

Title: Impact assessment: Rebalancing medicines legislation and pharmacy regulation programme: Dispensing errors (IA 1 of 2)	Impact Assessment (IA)
IA No:	Date: November 2014
Lead department or agency: Department of Health	Stage: Consultation IA 1 of 2
Other departments or agencies: Medicines and Healthcare products Regulatory Agency, Devolved Administrations, NHS England	Source of intervention: Domestic Type of measure: Other
	Contact for enquiries: John Roberts – 0207 972 5922

Summary: Intervention and Options	RPC Opinion: Green
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Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Measure qualifies as Two-Out?	
£0.69m	£0.17m	-£0.02m	YES	OUT

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

The criminalisation of dispensing errors addresses a problem where those involved in the supply of medicines could act against the best interests of the patient. However, there is evidence that fear of prosecution has a counter-productive effect 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. This could lead to risks for patients, as pharmacy professionals and pharmacies are not fully informed about errors, and are less able to address their causes. Government intervention is therefore required to amend legislation which criminalises such errors to enable full 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.

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 dispensing errors 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.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: Within 3 years after enactment					
Does implementation go beyond minimum EU requirements?				N/A	
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes	< 20 Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/A	Non-traded: N/A	

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

Signed by the responsible Minister:

EARL HOWE

Date: 11 Feb 2015

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: N/A	High: N/A	Best Estimate:	
COSTS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)	
Low	N/A		N/A	N/A	N/A	
High	N/A		N/A	N/A	N/A	
Best Estimate						
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)	
			Optional	Optional	Optional	
Low	Optional		Optional	Optional	Optional	
High	Optional		Optional	Optional	Optional	
Best Estimate						
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						

BUSINESS ASSESSMENT (Option 1)

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

Summary: Analysis & Evidence

Policy Option 2

Description: Remove the criminal sanctions concerning dispensing errors from the Medicines Act 1968

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	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									
High									
Best Estimate			£0m		£0m				
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)				
			Optional		Optional				
Low			Optional		Optional				
High			Optional		Optional				
Best Estimate			£0m		£0m				
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:	In scope of OIOO?	Measure qualifies as
Costs: £0m Benefits: £0m Net: £0m	N/A	N/A

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 2014	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)			
			Low: Optional	High: Optional	Best Estimate: £0.69m	
COSTS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)	
Low	Optional		Optional	Optional	Optional	
High	Optional		Optional	Optional	Optional	
Best Estimate	£0.3m		£0.4m		£4.1m	
Description and scale of key monetised costs by 'main affected groups'						
Cost 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)	
			Optional	Optional	Optional	
Low	Optional		Optional	Optional	Optional	
High	Optional		Optional	Optional	Optional	
Best Estimate	£0m		£0.6m		£4.8m	
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 errors 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% less errors being made.						
Additional time needed for staff to familiarize themselves with legislation whilst at work is 20 minutes.						
Individual 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%)						
The Economic Analysis section includes a sensitivity analysis of the results to changes in the assumptions.						

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:	In scope of OIOO?	Measure qualifies as
Costs: £0.03m Benefits: £0.05m Net: £0.02m	Yes	OUT

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 2014	PV Base Year 2014	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 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	£0m		£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 (%)	3.5%			

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £0	Benefits: £0	Net: £0	Yes	OUT

Rebalancing Medicines Legislation and Pharmacy Regulation –

Overarching background to a series of three Impact Assessments

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. 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).
4. Government intervention is necessary in order to make changes to the legislative frameworks involved to achieve these objectives.
5. These changes cannot be delivered through conventional market mechanisms (price, exchange, permits, quotas) or some other mechanism that does not involve legislation.

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/TER_MS_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 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.
 - 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. The results are available at: <http://www.rpharms.com/professional-empowerment/responsible-pharmacist-impact-research.asp>. 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 the enabling powers contained within the Act, as amended by the Health Act 2006, to make regulations remain necessary.
 - 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. 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 dispensing errors for pharmacy professionals in hospitals.
 - 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 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, but in tandem with these elements, the GPhC, which administers the professional and premises registration requirements under the Pharmacy Order 2010 for England, Wales and Scotland, wishes to move to 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. New specifically modelled powers to draw up codes of practice would 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 has incorporated these proposals as part of the Rebalancing programme and supports them.

