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Rebalancing Medicines Legislation and Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999

Consultation document

February 2015

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Rebalancing Medicines Legislation and Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999

Consultation document

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Executive summary

- This UK-wide consultation, issued on behalf of the four UK Health Departments, seeks comments and views on two pharmacy related draft Orders being made under the powers in section 60 of the Health Act 1999. Section 60 orders are subject to Parliamentary scrutiny through the affirmative resolution procedure. The requirement to consult is provided for in the Health Act 1999, in paragraph 9 of Schedule 3.
- Because the regulation of pharmacy technicians is a devolved matter as regards Scotland, the draft Orders must be laid before the Scottish Parliament, as well as the UK Parliament. While there is no legislative requirement for the draft Orders to be laid before either the Northern Ireland Assembly, or the National Assembly for Wales, the policy proposals have the support of the Ministers in Northern Ireland, Scotland and Wales and the outcome of the consultation will be reported to all UK health ministers.
- The two pharmacy-related draft Orders are:
 - i) The Pharmacy (Preparation and Dispensing Errors) Order 2015
 - ii) The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2015
- **The Pharmacy (Preparation and Dispensing Errors) Order 2015**, in summary, makes provision for:
 - a defence to prosecution under section 63 (adulteration of medicinal products) of the Medicines Act 1968, in cases of errors where medicines are prepared by a registered pharmacist or a registered pharmacy technician, or under the supervision of a registered pharmacist;
 - a defence to prosecution under section 64 (medicinal products not of the nature or quality ordered) of the Medicines Act 1968, in cases of errors where medicines are dispensed by a registered pharmacist or registered pharmacy technician, or under the supervision of a registered pharmacist; and
 - the conditions to be met if the new defences are to apply.
- This proposal is part of broader proposals for the rebalancing between criminal law and professional regulation so that matters that should properly be within the ambit of pharmacy regulators, the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI), are in fact dealt with by them – and by registration sanctions, rather than by the criminal courts.
- It builds on learning from the Francis and Berwick reports and work done by the professional and regulatory bodies for pharmacy. With the safety of users of pharmacy as a core principle and supporting openness and a learning culture, the intention is to remove the threat of criminal sanction for inadvertent preparation and dispensing errors, while retaining the criminal sanction for those errors or deliberate acts that are such that the pharmacy professionals responsible for them cannot properly be said to have been acting professionally. The Berwick Report makes the point that fear is toxic to both safety and improvement. This is especially so in the case of dispensing errors, where all such errors are

strict liability offences, which means that a criminal offence is committed even if the error itself is unintentional and regardless of the level of patient impact.

- This is not to say that there will be no accountability for dispensing errors. As now, the pharmacy regulators will be able to use ‘fitness to practise’ measures to determine what, if any, action is to be taken, which includes the ultimate sanction of striking the individual off the professional register.
- Criminal sanction will remain in place for dispensing errors falling outside the proposed defences, for example, where pharmacy professionals do not act in the course of their profession or show a deliberate disregard for patient safety. General criminal law may also apply.
- The proposals to change current arrangements are designed to contribute to openness and increased reporting of inadvertent dispensing errors so that everyone can learn from mistakes.
- Removing the threat of criminal sanction for inadvertent preparation and dispensing errors will address a significant fear amongst pharmacy professionals, which is currently inhibiting the reporting of such errors. Ultimately, this change should support increased reporting and learning from errors, thereby improving patient safety and promoting better professional practice. Promoting a virtuous cycle of reporting and learning, as well as removing the “fear factor” of prosecution, is at the heart of the proposed overall approach to this issue.
- **The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2015** amends the provisions of the Pharmacy Order 2010 in respect of the GPhC setting standards for registered pharmacy premises, so that these will no longer be in rules. Breach of standards will be dealt with through registration sanctions rather than, as at present, through enforcement notices, breach of which could lead to criminal proceedings or disqualification proceedings. The Order also makes provision for the PSNI to set standards for registered pharmacy premises. Provisions on interim orders, publication of inspection reports and a correction of a provision in the Pharmacy Order 2010 relating to notification of the death of a registered pharmacist or registered pharmacy technician are also included in the draft Order.
- The consultation will run for a period of 13 weeks, to 14 May 2015.

Policy background

Background

1. The UK Governments are committed to delivering a modern approach to healthcare regulation, which promotes patient safety, while supporting professional and quality systems development. In line with this, and with broader developments in the delivery of healthcare, the opportunity has been taken to examine the different systems underpinning the regulation of pharmacy.
2. Pharmacy practice is governed by medicines legislation and professional regulation legislation. In addition, NHS legislation governs the provision of NHS pharmaceutical services. The framework legislation covering the essential matters relating to the preparation, sale and supply of medicines for human use is the Medicines Act 1968, as amended, and the Human Medicines Regulations 2012, which consolidated much of the law relating to the supply of medicines for human use in the UK, including some provisions formerly in the Medicines Act. A number of pharmacy specific matters are covered in the Pharmacy Order 2010 (covering Great Britain) and the Pharmacy (Northern Ireland) Order 1976.

Dispensing errors

3. Pharmacy professionals (registered pharmacists and registered pharmacy technicians) have long expressed concerns about the risk of criminal prosecution for single dispensing errors, which was highlighted most recently during the passage of the bill which became the Health and Social Care Act 2012. A review of the law in this area, as it affects pharmacy professionals, forms part of the “rebalancing” work programme.

Better regulation

4. The UK Government’s Red Tape Challenge on medicines included The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. Those Regulations were also subject to an evaluation commissioned by the Royal Pharmaceutical Society (RPS) and the Pharmacy Forum of the Pharmaceutical Society of Northern Ireland (PFPSNI) in 2011. In the course of reviewing the outcome from both initiatives, it became clear that there was a need to examine the broader landscape of arrangements for pharmacy governance in the round, rather than simply dealing with aspects in isolation.
5. In addition, there was a need to take account of the activities being undertaken by others, including:
 - the pharmacy regulators’ work programme, which includes registered pharmacy standards, inspection and new enforcement mechanisms;
 - work by the professional bodies on professionalism, professional leadership, quality systems and culture;

- the Law Commission review of professional regulation and the draft Bill that has resulted from that;
 - changes to NHS regulation; and
 - work planned or under way in relation to the report of the Francis inquiry. In a statement on 19th November 2013, the Government accepted the recommendations of the Francis report on the Mid Staffordshire NHS Foundation Trust public inquiry. As part of the work to take forward the recommendations, proposals for the development of new and specific offences of ill-treatment or wilful neglect of patients and service users are reaching an advanced stage.
6. The task therefore is to ensure that legislative and regulatory arrangements accommodate progress and development in pharmacy practice without losing sight of the fundamental function of such legislation and regulation, which is to protect, promote and improve people's health through the safe use and management of medicines. The interplay of the medicine supply components of medicines legislation and the regulation of both professional practice and pharmacy premises has been considered in the round, rather than each aspect considered in isolation.

Policy, legislative framework and regulation

7. As mentioned earlier, the main domestic legislation for medicines in the UK is the Human Medicines Regulations 2012, into which much of the Medicines Act 1968 was consolidated, and the surviving provisions of the Medicines Act 1968 itself. Certain elements of the Medicines Act 1968 that pertain to medicines supply and pharmacy regulation have been retained within the Act, for example section 10, which contains the pharmacy exemption from the main licensing provisions for the preparation and assembly of medicines at pharmacies, and Part IV on registration of retail pharmacies.
8. Although the UK Health Departments set the overarching policy, the role of the pharmacy regulators is key to safeguarding the public and in particular members of the public, who use or need the services of pharmacy professionals or the services provided by a registered pharmacy. As part of that, pharmacy regulators have legal functions and powers to set and require compliance with standards and to take action when these are not met.

Arrangements to bring forward proposals

9. A programme board under the independent chairmanship of Ken Jarrold, CBE, was set up to consider and review the pertinent legislation and regulation and to advise UK Ministers on policy. Ministers in the Devolved Administrations are kept informed by their officials. The board's role also extends to co-ordination and oversight of implementation of the policy outcomes.

10. The programme board for “rebalancing” medicines legislation and pharmacy regulation was tasked with examining the respective scope of legislation and regulation, and the interface between them, with a view to ensuring these are optimally designed to provide safety for users of pharmacy services, while facilitating and reducing the barriers to responsible development of practice, innovation and a systematic approach to quality in pharmacy. Programme board membership and terms of reference are shown at Annex B.
11. A partners' forum, which includes key stakeholders, patients and public has been set up as part of the policy review process. The forum acts as a sounding board and provides feedback on proposals from the programme board.

The work programme

12. The programme addresses a number of key areas and is being taken forward in phases with proposals on dispensing errors and registered pharmacy standards and related matters being taken forward as a priority :

First Phase

- a. **Dispensing Errors:** Review the criminal offences in sections 63 and 64 of the Medicines Act 1968 in relation to regulated pharmacy professions, operating from regulated pharmacy premises. The threat of criminal sanction is widely believed to hinder the reporting of errors and therefore the learning from such errors. There is evidence that reporting and learning from errors supports patient safety.
- b. **Registered Pharmacy Standards and Related Matters:** In tandem with the board's work, changes are required to legislation to enable the GPhC to implement work on registered pharmacy standards already developed in consultation with key stakeholders. In addition, changes relating to inspections, inspection reports and enforcement are also proposed. Similar changes apply for PSNI, where appropriate.
- c. **Pharmacy Owners, Superintendent Pharmacists and Responsible Pharmacists:** The board was asked to examine the legislative and regulatory framework in terms of the effectiveness of components of the system, which support patient safety, not only in relation to responsible pharmacists, but also the role of pharmacy owners and superintendent pharmacists, in order to provide greater clarity on role, accountability and competence. Proposals for this area of the board's work will follow in a later consultation.

