

<b>Title:</b> INSPECTIONS OF PHARMACY BUSINESSES (PARTIAL IMPACT ASSESSMENT) <b>IA No:</b> N/A  <b>Lead department or agency:</b> DEPARTMENT OF HEALTH  <b>Other departments or agencies:</b> CABINET OFFICE MHRA DEVOLVED ADMINISTRATIONS	<b>Impact Assessment (IA)</b>		
	<b>Date:</b> 02/09/2013		
	<b>Stage:</b> Development/Options		
	<b>Source of intervention:</b> Domestic		
	<b>Type of measure:</b> Other		
<b>Contact for enquiries:</b> Peter Dunlevy, MPI			
<b>Summary: Intervention and Options</b>			<b>RPC Opinion:</b> Not Applicable

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, Two-Out? Measure qualifies as
£0.0075m	£0.0075m	£m	No   Zero Net Cost

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

Community pharmacies are subject to a wide range of information and inspection requirements under regulations. As the range of services pharmacies offer increases, the risk of further requirements which may replicate existing ones similarly increases. Community pharmacy is concerned at the potential time and resources required away from front-line patient care. Government is determined to minimise or remove burdens and that regulations, where warranted, are necessary and proportionate to protect consumers, employees and health. The Red Tape Challenge seeks alternatives to regulation and to eliminate the avoidable burdens of complex regulation and bureaucracy, to promote growth, innovation and social action.

**What are the policy objectives and the intended effects?**

The main policy objective is to ensure that burdens on pharmacies arising from inspections are kept to the minimum necessary to ensure compliance with professional standards and necessary regulatory requirements, whilst maintaining patient and public safety. The intended effects are to avoid, remove or reduce regulatory and compliance requirements from community pharmacies, freeing them from unnecessary bureaucracy and allowing them to focus on delivering high quality NHS pharmaceutical services.

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

- 1) Remove all inspection powers from all bodies except for the pharmacy regulator (the General Pharmaceutical Council (GPhC)).
- 2) Legislate for a body, such as the GPhC, to be the single regulator and inspector for pharmacies.
- 3) A body, such as the GPhC, to be the principal regulator of pharmacies, except in tightly defined circumstances where other inspectors also had a role.
- 4) Establish a self-assessment compliance regime for pharmacies.

Option 3 is preferred for having both greater support from external stakeholders, and the highest Net Present Value in the economic assessment.

<b>Will the policy be reviewed?</b> It will be reviewed. <b>If applicable, set review date:</b> 09/2014					
Does implementation go beyond minimum EU requirements?				Yes / No / N/A	
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.		<b>Micro</b> Yes/No	<b>&lt; 20</b> Yes/No	<b>Small</b> Yes/No	<b>Medium</b> Yes/No
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)				<b>Traded:</b>	
				<b>Non-traded:</b>	

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

Signed by the responsible SELECT SIGNATORY: \_\_\_\_\_ Date: \_\_\_\_\_

# Summary: Analysis & Evidence

Policy Option 1

Description:

## FULL ECONOMIC ASSESSMENT

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

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			

Description and scale of key monetised costs by 'main affected groups'  
SEE SUMMARY FINDINGS ON NEXT PAGE

Other key non-monetised costs by 'main affected groups'  
SEE SUMMARY FINDINGS ON NEXT PAGE

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			

Description and scale of key monetised benefits by 'main affected groups'  
SEE SUMMARY FINDINGS ON NEXT PAGE

Other key non-monetised benefits by 'main affected groups'  
SEE SUMMARY FINDINGS ON NEXT PAGE

Key assumptions/sensitivities/risks  
SEE SUMMARY FINDINGS ON NEXT PAGE

Discount rate (%)

## BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs:	Benefits:	Net:	Yes/No	IN/OUT/Zero net cost

## Evidence Base (for summary sheets)

There is discretion for departments and regulators as to how to set out the evidence base. However, it is desirable that the following points are covered:

### Summary findings:

- Option 3 is the preferred option, as it scores best in the basic economic (cost-benefit) analysis, and in the qualitative criteria analysis.
- Option 4 also scores positively in both analyses, but option 3 is preferred as it fits most closely with the policy intent and stakeholder feedback.
- Options 1 and 2 are projected to generate negative Net Present Values.

### Problem under consideration:

In its blueprint for reducing burdens on pharmacies published in response to the Red Tape Challenge in February 2012, Pharmacy Voice stated that:

*“Administrative burden can take many forms – NHS paperwork, local authority requirements, health and safety regulations, pharmacy professional regulation, compliance with employment law, audits, Government initiatives and so on. Some of these requirements are necessary but many others are not.”*

It also referred to the role of the Care Quality Commission (CQC) and said that:

*“As pharmacy offers more clinical services, the likelihood that their activities fall within the remit of the CQC increases. It is important that the result of these is not that pharmacies face double regulation with two regulators duplicating inspections. A process of joint licensing or regulators accepting the inspection reports of the other regulator should be considered.”*

More recently, the National Pharmacy Association (NPA) Representation Manager for Wales submitted ‘Freeing pharmacy teams to deliver patient care’ (December 2012) to the Welsh Government. It sets out a 10-point plan to help reduce burdens on pharmacies, including:

7 Define lines of accountability with other agencies such as the General Pharmaceutical Council and the Environment Agency to avoid dual inspection and monitoring of community pharmacies.

It outlines a further ten point plan in which it believes Welsh Health Boards can support community pharmacy, including:

5 Limit unproductive inspection and monitoring of community pharmacy by moving the focus to monitoring those activities that have a direct patient benefit, and;

10 Establish operating protocols with other bodies that inspect community pharmacies to avoid duplicate inspection.

Both the Pharmacy Voice and the Welsh NPA document include appendices which set out the range of information and inspection requirements to which community pharmacy may be subject (e.g. by Health Departments, the NHS, by regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA), the CQC and General Pharmaceutical Council (GPhC), by other Government departments such as the Environment Agency, Home Office, Department for Work and Pensions (DWP), Ministry of Justice (MoJ), HM Revenue and Customs (HMRC) and from Europe (e.g. new Directives), by local authorities, by the police or others).

### Rationale for intervention:

By 2015, the Government is committed to reducing the overall volume of regulations with particular attention paid to those that impose unjustified or disproportionate costs or unduly bureaucratic burdens on businesses in the UK. As part of this work, the Cabinet Office has hosted “Red Tape Challenge” initiatives on behalf of Departments which expose their existing regulatory requirements to in-depth scrutiny and analysis, challenging Departments to justify their continued retention and to explore alternatives to legislation.

**Scope of exercise:**

The policy options considered here cover England only. However, it is worth noting that in some circumstances, policy decisions would create a situation where a Great Britain wide organisation – in this case the GPhC – would have to undertake activities in a certain framework for England only, with different arrangements for Scotland and Wales, unless there was a corresponding change in regulatory approach in these countries.

**Better Regulation Status:**

In accordance with the guidance set out by the Department for Business, Innovation and Skills (BIS) in the “Better Regulation Framework Manual – Practical Guidance for UK Government Officials”, published in July 2013, as this impact assessment is considering a Red Tape Challenge measure, it automatically qualifies for the “fast track”. In practice, this means that these proposals can proceed to Reducing Regulation sub-Committee (RRC) approval without prior Regulatory Policy Committee (RPC) scrutiny.

**Policy Objective:**

The Department of Health is committed to achieving regulatory excellence across all areas for which it has legislative responsibilities. The Department therefore wishes to ensure that the burdens placed on pharmacies arising from inspections are kept to the minimum necessary to ensure compliance with professional standards and necessary regulatory requirements, whilst maintaining patient and public safety.

Consistent with the overarching aims of the Red Tape Challenge, Ministers believe that, as far as possible, pharmacy business would prefer a uniform inspection regime across the UK and therefore it should make every effort to ensure all and any such inspections are warranted and proportionate in relation to the potential risks involved.

**Evidence on the extent of inspections in community pharmacy:**

The Department of Health has undertaken a range of activities to gather evidence to support the analysis of some policy options. This included:

- Review of existing evidence provided by the pharmacy sector in respect of the Red Tape Challenge;
- Stakeholder engagement with community pharmacy contractors and representative organisations;
- Discussions with organisations with inspection powers;
- A survey of community pharmacy contractors on inspection activity and their views on inspections.

**Review of existing evidence collected as part of the Red Tape Challenge:**

In addition to the views of Pharmacy Voice and the NPA described above, the views of existing regulators are also important. In its response to the Healthy Living and Social Care Theme of the Red Tape Challenge which ended on 30th January 2013, the GPhC cited a number of areas where it believed reform of the overarching legislation would improve how it works and reduce burdens.

Their priority changes were:

- more flexible administration of registration periods and expiry dates through rules rather than statutory requirements;
- greater flexibility at the initial stages of considering “fitness to practise” matters for individual registered professionals;
- promoting more joined-up working with other regulators and authorities, like the police, by requiring third parties to provide information about people applying for registration;
- removing the requirements to specify the intervals for routine inspections and the circumstances for special inspections and other visits, in order to assist to help develop a risk-based and proportionate inspection regime; and
- enabling them to require evidence of English language competence from European Economic Area (EEA) applicants for registration.

It also referred to the importance of the work of the Law Commission, which is reviewing the regulation of healthcare professionals and is expected to publish its draft legislative proposals in early 2014. Reform of inspection requirements must also dovetail with other initiatives underway such as the re-balancing of medicines legislation and pharmacy regulation (<https://www.gov.uk/government/policy-advisory-groups/pharmacy-regulation-programme-board>).

The GPhC has confirmed it considers these priority changes would enable it either to reduce administrative burdens on its registrants or improve the efficiency of its regulatory work, including its capability to protect patients and the public.

#### Stakeholder engagement with community pharmacy contractors and representative organisations:

A stakeholder event took place in May 2013, which brought together a number of key stakeholders from across community pharmacy (e.g. representatives of Pharmacy Voice, the NPA, the Pharmaceutical Services Negotiating Committee (PSNC), and individual companies), and government (the Department of Health and the Cabinet Office).

The purpose of the meeting was to engage key stakeholders to probe and test further the issue of inspections, by gathering their views on what the purpose of pharmacy inspections should be, what functions well, what functions less well, and to modify the existing inspections regime, to make it fit for purpose within the scope of the wider aims and objectives of the Red Tape Challenge.

These exploratory discussions with a range of pharmacy interests suggest that, whilst reasonably positive, the picture on inspections is mixed. Smaller businesses may be particularly concerned about inspections from local authorities and the demands from the NHS, with a view that the burden of inspection falls proportionally more on small businesses. Larger businesses may view inspections as a means of assuring that their own internal quality standards are adequate, and may be more concerned with the potential overlap between different inspection regimes concerned with healthcare. The degree to which an inspection places a burden on business may be as much down to the approach of an individual inspector as to the requirements of particular inspection regimes.

In respect of any reforms to the inspections landscape, the following issues were flagged as important by contractors and pharmacy representative organisations:

- There is a need for consistency in the delivery of different inspections;
- Any reforms should seek to remove duplication, and any “gold-plating” of inspection activity;
- There should be more clarity around inspection terminology, which could perhaps be achieved through a standard glossary of inspection terms, developing a common understanding between inspection agencies, and to promote information sharing;
- Inspections should be a means of improving quality. Part of this requires adapting different approaches as to how inspections are delivered, e.g. by engaging pharmacists and their support staff in the process of inspection, rather than inspecting around them;
- Self-assessment regimes, whilst attractive, may take some time to test, agree and implement (the example of a self-assessment regime for NHS contractual compliance in Wales was cited. This has recently become mandatory for all Welsh NHS pharmacies. The initial work on self-assessment began in 2005).

The stakeholder group highlighted various elements that reform to inspection regimes might consider, including:

- Consideration of a single multi-purpose inspection regime, which is supported by self-assessment and the appropriate use of available inspection resources;
- Differentiating between inspections and investigations, by allowing existing bodies to retain residual investigation powers;
- The GPhC would appear best placed to fulfil a single inspector function for the pharmacy sector.

#### Discussions with organisations with inspection powers:

DH officials organised a series of discussions with the different organisations that may inspect a pharmacy. The purpose was to gather evidence about the nature, and extent, of inspections in pharmacy businesses. Officials discussed this with inspectors and other officials from the following organisations –

the Health and Safety Executive (HSE), Local Authorities (LA) (Trading Standards), the GPhC, the MHRA and the CQC. Areas of interest included:

*Inspection specific:*

- Who undertakes an inspection of a pharmacy?
- How many pharmacies do you inspect per year?
- How often might a pharmacy expect to be inspected?
- How long does a typical pharmacy inspection take place?
- What does the inspection involve?
- Is there any interaction with pharmacy staff?
- Do you interact with other organisations that have an interest in your inspections of pharmacies?

*Inspector specific:*

- What skills do your inspectors require?
- How long does it take to train to be a qualified inspector?
- What is the cost of training?
- Salary levels of inspectors
- Is there any specialist equipment required by inspectors?

*General Pharmaceutical Council (GPhC):*

The GPhC is the regulator of the pharmacy profession and of pharmacy premises in Great Britain. The main issue flagged by the GPhC is the balance between regulatory requirements and contract monitoring (qualitative inspections vs. quantitative contract monitoring). The GPhC and NHS England are at an advanced stage of negotiating a Memorandum of Understanding (MoU) regarding their respective inspection functions.

