Title:
Control of Entry and Exit in the NHS pharmaceutical market
IA No: 5035

Lead department or agency:
Department of Health

Other departments or agencies:

Impact Assessment (IA)

Date: 11/06/2012

Stage: Final

Source of intervention: Domestic

Type of measure: Secondary legislation

Contact for enquiries:
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Summary: Intervention and Options

RPC Opinion: Amber

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**
£952m	£966m	£0.4m	No	NA

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. The current regulatory system, which is a requirement under the NHS Act 2006, may stimulate provision in areas already well-served, without ensuring the benefits of any increased provision outweigh the costs incurred. More chemists produce more fixed costs. Either the NHS bears these costs or, with no funding increase, all chemists bear the costs, reducing the income each receives. Whichever route is followed, these are costs to society.

What are the policy objectives and the intended effects?

The policy objective is to ensure a proportionate regulatory regime which encourages the supply of NHS 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 service provision overall, and increase patient and consumer benefits by aligning services more closely with the requirements and needs of the local population.

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 whilst they do yield greater NPVs, 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:** 04/2016

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:** N/A	**Non-traded:** N/A	

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 Minister: Date: 17th July 2012

Summary: Analysis & Evidence

Policy Option 1

Description: Change of the NHS market entry and exit management regimes.

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 952.1

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	1.5		1.9	**17**

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

Market Entry: PCT transition costs of adapting to new market entry system estimated at £1.5m.

Market Exit:: ongoing costs of administering the system valued at annual average of £1.45m, and 10 year NPV of £12.1m.

Contractors Costs: average annual costs £0.4m, and 10 year NPV of £3.4m.

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	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		121.1	**969.1**

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

Societal benefits from a reduction in private costs incurred from pharmacies entering the market. These savings are worth £969.1m over the 10-year period.

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 Health and Social Care Act. (2) Cost savings are based on estimates of pharmacy entry and exit which are subject to uncertainty. (3) 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.

BUSINESS ASSESSMENT (Option 1)

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

Summary: Analysis & Evidence

Policy Option 2

Description: Removal of exemptions and introduction of an exit regime.

FULL ECONOMIC ASSESSMENT

Price Base Year **2011**	PV Base Year **2011**	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** 1,047.8*

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	1.5		1.9	**17**

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

Market Entry: PCT transition costs of adapting to new market entry system estimated at £1.5m.

Market Exit:: ongoing costs of administering the system valued at annual average of £1.45m, and 10 year NPV of £12.1m.

Contractors Costs: average annual costs £0.4m, and 10 year NPV of £3.4m.

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

A negative impact on patient access from the reduction in pharmacy numbers.

*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 provided by 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		133.1	**1,064.8**

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

Reduction in fixed costs, £1,064.8m NPV.

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

Improved quality of service due to market 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 Health and Social Care Act (2) Cost savings are based on estimates of pharmacy entry and exit which are subject to uncertainty. (3) 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.

BUSINESS ASSESSMENT (Option 2)

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

Summary: Analysis & Evidence

Policy Option 3

Description: Reversal to pre-2005 entry regime and introduction of an exit regime.

FULL ECONOMIC ASSESSMENT

Price Base Year **2011**	PV Base Year **2011**	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** 1,233.3*

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	1.5		1.9	**17**

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

Market Entry: PCT transition costs of adapting to new market entry system estimated at £1.5m.

Market Exit:: ongoing costs of administering the system valued at annual average of £1.45m, and 10 year NPV of £12.1m.

Contractors Costs: average annual costs £0.4m, and 10 year NPV of £3.4m.

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

A negative impact on patient access from the reduction in pharmacy numbers.

*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 provided by 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		156.6	**1,250.3**

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

Reduction in fixed costs, £1,250.3m NPV.

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

Improved quality of service due to market 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 Health and Social Care Act. (2) Cost savings are based on estimates of pharmacy entry and exit which are subject to uncertainty. (3) 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.

BUSINESS ASSESSMENT (Option 3)

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

Summary: Analysis & Evidence

Policy Option 4

Description: Abolition of "control of entry" arrangements.

FULL ECONOMIC ASSESSMENT

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

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	N/A		N/A	**N/A**

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

Key monetised costs have not been quantified due to the unprecedented nature of such a change, which would require legislative change and lack of clarity as to the likely outcomes of such changes.

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

Key non-monetised costs have not been quantified due to the unprecedented nature of such a change, which would require legislative change and lack of clarity as to the likely outcomes of such changes.

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	N/A		N/A	**N/A**

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

Key monetised benefits have not been quantified due to the unprecedented nature of such a change, which would require legislative change and lack of clarity as to the likely outcomes of such changes.

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

Key non-monetised benefits have not been quantified due to the unprecedented nature of such a change, which would require legislative change and lack of clarity as to the likely outcomes of such changes.

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

It is exceptionally difficult to make plausible assumptions regarding the costs and benefits of allowing the market forces to determine market entry and exit. This is mostly due to the unprecedented nature of such a change, which results in an unparalleled uncertainty in any entry and exit predictions. The necessary step change in legislation, combined with lack of certainty of meeting any of the policy objectives renders this option unsatisfactory and therefore it has not been quantified.