Second Phase

- d. **Hospital Pharmacy:** The board is also considering regulatory arrangements for hospital pharmacies. In underpinning high quality hospital pharmacy services, these would enable the removal of the criminal sanction for preparation or dispensing errors for pharmacy professionals in hospitals. Provision of medicines to patients in hospital does not, for the most part, require registration of pharmacy premises, although all hospital pharmacy professionals are subject to professional regulation in the normal way.

- e. **Pharmacist Supervision:** Building on the foundations above, the programme board has been asked to develop proposals on supervision. These should identify and review the medicines legislation, which may restrict the full use of the skills of the pharmacy workforce or impede the deployment of modern technologies or put unnecessary obstacles in the way of new models of pharmacy service, while maintaining patient and public safety.
13. Proposals for changes to the legislation for (i) dispensing errors and (ii) registered pharmacy standards and related matters, as mentioned above, are reflected in the two draft Orders, which accompany and are the subject of this consultation document.

Process

14. As mentioned earlier, the legislative instruments being used are orders under section 60 of the Health Act 1999, which permit changes to primary legislation (i.e. Acts of Parliament) through secondary legislation, and which are affirmative instruments. That is they must be debated and approved by both Houses of Parliament before they can be presented for signature at a meeting of the Privy Council.
15. There are constitutional, regulatory and operational differences in relation to pharmacy matters in the devolved administrations. Pharmacy regulation is a fully devolved matter as regards Northern Ireland, and the pharmacy regulator function is not separated from the professional body in the same way as it is in Great Britain. Additionally, pharmacy technicians are not a registered health profession in Northern Ireland.
16. Although professional regulation of all health care professions is a devolved matter as regards Northern Ireland, it is only in respect of pharmacists that there is a separate regulatory body just for Northern Ireland. This distinct position is reflected in the bar that currently exists in paragraph 12 of Schedule 3 to the Health Act 1999, which prevents section 60 Orders being used to regulate both pharmacists in Northern Ireland and the activities of individuals who are not pharmacists but who carry on activities in connection with the practice of pharmacy. Legislation was enacted in 2008 to repeal that bar, but that repeal was not commenced at the time.
17. UK Ministers are now preparing to commence that repeal. However, its commencement does not affect the fully devolved nature of pharmacy regulation as regards Northern Ireland. Indeed, to reflect the distinct arrangements for pharmacy in Northern Ireland, article 3(5) of the draft Pharmacy (Preparation and Dispensing Errors) Order 2015 provides that the changes to the Medicines Act 1968 in the Order will only be commenced in relation to Northern Ireland with the agreement of the Minister for Health, Social Services and Public Safety.
18. For Scotland, professional regulation of pharmacists and the Medicines Act 1968 regulation of retail pharmacy premises are reserved matters, whereas professional

regulation of pharmacy technicians is a devolved matter. Because the changes made by the draft Pharmacy (Preparation and Dispensing Errors) Order 2015 affect pharmacy technicians, by virtue of section 62(10) of the Health Act 1999, the legislative proposals will require debate and approval by the Scottish Parliament before they can be presented for signature at a Privy Council Meeting.

19. The proposals for changes set out in the draft Pharmacy (Premises Standards , Information Obligations, etc.) Order 2015 include, among other matters, amendments to the Pharmacy Order 2010 to remove the requirement to set premises standards in rules. Up until now, the approval of any changes to registered premises standards made by Order of the Privy Council would be subject to annulment by resolution in the UK Parliament as well as the Scottish Parliament. Removing the requirement for registered pharmacy standards to be in GPhC rules will change that. Instead, there is an explicit requirement for the GPhC to consult Scottish Ministers, as well as English and Welsh Ministers, on those standards.

Dispensing errors

20. This section deals with the proposals in the draft Pharmacy (Preparation and Dispensing Errors) Order 2015.

Paragraphs	What this section covers
Paragraphs 21- 32	<p>This describes what we mean by dispensing errors. We give examples. Generally, such errors are not intended.</p> <p>However, they are crimes under the current law.</p> <p>We want to encourage more reporting and openness about errors so that everyone can learn from mistakes and patient safety, which is extremely important, is maintained and, we hope, improved.</p> <p>However, the fear of prosecution is stopping this happening.</p> <p>We, therefore, want to hear your views on our proposals to change the current arrangements.</p>

Background

21. There is no universal definition of a dispensing error. For the purposes of this consultation a dispensing error is viewed as an error which has been made during the dispensing process from receipt of the prescription, or a decision to dispense against a direction, through to the supply of the dispensed medicine, where the error means that the patient actually receives a product that they should not. Errors could include:
- incorrect labelling of the medicine;
 - a medicine intended for another patient being dispensed to the wrong patient;
 - the wrong medicine being dispensed;
 - the medicine being dispensed at the wrong strength or in the wrong dosage form; or
 - the supply of an out of date medicine.
22. Although most dispensed medicines are manufactured away from the pharmacy, on occasion, pharmacists may have to make up (compound) a medicine from individual ingredients. Errors may therefore occur if, for example, an ingredient is omitted or inadvertently added, which “adulterates” the medicine.
23. The sale and supply of medicines is governed by the Medicines Act 1968 and the Human Medicines Regulations 2012, as well as a number of pharmacy specific matters being covered in the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976.

24. A number of contraventions of medicines legislation are criminal offences. This applies to the provisions that are generally used to deal with dispensing errors. These are strict liability offences, which means that a criminal offence is committed if a dispensing error is made even though the error itself is unintentional and regardless of the level of patient impact.
25. As pharmacies are the major suppliers of medicines and pharmacists have been prosecuted for apparent errors, there is an urgent need to address the fear among pharmacy professionals (pharmacists and pharmacy technicians) of being the subject of criminal proceedings when any dispensing error is made.
26. It is well recognised that in any process involving people, there is always the possibility of a human error – “to err is human”. However, pharmacy professionals are in an unusual position of being concerned that any error when dispensing a medicine could result in them facing an investigation and criminal prosecution. This impacts on their willingness to record and report errors, which in turn impacts on the opportunity to learn from errors - a vitally important contributor to improving patient safety. As an analogy, the airline industry demonstrates the benefits of a culture of openness and transparency in learning from errors and ultimately enhancing public safety. Where reporting levels are low, data are less comprehensive, leading to reduced opportunities to learn from such events and a reduction in public confidence in the system.
27. The policy objective is therefore twofold. It aims to remove the threat of criminal sanction for inadvertent dispensing errors, while retaining the criminal sanction for errors that do not meet the criteria for the new defences. It seeks to support safety for the users of pharmacy services while recognising that healthcare will always involve risks, but that these risks can be reduced through reporting, analysing, increasing awareness and tackling the causes of patient safety incidents. Knowing that a mistake can result in a criminal prosecution doesn't necessarily mean that patients and the public are better protected. It can lead the pharmacy professional to practise defensively. One of the aims of this work is to support the professional leadership in encouraging a culture of reporting mistakes, learning from them and sharing that learning. By removing from pharmacy professionals the threat of criminal sanction for inadvertent dispensing errors we will be actively encouraging a culture of reporting and learning from errors and thereby promoting better practice and improving patient safety.
28. The *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry*, chaired by Robert Francis QC and published in February 2013, called for a ‘fundamental culture change’ across the health and social care system to put patients first at all times. Robert Francis QC, the Inquiry Chair, called for action across six core themes: culture, compassionate care, leadership, standards, information, and openness, transparency and candour.
29. As a result, the government commissioned six independent reviews to consider some of the key issues identified by the Inquiry. Among these, the National Advisory Group on the Safety of Patients in England chaired by Professor Don Berwick was tasked with providing advice on next steps toward a better and safer NHS. Its report entitled *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* was published in August 2013.

30. The approach being taken in respect of dispensing errors aligns with the recommendations in the Berwick report. This focussed on the importance of achieving a careful balance between culture changes, which support openness and transparency to encourage learning from errors leading to improvement in practice and safety, with the need to assure accountability to the patient.
31. Wider factors will also contribute to handling and learning from dispensing errors. For example, pharmacy owners, whether corporate bodies or individuals, will have their own systems regarding the handling of dispensing errors, which may include reporting responsibilities and disciplinary sanctions that sit within the terms of contracts for employees.
32. The programme board in its discussions put public safety at the heart of its deliberations and was clear that deliberate errors should continue to be subject to criminal sanction. Proposing a change to the sanctions arrangements in the Medicines Act 1968 for inadvertent dispensing errors by pharmacy professionals at registered pharmacy premises does not imply impunity for such errors. Instead such errors will be dealt with by the pharmacy regulators, which continue to have responsibility in the context of the registration of individual pharmacy professionals to deal with such matters through registration sanctions.

The proposal to add a new defence in relation to section 64

Paragraphs	What this section covers
Paragraphs 33 - 36	<p>This section describes the law which says that a criminal offence occurs when a dispensing error is made.</p> <p>It includes errors that occur when medicines are sold over the counter or supplied against a prescription.</p> <p>We think it is important that we do not remove the criminal offence entirely. That would be too great a risk for patients and consumers.</p> <p>Instead, we propose introducing a new “defence” where a dispensing error occurs. However, this “defence” would only operate if strict conditions are met.</p> <p>We ask if you agree this approach. Further details of the “defence” are given in the section that follows.</p>

33. The greatest fear among pharmacy professionals is fear of prosecution under section 64 of the Medicines Act 1968. This section provides protection for purchasers of medicinal products such that *“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.”* This includes

sales or supplies of medicines in pursuance of a prescription. Errors, including dispensing errors, would be caught by this provision and therefore potentially liable to prosecution. In practice, there have been few prosecutions, but errors brought to the attention of the regulators, the Medicines and Healthcare Products Regulatory Agency (MHRA), the Crown Prosecution Service, the Public Prosecution Service of Northern Ireland, the Crown Office and Procurator Fiscal Service or the police will usually be investigated. The decision to proceed to criminal prosecution is taken based on the facts of individual cases and prosecution guidelines.

