Title: **Control of Entry and Exit in the NHS pharmaceutical market** **Lead department or agency:** Department of Health **Other departments or agencies:**	**Impact Assessment (IA)** **IA No:** 5035 **Date:** 11/07/2011 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Primary legislation

Summary: Intervention and Options

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

NHS resources fund the provision of NHS pharmaceutical services via community pharmacies and dispensing appliance contractors - collectively known as chemists. NHS chemists incur fixed costs (e.g. premises, utilities, minimum staffing levels). More chemists produce more such fixed costs. Either the NHS bears these costs (reducing funding available for other NHS priorities) or, with no funding increase, all chemists bear the costs, reducing what each receives. Whichever route is followed, these are costs to society. The current regulatory system, which is a requirement under the NHS Act 2006, may stimulate provision in areas already well-served, including a reasonable choice of providers, without ensuring the benefits of any increased provision outweigh the costs incurred.

What are the policy objectives and the intended effects?

The policy objective is to ensure a proportionate regulatory regime which encourages the supply of pharmaceutical services without excessive provision in areas already adequately meeting demand, to ensure the benefits of new entry outweigh costs and to align provision more transparently with local needs. Achievement of this objective would mitigate the impact of current imperfections in the regulatory system, improve the economic efficiency of pharmaceutical provision overall, and increase patient and consumer benefits by aligning services more closely with the requirements and needs of populations.

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

As well as "do nothing", the options considered are:
1. Change NHS market entry and exit management regimes. Reduce automatic entry through exemptions, ensure new pharmaceutical services are commissioned according to local Pharmaceutical Needs Assessments, and introduce a market exit regime for providers failing to meet service obligations.
2. Remove exemptions from the current control of entry regime and introduce an exit regime as in 1.
3. Revert to the regulatory regime which existed pre April 2005 and introduce an exit regime as in 1.
4. Abolish "control of entry" arrangements.

Options 2 and 3 are more retrograde than 1 and do not meet the policy objectives and intended effects. Option 4 is not possible without significant primary legislation and does not meet the objective and intended effects. Option 1 is preferred.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 1/2015 **What is the basis for this review?** Duty to review. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

SELECT SIGNATORY Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: _____ Date: 12th July 2011

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Summary: Analysis and Evidence

Policy Option 1

Description:

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: 240**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate	4		4	**39**

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

Market Entry - health losses to patients: transition costs in adapting to new market entry system displace treatments providing patients with 25 Quality-Adjusted Life Years (QALYs), worth £3.6m.
Market Exit - health losses to patients: costs displace treatments providing patients with 62 QALYs annually, valued at £3.7m, and 10 year NPV of £31m.
Contractors Costs: annual costs £0.5m, and 10 year NPV of £4.4m.

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

A negative impact on patient access from any reduction in chemists in well-served areas. However, this is expected to be more than outweighed by non-monetised benefits of better aligning entry to local needs, and increases in provision of local enhanced services and the quality of all pharmaceutical services.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	0		34	**279**

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

Patient benefits from released NHS funds: reduction in fixed costs enables provision of additional treatments generating 4,640 QALYs worth £279m NPV.

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

Increased patient convenience and access to chemist network as new entry is increasingly matched to local population needs, using Pharmaceutical Needs Assessments. Patient benefits from increased provision of local enhanced services, and improved quality of all pharmaceutical services due to PNAs and exit regime.

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

(1) Impacts are analysed for 10 years - implying that they will continue after reorganisation of commissioning in the current Health and Social Care Bill, if approved by Parliament. (2) According to standard DH practice, health benefits are discounted at 1.5%. Cost savings are based on estimates of pharmacy entry and exit which are subject to uncertainty. The impact on patients assumes that the negative effect of fewer pharmacies on patient access will be exactly offset by benefits from better alignment of entry with local needs, and higher quality. In fact the true benefits are likely to significantly outweigh the negative effects on patients.

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

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/01/2012		
Which organisation(s) will enforce the policy?			PCTs (until April 2013)		
What is the annual change in enforcement cost (£m)?			£12m		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** n/a	**Non-traded:** n/a	
Does the proposal have an impact on competition?			Yes		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** 0%	**Benefits:** 0%	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** 10%	**< 20** 15%	**Small** 15%	**Medium** 25%	**Large** 35%
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	EIA
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	24
Small firms Small Firms Impact Test guidance	No	24
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	Yes	26
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	26
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	27
Rural proofing Rural Proofing Impact Test guidance	Yes	27
Sustainable development Sustainable Development Impact Test guidance	No	

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 2

Description:

Remove Exemptions, and introduce exit regime

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: 891***

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	4		4	**39**

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

Market Entry - health losses to patients: transition costs in adapting to new market entry system displace treatments providing patients with 25 Quality-Adjusted Life Years (QALYs), worth £3.6m.

Market Exit - health losses to patients: costs displace treatments providing patients with 62 QALYs annually, valued at £3.7m, and 10 year NPV.
Contractors Costs: annual costs £0.5m, and 10 year NPV of £4.4m.

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

A considerable negative impact on patient access and competition from the expected reduction in pharmacy numbers (see para 66).
*Note that the best estimate of net benefits presented does not include these costs. Furthermore, option 1 is expected to generate non-monetised benefits, by aligning new entry with local needs, that will not be realised under this option.

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		116	**930**

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

Patient benefits from released NHS funds: reduction in fixed costs enables provision of additional treatments generating 15,500 QALYs worth £930m NPV

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

Improved quality of service due to market exit regime as for option 1.

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

As for Option 1

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

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/01/2012		
Which organisation(s) will enforce the policy?			PCTs (until April 2013)		
What is the annual change in enforcement cost (£m)?			£12m		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** n/a	**Non-traded:** n/a	
Does the proposal have an impact on competition?			Yes		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** 0%	**Benefits:** 0%	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** 10%	**< 20** 15%	**Small** 15%	**Medium** 25%	**Large** 35%
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	EIA
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	24
Small firms Small Firms Impact Test guidance	No	24
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	Yes	26
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	26
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	27
Rural proofing Rural Proofing Impact Test guidance	Yes	27
Sustainable development Sustainable Development Impact Test guidance	No	

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 3

Description:

Revert to pre-2005 entry regime, and introduce exit regime

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: 1347***

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	4		4	**39**

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

Market Entry - health losses to patients: transition costs in adapting to new market entry system displace treatments providing patients with 25 Quality-Adjusted Life Years (QALYs), worth £3.6m.
Market Exit - health losses to patients: costs displace treatments providing patients with 62 QALYs annually, valued at £3.7m, and 10 year NPV.
Contractors Costs: annual costs £0.5m, and 10 year NPV of £4.4m.

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

A severe negative impact on patient access and competitionfrom the expected reduction in pharmacy numbers (see para 67)
*Note that the best estimate of net benefits presented does not include these costs. Furthermore, option 1 is expected to generate non-monetised benefits, by aligning new entry with local needs, that will not be realised under option 3.

