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Rebalancing Medicines Legislation and Pharmacy Regulation

Consultation Report: Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018

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Author:

Community Care Group/Medicines and Pharmacy Directorate, Pharmacy Team/CC-MP-P/17060

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Pharmacy professionals, pharmacy owners, pharmacy regulatory bodies, pharmacy professional and representative bodies, unions, patients and the public, health organisations

Contact details:

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

Email: MB-Rebalancing >21@dh.gsi.gov.uk

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Rebalancing Medicines Legislation and Pharmacy Regulation

Consultation Report: Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018

Prepared by

Medicines and Pharmacy Directorate, Pharmacy Team
Community Care Group
Department of Health

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Executive summary

On 12 February 2015, the Department of Health, on behalf of the four UK Health Departments, published a consultation seeking views on a series of proposals in two draft Orders:

- The Pharmacy (Preparation and Dispensing Errors) Order
- The Pharmacy (Premises Standards, Information Obligations, etc.) Order

The first of these Orders, now titled the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018, 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 (i.e. a registered pharmacy professional), or someone else acting under the supervision of a registered pharmacy professional;
- 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 pharmacy professional, or someone else acting under the supervision of a registered pharmacy professional; and
- the conditions to be met if the new defences are to apply.

This report provides a summary of the responses received to the consultation on what is now the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018. It summarises what we heard during the consultation and feedback from engagement events, and our response to those points.

A separate report was published in February 2016 on the responses to the consultation questions that related to the draft Pharmacy (Premises Standards, Information Obligations, etc) Order when that draft Order was laid before the United Kingdom and Scottish Parliaments. That draft Order became the Pharmacy (Premises Standards, Information Obligations etc.) Order 2016 (S.I. 2016/372).

Overview of the consultation

1. The UK wide consultation, was run between 12th February 2015 and 14th May 2015, on behalf of the four UK Health Departments, seeking views on a series of proposals in two draft Orders:

    i. The Pharmacy (Preparation and Dispensing Errors) Order, now titled the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018.

    ii. The Pharmacy (Premises Standards, Information Obligations, etc.) Order, which has since been made.

Overview of responses

2. This consultation report responds to the consultation on The Pharmacy (Preparation and Dispensing Errors) Order. The change in title – to the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order – is to take account of the parallel work being undertaken on a draft Order in relation to preparation and dispensing errors at hospitals and during the provision of other specified pharmacy services. The four UK health departments aim to consult on this draft Order in due course.

3. In total the consultation drew 159 responses from a variety of respondents including pharmacy professionals, patients and the public, representative groups and organisations. A breakdown of respondents is attached at **Annex A** and a list of organisations / businesses can be found at **Annex B**. Of these responses nine were general responses and not provided to a specific question. In each case, a view was given on an area of interest or on specific points.

4. The overwhelming majority of respondents supported the proposals. More generally, there was a view that if the draft Order was taken forward it would constitute a further opportunity to develop pharmacy practice and improve outcomes and safety for patients.

5. A number of respondents commented that the proposals were long overdue. It was considered important that progress was made in moving the process forward, recognising that the proposed changes were part of wider changes in, for example, development, regulation and oversight of pharmacy practice.

6. Achieving the intended aims of the package was widely accepted, including the aim of increased learning from dispensing errors. However, it was important that possible unintended consequences of, or further barriers to, the changes proposed were identified and resolved, if the sector and the pharmacy professions were to develop and thrive in the future.

7. The need for guidance was raised in response to a number of the proposals, whether from regulatory, professional bodies or others, to help understand the proposed changes and their impact in practice.

8. To support patient and public engagement, a number of events were arranged across the UK, to inform participants about the proposed legislative changes and to elicit their

views. The majority supported the proposed approach. It was also generally agreed that reporting errors was key to identifying lessons to be learned, and therefore enhancing patient safety. Some participants expressed this as being “part of the deal” i.e. if the defence was provided to remove the fear of reporting dispensing errors, then pharmacy professionals should follow through and do so, to improve patient safety. Pharmacy professional bodies (Royal Pharmaceutical Society, Pharmacy Forum Northern Ireland and the Association of Pharmacy Technicians United Kingdom) also held events for their members across the UK.

9. With respect to the duty of candour proposals, a majority felt that, in addition to the professional duty to notify the patient of an error in the medicine(s) dispensed, there should also be a duty in legislation.