Within its own sphere, the GPhC has been trialling a new approach to inspections for businesses with more than 50 premises. This involves comparing, at head office level, corporate systems across the business and their quality assurance processes. If satisfactory, the need for individual premises inspections is removed. The GPhC is also preparing its own set of rules for premises inspection on which it plans to consult later in 2013 following an earlier consultation in 2012. These focus on achieving better outcomes for patients and signal a move away from a prescriptive, rules-based approach to inspections. Whilst it does not do so yet, the GPhC would also be prepared to publish core information on its inspections through the statutory register it maintains. This would be available to other inspection bodies. It is carrying out thorough testing of its registration information requirements, the new inspection model and a proposed model for presenting inspection reports and has established a number of informal "sounding boards" with representatives of pharmacy to ensure it takes full account of their current processes and procedures in designing these models.

The GPhC, in general, considers there is read across amongst the different inspection regime. It considers the key challenge for all regulators is minimising duplication or gaps in regulation, and is aware of contractors' concerns about possible duplication between the GPhC and NHS primary care organisations. The GPhC favours structured agreements to avoid or minimise the potential burden and, as noted above, is in advanced discussions with NHS England on concluding an agreement. It regularly meets with the Care Quality Commission and has begun work on a draft MoU. As such, these agreements give effect to their current operational practice of working closely with other regulators such as the MHRA (e.g. on anti-counterfeit work) although there is currently no formal MoU in place. These agreements might be achieved at different levels of interaction – for example, by a first stage of simple notifications between bodies, followed by greater GPhC involvement if they undertook an inspection on behalf of another regulatory body, but with the ultimate responsibility for further action resting with the appropriate regulator. The GPhC is not against this being underpinned by legislation but only as long the

parties have corresponding powers to take account of each other's inspection processes to deliver accountability. The GPhC is looking to develop further agreements with other inspection bodies in the future and to work with other bodies as appropriate in sharing intelligence, carrying out joint inspections and avoiding duplication of data requirements.

From the GPhC perspective, they have not done any formal or structured mapping of the various inspection and enforcement activities undertaken by local authorities. It is unclear whether this is a major issue for pharmacy businesses, a matter of perception or a new phenomenon. The GPhC is aware that LA inspections may cover a broad range of activities including environmental health, trading standards and food hygiene, health and safety, planning, building and waste management.

#### *Care Quality Commission:*

The CQC is the national regulatory body responsible for ensuring hospitals, care homes, GP and dental surgeries and all other care services in England provide people with safe, effective, high quality and compassionate care, and encourage such services to make improvements. As such, the CQC inspects and licences the "whole system" provided at a site. The CQC would inspect a pharmacy if it is part of a wider healthcare system, for example, in a hospital even if the pharmacy was registered with the GPhC. However, the CQC does not inspect registered pharmacy premises which are not part of such a system, such as high street pharmacies. This is entirely the responsibility of the GPhC.

Where a community pharmacy wishes to provide services beyond the "traditional" model of dispensing and pharmaceutical services (for example, setting up a clinic to monitor patients' anticoagulation treatments) then this may require registration with the CQC. The CQC would expect commissioners to have governance standards for pharmacist-led clinics based in a GP surgery.

#### *Health and Safety Executive (HSE):*

The HSE cite a very small presence in the inspection of pharmacies. They tend to focus on the inspection of GP surgeries that have pharmacies, and hospital pharmacies. LAs inspect community pharmacies for health and safety issues. This is reflected in the number of pharmacies inspected by the HSE, with only a small number of premises identified over several years. Following publication of the DWP document "Good Health and Safety, Good for Everyone", the HSE do not proactively inspect healthcare premises, and are only likely to undertake an inspection resulting from a complaint, a death, or some other poor performance, which is flagged up by the CQC. Regular HSE inspections do not incur a fee. However, the HSE can charge a "Fee for Intervention" if a significant breach is detected whilst an inspection takes place. LAs do not apply such fees.

The HSE have a "Local Authority Unit" (LAU), which deals with LAs, and with which they are developing a "LA Code" for joined-up working. LAs typically inspect high-risk activities, and community pharmacy businesses are unlikely to be captured in this category. The HSE have never had a referral from the GPhC, and there is no MoU between the two organisations. In contrast, there is a MoU agreement between the HSE, the CQC and the General Medical Council. In addition, the HSE publishes guidance entitled "Who regulates in health and social care" on its website at [www.hse.gov.uk](http://www.hse.gov.uk).

On the legislative side, removing pharmacies from Section 18 of the Health and Safety at Work Act 1974 (which sets out the bodies responsible for the enforcement of relevant provisions) would require legislative amendments, and would give pharmacy employees no power over health and safety issues that they had concerns over. A transfer of health and safety powers would require the organisation taking up this role needing powers to criminally prosecute. Furthermore, as pharmacy inspection numbers are so low, any transfer of responsibility would not free up HSE staff resources. In addition, as HSE inspectors have a level of expertise and job specific training (e.g. in asbestos issues, estates, and electrical issues), existing inspectors in organisations such as the GPhC are unlikely to have this skill set, and therefore there is likely to be a demand to recruit such staff. Thus, a clear implication of transferring powers over to an organisation such as the GPhC would be a potentially high marginal cost of training existing inspectors to a suitable level of competence, for potentially low levels of inspection activity. Alternatively, stand-alone health and safety inspectors may be recruited to or contracted for the stand-alone organisation, but again at a relatively high cost for low activity levels.

### *MHRA:*

The Medicines and Healthcare products Regulatory Agency (MHRA) an executive agency of the Department of Health, regulates manufacturers and wholesale dealers of medicinal products for human use in the UK on behalf of the UK Licensing Authority (LA).

A wholesale dealer's licence enables the holder to wholesale deal in human medicines with other legal entities that are entitled to receive human medicines. All licensed wholesalers must comply with the European Community's agreed standards of Good Distribution Practice and there exist strict licensing and regulatory requirements enshrined in UK domestic legislation to safeguard patients against potential hazards arising from poor distribution practices.

A wholesale dealer's licence can be issued to a registered pharmacy business which wants its own sites licensed so that it can conduct wholesale trade in human medicines from those sites (e.g. Boots, Lloyds).

The wholesale distribution of a medicine is a different activity to a retail supply activity which a pharmacy normally conducts.

In the UK there are approximately 1,800 licensed wholesale dealers. A small proportion of these are registered pharmacies. MHRA operates a risk based inspection programme of the licensed sites and aims to inspect each site no less than once every 4 years.

The MHRA inspects pharmacies which apply for and hold a wholesale dealer's licence.

Where a licence holder has multiple sites, MHRA inspect a sample and if satisfactory sign all premises off. If not, they continue to inspect further sites until they are satisfied about compliance. Where non-compliance is evident or suspected, MHRA undertake a more intensive monitoring and inspection regime – perhaps as frequently as every 6 months. MHRA has the power to revoke licences for persistent non-compliance.

Inspections vary enormously in duration – from a couple of hours to all day. It is therefore not possible to establish an average or median duration.

The MHRA does not have a memorandum of understanding with the GPhC or Home Office but is developing one with HMRC concerning action to tackle illegal activity concerning counterfeit medicines and related matters.

### *Home Office:*

The Home Office inspects pharmacies in the UK (NHS or private, hospital or community based) that wish to supply controlled drugs (CDs) such as opioids as a wholesale dealer. To do so requires a 'supply' licence, application for which is normally considered when the pharmacy holds an MHRA Wholesale Dealer's Licence. A first-time application to supply controlled drugs costs £3,655. Licence holders return compliance statements at the end of a year as a condition of their licence. This is used, along with any other intelligence gathered to judge whether a compliance visit is required at the renewal stage, or even sooner. Renewals cost £326 per annum if no visit is required to check compliance on an existing licensee. If a visit is required to an existing licensee, the fee is £1,371. Licences are site specific. High street pharmacies do not require a licence to supply controlled drugs as part of dispensing activity, only if they are selling controlled drugs stock to a third party. The Home Office aims to inspect licence holders every 3-4 years, though this may be more frequent where there is evidence, or suspicion of non-compliance. Compliance visits normally last approximately 3 hours.

The Home Office liaises and shares information with other agencies, where appropriate, including the MHRA. There is no formal MoU between the two bodies.

### *Local Authorities:*

Phone interviews were conducted with two Trading Standards inspectors (one from an area in Yorkshire, the other from an area in Hampshire). In both cases they noted that there are a number of enforcement teams covering the likes of food services and weights and measures.

The frequency of pharmacy inspections by Trading Standards is low. In the Yorkshire area, 56 businesses were primarily registered as a pharmacy – although this would not pick up Supermarket pharmacies. Of these 56 pharmacies, 51 pharmacies had been inspected since 2005, or approximately 6 per annum (or 11 per cent of all pharmacies in this area over any 12 month period). In the Hampshire area, there are 198 pharmacies, and based upon the last five years data (see Figure 1, below) 28 pharmacies were inspected per annum (or 14 per cent of all pharmacies in this area). The time-series shows that more inspections took place in 2009/10 and 2010/11, but the number of inspections has declined in the last two years of data. Over the two areas, the findings are reasonably consistent.

**Figure 1** – Numbers of pharmacy inspections (Area in Hampshire), for the last 5 years

<i>Hampshire area - 198 pharmacies registered</i>		
<b>Year</b>	<b>Number of pharmacy inspections</b>	<b>% of all</b>
2008/09	17	9%
2009/10	44	22%
2010/11	40	20%
2011/12	25	13%
2012/13	14	7%
Average	28	14%
Median	27	13%

In both cases, pharmacies are likely to expect an inspection once every five years, as most pharmacies have been classed as “low risk” under the Trading Standards risk based inspections criteria (F08). In Hampshire it was also noted that the bulk of pharmacies are classed as risk band code “Band C”, with no recommended frequency of inspection.

On the amount of time taken per inspection, the results across both areas were similar. An inspection can take as little as 10 minutes per pharmacy, although for larger pharmacies selling a range of items this could take up to between 90 and 120 minutes. The inspection itself might involve checking the pricing of certain types of goods, and where appropriate looking at ingredient lists on food products, taking some food samples, as well as checking toys, cosmetics and the best before dates of perishable items. An inspector is likely to introduce themselves upon arrival at the pharmacy, and then would proceed with their inspection work. They will offer the opportunity for a pharmacy staff member to join them during the inspection if they wish. The introduction may take 5-10 minutes at the beginning, depending on the size of the pharmacy, and a similar amount of time at the end of the inspection, to discuss the outcomes, which may vary depending on what has been found.

The inspectors who would typically visit pharmacies do not need any pharmacy specific skills, but would need to have a Diploma in Consumer Affairs and Trading Standards. In addition, to undertake Weights and Measures inspections, inspectors require a module in Legal Metrology. According to Bureau International de Poids et Mesures (BIPM), “The overall process is certainly measurement science, but legal metrology is metrology which ensures the quality and credibility of measurements that are used directly in regulation and in areas of commerce.” Previously, this training would take typically three years to complete, with exams. However, a foundation course in Trading Standards can enable completion of core modules, which can then be supplemented. The training involves on the job learning, mentoring and the completion of module exams. The training may cost around £2,000-£3,000 per module (through the Trading Standards Institute), which may lead to a total training cost of more than £10,000. In addition, there is the opportunity cost of work based training. Inspectors who conduct Weights and Measures inspections require specialist equipment – F1 and F2 weights. This equipment is purchased by the LA.

In respect of sharing information, Trading Standards inspectors might share information on weights and measures with the National Measurement Office, although this may not be as relevant to pharmacies these days, as pharmacies seldom measure drugs for dispensing, instead of dispensing pre-packaged drugs. In addition, information may be shared with the MHRA on counterfeit drugs. On the Environmental Standards side, the contact in Hampshire noted a twice-annual catch up with the respective organisations, although this could occur more frequently if there is a food scare. In addition, there was a Retail Enforcement Pilot where Environmental Health Officers undertake work on behalf of Trading Standards.

On transferring inspection powers, LAs are bound to deliver Trading Standards inspections in legislation. Hence, for areas like Weights and Measures and Food Standards the duty would transfer to other organisations. This would require parliamentary time, and the input of a range of staff to deliver. A more general issue raised was the potential investment required by an organisation such as the GPhC taking over the responsibility of inspections where they might lack institutional knowledge. Clear advantages of a well-defined inspection regime within LA might include the benefits to delivering an inspection regime within an environment that has a depth of institutional knowledge, the ability to transfer this knowledge in the process of supporting the training of new inspectors, and the intangible value of local information networks.

#### *NHS England:*

NHS England (formally constituted under the Health and Social Care Act 2012 as the NHS Commissioning Board) is a new non-departmental public body which, from April 2013, has broad overarching duties, in conjunction with the Secretary of State for Health, to promote a comprehensive health service (other than in relation to public health). In addition, it has specific commissioning responsibilities, including those for primary care medical, dental, eye test and pharmaceutical services which are collectively known as NHS primary care services. NHS England took over these responsibilities from NHS Primary Care Trusts. It has powers to monitor and inspect community pharmacies. NHS England has powers to monitor and inspect NHS community pharmacies to ensure compliance with their contractual terms and conditions. Discussions between NHS England and the GPhC on an administrative MoU, in part designed to help alleviate resource constraints on NHS England, are at an advanced stage.