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		173	**1386**

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

Patient benefits from released NHS funds: reduction in fixed costs enables provision of additional treatments generating 23,100 QALYs worth £1,386m NPV

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

Improved quality of service due to market exit regime as for option 1.

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

As for Option 1

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

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/01/2012		
Which organisation(s) will enforce the policy?			PCTs (until April 2013)		
What is the annual change in enforcement cost (£m)?			£12		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** n/a	**Non-traded:** n/a	
Does the proposal have an impact on competition?			Yes		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** 0%	**Benefits:** 0%	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** 10%	**< 20** 15%	**Small** 15%	**Medium** 25%	**Large** 35%
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

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Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	26
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	27
Rural proofing Rural Proofing Impact Test guidance	Yes	27
Sustainable development Sustainable Development Impact Test guidance	No	

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

No.	Legislation or publication
1	The previous Government's White Paper: *Pharmacy in England: Building on strengths – delivering the future* - http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083815
2	The previous Government's White Paper: proposals for legislative change - http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_093264
3	Regulations under the Health Act 2009: pharmaceutical needs assessments – information for PCTs - http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_114953
4	Consultation impact assessment of proposals to reform "market entry" based on pharmaceutical needs assessments - http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_087324
5	Implementation impact assessment to require PCTs to devise and to publish pharmaceutical needs assessments - http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_114809

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Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs										
Annual recurring cost										
Total annual costs										
Transition benefits										
Annual recurring benefits										
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office Excel Worksheet

Evidence Base (for summary sheets)

Compliance with "One-In, One-Out" Requirements

A. These proposals would, if implemented, as regards new market entry arrangements, replace or consolidate as appropriate the NHS (Pharmaceutical Services) Regulations 2005 (SI 2005/641) and sixteen subsequent amending Regulations.

B. As regards market exit arrangements, they would also revoke the NHS (Service Committees and Tribunal) Amendment Regulations (SI 1996/703).

C. As identified in paragraph 16 of the One-In, One-Out Methodology guidance (July 2011) "What is out of scope of OIOO?" (xi) "**contractual obligations** – costs associated with obligations on business and civil society organisations which result from negotiating or entering into contractual arrangements with government and public sector organisations" and (viii) "**specific enforcement action** – individual enforcement or inspection activities, or actions to ensure compliance with regulations" are excluded from the general terms of the One-In, One-Out Rule. However, we have none the less assessed the impact of these Regulations on business as we have always done.

Introduction

1. The general duty to provide NHS pharmaceutical services (PS), as with other aspects of NHS primary care services, is conferred directly on NHS primary care trusts (PCTs) under the NHS Act 2006. PCTs construct local pharmaceutical lists of approved providers. The inclusion of chemists' premises on such pharmaceutical lists entitles the chemists to provide NHS pharmaceutical services at those premises. These arrangements govern the provision of NHS pharmaceutical services and not the right to open and conduct a pharmacy business in England which is dealt with under separate legislation - The Medicines Act 1968.

2. The Secretary of State has extensive powers and duties to make regulations, and to issue directions to PCTs, which govern the detail of the PS system, such as specifying the terms of the NHS community pharmacy contractual framework (CPCF).

3. The PS provisions are set out in Sections 126 – 168 of the NHS Act 2006 Act. Sections 126 and 129 of the NHS Act in particular impose an unavoidable duty on Secretary of State to make regulations governing PS. All regulations governing the provision of PS are laid in Parliament using the negative resolution procedure – i.e. regulations are laid before Parliament but come into effect at least 21 days after they are laid without a debate or vote.

4. The Health Act 2009 included amendments to the NHS Act 2006 requiring PCTs to develop and publish pharmaceutical needs assessments (PNAs) and for their PNA then to be used in future for determining entry to PCTs' pharmaceutical lists. Regulations about the development of PNAs came into force in May 2010. These require PCTs to have published their first PNA by 1st February 2011. All PCTs have fulfilled this requirement.

5. The Health Act 2009 also contained amendments to the NHS Act 2006 allowing the Secretary of State to make regulations to enable PCTs to issue breach and remedial notices, and to withhold payments, in order to deal more effectively with poorly performing contractors. Under the Health and Social Care Bill 2011 currently before Parliament, the responsibilities of PCTs in respect of PS will pass, on abolition of PCTs, to the NHS Commissioning Board.

Description of the NHS pharmaceutical market and activity in England

6. NHS pharmaceutical providers are almost 100% private contractors. There are three main contractor groups:

- community pharmacy contractors;
- dispensing doctors; and
- dispensing appliance contractors.

7. In England, there were 10,691 NHS pharmacies as at 31 March 2010. This compares with 9,736 at 31 March 2005 or an increase of just under 1,000 or some 9%. 39% of pharmacies were owned by “independent” contractors (five NHS premises or fewer). 61% were owned by larger businesses with six or more NHS premises including multi-nationals and supermarkets such as ASDA, Sainsburys and Tesco. The three largest NHS contractors with an estimated 35% of the market are Boots, Lloyds and the Co-operative Society. Like other retail sectors, a trend to greater market consolidation has been underway for the past two decades. Whilst purely private community pharmacies exist, it is a generally accepted precept that without NHS funding (which can account for 85% or more of total annual income) a new pharmacy would usually struggle to be viable. An estimated 23,000 pharmacists work in the community.

8. Nationally, an estimated 99% of the population can get to a pharmacy within 20 minutes by car. This approaches 100% in more economically deprived areas. 96% of the population can get to a pharmacy within 20 minutes by public transport or walking. However, access is not uniform for all population groups in all areas.

9. There are some 1,130 NHS dispensing doctor practices. They principally serve rural populations. They are outside the scope of the proposals discussed in this Impact Assessment.

10. As at 31 March 2010, there were 137 dispensing appliance contractors (who can only supply appliances such as incontinence aids, dressings and bandages, not medicines) of whom 95 were active. They are run by around 50 – 60 small to medium sized enterprises. Like pharmacies, there is evidence of market consolidation in recent years. However, in contrast to pharmacies, total numbers overall have declined. As at 31 March 2005, there were 167 dispensing appliance contractors of whom 134 were active, and as at 31 March 2001, there were 181 contractors of whom 159 were active. NB: Because of the smaller numbers of active dispensing appliance contractors compared to pharmacies, discussion of the specific options and impacts below applies to pharmacies only, unless otherwise stated. However, it is estimated that the costs and benefits that would arise in respect of changes to market entry and exit arrangements for dispensing appliance contractors would be similar to those for pharmacies.

11. Pharmacies dispense the vast majority (91%) of the 897 million NHS prescription items that are dispensed as part of NHS primary care annually. Dispensing doctors dispense 7% or 64 million items. Appliance contractors dispense about 0.6% or some 5.2 million items. The remaining prescription items are accounted for by those items, outside the scope of PS, which are personally administered by prescribers in a GP practice or in schools etc., such as vaccinations.

