Title: **Pharmacy proposals - Repeal of Section 10(7) of the Medicines Act** **Lead department or agency:** Medicines and Healthcare products Regulatory Agency **Other departments or agencies:** Department of Health	Impact Assessment (IA) **IA No:** 4023 **Date:** 27/07/2010 **Stage:** Final **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** **MHRA central enquiry point:** info@mhra.gsi.gov.uk

Summary: Intervention and Options

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

The Medicines Act 1968 contains an exemption which allows pharmacies in the UK to trade pharmaceutical products without the requirement to hold a wholesale dealers' licence. This law is incompatible with more recent EU legislation (see page 5), and trading in future will need to be only where it meets the needs of public health, is in small quantities, is infrequent, and is not for profit. There is a great deal of trading between pharmacies at present, particularly within the NHS, and we would not wish to impose the full licensing arrangements upon a public service, as this would be disproportionate. Government intervention is necessary for the repeal of Section 10(7), but also to provide a regime under which essential supplies of medicines continue to reach patients in need.

What are the policy objectives and the intended effects?

The policy objectives are to create a regime which brings the UK into compliance with EU legislation, whilst taking account of the UK's National Health Service (which is relatively unique among Member States as a health service open to all without the need for private insurance). A repeal of the 10(7) exemption without any mitigating solutions would cause serious problems in terms of supplies of medicines for patient care, extra regulatory cost and administrative burden, particularly for the NHS, and the policy seeks to preserve continued medical supplies above all other concerns.

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

1. Repeal section 10(7) and allow trade in medicines where this performed to the direct benefit of patients (the 'healthcare suppliers' model). This is the preferred option. Non-regulatory action has been considered, but a repeal of legislation cannot take place without legislative instruction.

2. Do nothing - no change to the law but running the risk of possible EU infraction proceedings

3(a) Repeal the 10(7) exemption without any further mitigating factors - essentially requiring all trading in medicines beyond limited perameters to be undertaken under a wholesale dealers' licence

3(b) Implement a 'hub and spoke' model by which smaller pharmacies become satellites of a larger pharmacy

3(c) Implement an 'agency' model by which smaller companies can be considered as part of a larger central pharmacy for pharmaceutical trading purposes.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 5/2017 **What is the basis for this review?** Duty to review. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off For final proposal stage Impact Assessments:

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) the benefits justify the costs.

Signed by the responsible Minister: ..... Date: .....

Summary: Analysis and Evidence

Policy Option 1

Description:

The 'healthcare suppliers' model

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£47.215	**High:** -£9.443	**Best Estimate: -£28.328**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£0.303		£1.061	**£9.443**
High	£1.516		£5.309	**£47.215**
Best Estimate	£0.910		£3.185	**£28.328**

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

Costs to any pharmacist (or other entity) that wishes to trade in medicines for profit - a wholesale dealers' licence will be required (present value £19.0 million, annualised £2.2 million).

Costs to a small proportion of 'end users' who will need to trade with wholesale dealers' licence holders in future (present value £9.4 million, annualised £1.1 million).

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

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

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

Massive reduction in administrative cost and regulatory burden associated with other opions. Avoidance of infraction proceedings from the Commission.

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

Effectively excludes much of the current practice in medicines trading between pharmacies whereby compliance with EU legislation is achieved through minimum impact on the UK. NHS almost entirely excluded.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: £3.291	**Benefits:** £0	**Net:** -£3.291	No	NA

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			02/06/2012		
Which organisation(s) will enforce the policy?			MHRA		
What is the annual change in enforcement cost (£m)?			None		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** n/a	**Non-traded:** n/a	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** n/a	**Benefits:** n/a	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

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

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

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	17
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	14
Small firms Small Firms Impact Test guidance	No	14
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	15
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	15
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	14
Human rights Human Rights Impact Test guidance	No	15
Justice system Justice Impact Test guidance	No	14
Rural proofing Rural Proofing Impact Test guidance	No	15
Sustainable development Sustainable Development Impact Test guidance	No	15

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

Evidence Base (for summary sheets) – Notes

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

References

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

No.	Legislation or publication
1	MLX 357: Consultation on measures to strengthen the supply chain and reduce the risk from counterfeit medicines: http://tiny.cc/eofui
2	MLX 365: Measures to strengthen the medicines' supply chain and reduce the risk from counterfeit medicines: http://tiny.cc/j716a
3	EC consultation and impact assessment on falsified medicines proposals: http://tiny.cc/ad2cn
4	Directive 2001/83/EC - http://tiny.cc/1aq8p

+ Add another row

Evidence Base

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

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

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

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Total Transition costs	0.910	0	0	0	0	0	0	0	0	0
Total Annual recurring cost	3.547	2.944	2.944	3.547	2.944	2.944	3.547	2.994	2.994	3.547
Total annual costs	3.547	2.944	2.944	3.547	2.944	2.944	3.547	2.944	2.944	3.547
Total Transition benefits										
Total Annual recurring benefits										
Total annual benefits										
Business transition costs	0.910	0	0	0	0	0	0	0	0	0
Business annual recurring costs	3.547	2.944	2.944	3.547	2.944	2.944	3.547	2.944	2.944	3.547
Business annual costs	3.547	2.944	2.944	3.547	2.944	2.944	3.547	2.944	2.944	3.547
Business transition benefits	0	0	0	0	0	0	0	0	0	0
Business annual recurring benefits	0	0	0	0	0	0	0	0	0	0
Business total annual benefits	0	0	0	0	0	0	0	0	0	0

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

Evidence Base (for summary sheets)

What is the problem under consideration?

The vast majority of trading of pharmaceuticals within the EU is undertaken by companies that hold a Wholesale Dealer's Licence. These licences require the holder to meet a specific standard of expertise for storing and trading medicines, as well as employ others (particularly a 'Responsible Person') who have responsibilities to ensure that these standards are upheld on the trading sites.

Arrangements under Section 10(7) of the Medicines Act 1968 allow trading between pharmacies without the need for a Wholesale Dealer's Licence. It has been informally accepted by companies and the MHRA that this applies for up to 5% of the pharmacy company's turnover, although this has never been codified in law. The MHRA considered that the 5% limit could be open to exploitation, as the amounts traded could vary hugely dependent on the pharmacy's turnover, and were subject to no regulatory oversight or guidelines to pharmacists on how they should behave.