#### *NHS Protect:*

NHS Protect leads on protecting NHS staff, and has national responsibility for tackling a range of issues including fraud, bribery, violence, corruption, theft, and criminal damage. Its wider remit is to educate those who interact with the health service around health service crime, and what to do about it; to prevent and deter crime in the NHS, and to hold to account those who have committed crimes in the NHS through prosecution.

A MoU existed between the GPhC's predecessor organisation, The Royal Pharmaceutical Society for Great Britain (RPSGB), and the NHS Counter Fraud and Security Management Service, the predecessor of NHS Protect.

In light of NHS reforms, the NHS Standard Contract for 2013/2014, requires all organisations providing NHS services to put in place and maintain appropriate counter fraud and security management arrangements. NHS Protect then reviews this information, and assigns a risk level to the organisation. NHS Protect offers some self-review tools, to support organisations completing their annual report on their anti-fraud, bribery and corruption work.

#### *Survey of community pharmacy contractors on inspection activity and views on inspections:*

DH officials developed a questionnaire with a number of questions around the frequency, requirements and burden of inspections, to sample community pharmacy businesses. The questionnaire comprised a mix of quantitative and qualitative questions, enabling respondents to enlarge on the data supplied.

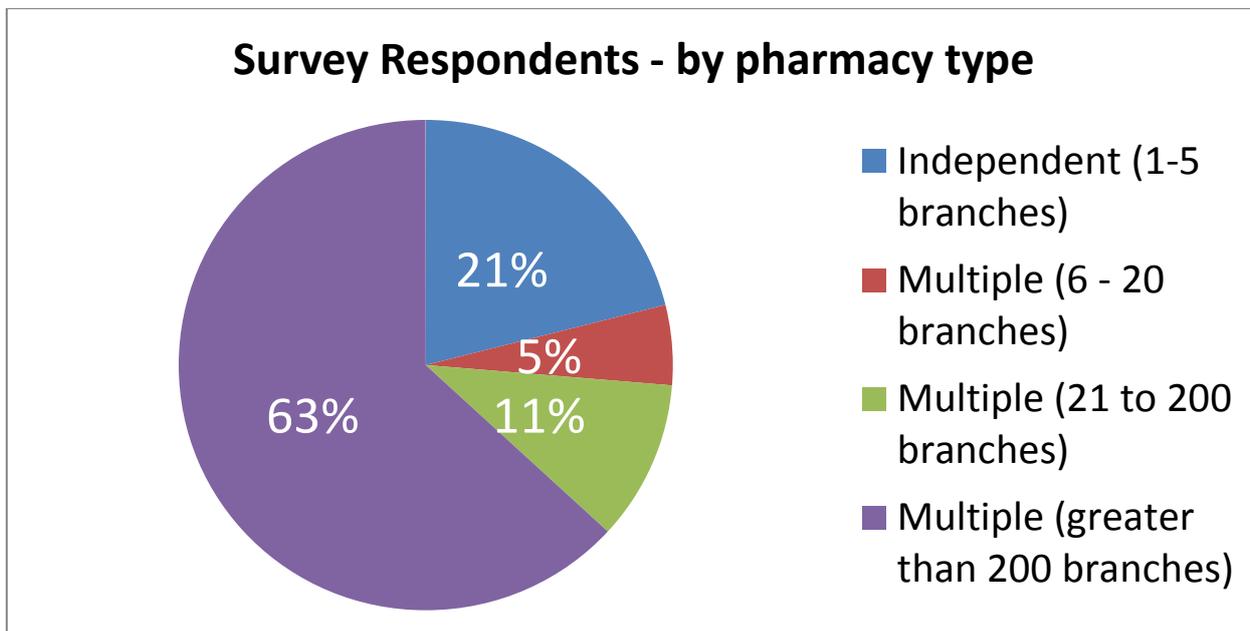
With the support of Pharmacy Voice (covering both the NPA and the Company Chemists Association (CCA)), the survey template was shared with a sample of pharmacy contractors. The aim was to obtain a statistically significant sample of around fifty (50) contractors, covering a representative cross-section of views. Twenty-three (23) survey responses were returned. This is a small evidence base, and therefore it may be difficult to infer whether the responses given are statistically representative of the entire community pharmacy sector. However, it should be noted that organisations with multiple branches were asked to provide evidence based on a branch most representative of their group of branches. In addition, the level of response might indicate a general sense of strength of views on the burden and duplication of inspections, although this cannot be proven conclusively without a sufficiently large and representative sample of responses.

The introductory question asked the respondent to categorise themselves in one of four pharmacy type groupings:

1. Independent (1-5 branches);
2. Multiple (6-20 branches);
3. Multiple (21-200 branches);
4. Multiple (greater than 200 branches).

The composition of survey respondents is shown in Figure 2, below. The basic finding is that the Independent sector is under represented in the sample, relative to the entire community pharmacy sector, 21 per cent of the survey responses came from Independents, whereas the NHS Information Centre “General Pharmaceutical Services in England: 2002-03 to 2011-12” statistical bulletin finds that “At 31 March 2012, 38.7 per cent (4,346) of the pharmacies were classified as independent.” However, regardless, we are dealing with very small numbers of responses, so one should treat the findings with caution. This survey could be repeated to obtain a larger and statistically more significant sample size, although this cannot be guaranteed.

**Figure 2 - Survey Respondents by pharmacy type**



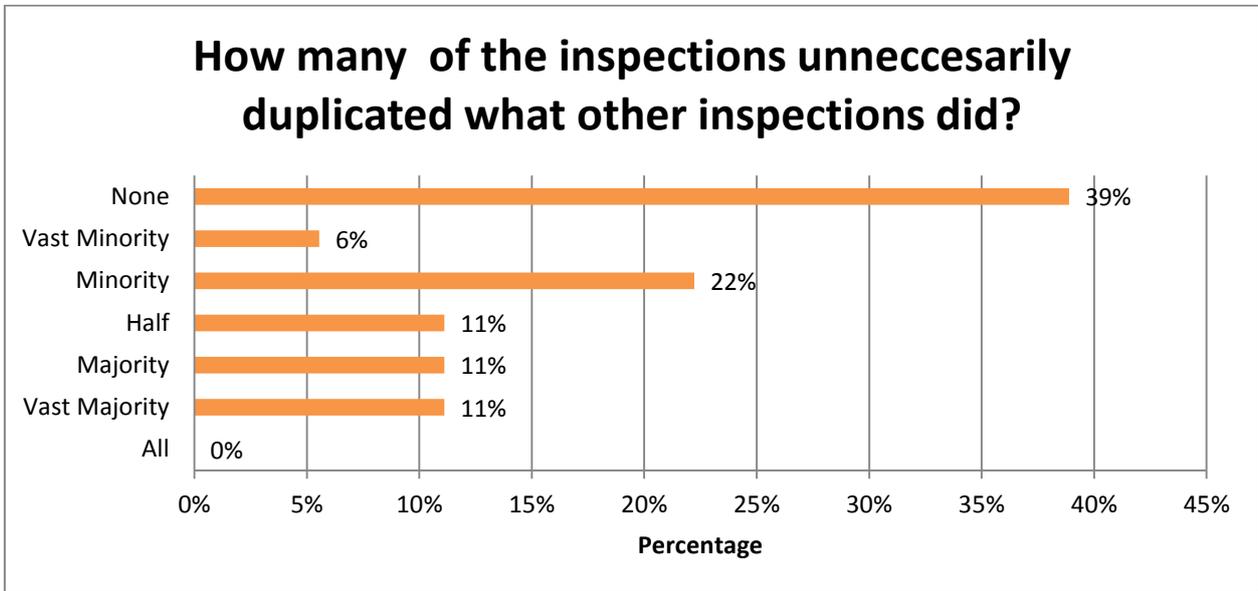
Respondents were asked two questions, one on the degree of duplication, the other on the degree of burden. Some of the survey responses were incomplete, thus only 18 of the original 23 responses gave answers to these questions.

Question 3: In your view, how many of the inspections unnecessarily duplicated what other inspections did?

With a scoring scale as follows:

All	Vast Majority	Majority	Half	Minority	Vast Minority	None
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**Figure 3 – Degree of duplication across inspections**



The responses from the question on duplication provide a mixed picture, see figure 3 above. Almost four in ten of the responses say there is no duplication at all. More than a quarter of responses say that at most the duplication is in the “Minority” or “Vast Minority”. One-third of responses suggest that duplication occurs in at least “Half” or greater (i.e. “Majority” or “Vast Majority”) of inspections.

Digging deeper, by cross-referencing pharmacy type with the response on duplication, the bulk of the responses of a Minority or less (i.e. Vast Minority or None) came from the largest multiple pharmacies (greater than 200 branches). Most of the Majority or All responses came from Independents or multiples (21 to 200 branches). Hence, it is unclear whether pharmacy size matters in this dimension. As before, the sample size is very small so one needs to treat these results with caution.

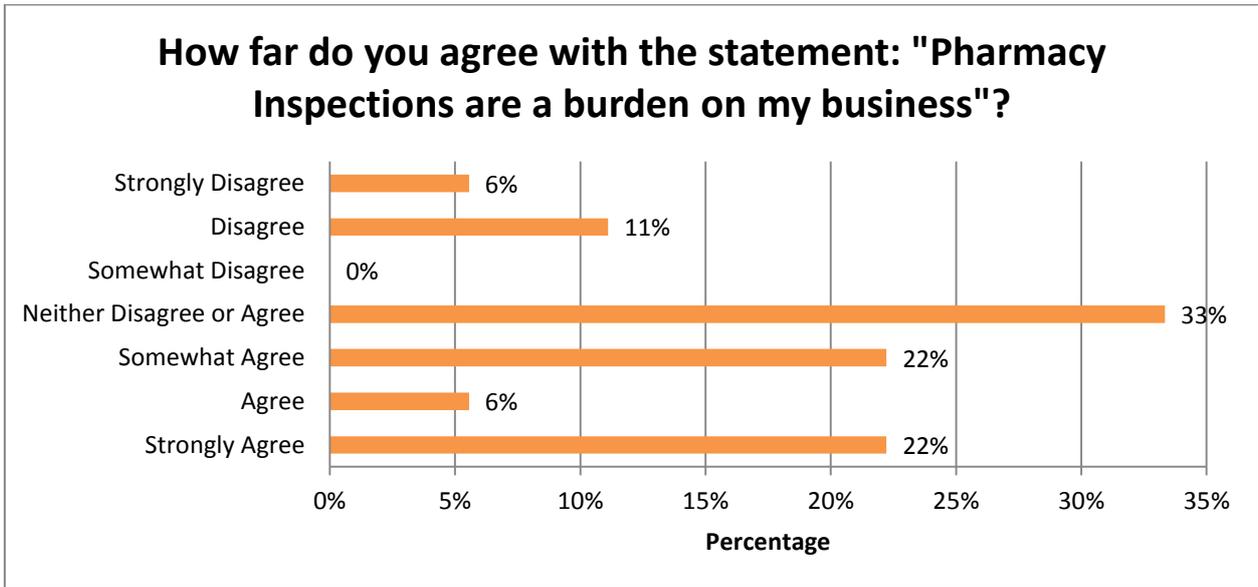
For the degree of burden, the survey asked the following question:

Question 4: How far do you agree with the statement: "Pharmacy Inspections are a burden on my business"?

With a scoring scale as follows:

Strongly Agree	Agree	Somewhat Agree	Neither Disagree or Agree	Somewhat Disagree	Disagree	Strongly Disagree
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**Figure 4 – Degree of burden from inspections**



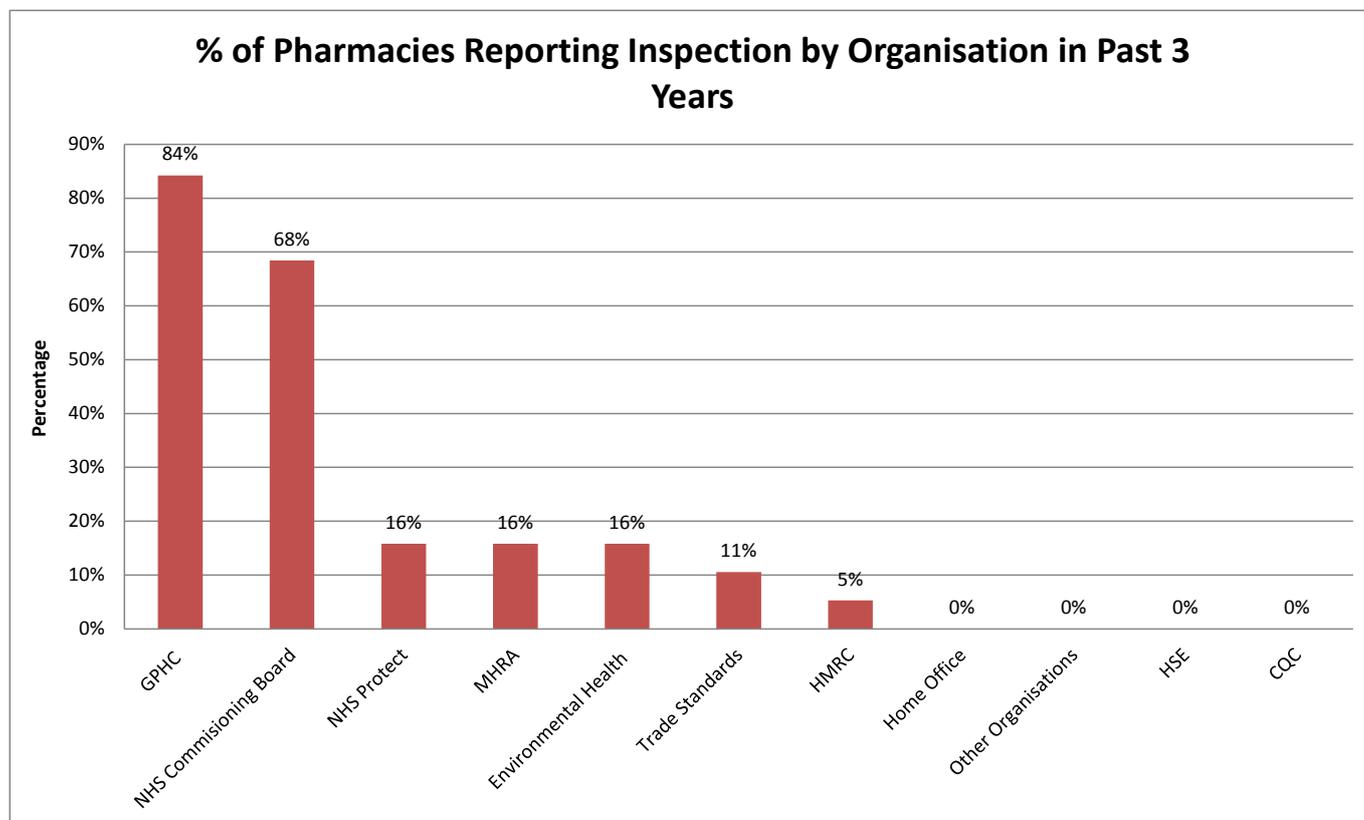
Once more, the picture is mixed on the degree of burden (figure 4 above). A half of survey respondents agree in some form that inspections are a burden on their business, with almost one-quarter strongly

agreeing with the statement posed. One third of responses offer a neutral view – “Neither Disagree or Agree”. Just under a fifth of responses disagreed with the statement, although only 6 per cent strongly disagreed.