10. Following the consultation, there was further consideration of whether, due to section 62(10) of the Health Act 1999, the draft Order required an affirmative resolution of the Scottish Parliament. Prior to the consultation the view was taken that, due to a provision relating to pharmacy technicians within the draft Order, an affirmative resolution was required. However, the legal view now is that section 62(10) is not engaged – largely because of the medicines etc. reservation at Section J4 of Schedule 5 to the Scotland Act 1998 – and a resolution is not needed. It remains the case, however, that the draft Order has the support of all four UK Health Departments – and indeed both the consultation and the final stages of the legislative process have been undertaken on that basis.

Responses submitted to the consultation:

Consultation 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?

Responses	Agree	Disagree	Not Answered
Number	124	17	18
%	78%	11%	11%

What we proposed

11. We proposed to introduce a new defence to prosecutions under section 64 for pharmacy professionals, for inadvertent errors where certain conditions are met. This would mean, 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.

What we heard

12. 78% of responses indicated agreement with the overall proposed approach. 35 of these responses suggested the defence should also apply to inadvertent dispensing errors made by hospital pharmacy professionals in the course of the provision of hospital pharmacy services. Some respondents requested clarity on the issue of dispensing errors arising in cases where dispensing was from a satellite pharmacy, clinic or off-site provision.

13. Of the 17 respondents that disagreed with the proposed approach, 12 took the view that criminal sanctions should be removed for inadvertent dispensing errors, with some also commenting that there were already sanctions in place under general criminal law to deal with situations of deliberate acts/gross negligence. Concern was raised by some respondents that a key category of dispensing error – labelling errors – was not addressed by the amendments to section 63 and 64 of the Medicines Act 1968 because of the separate offence in relation to labelling errors in Regulation 269 of the Human Medicines Regulations 2012. 5 responses argued that dispensing errors should be decriminalised, proposing the complete removal of the section 64 criminal offence for pharmacy professionals, thereby putting pharmacy professionals on the same footing as other health professionals.

Quotes:

"I think this is a good move and will allow pharmacists to report errors or near misses. We must learn to improve from our mistakes".

"Very sensible way forward - should increase the number of errors reported - which in turn will increase patient safety."

"A similar defence needs to be provided to hospital pharmacies - these generally are not registered with the General Pharmaceutical Council (GPhC), and it would be inequitable if for this reason alone they were left vulnerable to prosecution as a result of human error"

"The defence only applies to GPhC registered pharmacies, so hospital pharmacies which are not registered with the GPhC are not covered. Hospitals treat sicker and more complex patients often involving complex high risk medicines. This leaves many hospital pharmacies more vulnerable to prosecution as a result of genuine dispensing errors not due to negligence".

"The offence should simply be removed. There are plenty of other laws on the statute book to deal with those who are committing murder or manslaughter".

"It is unfair and unjustified that pharmacists are the only health professionals to be at risk of criminal prosecution when a human error happens in the course of their duty".

What we have done

14. The concerns expressed in relation to the related labelling offences highlighted a transposition error which occurred when the Human Medicines Regulations 2012 were consolidated. This has already been corrected. With effect from 1 July 2015, the Human Medicines Regulations 2012 have been amended to reinstate the previous provision. Regulation 269(1) now reads:

> "This regulation applies to a person, …….., who, in the course of a business carried on by that person, sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply."

The underlined text is the text that has been reinstated. The offence is in regulation 269(2).

15. This means the labelling offence in regulation 269 applies to a pharmacy business, not an individual pharmacy professional. This returns the position to the previous position, and means that an individual pharmacist, rather than a pharmacy business, cannot be prosecuted under the related labelling offences.

Our response

16. We will retain the criminal offence in section 64 and provide a new defence for pharmacy professionals against prosecution for inadvertent dispensing errors, subject to certain conditions. The concerns raised with respect to putting hospital pharmacy on an equal footing are being taken forward separately.

Consultation 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?

Responses	Agree	Disagree	Not Answered
Number	134	6	19
%	84%	4%	12%

What we proposed

17. For a pharmacy professional to rely on the defence to section 64 of the Medicines Act 1968, we proposed 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;

    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 Pharmaceutical Society Northern Ireland (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.

18. Where a pharmacy professional seeks to rely on the new defence, all the conditions will need to be met. Basic elements, such as the dispensing of the medicine by a registered pharmacist or under the supervision of a pharmacist, at/ or from registered premises, should be straightforward to prove.

