009 and changes now being introduced to the main NHS (Pharmaceutical Services) Regulations from summer 2012 which govern entry to the NHS market.

What are the policy objectives and the intended effects?

This initiative represented one of the final elements of a series of reforms to the regulatory regime known as "control of entry"" first introduced by the previous administration from April 2005. This measure helps defray NHS costs and discourages speculative or "blocking" applications which can reduce competition and entry.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Two options were considered in 2008:

(1) No change (or a voluntary non-regulatory scheme) will not achieve the policy objectives.

(2) Introducing permanent reforms will achieve the policy objectives, defraying NHS costs and reducing unnecessary workloads. This system will continue under the new 2012 regulations.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 04/2012

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible SELECT SIGNATORY: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2005	PV Base Year	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -12.1

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		1.4	**12.1**

Description and scale of key monetised costs by 'main affected groups'

Annual cost of £1.1m - £2.1m NHS (IA) (does not include enforcement)

Unquantified costs for organisations, businesses and other groups consulted on applications.

Other key non-monetised costs by 'main affected groups'

The NHS would continue to bear all its own costs as well as dealing with speculative applications.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

None monetised.

Other key non-monetised benefits by 'main affected groups'

Operation of existing charging regime unchanged. Maintains status quo and reassures existing contractors. No change to current competitive impact.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

NHS continues to bear costs of applications.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	NA

Summary: Analysis & Evidence

Policy Option 2

Description: Make Permanent Reforms

FULL ECONOMIC ASSESSMENT

Price Base Year **2005**	PV Base Year	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** -3.96

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		1.4	**12.1**

Description and scale of key monetised costs by 'main affected groups'

Annual cost of £1.1m - £2.1m NHS (IA) (does not include enforcement)

Unquantified costs for organisations, businesses and other groups consulted on applications.

Other key non-monetised costs by 'main affected groups'

The NHS would continue to bear costs related to NHS pharmaceutical services applications but some costs would transfer to business. As this is a policy cost, it would not affect the Department's baseline of administrative activity.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate			0.94	**8.1**

Description and scale of key monetised benefits by 'main affected groups'

Benefit to NHS as defrays some of the costs. Estimated £850k annual benefit from charging (NPV £7.3m) and annual benefit of up to £90k (NPV £0.8m) if all speculative applications prevented.

Other key non-monetised benefits by 'main affected groups'

Helps deter speculative, "blocking" or repeat applications which create further costs for the NHS.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

Contribution to NHS costs transfers to business. Proposals assume this will not deter businesses from applying to provide NHS pharmaceutical services or stay in unsuitable premises.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: 0.85	**Benefits:** 0	**Net:** -0.85	No	NA

Evidence Base (for summary sheets)

Introduction

1. This impact assessment outlines the options considered for implementing one of the final elements of the then Government's 2003 reform programme for NHS pharmaceutical services in England. Specifically, the Department wished to provide, as enacted by Sections 131(4) and 129(5) of the NHS Act 2006, for charges at variable levels to be levied for applications concerning a chemists' inclusion on a NHS Primary Care Trust (PCT)'s list. The Government did not implement a second element where PCTs would consider in their assessment of competing applications from chemists to provide NHS services what improvements they bring to the provision of, or access to over-the-counter medicines and other healthcare products.
2. During the passage of the Health Act 2006 a general review, after 18 months of implementation, of charging for NHS pharmaceutical services applications was promised (September 2009). The review looked at progress in implementing charging as well as the impact of charging on the NHS, pharmacy and appliance contractors. It also sought to find out whether the current fee levels were fair and reasonable.
3. The review included a twelve-week consultation between 12 October 2009 and 12 January 2010. The Government's response to the review was published in September 2011. For further details of the review, see below.
4. A new market entry and performance sanctions regime has been introduced from summer 2012. Under the 2012 Regulations, applications for inclusion on a NHS pharmaceutical list are now judged against PCTs' pharmaceutical needs assessments (PNAs). The Department consulted key stakeholders during February 2012 on new Directions – the NHS (Pharmaceutical Services) Fees Directions 2012. The NHS (Pharmaceutical Services) Fees for applications Directions 2008 and their subsequent amendment in 2008 related to applications under the NHS (Pharmaceutical Services) Regulations 2005 have therefore now been superseded and consolidated in the 2012 Directions. The opportunity has also been taken, therefore, to update the final impact assessment published in April 2008. A separate equality analysis has also been produced.
5. This impact assessment updates information including numerical data provided in previous assessments that accompanied the Health Act 2006 and responses to formal consultation. It includes the latest statistical data on NHS pharmaceutical services published by the Information Centre on 23 November 2011 (*General Pharmaceutical Services in England and Wales 2001-2002 to 2010-2011*) and available on their website at www.ic.nhs.uk. The benefits and costs of the preferred option as originally considered by the Department in 2008 on how best to achieve the policy have been revised and updated and are set out below.