Problem and justification for government intervention

12. Additional pharmacies can benefit consumers in terms of improvements in access, choice and competition (see below). However, there are fixed costs associated with providing PS through an NHS pharmacy. Each new NHS pharmacy therefore increases the aggregate costs of NHS provision. Any increase in the number of NHS pharmacies means one of two things:

- Either more costs borne by the NHS where NHS funding is increased to take account of the extra (fixed) costs from more NHS pharmacies;
- Or if NHS funding is not adjusted, these costs are borne by all NHS pharmacies. In practice, this will manifest itself in terms of less funding per pharmacy because the same overall pot of money is allocated across a greater number of pharmacies, effectively sharing all such additional fixed 'costs' across all pharmacies. This could have secondary impacts since, if the average funding each pharmacy receives to meet its fixed costs reduces, pharmacies in areas of lower demand or serving wider population catchments (e.g. more rural areas) may encounter increased financial pressures, leading to reduction in the services available or withdrawal from the market and risking the availability of PS overall to such areas becoming inequitable.

13. The objective therefore is to ensure that the benefits of new entry outweigh unavoidable costs.

14. The current approach to meeting this objective is through the regulatory "control of entry" regime (for more information, see "Background to the current approach" below). The effects of this regime, which was previously criticised for imposing too high a barrier to entry, were mitigated in April 2005 in England by the introduction of a revised test which introduced a new decision criterion of promoting choice through competition and specific exemptions to that test. However, certain problems persisted as discussed below. The fundamental justification for intervention remains that improvements to the regulatory regime can be made in order better to maintain or to improve access whilst assuring adequate and proportionate controls on expenditure.

Background to the current approach

15. For the last 25 years, whether or not a pharmacy contractor provides NHS services has been largely determined by the regulatory system known as 'control of entry'. This is set out in section 129 of the NHS Act 2006. Broadly speaking, an application will only succeed if a PCT considers it "necessary or expedient" to grant it in order to secure adequate provision of NHS pharmaceutical services locally. Over the years, this test was subject to considerable review by the Courts. Their decisions established various precedents and criteria as to how PCTs should apply the test when considering applications.

16. Following a review of this system, the Office of Fair Trading (OFT) recommended in January 2003 total deregulation by abolition of this test in order to improve competition, to reduce prices and to improve access to, and the quality of, pharmaceutical services.

Exemptions from control of entry

17. The previous administration, in response, revised but did not remove this test in April 2005 by introducing new requirements that were designed to promote choice through more competition e.g. a reformed control of entry test and streamlined application process as well as four exemptions to the control of entry test (subject to certain criteria). These four exemptions comprise:

- Pharmacies open for at least 100 hours per week;
- Pharmacies based in large out-of-town shopping centres;
- Pharmacies based in new large one-stop primary care centres with a range of facilities; and
- Wholly internet or mail-order only pharmacies.

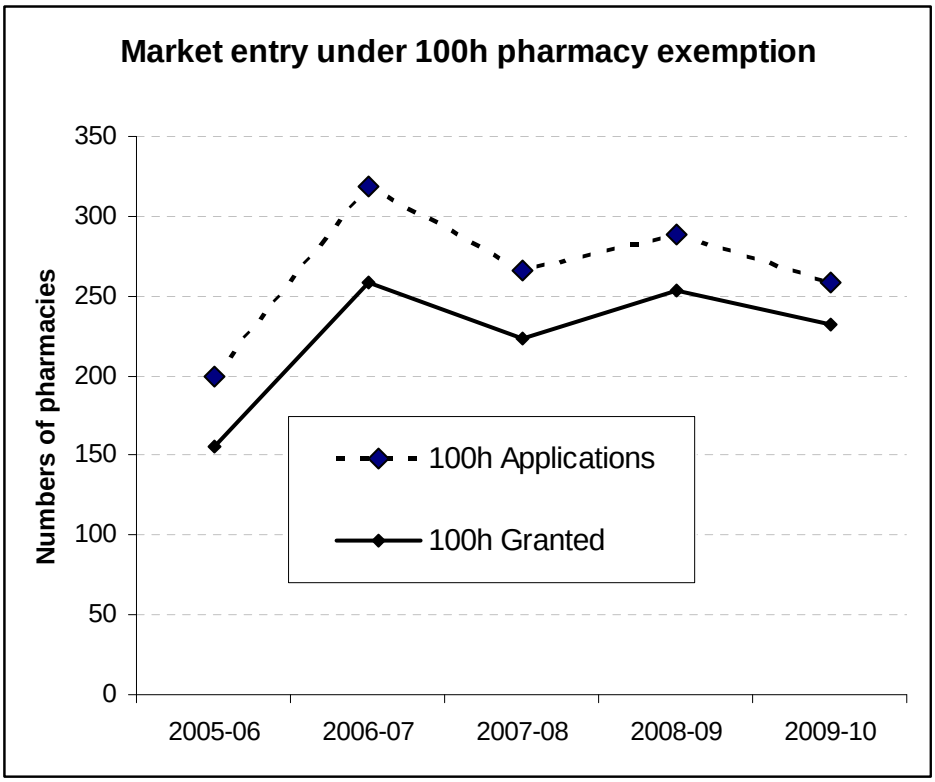
Under the current legislation, the principal test for entry to the pharmaceutical list must be one based on necessity or expedience (set out in paragraph 15). The use of the exemptions must be subsidiary to this principal test.

18. Of these, the exemption relating to pharmacies prepared to open for at least 100 hours per week has facilitated the greatest new entry. The Department published a review of these measures in January 2007 - http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063460. The OFT published an independent review prepared by DotEcon in March 2010 – see http://www.oft.gov.uk/news-and-updates/press/2010/31-10. For further discussion, see paragraphs 22 – 28 below.

19. The Department's review reported that the revised arrangements had improved access, especially where new 100 hours per week pharmacies opened, with no overall adverse impact on the network. However, the NHS reported problems especially with this particular exemption. These were summarised in the 2008 pharmacy White Paper "Pharmacy in England: Building on strengths - delivering the future" (paragraph 8.60) as:

- A lack of PCT control over where such pharmacies located;
- No match between the better access that a pharmacy open at least 100 hours per week delivers and the need for such an improvement locally;
- Clustering of such pharmacies close to each other or around income sources; and
- Unbudgeted additional expenditure if thresholds for additional allowances were reached.

20. For information, the following graph shows historical data of applications for pharmacies prepared to open at least 100 hours per week from 2005/06 to 2009/10. It should be noted that the grant of such applications does not automatically result in these pharmacies subsequently becoming an NHS provider. Circumstances may change following grant (e.g. an approved contractor cannot secure premises).



21. Through its 2009 Health Act, the previous administration amended these arrangements to address these concerns and to make PCTs responsible for assessing patients' pharmaceutical needs locally. PCTs would commission PS against those assessments and their local health priorities. In this way, the intention was to link pharmacy more closely to strategic planning, to drive up standards and quality and enhance pharmacy's contribution through expanded access and improved patient choice. In addition, the reformed entry system would help stimulate the market where needs were identified that were not currently being met and provide a more objective basis than the current system for determining whether or not to commission services or to expand existing provision.