- 34. It is proposed to leave the offence itself – as well as the current defences – unaltered (for example, the defendant will be acquitted if it turns out that the contravention was due to someone else’s fault and the defendant exercised all due diligence). This is because, as a matter of public policy, we need to retain the ability to prosecute in certain circumstances. Section 64 also applies to anyone who supplies medicines – for example other registered healthcare professionals, and shops that sell small quantities of medicines for common ailments.
- 35. The role of the pharmacy regulators – the GPhC and PSNI – is key to safeguarding the public and, in particular, those who use or need the services of registered pharmacy professionals or the services provided by a registered pharmacy. As such, pharmacy regulators set and require compliance with standards and rules and have the ability to take action when these are not met.
- 36. We therefore propose to introduce a new defence to prosecutions under section 64 for pharmacy professionals, **but only where certain conditions are met**. The effect of this will be that pharmacy professionals making an inadvertent dispensing error and satisfying the conditions for the new defence, would no longer face the risk of criminal prosecution under the Medicines Act 1968, although they would continue to be subject to the scrutiny arrangements of their professional regulator. Depending on the circumstances and effects of the error, an individual may be subject to regulatory fitness to practise procedures. In more serious cases, that individual could ultimately be removed from the register. In addition, the general criminal law would continue to apply, for example, in cases of gross negligence manslaughter or culpable homicide.

Question 1:

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

Introduction of a new defence in relation to section 64

Paragraphs	What this section covers
Paragraphs 37- 43	<p>This section gives further details on the new defence in relation to section 64 of the Medicines Act 1968.</p> <p>It outlines the conditions that pharmacy professionals must satisfy in order to be able to rely on this defence. These are explained more fully in the sections below.</p>

Except where indicated, it will be for the pharmacy professional to prove that, on the balance of probabilities, they meet the conditions for the defence to apply.

For a person to be convicted under section 64, the prosecution needs to prove each and every element of the offence, beyond a reasonable doubt.

A pharmacy professional needing to prove matters on a balance of probabilities is in keeping with society's general expectation that professionals should be willing and able to account for their actions.

37. Section 64 of the Medicines Act 1968 already includes exemptions from its provisions in certain circumstances (for example, extraneous matter that is an inevitable part of a manufacturing process), and there are the general defences in sections 121 and 122 of the Act. None of these address inadvertent dispensing errors. The new defence is set out in the proposed new section 67C in the draft Order.
38. For a pharmacy professional to rely on the defence, the following conditions must be satisfied:
- i) The sale or supply is of a medicine dispensed by a registrant, i.e. a registered pharmacist or registered pharmacy technician, or by someone acting under their supervision (but see paragraphs 46 and 47 concerning "supervision");
 - ii) The registrant was acting in the course of their profession;
 - iii) The medicine must have been dispensed at or from registered premises, i.e. premises entered in the premises register of the relevant pharmacy regulator (GPhC or PSNI);
 - iv) The sale or supply must have been in pursuance of a prescription or directions; and
 - v) If the error is discovered before the defendant is charged, there was prompt notification of the error.
39. Each condition is explored more fully in the following paragraphs. Where a pharmacy professional seeks to rely on the new defence, the conditions described earlier will **all** need to be met. These basic elements, such as the dispensing of the medicine by a registered pharmacist or under the supervision of a pharmacist, including a registered pharmacy technician, at or from a registered premises, should be straight-forward to prove.
40. Except where indicated, it will be for the pharmacy professional to prove that, on the balance of probabilities, they meet the conditions attaching to the defence. The terms "defendant" and "prosecution" are used to support clarity in assessing evidence prior to any decision as to whether the conditions for the defence in section 67C, specified earlier, are met. In practice, however, cases are only brought if they are in the public interest and there is a realistic prospect of success, so the intention is that the pharmacy professional

would not routinely become a “defendant” as such, even though that is the language used in the legislation and for the purposes of this description.

41. For a person to be convicted under section 64, the prosecution needs to prove each and every element of the offence, beyond a reasonable doubt. So, for example, in the case of a sale of a medicine, the prosecution would have to prove beyond a reasonable doubt that the transaction took place. For a prosecution under section 64 to succeed, they would also have to prove “prejudice” to the purchaser – which in the case of supply in pursuance of a prescription, would mean prejudice to the patient – as that is one of the elements of the offence.
42. The prosecution’s obligation to prove each and every element of the offence beyond a reasonable doubt does not extend to proving beyond a reasonable doubt that each and every possible exemption or defence that the defendant might have does not apply. In the case of the new defences in the draft Order, there is a burden on the defendant to show that a particular defence might apply before it becomes a live issue before the court.
43. In the case of these new defences, the general position is that the defendant, most probably a pharmacy professional, will need to prove that they meet all the requirements of the defence, on a balance of probabilities – although for practical reasons, for some elements of the defence, the prosecution will instead have to prove that they don’t apply once it is clear that they might apply. This is explained in more detail below. The general position of the pharmacy professional needing to prove matters on a balance of probabilities is in keeping with society’s general expectation that professionals should be willing and able to account for their actions.

A medicine dispensed by, or under the supervision of, a registrant

Paragraphs	What this section covers
Paragraphs 44- 47	<p>This section explains the first condition of the new defence under section 64 in more detail.</p> <p>The person who “dispensed” must be a registered pharmacist or registered pharmacy technician.</p> <p>We are not defining the term “dispensing” – it would be up the defendant to prove the defence applied on a balance of probabilities.</p> <p>These new defences do not change the position in medicines legislation about who may or may not “supervise” the sale or supply of pharmacy or prescription only medicines – this cannot be supervised by a registered pharmacy technician.</p>

44. The first condition of the defence is that the person who dispensed the medicinal product was either a registrant or a person acting under the supervision of a registrant (section 67C(2)(b)). The new section 67E(1) makes it clear that “registrant” for these purposes is a pharmacist registered by the GPhC or PSNI – or, in Great Britain, a person registered as a pharmacy technician by the GPhC.

45. The term “dispensing”, although already used in the Act, is not defined. We do not propose to define this here. Whether or not a medicine was in fact dispensed by or under the supervision of a registrant would be a matter that the defendant (who need not be the registrant) would have to prove on a balance of probabilities, in keeping with the usual common law position.
46. It is important to emphasise that nothing in the new defences changes the position that exists elsewhere in medicines legislation as to who may or may not “supervise” the sale or supply of pharmacy or prescription only medicines. Currently, by virtue of regulation 220(2)(c) of the Human Medicines Regulations 2012, such transactions have to be supervised by a registered pharmacist. They cannot be supervised by a registered pharmacy technician. A registered pharmacy technician who purported to “supervise” the sale or supply of a pharmacy or prescription only medicine would not, as matters stand, be “acting in the course of their profession”, so the new defence would not be made out in such a case.
47. As mentioned above, phase 2 of the work programme will be looking at pharmacist supervision, and so there has been some “future proofing” in the way that section 67C(2) has been drafted – to accommodate the possibility of supervision of transactions by registered pharmacy technicians, should that possibility come to pass. If it did come to pass, its effect would be limited to Great Britain, unless or until pharmacy technicians became a registered profession in Northern Ireland.

Acting in the course of his or her profession

Paragraphs	What this section covers
Paragraphs 48 - 57	<p>This section explains the second condition of the new defence under section 64 in more detail.</p> <p>The person acted “in the course of his or her profession” as a pharmacy professional.</p> <p>A key part of pharmacy professionals’ professional practice is that they will always exercise their professional judgement in the interests of patients and the public.</p> <p>Again, we do not define “acting in the course of his or her profession”. It will be up to the prosecution to prove the registrant was not acting in the course of his or her profession if this comes up in court.</p> <p>Defendants will need to provide sufficient evidence to show that they were acting in the course of their profession.</p> <p>The draft Order gives two illustrative grounds that the prosecution might</p>

wish to rely on to demonstrate that the registrant was not “acting in the course of his or her profession”.

We ask if you agree that it is up to the prosecution to prove that the registrant was not acting in the course of the profession subject to sufficient evidence being brought to court by defendants. We also ask whether you agree with the illustrative grounds.

We suggest that where pharmacy professionals do not follow standard operating procedures, this should not, in itself, constitute them “not acting in the course of their profession” and we ask whether you agree with this.