With reference to pharmacy type, the Disagree and Strongly Disagree responses came from the largest multiples (greater than 200 branches). Both the neutral (Neither Disagree or Agree), and agree responses came from a mixture of pharmacy types.

Surrounding the questions on the nature of inspections, the headline figure on inspections was that there were two (2) main organisations that pharmacies can expect to be visited by over a three year period- the General Pharmaceutical Council and NHS Commissioning Board (or more precisely the data reported here related to Primary Care Trusts, which ceased to exist in March 2013 – NB this applies to any reference of this type). The rest of the organisations were reported to inspect between only 5 per cent and 16 per cent of pharmacies over the past 3 years, see figure 5 below.

**Figure 5** – Percentage of pharmacies reporting an inspection during the past three years, by organisation



Over the past year, the following percentages of pharmacies reported being inspected by these respective organisations – NHS (53 per cent) [i.e. the percentage of pharmacies in the sample subject to an NHS (PCT) inspection], GPhC (47 per cent), Environmental Health (16 per cent), MHRA (11 per cent), Trading Standards (5 per cent), NHS protect (5 per cent). The other organisations did not inspect the pharmacies picked up in the sample over the last 12 months.

In line with this, point, the data reported above relates to the small sample size, hence for organisations reported as zero per cent, they could in fact be inspecting some pharmacies over a three-year (or one-year) period, but the sample has not picked this up.

Of those pharmacies inspected, the survey collected the time spent per inspection by the different organisations that inspect pharmacies. This is in the context of pharmacy staff time spent on inspection activities, covering work before, during and after an inspection. This might be viewed as a reasonable proxy for burden. The data has been analysed in more detail, and the average time (in minutes) spent (diverted from usual business activity) by a pharmacy staff member in respect of an inspection is reported below (Figure 6 below). HMRC inspections lasted for 3,600 minutes of pharmacy staff time, which also required accountant and account clerk involvement. This was significantly higher than all

other types of inspection. This may stem from our small sample size, where only one pharmacy reported an HMRC inspection. However, this amount of time may not be unrealistic, as where a detailed HMRC inspection takes place it might be expected to revolve around a significant issue that needs resolution. It is therefore not possible to say that 3,600 minutes, or 60 hours inspection time, is an average, or representative duration for such inspections. However, for completeness, it is reported in figure 6.

**Figure 6 – Average time spent per inspection, by inspecting organisation**

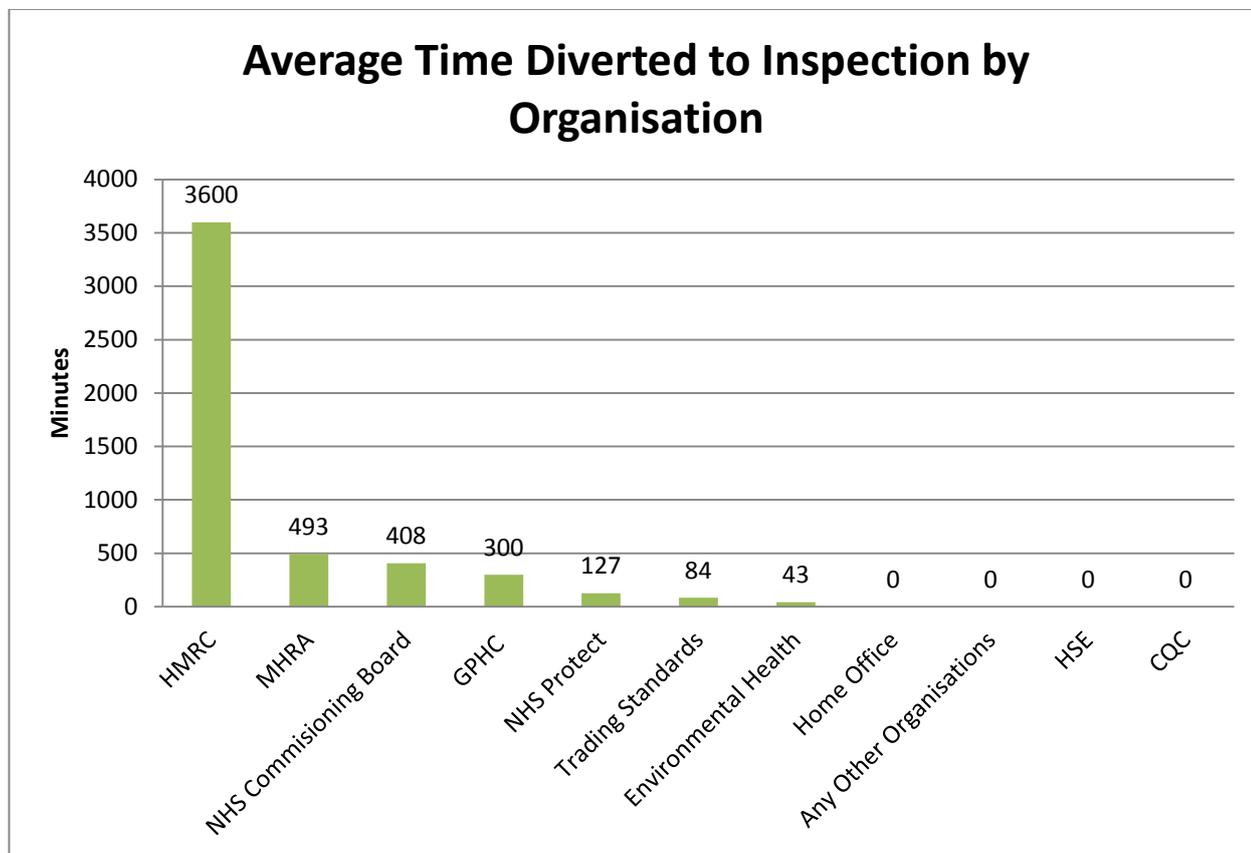
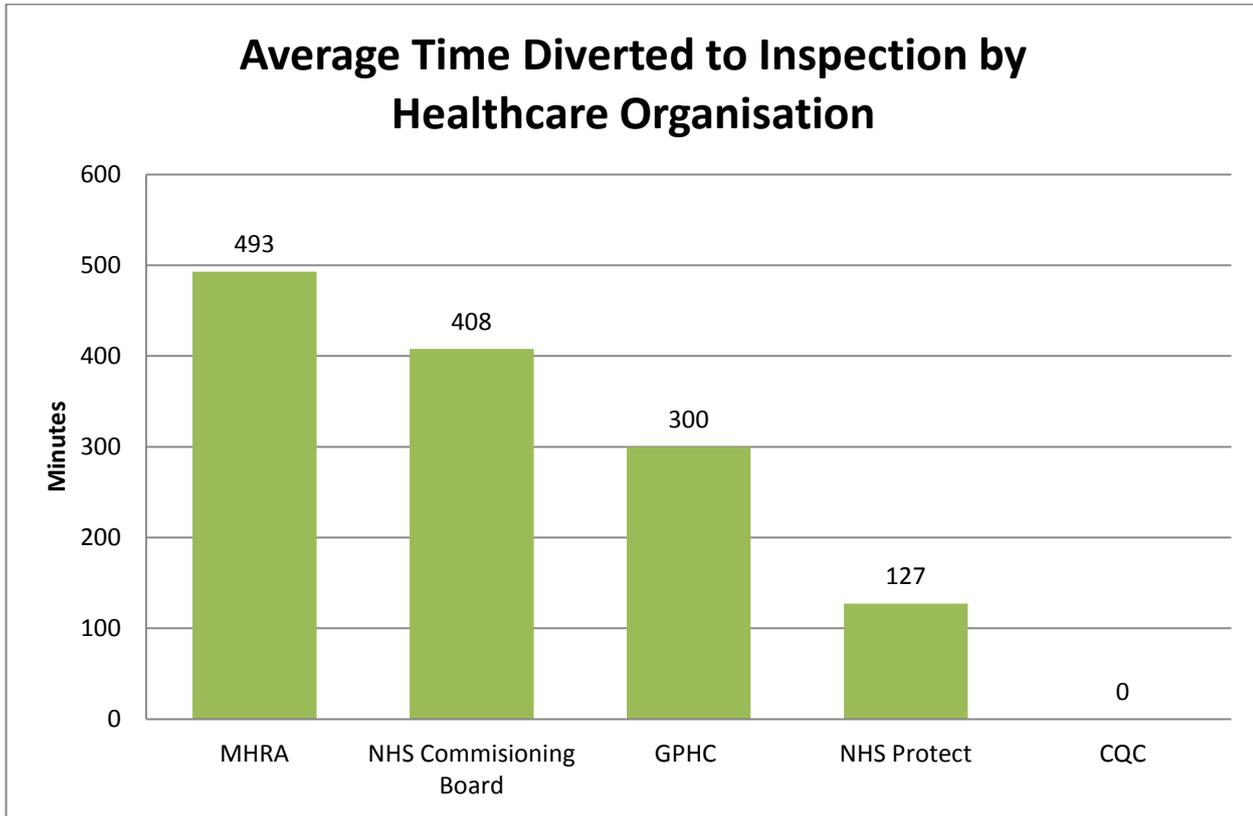


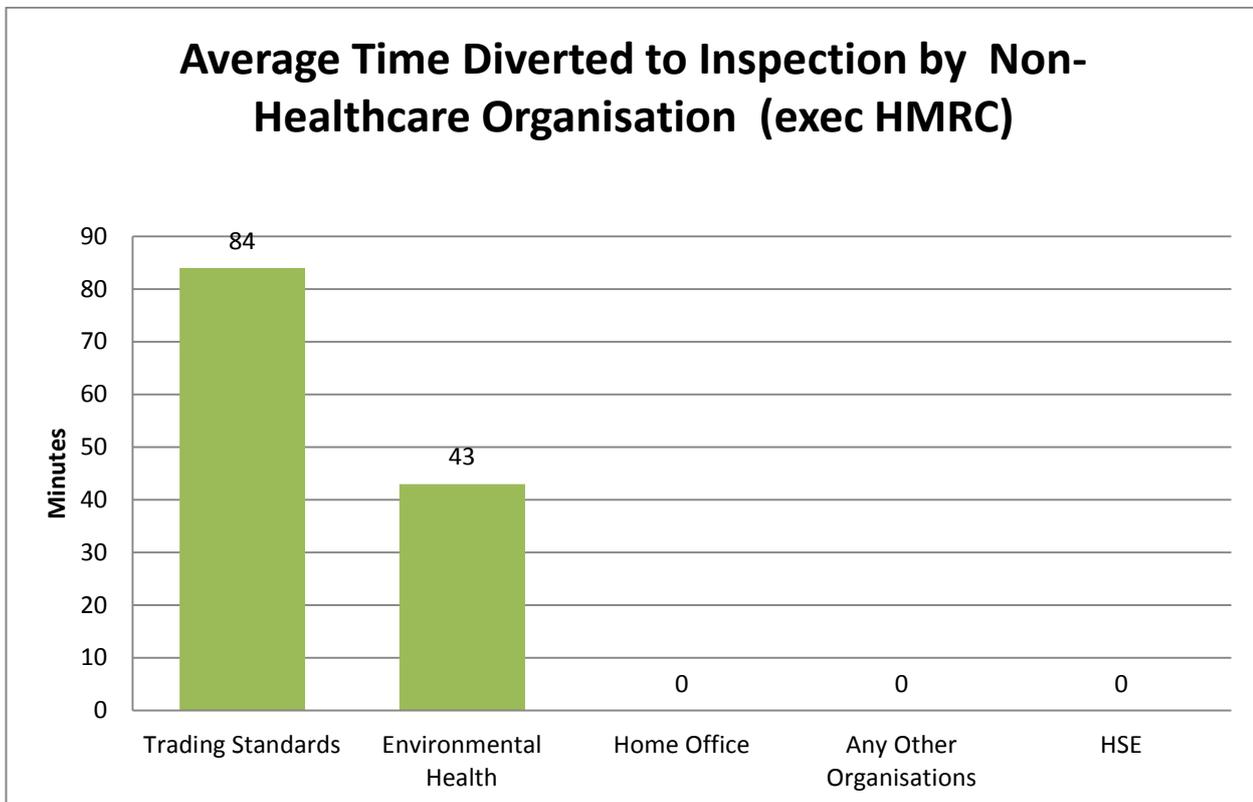
Figure 7, below, suggests that, on average, an MHRA inspection lasts approximately eight hours in total (493 minutes each), an NHS (PCT) inspection seven hours, and a GPhC inspection five hours. This covers all work before, during and after the inspection. Whilst pharmacy business survey respondents did not report any data on Home Office inspections, some evidence was sourced from the Home Office that indicates a typical compliance visit time of three hours (180 minutes). Thus, one can assume this to be the minimum amount of time taken during a Home Office inspection. This is likely to be higher if pharmacy staff also needs to undertake work before or after an inspection.