Problems with the current regulatory regime and approach

22. The general problem with the current control of entry regime relates to the loosening of entry controls, which may have led to over-supply of pharmacies. There is, for example, evidence of "clustering" of new pharmacies in some areas and speculative applications for any given location. The 2010 OFT review found that market entry had increased by 8.8% which was confirmed in the Information Centre's statistical bulletin on NHS pharmaceutical services published in November 2010. As noted above, this results in an increase in costs that will be borne either by the NHS, or by pharmacy providers.

23. The DotEcon study reported that, with some exceptions, such as new entrants locating in supermarkets or out-of-town shopping centres, new entry had tended to concentrate in localities already served by pharmacies, including around GP surgeries where prescription demand is higher (paragraphs 4.24 and 4.25) and often involves the 100 hours per week pharmacy exemption. This clustering might, in other industries, lead to consumer benefits through increased competition. However, the main activity of most pharmacies is dispensing of NHS prescriptions at a fixed price (at the relevant prescription charge, or, in most cases, free at the point of dispensing). Therefore, the benefits of price competition cannot occur with regard to NHS prescriptions.

24. However, there are benefits to having more pharmacies. The DotEcon report attempted to evaluate and monetise these benefits in relation to the increase in the number of pharmacies that had resulted from around 850 new pharmacies which had opened at the time they reported since the control of entry was amended in April 2005. This report estimated benefits of:

- Travel time savings worth between £16.4 million and £24.5 million;
- Waiting time savings to consumers worth £3.3 million per year as a result of prescription demand being spread over more pharmacies; and
- Wider availability of supermarket pharmacies and over-the-counter (OTC) medicines with conservative annual savings estimated at £5 million.

25. In addition, there were other benefits that DotEcon were not able to monetise. These included:

- The value of increased availability and use of extended opening hours;
- Improved choice and convenience;
- Increased availability of collection and delivery service;
- Possible reduction in general OTC prices; and
- Benefits to non-prescription customers.

26. DotEcon also developed a survey-based "holistic" approach to assessing the benefits of new entrants since 2005. This generated an estimated benefit ranging from £21 million - £68 million. This did not include any benefits of access to cheaper supermarket OTC medicines.

27. However, set against this is the extra (fixed) costs of the new pharmacies. Recent work undertaken by PriceWaterhouseCoopers, as part of the pharmacy Cost of Service Inquiry - http://www.dh.gov.uk/en/Healthcare/Primarycare/Communitypharmacy/Communitypharmacycontractualframework/DH_128128, used a bottom-up approach to estimate the start up costs of a new pharmacy – i.e. those costs that would be incurred no matter what the turnover of the pharmacy. These costs comprised mainly staff costs (pharmacist, technicians and counter assistant), and premises costs and associated utilities costs. These were estimated in the region of £123,000 per pharmacy. Applying this to some 850 new pharmacies as identified in the DotEcon report means an extra cost to society of some £104 million.

28. On the face of it, the extra costs associated with new entries outweigh the estimated monetised benefits of new NHS pharmacies – a shortfall of at least £30 million. However, this ignores the benefits that DotEcon were unable to monetise (see paragraph 25 above). We have not been able to assess whether or not these benefits, if it were possible to monetise them, would cover this shortfall. Nor have we estimated the value of the decrease in incremental benefits which would be expected where more pharmacies located in areas already well served (as evidenced through "clustering") at the expense of locating in areas where there is evidence of identified or unmet patient need.

Policy objectives and intended effects

29. The objectives of the policy are to reduce the incentives leading to excessive supply, and to align provision more closely with local needs whilst maintaining and, where desirable, improving access to and choice of the best pharmaceutical services, through a regulatory system which enables both competition and closer working and integration with other health services. Achievement of these objectives would improve the economic efficiency of pharmacy provision, whilst enabling the patient and consumer benefits realised by aligning services more closely with the requirements of local populations. Ultimately, this should ensure that the benefits of new entrant pharmacies outweigh the fixed costs associated with more pharmacies generally.

Do-nothing option

30. If no policy action were to be taken, it is anticipated that new entry, principally by making use of the exemptions, would continue. This could lead to continued and possibly increased over-provision of services, most likely in areas already well served, and to greater financial pressures. These would need to be met either by increased payments by the NHS, or met by pharmacies if funding remained unchanged. As noted above, it is highly uncertain whether, under these arrangements, the benefits would outweigh the costs. Whilst the existing regulatory system may continue to improve access and choice, such improvements would be neither equitably available to all nor related to identified patient needs. Benefits derived from increased competition would most likely continue to be localised in areas where there is already adequate existing provision.

Option 1: Replace current system with market entry based on Pharmaceutical Needs Assessments (PNAs), and introduce a market exit regime that allows effective action to be taken against under-performing providers or those in breach of their terms of service

31. Under this option, the potential to enter the market by virtue of the exemption of opening at least 100 hours per week would be removed along with two other exemptions. Of the current exemptions, it is proposed that only wholly-internet and mail order based pharmacies would remain. This is because such types of pharmacy would likely wish to offer services to a catchment area wider than that covered by a PCT's PNA.

32. Pharmacies would instead be permitted to enter the market if they are able to demonstrate that in doing so they will meet a particular unmet local need or service requirement identified in a PNA carried out by a PCT, or if they can make a case that they will provide "unforeseen benefits" not anticipated at the time of the PNA, but which may well confer significant benefits on the local population. To this extent, it is expected that the introduction of this new provision would help offset the removal of three of the existing four exemptions to the control of entry test. It would also alleviate a block under the current regulatory system that makes it more difficult for dispensing appliance contractors to enter the market or to move premises.

33. Such impacts are likely because, importantly, the PNA is a transparent, published document that gives contractors and potential new entrants greater clarity and certainty in respect of the criteria used to assess applications. The PNA should enable new entry to be aligned more effectively with local needs. We do not believe this will lead to all such applicants, who would otherwise have made use of the exemptions, automatically deciding not to proceed with an application. Instead, applicants would be freed up to focus in future on preparing robust, tailored business cases to persuade the PCT of the need and/or desirability for approving their particular application. An applicant might, for example, offer to open for extended hours beyond the minimum contractually required 40 hours per week in an under-served location. Alternatively, an applicant might want to offer to open in a new shopping development inside a town centre which is not currently permitted within the terms of the exemption in the 2005 Regulations.

34. There is, therefore, a distinction to be drawn between how the current and a new regulatory regime would operate. In future, applicants will be able to use their commercial judgement to determine and argue the case for a specific location, pattern and length of opening hours or range of services. They will not be constrained by the current exemptions, which restrict applicants to offer to open for a mandatory minimum of at least 100 hours per week or to satisfy the PCT that a particular type of shopping centre or primary medical facility meets the current criteria for those types of exempt application.