19. In relation to the second condition – "the registrant was acting in the course of their profession". The phrase "acting in the course of his or her profession" is not defined, and there is no 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.

What we heard

20. 84% of responses agreed with the proposal. Not all respondents who indicated agreement with the proposal provided further comment, but of those who did there were three themes:

    - Greater clarity about what "acting in the course of his or her profession" means

- Concern about the situation for non-registrants, for example, pre-registrants
- The need for guidance

Need for guidance

21. Some respondents sought further clarification and detailed guidance as to what "acting in the course of his or her profession" means and the interpretation of the illustrative grounds – "misusing his or her professional skills for an improper purpose" and "acting in a manner that showed a deliberate disregard for patient safety". Sufficiently detailed guidance was sought to avoid misinterpretation, including guidance for prosecutors.

> **Quotes:**
>
> "We agree that it should be the prosecution that needs to show the pharmacist was not 'acting in the course of his or her profession' as defined".
>
> "We agree that the burden of proof should lie with the prosecution as described".
>
> "However, if the defendant is not a registrant, there needs to be a clearly thought out process to indicate how the individual is supported, where they have been working within the remit of their role".

Our response

22. We will include the conditions as originally proposed during the consultation (and set out at paragraph 17 of this document). For example, (i) "acting in the course of his or her profession" will be a condition of the defence; and (ii) the burden of proof will be for the prosecution to show otherwise beyond reasonable doubt.

23. In relation to guidance, we would not anticipate the pharmacy regulators advising on the meaning of "acting in the course of his or her profession", i.e. simply on the proper construction of the legislation. We would however anticipate that the pharmacy regulators will advise on what is appropriate professional conduct in a given situation or particular types of situation. If a pharmacy professional departs from those standards, it does not necessarily mean that they are not acting in the course of their profession. In general, if a pharmacy professional is dispensing a medicine as part of normal practice, it would be difficult to reach a view that they were not acting in course of their profession.

24. It would be for the prosecution to prove beyond reasonable doubt that a pharmacy professional was not acting in the course of their profession. The illustrative grounds will guide that view. The court would, we anticipate, look for 'authoritative guidance' to influence its view on what is or is not viewed as acting in the course of their profession. This could include the pharmacy regulators' professional standards, e.g. the GPhC's *Standards of conduct, ethics and performance*, as well as other sources of 'authoritative guidance', e.g. from the professional bodies. We do not believe it necessary for the Department of Health to produce additional guidance.

25. The situation for non-registrants, for example, pre-registrants is similar to that for other pharmacy staff, i.e. it is proposed that the defence will apply to all possible defendants. See also the report on Question 7 later in this document.

Consultation 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?

Responses	Agree	Disagree	Not Answered
Number	125	11	23
%	79%	7%	14%

What we proposed

26. We consulted on two illustrative grounds that the prosecution might wish to rely on to demonstrate that the registrant "was not acting in the course of their profession". The first was where the prosecution could show that the registrant was "misusing his or her professional skills for an improper purpose" and the second was 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".

What we heard

27. 79% agreed with the proposed illustrative grounds. Some respondents indicated that, while agreeing with the proposal, further clarity was required on both of the grounds described but especially in respect to "acting in a manner that showed a deliberate disregard for patient safety" which could be overly subjective in practice until there is established case law. Others expressed concerns about how it might play out in an actual case.

28. There was a recognition that it would take some time for case law, or more likely prosecuting practice, to develop. It was also suggested in a number of responses that until then, sufficiently detailed guidance would be required to avoid misinterpretation. Additionally, it was suggested that the Department of Health should ensure that prosecutors also have appropriate detailed guidance to assist their interpretation of this aspect of any new regulations.

Quotes:

"The prosecution must prove beyond reasonable doubt that there has been a deliberate misuse of professional skills for improper purposes or blatant disregard for patient safety."

"We accept that this is not an exhaustive list but it does set an appropriate bar."

"These are two extreme situations for which there can be no argument that the registrant was not acting in the course of their profession. I would like to see further clarity as to what constitutes a pharmacy professional not acting in the course of their profession"

"We support the use of illustrative grounds but consider more need to be included to give guidance on what could be a very grey area. A pharmacy professional must be able to explain how they used their professional judgement when coming to a decision. Time may also be a critical factor. While case law is being developed the Department needs to ensure that prosecutors have sufficient detailed guidance to be able to interpret the new regulations in the spirit in which they are intended".