BUSINESS ASSESSMENT (Option 4)

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

Evidence Base (for summary sheets)

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

A. These proposals will, when 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.

D. The Department for Business Innovation and Skills has agreed this assessment.

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 manage 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. PNAs must be revised every 3 years, allowing for alignment of the assessment with the changing needs of the local population. As a result, three PNA revisions are expected to take place over the 10-year appraisal period.

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 Act 2012, the responsibilities of PCTs in respect of PS will pass, on abolition of PCTs, to

the NHS Commissioning Board. Responsibilities for PNAs will pass to local authority Health and Wellbeing Boards.

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. Information in this section of the IA is mainly obtained from the General Pharmaceutical Services in England 2001-02 to 2010-11 NHS Information Centre report, according to which in England, there were 10,951 NHS pharmacies as at 31 March 2011. This compares with 9,736 at 31 March 2005 or an increase of 1,215 or 12.5%. 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 38.5% 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, although it may have plateaued in the last four years. Whilst community pharmacies providing purely privately funded services exist, it is a generally accepted precept that without NHS funding (which can account for the majority of total annual income) a new pharmacy would usually struggle to be viable.

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.[1]

9. There were 1,129 NHS dispensing doctor practices as at 31 March 2011. They principally serve rural populations. They are outside the scope of the proposals discussed in this Impact Assessment.

10. As at 31 March 2011, there were 125 dispensing appliance contractors (who can only supply appliances such as incontinence aids, dressings and bandages, not medicines) of whom 100 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 in proportionate magnitude to those for pharmacies.

11. Pharmacies dispensed the great majority (850.7 million) of all NHS prescription items provided as part of NHS primary care in 2010/11. Dispensing doctors dispensed 80.7 million items. Appliance contractors dispensed 5.8 million items. These figures exclude the proportionately much smaller number of prescription items outside the scope of PS, which are personally administered by prescribers in a GP practice or in schools etc., such as vaccinations.

[1] Pharmacy in England: building on strengths – delivering the future; White Paper published April 2008; PDF version available at: http://www.official-documents.gov.uk/document/cm73/7341/7341.pdf

Problem and justification for government intervention

12. Additional pharmacies can benefit consumers in terms of improvements in access, choice and competition (see paragraphs 23-27). However, there are fixed costs associated with providing PS through an NHS pharmacy. Each new NHS pharmacy therefore increases the aggregate costs of provision of NHS services. 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 is reduced, 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. This is the simplifying scenario modelled in this analysis – i.e. all additional fixed cost expenditure/saving is assumed to be accompanied by no change to total NHS funding for pharmaceutical services.

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 to better maintain or to improve access whilst assuring adequate and proportionate controls on costs.

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[2] 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.

[2] Pharmacy Report 2003 – OFT; PDF available at: http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft609.pdf

Exemptions from control of entry

17. In response to the OFT recommendation, the previous administration revised (but did not remove) this test in April 2005 by introducing new requirements that were designed to promote choice through more competition. This consisted of 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.

18. 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.

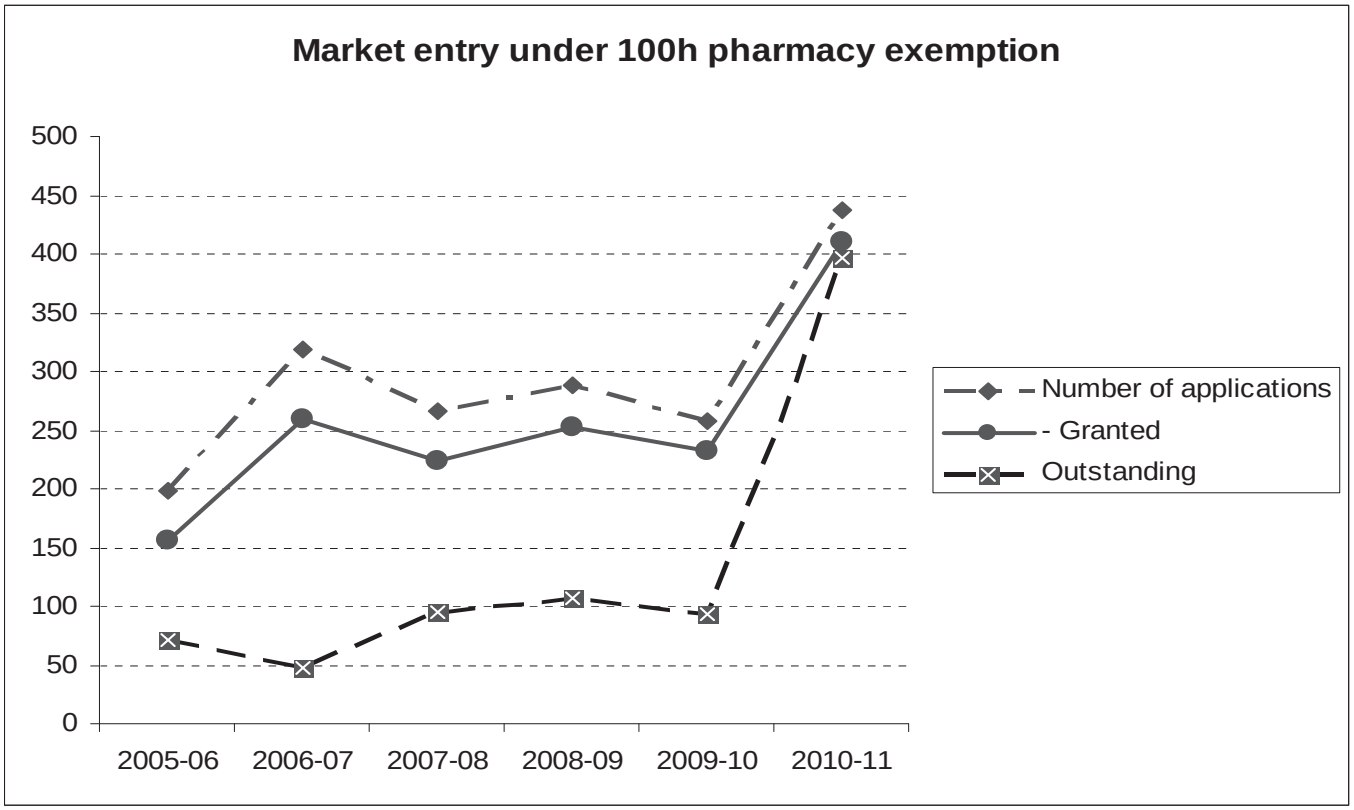
19. Of these, the exemption relating to pharmacies prepared to open for at least 100 hours per week has facilitated the greatest new entry. The Department published a review of these measures in January 2007 - http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063460. 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.