**Figure 7 – Average time spent per inspection, by inspecting organisation (healthcare only)**



Furthermore, an inspection from a 'Healthcare' organisation is likely to be longer than that from a 'non-Healthcare' organisation, averaging 5.5 hours, compared to 1 hour.

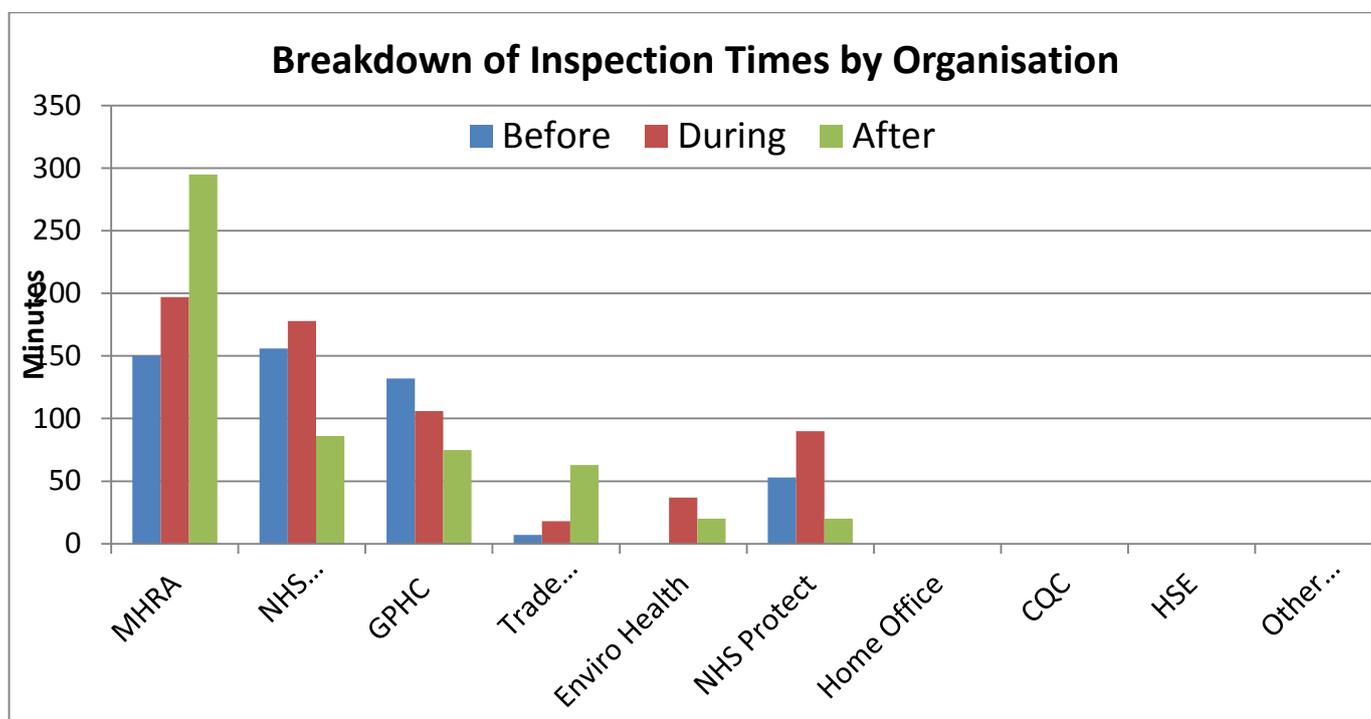
**Figure 8 – Average time spent per inspection, by inspecting organisation (non-healthcare only, excluding HMRC)**



Breaking down the figures into more detail, the majority of the time spent by pharmacy staff is on preparation before and during an inspection (see figure 9 below). Preparation time for the two most common inspections, the GPhC and NHS (approximately 150 minutes) takes relatively longer than the overall average time (123 minutes). However, the time taken during and after the inspection was not substantially different from the average.

Inspections from the MHRA required significantly more time after an inspection. Similarly, Environmental Health and Trading Standards inspections required relatively short amounts of time before the inspection, with Environmental Health reporting no time at all. This correlates with the phone conversations with trading standards inspectors, who may call without prior appointment, and may simply engage a pharmacy staff member for a few minutes by means of introduction before proceeding with an inspection.

**Figure 9 – Average time spent per inspection, by inspecting organisation (non-healthcare only, excluding HMRC)**



**Preamble to the policy options analysis:**

The market failure that justifies regulation and inspection of pharmacy is asymmetric or imperfect information. Demand for inspections draws from the limited information patients, the public and the commissioners of services have about quality, and the relatively high costs of obtaining this information. Inspections are an efficient way of ensuring that patients know pharmacies have a minimum standard of care, aligning the pharmacist’s incentives with patients and correcting for information market failures.

Inspecting pharmacies to some degree aligns the incentives of patients and pharmacists towards higher standards of quality, resulting in safer and more effective practise. As the GPhC states on their website, “Inspector[s] will examine how the pharmacy operates with the aim of securing and promoting the safe and effective practice of pharmacy at the registered pharmacy premises.”

Inspections work because the information they provide impact in three ways to correct market failures caused by the asymmetry of information between patient and the provider of a pharmaceutical service:

- **Moral Hazard.** Moral hazard is a situation where a party will have a tendency to take risks because the costs that could arise will not be felt by the party taking the risk.
- **Adverse selection.** This situation relates to when a buyer cannot accurately gauge the quality of services from a provider. Without any information, a purchaser’s best guess of provider quality is

'average', and they will only pay for this. Therefore, theoretically, 'higher-than-average' quality providers would withdraw from, or not enter, a market, leading to a reduction in the average quality of service downward. This would cause the consumer to revise downward their expectations of what constitutes "average" quality, which results in quality spiralling downwards. In this sense, such a "race to the bottom" leads to the poor quality driving out the good quality as the providers that select to stay in the market have perverse incentives to offer services of a lower quality. Inspections can ensure a minimum standard of quality to prevent this.

- **Reputation goods.** Service providers in any sector are not identical, and do not offer identical levels of service. Thus, consumers rely on information provided by friends, neighbours and others to select from the various services available in the market. Inspections ensure that good quality information is supplied to consumers.

### **Policy options analysis:**

The following policy options have been analysed, in respect of their respective and relative costs, benefits, risks and wider impacts:

Option 1 - remove all inspection powers from all bodies except for the pharmacy regulator (the General Pharmaceutical Council (GPhC)).

Option 2 - legislate for a body, such as the GPhC, to be the single regulator and inspector for pharmacies.

Option 3 - a body, such as the GPhC, to be the principal regulator of pharmacies, except in tightly defined circumstances where other inspectors also had a role.

Option 4 - establish a self-assessment compliance regime for pharmacies.

These options are not necessarily mutually exclusive, but the analysis looks at them in isolation. This covers both a quantitative analysis, i.e. a cost-benefit analysis (CBA), and a qualitative analysis, where it is either impossible, or disproportionate, to quantify the costs and benefits.

In addition, each option has been assessed, qualitatively, against the following criteria:

- a) Impact on regulatory requirements [i.e. the general functioning of the regulatory system, or extent of the regulation]
- b) Impact on administration of regulatory requirements
- c) Impact on legislative requirements [i.e. the need to legislate, or change legislation]
- d) Impact on costs/resources to business
- e) Impact on costs/resources to regulators/inspection bodies
- f) Impact on maintaining/improving patient/consumer protection and public health
- g) Impact on operational feasibility (i.e. would this work in practice)

In respect of the CBA component, all options are analysed relative to the “do-nothing” option, i.e. keeping the existing arrangements.

In addition, the survey evidence, above, highlights the main burden of inspections comes from healthcare/medicines related inspections, and therefore the analysis should be proportionate to this context, keeping in mind that the activities of MHRA and the Home Office are considered out of context.

Furthermore, the options are considered in reference to the Government’s Principles of Regulation:

*“The Government will regulate to achieve its policy objectives only:*

*(i) having demonstrated that satisfactory outcomes cannot be achieved by alternative, self-regulatory, or non-regulatory approaches*

*(ii) where analysis of the costs and benefits demonstrates that the regulatory approach is superior by a clear margin to alternative, self-regulatory or non-regulatory approaches*

*(iii) where the regulation and the enforcement framework can be implemented in a fashion which is demonstrably proportionate; accountable; consistent; transparent and targeted.*

*There will be a general presumption that regulation should not impose costs and obligations on business, social enterprises, individuals and community groups unless a robust and compelling case has been made.*

*The Government will adopt a One-in, One-out approach [now a One-in, Two-out approach]”*

The benefits arising predominantly relate to the monetised opportunity cost of time saved from the reduction in regulatory burdens currently imposed by inspection. This is the estimated amount of time saved, and the respective value of time of pharmacy staff and inspector input.

Other benefits, for example, better quality service delivery from more time freed to undertake appropriate activities are considered second-order and thus not quantified or monetised. However, such benefits may result from some of the options considered.

The costs of the options tend to focus on additional costs to an organisation, or organisations, from a change in legislative or regulatory requirement. Once more, there could be a wide range of potential costs, many of which are difficult to predict (in terms of their likelihood), and scale.

In general, the CBA seeks to be proportionate to the scale and type of issues at hand.

### Cost-benefit analysis of policy options

#### **Option 1: Remove all inspection powers from all bodies except for the pharmacy regulator (the General Pharmaceutical Council (GPhC)).**

In practice, this option would mean that the only body with the necessary powers to inspect a pharmacy would be the GPhC. As this would remove inspection powers from a wide range of organisations, this would arguably be the most radical option available. However, the MHRA, the Home Office, and HMRC are considered out of scope due to the nature of their activities.

## CBA of Option 1:

Considering the quantitative costs and benefits of Option 1, the removal of inspection powers to all applicable bodies except the GPhC would lead to fewer inspections overall. Based upon the survey evidence, this is likely to have the biggest impact on the monitoring and inspection activity of NHS England. This would mean that there would be less pharmacy staff diverted from usual business activities, and it would also free up NHS England staff and other inspectors time to dedicate to their other activities. Relative to the do-nothing option, option 1 has the benefit that as inspectors would not have to inspect pharmacies, the total number of inspections could be reduced which would represent a saving (benefit) to business and the inspecting organisation.

### Benefits:

The quantitative benefits of option 1 relate to the saved opportunity cost of staff time in a community pharmacy from existing inspection activity. To quantify this:

1. Pharmacy staff salaries, reported in the survey, and an estimate of on cost (25 per cent of salary), are used to quantify per minute business costs for each staff member – and then combined with the average amount of time per inspection to generate the “Average staff salary and on cost per inspection”.
2. Taking the probability of being inspected per annum – “Probability of inspection per annum” and multiplying it by the number of pharmacies (11,236), gives us an estimate of “Projected number of inspections per annum”.
3. This number is then multiplied by the average opportunity cost of an inspection, to provide an aggregate saving (benefit) to the pharmacy sector from option 1 – “Aggregate cost of inspections”.

Number of pharmacies in England - 31 March 2012

**11,236**

### Central scenario

<i>Inspecting organisation</i>	<b>Average staff salary and on cost per inspection</b>	<b>Probability of inspection per annum</b>	<b>Projected number of inspections per annum</b>	<b>Aggregate cost of inspections</b>
<b>Trading Standards</b>	£46.24	13%	1,405	£60,000
<b>NHS England</b>	£199.67	23%	2,563	£510,000
<b>HSE</b>	£0.00	0%	0	£0
<b>Environmental Health</b>	£50.07	14%	1,605	£80,000
<b>CQC</b>	£0.00	0%	0	£0

Total Cost of inspections per annum (i.e. BENEFIT SAVED TO PHARMACY)

**£650,000**

The organisations considered in this option are Trading Standards, NHS England, the HSE, and Environmental Health. No evidence was found of pharmacy inspections by the HSE, and the phone interview with the HSE indicates that this is valid. The central estimate of the benefit to business is approximately **£650,000 per annum**. Assuming this benefit remained the same over time, the total benefit over five-years would be approximately **£3,000,000** discounted at a rate of 3.5 per cent.