48. The second condition of the defence is that the registrant was “acting in the course of his or her profession”. This concept is key to the whole approach to dispensing errors in the draft Order and underlies why a section 60 Order has been chosen as the suggested route to make the legislative changes.
49. Pharmacy professionals demonstrate their professionalism through the behaviours, attitudes and values expected of professionals on a day to day basis whatever the setting. It is a key part of their professional practice that they will always exercise their professional judgement in the interests of patients and the public. Using the basis of “acting in the course of his or her profession” as a key element of the defence has the practical advantage of “localising” the defence to a specific category of activities – professional activities.
50. The phrase “acting in the course of his or her profession” is not defined, and there is no simple clear definition of what amounts to “acting in the course of his or her profession”. Because of this, instead of the defendant (who may or may not be the registrant) having to prove that the registrant was acting in the course of their profession, it is proposed that the prosecution should have to prove that the registrant was not so acting, if the defendant makes this a live issue before the court (section 67D(2)).
51. This is the first of two important ways in which the general position of the burden of proof in these new provisions – i.e. that the defendant has to prove that they are covered by the defence – is overridden. This places an “evidential burden” on the defendant. In other words, the defendant (who may or may not be the registrant) must provide enough evidence to show that the registrant was “acting in the course of his or her profession” to make this a live issue before the court – if they want to rely on the new defence. If the defendant discharges this “evidential burden”, the burden of proof then shifts to the prosecution. To secure a conviction, the prosecution then has to prove beyond a reasonable doubt that the registrant was not “acting in the course of his or her profession”.
52. While it is not intended to be overly prescriptive, the draft Order nevertheless includes illustrative grounds in draft section 67D(3) that the prosecution might wish to rely on to demonstrate that the registrant was not “acting in the course of his or her profession”.
53. The first of these illustrative grounds is that if the prosecution could establish beyond a reasonable doubt that the registrant was “misusing his or her professional skills for an improper purpose” – that would be sufficient to show that they were not “acting in the course of their profession”. This ground might be made out if, for example, a pharmacy

professional were to dispense in a manner that is not in accordance with the prescription and do so for improper and unprofessional reasons, for example, selling opiates to a heroin addict without a prescription and inadvertently selling the person a massive overdose. In such cases, the pharmacy professional could be said to be misusing their professional skills for improper purposes. This needs to be spelt out in the legislation because, as a matter of general common law, it might be said that a person who is misusing their professional skills for an improper purpose is in fact, nevertheless, acting in the course of their profession.

54. The second of these illustrative grounds is where the prosecution proves that the registered pharmacist or registered pharmacy technician was “acting in a manner that showed a deliberate disregard for patient safety”. The prosecution would again have to prove this beyond a reasonable doubt. Again, this picks up on the possibility that a registrant could be performing “authorised activities” in what might be considered “unauthorised modes”. In other words, while a registrant could be performing “authorised activities”, for example, dispensing medicines, and so to that extent be acting in the course of their profession, but if they were to be so unprofessional as to show a deliberate disregard for patient safety, we want it to be clear that the defence is not made out.

Question 2:

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

Question 3:

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

55. The draft Order includes a clarification, in the proposed new section 67D(4), that where a pharmacy professional departs from, or does not fully comply with, the operational protocols established for that pharmacy (sometimes referred to as standard operating procedures or SOPs), this in itself does not mean that a pharmacy professional is not acting in the course of his or her profession. This reflects the fact that professional autonomy is a key component of professional practice, necessarily linking in with professional accountability and professional judgement.
56. For example, a pharmacy premises may have an SOP that says that all supplies must be dispensed in accordance with prescriptions presented. A pharmacy professional may, for good reason, need to exercise their professional judgement to override what has been written on the prescription by a prescriber. In such cases, the pharmacy professional, acting wholly properly, may intentionally dispense in pursuance of a prescription in a

manner that is not in accordance with the prescription, but nevertheless is appropriate to the specific patient in the circumstances. Medicines legislation makes allowance for this and we are not proposing to make any changes, which could have the effect of restricting the exercise of professional judgement in the interests of the patient.

- 57. An illustration of this is where a prescription specifies 20mg (milligrams) of medicine to be taken twice daily and instructs that fifty-six 20mg tablets be dispensed. However, it could be that the 20mg tablets are of a large size, and the patient finds this particular medicine difficult to swallow. The pharmacist, in the exercise of their professional judgement and, taking account of other medicines the patient takes daily, could dispense 10mg tablets, which are smaller to swallow, instructing that two tablets be taken twice a day, and supply 112 tablets sufficient for 28 days, in keeping with the duration of the prescription. In other words, the pharmacist intentionally dispenses something other than what was ordered on the prescription, for entirely proper reasons. There is no intention to curtail the exercise of such professional judgement in the interests of the patient. Indeed, professional judgement should lie behind each and every dispensing decision, not solely a procedure.

Question 4:

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

Sale or supply of medicines at or from registered premises

Paragraphs	What this section covers
Paragraphs 58 - 62	<p>This section explains the third condition of the new defence under section 64 in more detail.</p> <p>The sale or supply of the medicine must have been at, or from, a registered pharmacy.</p>

- 58. The third condition of the new defence is that the sale or supply of the medicine must have been at or from a registered pharmacy (section 67C(2)(a)). The pharmacy regulators, GPhC and PSNI, are unusual among healthcare regulators in that they are responsible for the registration of premises, as well as for the regulation of pharmacy professionals. This provides an added safeguard for patients and the public as the pharmacy professionals are operating within a quality system in regulated premises.
- 59. Sales, or supplies pursuant to a prescription, of a medicine from hospital pharmacies that are not registered with the pharmacy regulators or from dispensaries in GP practices or other forms of “pharmacy” premises that are not registered with GPhC or PSNI, will not benefit from the defence.
- 60. As indicated above, the board is considering regulatory arrangements for hospital pharmacies as part of phase 2 of this work. A large proportion of medicine transactions in hospitals are a supply against the direction of a doctor. Section 64, which concerns the

nature or quality of the medicine demanded, is silent on this type of transaction and so no criminal offence is committed if a dispensing error is made when a medicine is supplied against the direction of a doctor or other appropriate practitioner, in hospitals or elsewhere. However, if a dispensing error was made when a medicine is supplied against a prescription or sold the section 64 offence would apply. Also the section 63 offence, concerning the adulteration of medicines, applies to all dispensing transactions, including sale or supply against a prescription or the directions of doctor or other appropriate practitioner.

61. The current proposals to mitigate the criminal offences in section 63 and 64 for dispensing errors, aimed at community pharmacies, as part of the conditions of the defence require the medicine to have been sold or supplied from a registered pharmacy. Hospital pharmacies are not required to be registered, so many are not and thus would not be able to make out the defence currently being proposed for community pharmacies.
62. Work is already underway to explore how the governance element of the defence can be captured, in terms of relating it to a hospital pharmacy service which is under the direction of a pharmacist, rather than registration of pharmacy premises. The board is considering this matter further and will bring forward firmer proposals for discussion with stakeholders, and then formal consultation will follow.

In pursuance of a prescription or directions

Paragraphs	What this section covers
Paragraphs 63 - 71	<p>This section explains the fourth condition of the new defence under section 64 in more detail.</p> <p>When dispensing, it is commonly understood that the pharmacy professional acts on the basis of instructions – these can either be prescriptions or patient group directions.</p> <p>Section 64 does not relate to inpatient NHS hospital supplies, but will relate to hospital supplies where a patient is charged for a medicine given under the direction of an appropriate practitioner, such as under some arrangements in private health care.</p> <p>We ask if you agree with the condition that the sale or supply of medicine must be by way of a prescription or direction from an appropriate prescriber.</p>

63. The fourth element of the defence is that the sale or supply of a medicine is in pursuance of a prescription or directions given by another appropriate practitioner who is not also the person dispensing the medicine. Fundamental to the notion of dispensing is the notion

that the pharmacy professional was acting on the basis of instructions. However, It should be noted that section 64 applies to:

- (i) all sales, including sales against a prescription or direction; and
- (ii) supply against a prescription but not other supplies.

- 64. Section 64 does not apply in the case of inpatient NHS hospital supplies, as those medicines are supplied against the directions of a doctor. The section will however apply to hospital supplies where a patient is charged for a medicine given pursuant to an appropriate practitioner's direction – which may happen under some arrangements for the provision of private health care.
- 65. Historically, and currently for the majority of patients in the community, a doctor (or dentist) would prescribe medicines for individual patients. A pharmacist dispenses the medicine against the prescription and supplies the medicine to the patient.

In pursuance of directions

- 66. More recently, legal frameworks were developed that have allowed services to be redesigned and health professionals to work more flexibly for the benefit of patients. As a result of these changes, there are now several legal options for supplying and/or administering medicines, including under patient group directions (PGDs).
- 67. PGDs provide a legal framework that allow some registered health professionals to supply or administer specified medicines to a pre-defined group of patients, without them having to see a doctor (or dentist). Supplying or administering medicines under PGDs is generally reserved for situations in which this offers an advantage for patient care, without compromising patient safety.
- 68. It is generally the case that pharmacy professionals will not be able to rely on the defence if they are the joint or sole authors of the prescription/direction against which a supply of medicines has been made. These arrangements involve a different type of professional relationship with the patient – being more akin to a doctor or a nurse supplying a medicine that they have determined that the patient should have.
- 69. PGDs, however, represent a special case – needing to be signed off by both a registered pharmacist and a doctor/dentist (as well as potentially others, for example a body commissioning the service to which the PGD relates). Although, as indicated above, NHS supplies pursuant to PGDs, i.e. where there is no sale, do not currently come within the offence in section 64, the possibility exists of private sales pursuant to PGDs, for example some immunisation services, coming within the scope of the offence. A registered pharmacist could conceivably be selling against a PGD that they have signed, even though this will by no means be necessarily or even generally the case.
- 70. Provision has been made in the draft Order (section 67E(2)) to provide that a PGD is not taken to be given by the pharmacist who was required to sign it. This means that a registered pharmacist who sells a medicine against any PGD, including one they have signed off themselves with an appropriate prescriber, will be able to rely on the proposed defence if they make an inadvertent error in selling a medicine.