Purpose and intended effect

The objective

6. The overall objective for health policy is to maintain and improve access to and the choice of community pharmaceutical services whilst continuing to raise the quality of such services provided, to utilise professional skills to best effect and to ensure services reflect and contribute to wider developments in primary care provision. This has primarily been achieved through the introduction of a new contractual framework for community pharmacy and through reforms to the regulatory system governing who provides NHS pharmaceutical services from April 2005. Those measures promoted more competition and new entry, alongside the wider social and health objectives for community pharmacy. This measure aims to help defray NHS costs and to discourage speculative or "blocking" applications (which can reduce competition and entry).

The background

The previous Government's response to the Office of Fair Trading's report

7. Following its response in July 2003 to the Office of Fair Trading (OFT)'s report, *The control of entry regulations and retail pharmacy services in the UK*, the then Government announced a consultation on 18 August 2004 on the Department's website. The consultation also invited views on other possible options, including whether to allow charges for pharmacy applications and any appeals arising from PCT decisions on such applications to be introduced. This was assessed as requiring changes to primary legislation within the NHS Act 1977 (now consolidated by the NHS Act 2006).
8. The Department set up an expert advisory group to advise how best to implement the proposals in the consultation. The Group reported in January 2004 and supported the introduction of charges for applications. The Group was more equivocal on the introduction of charges for appeals and the then Government decided not to pursue this idea so that there could be no doubt as to financial interests influencing appellate procedures and outcomes.
9. On 18 August 2004, the then Government announced it had accepted the great majority of the Advisory Group's recommendations and would proceed to implement them. Amendments to the 1992 Regulations came into force on 1 April 2005 and fees for NHS pharmaceutical services regulations were introduced to Parliament as part of the Health Bill in October 2005. The Bill gained Royal Assent in 2006. Directions were made in April 2008 to introduce this measure.

Risk assessment

10. The risks associated with not implementing the measure were that applications who wished to deter other applicants by entering speculative applications or using "blocking tactics" would continue to be able to do so with relatively little cost, potentially restricting legitimate competition. There was no effective deterrent to the small number of applications which, having failed once, essentially repeat the same information on further time-wasting applications. The NHS would continue to bear the full costs of dealing with such applications that must all follow the same process, including notification to interested parties, considering the views received and making a determination.