20. 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 previous administration's 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.

21. For information, diagram 1 below 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 approval (e.g. an approved contractor cannot secure premises). For example, net of market exits, we estimate that below 50% of 100 hours per week pharmacy applications that are granted resulted in new openings.

Diagram 1 – 100h pharmacy exemption applications.



22. 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 to public health 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 rounded 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

23. 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[3]. 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.

24. 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 price 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.

[3] Evaluation of the impact of the 2003 OFT study on the Control of Entry regulations in the retail pharmacies market, DotEcon, March 2010; PDF available at: http://www.oft.gov.uk/shared_oft/reports/Evaluating-OFTs-work/OFT1219.pdf

25. 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.

26. 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.

27. 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.

28. However, set against this is the extra (fixed) costs of the new pharmacies. Recent work undertaken by PriceWaterhouseCoopers (PWC) in 2011[4], as part of the pharmacy Cost of Service Inquiry (COSI), used a bottom-up approach to estimate the start up NHS costs of a new pharmacy – i.e. the costs associated with NHS services that would be incurred regardless of the turnover of the pharmacy. These costs comprised mainly staff costs (pharmacist, technicians and counter assistant), and premises costs and associated utilities costs. The median average was estimated in the region of £123,000 per pharmacy.

29. Considering the 850 new pharmacies identified in the DotEcon report, there is reason to adjust the fixed cost for changes in the market entrant composition, which is affected by the 100-hour pharmacies opening under the exemption[5]. Following assumptions developed in the COSI report, the new weighted average for a market entrant since 2005 is estimated at £143,000 per pharmacy (for derivation of the figure, see Annex A). Extrapolating this to the 850 new pharmacies results in an extra cost to society of approximately £121.6 million.

30. The extra costs associated with new entries clearly outweigh the estimated monetised benefits of new NHS pharmacies – a shortfall of at least £50 million (£121.6m - £68m). However, this ignores the benefits that DotEcon were unable to monetise (see paragraph 26 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" explored in the DotEcon report) at the expense of locating in areas where there is evidence of identified unmet patient need.

[4] For the report, please see:
http://www.dh.gov.uk/en/Healthcare/Primarycare/Communitypharmacy/Communitypharmacycontractualframework/DH_128128

[5] According to the General Pharmaceutical Services in England 2001-02 to 2010-11 NHS Information Centre report, over 50% of market entrants since 2005 have been through the 100h exemption.

Policy objectives and intended effects

31. The objectives of the policy are to reduce the incentives leading to excessive supply, through aligning provision more closely with local needs whilst maintaining and, where desirable, improving access to and choice of the best pharmaceutical services. These objectives are expected to be achieved through a regulatory system, which enables both competition and closer working and integration with other health services. Attainment 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

32. 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 by pharmacies if funding remained unchanged, which is assumed, for simplicity, in this analysis. 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. It is worth reiterating here that due to new pharmacy entrants clustering in high-provision areas, the benefits identified in the DotEcon report would naturally decrease over time, whereas the fixed costs would remain relatively unchanged.

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

33. 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, only wholly-internet and mail order pharmacies would remain. Such types of pharmacy would likely wish to offer services to a catchment area wider than that covered by a PCT's PNA, resulting in very few, if any, successful applications without retention of this exemption. Additional tightening up of the exemption conditions will result in distance selling pharmacies having to be able to provide their services to anyone in England, so as to avoid certain providers 'cherry-picking' the most profitable NHS services. This requirement will also be applicable to existing distance selling pharmacies, which will have 6 months to comply with the new requirements.

34. 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. Alternatively, entry can be granted 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 to partially 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.

35. 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.

36. 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.

37. 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 NHS remuneration 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 system could be viewed as overly bureaucratic and ineffectual. The new performance monitoring system will allow for gradual improvement of quality of service, without the very limited benefits of the current system.

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

38. The costs would remain similar to the do-nothing, 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.

39. 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 that 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

40. 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. As explained in paragraph 32, 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.