35. Along with this change to market entry requirements, a system of market exit would be introduced that would lead to effective, graduated actions being taken to deal with those providers who were under-performing or failing to meet their terms of service obligations – and who therefore may be receiving fixed costs payments without adequately fulfilling their contractual requirements. Such graduated actions could, if unresolved, ultimately lead to removal of a provider from the PCT's pharmaceutical list. The current mechanism for dealing with breaches of terms of service is by means of referral of the matter to the discipline committee of another PCT. This is widely recognised to be overly bureaucratic and ineffectual.

Option 2: Remove exemptions from the current control of entry regime but retain the other changes introduced in 2005 (reformed control of entry & streamlined application process) and introduce a market exit regime as in Option 1

36. The costs would remain similar to now although the evidence strongly indicates that there would be fewer applications, as there would be fewer exemptions. The OFT report in 2010 found (paragraph 4.14) that around 25% of new entrants had applied using the revised control of entry test as opposed to one of the exemptions. However, it is likely that with the removal of the exemptions without some further compensatory action, some pharmacy applicants that could bring benefits to patient/consumers would not be granted approval. At the same time, and possibly more likely, some pharmacies would still be able to gain entry where there was limited additional benefit to be gained by patients/consumers. The expected impact is therefore likely to reduce significantly the opportunity to enter the market without compensatory benefits in achieving the overall objective and intended effects. It would be a retrograde step and for these reasons, this option is considered inferior to Option 1.

Option 3: Revert to the regulatory regime which existed pre-April 2005 (remove the exemptions from the control of entry test as well as the other 2005 reforms) and introduce a market exit regime as in Option 1.

37. The evidence to date indicates the revised regulatory regime has brought benefits that may or may not outweigh the costs involved. Reverting to a system which existed pre-April 2005 would remove all opportunity of further such benefits although it would have a positive impact in terms of avoiding further cost liabilities. However, it would not achieve the policy objectives of improving the economic efficiency of pharmaceutical provision overall nor deliver increased patient and consumer benefits. As with Option 2, this would be a retrograde step, inferior to Option 1.

Option 4: Abolish "control of entry" arrangements

38. This option derives from recommendations made in 2003 by the OFT and would enable market forces to determine the scale and configuration of supply of pharmacies. It is likely that this would result in further growth in the total number of pharmacies, but with growth also in the associated costs described earlier. It is not possible to estimate how significant the growth may be as it is reasonable to assume that the revised entry regime introduced in April 2005 has already met some of the market's previously suppressed appetite for entry. Removal would likely bring some further benefits to consumers in terms of improved access, choice and competition similar in nature to those reported by DotEcon. However, this is most likely to occur in areas of highest economic demand, which are already well served. This would lead to diminishing economic returns since each incremental new entrant (all other things being equal) would bring lower associated benefits but the same associated fixed costs.

39. However, such a change could not be achieved under the current provisions of the NHS Act 2006 nor within the current changes proposed by the Health and Social Care Bill currently before Parliament. It would require significant changes to the primary (& secondary) legislation, which we estimate, could not be implemented before May 2015. Removing the required statutory framework without changing the primary legislation would present a real risk to the Department and Ministers. A change to the legislation, whilst of course feasible, is likely to lead to a high level of disquiet and market disruption, at least during the period it took to secure the necessary changes and implement such a new system estimated at a minimum of four years. Since entry would likely focus in the future on securing the most advantageous trading positions in order to maximise dispensing revenue, it may jeopardise other Government priorities and policies as set out in paragraph 3.22 of the *White Paper Equity and excellence: Liberating the NHS*. These are to incentivise and support high quality and efficient pharmaceutical services through better value in the use of medicines and to develop the pharmacist's role, working alongside doctors and other health professionals in optimising the use of medicines and supporting better health. For these reasons, this option is not evaluated further.

Option 1: Overview of impacts

40. Changes to market entry are expected to reduce the future overall number of new entrants, compared to the do-nothing option. This will reduce the fixed costs incurred by operating more premises – which must be borne by some part of the current system. This cost saving will be partially offset by some additional net costs in administration and compliance with the new system. The sum of these effects is expected to be beneficial overall – that is, the savings in fixed costs are expected to exceed the additional costs of administration and compliance.

41. In addition to the impacts on costs, the new regime will also affect the patient and consumer benefits realised from pharmacy. There are several distinct effects, of which one is negative, and several are positive.

42. The reduction in new pharmacy entrants compared to the do-nothing situation will reduce convenience of access – and increase access costs – for patients who might otherwise have used such pharmacies had they opened. However, the evidence suggests that more such pharmacies would have preferred to locate in areas that PCTs determine are already well served, as assessed under the PNA (see, for example, paragraphs 4.21 – 4.26 of the DotEcon report). Therefore, any associated losses to patients are expected to be relatively low, or minimal.

43. Any negative effect on patient access in areas already well-served would be offset by gains elsewhere across the pharmacy network, as we can expect new entrants under the PNA system to be encouraged to select sites in locations where they are deemed most needed. Thus, patient access across the rest of the pharmacy network is expected to improve.

44. Use of PNAs is also expected to result in pharmacies increasing provision of local enhanced services that generate additional health benefits for patients – for instance, through stop smoking services.

45. Finally, introduction of a new exit regime based on PCT actions where breaches of terms of service are identified, is expected to improve the quality of pharmacy services overall. This will give contractors increased incentives to address poor or under-performance, improving patient experience and ensuring appropriate measures are in place to deal with the expected very small number of contractors whose performance is unsatisfactory.

46. The magnitudes of these effects on patients have not been quantified. However, it is reasonable to estimate that the benefits described above will more than offset any losses from reduced access to pharmacy services from new entrants which do not open in areas which PCTs determine are already well served.

Benefits of Option 1

Lower Fixed Costs from fewer new entrants

47. Just as application volumes are expected to decrease, so it is anticipated that entry based on PNAs would result in fewer new market entries than under current arrangements. There will be two offsetting effects. The policy is expected to reduce entries that would have been expected through exemptions in the current system; this reduction will be partly offset by increased entry through the internet-only exemption, and through use of PNAs.

48. The exact magnitude of these effects is very difficult to anticipate, and precise estimates are not available. This analysis therefore uses a plausible estimate, based on the Department's understanding of the pharmacy market. Using this approach, it has been estimated that under the current system, entry by exemption would continue at its current rate of approximately 150 pharmacies per year for two years, declining to 20 per year in year 10 of the policy. This would result in an additional 915 entrants through exemption over the 10-year period. These pharmacies would no longer enter under the proposed policy. It is estimated that the internet-only exemption would result in the entry of an additional 50 pharmacies in years 1 and 2, declining to 20 in year 10. Entry through PNAs is estimated to result in an additional 60 pharmacies in each of years 1 and 2, declining to 30 in year 10. The cumulative total additional entry by the two mechanisms in this scenario is 830 in year 10. These entry estimates are expressed net of any reduction in pharmacy numbers through the market exit regime. When set against the reduction in entries through the removal of exemptions, this results in a cumulative reduction of 85 pharmacies in year 10, compared to the number that would have been expected under the current regime. Over the 10-year period, the cumulative reduction will average 115 pharmacies.