This calculation does not include the inspector time saved, as this is assumed to be absorbed by their other business activities in the affected organisations, partly due to the low level of inspection activity in community pharmacy. However, based upon a greater number of inspections, there may also be scope to reduce the number of staff in NHS England involved in monitoring and inspection.

Considering this in more detail, the average amount of time spent per NHS England inspection is 122 minutes per inspection. In addition to this, one might assume that inspectors take some more time to fulfil paperwork, or other administrative tasks. This is assumed to be 30 minutes per inspection.

Using the average number of minutes, and the number of inspections across England, one can calculate an aggregate number of minutes spent on inspecting community pharmacy businesses, per annum. As a next step, this is converted into Whole Time Equivalent (WTE) terms. This leads to NHS England needing 1.23 WTE staff, based on a 220 day working year.

To convert into cost terms, assuming that the average business cost (i.e. salary plus on cost) to NHS England is £50,000 per WTE staff, 1.23 WTE is worth £61,000 per annum. However, as this is a public sector saving, this would only apply if it is a cash-releasing saving. If not, then a reasonable assumption of what benefit would be generated is required. It is unclear whether this would be a pure cash-releasing saving (£31k) to NHS England. Thus, in the central scenario, it is assumed that 50 per cent of the WTE value is cash-releasing. For the lower scenario, the benefit is assumed to be 25 per cent of the WTE cost and in the upper scenario the full 100 per cent of WTE staff cost is used.

#### *Sensitivity analysis:*

Other assumptions are made in the upper and lower scenarios. In general, the upper scenario assumes more inspections take place, and therefore more opportunity cost time can be saved, and vice versa for the lower scenario. The central scenario uses the average time, converted into staff cost, for each type of inspection. As described above, there is an additional benefit from 50 per cent of the WTE staff cost to NHS England. However, this may be a very optimistic assumption, as it would be more likely that the NHS England staff members engaged in monitoring and inspecting community pharmacy would be re-deployed, i.e. there would be no cash releasing benefit.

<b>Summary - benefits of option 1</b>	<i>Sensitivity Analysis</i>		
	<b>Central</b>	<b>Lower</b>	<b>Upper</b>
Opportunity cost time saved to business p/a	£650,000	£390,000	£1,670,000
Reduced cost to NHS England p/a	£31,000	£15,000	£61,000
<b>Total benefit p/a</b>	<b>£681,000</b>	<b>£405,000</b>	<b>£1,731,000</b>
<b>Discounted 5-year benefit</b>	<b>£3,180,000</b>	<b>£1,890,000</b>	<b>£8,090,000</b>

Per annum, the total benefit of removing the inspection powers is estimated to be £680,000, with a range of £400,000 - £1.7 million. Over a five-year period, the respective amount of benefit, discounted, is £3.18 million in the central scenario, with a range of £1.89 million to £8 million benefit.

#### *Costs:*

On the cost side, costs could be either *transitional* or *permanent* costs. There are no obvious transitional costs for option 1, relative to the do-nothing option. At most, there may be some relatively minor information costs surrounding the need for organisations that currently have powers of inspection in the community pharmacy sector to inform their staff, and any relevant stakeholders, of the change in situation. These have not been quantified on the grounds of proportionality.

In respect of permanent costs, these could be either:

- The lost benefit from the existence of certain types of inspection
- Costs associated with events resulting from the narrower inspections environment.

The removal of powers to inspect on the basis of trading standards and environmental health in community pharmacy would expose consumers to risks such as where food standards inspections are undertaken to ensure "...that the food we buy is correctly labelled, contains legal ingredients, and is the right quality and quantity" (Trading Standards website). In practice, this ensures that food packaging flags ingredients, clearly marking where there is a risk of an allergic reaction. In addition, food packaging should flag up the fat content, and type of fat content (i.e. saturated or unsaturated fat) in foods. Without such information, consumers are at risk of adverse outcomes.

The Office for Fair Trading (OFT) undertook a study of the benefit to cost ratio of local authority 'Trading Standards Services' (TSS), and found that these services delivered a benefit to cost ratio of 6:1, i.e. every pound (£1) spent on TSS generates six pounds (£6) of benefit to consumers.

For this analysis, in the context of Trading Standards, one can look at the total cost of trading standards inspection activity, with the proxy being the business cost (i.e. staff salary and on cost) across all trading standards inspectorates, i.e. what is the WTE number of trading standards inspectors needed to deliver the projected number of inspections across England, for community pharmacy.

The quantitative costs of option 1 are therefore estimated from the foregone benefits from the inspection activities. Put another way, regulation exists to ensure that certain standards are met in a respective area. Without this regulation, there are risks that the market will not deliver the type of service expected, i.e. there are likely to be market failures, to the detriment of consumers and patients. As an example, to quantify this for Trading Standards:

4. Estimates from phone interviews with Trading Standards inspectors flagged the typical salary of a trading standards inspector ranging from £20,000 to £35,000, dependent on qualifications, experience and location. The midpoint of the range, £27,500 has been used, with another 25 per cent added as on cost, to calculate the business cost of an inspector.
5. Using the projected number of inspections, by scenario, one can quantify the total amount of minutes taken, per annum, undertaking pharmacy inspections, by these inspectors. This uses information provided during phone interviews, which indicated a smaller pharmacy may take between 10 to 15 minutes to inspect, and a larger pharmacy between 90 and 120 minutes. A weighted average time has been generated for the central scenario – of 38 minutes – where 40 per cent of the sector (equivalent to the proportion of independent pharmacies) are assumed to take 15 minutes to inspect, medium sized firms (accounting for another 40 per cent) are assumed to take 30 minutes, and the remaining 20 per cent (proxy for the larger multiples) are assumed to take 120 minutes. An additional 30 minutes is added, per inspection, for any time taken after an inspection, by an inspector, to complete paperwork and other related tasks.
6. A WTE number of inspectors are then calculated for each scenario. The total number of minutes is converted into hours (dividing by 60), days (dividing by 24), and then into working days (dividing by 220).
7. The number of WTE is then multiplied by the business cost of an inspector, to calculate the total cost (foregone benefit) to the inspecting organisation. This is assumed to generate six times the cost as benefit. This is the estimated cost (i.e. the foregone benefit).

Trading Standards Inspector salary and on cost £34,375

	Central	Lower	Upper
Proj. number of trading standards inspections	1,405	394	2,247
Total number of minutes inspecting	95,506	15,770	337,080
Whole Time Equivalents (220 working days)	0.30	0.05	1.06
Total Cost of WTE	£10,000	£2,000	£37,000
Benefit - Cost ratio	6	6	6
<b>Cost - Inverse of benefit (6:1 ratio)</b>	<b>£60,000</b>	<b>£12,000</b>	<b>£222,000</b>
Discounted 5-year cost	£280,000	£60,000	£1,040,000

Assuming the same benefit to cost ratio applies for the other comparable inspections covered by option 1, i.e. environmental health inspections, the total costs (foregone benefit) from these inspections is as follows:

Environmental Health Inspector salary and on cost £34,375

	Central	Lower	Upper
Proj. number of environ health inspections	1,605	591	2,247
Total number of minutes inspecting	58,855	11,827	134,832
Whole Time Equivalents (220 working days)	0.19	0.04	0.43
Total Cost of WTE	£6,000	£1,000	£15,000
Benefit - Cost ratio	6	6	6
<b>Cost - Inverse of benefit (6:1 ratio)</b>	<b>£36,000</b>	<b>£6,000</b>	<b>£90,000</b>
Discounted 5-year cost	£170,000	£30,000	£420,000

For NHS England contractual inspections, undertaking a quantitative cost-benefit analysis is very difficult. Whilst we have some feel for the cost of NHS inspection activity, in essence the monitoring and inspection of community pharmacy acts to ensure that NHS contract terms and conditions are met.

To put this in context, the pharmaceutical services contract is currently worth approximately £2.5 billion per annum. This contract delivers various services, including the dispensing of medicines. The value of the medicines dispensed is worth approximately £10 billion per annum. The contractual funding offers different types of payment, some of which make it easier to monitor the delivery of certain services. For example, pharmacies are currently paid a dispensing (Part IIIA - Professional Fees (Pharmacy Contractors)) fee, for every prescription (P(x)) item dispensed, of 90 pence per P(x) (as at July 2013 Drug Tariff - [http://www.ppa.org.uk/ppa/edt\\_intro.htm](http://www.ppa.org.uk/ppa/edt_intro.htm)). Other activity contingent payments such as the “Establishment Payment” and “Practice Payment” also offer a direct incentive to undertake dispensing activities.

However, implicit in the level of contractual funding is the delivery of a wider range of essential services, such as provision of i) “Healthy Lifestyle” advice, ii) Self-care support, iii) the disposal of medicines and iv) ensuring that Clinical Governance requirements are met, including holding training and patient records. Such services are more difficult to monitor, and it is assumed, in line with the negotiated contractual agreement, and some degree of monitoring and inspection, that these essential services are delivered to an agreeable standard. Inevitably, the extent, and quality, of service provision will vary across pharmacy business, but the process of monitoring and inspection exists to assure standards of service provision.

In practice, the removal of the need for NHS England to monitor and inspect pharmacy businesses in respect of their contractual terms and conditions may put at risk the delivery of some essential services, like those described above, which are more difficult to monitor. The assumed value of the four essential services listed above is £230 million of contractual funding. This estimate is based upon calculations undertaken at the time of the new Community Pharmacy Contractual Framework (CPCF) being agreed, from 2005/06, uprated to 2011/12 prices.

In basic cost terms, a one (1) per cent reduction in the quality of provision of these services would be worth (£230,000,000 \* 0.01 =) £2.3 million. As this is a Government cost, this has an exchequer cost of (£2,300,000 \* 2.4 =) £5.52 million. This exchequer cost exceeds any potential benefit of relaxing inspection requirements on pharmacy businesses from across Trading Standards, Environmental Health, NHS England, and the HSE.

NHS England

	Central	Lower	Upper
Value of Four Essential Services (Aggregate)	£230,000,000	£230,000,000	£230,000,000
Projected reduction in service provision	1%	0.5%	5%
Estimated cost	£2,300,000	£1,150,000	£11,500,000
<b>Exchequer Cost (2.4 times cost)</b>	<b>£5,520,000</b>	<b>£2,760,000</b>	<b>£27,600,000</b>
Discounted 5-year cost	£25,800,000	£12,900,000	£128,980,000

Bringing the respective costs together, the analysis shows that there are potentially large costs from removing inspections powers from Trading Standards, Environmental Health, HSE, and NHS England. Despite offering a benefit to pharmacy businesses, the potential outcomes would be sufficiently negative to generate a negative net present value (NPV).

Summary - costs of option 1	Sensitivity Analysis		
	Central	Lower	Upper
Cost from no Trading Standards inspections	£60,000	£12,000	£222,000
Cost from no NHS England inspections	£5,520,000	£2,760,000	£27,600,000
Cost from no Environ Health inspections	£36,000	£6,000	£90,000
Total cost p/a	£5,616,000	£2,778,000	£27,912,000
Discounted 5-year cost	<b>£26,240,000</b>	£12,980,000	£130,430,000

In summary, option 1 is forecast to have a negative NPV of £2.4 million per annum, or £11.4 million discounted over a five-year period.

*Sensitivity Analysis*

<b>Summary - costs and benefits of option 1</b>	<b>Central</b>	<b>Lower</b>	<b>Upper</b>
Total benefit p/a	£3,180,000	£1,890,000	£8,090,000
Total cost p/a	£5,616,000	£2,778,000	£27,912,000
Net benefit p/a	-£2,436,000	-£888,000	-£19,822,000
Discounted 5-year net benefit(- cost)	<b>-£11,380,000</b>	-£4,150,000	-£92,630,000

*Qualitative costs, benefits, risks and wider impacts:*

In qualitative terms, this option would be very advantageous to pharmacy businesses, notably in both removing a raft of regulatory requirements, as well as simplifying both their, and existing inspection organisations', administration. However, there could be risks around impact on patient and consumer protection, and public health.

At the most basic level, NHS has the power to monitor and inspect community pharmacies to ensure compliance with NHS contract terms and conditions. Option 1 would remove this power, leaving no organisation in a position to ensure that community pharmacies holding an NHS contract are meeting their contractual requirements. In practical terms, this would put at risk the appropriate delivery of *essential services* such as dispensing, repeat dispensing, disposal of unwanted medicines and the provision of healthy lifestyle advice. Removing NHS England's powers of monitoring contractual compliance in respect of pharmacies alone would also lead to a different compliance regime for pharmacies compared to the other chief NHS primary care contractors. In England, there were 11,236 pharmacies providing NHS services, on 31 March 2012. There are an estimated 50,000 contractors and individuals providing NHS medical, dental and eye care services.

Moreover, in operational terms, this would expose the risk of intra-sector issues. For example, a supermarket would be required to conform to certain inspection requirements, but any on-site pharmacy in the supermarket would not. There would likely be major pushback from other business sectors if this led to accusations that this was creating an unfair competitive advantage for the pharmacy sector alone, or distorting the retail market more generally.