71. It should be noted that the sale of pharmacy-only (“P” medicines) or general sale list (GSL) medicines from pharmacies are unlikely to come within the proposed defence, should an error be made. They would only do so if the sale of the P or GSL medicines was made pursuant to a prescription or directions. This would be unusual since pharmacists can sell P or GSL medicines without a prescription or directions.

Question 5:

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

Notification when an error has occurred

Paragraphs	What this section covers
Paragraphs 72 - 90	<p>This section explains the fifth condition of the new defence under section 64 in more detail.</p> <p>This requires an appropriate person to ensure the person for whom the product was intended is made aware of the error promptly when it comes to light.</p> <p>Notification must be by an “appropriate person” – those people who are listed as appropriate people is explained.</p> <p>It will not always be appropriate or necessary to notify the patient but this needs to be considered in the light, for example, of guidance by regulators or discussions with lawyers.</p> <p>Notification has to be considered once a responsible person actually becomes aware that there is problem – it is not triggered by suspicion.</p> <p>Therefore, for a defendant to be able to rely on the defence, it will need to be established on the balance of probabilities whether the defendant was aware of the error or not.</p> <p>We ask at the end whether you agree with the proposals.</p>

72. The fifth condition requires an appropriate person to ensure promptly, on becoming aware of the error, that the person to whom the product was intended to be administered, i.e. the patient, is informed of the error.
73. In the overwhelming majority of cases, it will be the patient or someone acting on the patient’s behalf who discovers a dispensing error. So, it is only in a minority of cases that

the issue of notifying the patient of an error will arise. In practice, the discovery of an error is likely to take place in a comparatively short period after the error occurs, especially given that NHS prescriptions have to be sent for payment on a monthly basis.

74. The new legislation does not provide a definition of “promptly” recognising that the circumstances of each case have to be examined on its own merits. In recognition of the difficulty in deciding whether or not, where a patient needed to be notified, action was taken promptly, the burden of proof on this issue is changed so that the burden on the defendant is simply to raise sufficient evidence that the notification might have been prompt for this to be a live issue before the court. If the defendant does this, the prosecution would then have to prove that the notification was not “prompt” beyond reasonable doubt, if the prosecution are to secure a conviction (section 67D(6)).
75. For the defence to be made out, notification must be by an “appropriate person”, and the legislation identifies the following as people who could discharge this responsibility (section 67C(6)):
 - i) the person who dispensed the product;
 - ii) the supervising registrant, if the product was dispensed under the supervision of a registrant rather than by a registrant;
 - iii) the person carrying on the pharmacy business (i.e. the pharmacy’s registered owner), and
 - iv) a person acting on behalf of the person carrying on the pharmacy business – which could be anyone with authority to act on the owner’s behalf.
76. This recognises that both professional and corporate duties of candour come into play once an error is discovered – and also that it is perfectly possible that the error maker may not be the person who discovers the error. Indeed conceivably, the error maker could never find out about the error (for example, if they were a locum at the pharmacy just for the day), but another “appropriate person” could, and would then need to decide, what action needed to be taken.
77. It is also recognised that it may not always be appropriate or necessary to notify the patient. If an appropriate person reasonably forms the view that it is not necessary or appropriate to notify the patient in the particular circumstances of the case, the notification condition is met (section 67C(5)(a)(ii)).
78. In the case of a registrant who is on notice of an error, they might reasonably form the view that notification is not appropriate, for example, in the light of guidance of the pharmacy regulators or discussions with legal representatives or insurers. That view might arise from reading the standards of conduct, ethics and practice of the relevant regulator (GPhC or PSNI). There will be certain standard cases where the registrant is bound to form that reasonable belief, for example:
 - i) there may be some types of errors, which are generally accepted to be too trivial to merit contact with a patient;
 - ii) where notification to the patient would do more harm than good (a patient with a nervous disposition, for example, might be better off hearing of the error from their GP, and the registrant may have agreed this with the patient’s GP);
 - iii) the patient is already receiving treatment as a consequence of the error even though they have not been notified of it (for example they may be in hospital); or

- iv) somebody else might be the most appropriate person to notify about the error, most obviously in the case of a young child or someone lacking mental capacity.
79. Not everyone who is an “appropriate person” in the sense of being aware of an error could reasonably form the view that the patient did not need to be notified. For example a pharmacy student could not “reasonably” take such a view on their own account – even if they made the error. They would need to refer the matter to the supervising pharmacist. Also, a counter assistant could not “reasonably” form that view. In essence, the view has to be taken by someone who can reasonably be responsible for that decision, having regard to their professional or corporate duty of candour – or both.
80. If it is appropriate to notify the patient, the requirement is simply to take all reasonable steps to notify the patient – it is not necessary for the patient to have been located for the defence to be made out. If all reasonable steps have been taken, but it has not proven to be possible to contact the patient – for example, they have become untraceable because they have gone abroad – the defendant can still rely on the defence, where all reasonable steps have been taken.
81. Importantly, the notification provisions only apply once a responsible person actually becomes aware that there is a problem (section 67C(5)(a)). Awareness, rather than suspicion, is required before notification of the patient necessarily has to be considered. This is because the professional and corporate obligations are subtly different in the case of suspicion of a problem and actually knowing about a problem (the immediate task, on suspecting that there is a problem, may be investigating that suspicion rather than contacting the patient) – and the intention is not to add a further level of complexity by attempting to deal with “suspicion” as well. Knowledge, one way or the other, is therefore the key to this part of the defences, and is the key to understanding its structure (section 67C(3) to (5)).
82. Generally speaking, if before the defendant is charged, they did not know about the problem, the notification obligation is irrelevant.
83. There are, however, two important exceptions to this – one that applies to pharmacy owners and the other, which applies, where a pharmacist has supervised someone other than a registered pharmacy technician dispensing a product.
84. The net effect of section 67C(3)(b) and (4) is that if the defendant is the pharmacy owner, the notification obligation is only irrelevant to them – assuming they did not know about the problem before they were charged with the offence – if neither the person who dispensed the product nor – in a case where a pharmacist is supervising a non-registrant – the supervising registrant knew about the problem.
85. This extra onus on the pharmacy owner reflects the particular responsibilities that arise out of their corporate duty of candour. If the owner does not know about the error, but the registrant who is most directly professionally accountable for the error does know, but unreasonably does nothing, then the owner remains potentially liable to prosecution. This

is intended to create a powerful incentive for owners to remain on top of what is happening in their pharmacy businesses.

86. Similarly, if a pharmacist is supervising a non-registrant dispensing a product, and the dispenser of the product knows that there is a problem, but does nothing about it, the supervising pharmacist cannot rely on their own ignorance of the problem as a way of avoiding liability. Again, this is intended to create a powerful incentive for pharmacists who are supervising non-registrants (which, in Northern Ireland, would include pharmacy technicians) to remain on top of the activities that they are supervising. In their case, however, if they have not been involved in the actual supply of the product, the likelihood is that they could only be prosecuted under section 64 as a secondary party to the offence (i.e. for aiding, abetting, counselling or procuring the commissioning of an offence), so there would need to be further aggravating factors for a supervising pharmacist still to face possible prosecution in these circumstances.
87. Although “knowledge” is linked to the moment that a defendant is charged, to avoid defendants needing to do something after they have been contacted as part of a criminal investigation, defendants are deemed to be ignorant of things that they find out about as a result of a criminal investigation (section 67D(5)).
88. For a defendant to be able to rely on the defence, it will therefore need to be established on the basis of a balance of probabilities whether they were aware of the error or not. If a pharmacist who dispensed a product is seeking to rely on the defence, therefore, and their defence is that they did not know about the error until the police contacted them, they will need to establish this on a balance of probabilities.
89. If they state that to be the case and it is uncontested, that should be the end of the matter. If the evidence is contested – for example, if the pharmacist said something to a colleague that indicated that they suspected that the wrong product had been dispensed – then the pharmacist would have to show from the surrounding circumstances that their suspicion never became knowledge – for example, by showing that they had sought to confirm or refute their suspicion, but had not been able to do so before the police contacted them.
90. In considering the duty to notify, there were a range of views within the programme board as to whether or not the duty to notify should be a requirement of the defence. The board agreed that the proposal should be put forward for consultation.

Question 6:

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

Unregistered pharmacy staff and pharmacy owners

Paragraphs	What this section covers
Paragraphs 91 - 93	<p>This section explains why this draft Order applies to all possible defendants, including owners, dispensers who are not registered pharmacy technicians and delivery drivers.</p> <p>For the defence to apply, the error need not necessarily have been made by the dispenser – it could be unqualified staff, known as intermediaries.</p> <p>The dispensing error though, as with registered pharmacy staff, must be inadvertent and not deliberate for the defence to apply.</p> <p>We ask if you agree that unregistered staff are able to use the new defences for inadvertent dispensing errors but that they should not apply for deliberate or intentional errors.</p>

91. The defences in the draft Pharmacy (Preparation and Dispensing Errors) Order 2014 apply to all possible defendants, even though it is because the product was dispensed by a pharmacy professional that the defences are potentially engaged. The most likely other defendants are the pharmacy owner (i.e. the person carrying on the retail pharmacy business), dispensers who are not registered pharmacy technicians and any unqualified person who actually hands over the product – here referred to as intermediaries - such as a counter assistant or a delivery driver, after the product has been dispensed.
92. However, for the defence to apply, the error need not necessarily have been by the dispenser. The possibility exists that an intermediary did something that results in the patient getting the wrong medicine. The intermediary may, for example, simply hand over the wrong medicine by mistake – so it is not a dispensing error as such but a handling error. In this situation, so long as the intermediary does not know about the error before they are charged (or are contacted as part of the criminal investigation), the offence will not be committed provided the conditions for the defence are made out (section 67D(7)).
93. There may, however, be cases where an intermediary deliberately gives the patient the wrong medicine. For example, the intermediary simply hands over a different medicine and keeps back the medicine that was dispensed for the patient (whether to self-medicate or supply to someone else). A further example might be where the intermediary alters the composition of the dispensed medicine in some way (for example diluting it), in order to keep back part of the dispensed medicine. In both cases, because the intermediary knows about the problem at the time of the supply, the defence will not apply and the assistant or delivery driver remains liable for prosecution – even if someone else at the pharmacy business discovers what has happened and alerts the patient (section 67C(5)(b)).