Our response

29. We will proceed with 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 beyond reasonable doubt.

30. The issue of guidance has been addressed earlier in this document (in paragraph 24).

Consultation 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?

Responses	Agree	Disagree	Not Answered
Number	139	2	18
%	88%	1%	11%

What we proposed

31. We proposed to include a clarification 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.

What we heard

32. 88% of responses indicated agreement with the proposal. A number commented that it is fundamental for professionals to act in the best interests of the patient. Where this requires a departure from established safe procedures (such as set out in SOPs), professionals should be prepared to demonstrate how the action they have taken is in the best interests of the patient. It was also felt that the exercise of professional judgement in the best interests of the patient should not be grounds for a decision in criminal proceedings that the pharmacy professional was not acting in the course of their profession.

Quotes:

"Pharmacy professionals need to be able to use their own professional judgement as long as that judgement is informed, reasoned and in the best interest of the patient. SOPs vary in quality and should not be prescriptive".

"Pharmacy staff may have to use professional judgement to support patients with the best outcome and decision. This can sometimes be in breach of procedures and have unintentional consequences. Staff should not be judged on this alone".

> "There are always exceptions. We are required to make care of the patient our first concern and this may mean that sometimes we work outside of procedures to get the best result for the patient".
>
> "We believe that professional autonomy must be respected and that professionals should be allowed to act outwith process when they believe it is in the best interests of patients. It would be beneficial for registrants if initial guidance could be produced on how to outline best practice in scenarios where a registrant has been acting outwith agreed process".

Our response

33. We will proceed with the clarification 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.

Consultation 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?

Responses	Agree	Disagree	Not Answered
Number	108	30	21
%	68%	19%	13%

What we proposed

34. The fourth element of the defence (provided in paragraph 17) 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. This is fundamental to the notion that in dispensing 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.

35. Section 64 does not apply in the case of inpatient NHS hospital supplies, as those medicines are supplied against the directions of a doctor or other authorised prescriber. This 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. For the majority of patients in the community, a doctor, dentist or nurse prescriber 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

36. Legal frameworks have been developed recently that allow services to be redesigned and for 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).

37. PGDs provide a legal framework that allows some registered health professionals to supply or administer specified medicines to a pre-defined group of patients, without them having to see a doctor, dentist or nurse prescriber. Supplying or administering medicines under PGDs is generally reserved for situations in which this offers an advantage for patient care, without compromising patient safety.

38. In general, it was proposed 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.

What we heard

39. 68% supported the proposal. A number of the respondents who did not support it made the point that the proposal excluded pharmacy professionals providing medicines in hospitals, although some acknowledged that proposals will be brought forward for hospital pharmacy.

Emergency supply of medicines

40. A number of respondents made the point that emergency supplies provided by the pharmacy at the request of a patient would not be covered by the proposal. It was also suggested that this aspect needed further consideration, as the provision of emergency supplies at the request of the patient, where at the time there is no prescription, is a common scenario in community pharmacy.

Sale or supply of pharmacy and general sale list medicines

41. A number of respondents made the point that the sale of pharmacy-only ('P' medicines) and general sale list (GSL) medicines should come within the defence as well as all medicines provided under minor ailment schemes and through other NHS contractual activity.

When a pharmacist is both the prescriber and the dispenser

42. It was proposed that the defence should not cover an inadvertent dispensing error by a pharmacist where they were also the prescriber as this was analogous to the activity of a doctor. Several consultation responses expressed the view that the defence should include situations where, exceptionally, a pharmacist does need to dispense their own prescription. Where, exceptionally, a pharmacist does need to dispense their own prescription a view was expressed in consultation responses that consideration should be given to bringing this situation within the defence. It was noted that given the number

of pharmacist prescribers in hospitals, this was likely to be even more relevant in respect of the dispensing error defence proposals for hospital pharmacy professionals.

Quotes:

"Provision should also be made for supplies made at the patient request, i.e. Emergency Supplies".

"Emergency situations must be included. This would include out-of-hours situations and genuine emergencies, where contacting a prescriber is either impossible or so impractical as to create a real clinical risk in delaying treatment."

"Needs to include the supply of all medicine transactions and not limited to the above proposal".

"The defence of the registered pharmacy leaves inconsistency for hospital registrants. Hospital inpatient supply needs to be open to the same defence as community. This will presumably be addressed in terms of supply from a hospital pharmacy in due course".