Organisation of the overall programme

11. To ensure this overall programme is manageable, the elements in paragraphs 9 (a) – (c) and 10 above comprise the first phase of the Board's work. Hospital pharmacies and pharmacy supervision requirements are being considered in the next phase.
12. Three consultation Impact Assessments have been prepared. These address:
 - Dispensing errors – where three reform options are considered;
 - The proposals for RPs and SPs together, where two reform options are considered; and
 - Proposals in respect of standards for registered pharmacies, where two reform options are considered.

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 46 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 dispensing errors from 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.

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 unamended.

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. The National Reporting and Learning Systems (NRLS) is a central database of patient safety incident reports, run by NHS England. 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 through 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** (see pages 28 et seq).
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 supplied 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 67 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 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 misdispensing 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 Crown Prosecution Service (CPS) 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 misdispensing by pharmacists. This is available at: http://www.cps.gov.uk/legal/I_to_o/medicines_act_1968/

Case study

Elizabeth Lee, 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. Ms Lee 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 Ms Lee 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 her conviction under section 85(5) with a conviction under section 64, and her suspended custodial sentence for a fine of £300.

The perceived impacts

14. Whilst the appeal ruling in the Lee case indicated a monetary penalty rather than a custodial sentence may be more appropriate in cases of inadvertent error similar to hers, 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 the criminal sanctions concerning dispensing errors from the Medicines Act 1968

18. This option removes the criminal sanctions for dispensing errors entirely from the legislation.

Benefits

19. This is the most straightforward option. It may 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 an 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 section 67 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, 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 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 or 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:

<i>General description</i>	<i>Interpretation</i>
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 medicine must have been at or from a registered premises	The GPhC and the PSNI have, exceptionally amongst healthcare regulators, 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 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, 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 the Economic Analysis section.

30. Further benefits are expected from better 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 recent actions by NHS England and the MHRA – see Annex A paragraph 14 - 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 attaching 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 were 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 (paragraph 35 above).
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 England), 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 £0.69million (benefit) over 10 years for Option 3. The main costs to businesses identified are familiarisation costs and those stemming from the higher number of dispensing errors 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 the Government for the purposes of 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.
44. However, there is a 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.
45. 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

46. The criminal offences that apply where the wrong medicine or a medicine of unsuitable quality is supplied incentivise medicine suppliers to act in the best interests of the patient or consumer and provide an effective sanction where they do not. Without Government intervention, medicine suppliers would have a commercial incentive to minimise their costs and efforts to avoid errors in the supply of medicines.
47. 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.
48. 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, giving 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.
49. 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.
50. 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

51. The objective is to amend the current legislative regime, such that pharmacists and pharmacy technicians do not experience a needless fear of prosecution and are not deterred from reporting errors, whilst still maintaining patient and consumer safety by ensuring errors are minimised.

Development of options

52. 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

53. 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 dispensing errors from the Medicines Act 1968

54. This option would remove the criminal sanctions under section 67 concerning errors committed under section 63 and section 64 of the Medicines Act 1968.

Description of likely impacts

55. 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 and 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.

56. 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

57. 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

58. 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. These benefits are left unquantified – but this means the true net benefit is likely to be greater than estimated below.

59. 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
<i>Familiarisation costs</i>	Direct	Follows directly from the implementation of the policy, as staff will need to familiarize themselves with new policy
<i>Cost of increases in reports</i>	Indirect	Does not follow directly from the implementation of the policy, as other issues also affect reporting behaviour
<i>Benefits from reduction in risk of prosecution</i>	Direct	Follows directly from the creation of the specific defence for pharmacy professionals.
<i>Benefits from increased information and learning</i>	Indirect	Does not follow directly from the implementation of the policy, as other issues also affect learning behaviour.

Familiarisation cost impacts

60. 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, and 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.
61. It is assumed 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.
62. The ONS 2013 Annual Survey of Hours and Earnings (ASHE) indicates earnings for pharmacists and pharmacy technicians of **£19.90** and **£11.30** per hour¹ 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 **£25.87 per hour** and **£14.69 per hour** for pharmacists and pharmacy technicians, respectively.
63. 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) shows that **32,850 pharmacists** and **11,660 pharmacy technicians** work in community pharmacies² in Great Britain (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.