Whilst exploring the options for codifying the duties of those trading under the Section 10(7) exemption, the MHRA became aware of a conflict between the UK's stance on trading and that of the European Union. It became clear that EU law required any trading between pharmacies undertaken without a Wholesale Dealer's Licence to be limited to a set of defined circumstances, namely that it be in the interests of public health, in limited circumstances, in small quantities, and not for profit. The current informal arrangement of allowing 5% trading without the need for a Wholesale Dealer's Licence is clearly incompatible with the intentions of the European Union, and will need to change if we are to avoid infraction proceedings.

Many pharmacies and other businesses (such as optometrists, midwives, nursing homes, dentists and oil rigs) rely on the Section 10(7) exemption to get limited supplies of pharmaceutical stock from pharmacies, as well as return unused stock to those pharmacies without the need for either party to hold a Wholesale Dealer's Licence. It is clear that the impact upon these businesses, should the Section 10(7) exemption be repealed, could be huge, and so the MHRA has considered a number of different solutions to try to resolve this problem.

Another significant series of entities that currently utilises the Section 10(7) exemption is the National Health Service. Now increasingly decentralised, the NHS is a series of separate legal entities, ranging in size from large hospital trusts to legal entities that exist as small mental health wards in a wider hospital. These legal entities use Section 10(7) to trade pharmaceutical supplies and return unwanted stock within the NHS structure. Any repeal of the exemption could have a massive impact on UK NHS services, both in terms of continued supply of medicines and imposing cost upon the NHS.

The MHRA, in conjunction with the Department for Health and the General Pharmaceutical Council, has considered a number of options available to try to alleviate the impact of this conflict with European legislation. These were developed by a specific group, and the options discussed below have received approval from legal counsel as methods to address the problem. The costs and benefits laid out below have been sourced from the pharmaceutical industry and the Department of Health.

One In One Out

Whilst these proposals will have an effect on the private sector, they are considered in the context of achieving compliance with existing EU legislation under Directive 2001/83/EC (see Ref 4, above). The Government's policy on the implementation of European legislation is that this is not covered by OIOO, and instead effort should be made at negotiation and formulation stage to ensure that European legislation imposes as little burden and as much benefit to UK businesses ads possible. Unfortunately, as 2001/83 EC was negotiated well before the introduction of this policy, and its subsequent transposition missed the areas of incompatibility with the Medicines Act 1968, we now need to implement European legislation that may increase the burden upon industry. We have thus explored five options that could allow us to do this, and we propose to take forward the one that imposes the least regulatory burden upon industry.

Sunset Clause

Section 10(7) of the Medicines Act – that which is in conflict with the European Directive – will be repealed via a domestic legislative instrument. It is not appropriate to set a sunset clause upon a repeal achieving compliance with European law, although a review of the repeal of the exemption and its effects will be undertaken after 5 years, as discussed in Annex 1.

Policy objectives and their intended effects

The policy objectives are to ensure that the UK becomes compliant with EU law whilst at the time limiting the cost to the pharmaceutical and healthcare sector (particularly the NHS), and ensuring a continued supply of medicines to the public. Whilst we expect that as a result of these changes, some entities will need to or choose to become Wholesale Dealers, we would seek to limit the impact and cost of the changes upon others wherever possible.

The existing Section 10(7) exemption has been in place for a long time; transition from it will be difficult and may throw up unforeseen challenges. The MHRA has sought to mitigate this risk by spending 9 months considering the responses to consultation MLX 365 (Ref 1 and 2 above) to try to find the most equitable solutions for as many of the businesses involved as possible, as well as collecting information from the industry to outline the true impact of the proposals on current trading practices.

Policy options considered

Although this is a final stage impact assessment, we have chosen to lay out the costs of all of the policy options considered during the development process. The reasons for this are twofold – firstly that the costs of the options are the reasons that further options have been explored, and secondly to give a true understanding to readers of the impact that these proposals could have on the UK market if not properly formulated to suit the intricacies of NHS and industry relationships.

The options considered below were selected on the basis of best fit and adaptability to the varied circumstances of pharmacies trading in medicines at present. The overriding concern was to make sure that the proposals put forward achieved compliance with European law to reduce the risk of infraction from the EU. The second concern was to make sure that NHS supply to the general public was not compromised through these changes. The third concern was to make sure that the proposals were the most cost effective for all those involved in the trading of medicines whilst still meeting the first two criteria.

Preferred option: Option 1: The ‘healthcare suppliers’ model

Under this model we would repeal Section 10(7) of the Medicines Act, and thus remove UK legislation that is in conflict with EU provisions. This would also have the effect of removing the schedule under which a large range of individual healthcare providers and organisations (such as oilrigs, hospices etc.) that need to hold stocks of medicines from which to supply individual patients’ needs are currently supplied.

We would require community and hospital pharmacies that wanted to engage in commercial trade in medicines to hold a Wholesale Dealer’s licence to comply with all the regulatory obligations associated with this, including the requirement to be or to have available a Responsible Person and for inspection of their commercial trading outlet by the MHRA.

We would exempt pharmacies that sell only to individuals and organisations that hold stocks for onward supply to patients from the requirement to hold a Wholesale Dealer’s licence. We would also not require the recipients of such stocks of medicines to apply for Wholesale Dealers’ licences. We would provide advice on how to ensure stocks of medicines held in this way meet appropriate standards for their storage. We could also, to provide additional reassurance about compliance with appropriate standards and to facilitate returns of unused stock (for example from outstationed wards to hospital pharmacy), require an agreement on appropriate standards for storage to be drawn up between supplier and recipient. This regime would also permit pharmacies to supply small amounts of medicines on an occasional, not for profit basis to meet individual patients’ needs.

The MHRA would take action if evidence came to light that in fact such a pharmacy was “trading on” medicines as opposed to supplying them for stock for later supply to patients.

Rejected options

Option 2: Do Nothing

This is the baseline option. The current situation of the UK has been described in detail above, but in short there is currently an exemption under UK law that allows for pharmacies to trade without a

Wholesale Dealer's Licence. To do nothing would allow the current informal arrangement of 5% trading between pharmacies and other legal entities without any further requirements. This will allow the established practice of pharmacies supplying (relatively) small quantities of stock to other pharmacies and end users (such as optometrists, midwives etc.) without compliance with any Wholesale Dealing Licence requirements. Pharmacies are also able to return and be refunded for unused stock by their supplier without the need for a licence, and also have the ability to supply medicines nearing the end of their shelf life to pharmacies where they can be allocated to patients, thus reducing wastage.