41. However, such a change could not be achieved under the current provisions of the NHS Act 2006 nor within the changes made by the Health and Social Care Act. It would require significant changes to the primary (and secondary) legislation, which we estimate could not be implemented before 2016. 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

42. 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.

43. 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.

44. 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.

45. 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.

46. 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.

47. 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, which will have a positive effect on population's health outcomes. 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. At the same time, this will provide a 'safety-net' effect, which should result in a positive natural selection of only the best-performing new market entrants.

48. The magnitudes of these effects on patients have not been quantified. However, it is reasonable to assume 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

49. 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 (1) reduce entries that would have been expected through exemptions in the current system; (2) this reduction will be partly offset by increased entry through the internet-only exemption, and through the specific provisions relating to "unforseen benefits" applications (see paragraph 34).

50. 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 analysis of recent trends in the pharmacy market. Table 1 provides a general outline of the anticipated market entry and exit trends for the coming 10 years. A detailed derivation of this forecast, including assumptions regarding the range of possible figures, is in Annex A.

Table 1 – Future market entry and exit (Option 1)

Number of New Market Entrants

Year	Do-nothing	Option 1				Difference in entrants between Do-nothing and Option1
		Internet and Distance-selling	PNAs	De-listings	Net Entrants	
2012-13	320	55	40	66	29	291
2013-14	135	20	40	66	-6	141
2014-15	135	25	38	49	14	121
2015-16	135	30	35	33	32	103
2016-17	135	30	33	33	30	105
2017-18	135	30	30	16	44	91
2018-19	135	30	28	16	42	93
2019-20	135	30	25	16	39	96
2020-21	135	30	23	16	37	98
2021-22	135	30	20	16	34	101
TOTAL	**1535**	**310**	**312**	**329**	**293**	**1242**

51. Under the do-nothing, an additional 1535 entrants are expected through the current market entry mechanisms (including exemptions) over the 10-year period. Some of these pharmacies would no longer enter the market under the proposed policy. It is estimated that under Option 1, the internet-only exemption would result in the entry of an additional 310 pharmacies over 10 years. Also, entry through PNAs is estimated to result in further 312 pharmacies over this time period. The total number of contractors' premises removed from a PCT pharmaceutical list is not expected to exceed 330 pharmacies. Therefore, the estimated cumulative total net entry under Option 1 is approximately 290 pharmacies. When set against the reduction in entries through the removal of exemptions, the cumulative reduction amounts to approximately 1240 pharmacies over the 10-year period.

52. As noted above, each new market entrant under the current entry regime has average fixed costs of provision of NHS pharmaceutical services in the region of £143,000. As explained in Annex A, there are reasons why fixed costs of internet and distance selling pharmacies could be lower on average. As a result, the average fixed cost of an internet pharmacy is estimated at approximately £98,000. The scenario described above would result in an average saving of £121m annually, with a present value over 10 years, of £969.1m[6]. This reform of the current market entry arrangements ensures that unnecessary dilution of a fixed NHS budget would be prevented.

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

53. 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. This impact is left un-monetised and is considered an underestimate of the true benefit of the policy.

Reduced contractor application costs in new market entry regime

54. Lower volumes of applications would also be expected to reduce costs to contractors. As above, this impact is left un-monetised.

Costs of Option 1

Transitory administration costs to PCTs of adopting new market entry regime

55. 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 PCTs, based on the Department's understanding of the activities required to carry out the necessary functions. The value of the transition costs is therefore £3.5m.

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

56. 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.

[6] Please note that the business NPV, as set out on the cover page, is calculated based on business costs and benefits. In effect, the benefits identified in paragraph 52 (£969.1m) are business benefits, whereas business costs are identified in paragraph 58 (£3.4m). As a result, the business NPV is £966m (rounded to the nearest million, derived by subtracting £3.4m from £969.1m).

Costs to PCTs of administering market exit regime

57. We have assumed that PCTs would annually issue warning letters to 10% of the 10,951 pharmacies, each taking 3 days of management time (allowing for the required effort in assessing pharmacies). Approximately 40% of these would result in breach notices, each taking a further 2 days of management time. Funding would then be withheld from one third of pharmacies that received a breach notice, each taking 5 days of management time and incurring £750 in legal costs. The costs are assumed to remain stable year-on-year. Finally, we have assumed PCTs would take action to de-list a total of 3% of pharmacies over the 10-year period, at an annually decreasing rate (therefore the average annual rate is 0.3%). This assumption is explained in detail in Annex A. Each de-listing is assumed to cause a PCT to incur 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[7], these assumptions imply an average annual cost of £1.45m p.a. for all PCTs, corresponding to a present value of £12.1m.[8]

Costs to pharmacies of responding to market entry and exit decisions

58. We have assumed that contractors will continue incurring current costs of challenging PCT decisions on applications, with an unquantified, albeit low, spike over the first three years until case law becomes established. We have assumed that contractors will also incur the same costs as PCTs in defending the last two stages of market exit action – that is, in responding to the withholding of funds, and managing the process of de-listing and any appeals. Over 10 years this corresponds to a net present value of £3.4m. Note that any legal and managerial time costs associated with responding to market entry or exit action are limited by the NHS Litigation Authority Family Health Services Appeal Unit (NHSLA FHSAU) appellate function, which does not levy a fee or otherwise charge appellants for providing resolution of disputes between PCTs and contractors. Therefore, the only costs appellants to the FHSAU incur is in reviewing and preparing the arguments they wish to deploy at appeal and any related travel and attendance costs. It is only further appeals to the High Court that could potentially result in further legal costs. Because of the nature of the changes introduced by the preferred option, we may expect the scale and nature of legal challenges to change, but not their magnitude. In other words, we may expect more challenges, including to the High Court, in the early years of implementation but we assess the overall effect to be relatively low. As case law becomes established, this will lead to a fairly rapid decrease in challenges, and legal costs, over time.

