Title: Impact assessment: Rebalancing medicines legislation and pharmacy regulation programme: Dispensing errors – registered pharmacies **IA Number:** DH6001 **RPC Reference No:** **RPC-DH-3099(1)** **Lead department or agency:** Department of Health **Other departments or agencies:** Medicines and Healthcare products Regulatory Agency, Devolved Administrations, NHS England	**Impact Assessment (IA)** **Date:** November 2017 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:** Stephen.Knight@dh.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: GREEN

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
£0.87m	£0.17m	£0.0m	Out of Scope	Qualifying provision

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

The criminalisation of dispensing errors was originally enacted as one aspect of consumer protection offences which were intended to support the best interests of the patient. However, there is evidence that fear of prosecution has a counter-productive effect on patient safety as it deters reporting of errors by pharmacy professionals (pharmacists and pharmacy technicians) and pharmacies – who are, in any case, regulated by the pharmacy regulators. Government intervention is therefore required to amend legislation which criminalises such errors to enable increased reporting of errors by pharmacy professionals and pharmacies, in order to maximise patient safety.

What are the policy objectives and the intended effects?

The objective is to amend the current legislative regime, such that pharmacy professionals do not experience a needless fear of prosecution and are not deterred from reporting errors, so that there is more reporting and learning from errors to improve patient and consumer safety, and improve the services provided by pharmacy professionals. The objective is to remove this fear from all the phases of activity that come under the general heading of "dispensing", and so from receipt of the prescription/directions through preparation or assembly to the sale or supply of the dispensed medicine(s).

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

- Option 1: Do Nothing
- Option 2: Remove the criminal sanctions concerning adulteration, sale or supply from the Medicines Act 1968
- Option 3: Introduce an exemption from criminal liability where an inadvertent dispensing error occurs when a pharmacy professional is acting in the course of their profession
- Option 4: Strengthen existing guidance to explain more clearly the grounds under which prosecutions may occur

Option 3 is preferred because it reduces the deterrence on pharmacists and pharmacy technicians from reporting errors, while retaining sanctions over other suppliers of medicines that are not subject to professional regulation. The consultation confirmed wide support for this option.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 5 years after enactment

Does implementation go beyond minimum EU requirements?		N/A		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

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

Signed by the responsible Minister: Steve Brine ***Date*** 6/11/17

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

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

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

N/A

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

N/A

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

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

N/A

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

N/A

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

N/A

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

Summary: Analysis & Evidence

Policy Option 2

- **Description:** Remove the criminal sanctions concerning adulteration, sale or supply from the Medicines Act 1968

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** £0M

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

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

This policy option is not analysed in detail, as it is expected to increase risks to patients, by removing the safeguard of liability to prosecution from other suppliers of medicines, including those not subject to professional regulation, and not just pharmacies.

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

Patient safety risks are increased, as the power to prosecute for medicine supply errors is removed from all suppliers of medicines, including those not subject to professional regulation, not just pharmacy professionals.

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

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

This policy option is not analysed in detail, as it is expected to increase risks to patients, by removing the safeguard of liability to prosecution from all suppliers of medicines, including those not subject to professional regulation, not just pharmacy professionals.

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

Removal of the fear of prosecution, where appropriate, in respect of reporting errors in the sale and supply of medicines, including dispensing errors.
Support improved evidence collection to drive patient safety initiatives.

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

Potential increase in risks to patient safety and removal of policy tools to deter malpractices from non-regulated entities are considered likely to outweigh any potential benefit from transparency.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	**Benefits: 0**	**Net: 0**	

Summary: Analysis & Evidence

Policy Option 3

Description: Introduce an exemption from criminal liability where an inadvertent dispensing error occurs when a pharmacy professional is acting in the course of their profession

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0.87

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	0.4		0.6	**5.1**

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

Costs taken into account and monetised focused on those potentially incurred by pharmacy businesses only. These refer to the direct costs of staff familiarisation with the new policy and the indirect costs of an increase in reported dispensed errors.

No direct costs to the consumer were identified.

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

Costs to the professional regulator and prosecution agencies of creating a new defence (an administrative cost).

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0.0		0.7	**6.0**

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

Benefits taken into account and monetised focused on those potentially incurred by pharmacy businesses only. These refer mainly to the direct benefit from the reduction in the risk of prosecution and indirect cost-savings from the handling of fewer errors, as a result of increased reporting and from learning from errors and greater transparency.

No direct benefits to the consumer were identified.

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

Increased efficiency in dealing with dispensing error cases leading to cost-savings to businesses, as it reduces temporary staff replacement costs.

Patient safety benefit from increased reporting and learning from dispensing errors.

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

Real wages are assumed to increase by 1% per year; Dispensing error reports to increase by 20% of currently unreported errors, following reduced risk of prosecution; Learning as a result of increased information availability leads to 30% *fewer errors being made*; Additional time needed for staff to familiarize themselves with legislation whilst at work is 20 minutes; Individuals and companies' value of the risk of prosecutions is reflected in their legal and insurance costs; The number of pharmacy professionals grows at the same rate as annual population growth (0.7%). NB: We received wide support regarding the credibility of these assumptions from responses to consultation.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0.0	**Benefits:** 0.1	**Net: 0.0**	0.0

Summary: Analysis & Evidence

Policy Option 4

Description: Strengthen existing guidance to explain more clearly the grounds under which prosecutions may occur

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

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

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

N/A

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

Current training and guidance (the Crown Prosecution Service (CPS) is expected to issue an update to this guidance) is already assumed to be adequate and as a result there is little difference in the costs for this option compared to option 1 of "do nothing".

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

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

N/A

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

It is assumed that current training and guidance is already adequate and as a result there is little difference in the benefits compared to option 1 of "do nothing".

Key assumptions/sensitivities/risks

Discount rate (%) N/A

N/A

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

Evidence Base (for summary sheets)

Rebalancing Medicines Legislation and Pharmacy Regulation –

Overarching policy background

Purpose and rationale

1. The Rebalancing Medicines Legislation and Pharmacy Regulation programme was set up by the Department of Health (DH - England) – on behalf of all UK Health Ministries.

2. Its purpose is to examine the respective scope of current UK legislation and regulation, and the relationship between them, in order to:

   - ensure these are optimally designed to provide safety for the users of pharmacy services;
   - facilitate, and reduce the barriers to, the development of professional practice; and
   - promote innovation and a systematic approach to quality in pharmacy.

3. Government intervention is necessary in order to make changes to the legislative frameworks involved to achieve these objectives.

4. These changes cannot be delivered through conventional market mechanisms (price, exchange, permits, quotas) or some other mechanism that does not involve legislation.

5. There are other sanctions and penalties in UK medicines legislation which are not the subject of this Impact Assessment. Responsibility for reviewing such offences lies with the Medicines and Healthcare products Regulatory Agency (MHRA).

Establishment of a Programme Board

6. A Programme Board was established in May 2013, chaired by Ken Jarrold, CBE, to consider how best to deliver the objectives. Its role is to:

   - advise Ministers and the devolved administrations (Scotland, Wales and Northern Ireland) on the development of policy within the terms of reference set for the board. The full terms of reference for the Board are available at: (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/193999/TERMS_OF_REFERENCE.pdf; and
   - oversee the implementation of policy outcomes agreed by Ministers and the devolved administrations.

7. The Board's work includes to:

   "(i) build on and propose amendments to legislation, as required, to deliver a modern approach to regulation which maintains patient and public safety, whilst supporting professional and quality systems development, including learning from dispensing errors made in registered pharmacies;

   (ii) examine the legislative and regulatory framework for pharmacy premises to make recommendations that strengthen the professional regulatory framework as required, with a view to mitigating identified risks while ensuring:

   - the effectiveness of components of the system which support patient safety, such as the role of superintendent and the responsible pharmacist;

- the legislative and regulatory framework for pharmacy premises supports the development and maintenance of a quality systems approach to pharmacy practice;

(iii) build on these foundations to address in parallel medicines and professional regulatory matters (e.g. supervision), which are considered to restrict full use of the skills of registered pharmacists and registered pharmacy technicians, impede the deployment of modern technologies and put disproportionate or unnecessary obstacles in the way of new models of service delivery by and/or involving pharmacy;

(iv) set out the principles underlying policy recommendations about the future scope of pharmacy regulation, ensuring that these are in line with the principles of good regulation."

The elements of the Board's programme

8. The Rebalancing programme of work comprises a number of linked, but distinct, elements with complementary, but differing, objectives.

9. In summary, these are:

a. Dispensing Errors: to review the criminal offences under the Medicines Act 1968 ("the Act") that could be used to prosecute a dispensing error by a regulated pharmacy professional operating from regulated pharmacy premises. The threat of such criminal sanctions is widely believed to hinder the reporting of errors and therefore wider learning. There is evidence that improving the rate of reporting and learning from such errors supports better patient safety and improves the quality of service provision.

b. Responsible Pharmacist: a responsible pharmacist (RP) is the pharmacist in operational charge of an individual retail pharmacy at any one time. The requirements for RPs in the UK are set out in section 72A of the Medicines Act 1968 and in regulations – The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 (SI 2008/2789). They came into force on 1st October 2009. These were evaluated in a study commissioned by the Royal Pharmaceutical Society of Great Britain (RPSGB) and the Pharmaceutical Society of Northern Ireland (PSNI) in 2011. Whilst awareness was high, a number of implementation and operational problems were reported, with concerns that the requirements were leading to more defensive professional practices. In 2012, these regulations were included as part of the Department of Health's Medicines phase of the "Red Tape Challenge", co-ordinated by Cabinet Office. The current Government's policy is to avoid, where possible, detailed legislation which regulates professional activity. The Board has examined the scope for reducing (or removing) the detail within the regulations and whether more could be done via professional rules or standards instead of Government regulations.

c. Superintendent Pharmacist: A superintendent pharmacist (SP) is the professional lead in a retail pharmacy business that is run by a "body corporate" rather than a partnership or individual pharmacist. The SP currently has overarching responsibility for the management of the sale and supply of prescription only and pharmacy medicines by the "retail pharmacy business" of the body corporate. The Board has been examining the current legislative framework for SPs (as amended by the Health Act 2006) in terms of the effectiveness of these requirements in supporting patient safety and the scope to remove and/or replace them with equivalent professional standards to provide greater clarity for the role, accountability and required professional competences.

d. Hospital Pharmacies: The Board is also considering the legislative requirements for hospital pharmacies (whether publicly or privately funded) under the Act. The supply of medicines by hospital pharmacies does not, for the most part, require the registration of the hospital pharmacy's premises with the General Pharmaceutical Council (GPhC) or PSNI, although regulated activities at those pharmacies may, in England, be subject to alternative licensing arrangements by the Care Quality Commission and other arrangements for system regulation in Scotland, Northern Ireland and Wales. Nonetheless, all hospital pharmacy professionals are subject to professional standards and regulation in the normal way. The Board's work is designed to underpin high quality hospital pharmacy services and enable the removal of the criminal sanction for preparation or dispensing errors for pharmacy

professionals in hospitals and other parallel working environments where appropriate system regulation is in place.

e. Pharmacy Supervision: Building on the elements above, the Board has been asked to develop proposals regarding the requirements, under the Human Medicines Regulations 2012, for pharmacy professionals to supervise medicines preparation and assembly, and individual transactions in pharmacies which involve the supply of prescription only or pharmacy medicines. The aim is to identify and review all legislative requirements which may:

- restrict the full use of the skills and expertise of registered pharmacists and registered pharmacy technicians;
- impede the deployment of modern technologies; or
- put unnecessary obstacles in the way of developing new models of pharmacy services and pharmaceutical care.

Registered pharmacy standards

10. Separately, the GPhC, which administers the professional and premises registration requirements under the Pharmacy Order 2010 for England, Wales and Scotland, will have a system whereby pharmacy owners meet agreed requirements for pharmacy premises through registration standards that are set in a code of practice, rather than legislative rules. The PSNI (the equivalent body for Northern Ireland), which currently has standards for registered pharmacies but no statutory basis for them, supports this approach and will also move to a statutory code of practice. New specifically modelled powers to draw up codes of practice will facilitate the regulators to implement a pharmacy inspection regime based on the outcomes achieved at the premises. The GPhC has also requested express powers to enable the publication of inspection reports. The Government supports these aims. The Board incorporated these proposals as part of the Rebalancing programme and supported them. The Pharmacy (Premises Standards, Information Obligations etc.) Order 2016 (S.I. 2016/372) enables these changes.