This option would perpetuate our continuing non-compliance with EU legislation, which could be brought to the attention of the Commission at any point, leading to infraction proceedings against the UK and a required change to UK law and/or unlimited fine. Whilst it is unknown whether the Commission has noted our proposals to change the procedures around pharmacy trading, the Commission has shown interest in UK pharmaceutical developments in the past.

Option 3(a): Enforce the requirement that any pharmacy dealing in medicines must hold a Wholesale Dealer's licence

This option considers a simple revocation of the current Section 10(7) exemption under the Medicines Act 1968 with no further action. All pharmacists would immediately be required to comply with EU requirements that all trading without a Wholesale Dealer's Licence be in the interests of public health, occasional, not for profit and in small quantities. Effectively, this would require any supplying (hospital or community) pharmacy to hold a Wholesale Dealer's Licence and, if we require a regime that will allow unused medicines supplied under this regime to be returned to the pharmacy, so would the recipient. The recipient could be the out-stationed ward in a hospital Trust – but it could also be, for example, a dispensing GP, an optometrist or other similar independent healthcare providers or a hospice. This option would significantly increase the numbers of Wholesale Dealer Licence holders, requiring them to comply with full Good Distribution Practice standards, have at their disposal (or be qualified themselves as) a "Responsible Person" to ensure standards are maintained, and pay the necessary fee to the MHRA. Under this regime they would also be subject to routine inspection to ensure standards are maintained.

Some manufacturers have chosen not to supply their high value, low volume products (such as Glivec: http://tiny.cc/f2lva) to wholesalers. Instead, pharmacies must contact the manufacturer directly and have the order dispatched by courier. This has increased procurement costs as pharmacies often do not have the electronic ordering systems required to order directly from the manufacturer. Medicines also take longer to reach patients – dispatch in these cases can take between 24-48 hours. The options proposed will likely not impact on this practice, although it is worth noting that option 3(a) will therefore not solve all wholesaling issues. All pharmacy and end-user supply will be impacted when the 10(7) exemption is removed – pharmacies and end users will no longer have the option of approaching other pharmacies to obtain medicines – they may instead need to contact the manufacturer directly.

Whilst this is, of course, the safest option and would ensure that we are fully compliant with the EU legislation, it is not a solution that is proportionate to the risks from counterfeit medicines entering this part of the supply chain, nor does it meet the "reducing regulation" test. It would significantly increase the costs and administrative burden on a wide range of healthcare providers and private pharmacies as well as on the MHRA.

Option 3(b): A 'hub and spoke' model

This option arose as a consideration of the German model used to deal with a similar issue. It appeared that Germany had solved problems with trading without a Wholesale Dealer's Licence by creating a single legal entity comprising a central pharmacy with "satellite" pharmacies across several hospital entities. In this model, neither the central pharmacy nor the "satellites" would require Wholesale Dealer's licences as they would be deemed to be a part of the same legal entity. Under the German pharmacies' supply contract, an individual hospital pharmacy, named "the central pharmacy", contracts for a period of five years with a group of named hospitals to supply the latter with "a sufficient stock" of medicines and also to take over the supply of medicines to patients. The hospitals agree to obtain medicines exclusively from the central pharmacy. The central pharmacy agrees to handle the medicines in accordance with statutory requirements and to supply appropriate staff. The contract lays down arrangements for the ordering and delivery of medicines, for emergency supplies, for storage, for inventories and for the destruction of expired or otherwise unusable medicines, for the transfer of medicines between different units operated by the receiving hospitals and for the crediting of unused medicines in good condition with at least 6 months validity. The central pharmacy also agrees to maintain drug information documentation and records, provide advice, provide training to carers and other non-professional staff, undertake data

collection and analysis, provide recommendations for the planning, organising and monitoring of drug traffic, changes and additions to the drug list and for the storage of medicines in the wards.

However, whilst this option could be made available for use it is not an option that would solve the majority of the NHS' problems as in general the recipients of medicines in out-stationed wards in the UK are not pharmacies, and thus cannot be considered as part of a single 'pharmacy' entity. Neither would this provide a solution for healthcare providers in the community as the recipients of supplies of medicines do not tend to have pharmacies.

Nevertheless, this option is judged to be legally sound - although in drawing up guidance the UK Government would need to have regard to EU competition law and procurement rules. Some NHS hospital pharmacies may be attracted to this option where supplier and recipients of supplies of medicines are pharmacies and this would avoid the need for either operator to hold a Wholesale Dealer's Licence. The framework underpinning this arrangement could be set out in guidance issued by MHRA and checked on inspection.

Option 3(c): 'Contracting out' pharmacy supplies – the 'agency' model

Under this model we remove Section 10(7) and the supplying pharmacy (hospital or community) would need to hold a Wholesale Dealer's licence in order to supply the recipient with stocks of medicines. The supplier will act as the recipient's agent. However, because the supplies would remain the property of the supplier, but held under a contract arrangement by the recipient (e.g. an out-stationed ward, a healthcare professional in the community, a hospice), the recipient would not need a Wholesale Dealer's licence. The contract between supplier and recipient would cover arrangements for storage etc and include provisions for return of the supplier's unused stock to his pharmacy. Payment to the agent would be retrospective (eg monthly) based on the stock used, and the supplier could charge an administrative fee for the service.

Agency arrangements are already used in the context of pharmaceutical trading, although primarily between manufacturers and wholesalers at present, allowing the manufacturer to effectively continue to own the stock held by the manufacturer and therefore have more control over the terms of supply to other entities, including discounts offered to pharmacies.

Lawyers are confident that such a regime is reasonably safe from legal challenge, although they point out that – as with any contracting arrangement – there is a risk of problems arising from failure to pay for medicines used. We will also need to have regard to EU competition law and procurement rules. The framework for contracts to underpin this arrangement could be set out in guidance issued by MHRA and checked on inspection.

COSTS AND BENEFITS

Summary of Findings

Our estimated compliance costs of scenarios considered in this IA are summarised in the table below

	Present value of costs (£million)	Annualised costs (£million)
Option 1 (preferred)		
Lower bound	9	1
Upper bound	47	5
Option 3a		
Lower bound	851	99
Upper bound	1,358	158
Option 3b		
Lower bound	848	99
Upper bound	1,352	157
Option 3c		
Lower bound	165	19
Upper bound	769	89

We have noted below that public and private sector organisations would be free to innovate in order to minimise their compliance costs, probably using widespread contractual arrangements. Consequently, Options 3a and 3b are extremely pessimistic scenarios. Option 3c is therefore a more realistic comparator to our preferred Option 1.