59. 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

60. 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 to enter the market under the do-nothing

[7] Estimated; includes on-costs and overheads.

[8] The assumptions regarding the proportion of pharmacies receiving warning letters (10%) and breach notices (40% of 10% = 4% of all pharmacies) were developed internally. As this is a new provision, there are no existing data. The estimates used attracted no significant negative comments in the consultation process and we will monitor the outcomes as they are rolled out. The estimated management time cost was approximated by an 8-hour working day with 30% on-cost, resulting in an hourly wage estimate of £24. This is closely matched by responses to the annual Chemist and Druggist Salary Survey, which was used to validate the internal management cost assumptions. Once again, this assumption did not attract any negative comments in the consultation. The legal cost estimates were also developed internally. Based on the fact that the NHS Litigation Authority Family Health Services Appeal Unit does not charge appellants for providing resolution of disputes between PCTs and contractors, the assumed figures are expected to be over-estimates of the true underlying legal costs. Following some consultation responses suggesting higher legal costs, the sensitivity analysis carried out in paragraph 68 shows that the policy recommendation to remain value for money even with a significant (10-fold) increase in the proposed costs.

option, 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, as explained in paragraphs 30 and 32, the benefits associated with better access diminish over time as an area becomes saturated with pharmacies. The location patterns of new market entrants using the 100h exemption show evidence of clustering (as explained in the 2010 OFT report). Moreover, 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

61. Use of a PNA-based entry system will enable PCTs and contractors to better 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

62. 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 found that stop smoking services provided through pharmacies generated benefits to patients at a cost of £2,600 per quality adjusted life year (QALY)[9]. 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 385 additional QALYs, valued at £23m. Over the last 5 years, provision of stop smoking services has increased by 142%[10]. This trend is expected to continue, possibly at an increased rate, under the proposed changes to the PNA entry system, generating additional patient health benefits. These effects have not been monetised, but are expected to be significant.

Improved quality throughout the pharmacy network

63. In addition to increases in the 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. Crucially, it will insure that any pharmacy businesses that do not meet the standards required of them will have to improve their standards or risk the full impact of the exit regime. In addition, contractors might be better informed of the standards expected, and may have stronger incentives to improve the quality of their service. Moreover, a positive natural selection of new market entrants is expected, as contractors entering the market will have to consider the new quality standards. 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

64. As described above, there are offsetting effects on the patient benefits realised from changes in pharmacy market entry and exit. While the reduction in numbers of new pharmacy entrants may

9 BAULD, L., BOYD, K. A., BRIGGS, A. H. et al. (2010) One-Year Outcomes and a Cost-Effectiveness Analysis for Smokers Accessing Group-Based and Pharmacy-Led Cessation Services, *Nicotine Tob Res*.

10 General pharmaceutical Services in England 2001-02 to 2010-11, NHS Information Centre report (table 15).

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.

65. 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 an under-estimate of the net benefits of the policy overall.

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. Please note that any benefits from improvements in the delivery of services resulting from graduated actions under market exit proposals are excluded from this calculation. The unquantified impact on patients is assumed to be neutral – although, as described earlier, it is likely that the benefits to patients would outweigh any losses. This results in an overall net benefit derived from savings in net costs – although the true net benefit is expected to exceed this. The table below provides a general summary of costs and benefits of Option 1, marginal to the do-nothing option.

Table 2 – quantified costs and benefits of Option 1, marginal to the do-nothing (counterfactual)

	Transition	***Annual equivalent***	***10-YEAR NPV***
COSTS			
Transition cost of market entry, £m	1.5		1.5
PCT costs of market exit, £m		1.4	12.1
Contractor costs in market exit, £m		0.4	3.4
Reduced patient access			UNQUANTIFIED
Increased PCT processing cost per application			UNQUANTIFIED
Increased contractor cost per application			UNQUANTIFIED
TOTAL COSTS, £m	1.5	1.9	17.0
BENEFITS			
Reduction in pharmacy fixed costs, £m		121.1	969.1
Reduced ongoing PCT administration costs			UNQUANTIFIED
Contractors: reduced volume of applications			UNQUANTIFIED
Improved service quality			UNQUANTIFIED
Increased provision of Enhanced Services			UNQUANTIFIED
Enhanced targetting of new entry			UNQUANTIFIED
TOTAL BENEFITS, £m		121.1	969.1
NET BENEFIT			**952.1**

67. The main assumptions underpinning the above analysis, as outlined in Annex A, are thought to be prudent. Sensitivity testing presented below explores the main risks, the outcome of which reaffirms the robustness of the above positive net benefit results.