Organisation of the overall programme

11. To ensure this overall programme is manageable, the elements in paragraphs 9(a) and 10 above comprise the first phase of the Board's work. Hospital pharmacies and proposals for Superintendent Pharmacists and Responsible Pharmacists are being considered separately to this Order. The final phase will cover pharmacy supervision requirements.

Impact Assessment 1: Dispensing Errors

1. The following options have been identified. They are not mutually exclusive. The quantification and monetisation of the potential impacts are considered in the Economic Analysis section at paragraphs 45 onwards.

Option 1: Do Nothing

Option 1 is the default "do nothing" option. No changes to the existing legislative framework occur. Whilst no new costs arise, no benefits have been identified. This option is not considered further.

Option 2: Remove the criminal sanctions concerning preparation, sales or supplies of adulterated products, or sales or supplies on prescription of products not of the nature or quality demanded by the purchaser/patient ,from the Medicines Act 1968 (i.e. simply repealing sections 63 and 64 of the Medicines Act 1968)

Option 2 would remove all criminal sanctions relating to a dispensing error by a pharmacy professional from the Act, as well as criminal sanctions relating to acts of sale and supply where the wrong medicine (in terms e.g. of dosage, form, strength or validity) or a medicine of unsuitable quality was supplied by a non-pharmacy professional e.g. a shop or via the internet. The general criminal law offences for dealing with the most serious cases – for example, where an error causes death - would still stand as would potential civil liability under negligence law.

Option 3: Introduce an exemption from criminal liability where an inadvertent dispensing error occurs when a pharmacy professional is acting in the course of their profession

Option 3 would introduce a new legislative provision whereby, if a pharmacy professional makes a dispensing error at a registered pharmacy while acting in the course of their profession, it would be exempt from the criminal sanctions in the Act, unless they had used their professional skills for an improper purpose or shown a deliberate disregard of patient safety. It would not otherwise change the relevant offences, which would continue un-amended.

Option 4: Strengthen existing guidance to explain more clearly the grounds under which prosecutions may occur

Option 4 is a non-legislative solution. The Crown Prosecution Service (CPS) has produced guidance on the circumstances under which a prosecution may occur under the Act.

Definition of dispensing error

2. "Dispensing error" is used in this IA as short-hand for a number of mistakes that could lead to prosecution under section 63 or 64 of the Medicines Act 1968. Section 63 is targeted essentially at adulteration of products – either mistakes in the preparation of a medicine or deliberate adulteration of the product. If that product is to be sold or supplied, in the general run of cases, prosecution would also be possible under section 64 – supplies in NHS hospitals pursuant to a direction being an exception to that. However, generally, it is section 64 that is used where an error is identified and a prosecution is being considered. The recording systems for errors use different terminology. The National Reporting and Learning Systems (NRLS) is a central database of patient safety incident reports, run by NHS Improvement. It defines a 'patient safety incident' (PSI) as "any unintended or unexpected incident, which could have or did lead to harm for one or more patients receiving NHS care." Dispensing errors are a subset of PSIs, where the error has impacted on a patient.

3. There is no universal definition of a dispensing error. However, for the purposes of consulting and this IA, they chiefly comprise errors made during the dispensing process. An error can occur at any time from receipt of the prescription/direction through preparation or assembly to the supply of the dispensed medicine(s).

Where and how errors occur

4. Errors may be detected and corrected within the pharmacy. These are termed "prevented" dispensing errors, or "near misses". Except where a medicinal product is adulterated, errors which are picked up before a medicine is supplied to the patient are not subject to a criminal sanction. Other errors, however, may not be detected until after the medicine has left the pharmacy. Further general background information is given in **Annex A**.

5. Most dispensed medicines are manufactured away from the pharmacy. However, on occasion, pharmacists may have to make up ("compound") a medicine from ingredients on the premises. In doing so, if an ingredient is omitted or added in error, which adulterates the medicine supplied, then this is a criminal offence as it contravenes section 63 of the Act. If the medicine dispensed is not of the nature or quality intended, for example because an error has been made, this too is a criminal offence as it contravenes section 64 of the Act.

6. A pharmacy professional who makes an error in selling a medicine, or supplying a medicine in pursuance of a prescription (whether NHS or private), is guilty of a criminal offence under section 64 of the Act. As with many of the offences relating to medicines, this is a strict liability offence. The very fact that a wrong medicine is supplied means a criminal offence has been committed. The legislation does not distinguish between classes or types of error. Therefore, a dispensing error occurs if there is a simple mistake in a patient's name, meaning the patient takes a medicine intended for someone else instead of the one they have been prescribed, or a medicine supplied is incorrect or wrongly compounded.

The provisions of the Act relating to offences concerning the supply of medicines

7. Section 63 of the Act relates to the adulteration of medicines. It says that

   "No person shall –

   (a) add any substance to, or abstract any substance from, a medicinal product so as to affect injuriously the composition of the product, with intent that the product shall be sold or supplied in that state; or

   (b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance.

8. Section 64 of the Act is designed to protect consumers and patients. It says that:

   "(1) No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser."

9. Section 64(5) of the Act applies this protection to patients who are dispensed medicines against a prescription. Sections 64(2) – (4) of the Act allow for three exemptions to these protections – where a product is supplied for research or examination purposes, where a product contains some extraneous matter as an inevitable consequence of the manufacturing process or where something has been added or taken away from a medicine but (a) that was not done fraudulently, and (b) that did not affect its composition injuriously, and (c) the medicine is supplied with a conspicuous warning notice to alert the buyer or patient.

10. Section 67(2) of the Act specifies that people who contravene Sections 63 or 64 are guilty of an offence. Under section 67(4), the penalties for those found guilty can be a fine or imprisonment for up to two years or both.

Liability for errors and prosecutions under the Act

11. Whilst most attention has focused on the concerns of pharmacists, these provisions are framed so that they can apply to a range of other healthcare professionals and businesses as appropriate, including manufacturers, hospitals, herbalists and generalist retailers. In short they can apply to anyone involved in the supply of medicines.

12. In practice, however, there have been very few prosecutions for dispensing errors in recent years. The MHRA has prosecuted three times since 2003. Only one of these cases involved a pharmacist: the other two related to prosecutions of a hospital and an herbal medicine practitioner. The MHRA has investigated two other cases which both concerned the mis-dispensing of a powerful pain killer, one by a pharmacist, the other in a hospital. In both cases, it was decided that a prosecution was not in the public interest. Incidents currently under investigation are not covered in this Impact Assessment.

13. The CPS (and Public Prosecution Service for Northern Ireland (PPS)) is believed to have brought a similarly low number of prosecutions. The CPS is usually alerted following a referral from the police investigating a fatality. The Code for Crown Prosecutors requires that all cases must pass a two stage test before a prosecution may be commenced. The prosecutor must first be satisfied that the evidence on the file is sufficient to give rise to a realistic prospect of conviction. Only if satisfied does the second stage begin – whether a prosecution is in the public interest. The public interest test involves consideration of various factors including the degree of negligence or intent in committing the error, its seriousness and consequences and the actions the individual pharmacist or others involved took at the time. The CPS has published guidance for its prosecutors setting out the criteria they should apply when considering cases involving errors and in particular where these relate to mis-dispensing by pharmacists. This is available at: http://www.cps.gov.uk/news/latest_news/cps_publishes_guidance_on_prosecuting_medicines_act_offences_where_a_dispensing_error_has_occurred_/index.html

> ***Case study***
> *A locum pharmacist dispensed propranolol (a beta-blocking drug used to treat various heart conditions) instead of prednisolone (a steroid) in 2007. The patient subsequently died. However, the dispensing error was not the cause of death. The CPS prosecuted. The defendant pleaded guilty in 2009 to an offence under Section 85(5) of the Act for a labelling mistake and was given a suspended sentence of 3 months' imprisonment. On appeal in 2010, the Court of Appeal ruled that the defendant could not be prosecuted under section 85(5) because, in effect, the provision could only be used to prosecute businesses. However, the Court of Appeal substituted the defendant's conviction under section 85(5) with a conviction under section 64, a suspended custodial sentence and a fine of £300.*

The perceived impacts

14. Whilst the appeal ruling in the above case indicated the likelihood of a custodial sentence being suspended in cases of inadvertent error similar to this, the original judgment and appeal raised awareness of the risks and created considerable parliamentary, media and professional concern. In its *Insight* publication in summer 2009, the Chairman of the Pharmacist Defence Association said (www.the-pda.org)

> *"Inappropriate use of the criminal sanction will lead to defensive practice; less innovation, fewer professional decisions and will harm new service provision. Surveys show that 40% of pharmacists may no longer be making error log reports for fear of incriminating themselves."*

15. During the passage of the Health and Social Care Bill in 2011, Earl Howe, the Parliamentary Under-Secretary of State for Quality at the Department of Health, committed to review the legislation so that criminal liability did not arise for genuine dispensing errors. Although the evidence to date suggests that the risk of prosecution of a pharmacist for an error is extremely low, and the likelihood of a custodial sentence even less, the concerns of the profession as a whole and pharmacy businesses have not gone away.

16. Such fears of prosecution may lead to undesirable defensive practices being adopted on a wider scale which will discourage greater reporting of dispensing errors. This will have an adverse impact on the potential at a national level for increasing relevant information about dispensing errors, and thereby adversely reduce the potential to share information to avoid similar errors being made. There are potentially serious personal consequences concerning their health and professional

reputation for individual pharmacists and pharmacy technicians at risk of being, or charged, with an offence and consequent knock-on costs to pharmacy businesses, which employ them.

17. The Government therefore believes that further action is required to support enhanced and effective reporting of dispensing errors, by considering, as appropriate, options to reduce or remove such fears when errors are made. In this respect, the great majority of all dispensing activity falls to pharmacies. Therefore, the options considered relate to registered pharmacists and pharmacy technicians.

Option 2 – Remove sections 63 and sections 64 from the Medicines Act 1968

18. These offences are set out above. This option removes the criminal sanctions for dispensing errors entirely from the legislation, as a consequence of removing entirely the offences relating to adulteration and the sale or supply on prescription of medicines not of the nature or quality demanded by the purchaser/patient.

Benefits

19. This is the most straightforward option, which would require primary legislation. It offers, subject to the necessary parliamentary scrutiny, the clearest possible assurance for all parties involved in the medicines supply chain, that dispensing errors will no longer attract criminal action under Section 67 of the Act. It is therefore likely to maximise the scope for reporting errors. In the period leading up to repeal, prosecutors would continue to rely on the CPS guidance (see paragraph 13 above) to consider any cases that came to their attention. On the available data, the likelihood of a prosecution during this period is very small. There would be benefits to employees and business from the enhanced security and knowledge that errors will not incur costs from defending criminal prosecutions under the Act. (The general criminal law offences for dealing with the most serious cases – for example, where a grossly negligent error causes death - would still stand.) In a civil law context, we can assume that employers will generally assume vicarious liability for any employee's dispensing error, but potential civil liability under negligence law is unaffected by these proposals.

Costs

20. No significant compliance or familiarisation costs for individual professionals or retail pharmacy business have been identified. Pharmacy professionals, as part of their normal professional behaviour, are already required to keep up to date about changes to the law and practice of pharmacy that directly affect them, and the Government would expect them to be adequately aware of changes to the law about dispensing errors through their usual information and publicity channels. Similarly, pharmacy owners, in order to operate their businesses within an area of law and practice where constant change is inevitable, will already have in place mechanisms for ensuring that they and their staff keep up to date. In England, for the overwhelming majority of retail pharmacies that wish to dispense NHS prescriptions, this has been formalised into a requirement on pharmacy owners to have in place clinical governance arrangements that include appropriate training for all staff and arrangements for supporting their developmental needs.