Consultation

11. The Department consulted in Autumn 2003 on its complete package of reform measures including this measure – it received broad support (60 in favour and 25 against). Further consultations took place from July to September 2005. The majority of the 26 responses received were in favour of charging, and that these should not discriminate between applicants based on their relative economic strength. The measure was enacted in July 2006 under the Health Act 2006, now consolidated in the NHS Act 2006.
12. Following enactment, the Department formally invited the views of NHS Employers, representing PCTs, the Pharmaceutical Services Negotiating Committee (PSNC) representing pharmacy contractors and the British Healthcare Trades Association (BHTA) representing appliance contractors on the implementation of these proposals. As it was the first such consultation following enactment, the Department also published its proposals in full in February 2007, including the associated draft legislation so that PCTs, pharmaceutical contractors and other interested parties could also comment on the proposals. 33 responses were received for this consultation. NHS Employers indicated they broadly supported the proposal for PCTs to charge for applications; the PSNC largely supported the proposals although they did not feel that fees should be charged for minor relocations or changes of ownership. There was agreement across all parties that the fee levels should stay as a contribution towards costs.
13. Before publishing the NHS (Pharmaceutical Services) Fees Directions 2012, the Department carried out a four-week consultation with key stakeholders – NHS Employers, the PSNC and representatives of dispensing appliance contractors. The consultation ran from 7 February to 7 March 2012. Two responses were received from the PSNC and NHS Employers. Both organisations felt that the nominal fee of £100 should not be charged for applications for directed services as its

introduction is counter to the commissioning landscape within the NHS. Otherwise, they both felt that the proposed fee levels were fair and reasonable. The PSNC requested a review of the policy not to charge a fee for dispensing doctor applications.

14. The Government's response to these comments is as follows. The intention of the fee for directed services is for situations where a PCT's PNA has identified a gap for a directed service and an existing contractor or applicant not included in the relevant PCT's list applies to the PCT to fill that need. Where a PCT identifies such a gap in need and invites applications to fill that gap, it is expected that PCTs will use their discretion as to whether to waive the fee or not. However, it is expected a PCT will levy a fee where new applications to provide directed services have been received rather than where any changes have been identified at an annual review. The fee has therefore been included in the new Directions. There is no intention to charge for dispensing doctors' applications because technically any request to provide dispensing services is made by or on behalf of the patient and there are now very few applications being received for doctors to dispense (31 in 2005/06 and 5 in 2010/11). The Government will in due course review the fees structure in light of the changes to the NHS architecture contained in the Health and Social Care Act 2012 and due to come into force from April 2013.

Options

15. Two options were originally identified in 2008 for achieving the policy:

- Option 1: **No change** i.e. do not implement legislation, but apply through voluntary agreement.
- Option 2: **Make reforms** by means of Directions to PCTs to allow fees for applications to be set by the Secretary of State.

Benefits and costs

16. *Option 1: no change* – this benefits applicants who would continue to be able to submit applications charge-free. There is no limit on the number of applications that can be made to PCTs. A voluntary agreement would not require enforcement.
17. *Option 2*: *make reforms by means of directions to PCTs* – introducing charges will help defray some of the existing costs the NHS already incurs and will reduce the cost impact from any rise in applications as a result of the liberalisation of the regulatory system. It will also help deter speculative "blocking" and repeat applications.

Sectors and groups affected

18. As at 31 March 2011, there were 10,951 community pharmacies in England providing NHS pharmaceutical services. Of these, around 61.5% were in chains of six or more pharmacies (known as "multiples"). There were 125 appliance contractors supplying NHS appliances in England, of which 100 were actively dispensing appliances.

Analysis of costs

19. The costs of each option in terms of the policy objectives are as follows:

- Option 1: **No change (or a voluntary scheme)** - the NHS would continue to bear all costs associated with applications to provide pharmaceutical services including any continued exploitation of the current system by businesses to make speculative or spoiling applications. There would be no new costs to business where business did not voluntarily pay the charges.
- Option 2: **Make reforms** – businesses would now incur new costs that will displace some of the existing cost burden that is borne by the NHS. In estimating these costs, the Department initially used revised data for 2005/06 and 2006/07 as these were the first two years of operating the new regulatory regime. This has been updated to include data for 2009/10 and 2010/11 obtained from the NHS Information Centre (General Pharmaceutical Services in England and Wales 2001-2002 to 2010-2011). The Department estimates the total costs for the NHS of determining chemist applications in 2009/10 in England was between £1.1 million and £1.4 million and for 2010/11 was