Risks, Sensitivities and Assumptions

68. As a result of comments received in the consultation, it became apparent that the underlying analysis might be vulnerable to a number of sensitivities that should be explored further. Below, each of the suggested changes is examined and its impact on the net present value (NPV) of Option 1 is assessed, marginal to the do-nothing option.

    i. The cost savings accounted depend on the assumptions made about 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. As a result, best- and worst-case scenarios are developed (see Annex A), both of which correspond to positive NPV values of £1,612m and £415m respectively. It is important to note here, that the worst-case benefits remain positive, even with no de-listings taking place.

    ii. Analysis of Option 1 also assumes 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. Even though this assumption is deliberately pessimistic, it is possible to test the reliability of the proposal by assuming that all consumer benefits monetised in the DotEcon study are lost under Option 1. If patient benefits are applied consistently to all the pharmacies, on average, these are estimated at £80,000 per pharmacy (see paragraphs 24 – 26: £68 million divided by 850 new entrant pharmacies). Applied to the assumed reduction in market entry, this corresponds to a consumer disbenefit of £55.5m (£80,000 multiplier by 695 pharmacies), which can be extrapolated to £222m over a 10-year period. Accounting for this theoretical outcome, Option1 remains strongly positive with an NPV of £730m. It is important to note here that this scenario is only theoretical, as in fact, it completely disregards the offsetting effect of PNAs.

    iii. It is assumed that the transition costs to the PCTs amount to £10k per PCT. It has been suggested that these costs could be up to 5 times higher. Having consulted with PCT employees, it is reasonable to assume that the upper bound of transition costs would be £30k per PCT. Even after accounting for this theoretical increase in PCT costs, Option 1 remains positive with an NPV of £949m.

    iv. Legal costs could also be under-estimated and justice impacts, which could have cost implications beyond the NHS Litigation Authority. In order to arrive at prudent cost estimates, even a 10-fold increase in legal and litigation costs would still result in a strongly positive NPV of £924m. It is important to note here that we do not anticipate significant increases in legal costs due to the nature of the litigation process described in paragraph 58.

69. This sensitivity analysis therefore suggests that the policy recommendation remains value for money, as it is relatively unaffected by the main assumptions underpinning the analysis. Accounting for the fact that the current best estimates of market entry and exit are considered to be prudent, the total identified costs would have to increase 57-fold in order to cause Option1 to become not value for money. Moreover, even considering the worst-case scenario of entry and exit estimates, the total identified costs would have to increase more than close to 29-fold in order to make the policy recommendation not value for money.

Costs and Benefits of Options 2 and 3

70. 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. All transitional and annual costs identified for Option 1 apply to both Options

2 and 3. The table below provides the expected number of entrants and exits under Options 2 and 3, set against the do-nothing.

Table 3 – Future market entry and exit (Options 2 and 3)

Number of New Market Entrants

Year	Do-nothing	Option 2			Option 3		
		Non-exemption	De-listing	Difference Do-nothing & Option 2	Non-exemption	De-listing	Difference Do-nothing & Option 3
2012-13	320	55	66	331	10	66	376
2013-14	135	40	66	161	10	66	191
2014-15	135	40	49	144	9	49	175
2015-16	135	40	33	128	8	33	160
2016-17	135	40	33	128	7	33	161
2017-18	135	40	16	111	6	16	145
2018-19	135	40	16	111	5	16	146
2019-20	135	40	16	111	4	16	147
2020-21	135	40	16	111	3	16	148
2021-22	135	40	16	111	2	16	149
TOTAL	**1535**	**415**	**329**	**1449**	**64**	**329**	**1800**

71. In Option 2, it is estimated that the proposed control of entry regime would result in an additional 55 pharmacies in year 1, Applying the estimation methodology used for Option 1 (see Annex A), this number is then expected to decrease to 40 market entrants for each of the remaining 9 years. Over the 10-year period, this implies entry of an additional 415 pharmacies by these means. The number of market exits is assumed the same as under Option 1, which arrives at net market entry under Option 2 of approximately 85 pharmacies over the 10-year period (415 entrants minus 329 exits). Subtracted from the assumed number of entrants under the do-nothing, this corresponds to a net reduction of approximately 1450 pharmacies compared to the levels that would have been expected in the current system. This implies equivalent cost savings of £128m per year on average, with a NPV over 10 years of £1,048m.

72. 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. The number of market exits is assumed the same as under Option 1, which arrives at net market exit under Option 2 of approximately 265 pharmacies over the 10-year period (64 entrants minus 329 exits). When subtracted from the reductions in entry due to withdrawal of exemptions, this corresponds to a net reduction of 1800 pharmacies compared to the levels that would have been expected in the current system. This implies equivalent annual cost savings of £150m, with a NPV over 10 years of £1,233m.

73. Both these options result in greater cost savings as a result of reduced number of pharmacy market entrants. However, these reductions are expected to have a significant effect on the patient benefits derived from pharmacy services. Whilst use of PNAs will ensure that new entry under 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 enhanced pharmaceutical services (such as stop smoking) that would be otherwise encouraged under PNAs, both of 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, but is expected to be significant.

Costs and Benefits of Option 4

74. Unlike the previous options, Option 4 would enable market forces to determine the scale and configuration of supply of pharmacies. As explained in paragraphs 40 and 41, it is exceptionally difficult to make plausible assumptions regarding the costs and benefits of this option. It is likely that deregulation of market entry would result in further growth in the number of market entrants, corresponding to increase in fixed costs. This growth is likely to occur in areas of highest economic demand, which are already well served, as identified in the DotEcon report. This would inevitably lead to diminishing social benefits, as each new entrant would bring lower benefits at the same corresponding fixed cost.