Our response

43. The Government has given further consideration to the points raised during the consultation in respect to a dispensing error made when making an emergency supply. A dispensing error could indeed occur in circumstances where:

- the emergency supply is made at the request of the patient, e.g. the patient could have provided a written request for the emergency supply and the pharmacy professional mistakenly supplied the wrong medicine;
- the pharmacy professional may have consulted the patient's medication record and mistakenly supplied the wrong dose.

44. Where an emergency supply of a medicine is made by a pharmacy and the patient is not charged for the medicine, i.e. there is no purchase, the transaction falls outside the remit of the offence in section 64. If the emergency medicine is sold to the patient, then the transaction comes with the remit of the offence in section 64. Having considered the views expressed in the responses to the consultation we are extending the defence to the sale of a prescription only medicine in an emergency.

45. Where the emergency supply of a medicine is made at the request of a prescriber by a pharmacy, this will be pursuant of the directions of the prescriber. In those circumstances, if the transaction involved the sale of the emergency medicine and an error was made, it will come within the defence. Alternatively, if the transaction involved the supply of the emergency medicine and an error was made, it would not come within the remit of the offence in section 64 anyway.

46. Where P or GSL medicines are supplied, rather than sold, for example as part of an NHS minor ailment scheme or other NHS service, e.g. nicotine replacement treatment as part of a stop smoking service, the transaction is outside the remit of the offence in section 64. For completeness, where an NHS minor ailment scheme includes prescription only medicines, the supply will be authorised through a patient group direction. Section 64 is silent in respect of supplies pursuant to directions and so such transactions would also be outside the remit of the offence in section 64.

47. In light of the consultation responses we have taken out the wording which meant that, where a pharmacist makes an error dispensing a prescription they have written themselves, the defence is not available to them. After careful consideration of the consultation responses we recognise it is right to make that change. In these circumstances, the defence will however only be available if all the other standard conditions are made out, including the candour obligations.

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?

Responses	Agree	Disagree	Not Answered
Number	134	7	18
%	84%	5%	11%

What we proposed

48. The fifth condition we consulted on (and provided in paragraph 17 of this document) 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.

49. No definition of "promptly" was provided, 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 action was taken promptly, the burden of proof is on the defendant to provide evidence that the notification might have been prompt before a court. If the defendant does this, the prosecution would then have to prove, beyond reasonable doubt, that the notification was not "prompt" in order to secure a conviction.

50. For the defence to be used, notification must be by an "appropriate person". An appropriate person is identified as people who could discharge this responsibility:

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.

What we heard

51. 84% of responses supported the proposal. A number of respondents made the point that the duty to inform a patient provides reassurance for patients and the public at large and

an opportunity to reflect on the learning from the error and make timely improvements. While agreeing with the proposal, two respondents recommended that consideration was given to whether it was appropriate to create a specific requirement in legislation. The rationale being that a duty of candour already exists as part of a culture of openness and honesty for all pharmacy professionals, and is encouraged by the pharmacy regulators' published standards of conduct.

52. A number of respondents suggested it could be counter-productive and erode confidence in pharmacy if patients and the public were informed of all errors. Among the 7 respondents who disagreed with the proposal, 2 suggested that patients should only be contacted where the error has some clinical impact on the patient. 3 respondents suggested that the GP might play a role either in becoming aware of a dispensing error or as part of the measures taken to help tackle any ill effect arising from an error.

53. It was also suggested that the word 'promptly' should be replaced by 'as soon as reasonably practicable after becoming aware' to align with the wording used in Health & Social Care Act 2008 legislation, in particular the registration of provision of health or social care in England and regulated activities.

54. A number of respondents who agreed that pharmacy owners should be aware of what is happening in their business also expressed the view that if knowledge of the error is deliberately concealed, that the pharmacy owner should not be held liable.

Quotes:

"This provides reassurance to patients, that all will be done to rectify any dispensing errors, thus improving patient safety. It is also consistent with recent reports into care standards, which concluded that patient safety is everyone's responsibility".

"This is part of the culture of honesty and responsibility to patients and indicates there was no intention to cover up or refuse to acknowledge the consequences of an error".

"I think it is good professional practice to report the error and to seek a remedy with the patient i.e. prevent them taking medicine if possible or advise a course of action if medication taken. Trying to cover up the error would be poor professional practice and should be dealt with by the regulator".