between £1.6 million and £2.1 million. Details of these calculations can be found in Annex A. Annually, the Department estimates the total costs transferred to businesses would be in the region of £850,000. This annual cost is approximated and based on the expected future changes in the number of applications (see paragraph 21) and past trends in the years 2005/06 – 2010/11. As this would be a policy cost, it would therefore not be added to the Department's baseline of administrative activity. The Department considered in 2008 that the cost of any new administrative activity associated with introducing fees was negligible and this view has not changed since. Depending on the type of application, the Department proposed charges, which would be a contribution towards, but not meet, the full costs for the NHS of dealing with chemist applications. In previous consultations, the Department suggested a range of fees, depending on the type of application, from £150 to £500. As costs for processing a full application are estimated at a minimum of £1,100, the Department proposed this fee should be set at £750 as set out in Table 1 of the proposed fee levels below.

Table 1: Proposed fee levels

Type of application (includes preliminary consent)	**Fee level (£)**	**Number of applications in 2009/10**	**Total cost (£)**	**Number of applications in 2010/11**	**Total cost (£)**
Total number of applications decided		2,043		1,900	
Full application (reformed control of entry test, exemptions, major relocations, additional services from same premises, appliances only)	750	819	614,250	1307	980,250
Minor relocation under 500 metres (within or across PCT boundary)	150	231	34,650	219	32,850
Minor relocation over 500 metres (within or across PCT boundary)	250	209	52,250	29	7,250
Relocation of premises over 500 metres which are not minor relocations (within or across a PCT boundary)	750	Included in full application statistics	N/A	Included in full application statistics	n/a
Change of ownership (applicant already on the list)	150	100*	15,000	100*	15,000
Change of ownership (applicant not on PCT list)	250	80*	20,000	80*	20,000
Conversion from preliminary consent to full consent, no change in details	150	50*	7,500	50*	7,500
Conversion from preliminary consent to full consent, change in details	250	20*	5,000	20*	5,000
Subsequent application where original failed	1,500	20*	30,000	20*	30,000
Duplicate subsequent application where original failed	3,000	10*	30,000	10*	30,000
TOTAL COST			**808,650**		**1,127,850**

* estimated figure

20. The total number of applications in the table above includes those for which no fee are chargeable. Fees are not charged in respect of applications from dispensing doctors, since the "control of entry" test and exemptions etc do not apply to them and their applications to dispense are made at the request of the patient. Similarly, no fee is payable where a PCT decides to determine whether or not an area is rural in character or whether a particular area should be designated a "reserved location" under regulation 35. No fees are payable where a suspended contractor, or a LPS contractor, applies to re-join the PCT's pharmaceutical list.

21. A new market entry and performance sanctions regime (see paragraphs 28-30) will reduce the number of future market entrants. Naturally, this is expected to correspond to a decrease in the number of applications in Table 1. Moreover, 2010/11 was greater than normal in terms of volumes of applications due to pre-emptive applications submitted ahead of the expected regulatory changes outlined in paragraphs 28-30. As a result, cost estimates for year 2010/11 are not expected to continue at the same levels over time and are expected to decrease significantly. Specifically, in line with the assumptions developed for the Control of Entry and Exit in the NHS pharmaceutical market Impact Assessment, published in summer 2012, it is estimated that annual costs to business should average approximately £850,000 annually over the next 10 years.

22. These costs may have a greater impact on a new applicant who is not already established or on smaller businesses than large retailers better placed to absorb such costs. Sole traders or smaller businesses may be deterred from making applications to the possible detriment of the local health economy. All businesses may seek to recoup the additional costs incurred from charging for applications by raising prices of other goods (e.g. non-pharmaceutical products) to the detriment of consumers. It is not possible to quantify this risk though its overall impact spread over a range of goods and services is likely to be small.