49. As noted above, each (net) new market entrant costs in the region of £123,000. The scenario described would result in an average saving of £14.1 million annually, with a net present value over 10 years, of £116m. Cost savings to the NHS allow the provision of more treatments from the NHS budget. The cost-effectiveness threshold used by the National Institute of Health and Clinical Excellence (NICE) to determine whether new treatments should be funded in the NHS implies that the cost of providing a Quality-Adjusted Life Year (QALY) at the margin in the NHS is £25,000. The cost savings generated are therefore expected to lead to provision of additional treatments that generate 4,640 QALYs for their recipients. The standard DH estimate of the value of a QALY is £60,000. The value of these additional treatments is therefore £279m.

Reduced ongoing PCT administration costs in managing applications under new market entry regime

50. It is expected that application volumes will decrease as a result of the proposed measures, as contractors are better informed of local requirements, through communication of the results of the PNA. Fewer unsuccessful applications are therefore expected and those who do apply will benefit from a more streamlined system than is currently the case. In order to generate a deliberate underestimate of the true benefits of the policy, this impact is left un-monetised.

Reduced contractor application costs in new market entry regime

51. Lower volumes of applications would also be expected to reduce costs to contractors. As before, in order to generate a deliberate underestimate of the true benefits of the policy, this impact is left un-monetised.

Costs of Option 1

Transitory administration costs to PCTs of adopting new market entry regime

52. Changes to the market entry regime will lead to transition costs for PCTs as the new system is introduced. These are estimated at £10,000 per PCT, or a total of £1.5m for all 152 PCTs, based on the Department's understanding of the activities required to carry out the necessary functions. These costs falling on the NHS budget mean that treatments elsewhere must be withdrawn, leading to the loss of 25 QALYs for patients, valued at £3.6m as explained above.

Ongoing costs to PCTs and applicant contractors of new market entry regime

53. Although individual applications under the PNA system may be more onerous for PCTs and applicants, it is expected that this additional burden will be at least offset by a reduction in the volume of applications made – as potential contractors are better informed about the basis on which their applications would be approved under the PNA.

Costs to PCTs of administering market exit regime

54. We have assumed that PCTs would annually issue warning letters to 10% of the 10,500 pharmacies, each taking 3 days of management time (allowing for the required effort in assessing pharmacies). Approximately 420 of these would result in breach notices, each taking a further 2 days of management time. Funding would then be withheld from 140 pharmacies, each taking 5 days of management time and incurring £750 in legal costs. Finally, we have assumed PCTs would take action to de-list 72 pharmacies, each incurring 5 days of management time, and £2,250 of legal fees. This would include management of any subsequent appeals. If management time costs £250 per day, these assumptions imply an annual cost of £1.5m p.a. for all PCTs, and the consequent withdrawal of treatments providing 25 QALYs to patients, as explained above. These QALYs have a value of £3.6m. Over 10 years this corresponds with a net present value of £31m.

55. As described above, these measures may have impacts on the costs to pharmacy contractors. However, pharmacies are funded by the NHS through an overall contractual framework, which provides contractors with remuneration that is based, in principle, on the costs they sustain in providing NHS services. Remuneration is paid through fees and allowances which are intended to cover both capital and running costs incurred by pharmacies (note: although pharmacies incur capital costs, this is not a capital cost to the NHS – these are covered by monthly payments to pharmacies through fees and allowances). It is therefore possible that at least some portion of the costs sustained by contractors could, ultimately, be passed back to the NHS through future higher fees and allowances. The actual sum remunerated is determined by many factors, and is the subject of complex negotiations between the Department and the Pharmacy Services Negotiating Committee. It is therefore not possible to give a definitive estimate of the extent to which any cost impacts arising from these measures would be borne by contractors or the NHS.

Costs to pharmacies of responding to market exit action

56. We have assumed that pharmacies will incur the same cost in defending the last two stages of market exit action as PCTs – that is, in responding to the withholding of funds, and managing the process of de-listing and any appeals. Over 10 years this corresponds with a net present value of £4.4m.

57. Such costs fall out of scope of the Better Regulation Executive's One-In, One-Out principle, as they are specifically and exclusively related to enforcement of the contractors' terms of service.

Impact on patient and consumer benefits

Reduced entry in well-served locations

58. Removal of entry exemptions will result in a net reduction in the number of new entrant pharmacies, compared to the number that would have been expected, as some new entries that would have been possible under the current system may be prevented from entering under the new regime. This will consequently reduce convenience of access for patients in areas that are affected – and will increase the costs to these patients of accessing pharmacy services. However, the policy is specifically designed to enable PCTs (and pharmacy contractors) to identify locations which are under-served by pharmacies. This means that new pharmacies which would have been approved under the current regime, but which may not be approved under the new entry system, will be in those areas that are already deemed well served. This implies that the losses to consumers in terms of reduced access are likely to be relatively low.

Targeting of new entry to under-served areas

59. Use of a PNA –based entry system will enable PCTs and contractors better to understand which locations are currently under-served in terms of pharmaceutical services. It is therefore expected that new entries under the PNA system will, on average, be in locations in which they provide significant patient and consumer benefits, as they address gaps in current provision. Overall, this will result in a net increase in the patient and consumer benefits from convenient access to pharmacy – or a reduction in the costs of patients in accessing pharmacy services.

Increased provision of Enhanced Services under PNAs

60. It is expected that PCTs will use the PNA entry system to ensure that pharmacies match provision of local enhanced services more closely to local needs, where these would be of benefit to local populations. Such services – for example, stop smoking services – are often extremely cost-effective, and generate significant net benefits. One study [reference to be added] found that stop smoking services provided through pharmacies generated benefits to patients at a cost of £2,600 per quality adjusted life year (QALY). This may be compared to the NICE cost-effectiveness threshold, which represents the conventional estimate of the cost of generating additional QALYs in the NHS, of £20,000 - £30,000 per QALY. At this level of cost-effectiveness, a spend of £1m on such services would generate 345 additional QALYs, valued at £21m.

Improved quality throughout the pharmacy network

61. In addition to increases in provision of services deemed beneficial to local populations under the PNA system, the proposed market exit regime is expected to result in overall improvements in the quality of service provision by pharmacies. Contractors will be better informed of the standards expected, and will have stronger incentives to improve the quality of their service. This will result in patient benefits from improved service and experience, and may also have positive health impacts where contractors effectively address any perceived shortcomings in service delivery.

Net impacts on patient benefits

62. As described above, there are offsetting effects on the patient benefits realised from pharmacy. While the reduction in numbers of new pharmacy entrants may negatively affect patient access, it is expected that this will occur largely in areas that are already well served. Greater offsetting benefits are expected from the improved targeting of new services to areas that are currently under-served, and from the improved alignment of provision with patient needs – including any increased provision of local enhanced services and greater quality of service provision.