21. There could be familiarisation costs to others involved in the supply chain, who are not recognised health professionals nor subject to professional standards and codes of ethics, and are not pharmacy owners – for example, owners of retail outlets other than retail pharmacy businesses. They would no longer be subject to the constraints that the sanctions attaching to breaches of sections 63 and section 64 attract. However, as the "fear" of prosecution under these sections has not been a major factor for such businesses, it is highly unlikely that they would incur any significant costs familiarising themselves with the removal of those sanctions. The most significant risk, however, is the cost to patient safety from complete removal of the available sanctions. There would be no safeguards beyond the general criminal law to protect patients and consumers against the actions of other medicines suppliers (e.g. retailers, garages etc.) that are not subject to professional regulation requirements. To rely solely on the general criminal law means that only the most serious offences, involving concepts of pre-meditated criminal intention, causation etc., would be pursued. Since the provisions of the Medicines Act are widely drawn and incur a strict liability

for all errors – and not just the most serious – it offers a strong degree of public protection against errors which fall short of the higher thresholds of the criminal law.

Overall

22. The Government recognises that it is essential for patient and public safety that the right medicines of the right quality are supplied. In policy terms, removal of all sanctions means the removal of public protection where it is considered to be in the public interest that effective sanctions, including prosecution, are able to take place where appropriate. The Government therefore considers it correct that the requirements in sections 63 and 64, and the associated criminal sanctions, are retained to maintain effective enforcement arrangements to protect patients and the public. This option is therefore not considered in further detail.

Option 3 – Introduce an exemption from criminal liability where an inadvertent dispensing error occurs when a pharmacy professional is acting in the course of their profession

23. Option 3 would introduce a specific defence for registered pharmacists and registered pharmacy technicians. Where an error occurs while a pharmacy professional, acting in the course of their profession, dispenses a medicine at a registered pharmacy and complies with their professional duty of candour, they would not be subject to the criminal sanctions attaching to the offences.
24. Currently, as well as potential disciplinary action from an employer, pharmacy professionals face a "triple" jeopardy where they commit an error – under the sanctions in the Act, under the general criminal law and under professional regulation requirements.

25. The effect of this option would be that, rather than risk facing criminal prosecution in all cases where an error occurs, pharmacy professionals who make a dispensing error but satisfy the conditions for the defence would be subject as the main line of external inquiry to the disciplinary arrangements of their professional regulator.

26. Depending on the circumstances and effects of the error, an individual who commits an error could be subject to regulatory fitness to practise procedures. In more serious cases, that individual could ultimately be removed from the professional register. The general criminal law would also continue to apply, for example, in cases of gross negligence manslaughter.

27. For a pharmacy professional – or any other defendant involved in the error at the pharmacy – to rely on the defence, a number of conditions would need to be met. These are set out in **Table 1** below. Apart from this, the criminal offences would otherwise continue to apply and be unaffected. By ensuring that criminal sanctions remain in place for other suppliers of medicines, especially those not subject to professional regulation, this option maintains the current legislative safeguards and protections for patients and consumers.

Table 1 – Summary of the conditions for an exemption to criminal prosecution to apply:

General description	*Interpretation*
The medicine must have been dispensed by a registered pharmacy professional or someone acting under their supervision	Registered pharmacy professional, for these purposes, means a pharmacist registered by the GPhC or PSNI – or, in Great Britain, a person registered as a pharmacy technician by the GPhC.
The registrant must have been acting in the course of their profession	Pharmacy comprises two regulated professions (pharmacists and, in Great Britain, pharmacist technicians). Pharmacy professionals demonstrate their professionalism on a day-to-day basis through the behaviours, attitudes and values expected of professionals whatever the setting. It is a key part of professional practice that they will always exercise their professional judgment in the interests of patients and the public and their professional skills for a proper purpose. For this reason, pharmacy professionals who misuse their professional skills for an improper purpose, or show a deliberate disregard for patient safety, will not be able to benefit from the defence.
The sale or supply of a	The GPhC and the PSNI have, exceptionally amongst heathcare regulators,

medicine must have been at or from a registered premises	responsibilities for the registration of pharmacy premises as well as of pharmacy professionals.
The sale or supply must have been in pursuance of a prescription or directions	Patients needing medical treatment in the community are likely to receive a prescription from their GP or other healthcare professional. A pharmacist then dispenses the medicine against the prescription and supplies it to the patient. However, medicines can also be sold or supplied against the directions of an appropriate practitioner. Patient Group Directions (PGDs) are an example of such directions. PGDs enable a wider range of registered health professionals, including pharmacists, to supply and/or administer medicines to patients, without the need for an individual prescription. Because the offence under section 64 does not cover supply in pursuance of directions, only sales in pursuance of directions, the defence has been tailored accordingly.
Prompt notification of an error	If the error is undiscovered before the criminal investigation, no notification obligation arises. If the error is known about, then the defence is only available if the dispenser, a supervising registrant or the pharmacy owner takes all reasonable steps to notify the patient or reasonably forms the view that it is neither necessary nor appropriate to do so. This duty therefore recognises it may not always be necessary or appropriate to notify the patient. This is in keeping with the duty of candour, which all health professionals must observe where mistakes are made.

Benefits

28. The main benefit of this option is to remove the existing barrier of fear of prosecution in the reporting of dispensing errors by registered pharmacists and pharmacy technicians. This is an intangible factor to quantify. It is, however, considered to create a significant qualitative benefit which promotes enhanced patient safety and professional learning and expertise.

29. The benefits to business arise from improved confidence that reporting errors no longer creates an automatic threat of criminal prosecution for individual employees nor potentially for the business itself. This is likely to lead to further indirect benefits for business. If an employee were charged under the Act currently, albeit the likelihood is low, it is reasonable to assume that the employee would be suspended by the employer pending the outcome of the criminal proceedings. Suspension is a neutral act. The employee would be entitled to continue to receive salary and other benefits which the employer would need to pay whilst also employing another person to provide cover for the suspended employee. It may take several months or longer for such a charge to be finally determined. An employer may be able to insure against these events but, either way, there would be certain beneficial impacts on staff costs. There may be additional reduced legal and administrative costs for business. Details of the quantification and monetisation of the direct benefits from the reduced risk of prosecution can be found in in the Economic Analysis section.

30. Further benefits are expected from improved dispensing error reporting measured through better patient safety outcomes and an improved safety culture. The value of these benefits is difficult to estimate quantitatively, but the Economic Analysis section sets out the details of the calculations and estimates. It is reasonable, however, to expect adoption to complement a wider set of existing activities to improve patient safety (e.g. the actions by NHS England (and now NHS Improvement, to which patient safety function has transferred) and the MHRA – see Annex A - and any similar actions agreed by other UK countries with the MHRA, alongside patient safety policy developments in those countries).

31. A further potential benefit will be to create a better balance between the roles and responsibilities of the legal system and regulators. Streamlining the involvement of the CPS (and the MHRA) in dealing only with dispensing error cases that warrant prosecution will impact on the overall costs of prosecutions. However, such benefits as may arise are expected to be very small, given the very few prosecutions that have taken place over the last decade. Such costs are difficult to quantify and in general, these are treated as a saved opportunity cost to the CPS and MHRA. For the purposes of this analysis, it is assumed that the costs to the CPS and MHRA of all other investigations which do not lead to a decision to prosecute continue unaffected.

32. Benefits may also accrue for the police force from a reduced need to undertake investigations. However, it is likely that the police will only be involved in the most serious cases involving death or very severe harm and where action under other provisions in the criminal law (e.g. charges for causing actual bodily harm or manslaughter) may be contemplated. So the scope for potential savings is very marginal. Any savings, whilst not quantified, would be a saved opportunity cost.

33. The inclusion of an exemption is expected to generate benefits, measured through increased and improved reporting of errors centrally, alongside other existing measures to report errors, and resulting actions by organisations with a remit to promote patient safety.

Costs

34. We asked pharmacy professional and business leaders for their views on the likely additional costs that would arise from creating this new defence. In general, they did not identify any specific direct costs if this measure were adopted. However, the Economic Analysis section provides a detailed analysis and monetisation of key costs. The conditions attached to the use of the exemption reflect the standards of behaviour already demanded of the profession so do not create new or unexpected requirements. Pharmacy professionals are already subject to fitness to practise sanctions as part of their registration requirements, so these will continue unaffected. Health professionals and business will need to make themselves familiar with the way in which the new system is to operate but we expect the professional and regulatory bodies and pharmacy trade associations to provide information and guidance on this as part of their day-to-day activities.

35. As indicated above, pharmacy professionals, as part of their normal professional behaviour, are already required to keep up to date about changes to the law and practice of pharmacy that directly affect them. Similarly, pharmacy owners, in order to operate their businesses within an area of law and practice where constant change is inevitable, already have in place mechanisms for ensuring that they and their staff keep up to date. In England, for the overwhelming majority of retail pharmacy businesses that wish to dispense NHS prescriptions, this has already been formalised into a requirement on pharmacy owners to have in place clinical governance arrangements that include appropriate training for all staff and arrangements for supporting development needs.

36. In the early days, it is possible that individual professionals and business may seek clarifications of whether particular errors fall within the scope of the exemption. It is difficult to estimate what such costs might be, not least because of the very few prosecutions that have taken place in the last decade. Those costs are unlikely to create exceptional additional cost pressures within pharmacy businesses or on individual pharmacists, and will just be absorbed as part of the costs they habitually incur as part of their custom of keeping up to date with regard to pharmacy law and practice. However, the costs that may arise for existing staff familiarising themselves with the new legislation are estimated in the Economic Analysis section.

37. We also asked business whether, if the new defence was introduced, this would have a downward impact on employee cost pressures. No specific impacts were reported by businesses.

38. We asked whether business would incur increased costs because of an expected general increase in reporting errors, were this defence to be introduced. Whilst businesses did not identify direct costs arising from this, the Economic Analysis section provides an estimate of the potential costs to businesses from an increase in reports. In contrast to the statement of the PDA Chairman in 2009 (see paragraph 14 above), business reported it is now experiencing some increase in error reports which is attributed to increased awareness of the work of the NRLS and other initiatives (see Annex A**)**, and in England, the contractual requirements for NHS pharmacies to have an incident reporting system as part of clinical governance (Annex A, paragraph 11).

39. Whilst it is difficult to estimate the costs definitively arising from this option for the main parties affected (specifically, registered pharmacists and pharmacy technicians, pharmacy owners, pharmacy regulators, those who manage centralised PSI reporting mechanisms (e.g. NHS), the MHRA and the CPS), the section on Economic Analysis of the options and their perceived impact on business indicates an overall NPV for **business** of £0.17million over 10 years for Option 3. The main costs to businesses identified are familiarisation costs and those stemming from the higher

number of dispensing error reports. However, cost-savings are also identified, which refer to benefits from the lower risk of prosecution, in addition to cost-savings from handling fewer errors, as a result of improved information availability and learning.

40. Whilst Option 3 may suggest fewer immediately obvious net benefits than Option 2, it is supported by a consensus of stakeholder views within the Rebalancing Programme Board, and from the responses to the consultation. Option 2 would, importantly, totally remove public safeguards from all suppliers of medicines, including those not subject to professional regulation. As such it is not considered proportionate to the problem being addressed.

Option 4 – strengthen existing guidance to tighten circumstances under which a prosecution is likely

41. This is a non-legislative solution. The CPS is expected to issue updated guidance on the circumstances under which a prosecution is likely to take place for a dispensing error.

Benefits

42. The main benefit is that guidance is already extant and a further revision is underway. This option is therefore quickly delivered and relatively cheap, as the main costs have already been incurred, subject to any further work that may be decided in the lead-up to publication.

Costs

43. No significant further costs are expected to arise or have been identified. However, there is an unquantifiable cost arising from the current professional and business perceptions about the risks of prosecution. Even with tightened guidance, these risks do not go away. It is impossible for prosecutor guidance to deliver any immunity from prosecution, as in the end, it is only guidance. The seriousness of the outcome of the error will also inevitably be a factor that no prosecution guidelines can simply dismiss. The prosecutions that have been brought have been in cases where the patient died in the aftermath of a dispensing error, and in the absence of a defendant having a complete defence to a charge in these circumstances, prosecution must inevitably be an option. Guidelines alone could never remove the fears that currently exist and which are detrimental to patient safety.