Summary of costs and benefits

Table 2: summary of costs and benefits

Option	Total cost per annum	Total benefit per annum
1. Do nothing (or a voluntary scheme)	NHS bears all costs of applications	Present applicants benefit as now. No new costs to business. No benefit to NHS.
2. Make reforms by means of Directions to PCTs	Estimated annual cost to business of £850,000 transferred from the NHS – this is a policy cost. Effect on total Departmental administrative burden is negligible. Businesses may be deterred from applying and/or seek to offset costs in higher costs in higher prices to consumers.	Defrays NHS costs and helps deter speculative, “blocking” or repeat applications.

Enforcement, sanctions and monitoring

23. Introduction of charges for applications will be for PCTs to enforce in that the sanction for non-compliance will be refusal of the application if the appropriate fee is unpaid. Any impact on market entry from introducing charges will be monitored through current channels using annual returns provided by PCTs and other central data.

Implementation and delivery plan

24. These proposals are implemented through Directions to PCTs.

Post-implementation review

25. The Government undertook during the passage of the 2005 Health Bill to consider a general review of this measure 18 months after it was introduced. The review looked at progress in implementing charging as well as the impact of charging on the NHS, pharmacy and appliance contractors and applicants. It also sought to find out whether the current fee levels were fair and reasonable. The review included a twelve-week consultation between 12 October 2009 and 12 January 2010 and included a stakeholder listening event. The Government published its response to the consultation in October 2011 - http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_130489.

26. The Government noted that the experience of the effect of charging by the NHS was variable. However, chemist contractors had not felt significantly affected by charging for applications. Thus, the fees for applications would be retained. The Government also noted that most respondents felt that the current fee levels are fair and reasonable. Therefore, it did not feel there was sufficient evidence to change current fee levels.

27. The National Health Services Pharmaceutical Services (Fees for Applications) Directions 2008 (as amended in April 2008) were not amended – http: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_083854. However, the Government undertook to strengthen the guidance on control of entry to include more guidance on the banking and clearing of fees. An Impact Assessment including an Equality Impact Assessment was published alongside the Directions – http: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_083854. The Government noted the comments received on these. Since there was no change to the policy after the review, the Impact and Equality Impact Assessments were not amended.

Fees under the NHS (Pharmaceutical Services) Regulations 2012

28. A new market entry and performance sanctions regime has been introduced in the summer of 2012. Under the 2012 Regulations, applications for inclusion on a NHS pharmaceutical list are now determined mostly against PCTs' PNAs. The NHS (Pharmaceutical Services) Fees for Applications Directions 2008 and its subsequent amendment in 2008 related to applications under the NHS (Pharmaceutical Services) Regulations 2005 and are now superseded and consolidated in new Directions – the NHS (Pharmaceutical Services) Fees Directions 2012. The opportunity has been taken, therefore, to update the final impact assessment published in April 2008.

29. This impact assessment updates information including numerical data provided in previous assessments, which accompanied the 2005 Health Bill and responses to previous formal consultations. It includes the latest statistical data on NHS pharmaceutical services published by the Information Centre on 22 November 2011 (General Pharmaceutical Services in England and Wales 2001-2002 to 2010-2011) and available on their website at www.ic.nhs.uk.

30. The fees for applications under the 2012 Regulations have been discussed with members of the Advisory Group (**DN Gillian do we mention this earlier – if not explain what it is or delete)** and stakeholders were subsequently formally consulted. The fees are as follows:

Table 3: Fee levels (as set out in the National Health Services Pharmaceutical Services [Fees for Applications] Directions 2012)