Under Option 1, we estimate that small and micro businesses would bear present value costs of between £3.651 million and £18.254 million (annualised at between £0.424 million and £2.120 million).

We can not estimate the benefits of this option because we do not know the probability that the EU will notice our non-compliance, and the added probability that the EU will not accept our “least cost” approach to compliance described by Option 1.

Analytical Assumptions

We have adopted the standard 10 year appraisal period and the standard Treasury social discount rate of 3.5%. Non-salary staff costs are assumed to add 30% to salary costs, and we have assumed a 215 day working year, and 7.5 hour working day.

Preferred Option: Option 1: The ‘healthcare suppliers’ model: Impacts, Costs and Benefits

Costs

This option has the advantage of being applied to the current market without the need for those players in the NHS or elsewhere to take steps to integrate themselves into a new regulatory or contractual system. There are no costs imposed upon the NHS or its contractors because these entities do not trade for profit. All healthcare providers can continue to gain their supplies from the usual routes as long as the healthcare provision is direct to patients.

Commercially, there may be larger pharmacies that make the decision that they wish to continue trading medicines for profit. This will be a commercial decision, based on the company’s projected turnover from the trade in medicines, and thus no party will be forced to obtain a wholesale dealers’ licence unless it is financially viable. We assume a range of between 1% and 5% of community pharmacies (There are 10,691 community pharmacies - NHS Business Services Authority, March 2010, http://tiny.cc/f75vt) in the UK that wish to get a wholesale dealers’ licence in future. We estimate that the cost of applying for a wholesale licence is £2,478, the annual cost of maintaining a licence is £5,822, and the three yearly costs of inspection are £1,882 (Table 1 in Annex 3 gives our assumptions).

Other commercial entities (we estimate 15,286 in total – see table 3 in Annex 3) that are also affected by the repeal who need to change to get their supplies from a wholesale dealer in future, and between 1% and 5% may need to switch suppliers. The incremental costs of dealing with wholesalers as opposed to pharmacies are £244 as a one-off cost and an annual cost of £2,347 (Table 2 of Annex 3 sets out our assumptions).

If 1-5% of the current community pharmacies decides to apply for wholesale dealers licences, there will be an impact on the MHRA, as an extra 106 to 535 new licence holders require more work for the wholesale licensing and inspectorate divisions. This will, however, be met by current fees charged for licensing.

We estimate that the total ten year present value costs are between £9.443 million and £47.215 million (annualised at between £1.097 million and £5.485 million).

The private sector would bear all of these costs. We believe that 3,909 of the community pharmacies are either small or micro businesses, and that 2,058 of the remaining private sector entities are small and micro businesses (see Annex 3 for our assumptions). We estimate that small and micro businesses would bear ten year present value costs of between £3.651 million and £18.254 million (annualised at between £0.424 million and £2.120 million)

Benefits

We can not estimate the benefits of this option because we do not know the probability that the EU will notice our non-compliance, and the added probability that the EU will not accept our "least cost" approach to compliance described by Option 1.

Rejected options

Option 2: Impacts, Costs and Benefits of a 'Do Nothing' Option

The impact on the targeted groups – pharmacies and their dependents - will be nothing, and will continue to be so unless we are targeted for infraction proceedings by the European Union. Infraction proceedings have recently been revised under the Lisbon Treaty (now the Treaty on the Functioning of the European Union) to allow for faster infraction proceedings and fines for member states not achieving compliance. In practice, according to Treasury Solicitors, the main cost of infraction proceedings tends to stem from the costs of legal counsel, and in a particularly difficult contest in 2007, amounted to around £45,000. More typical contested infraction trials usually cost the UK £15,000 per trial. Non-contested infraction proceedings (where the UK admits to its mistakes and agrees timescales by which they can be rectified) are drafted in-house by Treasury Solicitors and cost the UK a negligible amount.

It is worth noting that the reputational damage to the UK arising from infraction proceedings could be more costly than the legal costs. The UK is currently considered by the EU (particularly in the field of medicines regulation) to be knowledgeable, cooperative and a leader among the member states for innovative medicinal regulation. The damage from infraction proceedings could see us losing this position and a loss of any weight given to our opinions and suggestions when negotiating new EU medicines legislation.

The Commission, under TFEU Article 260(3), has the option to fine any Member State under infraction an amount that it deems fit for non-compliance. This fine is unlimited and can be applied retrospectively for every day of non-compliance that the member state has avoided proper implementation of the EU proposals. The minimum lump sum of for a fine that can be imposed upon the UK is €9.6m (£8.2m), with a variable daily charge (dependent on seriousness of the infringement) for every further day of non-compliance with the court's judgement (in the two most recent cases, this has been a daily charge of €178,560/£152,271 (case IT 2006/2114) and €36,926/£31,488 (Case IE 2002/5076)). Given that the parliamentary process in the UK takes a minimum of 21 days, this would cost a total of between £8,861,248 and £11,397,691 at a minimum. This is very unlikely to happen to us in this case – the UK has never been fined in infraction proceedings during its membership of the EU – but we would be wise to accept that it is a vague possibility, and could be even more damaging to our stance in Europe.

Option 3(a): Enforce the requirement that any pharmacy dealing in medicines must hold a Wholesale Dealer's licence: Impacts, Costs and Benefits

Costs

The impacts of the repeal of the Section 10(7) exemption would be wide ranging and very costly without any mitigating strategies available. It would require all those pharmacies wishing to trade in medicines

beyond the limited circumstances of in the interest of public health, in small quantities, occasionally and not for profit to apply for a Wholesale Dealer's Licence.

There are 10,691 community pharmacies (NHS Business Services Authority, March 2010, http://tiny.cc/f75vt) in the UK, and an estimated number of 130 acute trusts in the NHS (England only) not already in possession of a wholesale dealers' licence. If these entities wished to continue their current trading patterns, they would need to apply for and maintain wholesale dealer's licences (costs of doing this are summarised in Table 1 of Annex 3).

It is also possible that those pharmacies that do decide to become wholesale dealers will not wish to incur extra cost by licensing multiple premises, all of which would need to be inspected by the MHRA and therefore incur further inspection costs of £1,882 per day of inspection on a three-year rolling timetable. Where a pharmacy business has a number of premises, it is likely that only the largest will be licensed, meaning that community pharmacies and others may have to travel farther to obtain their stock. This outcome would also see a negative impact on community pharmacies in rural areas, which are much less likely to have a local wholesale dealer within easy reach. For illustrative purposes, we have assumed that between 10% and 90% of pharmacies (both commercial and NHS) choose to become wholesalers. We estimate that the cost of applying for a wholesale licence is £2,478, the annual cost of maintaining a licence is £5,822, and the three yearly costs of inspection are £1,882 (Table 1 in Annex 3 gives our assumptions).