75. The necessary step change to the primary and secondary legislation, combined with the lack of certainty of meeting any of the policy objectives renders this option unsatisfactory and therefore it has not been quantified.

Specific Impact Tests

Competition Assessment

76. 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?

77. There is no price competition at present for the majority of services provided by pharmacies, as NHS pharmaceutical services, which make the bulk of a typical 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.

78. 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

79. 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 23 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

80. 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 exact proportion of the 100 active dispensing appliance contractors that are small businesses is not known but we estimate these are run by 50-60 small to medium sized enterprises.

81. 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.

82. 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.

83. 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 expand 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.

84. 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 legislative measures, it is not proposed to implement this policy through piloting but fully to evaluate after implementation.

Market exit

85. 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.

86. 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 that 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.

87. 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.

88. 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 only 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

89. 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

90. 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.

91. No specific impacts have been identified on the wider determinants of health or on lifestyle behaviours.

Market exit

92. 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.

93. No specific impacts have been identified on the wider determinants of health.

Justice System Impacts

94. 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. This is mostly due to the limiting role of the NHS Litigation Authority Family Health Services Appeal Unit (NHSLA FHSAU) appellate function, which provides resolution of disputes between PCTs and contractors. The changes introduced by the preferred option may alter the scale and nature of legal challenges, but not their magnitude. More challenges may be expected, including to the High Court, in the early years of implementation, but this effect should be relatively modest. As case law becomes established, this will lead to a fairly rapid decrease in challenges, and legal costs, over time.

Rural proofing

Market entry

95. 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.

96. 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. If so, it is likely to result in a transfer of provision 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

97. 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.

98. The details of the quality standards set out in the 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.

Annex A

Technical Annex

Pharmacy fixed cost derivation

99. The underlying data for the median pharmacy fixed costs have been obtained from the Cost of Service Inquiry for Community Pharmacy (COSI) report prepared by PricewaterhouseCoopers (PwC) for the Department of Health and the Pharmaceutical Services Negotiating Committee. The qualitative assessment undertaken by PwC allows a number of adjustments to be made in order to fine-tune the median average NHS cost in line with pharmacy type. The reasoning behind this adjustment is the need to account for changing market entrant composition, which is predominantly affected by the 100-hour pharmacies opening under the exemption. In particular, the General Pharmaceutical Services in England 2001-02 to 2010-11 Bulletin, NHS Information Centre report (published November 2011) indicates that approximately 55% of net market entrants since 2005 have been 100 hour per week pharmacies.

100. The following hypothetical cost component assumptions were used for the COSI report (annual £,000s; rounded):

    a. 1 Pharmacist - 45.5

    b. 1 Counter Assistant - 3.4

    c. Other branch costs - 48.6

    d. Head office costs - 28.8

    e. Owner costs – 18.4

101. The median average of the above is approximately £123,000. Extrapolating from this allows us to alter the number of full-time equivalent Pharmacists, counter assistants, and vary the Branch and Head office costs. In particular, in order to arrive at a prudent approximation of 100 hour per week pharmacy fixed NHS costs, it was assumed that the median cost should be inflated by approximately 33%. Accounting for the above, the new 100 hour fixed NHS cost is estimated at £163,000 (£123,000 * 133%).

102. In lack of any clear evidence in the COSI analysis, the average internet pharmacy is estimated to operate at fixed costs that are at least 20% below the median. Using this assumption, we arrive at a fixed NHS cost estimation of approximately £98,000 per internet pharmacy (£123,000 * 80%). Internet pharmacies accounted for approximately 10% of new market entrants since 2005.

103. Combining the above assumptions with the corresponding proportions of new market entrants since 2005, we arrive at a new mean fixed NHS cost of market entrant under the do-nothing option of approximately £143,000 (55% * £163k + 10% * £98k + 35% * 123k). This derivation is considered to arrive at prudent cost estimations of new market entrants.

Market entry and exit derivation

Market Entrants

104. The data used for derivation of market entry forecast were obtained from the General Pharmaceutical Services in England 2001-02 to 2010-11 Bulletin, NHS Information Centre report (published November 2011). The main estimation methodology looks at the past application trends, as well as the approval and resulting opening rates. This is then extrapolated into the future in line with growing market demand for NHS services (number of dispensed prescription items).

105. The net total entrants via exemption and non-exemption routes since 2005 are estimated at 1,215 pharmacies. This corresponds to approximately 200 pharmacies annually since 2005. Approximately 55 of these net entrants were through the non-exemption route, with remaining pharmacies entering the market through one of the four exemptions.

106. The above trend has to be updated in line with the recent increase in the number of exemption-related applications, which is believed to have spiked in 2011/12. In particular, the backlog of un-

processed applications at the end of March 2011 indicated that the high proportion of exemption-driven entrants would continue for at least one year. Deriving the average proportion of openings to the number of applications, and a general idea of PCT processing capacity, the best estimate of new market entrants under the do-nothing scenario in 2011/12 is approximately 320[11] pharmacies.