44. For these reasons, this option is not preferred. It does not address the fundamental policy issue nor encourage the wider reporting of dispensing errors to enable learning and improved patient safety.

Economic analysis of options for dispensing errors

45. The criminal offences that apply where the wrong medicine or a medicine of unsuitable quality is supplied, incentivise medicine dispensers to act in the best interests of the patient. They also provide an effective sanction where dispensers do not act in the best interest of the patient. Without Government intervention, medicine suppliers would have a commercial incentive to minimise their costs and efforts to avoid errors in the supply of medicines.

46. The criminal offences apply to all medicine suppliers. This includes pharmacies and pharmacy professionals that supply most medicines, especially those dispensed against prescriptions, as well as other health professionals and others who are not subject to professional regulation.

47. However, there is evidence that the fear of prosecution has a counter-productive effect as it deters reporting of dispensing errors. This leads to less transparency and less scope for learning from dispensing mistakes. This, in turn, gives rise to unnecessary costs from increased risks to patient and consumer safety and less efficient pharmacy businesses. Pharmacists and pharmacy technicians are also subject to the general criminal law and professional regulation registration sanctions. Therefore, the costs of the current legislative arrangements may outweigh the benefits. As a result, alternatives to the current system, which maintain safety but reduce the negative impacts of an excessive fear of prosecution, can be expected to benefit patients, consumers and society generally.

48. Apart from the threat of potential prosecution, a number of other causes are cited as to why there is under reporting of dispensing errors. These include:

- excessive workload;
- a lack of perceived benefits from reporting errors;
- inconsistencies in local reporting systems; and
- a lack of knowledge regarding national reporting systems.

49. Whilst the policy options below address one particular aspect of the problem, the other issues could remain unchanged and continue to affect levels of reporting of such errors.

The policy objective

50. The objective is to amend the current legislative regime, such that pharmacy professionals do not experience a needless fear of prosecution and are not deterred from reporting errors, so that there is more reporting and learning from errors to improve patient and consumer safety. Ultimately, learning from errors should reduce future errors, improve patient and consumer safety, and so necessarily improve the service that pharmacy professionals provide.

Development of options

51. Evidence suggests that learning from previous dispensing mistakes reduces the likelihood of those dispensing errors recurring in the future (see *James et al (2009)*). However, evidence also suggests that the fear of prosecution is one of the main reasons why some pharmacy professionals do not report dispensing errors, as described above. Hence, the current criminal law imposes barriers to more transparent reporting and to improvement in professional practice through learning about previous dispensing mistakes. Nevertheless, some medicines suppliers are not subject to professional regulation, so the criminal law is the only way to constrain their activity and help ensure patient and consumer safety.

Policy options

Option 1: Do nothing

52. By definition “no change to the current policy” is used as the counterfactual so that this option provides no additional cost or benefits. At the same time, it is important to highlight that, given increasing efforts by the UK government and agencies to improve reporting practices for dispensing errors, the number of reports are expected to increase under this policy option.

Option 2: **Remove the criminal sanctions concerning adulteration, sale or supply from the Medicines Act 1968**

53. This option would remove the criminal sanctions concerning all breaches committed under section 63 and section 64 of the Medicines Act 1968.

Description of likely impacts

54. This option provides the clearest assurance that no prosecution would take place and hence should result in the biggest increase in transparency and reporting of errors. However, it would also represent the removal of a key tool that helps to safeguard the safety of patients and consumers. In particular, the criminal sanctions would be removed from all suppliers of medicines, including those not subject to professional regulation, not just pharmacy professionals. Fully eliminating these criminal sanctions would remove key incentives for suppliers of medicines to act in the interests of patients and consumers. This could lead to significant risks for safety arising from

errors made in the supply of medicines or where the medicines supplied are not of a suitable quality.

55. Under this option, it is likely that the benefits from increased transparency and reporting would be outweighed by the increased risks to patient and consumer safety and consequential costs. As a result, this option is not considered further.

Option 3: Introduce an exemption from criminal liability where an inadvertent dispensing error occurs when a pharmacy professional is acting in the course of their profession

56. This option keeps the criminal sanctions in place, but introduces a specific defence for registered pharmacists and registered pharmacy technicians. Where an error occurs, a pharmacy professional would not be subject to the criminal sanctions attaching to the offences, if they act in the course of their profession. Pharmacy professionals who make a dispensing error but satisfy the conditions of the defence would still be subject to proportionate professional disciplinary arrangements relative to the error – as they are in the current system. By ensuring that criminal sanctions remain in place for other suppliers of medicines, especially those not subject to professional regulation, this option maintains the current legislative safeguards and protections for patients and consumers.

Description of likely impacts

57. Introducing an exemption from criminal liability may have effects on **patient safety**. It is considered unlikely that the provision of a new defence will result in more dispensing errors, as pharmacy professionals will still be governed by professional standards and regulation, and other organisations which supply medicines will continue to be governed by the criminal law. Therefore, overall, improving the reporting of errors should be expected to reduce errors in the long term, providing benefits to patients. Some of these benefits are left unquantified – this means the true net benefit is likely to be greater than estimated below.

58. The remainder of this analysis assesses the potential **cost impacts on businesses**. These are summarised in this section, and analysed in detail in the following sections. Four potential impacts have been identified:

    i. familiarisation costs;

    ii. cost impacts arising from changes in the numbers of dispensing error reports;

    iii. benefits from the reduction in the risk of prosecution; and

    iv. cost reductions from reduced numbers of dispensing errors (beyond the impacts on costs of error reporting)

Quantification and categorisation of impacts under Option 2

Impact	Direct/ Indirect	Comment
Familiarisation costs	Direct	Follows directly from the implementation of the policy, as staff will need to familiarize themselves with new policy
Increases in error reports- cost	Indirect	Does not follow directly from the implementation of the policy, as other issues also affect reporting behaviour
Reduction in risk of prosecution- benefit	Direct	Follows directly from the creation of the specific defence for pharmacy professionals.
Increased information and learning- benefit	Indirect	Does not follow directly from the implementation of the policy, as other issues also affect learning behaviour.

Familiarisation cost impacts

59. Pharmacy staff will be required to spend some time familiarising themselves with the fact that a defence exists against prosecution for dispensing errors. The cost impact to businesses is expected to be relatively minimal, as it is normal for pharmacy professionals to routinely keep up to date with changes in legislation. In addition, they will receive communications about the changes in the course of their normal engagement with their professional bodies. However, to the extent that some staff do not become familiarised with the change in legislation through this means, it may impose a cost on their employers – who may have to grant their staff time to inform themselves of the changes. These impacts are estimated by considering the time taken by a staff member for familiarisation, and their employment costs.

60. It is assumed (and this was confirmed as reasonable by pharmacy owner representatives) that each professional will, on average, take **20 minutes** (0.33 hours) to familiarise themselves with the new legislation. This estimate only refers to additional time required, while at work, beyond the familiarisation that would already have occurred through engagement with professional bodies and other means. During the consultation process most respondents agreed that this was a reasonable assumption. Annex C, contains a summary of the questions asked in the consultation document. In question 19 we asked whether respondents thought '…the assumptions we have made are proportionate and realistic?' Of the respondents who answered the question 94% responded that they agreed. However, we still provide a sensitivity analysis showing the impact on the final net cost estimates if familiarisation costs were higher or lower.

61. The ONS 2016 Annual Survey of Hours and Earnings (ASHE) indicates earnings for pharmacists and pharmacy technicians of **£20.68** and **£10.85** per hour[1] respectively. Assuming that employment overheads add an extra 30% to the total labour costs (BIS estimate of on-costs), this implies hourly costs to employers of **£26.88 per hour** and **£14.11 per hour** for pharmacists and pharmacy technicians, respectively.

[1] ONS: ASHE 2016 (provisional), Table 14.5a. All Employees

62. To calculate the total familiarisation costs to businesses, an estimate is required of the numbers of staff affected. This is the number of pharmacists and pharmacy technicians employed in community pharmacies – which are affected by the changes. Data from the General Pharmaceutical Council **(**GPhC) and shows that **37,372 pharmacists** and **12,229 pharmacy technicians** work in community pharmacies[2] (the vast majority of which are privately employed as there are believed to be only a small number (circa fewer than 30) of NHS-owned community pharmacies). This we use as the basis for our general calculations hereafter.

63. The total cost to business of familiarisation is therefore estimated to be 0.33h x ([37,372 x £26.88] + [12,229 x £14.11]) = **£392,404**. This is a one-off cost for existing staff – as new staff would be expected to familiarise themselves with the current legislation at the time of their training and qualification.

Costs impacts from changes in number of error reports

64. There are likely to be impacts on businesses through changes in the numbers of dispensing error reports made. As explained below, two effects are expected: removal of the risk of prosecution is expected to increase the number of reported errors. In addition, over time learning from error reports leads to improvements in training and practices, which are likely to reduce the number of errors made[3]. Again, the consultation responses confirmed that this logic and the assumptions underlying it were seen as realistic.

Increases in error reports after removing the risk of prosecution

65. Removing the risk of prosecution where there is a genuine defence is expected to increase the willingness of pharmacists and pharmacy technicians to report dispensing errors, and therefore to increase the numbers of error reports. This section estimates the cost impacts to business by: a.) estimating the number of unprevented dispensing errors; b.) estimating the proportion of these that will now be reported; and c.) calculating the cost to business of these additional reports, using an estimate of the time taken per report, and the relevant employment costs.

Estimating the number of additional errors reported

66. Data from the NRLS suggest that **15,937** dispensing errors were reported by community pharmacies between October 2012 and September 2013 in England and Wales (taking "medication incidents reported by community pharmacies" as a proxy for dispensing errors). This implies a reported error rate of 0.0016% (15,937 reported errors divided by 996,000,000 items dispensed in England and Wales). Assuming the reported error rate is broadly similar in Northern Ireland and Scotland, when applied to 2016 UK dispensing volumes, we estimate there were **20,820** reported errors in the UK in 2016. (0.0016% * 1,301,178,750[UK]). (1,083,600,000 [Eng[4]] + 73,900,000 [Wal[5]] + 102,610,000 [Sco[6]] + 41,068,750 [NI[7]]).

67. In order to estimate the actual unprevented dispensing errors that occur in community pharmacies, the findings from the NHS[8] and evidence by James et al (2009) have been used. These suggest that dispensed errors represent **0.04%** of the total volume of NHS medicines dispensed by community pharmacies. Dispensed errors could also be smaller or larger than this as suggested by

---

[2] http://www.pharmacyregulation.org/sites/default/files/gphc_registrant_survey_2013_main_report_by_natcen.pdf; http://www.pharmacyregulation.org/annualreport/register

[3] No specific impacts are expected, and therefore have not been taken into account, arising from the *manufacturing* of medicines as a result of improved error reporting. Most medicines come pre-packaged. Whilst some errors might arise where a medicine is made up on the community pharmacy premises, that manufacturing process itself yields greater opportunity and time to discover and correct any such errors. For pre-packaged medicines, the manufacturing process is considered less likely to cause errors because of the standards already in place for the pharmaceutical industry as a whole (see e.g. *Good Manufacturing Practice* produced by the MHRA). It would, in any case, not be possible to quantify the costs of errors arising from made-up medicines since we would not know the costs of the raw ingredients, whether the product needed to be replaced in full or in part or whether it had to be discarded.

[4] NHS Digital; Prescriptions Dispensed in the Community, Statistics for England - 2005-2015 [NS]

[5] Welsh Government; Community pharmacy services, 2015-16

[6] ISD Scotland; Prescribing & Medicines: Prescription Cost Analysis

[7] DoH Northern Ireland. (2013 figure with assumed volume growth of 2% p.a.)

[8] http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59830

some studies and by the consultation responses. We have included this possibility in our sensitivity analysis.

68. Given the volume of prescription items dispensed in community pharmacies listed at paragraph 67 we estimate the number of actual unprevented dispensing errors by community pharmacies is estimated at 1,301,178,750 x 0.04% = **520,471** errors per year.