NHS, other public sector and commercial organisations (for example dentists, fire services and podiatrists) that hold prescription only medicines for onward supply to patients will no longer be able to get their supplies from pharmacists. Instead they will have to deal with wholesalers. The incremental costs of dealing with wholesalers as opposed to pharmacies are £244 as a one-off cost and an annual cost of £2,347 (Table 2 of Annex 3 sets out our assumptions). We estimate that there would be 13,449 NHS entities and 15,286 non-NHS entities affected (see table 3 in Annex 3 for a breakdown)

Given that the MHRA currently considers all applications for Wholesale Dealer Licences in the UK, and also aims to inspect each licence holder on a 5-year rolling basis, if every pharmacy in the UK were to become a wholesale dealer this would require a significant allocation of resource. Indeed there are currently 1744 wholesale dealers in the UK – a further influx of 1,100 (in the 10% scenario) would create a very serious backlog, although ultimately not more cost for the UK Government – the MHRA is a trading fund, and as such, recoups its costs (for example inspections, assessment and administrative work) from the fees it charges to industry for this work.

We estimate that the total ten year present value costs are between £851 million and £1,358 million (annualised at between £99 million and £158 million).

Of this amount, the private sector would bear between £572 million and £1,076 million (annualised a between £67 million and £125 million).

We should emphasise that in practise, the public and private sectors would innovate (probably through contractual solutions – see options 3b and 3c) to reduce their compliance costs. The headline cost figures given above therefore provide a very high upper-bound to potential costs.

Benefits

The benefits arising from Option 3(a) would be that of the greatest clarity within the UK – only those with a Wholesale Dealer's Licence authorising them to trade in medicines in the UK would be permitted to undertake this activity. It would provide legal clarity on these points and defend the UK from the possibility of reputational damage and the possibility of an unlimited fine – both issues that might arise from infraction proceedings.

Option 3(b): A 'hub and spoke' model: Impacts, Costs and Benefits

Costs

This option considers the possibility of a single central pharmacy becoming the 'hub', with other pharmacies that have agreed to become 'satellites' and thus part of the same legal entity. This option would mean that the satellites would need to relinquish a proportion of their individual decision making responsibilities in order to be considered a single legal entity.

This solution is unlikely to meet the needs of community pharmacies, and is not tailored to be appropriate for use between a pharmacy and any other entity. It is most likely that NHS hospital trusts would act as hubs in this instance, of which there are 388 in the UK at present. We have assumed that one hub serves nine spokes (costs are insensitive to this ratio and so we have not presented a range). Compared

with Option 3a, the NHS cost savings of Option 3b arise because of not having to maintain wholesale licences and to pay the annual incremental costs of dealing with wholesalers.

The main costs arise from the legal costs of setting up a recognised agreement between the entities which allows the hub to absorb the satellites under a single legal umbrella. Many of the initial costs could be avoided by the MHRA setting up a standard template contract and guidance for these agreements, which we would plan to have in place before any repeal of the Section 10(7) exemption, which have been taken into account when costing the proposals (Annex 3).

Our estimated cost of drawing up and signing a contract would be £2,183 (assumptions summarised in Annex 3).

All community pharmacies and end users would also be excluded from this option, leaving them with the costs that arise from Option 3(a) above, namely those of applying for or contracting with a company that holds a wholesale dealer's licence as well as an increased level of inspections and the possibility of greater wastage costs. For illustrative purposes (as with Option 3a) we have assumed that between 10% and 90% of community pharmacies become wholesalers. We estimate that the cost of applying for a wholesale licence is £2,478, the annual cost of maintaining a licence is £5,822, and the three yearly costs of inspection are £1,882 (Table 1 in Annex 3 gives our assumptions) (costs summarised in Table 1 of Annex 3). We also assume that all other entities bear the incremental costs of dealing with wholesalers. The incremental costs of dealing with wholesalers as opposed to pharmacies are £244 as a one-off cost and an annual cost of £2,347 (Table 2 of Annex 3 sets out our assumptions).

We estimate that the total ten year present value costs are between £848 million and £1,352 million (annualised at between £99 million and £157 million).

Of this amount, the private sector would bear between £572 million and £1,076 million (annualised a between £67 million and £125 million).

We should emphasise that this option only benefits the NHS because we have assumed that the private sector would not adopt this approach. However, the private sector would certainly innovate (probably through some other contractual means – see option 3c) to reduce its costs, and hence our headline figure for private sector costs represents a very high upper bound for potential compliance costs.

Benefits

The benefits arising from Option 3(b) would be that many of the key organisations in the NHS could continue to trade simply and without the need (and additional cost) of wholesale dealers' licences. This would avoid imposing extra burden upon the NHS at a time when the Government is looking to utilise its resources in healthcare in the most efficient manner possible.

Option 3(c): An 'agency' model: Impacts, Costs and Benefits

Costs

The agency model considers the possibility that, under contract, any entity can act under agency to procure from and return medicines to the principal. This option should be appropriate for a large number of the players that act within the framework of pharmaceutical supply, and should only incur the costs of a standard contract. We estimate that the cost of drawing up and signing a contract would be as considered by Option 3(b) above to be £2,183 per contract (assumptions summarised in Annex 3). For illustrative purposes, we have assumed that between 10% and 90% of public and private sector entities will enter into contractual relationships

Those who act as principals also have the option under this arrangement of charging a handling fee for their services. This may lead to a modest rise in the amount charged for pharmaceuticals, although we expect that it is currently standard practice for the vast majority of those currently acting under the section 10(7) exemption to charge a handling fee for their services. We therefore assume no incremental cost associated with handling fees.

The agency model necessitates companies to relinquish some of their decision-making powers, and some entities may be unwilling or unable to enter into contracts that allow another legal entity to have a degree of control over their business practices. Whilst the model contract envisaged would aim to keep the transfers of power to a minimum in order to allow for seamless trading between entities.

It should be considered that there may be some wholesalers who would be resistant to entering into an agency contract with those they currently supply, as this could cut their profits. Likewise, the agency model could become so widespread that it is the preferred trading arrangement, meaning that wholesale

dealers are no longer approached for trade by smaller pharmacies and end users. However, we assume that any loss of profit experienced by wholesalers is merely transferred to pharmacies as increased profit.