Question 7:

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

Question 8:

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

Section 63

Paragraphs	What this section covers
Paragraphs 94 - 97	<p>This section gives further details on the new defence in relation to section 63, which concerns the adulteration of medicinal products.</p> <p>We are intending to follow the defence and conditions outlined above for section 64. We ask if you are content with this approach.</p>

94. Section 63 of the Medicines Act concerns the adulteration of medicinal products (i.e. errors in the course of preparation of medicinal products, whether deliberate or inadvertent). It is proposed to follow the approach taken in relation to section 64 – retention of the criminal sanction, but providing a new defence where certain conditions are met. Parallel provisions have been created for the proposed new defences, in section 67B, against the two offences in that section, which are worded in very similar terms to section 67C. Indeed some of the provisions, for example those on what is meant by “acting in the course of their profession” and “registrant”, are common to both section 67B and 67C, i.e. those in sections 67D and 67E.
95. A notable difference between section 63 and section 64 is the “supplies” caught in section 63 are not simply those that are in pursuance of a prescription. This offence already applies, for example, to supplies from hospital pharmacies pursuant to directions from a hospital-based appropriate practitioner.
96. At the moment, a dispensing error in a hospital pharmacy, in the absence of a prescription, could potentially be prosecuted under section 63 (assuming the elements of the offence were made out) rather than section 64. However, it is proposed that it will remain a condition of the defence for pharmacy professionals being available in relation to this section that the preparation errors will need to have taken place at a registered pharmacy for the defence to apply. The question of errors – be they dispensing or preparation errors – at unregistered hospital pharmacy premises is being explored separately.

97. The rationale for including section 63 in this particular exercise is to preclude the possibility of prosecutors switching to alternative strict liability offences once section 64 is no longer available to them in the standard case of a pharmacy professional acting in the course of their profession at a registered pharmacy. The intention is to reassure pharmacy professionals that reporting errors will not leave them exposed to prosecution under easily provable offences.

Question 9:

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

Pharmacy standards and related matters

Introduction

Paragraphs	What this section covers
Paragraphs 98 - 100	This describes <ul style="list-style-type: none"> • what rebalancing is seeking to achieve in terms of the regulation of registered pharmacies • the role and approach of the pharmacy regulators
Paragraph 101 - 109	Outlines the overall changes proposed in the draft Order

98. The Rebalancing Programme Board in fulfilling its terms of reference is seeking to achieve a rebalancing between:
- criminal law and professional regulation so that matters that should properly be within the ambit of the pharmacy regulators, the GPhC and the PSNI, are in fact dealt with by them, by registration sanctions rather than by the criminal courts;
 - what is set by Ministers – and by Parliament in primary legislation – and what is set by the pharmacy regulators; and
 - legislation and standards so that less is set in legislation, which by its nature is binding and takes time to change, and more is set in standards, that generally are set in codes of practice. Developing and using standards would provide a better basis to achieve key goals, such as promotion of safe and effective practice at registered pharmacies.
99. As a consequence, a number of changes are proposed to existing legislation, mainly in the Pharmacy Order 2010 and, to a lesser extent, the Medicines Act 1968 and the Pharmacy (Northern Ireland) Order 1976, to provide the pharmacy regulators with the appropriate powers to give effect to the policy proposals.
100. This section deals with the proposals in the draft Pharmacy (Premises Standards, Information Obligations, etc.) Order 2015.

Background

101. The GPhC and the PSNI are unusual among professional regulators in that, alongside their role as the regulator of pharmacists, and pharmacy technicians for GPhC, they also provide varying degrees of system regulation through their role in registering and monitoring pharmacy premises.
102. In connection with this latter role, the GPhC, set up under the Pharmacy Order 2010 as the independent regulator for registered pharmacy professionals in Great Britain, is obliged to promote safe and effective practice at registered pharmacies, and to achieve that end, it has specific obligations to set standards for registered pharmacies, which pharmacy owners and superintendent pharmacists are accountable for meeting. As the law currently stands, those pharmacy standards have to be set in rules and failure to meet GPhC rules

relating to pharmacy standards could result in improvement notices, which if breached could lead either to criminal proceedings or suspension or removal of the premises from the premises register.

103. The GPhC has developed and approved, in consultation with key stakeholders, standards for registered pharmacies. The standards are outcome-based, focusing on the achievement of results for patients and moving away from prescriptive requirements. These outcomes-based standards will be supported by guidance on specific issues, where this is necessary.
104. The intention is to avoid a regulatory model which leads pharmacies towards a compliance-driven or checklist approach in meeting its standards. Instead the intention is to provide a clear framework through which owners of pharmacies are required to consider how best to meet GPhC standards, focusing on the needs of patients. This type of framework would build on the best practice of others, including the work of the Cabinet Office, the Better Regulation Executive's principles of good regulation, the Hampton principles for inspection and enforcement, and the Professional Standards Authority's view on "right touch regulation".
105. The proposal that the standards should not be placed in legislative rules follows as a consequence of this approach. A framework which requires standards to be placed into legislative rules is inflexible, and would restrict future opportunities to review and update the standards to keep pace with the increasingly rapid changes in pharmacy service provision. The GPhC, in common with the relevant Health Ministers, does not believe that this inflexibility would be in the best interests of patients and those using the services of pharmacies, since placing standards in rules would necessitate legislative change whenever an amendment is required, restricting the regulator's ability to respond quickly.
106. If this outcomes-based approach that the GPhC has been developing, with the support of English, Welsh and Scottish Health Ministers, is to be fully implemented, it needs a legislative framework which avoids a requirement for prescriptive rules.
107. The proposals on premises standards to a large extent accord with those proposed by the Law Commission in their report: "Regulation of Health Care Professionals: Regulation of Social Care Professionals in England" (Cm 8839: SG/2014/26), published in April 2014. Recommendation 98 of that Report indicated that the Law Commission recommended retaining the premises regulation provisions of the Pharmacy Order 2010 with some minor amendments. Paragraph 11.16 of the Report provides:

'...We propose some minor changes to the [General Pharmaceutical] Council's powers to regulate premises. In broad terms, the intention is to remove the duty to set standards in rules, and turn them into code of practice style obligations, and enforce them via the disciplinary procedures set out in section 80 of the Medicines Act 1968. The changes have been developed with the agreement of the General Pharmaceutical Council and the Government.'

Proposals

108. To support completion of the implementation of an outcomes based approach, it is proposed that amendments are made to the Pharmacy Order 2010. Overall, these will align the legal status of registered pharmacies standards with the status of standards for individual registrants, so that standards for registered pharmacies no longer have to be defined in rules.
109. Alongside removing the requirement for GPhC pharmacy standards to be in rules, there are five other areas of change proposed in this section 60 Order, namely:
- requiring the PSNI, like the GPhC, to set statutory pharmacy standards;
 - revising GPhC’s enforcement powers in respect of registered pharmacies, and to some extent making the same changes for PSNI, where appropriate;
 - facilitating publication of GPhC reports and outcomes from pharmacy inspections;
 - revising the requirements relating to notification of the GPhC of the death of a registrant; and
 - revising GPhC’s powers to obtain information from pharmacy owners.

Removal of the requirement for the GPhC’s standards for registered pharmacies to be in rules

Paragraphs	What this covers
Paragraphs 110 - 112	Removal of the requirement for GPhC to set standards for registered pharmacy premises in rules

110. The key change, and one of the Law Commission’s recommendations, is that the GPhC should no longer be required to set standards for registered pharmacies in rules. Instead these should be aligned with other regulatory standards and be non-binding, code of practice style obligations, enforced via disciplinary procedures.
111. It is proposed to make four refinements to the current legislation in the Pharmacy Order 2010, which support the GPhC’s approach to modernising pharmacy regulation:
- a) It is suggested that rather than require the standards to be drafted as inflexible rules, they should be code of practice style obligations, focussed on outcomes and consistent with other forms of regulatory standards or codes.
 - b) The proposed list of what the standards may in particular relate to has been changed to support this more flexible approach, covering broader areas or domains such as “governance arrangements”, “working environments”, and “the patient and public experience”, with less emphasis on specific activities like “record keeping”, “standard operating procedures” and “incident reporting mechanisms”, which characterise the current list within the Pharmacy Order 2010.
 - c) The list now also makes reference to setting standards in respect of associated premises, i.e. premises at which activities are carried on which are integral to the

provision of pharmacy services “at or from” registered pharmacies. The GPhC’s ability to set standards in respect of these premises is qualified by the fact that they are only permitted to do so to the extent appropriate for ensuring the safe and effective provision of pharmacy services at or from a registered pharmacy. This reference to “associated premises”, which was also part of the Law Commission proposals, reflects the fact that in some respects the traditional model of pharmacy premises being entirely self-contained operations at which all aspects of the retail pharmacy business are carried on is, for some businesses, outdated. Integral parts of the businesses operation – for example electronic data storage – may be elsewhere.