69. Using the above figures, the level of unreported dispensing errors can be calculated as approximately 520,471 – 20,820 = **499,651**.

70. To assess the potential costs to businesses, it is necessary to estimate the volume of additional dispensing errors that could be reported from implementation of the policy. Verma and Allinson (2012) identify fear of prosecution as one of five reasons why people do not report errors, and one of the principal reasons amongst those five. Introducing a defence to a prosecution aims to remove this fear. As a result, if 1/5 or 20% of non-reported errors were taken to be as a result of fear of prosecution, then this option would lead to **499,651** x 20% = 99,930 additional reports of dispensing errors being made. One of the consultation responses suggested that the increase in reported errors could be lower, in the region of 10% of non-reported errors. We have taken this into account in the sensitivity analysis.

71. The consultation responses have supported the idea that it is reasonable to assume that there will be a gradual change in reporting behaviour, resulting in an initial increase in dispensing error reports of 50% of 99,930 = 49,965 in the first year and 100% by the second year (for further information see the first column in Table 2).

72. Again, we sought to get additional feedback in the consultation regarding the analysis and specifically about our assumptions. Consultation respondents were widely supportive of those who responded to the Impact Assessment related question. The consultation responses also highlighted the importance of continuing to improve the NRLS reporting system to fully benefit from the change in policy.

Reduction in number of errors through improved information and learning

73. Reducing the barriers to reporting errors, and increasing the number of errors reported, is expected to increase the availability of information for pharmacies, pharmacists and pharmacy technicians to learn from mistakes. Thereby reducing/dispensing errors in the long term. This will happen through an increased awareness amongst staff, their ability to train and guide new staff in avoiding similar errors. In addition, the greater availability of dispensing error reports, information on trends and the feedback available to professionals will be important to achieving this outcome.

74. The potential benefits from increased transparency, information availability and reporting can be estimated and quantified using the evidence from the literature. James et al (2009) find that at least 17 out of the 27 (**62%**) main reasons for the occurrence of dispensing errors are related to issues which can be corrected via increased information and learning (e.g. mistakes prevented as a result of better handwriting can be learnt, whereas those that occur as a result of stress or workload cannot be improved by more information).

75. The estimate of the potential reduction in errors takes into account the room for improvement, but also the constraints that remain in place and working culture/habits. If a reduction of 62% in dispensing errors that occur is taken as the hypothetical full potential benefit of greater information availability, there will nonetheless be constraints which prevent this being fully achieved. As a result, giving an equal weight to both counter-acting elements (i.e. by only taking into account **half of the possible 62%**) yields an estimated benefit from learning and transparency **of an additional decrease of approximately 30%** in dispensing errors annually, compared with a case where no learning takes place.

76. Standard quality improvement methodology, such as that promoted by the Institute of Healthcare Improvement[9], suggests a 50% reduction in dispensing errors from learning is not unreasonable. Hence, the estimated 30% prevention of dispensing errors through learning enabled by increased error reporting is a conservative expectation in comparison. This was also part of the assumptions tested in the consultation and which responses supported (Question 19 in Annex C).

Projected overall impact on dispensing error reports

77. This section uses the results of the previous analysis to project the number of error reports over the next ten years, and calculate present value estimates for the cost impacts on business.

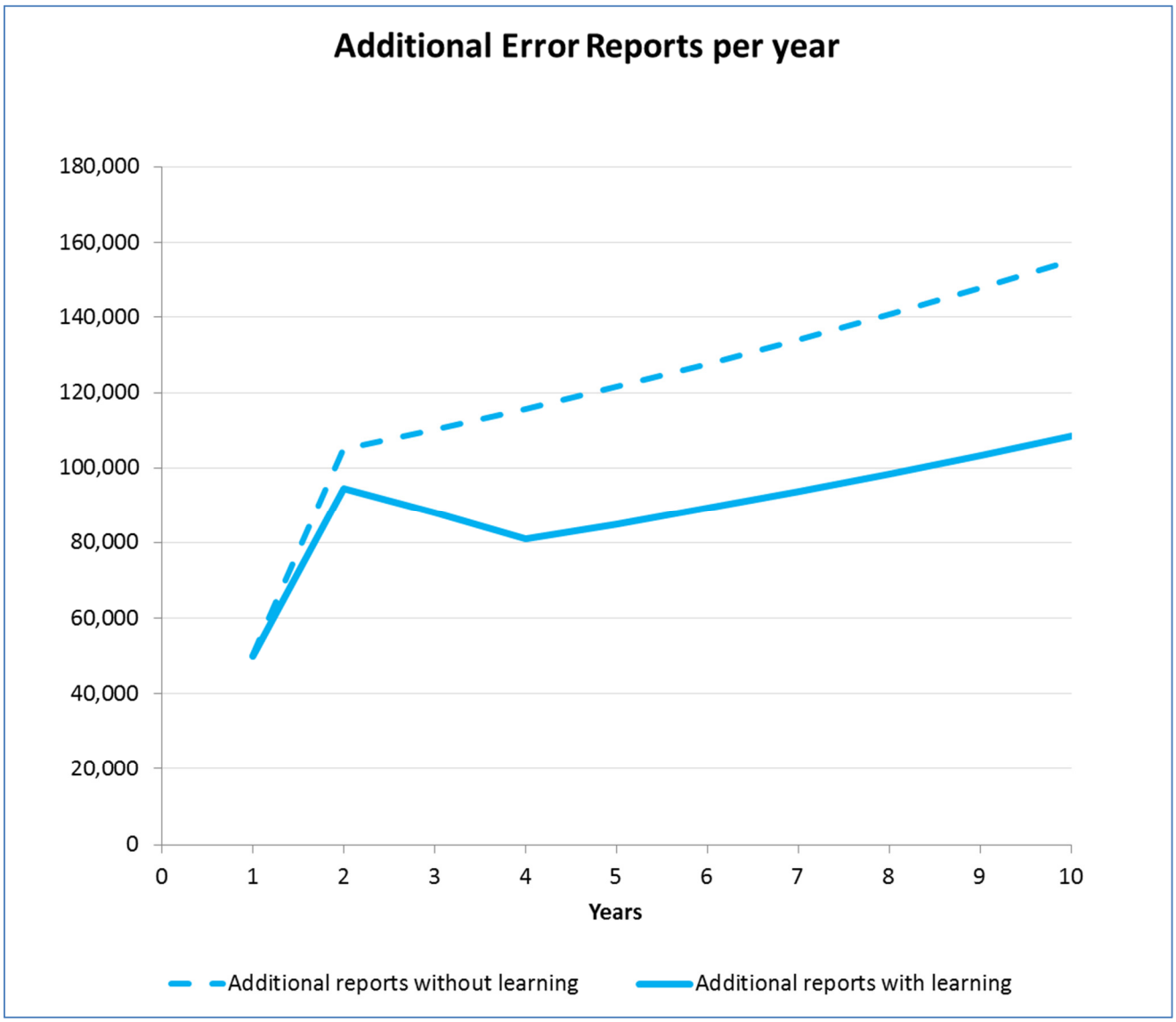
Projecting error reports

78. As shown in the graph below, the effect of reducing the risk of prosecution is expected to initially increase error reports by 49,965 and 99,930 in the first and second year respectively. As a result, total error reports are expected to increase from the current 20,820 to **120,750 by the second year.** It is assumed that, all else being equal, the number of dispensing errors and reports will rise in line with overall levels of prescriptions – estimated to grow at approximately **5%** pa.

79. Additionally, the improvements in availability of information, and the increased opportunities for learning from errors is expected to reduce errors overall by **30%** as described above. However this effect is not expected to occur immediately. It is therefore assumed that these reductions will take place evenly over a **4 year** period, beginning in the second year following implementation of the changes. As with the other assumptions, this was also tested in the consultation with wide support from respondents (Question 19 in Annex C). We assumed a period of 4 years to reflect the gradual change expected, as opposed to an immediate change in reporting culture. However, in the sensitivity analysis we provide estimates with different assumptions regarding this.

80. The following graph shows the implied projections of additional error reports over a ten year period, compared to the counterfactual "do nothing" scenario.

[9] http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTipsforSettingAims.aspx



Estimating the cost to business of error reports

81. The table below shows the expected numbers of error reports after implementation of the policy. To calculate the impacts on business requires estimates of the time taken by staff to file error reports, and the employment costs of those staff.

82. Dispensing errors can be reported to the NHS system in England online[10]. The process of reporting an error was simulated in order to estimate the approximate amount of time taken to report a dispensing error. This resulted in an estimated time taken of **15 minutes (0.25 hours)** to report a dispensing error. Again, this was part of the assumptions tested in the consultation and 94% of the respondents agreed that the assumption was reasonable. Consultation responses suggested that in some circumstances it may take longer to report errors and others suggested it could be less time. We take this into account in our sensitivity analysis. The cost to businesses is calculated using the estimates for staff costs and numbers above. These imply that **75%** of community pharmacy professionals are pharmacists, while **25%** are pharmacy technicians. From this, the estimate of the cost to businesses of reporting a dispensing error is ([£26.88 x 75%] + [£14.11 x 25%]) x 0.25 hours = **£5.93 per form.** We assume 1% wage inflation for the 10 year period.

Estimating the total cost to business of expected additional error reports

83. The estimates above are used to calculate the cost impacts to business of changes in error reports over time, and the present value of those costs.

[10] http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/

Table 2: Details of errors reporting estimates

year	0	1	2	3	4	5	6	7	8	9	Total
Phasing in of reporting change	50%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
Additional reports without learning	49,965	104,927	110,173	115,682	121,466	127,539	133,916	140,612	147,643	155,025	1,206,947
Learning profile (reduction in actual errors)	*0%*	*10%*	*20%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	
Additional reports with learning	49,965	94,434	88,138	80,977	85,026	89,277	93,741	98,428	103,350	108,517	891,855
Business cost of additional reports, at £5.93 per form (£)	296,460	565,912	533,467	495,024	524,973	556,734	590,416	626,136	664,017	704,190	5,557,330

84. This gives a total of £5.6million. Applying a discount rate of 3.5% and allowing for 1% annual increase wages in real terms, gives a net present value of the cost impacts to business of **£4.7m** (see Table A1 for details).

Cost-savings from reduced errors

85. As explained above, the policy measure is expected to reduce actual errors in dispensing by 30% (assumed to take effect over 4 years). The previous section included an estimate of the overall impact of the policy on dispensing error reports – taking into account the increase in the rate of reporting, but also the reduction in the number of errors that occur. However the latter effect of reducing the numbers of errors that occur will have additional impacts on pharmacies. This comes as a result of other costs associated with dispensing errors, beyond the costs of reporting. Hence, reducing dispensing errors also represents additional cost savings for pharmacies.

86. For example, errors might mean pharmacies are required to undertake some or all of the following actions:

    i. Reassuring patients
    ii. Replacing the medicine
    iii. Handling complaints
    iv. Supporting staff
    v. Replacement staff

87. Note that error reporting costs are not included here – to avoid double counting.

88. If the policy enables pharmacies to reduce dispensing errors, by learning from increased error reporting, then it will result in cost savings to businesses, as they will have to undertake fewer of these actions in response to errors. Again, feedback was sought during the consultation process regarding this logic (Question 15 in Annex C). It received wide support with 94% agreeing with our assessment and logic.

Estimating the reduction in number of errors through learning

89. To estimate the reduction in errors it is assumed – conservatively – that only errors that would be additionally reported as a result of the proposal will be affected by learning. The number of these errors has been calculated above, over the period of impact of the policy (shown as the difference between the dashed and solid blue lines in the graph above). These are a small fraction of the total number of errors that occur – and it is possible that other errors, unreported in either the "do

nothing" scenario, or under option 2, would also be reduced. However no cost-savings are attributed to any learning effects in respect of these unreported errors, in order to generate a conservative estimate of cost savings. The sensitivity analysis includes estimates incorporating higher benefits from learning.

90. This approach gives an estimate for the number of reduced errors over a ten year period of 315,092. This stems from the difference between the estimates in Table 2 of 'errors reported without learning' (1,206,947) compared to 'errors reported with learning' (891,855) (see row 'g.' in Table A1 below for details).