There will need to be some MHRA consideration of EU competition law and procurement rules to make sure that the Agency model is sound, although we expect that these legal issues should be resolved without greater resource required than the MHRA's current complement. It should be noted, however, that if an area of serious mismatch arises, this option may become non-viable.

To make the assumptions consistent with those adopted for option 1, we have assumed that between 1% and 5% of pharmacies would wish to apply for and maintain wholesale licences because they find it profitable to do so. We estimate that the cost of applying for a wholesale licence is £2,478, the annual cost of maintaining a licence is £5,822, and the three yearly costs of inspection are £1,882 (Table 1 in Annex 3 gives our assumptions).

We estimate that the total ten year present value costs are between £467 million and £769 million (annualised at between £19 million and £89 million). Note that the public and private sectors would be free to choose the most effective method of minimising their compliance costs and hence, we would expect actual compliance costs to be towards the lower end of our estimated range

Benefits

The benefits arising from Option 3(c) are that it is an option that can be used by the majority of healthcare organisations with minimal cost, and will not require the onerous and resource-intensive requirement that all trading be under a wholesale dealer's licence. There should be very little disruption to the 'business as usual' scenario, which is the main objective that the MHRA and the Department for Health are attempting to avoid. It will also reduce the possibility of wastage from unwanted or unused stock, and may improve current levels of wastage, as the principal has a greater margin of control over supply as at present.

Risks and Assumptions

We have come up against some difficulty in obtaining the figures for 'end users', which have in some cases been derived from unverifiable internet sources where estimates have been given. It should also be noted that we have used an assumption based on Northern Irish figures obtained to ascertain how the number of a certain type of professional relates to the number of individuals or companies that offer these services. In Northern Ireland (2008 data from NINIS), 864 dentists operate out of 349 surgeries, giving an approximate matrix of 2.48 dentists per surgery – a matrix that we have also applied to chiropodists/podiatrists and paramedics.

A number of the figures quoted, particularly those on the number of healthcare providers, are sourced from the NHS, which covers only England. Some of the information (such as that on wholesale dealers and responsible persons) comes from all of the UK. The overall costs that arise from this impact assessment will likely be higher when applied to all of the UK.

There are a number of risks that arise out of these options, many of which can be avoided, but some of which could create some tricky problems later on. One of these is the current trading practices of manufacturers (particularly those trading in branded medicines), some of whom who have recently begun limiting the number of wholesalers who can supply their products to two or three national suppliers. In general these are the full-line wholesalers – a limited number of wholesalers in the UK that stock almost all of the medicines required by the NHS in the UK, at least 20,000 product lines. If this trend continues, it would certainly have an impact on options 3(a)-(c) in terms of whom the wholesaler pharmacy, hub or principals able to trade with in future, as well as the number of specific wholesalers that pharmacies would need to have contracts with in order to be supplied with specific pharmaceutical products. Full-line wholesalers are also those who are most likely to be unwilling to trade in low volumes with smaller pharmacy and other businesses. A summary of key manufacturer's supply arrangements can be found on the Pharmaceutical Services Negotiating Committee's website at http://www.psnc.org.uk/distribution.

We have also tended to assume that the market for supplying medicines will adjust to take account of any changes that the MHRA makes, for instance where wastage costs may go up due to an inability to sell stock back to other companies, this will eventually lead to pharmacies and other end users keeping a closer eye on their stock levels in order to reduce this wastage. Also where the market currently charges surcharges to low-use trade, a greater number of wholesalers specializing in pharmacy trade will eventually emerge into the UK market to reduce these costs.

Public Sector burdens – data, reporting and admin

If we were to move forward with Options 3(a), (b) or (c), these would likely have high impact on the NHS, who would need to apply for a large number of wholesale dealers' licences, as well as put in place the necessary arrangements for making sure that the requirements of holding such a licence, such as having a qualified responsible person, continued to be met.

The MHRA's inspectorate team would need to take on more licensing of wholesale dealers and inspections of premises for any of the above options, although it should be noted that option 3(a) would be particularly onerous, requiring many new licences in the UK and raising the MHRA's workload by at least 100%. Our preferred option may see a rise in inspection and licensing workload of up to 33%, although this is likely to be a much lower figure.

Wider impacts

We have conducted a number of other assessments to ascertain the impact of this policy in certain areas:

Justice Impact Assessment and New Offences Clearance

We have considered the justice impact test and expect there to be no impact on the justice system, as we are not creating any new offences – merely aligning the UK with European law. We would also ensure that there is a well-advertised transition period before the repeal of the current 10(7) exemption. Those pharmacies found to be trading without a wholesale dealer's licence after the repeal will be targeted for compliance by the MHRA's enforcement team, and we do not expect there to be any rise in the number of cases brought before the courts.

Equalities Impact Assessment

We have considered the screening questions provided in the Equalities Impact assessment, and have concluded that there will be no significant positive or negative effects of the policy that affect the populations listed.

Health Impact Assessment

The health impact assessment identified three areas that might be affected by the proposals, these being a direct impact on health, which may arise from any temporary pharmaceutical supply shortages to pharmacies, particularly rural communities, a minor effect on the environment due to the possibility of greater numbers of pharmaceutical deliveries, and a possible shift in demand from one service provider to another if certain medicines cannot be sourced by those currently providing healthcare services. None of these impacts were deemed to be important (using the criteria of the assessment), particularly if our preferred option is taken forward. It was noted that any problems affecting rural communities could raise media interest, and that mitigation measures should be taken to avoid shortages wherever possible.

Small firms' impact

The proposals are intended to affect all companies equally, and as such will cost the same amount to small firms as large. The use of option 1 has sought to minimise the impact upon small businesses such as optometrists, podiatrists etc. It is accepted that there may be some minimal impact upon these businesses where they may need to switch suppliers, but we cannot see any way of exempting them from the repeal of section 10(7) without conflict with European law - other than applying option 1 above. We have consulted informally with the trade associations that represent these businesses, and many of the costs included in their responses have been incorporated into the calculations above.

As this is a repeal that brings us into compliance with EU law, it is considered that it is exempt from the microbusiness moratorium.

Competition impact

There is a possibility that the repeal of the Section 10(7) exemption will move those who currently get their supplies from a pharmacy to wholesalers, particularly those full-line wholesalers in the UK who can supply the 20,000 product lines needed by the NHS. The number of full-line wholesalers in the UK is limited to less than five, and the changes could be considered to be decreasing competition within the pharmaceutical trading sector. However, it is likely that these full-line wholesalers will need to adapt their trading practices to accommodate small businesses and pharmacies, and in time other smaller businesses will emerge to meet the needs of pharmacies and end users or act as intermediaries between wholesaler and pharmacist.