Type of application (including where the applicant applies for preliminary consent)	Fee level (£)
Routine application by a contractor who wishes to be included on the pharmaceutical list for the provision of services in a PCT's area (current/future needs; improvements or better access; unforeseen benefits and distance-selling exception); relocation of premises that do result in significant change; applications from those already on the list in respect of additional premises.	**750**
Routine application from those who are not included on the pharmaceutical list wishing to provide directed services only.	**100**
Relocation of premises that do not result in a significant change to pharmaceutical services provision.	**250**
Change of ownership (where the applicant is already on the PCT's pharmaceutical list).	**150**
Change of ownership (where the applicant is not already on the PCT's pharmaceutical list).	**250**
Change of ownership and relocation of premises that do not result in a significant change to pharmaceutical services provision (where the applicant is already on the PCT's pharmaceutical list).	**250**
Change of ownership and relocation of premises that do not result in a significant change to pharmaceutical services provision (where the applicant is not already on the PCT's pharmaceutical list).	**350**
Duplicate application for a routine, distance selling or significant change relocation application within 180 days of an original application failing.	**1,500**
Further subsequent application for a routine, distance selling or significant change to local provision within 180 days of the first further application failing.	**3,000**

Specific Impact Tests

Competition Assessment

The affected market

31. The product market affected directly is the dispensing of NHS medicines and appliances by community pharmacies and appliance contractors. Supply of pharmacy (P) and general sales list (GSL) medicines – collectively known as over-the-counter (OTC) medicines – are also likely to be affected. Although not obtaining a NHS contract does not directly rule out such supply, the economies of scope (reduction in operating costs through sharing common inputs – in this case the same staff, premises etc – over a range of activities) are such that supplying P medicines without being able to dispense NHS medicines is generally unviable. Entry to the GSL market is indirectly restricted by NHS contracts, as an estimated 20% of GSL sales are linked to the presence of a pharmacist for advice and it is only viable to employ a pharmacist when the pharmacy has an NHS dispensing contract. There is unlikely to be any substantive impact on other elements of the supply chain.

32. The nature of demand means that the geographical market is likely to be localised since a large proportion of consumers, patients or their carers expect to be able to access a substitute supplier speedily and conveniently. Supply side factors may indicate that the geographical market is wider. In particular, the largest contractors (Alliance Boots, Lloydspharmacy, Co-operative Group etc.) tend to set a national pricing strategy rather than reacting to local market conditions. This could suggest that an overlapping chain of substitution extends wider (e.g. in overlapping neighbourhoods, a pharmacy with a hypothetical monopoly in one neighbourhood may not be able to act in a non-competitive way because it would lose business to another competitor in a nearby neighbourhood).

33. The main barrier to entry is the NHS (Pharmaceutical Services) Regulations 2005. In the absence of these regulations, the barriers to entry would be low – that is the only barriers would be access to premises and the availability of a qualified pharmacist to meet the legal and professional requirements for operating a pharmacy.

The competitive process

34. The market in aggregate is not considered to be highly concentrated. As at 31 March 2011, there were 10,951 community pharmacies in England providing NHS pharmaceutical services. Of these, around 61.5% were in chains of six or more pharmacies (known as “multiples”). Competition law is designed to protect consumers from anti-competitive effects either through merger legislation or through the Competition Act (1998) that legislates against anti-competitive agreements and abuse of dominant market positions. Importantly, since NHS dispensing accounts for around 80% of a typical pharmacy’s revenue (as explained in the Office of Fair Trading report, 2003, paragraph 2.23), NHS pharmacies cannot compete on price for the bulk of their business.

Market outcomes

35. As noted above there is little scope for price competition in the majority of this market and so competition occurs largely on location and, to a lesser extent, on price and quality. The introduction of fees at the levels proposed above may deter some entry at the margin but would represent only a very small part of the total start-up costs incurred in establishing a new pharmacy. Introducing charges is therefore not expected to have a significant dampening effect on the market.

The impact of the legislation

Options

36. Option 1: no change (or a voluntary scheme) – the main impact would be that the objectives will not be achieved under a voluntary non-regulatory scheme.