"Paragraph 85 highlights that pharmacy owners need to be held accountable to what is occurring in their pharmacy. While we agree with this, we are concerned that where a pharmacist consciously decides not to inform the owner of an error, the owner remains potentially liable to prosecution. We believe that a similar defence should be available to the owner such that they would only be liable had they been told of an error but had taken no steps to contact the patient or their representative or had ensured that the pharmacist in the pharmacy had done so".

Our response

55. We do not agree that the word 'promptly' should be replaced by "as soon as reasonably practicable after becoming aware" as the suggested replacement wording could allow for additional time to notify the patient, in a situation when time is of the essence.

56. To remove the potential liability on the pharmacy owner, if a pharmacy professional concealed an error, would significantly limit the incentive to have systems for notifying patients of dispensing errors in place. Additionally, such an approach would not be consistent with greater emphasis on candour and the responses from patients and the public strongly supported patient notification of dispensing errors. The Government is therefore not persuaded to amend the patient notification condition of the defence.

57. However, should a pharmacy owner not know about an error as the matter has been deliberately concealed by the dispenser, it does not mean that the owner will automatically face prosecution. The owner may be able to rely on the 'due diligence' defence in section 121(2) of the Medicines Act 1968, if the owner can demonstrate that they exercised all due diligence to secure that section 64 would not be contravened, and that the contravention was actually due to the act of another person, i.e. the dispenser.

Consultation Questions 7 and 8

Q7. 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?

Q8. Do you agree that the defence should not apply in cases where unregistered staff involved in the sale or supply of medicine deliberately interfere with the medicine being sold or supplied at or from the pharmacy?

Response Q7	Agree	Disagree	Not Answered
Number	139	2	18
%	88%	1%	11%

Response Q8	Agree	Disagree	Not Answered
Number	130	10	19
%	82%	6%	12%

What we proposed

58. We consulted on proposals for defences to apply to all possible defendants. Other possible defendants, beyond pharmacy professionals, could include 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.

59. 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.

60. There may, however, be cases where an intermediary deliberately gives the patient the wrong medicine. In such 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.

What we heard

61. Both proposals commanded a high level of support. In relation to question 7 a number of respondents indicated that consideration needed to be given to the educational needs of this group of staff if the proposed changes are to be enacted.

62. In relation to question 8, of those who did not support the proposal, a number requested clarification of the term "deliberate interference". A couple of respondents appeared to suggest that unregistered staff could use the defence even in cases of deliberate interference, if supervised by a registrant, and the text of the remaining response appeared to indicate support for the proposal.

Quotes question 7:

"We believe that all of the staff in the pharmacy should have defence against prosecution for inadvertent errors in the course of their work in the registered premises".

"It is reasonable that those that are involved in the 'dispensing process' as defined in this document should be able to use the defence for 'inadvertent' errors".

"Consideration needs to be given to the educational needs of these groups of staff if the proposed changes are enacted and how these will be supported".

Quotes question 8:

"If they deliberately interfere with the medicine they are putting patients at risk and must feel the full force of the law".

"Very sensible - anyone who deliberately interferes with a medicine should not be protected - the public would query such a view".

"The defence should not apply to anyone – registered or otherwise – who deliberately interferes with a medicine with the intention of causing patient harm".

Our response

63. Given the support for the measures, the proposals as consulted upon will be taken forward. The concept of "deliberate interference" does not feature in the wording of the legislation. The test in the legislation is what the defendant knows at the relevant time.

Consultation 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?

Responses	Agree	Disagree	Not Answered
Number	108	22	29
%	68%	14%	18%

What we proposed

64. Section 63 of the Medicines Act 1968 concerns the adulteration of medicinal products (i.e. errors in the course of preparation of medicinal products, whether deliberate or inadvertent). We consulted on proposals to introduce a defence, for section 63 offences, in line with those proposed for section 64 offences. Parallel provisions have been created for the proposed new defences against the two offences in that section, which are worded in very similar terms. 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.

65. Currently 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.

What we heard

66. 68% of responses supported the overall approach to the new defence in relation to the offence in section 63. Some respondents indicated similar comments to those for Question 1 (proposal to add a new defence in relation to section 64). However, 13 respondents recommended that the criminal offence should be completely removed from the legislation – some referenced their comments to those made in respect of section 64, Question 1 - but in a number of cases, went on to say that they would support the approach.