Option 1 could also carry significant risk of gaming by business – i.e. transferring or starting to provide other types of retail activities to within the registered pharmacy premises in order to avoid inspections by other bodies which may risk the ability of the pharmacy to provide the core NHS services for which it is listed as providing with NHS England and affect traditional public perceptions of what a pharmacy offers. For example, this might run counter to efforts of successive governments to promote pharmacy as a first port of call for health advice and treatment. Whilst this might not occur in practice, the risk is reasonable to consider qualitatively.

**Option 2: Legislate for a body, such as the GPhC, to be the single regulator and inspector for pharmacies:**

In simple terms, this would require the GPhC to undertake all relevant inspection activity, excluding the exemptions described in option 1. Thus, building upon the analysis in option 1, this would predominantly cover inspections relating to Trading Standards, NHS England, and Environmental Health, i.e. the areas where we have data and evidence of inspection activity.

**CBA of option 2**

Transferring inspection responsibilities for Trading Standards, NHS England and Environmental Health inspections to the GPhC would entail the contracting of inspectors trained in these areas. The GPhC will incur training costs as well, in the process of ensuring that they meet the requirements placed upon them. This could result in significant transitional costs, which have not been quantified here on the basis of proportionality.

To quantify costs one can make use of evidence developed for option 1, i.e. the actual cost of inspection activity, on a WTE basis, by inspecting organisation. However, the typically low frequency of non-

healthcare/medicines inspections would not be expected to generate any additional benefit, notably a cash-releasing benefit, relative to the do nothing option. As the existing organisations may not reduce their staffing requirements, the basic outcome would be an additional cost to the GPhC without obvious tangible wider benefits in return. This cost is then likely to be passed through to its members, and ultimately the public purse, as NHS funding is implicit in the remunerating of NHS pharmacy contractors. Any increase in the GPhC cost base is likely to put pressure on the level of fees charged.

Therefore, excluding the six to one benefit to cost ratio outline in option 1, the projected cost to the GPhC of this option would be approximately £77,000 per annum under the central scenario. This cost ranges between £16,000 and £238,000 under the lower and upper sensitivity scenarios. What this costing does not factor in, is the ease in which the GPhC could employ part-time inspectors, and the ease of running a multi-purpose inspection operation across England. Thus, this costing could underestimate the true cost to the GPhC, as well as potentially risking the ability of delivering the same standard of inspection, without disproportionate investment.

#### In summary:

##### Costs

Trading Standards Inspector salary and on cost £34,375

	Central	Lower	Upper
Proj. number of trading standards inspections	1,405	394	2,247
Total number of minutes inspecting	95,506	15,770	337,080
Whole Time Equivalents (220 working days)	0.30	0.05	1
Total Cost of WTE	10,000	2,000	37,000
<b>Cost</b>	<b>£10,000</b>	<b>£2,000</b>	<b>£37,000</b>
Discounted 5-year cost	£50,000	£10,000	£170,000

NHS England £50,000

	Central	Lower	Upper
Proj. number of NHS England inspections	2,563	1,685	5,618
Total number of minutes inspecting	388,840	84,270	1,179,780
Whole Time Equivalents (220 working days)	1.23	0.27	3.72
Total Cost of WTE	61,370	13,300	186,203
<b>Cost</b>	<b>£61,370</b>	<b>£13,300</b>	<b>£186,203</b>
Discounted 5-year cost	£290,000	£60,000	£820,000

Environmental Health Inspector salary and on cost £34,375

	Central	Lower	Upper
Proj. number of environ health inspections	1,605	591	2,247
Total number of minutes inspecting	58,855	11,827	134,832
Whole Time Equivalents (220 working days)	0.19	0.04	0.43
Total Cost of WTE	6,000	1,000	15,000
<b>Cost</b>	<b>£6,000</b>	<b>£1,000</b>	<b>£15,000</b>
Discounted 5-year cost	£30,000	£0	£70,000

<b>TOTAL COST</b>	<b>£77,370</b>	<b>£16,300</b>	<b>£238,203</b>
Discounted 5-year cost	£370,000	£70,000	£1,060,000

In respect of the benefits of option 2, whilst the current inspecting organisations are likely to free up staff resource to undertake other activities, this is unlikely to be cash-releasing in practice. At most, as per option 1, there may be scope for NHS England to generate some cash-releasing benefits, and the same assumptions are used in option 2, i.e. for the central scenario 50 per cent of the existing NHS England cost is saved, and a range of 25 and 100 per cent for the lower and upper scenarios respectively. Regardless, there is a re-distribution of cost, where the GPhC would be expected to incur the costs of delivering a wider range of inspection activity. The general outcome of this analysis is that the expected NPV for each option would be negative.

*Sensitivity Analysis*

<b>Summary - costs and benefits of option 2</b>	<b>Central</b>	<b>Lower</b>	<b>Upper</b>
Cost to GPhC	£77,370	£16,300	£238,203
Benefits	£30,685	£15,342	£61,370
Net benefit p/a	-£46,685	-£958	-£176,833
Discounted 5-year benefit	<b>-£370,000</b>	-£70,000	-£1,060,000

The cost to the GPhC would be £77,000 per annum, the benefit (cost saved to NHS England) is approximately £30,000, and the overall net benefit -£47,000 per annum from option 2 – or -£370,000 over a five-year period, discounted.

*Qualitative costs, benefits, risks and wider impacts:*

Option 2 would provide some confidence for business that in future only the GPhC would routinely undertake inspections and that the likelihood of inspections by others would significantly decrease. It aligns closely with better regulation policy and would mean a significant number of pharmacies could expect “once and once only” inspections. In theory, the GPhC should seek to undertake the same task as the organisations with the current remit to inspect. However, it might be fair to assume that the administration of regulatory requirements is simplified. Yet, it is difficult to identify any tangible monetised benefits for option 2.

The main issue, on the cost side of option 2, is that it is likely to add increased costs to the GPhC, without necessarily making any savings or improvements in the outcomes of the current inspection organisations. Thus, this option does not score well in respect of criterion (e). For example, the survey evidence suggested that for a number of inspection organisations, such as LAs undertaking trading standards inspections, pharmacies are rarely inspected. This has been quantified. Hence, this is highly unlikely to reduce the need for inspectors in an organisation such as a LA. This view was backed up during phone interviews. Therefore, transfer of all inspection powers to the GPhC would create an additional demand for inspection skills. However, applying the same risk-based approach in some areas would lead to a small number of pharmacies being inspected per annum. Thus, employing staff on a full-time basis may not be viewed as a cost-effective measure by the GPhC.

Moreover, transfer of inspection powers to the GPhC might have the unintended consequence of increasing regulation through unnecessary over-inspection, in part to justify the need for employing a certain number of staff, suggesting a risk of a negative score against criterion (d). Furthermore, there is a risk that the GPhC would need time to develop the same institutional knowledge, and will need to easily access staff with the sufficient skillsets. This may impact the ability to maintain or improve the regulatory environment for patients, consumer and for wider public health in the short-term. In practical terms, the GPhC would incur administrative costs to recruit and train staff. This option would likely complicate legislative requirements, notably as the GPhC would be given a range of legislative requirements for pharmacies only, whilst the same legislative powers would continue to apply as before for the rest of the economy. Therefore, the viability of option 2 may come into conflict with the Government’s principles of regulation, specifically that “...regulation should not impose costs and obligations on business, social enterprises, individuals and community groups unless a robust and compelling case has been made.”

**Option 3: A body, such as the GPhC, to be the principal regulator of pharmacies, except in tightly defined circumstances where other inspectors also had a role.**

This option might be achieved via (a) amendments to legislation or (b) via the regulatory bodies concerned drawing up and agreeing administrative protocols or memoranda of understanding between them. In respect of option 3, both routes - the legislative and administrative – would require clear exposition of the remit and functions of the GPhC and the circumstances under which the GPhC would refer a matter to another body.

Option (a) has the advantage of clarity for all concerned – regulators, inspectors and contractors alike – but little flexibility. Option (b) has the advantage of increased flexibility for the GPhC but less clarity for other inspectors and contractors. Such memoranda would, in effect, become a code of practice as to when the principal regulator would notify other regulators of its findings in respect of a particular pharmacy inspection, and under what circumstances other regulators might take action without prior

reference to the principal regulator. Such administrative agreements could, if desirable, be underpinned by an administrative or legislative duty of co-operation on all relevant inspection bodies.

### CBA of option 3

There may be some small transitional costs associated with amending legislation, or through the drawing up and agreement of administrative protocols or memoranda of understanding. On the latter, there is existing activity to agree memoranda of understanding between the GPhC and other organisations. This has come in part as a natural consequence of the new NHS architecture, as well as the GPhC being a relatively new organisation in the pharmacy landscape. Therefore, for simplicity it is assumed that as these actions are already in train, there are no direct, additional, transitional costs associated with option 3.

On permanent costs, whilst it is difficult to predict how the GPhC may alter its activities as a result of a need to act as a principal regulator, it is reasonable to expect the GPhC to dedicate some human resource to these requirements. Thus, it is assumed that this role would require a small amount of dedicated resource, equivalent to 0.25 of a WTE staff member. For sensitivity analysis, in the lower scenario this is assumed to be 0.1 WTE, and 0.5 WTE for the upper scenario. Assuming a business cost of £50,000 per annum for this staff member leads to an annual cost of £12,500, or £60,000 discounted over a five-year period.

One might expect the benefits of option 3 to include a general improvement in working relationships between organisations, which will improve the overall regulatory horizon. In essence, this might mean, in practice, whenever an inspection does take place, it is founded from a stronger evidence base than under the current arrangements. Second, with an evolving culture of information sharing between organisations, this will limit the risk of duplication of effort. In quantitative benefit terms, this might lead to a reduction in inspection activity in pharmacies, where it would be deemed unnecessary. Thus, pharmacies would be subject to less time undertaking inspection activities, and inspecting organisations can dedicate more time to other inspections that are in line with their own methodology or risk-groupings. Whilst we might not expect a cash-releasing benefit in the inspecting organisation, as a minimum pharmacy businesses would have to undergo fewer inspections, and therefore this opportunity cost of time saved can be monetised as a benefit.

Using the opportunity cost of time from option 1, and making adjustments contingent on the scenario – i.e. a five (5) per cent reduction in the total number of inspections in the central scenario, and a one (1) per cent reduction in the lower and a ten (10) per cent reduction in the upper scenario – some potential benefits of this option are calculated.

The central scenario reduces inspections by 5 per cent. In practice, for Trading Standards this is a reduction of 71 inspections per annum, at an average (opportunity) cost of £46.24 per inspection. The biggest reduction would be around NHS England inspections, with a reduction of 129 inspections, at an average (opportunity) cost of £200 per inspection. Finally, there would be 80 fewer Environmental Health inspections, at £50 (opportunity cost) per inspection. This would lead to an approximate saving of £20,000 per annum, or £90,000 over a five-year period.

#### Central scenario

<i>Inspecting organisation</i>	Average staff salary and on cost per inspection	Probability of inspection per annum	Projected number of inspections per annum	New projected number of inspections (-5%)	Aggregate cost of inspections	Adjusted Aggregate Cost
<b>Trading Standards</b>	£46.24	13%	1,405	1,334	£60,000	£60,000
<b>NHS England</b>	£199.67	23%	2,563	2,434	£510,000	£490,000
<b>HSE</b>	£0.00	0%	0	0	£0	£0
<b>Environmental Health</b>	£50.07	14%	1,605	1,525	£80,000	£80,000
<b>CQC</b>	£0.00	0%	0	0	£0	£0

Total Cost of inspections per annum (i.e. BENEFIT SAVED TO PHARMACY)

**£650,000**      **£630,000**

Saving

**£20,000**

5-year discounted      **£90,000**

The lower scenario reduces inspections by 1 per cent, and leads to minor reductions in opportunity cost of staff time, estimated to be approximately £10,000 per annum, see below.

Lower Scenario

<i>Inspecting organisation</i>	Average staff salary and on cost per inspection	Probability of inspection per annum	Projected number of inspections per annum	New projected number of inspections (-1%)	Aggregate cost of inspections	Adjusted Aggregate Cost
<b>Trading Standards</b>	£46.24	4%	394	390	£20,000	£20,000
<b>NHS England</b>	£199.67	15%	1,685	1,669	£340,000	£330,000
<b>HSE</b>	£0.00	0%	0	0	£0	£0
<b>Environmental Health</b>	£50.07	5%	591	585	£30,000	£30,000
<b>CQC</b>	£0.00	0%	0	0	£0	£0

Total Cost of inspections per annum (i.e. BENEFIT SAVED TO PHARMACY)

Saving

<b>£390,000</b>	<b>£380,000</b>
	<b>£10,000</b>
5-year discounted	<b>£50,000</b>

The upper scenario, based upon option 1, involves a higher level of inspection activity. Therefore, a 10 per cent reduction in this higher figure, leads to a bigger reduction in inspections. This equates to a larger potential saving (benefit) to pharmacy businesses of approximately £170,000 to business.

Upper Scenario

<i>Inspecting organisation</i>	Average staff salary and on cost per inspection	Probability of inspection per annum	Projected number of inspections per annum	New projected number of inspections (-10%)	Aggregate cost of inspections	Adjusted Aggregate Cost
<b>Trading Standards</b>	£55.49	20%	2,247	2,022	£120,000	£110,000
<b>NHS England</b>	£239.60	50%	5,618	5,056	£1,350,000	£1,210,000
<b>HSE</b>	£57.79	1%	112	101	£10,000	£10,000
<b>Environmental Health</b>	£60.08	20%	2,247	2,022	£140,000	£120,000
<b>CQC</b>	£239.60	2%	225	202	£50,000	£50,000

Total Cost of inspections per annum (i.e. BENEFIT SAVED TO PHARMACY)

Saving

<b>£1,670,000</b>	<b>£1,500,000</b>
	<b>£170,000</b>
5-year discounted	<b>£790,000</b>

In summary, option 3 is estimated to generate a small, but positive, net benefit overall.