63. The magnitudes of these offsetting impacts have not been calculated. However, as explained above, it is expected that their overall effect will be beneficial. In order to generate a plausible conservative estimate of the net benefit of the policy overall, the impacts on patients are assumed to be neutral. As the true impacts are expected to actually be positive, this approach will lead to a deliberate under-estimate of the net benefits of the policy overall.

Risks, Sensitivities and Assumptions

64. The cost savings accounted depend on the assumptions made of pharmacy entry under the current and proposed systems. There is uncertainty around the growth in the number of pharmacies if regulations remain as now, and what will happen if the regulations change. The introduction of the exemptions has increased the number of pharmacies, and this is likely to continue if the exemptions remain, though it is highly uncertain by how much. How much entry would be lower if the exemptions were removed is also uncertain. As it is not possible to forecast with confidence the exact numbers of pharmacies that will enter under this policy, the total cost savings cannot be predicted exactly. However, the scenarios evaluated represent a reasonable estimate, given the information available – the review by DotEcon on behalf of the Office of Fair Trading and the Price Waterhouse Cooper Cost of Service Inquiry.

65. Analysis of Option 1 also makes the assumption that the negative impact on patients of fewer new entrant pharmacies will be exactly offset by the benefits arising from better alignment of new entry with patient need, and improvements in quality of service due to the exit regime. This assumption is deliberately pessimistic, as it is expected that the true benefits to patients from alignment of new entry to local needs, and the effect of the exit regime on quality, will significantly outweigh the negative impact on patient access of fewer pharmacies than would otherwise have been expected. Options 2 and 3 are not expected to deliver such large benefits.

Summary and net benefits

66. The policy proposal is expected to result in a net cost saving, as any increases in the costs of administration are more than offset by reductions in fixed costs from fewer new entrants. (Any benefits from improvements in the delivery of services as a result of graduated actions under market exit proposals are excluded from this calculation). The impact on patients is assumed to be neutral – although, as described earlier, it may actually be expected that the benefits to patients would outweigh any losses. We therefore estimate that this results in an overall net benefit derived from savings in net costs – although the true net benefit is expected to exceed this.

67. There are also measurable consumer benefits. On average, these are estimated at £80,000 per pharmacy (see paragraphs 24 – 26: £68 million divided by 850 new entrant pharmacies). There may be additional non-monetised benefits. A reduction each year of 115 new entrant pharmacies, as estimated in paragraph 47 above, would correspond with the loss of approximately £10m in consumer benefits if all pharmacies generated average benefits. This value is below the annual savings in net costs, indicating that the proposal would have a positive net value even if the offsetting benefits of PNAs were disregarded. In fact, as explained above, any pharmacies lost are likely to be below average in this respect – perhaps very significantly below average – as they are more likely to be located in areas already well served. It therefore seems likely that the overall impact of the policy would be positive.

Costs and Benefits of Options 2 and 3

68. As in Option 1, these options would discontinue exemptions and therefore result in less net entry than would have been expected under the current system. The numbers given below represent our best estimate of the impact based on the numbers of new entrants there have been each year since 2005. These options differ in the degree to which these reductions are offset by entry under the corresponding systems.

69. In Option 2, it is estimated that the proposed control of entry regime would result in an additional 50 pharmacies in each of years 1 and 2, diminishing to 25 pharmacies in year 10. Over the 10-year period, this implies entry of an additional 388 pharmacies by these means. When subtracted from the reductions in entry due to withdrawal of exemptions, this corresponds to a net reduction of 528 pharmacies compared to the levels that would have been expected in the current system. This implies cost savings of £48m per year on average, allowing provision of additional treatments generating a health gain with a NPV over 10 years of £930m.

70. Under Option 3, the proposed control of entry regime would result in very low levels of entry, estimated at an additional 10 pharmacies in each of years 1 and 2, diminishing to two pharmacies in year 10. Over the 10-year period this implies entry of an additional 64 pharmacies by these means. When subtracted from the reductions in entry due to withdrawal of exemptions, this corresponds to a net reduction of 851 pharmacies compared to the levels that would have been expected in the current system. This implies cost savings of £72m per year on average, allowing provision of additional treatments generating a health gain with an NPV over 10 years of £1386m.

71. Both these options result in greater cost savings as a result of reduced pharmacy numbers. However, these reductions are expected to have a significant effect on the patient benefits from pharmacy. Whilst use of PNAs will ensure that new entry in option 1 will be targeted to under-served areas, and aligned with local needs, the pharmacies entering under options 2 and 3 will primarily be located according to commercial considerations – which may not be fully aligned to local needs, as described above. Combined with the greater losses to patients from reduced access to pharmacy, these options are expected to result in much reduced patient benefits, compared to option 1. The scale of these impacts on patient benefits has not been quantified.

Specific Impact Tests

Competition Assessment

1. The OFT has developed a filter to determine whether a regulatory proposal is expected to have an impact on competition. It consists of the following questions:

Would the proposal

a) Directly impact the number or range of suppliers?

b) Indirectly impact the number or range of suppliers?

c) Limit the ability of suppliers to compete?

d) Reduce suppliers' incentives to compete vigorously?

2. There is no price competition at present for the majority of services provided by pharmacies, as NHS pharmaceutical services, which make the bulk (estimated at 85% or more) of contractors' income, are provided free of charge or by nationally set charges (i.e. prescription charges). Thus, any increase in competition would be based on the accessibility and quality of service provision.

3. As described above it is expected that the proposals will result in a reduction in new pharmacy entrants, as entry will be more restricted in areas that are already well served and in which competition is already well established. There will be an offsetting effect, as new pharmacy entry will target those areas that are currently under-served, which should introduce or improve patient choice and competition where it is either absent or less marked. The net effects are not easily quantified, but it is reasonable to expect that the increases in competition resulting from greater entry where provision is more limited would be expected to outweigh the losses resulting from lower entry in areas where choice and competition are already strong.

Small Firms Impact

Moratorium on new regulations affecting start-up and micro-businesses

4. Contractual arrangements entered into for the provision of public services are exempt from the three- year micro business moratorium announced by the Chancellor in the Budget on 23rd March 2011. The *Guidance on Moratorium on New Domestic Regulation for Micro-Businesses and Start-Ups* states in paragraph 3 that "the moratorium policy applies to all new domestic regulation within the scope of OIOO" Therefore, these regulations which govern the provision of NHS community pharmaceutical services, are outside the scope of the moratorium on new regulations applying to start-up and micro-businesses.

Market entry

5. Small firms (independent community pharmacies and pharmacies with five or fewer premises) comprise 39% of the market, though their number has gradually declined from around two-thirds in the early 1990s. The proportion of the 95 active dispensing appliance contractors which are small businesses is not known.

6. The set up costs for the provision of commissioned services (particularly if they are specialist services) are likely to be more burdensome for smaller firms, who may have less capital to invest for adequate facilities. Regardless of any potential Government support towards training and administration costs, costs of training (both financial and time costs) are also likely to be larger for smaller firms, relative to their revenues.