Estimating the cost savings to business from reduced errors through learning

91. Data from the NHS England (now NHS Improvement) Patient Safety Team (currently unpublished) for 2011 indicates that **6%** of all dispensing errors resulted in some form of harm to the patient. These errors are deemed to cause pharmacies the greatest cost. The exact costs of these errors are unknown. However an estimate of **6 hours** of staff time is used to estimate the cost per error (divided between pharmacists and pharmacy technicians, according to their relative numbers in community pharmacy).

92. The remaining **94%** of errors did not cause harm, for example because the patient spotted the error and returned the medicine to the pharmacy. Nevertheless they may result in costs to pharmacies, for example in reassuring patients and replacing the medicine. An estimate of **0.5 hours** of staff time per error is used to calculate the costs of errors, which did not cause harm.

93. The assumptions and calculations above give an average cost per error of **£19.70**. During the consultation period we sought to test these assumptions by asking respondents whether they thought these assumptions were realistic. The responses to the consultation agreed these were realistic assumptions. The sensitivity analysis shows how overall estimates change with modifications to this assumption.

Estimating the total cost saving to business from reduced errors through learning

94. The assumptions and calculation above are used to estimate the cost savings to business. In table A1, multiplying rows ('g.')*('k.') gives total cost-savings to businesses over the 10 year period of £6.6m. This is equivalent to a NPV of **£5.4m** (column h.)

Benefits from the reduction in prosecution risks

95. There are additional benefits stemming directly from the creation of the defence. In particular, the implementation of the policy would represent an important reduction in the probability of a pharmacy professional undergoing a criminal investigation. This represents a direct benefit to the pharmacy profession.

96. Individuals and companies' valuation of intrinsic risk and benefits from its decrease can be assessed by looking at their willingness to pay for protection from the relevant risk as a proxy for risk avoidance valuation[11]. There are a variety of resources that pharmacy professionals can use in order to protect themselves from the risk of criminal prosecution from their professional activities. These range from using the legal resources of the company they work for, to acquiring Professional Indemnity Insurance. Given the difficulty in separately estimating these costs, Professional Indemnity Insurance is used to assess the direct impact on businesses of the reduction in the risk of prosecution. The insurance is used as the mechanism providing a way to estimate the value to the pharmacy profession of a reduction in the risks of prosecution. This is illustrative, as all pharmacy professionals must have cover but may not arrange this personally – instead they rely on the employer.

[11] http://www.k-state.edu/economics/staff/websites/chang/publications/CJE-1985%20Insurance.pdf

97. Obtaining the value that individuals attach to risk (and decrease in risk) can be obtained by using the insurance market costs as a proxy[12]. Hence, to estimate the value to the profession of having a lower risk of being prosecuted, we use the current insurance premium for community pharmacists as a proxy for the valuation of the risks. The insurance premium is currently around £130-£165 per year. A midway figure of £145 is used to estimate savings. The creation of the defence explicit in this policy option directly reduces the probability of criminal prosecution. This is an important part of this insurance cover and directly factors into the calculation of individual's value of risk/ insurance and the company's insurance premium[13]. Hence, a decrease in the probability of prosecution can be equivalent to a conservative scenario of a 1% decrease in individual's valuation of risk, proxied by the premiums paid by pharmacists and pharmacy technicians. This would correspond with annual savings of around £1.45 per professional per year or approximately (49,602*£1.45) = £71,922 per year (see row 'i' in Table A1 for details).

98. This implies a benefit to businesses of **£565,770 (NPV)** over the ten year period. This is the figure used for the calculations below (See Table A1 for details). The consultation responses supported this part of the analysis. Moreover, the consultation response suggested that actual insurance premium decreases could come from a reduction in dispensing errors made over time. In addition, the sensitivity analysis provides alternative estimates based on different assumptions surrounding prosecution risks. This rationale was supported by the responses to the consultation.

Cost-savings from the reduction in prosecutions

99. Alternatively, the cost savings from the reduction in the probability of prosecutions can be estimated using a different method. The creation of the defence will reduce the number of prosecutions that take place during the period under analysis. The costs of prosecutions in general are known to be significant, even though they vary from case to case. In particular, the implementation of the policy would represent an important reduction in the probability of a pharmacy professional undergoing a criminal procedure.

100. During the consultation, we were able to obtain some additional details regarding the few cases related to dispensing errors in the last 15 years. Experience from recent prosecution cases related to dispensing errors made by a pharmacy professional suggests that this process is long and resource intensive. The well-known case (provided in paragraph 13 above) took more than a year to resolve[14]. This policy option directly avoids this sort of case, where the pharmacy professional acts according to professional norms. Hence, this policy directly results in cost-savings equal to the cost of a potential prosecution. These are likely to be significant as described by the Public Prosecution Service[15]. We do not have an exact estimate for this. Nevertheless, for the overall policy to be at least cost-neutral (based only on direct cost and benefits) the direct effect of avoiding a prosecution across the ten year period under analysis would have to be **higher than the £392,404** estimated as familiarisation costs. Based on the time and resources required for this type of case, this wouldn't seem unreasonable. This figure is not used for any of the calculations.

[12] http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.31.6495&rep=rep1&type=pdf

[13] https://www.npa.co.uk/insurance/professional-indemnity-insurance/

[14] http://news.bbc.co.uk/1/hi/health/8101446.stm

[15] http://www.ppsni.gov.uk/Branches/PPSNI/PPSNI/Files/Documents/Publications/Information%20Documents/PPS%20Prosecutions%20Fees%20Scheme.pdf

Summary of impacts

101. As described above, the impacts evaluated are the cost impacts on businesses.

    i. One off **familiarisation costs** are estimated at **£392,404;**

    ii. The net cost impact of changes in error reports is estimated to have a net present value of **£4,707,344;**

    iii. The cost savings resulting from reductions in the handling of dispensing errors is estimated to have a net present value of **£5,404,533;**

    iv. Net cost savings from the reduced risk of criminal prosecution is estimated to have a net present value of **£565,770.**

102. The net cost impact on business is therefore estimated to be **£870,555 in cost savings**. Exact details can be found in Table A1.

Table A1: Summary of projected impacts over 10 year period

	year	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**Total**
a.	Phasing in of reporting change	50%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
b.	Additional reports without learning	49,965	104,927	110,173	115,682	121,466	127,539	133,916	140,612	147,643	155,025	1,206,947
c.	*Learning profile (reduction in actual errors)*	*0%*	*10%*	*20%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	
d.	Additional reports with learning	49,965	94,434	88,138	80,977	85,026	89,277	93,741	98,428	103,350	108,517	891,855
e.	Business cost of additional reports (£)	296,460	565,912	533,467	495,024	524,973	556,734	590,416	626,136	664,017	704,190	5,557,330
f.	Business costs of familiarisation (£)	392,404	0	0	0	0	0	0	0	0	0	392,404
g.	Reduction in errors	0	10,493	22,035	34,705	36,440	38,262	40,175	42,184	44,293	46,507	315,092
h.	Business cost savings from reduced errors (£)	0	208,759	442,777	704,348	746,961	792,152	840,078	890,902	944,802	1,001,962	6,572,743
i.	Reduced risk of prosecution		72,426	72,933	73,443	73,957	74,475	74,996	75,521	76,050	76,582	670,384
j.	*Cost (£) per error report (additional)*	5.93	5.99	6.05	6.11	6.17	6.24	6.30	6.36	6.42	6.49	
k.	*Average handling costs (savings from reduced errors) (£)*	19.70	19.90	20.09	20.30	20.50	20.70	20.91	21.12	21.33	21.54	
	Discounted values (3.5% discount rate)											**NPV, £**
e.	Business cost of additional reports	296,460	546,775	497,997	446,483	457,483	468,755	480,304	492,137	504,263	516,686	4,707,344
f.	Business costs of familiarisation	392,404	-	-	-	-	-	-	-	-	-	392,404
h.	Business cost-savings from reduced errors	-	201,699	413,337	635,282	650,934	666,971	683,404	700,241	717,494	735,171	5,404,533
i.	Reduced risk of prosecution	-	69,977	68,083	66,242	64,450	62,706	61,010	59,359	57,753	56,191	565,770

Summary of NPV calculations-£NPV (negative number implies benefit)

SUMMARY (savings -ve)	**PV**	**Direct/Indirect**	**Cost/Benefit**
Impact of additional reports, £NPV	£ 4,707,344	Indirect	Cost
Impact of familiarisation, £NPV	£ 392,404	Direct	Cost
Impact of reduced handling errors	-£ 5,404,533	Indirect	Benefit
Impact of reduced prosecutions	-£ 565,770	Direct	Benefit
Net costs(-ve is cost saving)	**-£ 870,555**		Benefit

Sensitivity of NPV calculations to assumptions-£NPV (negative number implies benefit)

Sensitivity Analysis	***£NPV***
Base case	-870,555
	-
a) Reports increase by 20% more than expected - 24% of previously unreported errors are now reported (20% * 1.2 = 24%)	-1,009,993
b) Lower increased in reports (10% instead of 20%)	-521,960
c) Familiarisation time 40% higher - 28 mins now required (20 mins * 1.4 = 28)	-713,593
d) Underreporting higher than previously estimated (if actual dispensing errors were 0.05% of total rather than 0.04%)	-1,052,115
e) Time frame for culture change longer than assumed (6 years)	-50,387
f) Time frame for culture change faster than assumed (3 years)	-1,270,699
g) Effect of learning stronger (40% reduction in *additional* errors)	-1,270,699
h) Longer time to issue a report (30min instead of 15 mins)	3,836,789
i) Lower time spent on moderate dispensing errors (4 hours instead of 6 hours)	-89,177

Option 4: Strengthen existing guidance to explain more clearly the grounds under which prosecutions may occur

Description of the option

103. This option does not involve any change in legislation and simply entails further communication to clarify the existing policy.

Rationale of the impact

104. Assuming that current training and guidance is already adequate, there is little difference in the benefits and costs compared to option 1 of "do nothing". Indeed, the CPS is taking further steps to explain its policy in relation to prosecutions for dispensing errors and to increase clarity. If it were to have any impact, some increases in reporting of dispensing errors could be expected, but significant uncertainties around this exist.

105. The policy objective described above highlights the importance of promoting a system that makes the reporting of dispensing errors more transparent and encourages improvements in dispensing to reduce errors. Hence, given the passive nature of this option, and that it does not meet the objectives proposed, it is not considered further.

Evaluation

106. In line with best practice, it is proposed, if adopted, to monitor and evaluate the impact of the new defence within five years of implementation. This would gather new evidence on businesses', pharmacists' and pharmacy technicians' perceptions about reporting dispensing errors in the light of the new legislative framework. This would be expected to build upon earlier studies of attitudes to reporting, and to seek to distinguish between the various developments in incident reporting (i.e. the direct effect of the MHRA and NHS England, and now NHS Improvement, initiatives to increase reporting and the indirect effect of the introduction of a defence to the criminal sanction in the Act).

ADDITIONAL IMPACTS

COMPETITION

107. No impact expected.

SMALL AND MICRO BUSINESS ASSESSMENT (SaMBA)

108. The proposals considered in this impact assessment cover both small and large businesses. We do not expect this to have a disproportionately adverse impact on Small and Medium Size Businesses (SaMBs). It is an existing requirement for all pharmacist professionals to be familiar with the legislative provisions affecting their profession and to keep informed of significant changes in those provisions, which affect the standards of professional behaviour. Moreover, pharmacy law does not differentiate between pharmacies in terms of their overall business size, nor does the criminal law or the requirements for premises or professional registration. To introduce a more beneficial regime for SaMBs would:

    (a) undermine the purpose of pharmacy legislation to ensure that only those which meet the qualifying conditions can legally define themselves a “pharmacy” and offer medicines for sale or supply;

    (b) would encourage growth in companies illegally “passing off” as a pharmacy; and

    (c) might well encourage larger companies to divide their pharmacies in order to qualify as a SaMB and take advantage of a more beneficial regime.

    Since dispensing errors are not affected by the relative size of a pharmacy business, it would be unacceptable to have fewer safeguards in SaMBs for patients and consumers, or to introduce a discriminatory system that offered SaMBs a more beneficial regime or one with fewer impacts.