107. For the remaining 9 years of the analysis, the openings are expected to decrease to pre-spike levels. In line with recent drop in the growth rate of the number of prescription items dispensed, as reported by the NHS Business Service Authority, the openings are expected to remain constant over time, albeit lower than in the previous 5 years (note, the long-term average is not taken across 6 years in order to exclude the 2010/11 market entrant spike). Using this methodology, it is expected that market entrant trend will be constant over the post-spike 9 years with 135[12] net entrants annually. The non-exemption entrants are estimated to add up to approximately 40 pharmacies annually, in line with reasoning outlined in paragraph 104 (this entry is relevant for Option 2).

108. The number of internet pharmacies has been estimated using the methodology described above, which is expected to reach 55 new entrants in 2011/12. The point of divergence is the expected behavioural change resulting through greater applicant numbers for this exemption following discontinuation of 100 hour per week pharmacy exemption entry route. In order to arrive at expected market saturation for internet pharmacies, a comparison has been made between the UK and US online retail trends and prevalence of internet pharmacies. Given the relatively high online retail activity in the UK, the US data suggest that market saturation will not be reached during the 10 years of this analysis, even under the assumption that the UK population may have an inherent predisposition for traditional dispensing of pharmaceutical products.

109. In light of the above, the growth in the number of entrants through the internet exemption is expected to continue past the recent peak for 3 additional years. At this point, the number of new entrants will remain stable over the remaining 7 years at approximately 30 pharmacies. The initial growth rate is assumed to follow at pre-spike levels of approximately 5 additional market entrants annually, albeit from a pre-spike base of growth of 20 new entrants.

110. Entry through the PNA route under Option 1 is based on assumptions following local publication of PNAs. The upper and lower bounds reflect uncertainty of market entry through this route and the possibility of future reassessment of local needs through the process of revising PNAs (taking place every 3 years). New entry under PNAs is assumed to decrease linearly over the 10-year period.

111. Entry under Option 3 is based on pre-2005 market entry data and does not accommodate for upper- and lower- bound assumptions.

112. In order to arrive at banded estimates, we adjust the assumptions used to derive market entrants under the Do-nothing and Option 1 to present a more holistic set of predictions. Please note that increase in the number of market entrants under Option 1 decreases the benefits. Under the Do-nothing option, an increase in expected market entrants increases the benefits. In particular:

    a. High entry estimates assume that 100% of the backlog of current applications is processed in 2011/12 and that the future growth rate of the number of prescription items dispensed continues at historical levels of 5.25%.

    b. Low entry estimates assume that none of the backlog is processed in 2011/12 and the 2010/11 entry trend continues; the future growth rate of the number of prescription items dispensed is assumed to be lower at 3.5%. It is also assumed that the number of internet pharmacy entrants would continue to increase only for 1 year.

[11] Four exemptions: 490 unprocessed applications, with approximately 50% being cleared next year and additional 550 new applications, leading to approximately 265 new openings (compared with 2011 in 2010/11). Non-exemptions: trend remains the same as over past 6 years with approximately 55 net pharmacy openings. The total is therefore 320.

[12] 191 average entrants 2005-2010; previous prescription item annual growth rate estimated at 5.25%, future growth rate expected to fall to 3.75%, resulting in expected 191 / 5.25% * 3.75% = 136 entrants.

Table A1 – Market entry lower-, upper- and best assumptions (Do-nothing and Option 1)

Year	Do-nothing			Option 1					
	Total annual entrants			Internet and Distance-selling			PNAs		
	Best Estimate	Low Benefit	High Benefit	Best Estimate	Low Benefit	High Benefit	Best Estimate	Low Benefit	High Benefit
2012-13	320	260	375	55	65	45	40	60	30
2013-14	135	125	190	20	25	20	40	60	30
2014-15	135	125	190	25	30	20	38	58	28
2015-16	135	125	190	30	35	20	35	55	25
2016-17	135	125	190	30	35	20	33	53	23
2017-18	135	125	190	30	35	20	30	50	20
2018-19	135	125	190	30	35	20	28	48	18
2019-20	135	125	190	30	35	20	25	45	15
2020-21	135	125	190	30	35	20	23	43	13
2021-22	135	125	190	30	35	20	20	40	10
TOTAL	1535	1385	2085	310	365	225	310	510	210

Market Exits

113. The number of possible pharmacy de-listings has been estimated using a theoretical proportion of under-performing pharmacies in the market. This total number has then been extrapolated into a decreasing year-on-year pattern, with most de-listings happening in the first 5 years of the policy. The table below provides the low, high, and best estimates of de-listings over the 10 year period. These assumptions are constant across Options 1, 2, and 3.

Table A2 – Market exit lower-, upper- and best assumptions (Options 1, 2, and 3)

	Best Estimate	Low Benefit	High Benefit	
% of total pharmacies de-listed	**3%**	**0%**	**6%**	
Year	**Best Estimate**	**Low Benefit**	**High Benefit**	**Proportion of total pharmacies de-listed (best)**
2012-13	66	0	131	0.60%
2013-14	66	0	131	0.60%
2014-15	49	0	99	0.45%
2015-16	33	0	66	0.30%
2016-17	33	0	66	0.30%
2017-18	16	0	33	0.15%
2018-19	16	0	33	0.15%
2019-20	16	0	33	0.15%
2020-21	16	0	33	0.15%
2021-22	16	0	33	0.15%
TOTAL	329	0	657	3%