Charitable sector costs

There should be no impact on the charitable sector - charities that exist to provide healthcare to the public, such as hospices, will be exempted under the preferred Option 1.

Wider Environmental Impact and Greenhouse Gases Tests

There are no potentially significant impacts on air quality, water quality and quantity, flood risk, biodiversity, landscape or noise arising from these proposals. This policy will have no impact on greenhouse gas emissions.

Human Rights

The preferred option will have no impact on any of the 16 basic rights of the Human Rights Act.

Rural Proofing

The preferred option will have no significant impact on rural communities.

Sustainable impact test

The policies will have no impact upon sustainability and will not adversely affect future generations

Annexes

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

Annex 1: Post Implementation Review (PIR) Plan

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

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)];

Under Government guidance, the repeal of the exemption would need to be reviewed after five years.

Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]

We would be looking to make sure that the removal of the exemption has not interrupted essential medicines supplies, particularly within the NHS.

Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]

The review would consist of an evaluation of wholesale dealer applications over the previous five years, as well as an assessment of supply issues over the five years since implementation. Stakeholder views would be essential to ascertain how the repeal and mitigating options had bedded down.

Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]

Current numbers of wholesale dealers and trends for applications, compliance trends, supply shortages and medicines counterfieting activity (from cases brought by the MHRA, and medicines recalls within the supply chain).

Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]

Success would be a shift away from the use of the current exemption to a UK position compatible with EU law, with little or no disruption in medicines supply, particularly within the NHS.

Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]

The MHRA has a number of routes through which it can monitor the wholesale dealer and counterfeiting activity trends, including our own data recording from wholesale dealer applications and court cases that we bring on counterfeiting activities. We also monitor medicines supply shortages (in conjunction with the Department for Health) as a part of our routine work.

Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]

n/a

Annex 2: Equality Impact Assessment

Screening template

Title of policy:
Pharmacy proposals: Repeal of section 10(7) of the Medicines Act

Short description of policy:
The policy aims to align the UK with EU law to prevent pharmacists from trading in medicines for profit without holding a valid wholesale dealer's licence. The options are;

- Continue to operate as a pharmacists and source all medicines from someone who holds a wholesale dealer's licence;
- Apply for and meet the standards of the licence, giving the pharmacy an ability to undertake wholesale dealing activities;
- Apply a 'hub and spoke' model where by pharmacies become satellites of a larger pharmacy; or
- Employ the 'agency model' and where pharmacies and others become an agent of a principal pharmacy.
- Allow trading between pharmacies and other entities where they are providing healthcare to patients.

The last model is considered the most cost effective with the least impact on current medicines trading arrangements.

Negative impact
How could the policy have a **significant** negative impact on equality in relation to each area?
Age None
Disability None
Ethnicity None
Gender (including transgendered people) None
Religion or belief None
Sexual orientation None
Socio-economic groups None

Positive impact
How could the policy have a **significant** positive impact on equality in relation to each area?
Age None
Disability None
Ethnicity None
Gender (including transgendered people) None
Religion or belief None

Sexual orientation None
Socio-economic groups None

Positive impact
Could the policy have a **significant** positive impact on equality by reducing inequalities that already exist? Explain how will it meet our duty to:
1. Promote **equal opportunities** None
2. Get rid of **discrimination** None
3. Get rid of **harassment** None
4. Promote **good community relations** None
5. Promote **positive attitudes** towards disabled people None
6. Encourage **participation** by disabled people None
7. Consider **more favourable treatment** of disabled people None
8. Promote and protect **human rights** None

Evidence
What is the evidence for your answers to the above questions? The policy applies to the business practices of pharmacists and other end users in the medicines supply chain. Thus it does not promote or exacerbate inequalities in the community.
What does available research say? The available research considers that any changes will need to take place gradually to make sure that there is no interruption in supply to communities of much-needed medicines. Thus the MHRA has considered carefully the options proposed and believes that the preferred option is the most measured and proportionate available to bring us into compliance with EU law.
What further research or data do you need to fill any gaps in your understanding of the potential or known effects of the policy? None –although the repeal of the exemption will be reviewed in five years to monitor the effect that it has had on the current system.
Have you thought about commissioning new data or research? We do not anticipate that new data or research will be required, as we have spent nine months gathering the contents of the current impact assessment.

Screening assessment
Now that you have looked at the evidence, do you think that the policy needs a **Full EqIA**? No

Next steps
If you do **not** need to do a **Full EqIA**:
What else might you need to do to make sure the policy **promotes equality** and **gets rid of discrimination**? We do not feel that the policy requires amendment to address these issues.
How will you **monitor** the situation as the policy develops and takes effect? Through routine collection of data and a review following five years of the policy being in force.
What **further research** do you need? None

Annex 3: Parameters used in the cost calculations

The costs of applying for and maintaining a wholesale dealer's licence

Table 1: Estimated costs associated with a Wholesale Dealer's Licence

Activity	Transition cost	Annual Cost	Recurrent	Calculation notes
Administrative cost of application preparation	£733	N/A		20 hours at average national salary of £25,500 p/a* (£21 an hour), followed by 8 hour of verification/signoff at £50,000 p/a (£40 an hour)
Licence cost	£1754 application fee	N/A		
Cost of complying with regulatory requirements	N/A	£822		40 hours at average national salary of £25,500*
Cost of responsible person		£5,000		On-going training costs
Inspections	N/A		£1,882	Inspection first year and every three years subsequently
Total	£2,488	£5,822	£1,882	

* Office of National Statistics (http://www.statistics.gov.uk/cci/nugget.asp?id=285)
† Based on estimates from the Chartered Institute of Personnel and Development (2006)
‡ Based on estimates from respondents to previous MHRA consultations

Costs of dealing with wholesalers

Those pharmacies and other end users that did not become wholesale dealers would likely incur a higher level of wastage each year as unused or close to out-of date stock was not returned. Evidence from stakeholders responding to MLX 365 (RXchange reply) suggests that about 4% of stock is wasted in pharmacies at present, resulting in around £320m of costs per year. There is also evidence that wholesalers will only supply full packs of medicines to those with whom they trade – if only a part-pack is required by the pharmacy in question, this could also lead to a greater level of wastage of stock within pharmacies. It should be noted that many of these problems should either be mitigated by better stock control in future or by more flexible trading practices as trading between wholesalers and smaller businesses becomes more commonplace, but there would be an impact in the short to medium term as the market adjusts to these practices, and we have allowed for a possible 1% (or £80m) rise in wastage in our calculations.