¹ <http://www.ons.gov.uk/ons/datasets-and-tables/index.html>; ASHE 2013, Table 14.5a

² http://www.pharmacyregulation.org/sites/default/files/gphc_registrant_survey_2013_main_report_by_natcen.pdf

64. The total cost to business of familiarisation is therefore estimated to be $0.33h \times ([32,850 \times £25.87] + [11,660 \times £14.69]) = £340,000$. 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

65. There are likely to be impacts on business through changes in the numbers of dispensing error reports made. As explained below, two effects are expected: removal of the risk of prosecution where there is a genuine defence is expected to increase the number of reported errors and, over time, learning from error reports, and resulting improvements in training and practice are likely to reduce the number of errors made³.

Increases in error reports after removing the risk of prosecution

66. 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: estimating the number of unprevented dispensing errors, and the proportion of these that will now be reported; and 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

67. Data from the National Reporting and Learning System (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). Assuming that the proportion of dispensing errors reported in Scotland and Northern Ireland is in line with their share of prescription volumes relative to the whole of the UK (11%), then around **18,000** errors are estimated to have been reported across the UK.
68. In order to estimate the actual unprevented dispensing errors that occur in community pharmacies, the findings from the NHS⁴ 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.
69. There were around 1.03 billion prescription items dispensed in primary care in England during 2013 according to the HSCIC⁵. Of these, 90% (927million) are estimated to be dispensed by community pharmacies. NHS Scotland suggests there are approximately 96 million prescription items dispensed in Scotland⁶ of which 86 million are dispensed by community pharmacies. The number of prescription items dispensed by community pharmacies in Wales is 69 million⁷ and in Northern Ireland, 37 million. As a result, it is estimated that approximately 1.12 billion prescriptions were dispensed in the UK by community pharmacies in 2013. Hence, the minimum number of actual unprevented dispensing errors by community pharmacies is estimated at $1.12 \text{ billion} \times 0.04\% = 448,000$ errors every year.
70. Using the above figures, the level of unreported dispensing errors can be calculated as approximately $448,000 - 18,000 = 430,000$.
71. 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

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 <http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59830>

⁵ <http://www.hscic.gov.uk/catalogue/PUB14414>

⁶ [https://isdsctscotland.scot.nhs.uk/Health-Topics/Prescribing-and-Medicines/Publications/2013-06-25/Summary_Statistics_\(Scotland\)_2013.xls?71509564](https://isdsctscotland.scot.nhs.uk/Health-Topics/Prescribing-and-Medicines/Publications/2013-06-25/Summary_Statistics_(Scotland)_2013.xls?71509564)

⁷ <http://wales.gov.uk/statistics-and-research/community-pharmacy-services/?lang=en>

(2012) identify fear of prosecution as 1 of 5 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 $430,000 \times 20\% = 86,000$ additional reports of dispensing errors being made. However, 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 86,000= 43,000 in the first year and 100% by the second year (for further information see the table after paragraph 83).

Reduction in number of errors through improved information and learning

72. 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, and thereby reduce 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 and through the greater availability of dispensing error reports, information on trends and the feedback available to professionals.
73. 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).
74. The estimate of the potential reduction in errors takes into account the potential 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.
75. Standard quality improvement methodology, such as that promoted by the Institute of Healthcare Improvement⁸, 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.