67. 11 responses highlighted that the consultation document was silent on how the proposed defence would apply in 'hub and spoke' models of medicines provision. These are where medicines are prepared and dispensed ready for supply in a central pharmacy (the "hub") and then distributed to local pharmacies (the "spokes") for collection by patients. Further guidance was requested.

Quotes:

"We believe that the defence should apply to errors made in the course of the preparation of medicinal products, at a registered pharmacy".

"We support the approach for registered pharmacy premises but would like to explore implications for different models of dispensing / preparation. For example satellite pharmacies (hub and spoke)".

"We agree with the overall approach and the proposed condition that preparation errors will need to have taken place at a registered pharmacy. The consultation document is silent about how this condition would be applied in the case of a preparation error occurring within a hub and spoke dispensing model. We would wish to see some guidance on this issue in due course".

"We agree a defence should be introduced for inadvertent errors pharmacy professionals make while preparing (compounding) medicines. We hope that the Rebalancing Board will also find an appropriate way to extend this defence to pharmacy professionals who work in hospital pharmacies that have not elected to be registered with the GPhC / PSNI".

Our response

68. The Government will take forward the proposals for the defence as provided in the consultation document. The current proposals for a defence to section 63 and 64 criminal offences for dispensing errors are aimed at community pharmacies. As part of the conditions of the defence, there is a requirement for the medicine to have been sold or supplied from a registered pharmacy. Both hubs and spokes in "hub and spoke" models are registered pharmacies and so errors at both already potentially benefit from the defences.

69. Work is already under way to explore how all dispensing errors in hospital pharmacies can benefit from the new approach, so that they are adequately covered both in relation to section 63 and 64. Proposals will be subject to a separate public consultation.

Impact Assessments

70. Questions 15 to 19 relate to the material presented in the consultation Impact Assessment (IA), published alongside the draft Order in respect of both dispensing.

Consultation 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.

Responses	Agree	Disagree	Not Answered
Number	90	7	62
%	57%	4%	39%

What we heard

71. 57% of responses agreed with the assessment of costs and benefits which had been prepared in respect of the dispensing error proposals. One organisation which responded positively provided additional information to augment the assessment.

72. A high number, who responded to the consultation, did not answer this question. Of those who disagreed with the assessment, there was concern that insufficient consideration had been given to the increased regulatory burden of increased reporting and that greater responsibility placed on the regulator could mean that registrants would be faced with increased registration fees. One respondent was of the view that the current law inhibits good pharmacy practice and that the proposed changes do not go far enough to remove the "inhibitors" (term not defined by the respondent).

Consultation 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.

Responses	Agree	Disagree	Not Answered
Number	20	80	59
%	13%	50%	37%

What we heard

73. 50% of responses did not identify any additional significant impacts or benefits on any sector involved.

74. Those who did identify additional impacts mainly commented on the fact that hospital pharmacy professionals could not benefit from the defence for the most part.

75. One respondent commented that more consideration needed to be given to staff training and learning from errors and near miss reporting, although increased error reporting may give rise to increased 'fitness to practise' cases for regulators with the costs being passed to the registrants.

76. Another respondent noted that there was no national reporting system in Scotland. It was also noted that the independent sector will need to implement a system of reporting to the National Reporting and Learning System (NRLS) (to be piloted in 2015) and the impact of this will need to be assessed.

Consultation Question 17:

As part of preparing this IA we have asked business representatives whether, if the new defence 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?

Responses	Yes	No	Not Answered
Number	5	88	66
%	3%	55%	42%

What we heard

77. 55% of responses did not identify any specific cost impacts that might arise as a result of introducing the new defence. However a very small minority thought employee costs would increase as more staff time would be needed to administer any increase in incident reporting and that legal costs might well rise as test cases are taken to court and new case law takes time to be established. Some additional costs might also arise in advising patients and implementing new procedures.

Consultation 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?

Responses	Agree	Disagree	Not Answered
Number	108	5	46
%	68%	3%	29%

What we heard

78. 68% of responses agreed that it was not feasible to estimate a "typical" cost. However, one respondent (Law firm) offered to share information gathered over many years on fines and costs that convicted pharmacists have been ordered to pay.

Consultation 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?