It should also be considered that there will be costs imposed on those who choose not to become wholesale dealers, but will continue to need supplies sourced from an existing (or new) wholesale dealer. The MHRA engaged with industry bodies to source these costs. The first cost imposed on these operators is likely to be that of switching suppliers, which is calculated to cost £122.10, based on a calculation of 10 man-hours at the average UK salary of £25,500 (ONS statistic). There is also likely to be increased costs that arise from managing contracts with these suppliers (as these may need to be multiple with a number of suppliers), and the manpower required to chase and manage these supply problems, calculated to be at least another 30 man-hours per annum. Greater stock quantities may also need to be held, as sourcing from a licensed wholesaler is likely to take longer than simply sourcing from another local pharmacy – pharmacies will need the extra space (and possibly refrigerated conditions in some cases) in which to keep this stock.

Many of these operators will require small quantities of medicinal products on an infrequent basis – in many cases wholesale dealers are known to currently charge a 'low use' service charge. Currently it

would seem to be standard practice that premiums of at least 5% (and frequently higher) are charged to those businesses who do not regularly order large amounts of pharmaceuticals on a regular monthly basis. Discounts apply to those who order large quantities of stock – these are not likely to be able to be utilised by pharmacy and other end user trade. Fuel surcharges are also common practice, particularly when trading with full-line wholesalers – these are applied monthly to all accounts (in December 2010, Alliance Healthcare's fuel surcharge was £17.50 per month). Ordered in error surcharges are also applied to an account where the level of error stock is equal or greater than 2% of the number of units that month (in December 2010, Alliance Healthcare's charge was £50) - thus much more likely to apply to the smaller trades undertaken by pharmaceutical and other end users. Although the supply of lower amounts of medicine to such people is likely to become more widespread (and thus a reduction in costs would be expected in the medium to long term as the market adjusts), these charges will impact on end users such as podiatrists, optometrists etc. for at least the first one to two years.

Table 2: Summary of costs provided by industry contacts for those who require the services of a wholesale dealer following a repeal of the section 10(7) exemption

Activity	**Estimated Cost**	**Estimated frequency**	**Estimated total (annual)**
Switching wholesalers	£122	Twice (total)	£244 (first year only)
Managing supplies and deliveries	£366	Annual	£366
Wastage of pharmaceutical products	£1,671†	Annual	£1,671
Low use charge	5% of turnover	Monthly	[Not quantifiable]
Fuel surcharge	£17.50	Monthly	£210
Ordered in error surcharge	£50	Estimated twice yearly	£100
Total			**£2,591**

†This cost applies evenly across the sector, and thus a 1% rise of £80m is split evenly between end users and wholesale dealers.

There are a large number of other businesses, both NHS and private, that will be directly affected by the repeal of section 10(7). This is because, under the current legal framework, they regularly receive supplies of medicines from pharmacies, and would instead incur further costs by switching contracts to wholesalers in future. The numbers and types of these individuals are set out in table 2 below, and they will be referred to as 'end users' for the remainder of this document. In total, they number 15,286 private entities/sites and 13,449 NHS entities/sites that would likely be affected.

Cost of drawing up and signing contract

There are legal costs associated with the preparation of contracts, and we have estimated that even with model contracts for the NHS to work from, there would be need for each entity to consider legal advice to make sure that the contracts are legally enforceable and equitable. We have canvassed costs from a number of firms that specialise in the production and processing of contracts, but it is difficult to estimate how much would be charged, as a solicitor's work is charged on an hourly basis. At best guess, we calculate that the production of a contract will cost between £1,500 and £2,500 to prepare. The agent would also need to put aside some time to consider and sign these contracts – we expect this to take at least five hours of time at the standard UK wage of £25,500 p/a (£21 an hour including non-salary costs), plus time to be signed by a senior member of the organisation (at least two hours) at an estimated £50,000 p/a (£40 an hour including non-salary costs), with a total of £2,183 per contract.

Non-Pharmacy entities affected by the changes

Table 3: Estimates of UK healthcare providers and other UK businesses users') indirectly affected by the repeal of the Section 10(7) exemption

Individual/business	Private practitioners	NHS entities (England only)	Totals	Calculation notes
NHS Primary Care Trusts	n/a	145	145	England only
NHS non-acute trusts	n/a	55	55	England only
Podiatrists/chiropodists	1,793 sites†	3,330 sites†	5,123 sites†	According to a 2010 HPC headcount, there are 12,704, of which 50% work solely for the NHS. With others their time is split – it is assumed a 65/35 split.
Dispensing opticians	15 sites	85 sites	100 sites	There are very few dispensing opticians - less than 100. Most use NHS pharmacies for supplies.
Midwives	250	2,000	Approx 2,250	The NMC estimates that around 250 midwives operate independently. We assume a further 2,000 work for the NHS.
Dentist Practices	4,500 sites	4,500 sites	9,000 sites	Around 1,000 Dentists are exclusively private, and the same number work exclusively for the NHS. Others split their time evenly, so the remaining 7,000 are split between the two columns.
Paramedics	3,334 sites†	3,334 sites	6,668 sites†	According to a 2010 HPC headcount, 16,562 paramedics operate in the UK. We have assumed a 50/50 split between the NHS and private ambulances.
Fire Services	1,439 stations 3,261 vehicles	n/a	4,700	Figures for England only (from DCLG) – not clear whether both fire stations and vehicles carry prescription medicines, but numbers of both included for completeness.
Lifeboat services	150 sites	n/a	150 sites	RNLI figures for lifeguard stations in the UK - not clear whether lifeguards carry prescription medicines, but numbers included for completeness.
Police forces	400	n/a	400	Numbers of police stations in the UK as a rough estimate - not clear whether police stations carry prescription medicines, but numbers included for completeness.
Armed Forces	n/a	n/a	n/a	The armed forces source directly from AAH.

Prison services	144 prisons	n/a	144	Not clear whether prisons carry prescription medicines, although this is highly likely.
Totals	**15,286**	**13,449**	**28,735**	

† Northern Ireland matrix of 2.48 has been applied to estimate the number of sites in these circumstances – please see risks and assumptions section below for further information

Small firms

Data received from the National Pharmacy Association indicates that 3,909 community pharmacies are either small or micro businesses. For other private sector entities, we have assumed that all podiatrists/chiropodists, dispensing opticians, private sector midwives and private sector dentists are small and micro businesses. This yields a figure of 6,558.