- d) The current arrangements for pharmacy standards allow them to be set in such a way that they impose obligations not just on pharmacy owners but also on superintendent pharmacists, all of whom have to be individual registered pharmacists. A clarification is now proposed whereby standards for registered pharmacies just relate to the obligations on pharmacy owners. Additional professional obligations on superintendent pharmacists will simply form part of their obligations as individual registrants – this is part of the proposed changes to the requirements in respect to superintendent pharmacists and responsible pharmacists to follow in due course.

112. As a consequence of moving the standards out of rules, they would no longer be included in a statutory instrument that was subject to Privy Council approval, which had to be laid before both the United Kingdom and Scottish Parliaments. Standards for individual registrants are not subject to such procedures. Further increasing the autonomy of the GPhC in this way is in line with government policy (also a “deregulatory” gain, decreasing the amount of government control) and creates space for others to modernise and innovate where this is appropriate. However, the proposals include an explicit requirement for the GPhC to consult Scottish Ministers, as well as English and Welsh Ministers, on changes to standards.

Question 10:

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

PSNI standards for registered pharmacies

Paragraphs	What this section covers
Paragraph 113	Requires the PSNI to set registered pharmacy standards, currently set in guidance, on a statutory footing.
Paragraphs 114 – 115	Requires PSNI to publish their registered pharmacy standards.

113. It is proposed to place a statutory duty on the pharmacy regulator in Northern Ireland (the PSNI) to set standards for registered pharmacies and clarify what those standards can cover. This will enable the PSNI to put their premises standards, currently set in guidance, on a statutory footing so that in future they can be set in statutory codes of practice. It is proposed to use the same wording as for the GPhC for the list of what the standards may contain, so the PSNI could also take an outcomes based approach to registered pharmacy standards, albeit reflecting its own particular approach and circumstances. The discussion under the previous heading is therefore also relevant to the proposed arrangements for Northern Ireland.
114. Additionally, having regard to the different nature of the legislative scheme in Northern Ireland, it is also proposed to make a further change, through amendment of the provisions of the Pharmacy (NI) Order 1976 to require PSNI to publish their registered pharmacy standards.
115. The provisions for Northern Ireland would only be commenced when PSNI is in a position to introduce their new standards. The commencement order would require the agreement of the Northern Ireland Minister for Health Social Services and Public Safety (HSSPS), so effectively the implementation timetable would be subject to agreement with the Minister's Department.

Question 11 (for respondents in Northern Ireland):

Are you content to place a statutory duty on PSNI to set standards for registered pharmacies?

Changes to the GPhC's and PSNI's enforcement powers in respect to registered pharmacies

Paragraphs	What this section covers
Paragraph 118	Amends the powers to serve improvement notices.
Paragraph 119	Amends the sanctions provisions relating to breaches of improvement notices.
Paragraph 121	Enables interim suspension orders to be made pending hearings in respect of pharmacy owners and makes consequential changes to the rule and regulation making powers enabling the suspended premises entries to be still treated as registered.
Paragraph 122	Provides for interim suspensions prior to a disqualification decision or removal from premises register decision to take effect.

116. Some of the enforcement powers of GPhC and PSNI are common to both bodies but others are different. Essentially, where a common approach has already been adopted,

the proposals make changes that apply equally to GPhC and PSNI, but some additional proposals are also made which relate solely to the GPhC's statutory improvement notice procedure, for which there is no PSNI direct equivalent.

117. It is proposed to amend the GPhC's and PSNI's disqualification procedures for pharmacy owners, and the procedures for removing premises from the premises register (section 80 of the Medicines Act 1968), firstly, so they apply to retail pharmacy businesses owned by a pharmacist or a partnership, as well as bodies corporate, and, secondly, to clarify that the test to apply sanctions, where premises standards are not met, is whether or not the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively.
118. In Great Britain, this will replace in part the powers under article 14 of the Pharmacy Order 2010, which allowed the Registrar of the GPhC to suspend or remove entries from its register where a pharmacy owner failed to comply with an improvement notice that related to breaches of premises standards in the GPhC's rules. Those powers could be used against pharmacy owners that were individual pharmacists or partnerships, as well as bodies corporate. For Great Britain, the changes are intended to facilitate more proportionate sanctions by the pharmacy regulator where there are breaches of premises standards, and focus enforcement action on the GPhC's disciplinary procedures.
119. With similar intentions in mind, it is proposed to make two additional amendments to the sanctions provisions in the Pharmacy Order 2010 relating to breaches of improvement notices. Firstly it is proposed that prosecutions should no longer be brought in cases of breaches of premises standards and the matter must instead be dealt with as a disciplinary matter, by the Fitness to Practise Committee. Secondly, the option is removed of the breach being dealt with as a registration matter by the Registrar and potentially, on appeal, by the GPhC's Registration Appeals Committee. This streamlining means that all breaches of premises standards will be dealt with as disciplinary matters.
120. The disciplinary procedures of the GPhC and PSNI, where action is taken against individual registrants, both provide for possible interim suspension orders either while cases are ongoing or pending the outcome of an appeal. Use of these powers is subject to procedural safeguards to ensure that they are only used where the public interest calls for it, such as where suspension is necessary for the protection of the public.
121. Changes to the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976 are proposed to enable suspension orders to be made pending a full hearing of the case against the owners of pharmacy premises. This will be achieved through a modification of the current powers to make interim suspension orders in relation to individual registrants, and reflects the move to better align the disciplinary provisions for pharmacy owners in respect to breaches of pharmacy premises standards with those for individual registrants. Consequential changes are also made to the pharmacy regulators' regulation and rule making powers, which will include enabling them to be able to treat suspended entries in the premises registers as still on the register. This could be used to ensure premises registration fees could be collected even when premises are suspended during disciplinary proceedings against a pharmacy owner, or after an adverse finding but pending an appeal.

122. It is also proposed to provide for interim suspensions from the register, prior to a disqualification decision or removal decision taking effect – the decision will only take effect after the time for bringing an appeal has elapsed or, if an appeal is brought, until the appeal is disposed of by the court of first instance.
123. As with the current powers, these new powers will only be exercisable for the protection of members of the public or where otherwise in the public interest. The disciplinary procedures for pharmacy owners are currently out of step with the disciplinary procedures of the regulatory bodies for health care professions generally in not allowing for interim suspensions, which means a potential gap in public protection.

Question 12:

Do you agree with the approach we are taking to breaches of registered pharmacy standards by pharmacy owners?

Publication of GPhC reports and outcomes from pharmacy premises inspections

124. It is proposed to amend Article 9 of the Pharmacy Order 2010 to provide for publication of GPhC reports and outcomes from pharmacy premises inspections. Those changes will make clear that if such a report includes personal data it is assumed under data protection requirements that such information can be published as a result of the GPhC's pharmacy regulation function (paragraph 20 of the draft Order).

Notification of the GPhC of the death of a registrant

125. The opportunity is being taken to correct an error in the Pharmacy Order 2010 to require notification of the death of a registered pharmacist or registered pharmacy technician by a registrar of births and death rather than by the Register General, which is what the legislation states now (paragraphs 17 and 23 of the draft Order).

Changes to the GPhC's powers to obtain information from pharmacy owners

126. Article 7 of the Pharmacy Order 2010 currently requires the making of rules by GPhC not just in relation to premises standards but also in relation to the information obligations. It is proposed to amend the information provisions so they are permissive, such that the GPhC "may", rather than "must", make rules in respect to obtaining information from pharmacy owners.
127. It is also proposed to clarify when the GPhC can require pharmacy owners to provide such information through its rules. The information obligations cover such matters as the details of the key people responsible for the business (e.g. directors and superintendent

pharmacists of bodies corporate, and partners in partnerships), information about investigations of and offences committed by those key people (and in some cases by the business itself), business addresses, and details of the type or types of activities undertaken at registered pharmacy premises.

128. The Pharmacy Order 2010 makes no provision, currently, about how these information gathering rules are to be enforced, and this is a gap that needs filling. The most pragmatic solution is to make use of the existing enforcement regime, which is why the relevant Health Ministers are proposing that breaches of the Regulations should be enforced via the GPhC's improvement notice system.

129. However, this would mean that breaches of the rules could potentially lead to fines in the lower courts. This being so, it is recognised that it is important that there are safeguards to ensure that the rules do not impose disproportionate burdens. First and foremost among these are GPhC's own procedures, but there are backstop safeguards in that the rules will require approval by Order of the Privy Council and will be subject to Parliamentary 'negative resolution' procedures, which provide for the possibility of legislation being voted down.

Question 13:

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

Question 14:

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

Business and equality impact

130. Consultation stage impact assessments (IAs) have been prepared and are published alongside this consultation document. We would welcome comments on the IAs and any further evidence or information which would enable us to further elaborate the IAs, both generally and in relation to the assumptions or estimates we have made especially in terms of the impact on small and micro businesses.

131. Below are a number of questions which relate to the IAs. Questions 14 – 18 seek your views on the IA relating to dispensing errors. Questions 18 – 21 seek views on the IA relating to registered pharmacy standards.

Dispensing errors IA

Question 15:

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

Question 16:

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

Question 17:

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

Question 18:

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

Question 19:

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

Premises standards IA

Question 20:

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

Question 21:

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

Question 22:

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

Equality assessment

132. We have also published an initial assessment of the impact on equality, which is published alongside this consultation document and we welcome any additional information in relation to how the proposals on which we are consulting might impact on equality, both in relation to patients and the public who use the services available through pharmacies and the pharmacy teams within pharmacies.
133. We intend to update this equality analysis to include information received as part of this consultation. We plan to publish this analysis as part of the Department's response to the consultation.