Projected overall impact on dispensing error reports

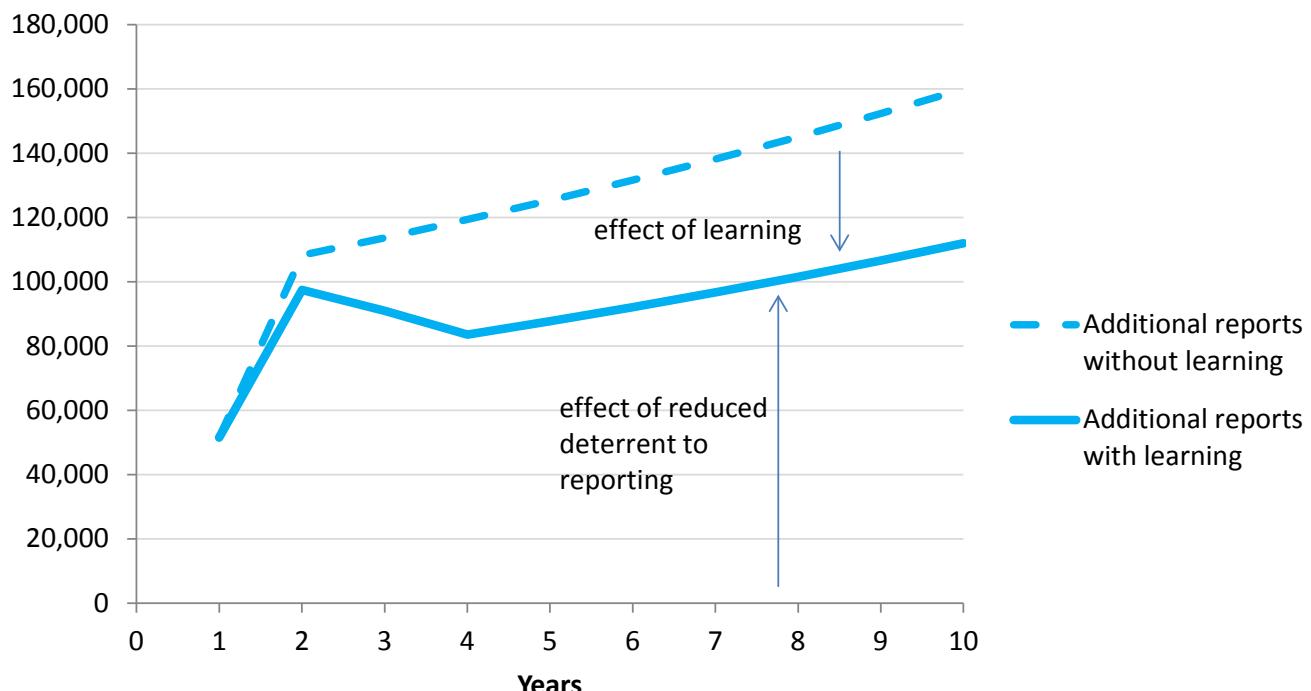
76. This section uses the results of the previous analysis to project the number of error reports over the next ten years, and calculate present value estimates for the cost impacts on business.

Projecting error reports

77. As shown in the graph below, the effect of reducing the risk of prosecution is expected to initially increase error reports by 43,000 and 81,000 in the first and second year respectively. As a result, total error reports are expected to increase from the current 18,000 to **99,000 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**.
78. 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.
79. The following graph shows the implied projections of additional error reports over a ten year period, compared to the counterfactual “do nothing” scenario.

⁸ <http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTipsforSettingAims.aspx>

Number of additional error reports, pa



Estimating the cost to business of error reports

80. 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.
81. Dispensing errors can be reported to the NHS system in England online⁹. 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 or 0.25 of an hour** to report a dispensing error.
82. The cost of this impact to businesses is calculated using the estimates for staff costs and numbers above. These imply that **74%** of community pharmacy professionals are pharmacists, while **26% are** pharmacy technicians. From this, the estimate of the cost to businesses of reporting a dispensing error is $([\£25.87 \times 74\%] + [\£14.69 \times 26\%]) \times 0.25 \text{ hours} = \text{£5.74 per form}$.

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.

Year:	1	2	3	4	5	6	7	8	9	10
Additional reports	42,969	81,212	75,798	69,639	73,121	76,777	80,616	84,647	88,879	93,323
Costs of reports	246,442	470,434	439,072	403,397	423,567	444,745	466,983	490,332	514,848	540,591

84. 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 **£3,771,000**.

⁹ <http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/>

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 – as they incur other costs associated with dispensing errors, beyond the costs of reporting.
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.

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.

90. This approach gives an estimate for the number of reduced errors over a ten year period of 271,000.

Estimating the cost savings to business from reduced errors through learning

91. Data from the NHS England 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 a conservative 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 calculation above give an average cost per error of **£19.04**.