<b>Summary - costs/benefits of option 3</b>	<i>Sensitivity Analysis</i>		
	<b>Central</b>	<b>Lower</b>	<b>Upper</b>
Opportunity cost time saved to business p/a	£20,000	£10,000	£170,000
Cost to GPhC	£12,500	£5,000	£25,000
Net benefit/(-cost) p/a	£7,500	£5,000	£145,000
Discounted 5-year Net Benefit/(-Cost)	<b>£35,000</b>	£20,000	£680,000

Whilst there could be some redistribution of cost, where the GPhC have to recruit more staff and/or have to rebalance their existing staff workload, this could either have a direct cash or opportunity cost. It is unclear first of all to what extent the GPhC would need extra staff, and second in the event of doing so, whether they would recruit additional staff or simply re-programme existing staff workload. This could be offset by the potential benefit to pharmacy businesses from less duplication of inspection activity, and crucially fewer unnecessary inspections overall. Over a five-year period, the estimated benefit is in the order of £35,000. Crucially, if this mechanism worked well, the sharing of information and better targeting of inspections would generate greater net benefit, per inspection. This is likely to be cumulative over time. For the purpose of proportionality, such benefits have not been quantified.

*Qualitative costs, benefits, risks and wider impacts:*

In general, this option is likely to improve the sharing of information between organisations, and gives one organisation – the GPhC – responsibility to lead the process of inspection. What might result are reductions in the duplication of activity, and thus a moderate reduction in regulatory requirements on pharmacy businesses, simplifying the system for all inspection organisations and pharmacy businesses. Referring back to the results of the contractor survey, one-third of respondents believe that half or more of the inspections

they have to undertake involve duplication. Whilst certain organisations have been considered as out of scope to the analysis of options to this point, it is not impossible, within the confines of option 3, for there to be similar arrangements between the GPhC, MHRA, Home Office and NHS Protect, which may further improve the inspection environment, with pharmacy businesses being the main beneficiary.

#### **Option 4: Establish a self-assessment compliance regime for pharmacies.**

Option 4 would mean all community pharmacies submit annual (or longer period) returns to the relevant regulatory body, providing an overview of compliance with the specific regulatory regimes and any risks. This would build on a model first road tested in Wales in 2005 and now adopted by Welsh Health Boards. As a result, NHS pharmacy contractors can now expect NHS inspections every three to four years in Wales. Option 4 assumes a slightly broader self-assessment regime to the one in effect in Wales, which only focuses on NHS pharmaceutical services.

#### **CBA of option 4**

There is no evidence on the amount of effort required by pharmacy businesses to complete a self-assessment, relative to the existing arrangements. Without such evidence, it is difficult to complete a meaningful quantitative analysis of option 4. It is assumed that in the central scenario, one might achieve net benefits similar to the order of magnitude of option 3, i.e. a small, positive net benefit.

#### *Qualitative costs, benefits, risks and wider impacts:*

A potential benefit to option 4 benefit would be to help inspection bodies better assess compliance across the sector and build up a core set of data which can be used for better targeting of those that need inspecting. Another benefit would be that businesses with multiple sites would also be able to develop or enhance internal quality assurance programmes for compliance. However, there is nothing to stop business doing this anyway without a need for government intervention if it were a useful organisational tool.

This option may reduce the regulatory requirements, in respect of the breadth of organisations to deal with, but it may also increase the tangible administrative burden on pharmacy businesses through the need to complete a lengthy questionnaire once a year, covering all aspects of their regulatory activity. This may require better record keeping, although this might only be felt in pockets of the sector where the standard of operating procedures and quality management systems are less developed. However, such a move may have wider benefits to the delivery of pharmaceutical services overall. On the general requirements, there may be a need for some testing of a system to see how well it operates, and what resources would be required to deliver it effectively in practice.

This option might leave the door open to some risks and potential unintended consequences to patient/consumer protection and public health. This might be tempered by the requirement to provide periodic returns to the GPhC, and the likelihood that any adverse situation could have major negative reputational consequences to an individual business or body corporate. In addition, this option scores less well on operational viability, in light of the time taken to develop a system in Wales.

From the legislative end, it would require some alteration of existing legislation, to exclude pharmacies from wider inspection powers. However, it is likely that lessons could be learned from this system to speed up the transition.

This is justified in a number of ways. First, some pharmacies may already have well-developed procedures, which with minor amendments, make it easier to complete a self-assessment, relative to the random probability of being inspected. However, the benefits may be unevenly distributed across the sector in the short-term. Second, over time, other pharmacies may be expected to develop such systems, and would therefore benefit from self-assessment. Finally, much like in option 3, the nature of the system reduces unnecessary duplication and the overall number of inspections.

#### **Summary of findings – criteria analysis:**

In summary, from a quantitative CBA perspective, options 1 and 2 are projected to generate negative net benefits. In the case of option 1, the risks associated with failure to monitor and inspect NHS contractual arrangements may lead to some large costs, which would impact on the quality of pharmaceutical

service delivered in England. Option 2 would lead to a direct transfer of cost to the GPhC, without necessarily generating tangible benefits.

Options 3 and 4 are estimated to be equivalent in cost-benefit terms, and most likely would generate moderate positive net benefits, through better working arrangements, information provision, and reduced duplication of inspection activity.

As a next step, scoring (subjectively) these options against the full range of criteria, option 3 scores best, followed by option 4, which also has a positive overall score. Option 2 comes out neutrally, and option 1 has a negative score. A simple scoring system has been used, and if appropriate, some form of weighting of criteria could also be considered.

Options Criteria Analysis	a) Impact on regulatory requirements	b) Impact on administration of regulatory requirements	c) Impact on legislative requirements	d) Impact on costs/resources to business	e) Impact on costs/resources to regulators/inspection bodies	f) Impact on maintaining/improving patient/consumer protection and public health	g) Impact on operational feasibility	Aggregate Scores
1) Remove all inspection powers from all bodies except for the pharmacy regulator (the General Pharmaceutical Council (GPhC))	+++	+	--	++	+	---	---	-1
2) Legislate for a body, such as the GPhC, to be the single regulator and inspector for pharmacies	+	+ -	-	+	-	+ -	+ -	0
3) A body, such as the GPhC, to be the principal regulator of pharmacies, except in tightly defined circumstances where other inspectors also had a role.	+	+	+ -	+	+	+ -	++	6
4) Establish a self-assessment compliance regime for pharmacies	++	+ -	++	+ -	+	-	-	3

SCORING KEY:		
+	-	Neutral outcome (0)
-		Slightly negative (-1)
--		Fairly Negative (-2)
---		Very negative (-3)
+		Slightly positive (+1)
++		Fairly Positive (+2)
+++		Very positive (+3)

Option 1 is clearly the most unbalanced option against the criterion. Whilst it scores very well in reducing regulatory impacts and costs to business, it would come at risk to maintaining and improving patient, consumer protection and public health. It would essentially create an anomaly between different NHS primary care contractors, where pharmacies would not be subject to appropriate monitoring and inspection to ensure they are meeting their contractual terms and conditions. Moreover, in terms of plausibility, this option would leave open the door to perverse incentives and potential gaming that would have significant second-order impacts. In both cases, these issues were scored as severely negative.

Option 2 may have a slightly positive impact on the regulatory environment. However, there are fairly low levels of activity in pharmacies across a number of inspection areas, although it assumes a transfer of these responsibilities to the GPhC. It is likely to be neutral around administrative burdens overall, but would require some legislation. As pharmacy businesses would have one point of reference around the entire regulatory environment, it is fair to assume a slight reduction in costs to business. From the regulator perspective, there are distributional impacts, with greater emphasis on one organisation to take the lead (the GPhC), relative to other organisations, which is a direct cost impact (covered in the CBA). In light of these outcomes, one might expect little tangible change to the current level of maintaining and improving patient, consumer protection and public health, and in practice may operate with little tangible difference to current arrangements (partly due to low levels of inspection activity in a number of areas.)

Option 3 appears to be the most balanced and attractive option. Against the various criteria it scores predominantly positively, although slightly positive, and would not appear to have any obvious negative features. For example, it is expected to moderately reduce regulatory requirements, administration and pharmacy business costs. It assumes that there would be no tangible change in these outcomes, and

this criterion therefore scores neutrally. This option is operationally viable, and scores well in this dimension.

Option 4 scores well on reducing regulatory and legislative requirements, and overall would be expected to reduce the costs to regulators. This option is likely to be slightly positive or neutral surrounding administration requirements – it would appear that the work required would change, and when this work is required – which in some cases would increase workload, and in other cases reduce workload (e.g. inspections that only occur once every 4-5 years). This option scores slightly negatively around maintaining and improving patient, consumer protection and public health. In practice, this may be less problematic, but at this point in time, without more evidence, a risk remains on what might occur in practice. Operationally, this option may work, but it might take some time, and some upfront regulatory burden, to work in practice. Hence, the slightly negative score against criterion (g).

**Identification of a preferred policy option:**

**In light of the CBA and criteria analysis work, on balance, option 3 would appear to offer the best balance of expected outcomes to meet the overarching aims and objectives of the policy intent. Namely, option 3 is likely to demonstrate an improvement in the level and quality of inspection activity, should promote better working relationships and information sharing between organisations with mutual interests, and can be achieved at relatively low cost and burden to the various stakeholders involved. In economic terms, it is expected to generate a small, but positive, net benefit, which may increase cumulatively over time.**

*Future review of preferred option:*

It is recommended that the outcome of this work is reviewed in two years' time, to measure the impact of the preferred option. In addition, in agreeing the policy decision, the Department of Health, working with stakeholders, will review and report back to the Cabinet Office on progress by the end of the financial year where this decision was taken (2013/14).

## **ANNEX A - Risks and assumptions**

- 1.** The main area for consideration is the strength of the assumptions used in the CBA. These assumptions are predominantly driven by the evidence collected through the contractor survey, interviews with inspecting organisations, and other stakeholder meetings.
- 2.** Inevitably, the actual monetised values of nation-wide inspection activity could vary over time, and may be subject to larger fluctuations as and when there is a need for specific inspection activity. For example, where some risk-based measures pick up an issue that requires deeper investigation.
- 3.** The survey data collected is a snapshot of activity at a point in time, and is based on a small number of observations. In addition, the survey responses are not entirely representative of the make-up of the pharmacy sector. Therefore, one cannot be entirely confident in these results, without a more statistically robust sample being available.
- 4.** Hence, the true situation may be slightly different in practice, compared to the figures presented here.
- 5.** However, and crucially, it is unlikely that the basic findings of the analysis would be markedly different, as there is a degree of consistency in the analysis, e.g. the same evidence is used in different options, and therefore if different data would come to light, this would apply across all options, to some extent.
- 6.** The analysis also considered the qualitative aspects of proposed options, using a criteria analysis, and found that the preferred option, option 3, was most preferable in this analysis as well. Finally, this option is also the closest fit to the feedback provided by stakeholders, and therefore meets the basic policy intent.

## ANNEX B

### Overview of inspection functions and powers in respect of pharmacies and their activities in Great Britain

Medicines legislation (e.g. Medicines Act 1968 and Human Medicines Regulations 2012/1916, Misuse of Drugs Act 1971)	Pharmacy premises (e.g. Pharmacy Order)	NHS contractual activity (e.g. under the NHS (Pharmaceutical Services) Regulations 2013)
<p>MHRA – inspect if a pharmacy is manufacturing or wholesaling medicines. Also inspect for possible breaches of sale and supply of medicines.</p> <p>The Home Office Drugs Inspectorate inspects where a pharmacy is licensed to deal wholesale in controlled drugs (such as morphine).</p> <p>The General Pharmaceutical Council (GPhC) inspects in relation to the standard reassembly of medicines on the premises, the preparation of unlicensed “specials” medicines which require a particular formulation or strength not commonly available and other matters.</p>	<p>The GPhC registers and inspects all retail pharmacy premises (including distance selling or internet-only pharmacies) in GB. It also inspects for compliance with the safe management and use of controlled drugs (such as morphine) on the premises.</p> <p><u>Local authorities:</u> Environmental Health Officers inspect in relation to environmental or health and public safety concerns.</p> <p>Trading Standards inspect under various powers. Food Standards Agency inspect for compliance with food safety (e.g. baby foods).</p> <p>Health and Safety Executive can inspect alongside LA inspectors for compliance with health and safety legislation</p> <p>The police have general powers of entry.</p> <p>The CQC can inspect if the pharmacy wishes to expand into new healthcare services which require registration with the CQC.</p> <p>HMRC inspects e.g. in relation to tax and VAT matters.</p>	<p>The NHS Commissioning Board inspects to ensure compliance with NHS contractual requirements. (The NHS Commissioning Board is looking to work closely with the GPhC to avoid duplication.)</p> <p>Authorised representatives of local Healthwatch organisations are authorised to enter and view NHS pharmacy premises to observe activities but this is not viewed as “inspection” by DH policy. NHS Protect (counter-fraud operations) can enter premises with police officers if included on a warrant.</p>