Question 23:

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

Summary of consultation questions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Question 19: We have provided an estimate of the magnitude of the cost and benefits that may arise from the potential implementation of the introduction of the change in approach to dispensing errors. These estimates rely on a number of general

assumptions – summarised in Annex B of the IA. These include the length of time it takes a pharmacist to deal with different types of dispensing errors. In addition, we have made assumptions regarding the potential benefits from learning and from a lower risk of prosecution. Do you think the assumptions we have made are proportionate and realistic? If not, what assumptions should we use? Please provide an estimate of the cost of such assumption.

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

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

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

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

Responding to this consultation

Consultation process

This document launches a consultation on proposed changes to the Medicines Act 1968, the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 976.

The consultation is being run, as far as is practical, in accordance with the Cabinet Office Code of Practice on Consultations (reproduced below). The closing date for the consultation is Thursday **14 May 2015**.

There is a response form on the GOV.UK website which can be printed and sent by post to:

Pharmacy Team
Medicines, Pharmacy and Industry Division
Department of Health
Ground Floor North
Wellington House
133 – 155 Waterloo Road
London
SE1 8UG

Completed response forms can also be sent electronically by e-mail to:

[MB-Rebalancing <21@dh.gsi.gov.uk](mailto:MB-Rebalancing<21@dh.gsi.gov.uk)

Alternatively you may also complete the online consultation response document at:

<http://consultations.dh.gov.uk>

It will help us to analyse the responses if respondents fill in the online consultation response document. However, responses that do not follow the structure of the questionnaire will be considered equally. It would be helpful if such responses could indicate who has contributed. It would also help if responses were sent in Word format, rather than in pdf format.

Criteria for consultation

This consultation follows the Government Code of Practice, in particular we aim to:

- Formally consult at a stage where there is scope to influence the policy outcome;
- Consult for a sufficient period.
- Be clear about the consultations process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- Ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- Keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;

- Analyse responses carefully and give clear feedback to participants following the consultation;
- Ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.
- The full text of the code of practice is on the Better Regulation website at: www.bis.gov.uk/policies/better-regulation/consultation-guidance

Annex A – List of consultees

Patients and the public

Community pharmacists and pharmacy technicians

Hospital pharmacists and pharmacy technicians

Action Against Medical Accidents

ASDA Group plc

Association of Independent Multiple Pharmacies

Association of Pharmacy Technicians UK

Association of Teaching Hospital Pharmacists

Boots plc

British Pharmaceutical Students' Association

Care Quality Commission

Centre for Pharmacy Postgraduate Education

College of Mental Health Pharmacy

Commission in Human Medicines

Community Pharmacy NI

Community Pharmacy Scotland

Community Pharmacy Wales

Company Chemists' Association

Crown Office and Procurator Fiscal Service

Crown Prosecution Service

Day Lewis Pharmacy Group

Dispensing Doctors Association

General Pharmaceutical Council

Guild of Healthcare Pharmacists

Health Education England

Health Inspectorate Wales

Healthcare Improvement Scotland

Healthwatch

Independent Hospital sector

Independent Pharmacy Federation

J Sainsbury's plc

Lloydspharmacy

National Pharmacy Association

National Voices

NHS Confederation

NHS Education for Scotland

NHS Employers

NHS England

NHS Pharmacy Education Development Committee

Northern Ireland Centre for Pharmacy Learning and Development

Northern Ireland Health and Social Care Trusts

Patients' Association

Pharmaceutical Services Negotiating Committee

Pharmaceutical Society of Northern Ireland

Pharmacists' Defence Association

Pharmacy Law Ethics Association

Pharmacy Forum – Northern Ireland
Pharmacy Schools Council
Pharmacy Voice
Professional Standards Authority for Health and Social Care
Public Prosecution Service of Northern Ireland
Regulation and Quality Improvement Authority
Rowlands Pharmacy
Royal Pharmaceutical Society
Royal Pharmaceutical Society, English Pharmacy Board
Royal Pharmaceutical Society, Scottish Pharmacy Board
Royal Pharmaceutical Society, Welsh Pharmacy Board
Superdrug Stores plc
Tesco plc
The Co-operative Group
Ulster Chemists' Association
United Kingdom Clinical Pharmacy Association
Welsh Centre for Pharmacy Professional Education
Wm Morrisons Supermarkets plc

Annex B – The Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board

Members

Ken Jarrold CBE - Chair
Nigel Clarke - General Pharmaceutical Council
Robert Darracott - Pharmacy Voice
Celia Davies - Lay member
Tess Fenn - Association of Pharmacy Technicians UK
David Gallier-Harris - Community pharmacist, Asda
Christine Gilmour - Director of Pharmacy, NHS Lanarkshire
Helen Gordon - Royal Pharmaceutical Society
Julie Greenfield - Pharmacy Forum of Northern Ireland
Karen Harrowing - Chief Pharmacist, Nuffield Health
Steve Howard - Superintendent Pharmacist, Lloydspharmacy
Jeannette Howe - Department of Health
Denzil Lloyd – Lay member
Alpana Mair - Deputy Chief Pharmaceutical Officer, Scotland
Sheelin McKeagney - Community Pharmacist, McKeagney Chemists
Sue Mirczuk - Pharmacy technician, Wrexham Maelor Hospital
Trevor Patterson - Pharmaceutical Society of Northern Ireland
Keith Ridge CBE - Chief Pharmaceutical Officer, NHS England
Bob Rihal - Locum pharmacist
Duncan Rudkin - General Pharmaceutical Council
Bernadette Sinclair-Jenkins - Medicines and Healthcare products Regulatory Agency
Ash Soni OBE - Royal Pharmaceutical Society
Lynn Strother - Lay member
Joanne Taylor - Pharmacy technician, Vittoria Healthcare
Mark Timoney - Chief Pharmaceutical Officer, Northern Ireland
Roger Walker - Chief Pharmaceutical Officer, Wales

Terms of Reference

The Programme Board for Rebalancing Medicines Legislation and Pharmacy Regulation will examine the respective scope of legislation and regulation, and the interface between them, with a view to ensuring these are optimally designed to provide safety for users of pharmacy services, while facilitating a systematic approach to quality in pharmacy and responsible development of practice and innovation, whilst reducing the burden of unnecessary and inflexible regulations.

Role of the Programme Board

The Board's role is

1. to advise Ministers and the Devolved Administrations on policy within these Terms of Reference; and
2. to oversee implementation of policy outcomes agreed by Ministers and the Devolved Administrations.

Areas of work

1. The Programme will
 - (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
 - a. the effectiveness of components of the system which support patient safety, such as the role of superintendent and the responsible pharmacist
 - b. 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.
2. The Programme Board will also
 - (i) establish a framework for clear governance for all aspects of the work programme to ensure that outcomes agreed by Ministers and the Devolved Administrations are achieved
 - (ii) take account, as appropriate, of interdependent work, including the wider Medicines and Healthcare products Regulatory Authority (MHRA) review of penalties and sanctions; the work programme of the pharmacy regulators, on-going implementation of Enabling Excellence, the Law Commissions' review of the legal framework for professional regulation and other relevant work programmes

- (iii) identify influencing factors in prioritising elements of the programme for early progress to legislation, taking account of the needs of England, Scotland, Wales & Northern Ireland
- (iv) bring forward proposals on areas of legislation that require change in order to support achievement of the aim of the programme and
- (v) oversee the management of risks which could threaten the objectives of the programme.

Ways of Working

The Programme Board will be chaired Ken Jarrold, who has been appointed by Ministers. The Secretariat will be provided by the Department of Health. The Board will focus on planning, prioritising, co-ordination and ensuring the necessary work is progressed with members undertaking detailed thinking and activity to ensure the programme's objectives are achieved.

Membership

Membership of the board includes officials from the four governments, professional and regulatory representatives and a range of stakeholder interests. A Partners Forum will also be established to contribute to the work programme, as appropriate. The engagement process adopted by the Board will ensure the views of the public and patients, amongst others, are sought and considered effectively.

Work programme and meeting arrangements

To be agreed at the first meeting.

Reporting Arrangements

The Chairman will report to Ministers on a regular basis, setting out key issues discussed by the Programme Board, making Ministers aware of any differences of opinion within the Board and action to progress the work programme.

Group members will be expected to be conduits of information for the constituents and groups they represent.

Annex C – References

Francis Report: *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*
<http://www.midstaffspublicinquiry.com/report>

Berwick Review: *A promise to learn – a commitment to act: improving the safety of patients in England*
<https://www.gov.uk/government/publications/Berwick-review-into-patient-safety>

Red Tape Challenge
<http://www.redtapechallenge.cabinetoffice.gov.uk/themehome/rtc-themes-2/>

Evaluation of the impact of the Responsible Pharmacist Regulations
<http://www.rpharms.com/promoting-pharmacy-pdfs/responsiblepharmacistreport.pdf>

Government response to the Francis report: *Mid Staffordshire NHS Foundation Trust public enquiry: government response*
<http://francisresponse.dh.gov.uk/>

Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board
<https://www.gov.uk/government/groups/pharmacy-regulation-programme-board>

The Medicines Act 1968
<http://www.legislation.gov.uk/ukpga/1968/67>

The Human Medicines Regulations 2012
<http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

The Pharmacy Order 2010
<http://www.legislation.gov.uk/ukdsi/2010/9780111487358/contents>

The Pharmacy (Northern Ireland) Order 1976
<http://www.legislation.gov.uk/nisi/1976/1213/contents>