WIDER ENVIRONMENTAL

110. The proposals are not expected to have any impacts on the wider environment.

HEALTH AND WELL-BEING

111. The proposals concerning dispensing errors are expected to complement wider initiatives to improve patient safety through a change in culture to reporting errors, so that appropriate action can be taken to improve health and wellbeing as a consequence.

HUMAN RIGHTS

112. The proposals are not expected to have any impacts on human rights.

JUSTICE SYSTEM

113. The proposals are likely to reduce the volume of cases going through the courts though the difference is expected to be minimal given the low number of prosecutions in recent years.

114. The proposals in this impact assessment shift the balance from dealing with matters in criminal law to doing so in professional regulation, by the pharmacy regulators, including, as necessary, through registration sanctions rather than the criminal courts. A number of criminal offences are effectively removed for dispensing errors by pharmacists and pharmacy technicians. New defences are introduced in relation to dispensing errors which, in principle, might further reduce the number of offences which result in prosecution. However, as there have been only a few prosecutions relating to dispensing errors in the last ten years, whilst the proposals are likely to reduce the call on the justice system, the difference is expected to be minimal. It has also not been possible to quantify the costs of prosecutions because very few have taken place in recent years and those

that have concerned very different types of errors and defendants. Nor is it considered reasonable to estimate a “typical” cost for the individual professional or pharmacy business.

RURAL PROOFING

115. The proposals are not expected to have any specific impacts on rural areas.

SUSTAINABLE DEVELOPMENT

116. The proposals are not expected to have any specific impacts on sustainable development.

REFERENCES/BIBLIOGRAPHY

Ashcroft et al (2006): Likelihood of reporting adverse events in community pharmacy: an experimental study, Qual Saf Health Care 2006;15:48–52.

Cousins et al. (2011): A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005–2010), British Journal of Clinical Pharmacology, 74:4 / 597–604.

James et al (2009): Incidence, type and causes of dispensing errors: a review of the literature, International Journal of Pharmacy Practice, 17: 9–30.

NHS National Patient Safety Agency (2004): Seven steps to patient safety - The full reference guide.

NHS National Patient Safety Agency (2007): Design for patient safety: a guide to the design of the dispensing environment.

Verma and Allinson (2012): An investigation into barriers to reporting dispensing errors in community pharmacy, International Journal of Pharmacy Practice, Royal Pharmaceutical Society Conference, Oral Session 6 – Safe use of medicines in hospital and community settings.

ANNEX A

Background information concerning dispensing errors

Why the reporting of dispensing errors is important for patient safety

1. Nieva and Sorra (2003) discussed the concept of "safety culture assessment" as a means of improving patient safety in healthcare organisations. They noted that "Healthcare systems must move away from the current "blame and shame" culture that prevents acknowledgement of error and therefore obstructs any possibility of learning from error." Moreover, they also highlight the importance of healthcare systems benefiting from robust information to support the development and promotion of systems to both prevent and mitigate the impact of errors in the delivery of healthcare.

2. In 2004, the National Patient Safety Agency (NPSA) (now part of NHS Improvement) published "Seven steps to patient safety: The full reference guide". This defined what is meant by a safety culture.

> **"A safety culture is where staff within an organisation have a constant and active awareness of the potential for things to go wrong. Both the staff and the organisation are able to acknowledge mistakes, learn from them, and take action to put things right.**
>
> **Being open and fair means sharing information openly and freely, and fair treatment for staff when an incident happens. This is vital for both the safety of patients and the well-being of those who provide their care.**
>
> **The systems approach to safety acknowledges that the causes of a patient safety incident cannot simply be linked to the actions of the individual healthcare staff involved. All incidents are also linked to the system in which the individuals were working.**
>
> **Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring."**

3. It went on to outline the benefits of a safety culture in the NHS. These include the "potential reduction in the recurrence and in the severity of patient safety incidents through increased reporting and organisational learning". Moreover, there could be benefit from a reduction in adverse health outcomes from errors, and adverse impacts on health professionals because of fewer incidents ("a lower number of staff suffering from distress, guilt, shame, loss of confidence and loss of morale because fewer incidents are occurring"). A further benefit could be a reduction in costs to the NHS and on the systems required to manage complaints, and more widely ("a decrease in wider financial and social costs incurred through patient safety incidents including lost work time and disability benefits").

4. It also defined the "seven steps to patient safety". These included "Step 1 - Promote a safety culture that is open and fair for sharing information and ensuring lessons are learned"; "Step 3 - Implement integrated risk management processes and routinely conduct organisation-wide assessments of the risk of error and incidents. Evaluate clinical care, procedures, processes and the working environment"; and "Step 7 - Implement patient safety improvements that avoid reliance on memory and vigilance."

Attitudes to reporting dispensing errors

5. There is a small body of evidence concerning attitudes to reporting dispensing errors in the UK. Ashcroft et al. (2006), undertook a study to "…examine the likelihood of community pharmacists and support staff reporting patient safety incidents which occur in community pharmacies" using a questionnaire of nine incident scenarios.

6. Outcomes of the study indicated that both pharmacists and support staff would be unlikely to report a dispensing error within the pharmacy, or to the NPSA. The questionnaire distinguished between

good, poor, and bad patient outcomes, where bad outcomes were most likely to be reported, as might be expected.

7. The study also makes reference to a "blame" culture, which may act as an inhibitor to accurate reporting, and referenced the existing criminal offences for dispensing errors. Crucially, the study suggests that staff need to be convinced of the benefits of reporting adverse incidents, and to be reassured that they will not have a detrimental impact on their future career prospects.

8. A more recent study by Verma and Allinson (2012) looked at barriers to reporting dispensing errors in community pharmacy. Using a semi-structured interview, a random sample of 15 pharmacists from Stoke Primary Care Trust were interviewed by telephone. The study identified five key themes that were considered barriers to reporting dispensing errors – 1) fear of prosecution, 2) time and workload pressure, 3) complications and inconsistencies in local reporting systems, 4) lack of knowledge with regards to national systems and 5) no perceived beneficial effect as a result of reporting. The main concern identified was the fear of prosecution. Potential solutions to this barrier put forward included changes to legislation to remove or to mitigate the criminal sanction for dispensing errors.

Existing provisions for reporting dispensing errors

9. In the UK, processes are in place to collect, review and act upon such incidents to share information and improve professional learning.

10. In terms of the pharmacy regulators, for Great Britain, the GPhC's standards require 'the safety and quality of pharmacy services to be reviewed and monitored'. Examples include mechanisms for monitoring and reviewing incidents such as near misses and dispensing errors. For Northern Ireland, the PSNI's Code of Ethics requires that "procedures are in place to minimise the risk of dispensing errors or contamination of medicines and a record of errors and 'near-miss' incidents must be made and practices reviewed in the light of such incidents". The professional bodies – the Royal Pharmaceutical Society, the Association of Pharmacy Technicians UK and the Pharmacy Forum of Northern Ireland - have also recently issued *Professional standards for the reporting, learning, sharing, taking action and review of incidents* (November 2016).

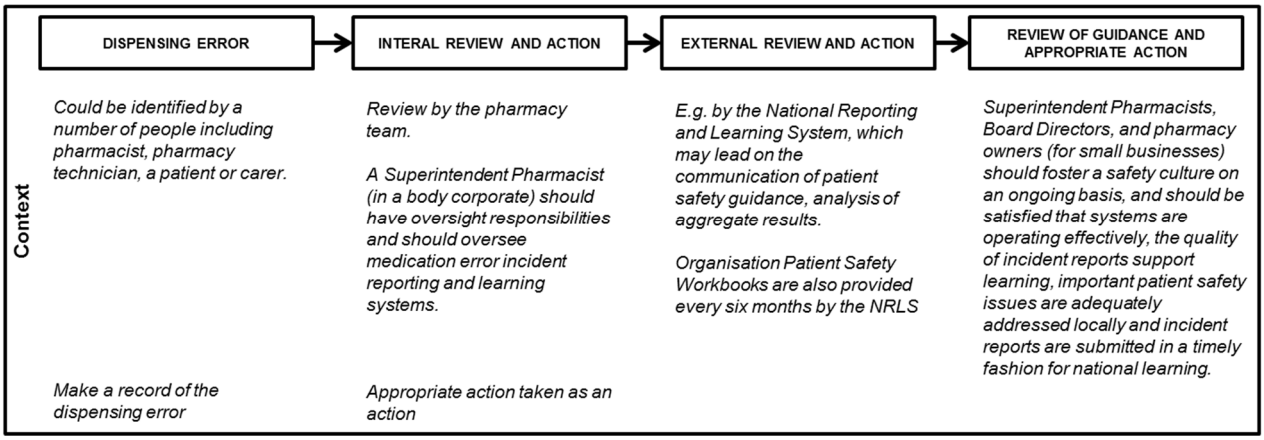
11. In England and Wales, there are existing regulatory requirements on community pharmacies providing NHS pharmaceutical services to report dispensing errors, including the requirement for "an approved incident reporting system, together with arrangements for analysing and responding to critical incidents". NHS pharmacy contractors, under their terms of service, as part of an acceptable system of clinical governance, are required to have these systems and arrangements.

12. There are particulars approved by the Secretary of State for Health that set out the detail of the regulatory requirements (although the approval function has now become the responsibility of NHS England). These are available at:

    https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215090/dh_133312.pdf

13. The NRLS (see paragraph 2 of the main assessment) has been in place in England since 2003. In simple terms, the process for reporting errors is as follows:

Figure 1: Simple depiction of the process to follow in the event of a dispensing error:



14. Others are taking action to encourage the reporting and learning from dispensing errors, as part of wider initiatives to improve patient safety, such as the EU Pharmacovigilance Directive encouraging greater reporting of errors. As a result, NHS England – now NHS Improvement - and the MHRA are jointly working on a collaborative programme to "simplify reporting, improve learning and guide practice to minimise harm from medication errors"[1]. Complementary to this is a need to consider the existing criminal offence where an error occurs, and whether appropriate improvements can be made to the legal environment in this respect.

15. The NHS in Scotland and Northern Ireland also promote a patient safety culture. In Scotland, the National Patient Safety Programme (NPSP) covers hospital and GP practices and is being extended to include pharmacists working in the community/primary care. In Northern Ireland, a Regional Medicines Safety Group provides strategic advice and support to the regional medicines governance teams working in primary and secondary care. The Group's overall aim is to identify, develop and oversee implementation of patient safety initiatives as they relate to medicines in Northern Ireland.

Dispensing Errors – evidence

16. According to Cousins et al. (2011), approximately 5.5 million patient safety incidents were reported to the NRLS[2] over the period 2005-2010. Of the 5.5 million incidents, just under 10% were categorised as medication incidents, of which dispensing errors are a sub-set. Around one-sixth (**87,057** of 526,379 incidents – or around 2% of all patient safety incidents) of all medication incidents were identified as taking place during the process for the preparation or dispensing of medicines. In respect of patient harm, an analysis of more aggregated data, specifically concerning all medication incidents, is given in Table 3 below:

[1] http://www.england.nhs.uk/2014/03/20/med-devices/

[2] Since the NRLS was set up in 2003, all information submitted is analysed to identify hazards, risks and opportunities to continuously improve the safety of patient care. (Source: https://report.nrls.nhs.uk/nrlsreporting/),

Table 3: Clinical Outcomes of medication incidents:

Actual clinical outcome	*Incidents*	*Percentage of medication incidents*
Death	271	0.05%
Severe	551	0.10%
Moderate	17,421	3.31%
Low	68,578	13.03%
No Harm	439,318	83.46%
Not Applicable	240	0.05%
Total	**526,379**	100.00%

Source: Table 5, reproduced from Cousins et al. (2011)

17. Assuming these percentages were consistent with specific dispensing errors, this would mean that there would have been 45 deaths (i.e. 0.05% of 87,057 dispensing errors), 91 (0.1%) cases of severe harm, and 2,881 (3.3%) cases of moderate harm over the period 2005-2010 resulting from dispensing errors. Other data from the NHS England (now NHS Improvement) Patient Safety Team (currently unpublished) concerning medication safety incidents reported by community pharmacy in 2011 indicate that 6% of all dispensing errors resulted in some form of harm to the patients, of which 0.01% involved a death and 94% caused no harm. Both sources indicate the importance of sharing learning, to develop new processes and procedures to reduce the likelihood of avoidable dispensing errors that may lead to serious patient safety incidents, including death.