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

94. The assumptions and calculation above give a NPV of cost savings to business of **£4,293,000**.

Cost-savings from the reduction in prosecutions and prosecution risks

95. There are additional cost-savings 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.

96. Individuals and companies' valuation of risk and benefits from its decrease can be assessed by looking at their willingness to pay for protection from the relevant risk¹⁰. 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 of a reduction in the risks of prosecution. This is illustrative as not all pharmacy professionals may use this type of insurance, even though they all do (personally or via their employer) face costs for legal protection, which should not differ significantly at the aggregate level.
97. The current insurance premium for community pharmacists is 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 the insurance premium. Hence, a decrease in the probability of prosecution can be equivalent to a conservative scenario of a 1% decrease in the premiums paid by pharmacists and pharmacy technicians. This would correspond with annual savings of around £1.45 per professional per year or approximately (44,510*£1.45) £64,500 each year.
98. This implies an NPV cost saving to businesses of **£508,000** over the ten year period. This is the figure used for the calculations below.

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. 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 concerning Elizabeth Lee took more than a year to resolve¹¹. This policy option directly avoids these sort of cases, where the pharmacy professional acts appropriately according to professional norms. Hence, this policy directly results in cost-saving equal to the cost of a potential prosecution. These are likely to be significant as described by the Public Prosecution Service¹². As a result, the direct effect of avoiding a prosecution in the ten year period under analysis can be expected to be **higher than the £301,000** estimated as familiarisation costs. This figure is not used for any of the calculations.

Summary of impacts

101. As described above, the impacts evaluated are the cost impacts on businesses.
- i. One off **familiarisation costs** are estimated at **£340,000**
 - ii. The net cost impact of changes in error reports is estimated to have a net present value of **£3,771,000**
 - iii. The cost savings resulting from reductions in the handling of dispensing errors is estimated to have a net present value of **£4,293,000**

¹⁰ <http://www.k-state.edu/05BDE8D7-642F-4FDF-A12F-E685EA808EC8/FinalDownload/DownloadId-0B24175458CDB093F616440A19DD1556/05BDE8D7-642F-4FDF-A12F-E685EA808EC8/economics/staff/websites/chang/publications/CJE-1985%20Insurance.pdf>

¹¹ <http://news.bbc.co.uk/1/hi/health/8101446.stm>

¹²

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

iv. Net cost savings from the reduced risk of criminal prosecution is estimated to have a net present value of **£508,000**.

102. The net cost impact on business is therefore estimated to be **£689,000 in cost savings**.

Summary of projected impacts over 10 year period

Year:	1	2	3	4	5	6	7	8	9	10
Phasing in of reporting change	50%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Additional reports without learning	42,969	90,236	94,747	99,485	104,459	109,682	115,166	120,924	126,971	133,319
Learning profile (reduction in actual errors)	0%	10%	20%	30%	30%	30%	30%	30%	30%	30%
Additional reports with learning	42,969	81,212	75,798	69,639	73,121	76,777	80,616	84,647	88,879	93,323
Business cost of additional reports	246,442	470,434	439,072	403,397	423,567	444,745	466,983	490,332	514,848	540,591
Business costs of familiarisation	340,372	0	0	0	0	0	0	0	0	0
Reduction in errors	0	9,024	18,949	29,845	31,338	32,905	34,550	36,277	38,091	39,996
Business cost savings from reduced errors	0	171,820	360,821	568,294	596,708	626,544	657,871	690,764	725,303	761,568
Reduced risk of prosecution		64,991	65,446	65,904	66,366	66,830	67,298	67,769	68,244	68,721

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

Impact of additional reports	3,771,183
Impact of familiarisation (direct)	340,372
Impact of reduced handling errors	-4,293,147
Reduced risk of prosecution (direct)	-507,694
Net costs to business	-689,287
-Net direct cost to business	-169,322

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

Assumptions modified	£NPV
Base case	-689,287
a.) Reports increase by 20% more than expected (no increases in learning)	-64,950
b.) Familiarisation time 40% higher	-553,138
c.) Handling of 'serious' errors takes 5 hours	-378,939
d.) Value of reduced risk of prosecution equivalent to 1.5% reduction in risk/insurance premium	-943,134
- Combined b.) and d.)	-806,985
- Combined a.) and b.)	201,099
- Combined a.), b.), c.) and d.)	257,600

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 three 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 initiatives to increase reporting and the indirect effect of the introduction of a defence to the criminal sanction in the Act). The draft legislation contains a longer-stop provision that a review must be conducted within seven years of it coming into force.