7. Nevertheless, it is likely that a smaller contractor would be more responsive to local needs than a national chain and better tailor service delivery to commissioning requirements. There might be lower risks to such applicants where PNAs identified specific needs for pharmaceutical services.

8. The Department has previously held a workshop for small businesses in October 2008 as part of the previous administration's consultation on the proposals. Concern was voiced about the impact this move would have on smaller contractors. Identification of "gaps" in supply by PNAs would favour entry of larger competitors at their expense. Raising barriers to entry could increase market consolidation with fewer and larger players. If basing entry on PNAs resulted in increased service provision in particular localities, this could further impact on the profit levels of smaller contractors, implying this would require their costs to be cut and/or a reduction in the quality of service provided. Thus, the potential benefits of using pharmacists to deliver services derived from the PNAs may not be realised, because smaller businesses will not make adequate money nor be able to "scale-up" in the way that is necessary. Nevertheless, a properly designed and funded programme could use pharmacists to deliver extremely cost-effective services. Therefore, testing the new arrangements either by "shadowing" or selecting a range of areas could be desirable to prove they can work although it was acknowledged this would prolong full rollout of any new arrangements.

9. Overall, whilst there may be some impact on small businesses from the new proposals for market entry, it is not clear that such an impact would be disproportionate. However, this impact can be assessed and any mitigating measures considered as part of a comprehensive evaluation of the proposals once introduced. As any changes to legislation would apply to all NHS contractors, the Department does not consider it would be appropriate to exempt (either fully or partially) smaller firms from these provisions. As piloting would require complex Regulatory measures it is not proposed to implement this policy through piloting but fully to evaluate after implementation.

Market exit

10. It is possible that small firms may be over-represented in the fraction of pharmacy contractors providing services at lower quality because larger organisations can be expected to use internal quality control processes across their premises. However, this effect is not considered inappropriate, as quality standards should be upheld universally.

11. In the Department's previous workshop consultation with small businesses in October 2008, delegates considered that a new quality regime should build on the existing regime (e.g. staffing, training and clinical governance) with clearer exposition of the benefits to engender buy-in and commitment. Whilst the need for assurances and measurable indicators was acknowledged, the additional burden and disproportionate cost this could create should not be underestimated. Larger companies can afford internal quality procedures which smaller businesses are not resourced for, although trade associations may have a support role here. Smaller businesses would be concerned if new standards for premises provided the NHS with an additional tool to impose unrealistic demands on providers when commissioning services, as an excuse not to commission services at all or as a means to de-list them. That said, the current proposals do not in themselves create new quality standards; they simply provide for effective and proportionate enforcement of whatever standards are in place. Where action to de-list was considered, smaller businesses believed they would incur much higher costs in defending or appealing such action. Without an NHS contract, their commercial viability was much less sustainable than larger, more diversified providers. The costs of any residual lease commitments if a business was forced to close also needed to be taken into account.

12. Small firms are therefore likely to incur disproportionately larger costs in complying with any additional administrative requirements, such as dealing with remedial notices or responding to more serious sanctions as larger contractors will benefit from economies of scale and in gathering and reporting quality information across multiple pharmacies.

13. However, the Department does not consider these are disproportionate in the circumstances of introducing a new performance and enforcement regime for all contractors that includes the possibility of de-listing as an ultimate sanction. The public should be able to expect consistent standards of delivery and high quality services irrespective of the type of contractor they choose. However, the Department recognises that there may be some issues of special relevance, including any impact from delisting on a contractor's continuing lease obligations which should be borne in mind.

Environmental and Sustainability Impacts

14. It is expected that the net effect of the proposed measures will be to move pharmacy provision from high-demand areas that are already well served, to regions of less demand, which are currently under-served. This would have the effect of reducing patient travel times, and use of transport – which may result in a small net environmental benefit, although this has not been quantified. This would be reduced if significant numbers of pharmacies in under-served areas where there is less competition were to leave or to be removed from the market by virtue of the new exit provisions although this is not anticipated at this stage by virtue of the small numbers of pharmacies expected to be subject to possible removal. A reduction in new pharmacy entrants (and consequent reduced economic activity) would be expected to have a marginal impact on power resources.

Health Impacts

Market entry

15. As set out above, the impact of these proposals on health is expected to be positive, as entry to the market and pharmaceutical service provision will better reflect the needs of the local communities to be served and thereby have an impact on health inequalities. This would give the NHS greater control over the services commissioned against needs and raise standards for NHS patients. In particular, the proposals are expected to increase patient access to pharmacy services and, in particular, to increase provision and use of Enhanced Services such as smoking cessation. This would have a strongly beneficial impact on public health, as described in the body of the Impact Assessment.

16. At this stage, no specific impacts have been identified on the wider determinants of health or on lifestyle behaviours.

Market exit

17. The proposals are expected to have a positive impact on health, through improved service standards of pharmaceutical contractors. A clearer emphasis on the quality of service delivery – together with adequate powers to take effective action where quality is not at acceptable levels - will further enhance public and patient satisfaction and confidence.

18. At this stage, no specific impacts have been identified on the wider determinants of health. The Department welcomes comments on any significant impacts these proposals might cause.

Justice System Impacts

19. Whilst it is likely that a new entry and exit regime would increase, at least in the early years, the number of appeals against decisions no significant impacts on the justice system have been identified. The Department welcomes comments on any significant impacts these proposals might cause.

Rural proofing

Market entry

20. The major expected impact of this policy is to encourage new pharmacy provision away from well-served areas of high demand to areas with lower current levels of provision.

21. This could benefit patients living in more rural areas as the NHS would assess local service provision to ensure that access to pharmaceutical services meets the needs of the local patient population in such areas. If so, it is likely to result in a transfer of provision including towards more rural locations which are traditionally underserved because pharmacies may be less economically viable. It is therefore expected that the policy will have a beneficial effect for rural communities.

Market exit

22. The proposals and their expected benefits would apply equally in rural and non-rural areas. They would impact on the availability of pharmaceutical services in rural areas if rural contractors were removed, or their activities reduced, for failing to meet the accepted minimum quality standards to be achieved by all contractors. Contractors in rural areas are more likely to be small businesses and to operate with minimal competition from other pharmacies. If an established sole contractor were to be removed on grounds of inadequate quality, other contractors can be expected to step in to fill such a gap where this makes sound commercial sense. New ways of providing pharmaceutical services, such as from internet operations, are also available.

23. The details of the quality standards set out in the draft Regulations apply equally to all contractors. The Department does not believe they impose any unforeseen or excessive requirements on rural pharmaceutical contractors or place them at a significant competitive disadvantage compared with contractors in non-rural areas. Nor, at this stage, is it expected that the costs of these proposals would be disproportionately higher for contractors in rural areas.

24. The Department welcomes comments on any significant impacts that these proposals might cause.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)];
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]