18. A systematic review of the dispensing errors literature was undertaken by James et al (2009). This study reviewed sixty papers from the UK, the US, Australia, Spain and Brazil. The bulk of the studies come from US and UK health care settings. Some studies were conducted solely in community pharmacy, others in hospital pharmacy. In addition, some studies were conducted in different settings, e.g. where dispensing was a manual process and also where it was an automated process. Most of the UK studies focus on the unprevented dispensing incident rate – which is described in short as the "dispensing error rate". However, in some studies, prevented dispensing incidents were also recorded. These are considered "near misses", and therefore not directly relevant to the main issue here. However, they do reflect where possible dispensing errors in other situations occur.

19. An inevitable challenge of these studies is to appropriately replicate the real-world working environment where dispensing errors occur. Thus, the review reports a wide variation in the rate of dispensing errors as a proportion of all dispensing activity from the studies. Moreover, businesses have a degree of flexibility in how they undertake delivery of their pharmaceutical services, which may itself generate a range of differing environments and situations where dispensing errors are more or less likely to occur. What the studies do not do is indicate the degree of under-reporting of dispensing errors, and whether there are different types, and causes, of such errors relative to what is reported. This is impossible to estimate, but is at the core of the policy objective here.

Types and incidence of dispensing errors

20. Within the set of studies reviewed by James et al. (2009), five UK-based studies looked at the type of unprevented dispensing errors in UK community pharmacies. In summary, the most common types of unprevented errors were dispensing the wrong drug, strength, form or quantity, or errors caused by the incorrect labelling of medications.

21. In three of the five studies, just over one-third of the errors reported were dispensing the wrong drug. In two of the five studies, around one-third of the errors reported were the wrong quantity of drug dispensed. In three of the five studies, over one-fifth of the errors reported were the wrong strength/dose dispensed.

22. Within the category of incorrect labelling there are a range of different labelling errors (i.e. errors when a label of information generally provided by the prescriber is added to the packaging of the

medicine), including “wrong drug name on label”, “wrong strength/dose on label”, “wrong form on label”, “wrong patient name on label”, “wrong quantity on label”, or “completely wrong label”. Collectively, different labelling errors account for a significant proportion of all errors.

23. Fourteen studies in the James et al. (2009) analysis looked at dispensing errors in UK hospitals, for both manual and automatic dispensing systems. Of these studies, five studies looked at unprevented errors, five studies at preventable errors, and the other four at both prevented and unprevented errors.

24. For both kinds of dispensing system, the most commonly identified unprevented error was supplying the wrong drug and the wrong strength of the drug. Supplying the wrong drug accounted for close to 30% of all unprevented dispensing errors in one study. In another study, the wrong strength of drug was found to be the cause of over 40% of all unprevented dispensing errors.

25. For prevented dispensing errors in the hospital pharmacy setting, the literature found that the most common prevented dispensing error was an “unspecified labelling error”, which accounted for the majority of prevented errors.

Causes of dispensing errors

26. According to James et al. (2009), twenty-three papers analysed the cause of dispensing errors. Of these, 13 cited workload as a contributory factor, and 12 studies found that similar drug names were an important issue. 9 studies cited similarities in drug packaging and problems with staffing levels as contributory factors to dispensing errors. Poor handwriting and interruptions/distractions were reasons also found in around a quarter of the literature.

27. Subjectively, reported factors included the risks associated with look-alike, sound-alike drugs, as well as staffing and IT related issues. More specific descriptions included high staff workload, interruptions, distractions, and poor lighting in the dispensary.

Rate and number of dispensing errors in practice

28. James et al. (2009), found that in the community pharmacy environment there was a degree of variation in the (unprevented) dispensing error rate, ranging between a minimum 0.04% of all prescriptions to 3.32% of prescriptions (a range of 3.28% with a median of 0.54%). In level terms, based on the median, this would relate to 36 errors, per pharmacy, per month, based on UK-wide dispensing activity. Similarly, the NHS National Patient Safety Agency guidance on the design of the dispensing environment (2007) suggests that the dispensing error rate in community pharmacies is 0.02%.

29. In addition, errors may occur where medicines are sold over-the-counter either in pharmacies or from a wider range of outlets (e.g. supermarkets, newsagents, petrol stations) that can sell the lowest risk medicines, such as low level pain relief, stomach treatments etc. These are normal commercial transactions, as opposed to a sale or supply of a medicine against a prescription, and as such are outside the scope of this Impact Assessment.

ANNEX B

General assumptions

The estimates shown earlier in the Impact Assessment rely on a number of general assumptions. These include:

a.) In addition to the usual time spent by staff familiarising themselves with any change in regulation, it will take them an extra 20 minutes to familiarise themselves with this potential policy change *(see Paragraph 60).*

b.) Average hourly cost of a pharmacist and a pharmacy technician (including wages and additional employment overheads) of £26.88 per hour and £14.11 per hours respectively *(see Paragraph 61).*

c.) Actual dispensing errors volumes in a given year (reported and non-reported) represent, on average, 0.04% of total dispensing volumes by a pharmacy (e.g. if a pharmacy dispenses 50,000 items in a year it is likely to make 20 dispensing errors, but these are not all reported) *(see Paragraph 67).*

d.) The decrease in fear of prosecution from making a dispensing error will increase the number of reported dispensing errors by around 20% of the currently unreported errors *(see Paragraph 70).*

e.) The increase in reported dispensing errors (assumption **d**.) is expected to occur gradually with 50% of the expected increase occurring in the first year and the full increase occurring thereafter *(see Paragraph 71).*

f.) Even though an increase in overall *reported dispensing errors* is expected, a counter-balancing element is expected from a *reduction in actual dispensing errors made* as a result of learning. This is assumed to take place gradually (over a 4 year period) from the increased information availability. It is expected to soften the increase in reported errors (assumption **d**.) by 30% (so that the increase in reported errors is 30% lower than it would have been otherwise without the benefits from learning (*see Paragraph 75 and Paragraph 81).*

g.) It takes 15minutes to report a dispensing error to the NHS system online *(see Paragraph 82)*.

h.) In addition to the cost of reporting a dispensing error, pharmacies may incur other costs as a result of a dispensing error. These potentially include reassuring patients, replacing the medicines, handling complaints, supporting staff, replacing staff *(see Paragraph 86).*

i.) On average, it takes 6 hours for a person working in a community pharmacy to deal with dispensing errors that result in some form of harm *(see Paragraph 91).*

j.) On average, it takes 30 minutes for a person working in a community pharmacy to deal with harmless dispensing errors *(see Paragraph 92).*

k.) The creation of a defence results in lower risk of prosecution. Hence, it is assumed that this leads to a reduction in the cost to pharmacy professionals of protecting themselves against the risk of criminal prosecution from their professional activities *(see Paragraph 99 and Paragraph 100).*

We have used a reduction in legal costs as an approximation of the estimated savings from 'assumption **k**'. In particular, we have assumed that it can lead to savings equivalent to a 1% reduction in the premium paid for Professional Indemnity Insurance or £1.45 per pharmacy professional (or a reduction in demand for this protection otherwise).

Annex C

Summary of consultation questions

Question 1: Do you agree with our overall approach, i.e. to retain the criminal offence in section 64 and to provide a new defence for pharmacy professionals against prosecution for inadvertent dispensing errors, subject to certain conditions?

Question 2: Do you agree that, once a defendant has done enough to show that the relevant pharmacy professional might have been acting in the course of his or her profession, the prosecution should have to show, beyond a reasonable doubt, that the pharmacy professional was not "acting in the course of his or her profession" in order to secure a conviction?

Question 3: Do you agree the two proposed illustrative grounds that the prosecution could rely on to establish that the pharmacy professional was not acting in the course of their profession, if they were proven beyond reasonable doubt?

Question 4: Do you agree that where a pharmacy professional does not follow procedures established for the pharmacy and an error takes place, this should not, on its own, constitute grounds for a decision in criminal proceedings that the pharmacy professional is not acting in the course of their profession?

Question 5: Do you agree that for the defence to apply, the sale or supply of the medicine must have been in pursuance of either a prescription or (in the case of sales) directions from an appropriate prescriber?

Question 6: In your view, should it be part of a defence where someone is charged with a dispensing error that if an appropriate person at the pharmacy knew about the problem before the defendant was charged, all reasonable attempts were made to contact the patient unless it was reasonably decided not to do so?

Question 7: Do you agree that the unregistered staff involved in the sale or supply of a medicine (including, for example pharmacy assistants who hand over medicines that have been dispensed or van drivers who deliver medicines to patients) or the owner of the pharmacy where a dispensing error occurs should potentially be able to benefit from the new defences?

Question 8: Do you agree that the defence should not apply in cases where unregistered staff involved in sale or supply of medicine deliberately interfere with the medicine being sold or supplied at or from the pharmacy?

Question 9: Do you agree with the overall approach to the new defence in section 67B in relation to the offence in section 63, i.e. to retain the criminal offence and provide a new defence subject to essentially the same conditions as will apply in relation to section 64? If you think different, additional or fewer conditions should apply, could you explain what, if any, conditions you think should apply.

Question 10: Do you agree that in relation to GPhC, the obligation to set standards in rules should be removed?

Question 11: (for respondents in Northern Ireland): Are you content to place a statutory duty on PSNI to set standards for registered pharmacies?

Question 12: Do you agree with the approach we are taking to breaches of premises standards by pharmacy owners?

Question 13: Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?

Question 14: Do you agree with the changes to the GPhC powers to obtain information from pharmacy owners?

Question 15: An IA has been prepared covering the costs and benefits of the dispensing error proposals. Do you agree our assessment? If not, please provide details and estimates of any impacts and costs that you consider are not relevant or, alternatively, have not been taken into account.

Question 16: Do you consider there are any additional significant impacts or benefits on any sector involved that we have not yet identified? Please provide details and estimates.

Question 17: As part of preparing this IA we have asked business representatives whether, if the new defence were introduced, it would have a downward impact on employee cost pressures (for instance, any reduction in the risk of being prosecuted could slightly reduce legal or insurance costs). No significant cost impacts have so far been identified. Are there specific impacts on small and micro-businesses that we need to take into account?

Question 18: At this stage, we do not consider it is feasible to estimate a "typical" cost of prosecutions for dispensing errors on individual professionals or pharmacy businesses because of the small numbers involved over the last decade. Do you agree with this? If not, do you have any relevant information which we can consider?

Question 19: We have provided an estimate of the magnitude of the cost and benefits that may arise from the potential implementation of the introduction of the change in approach to dispensing errors. These estimates rely on a number of general assumptions – summarised in Annex B of the IA. These include the length of time it takes a pharmacist to deal with different types of dispensing errors. In addition, we have made assumptions regarding the potential benefits from learning and from a lower risk of prosecution. Do you think the assumptions we have made are proportionate and realistic? If not, what assumptions should we use? Please provide an estimate of the cost of such assumption.

Question 20: We have prepared an IA covering costs and benefits of the premises standards proposals. Do you agree our assessment? If not, please provide additional information (with estimates) regarding other costs or benefits that you think have not been considered in the IA.

Question 21: Our initial analysis of the proposed changes to pharmacy premises standards suggests that our preferred option, Option 2, has no significant transition or ongoing costs relative to the current framework. This is based on assumptions in Annex A of the IA. Are our assumptions valid? If not, please identify what other costs and assumptions have not been identified and provide examples and estimates that will help us quantify and monetise the costs.

Question 22: We do not consider there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree? If not, please identify what these impacts are and their likely costs and explain why they are specific to small and micro businesses. Also, please provide evidence on how small and micro businesses would be affected by an alternative prescriptive rules-based approach compared to an outcome-based system. Please say (i) what assumptions we should use (ii)

identify the impacts and (iii) estimate their likely costs and explain why they are relevant to small and micro businesses.

Question 23: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?