37. Option 2: make reforms – the main impact would be that the objectives are achieved.

The Small Firms’ Impact Test

38. Small businesses are important to the supply of pharmaceutical services in England. As at March 2007, small businesses, defined as independents and chains with five or fewer outlets, accounted for around 41% of all contractors. This results from a trend towards greater market concentration with take-overs and mergers, the entry of new low cost retailers and the expansion of supermarket pharmacies. This trend is likely to continue. As at 31 March 2011, 38.5% of pharmacies were independents or in chains with five or fewer outlets.

39. In the 2003 consultation, a number of small businesses and representative organisations commented on the proposals for fees.

Environmental and Sustainability impacts

40. None has been identified under either option.

Health impacts

41. None has been identified under either option.

Justice system impacts

42. None has been identified under either option.

Rural proofing

43. No additional issues affecting access to services in rural communities have been identified.

ANNEX A

Table A1: Approximate cost of full pharmacy applications.

Activity	**Duration (hours)**	**Costing Assumption (NHS pay band or other)**	**Cost Per Application (Best)**	**Cost Per Application (Low)**	**Cost Per Application (High)**
Receipt & checking applications	1	Band 6-7	£22	£20	£24
Site Visit	2	Band 7-8	£62	£48	£77
Preparation & distribution of copies	2	Band 6-7	£44	£40	£48
Analysis of comments	0.5	Band 6-7	£11	£10	£12
Preparation of report	4	Band 8	£154	£116	£197
	4	Band 5	£66	£58	£75
Panel meeting	4	Band 8a	£116	£106	£127
	4	Band 7	£96	£83	£110
	2	Band 5	£33	£29	£38
	2	Band 8c	£82	£74	£92
	2	Band 8d	£99	£89	£110
Notification of outcome	2	Assumption	£42	£30	£54
Follow-up	2.5	Assumption	£53	£30	£75
Consultation meetings	8	Assumption	£210	£210	£210
Consultation queries	4	Assumption	£120	£120	£120
Travel costs/incidentals	1	Assumption	£50	£50	£50
TOTAL			**£1,260**	£1,114	£1,418

Costs for minor relocations, changes of ownership and conversion of preliminary to full consent applications have been costed on the basis of 2 hours to receive and check applications, 2 hours for a site visit (not applicable to changes of ownership), 1 – 2 hours for preparation of a report, 1 hour for the panel meeting, 30 minutes for notification of outcome and £50 for travel costs (not applicable to changes of ownership). An allowance of six hours at £30 per hour has been made for checking any fitness to practise matters in respect of changes of ownership.

Table A2: Total estimated costs in 2009/10 and 2010/11 for applications where charges are introduced.

Type of Application	**Number of applications 2009/10**	**Annual Cost (Best) 2009/10**	**Number of applications 2010/11**	**Annual Cost (Best) 2010/11**
Full Application	819	£1,032,327	1,307	£1,647,437
Minor Relocation	440	£198,774	248	£112,036
Changes of Ownership	180	£102,468	180	£102,468
Conversion of Preliminary Consent	70	£31,623	70	£31,623
TOTAL	1,509	**£1,351,192**	1,805	**£1,884,564**

Net Present Value Derivation

Using the standard assumption of a 3.5% discount rate, a 10-year evaluation period, and a relatively stable annual costs and benefits outlined below, we can derive a simple Present Value multiplier based on a modified annuity formula. In order to arrive at a 10-year value of a given annual cost or benefit, it has to be multiplied by 8.61 (as opposed to 10) in order to reflect discounting future cash flows.

Table A3: NPV derivation.

Assumptions	**Annual**	**10-year Present Value**
Estimated Annual NHS cost of processing applications (*cost*)	£1,400,000	£12,050,761
Estimated annual private cost of paying application fees (*benefit*)	£850,000	£7,316,534
Estimated annual benefit of deterred speculative applications (*benefit*)	£90,000	£774,692
NET	-£460,000	**-£3,959,536**