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

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

HEALTH AND WELL-BEING

110. 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

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

JUSTICE SYSTEM

112. 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.

113. 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 removed, for dispensing errors by pharmacists and pharmacy technicians. A new defence is 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. **However, we will ask business and relevant agencies for further information on this aspect as part of the proposed consultation.**

RURAL PROOFING

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

SUSTAINABLE DEVELOPMENT

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

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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 England) 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

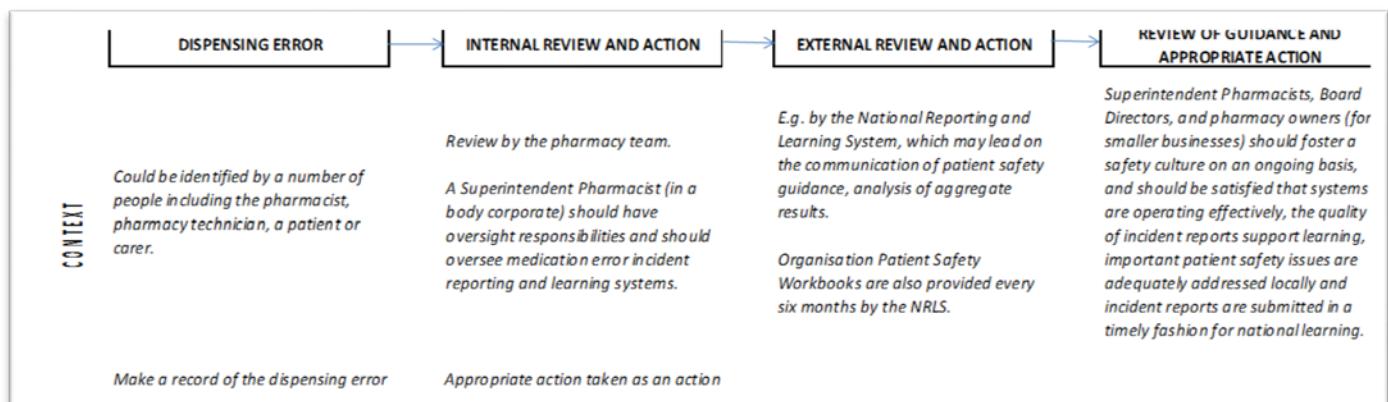
5. There is a small body of evidence concerning attitudes to reporting dispensing errors in the UK. Ashcroft et al. (2006), undertook a study to “...examine the likelihood of community pharmacists and support staff reporting patient safety incidents which occur in community pharmacies” using a questionnaire 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”.
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 and the MHRA are jointly working on a collaborative programme to “simplify reporting, improve learning and guide practice to minimise harm from medication errors”¹³. 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 NRLS¹⁴ 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 2 below:

Table 2: Clinical Outcomes of medication incidents:

<i>Actual clinical outcome</i>	<i>Incidents</i>	<i>Percentage of medication incidents</i>
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 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

¹³ <http://www.england.nhs.uk/2014/03/20/med-devices/>

¹⁴ 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/>),

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 (un.prevented) 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.
30. The traditional model of prescribing by medical practitioners and dentists has, in the past two decades, much changed, with other health professionals, including pharmacists, acquiring prescribing rights. Because the professional behaviours connected with supplying against one's own prescription, as opposed to dispensing against another's prescription, are different, it was decided not to include mistakes made where a health professional supplies a medicine to give effect to their own treatment decision as part of the Rebalancing Programme.

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 61).
- b.) Average hourly cost of a pharmacist and a pharmacy technician (including wages and additional employment overheads) of £25.87 per hour and £14.69 per hours respectively (see Paragraph 62).
- 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 68).
- 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 71).
- 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 74 and Paragraph 78).
- g.) It takes 15minutes to report a dispensing error to the NHS system online (see Paragraph 81).
- 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 96).
- l.) 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).