Responses	Yes	No	Not Answered
Number	90	6	63
%	56%	4%	40%

What we heard

79. 56% of those who answered agreed that the assumptions we have made were proportionate and realistic. However a very small minority thought the assumptions used in the IA (both time to record errors and increases in reporting) were understated, although no alternatives were suggested. Concern was also expressed about the accuracy of data reported via NRLS.

Overview of responses to questions on the Impact Assessments (IA)

80. Following the initial IA, a final IA has been prepared taking account of the results of the consultation. In addition to the questions highlighted in the consultation, DH undertook further work with pharmacy interests, drawing on their experience and obtaining additional evidence to inform the final IA that is published alongside this Report.

81. Overall, responses to the questions relating to the IA showed that a large majority of the respondents support the results of the analysis described in the IAs. This is, in itself, a reassurance.

82. Regarding additional benefits or costs that were perceived as not currently incorporated, the following comments were highlighted:

Benefits:

- "Reporting of patient safety incidents leads to national learning. This in turn enables dialogue with MHRA and ultimately with Manufacturers. This conduit between practice and manufacturers is very powerful in refining pharmaceutical products to be safer in practice".
- "In the future with the advent of more complex medicines (Biologics) enabling and facilitative ground-up feedback with the oversight of the community pharmacy Medication Safety Officer will be critical to patient safety. The Medication Safety Officer has formal responsibility for the quality and frequency of reporting for NHS-funded care. There are 18 named community pharmacy MSOs representing the practice of over 10,000 community pharmacies. By enabling reporting through this rebalancing initiative, ultimately MSOs are empowered and we have full linking from practice to pharmaceutical product".

Costs:

- "There is the impact on hospital pharmacists as they will not be able to use the defence as they do not work in a GPhC registered premises".
- "Minimum staffing levels in non-registered premises where employers show a disregard for safe practice due to excessive workloads. Where dispensing errors occur due to minimal staffing levels, lack of breaks and general tiredness the management should be charged. Following on from the Francis and Andrews Report (in Wales) management up to chief executive level should be made responsible if they are found to be culpable."
- "Standards of premises in non-registered premises should reach a minimum, and this combined with the registration of all pharmacies,"
- "I do not believe that sufficient consideration has been given to the regulatory burden of requiring increased reporting of errors to the NRLS".

Our Response

83. The IA has been reviewed in light of the views from the consultation. Further consideration has been given to the following points:

a) Review the assumptions regarding the time it may take pharmacists to report errors.

b) Include higher unreported levels in the sensitivity analysis and clarify existing evidence.

c) Review material on prosecution cost estimates put forward.

d) Review the sensitivity analysis, which already incorporates the burden of reporting being potentially higher.

Equality Assessment

84. An assessment of the impact of the proposals on equality, was published alongside the consultation document and responses were invited, including any additional information, in relation to how the proposals on which we were 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.

Consultation Question 23:

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

Responses	Yes	No	Not Answered
Number	9	102	48
%	6%	64%	30%

What we heard

85. No additional evidence was provided in 64% of responses. 6% suggested that additional evidence should be considered in that there was inequality in so far as the proposals did not address the needs of hospital pharmacy professionals, which are unrelated to equality issues and the protected characteristics.

Quotes:

"The programme board must continue to work to address the issue for hospital pharmacy"

"The proposals lead to inequality for pharmacy professionals being afforded different levels of defence against prosecution based on their location of service provision. It is important that this is addressed with a focus on hospital pharmacy professionals as a matter of urgency".

Next steps

86. Following consideration of the consultation responses, drafting changes have been made to The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018.

87. The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 together with this report on the consultation will be laid before the UK Parliament in accordance with affirmative resolution procedures.

Annex A: Respondents (by category, as self-recorded on the consultation responses)

A patient or carer	3
A patient or carer, pharmacist	1
A pharmacist	69
A pharmacy technician	8
A pharmacy owner	2
Other	9
A pharmacist on behalf of a healthcare organisation	20
A pharmacist on behalf of another organisation	4
A pharmacy technician on behalf of a healthcare organisation	1
A member of the pharmacy team on behalf of a healthcare organisation	1
A healthcare organisation	15
Other organisation	26

Annex B: Responses to the consultation

Abertawe Bro Morgannwg University Hospital

Action Against Medical Accidents

All Party Pharmacy Group

Association of Pharmacy Technicians UK

Attorney General for Northern Ireland

Barts Health, NHS Trust

Belfast Health and Social Care Trust

Bradford College

Cheshire and Wirral Local Pharmaceutical Committee

Colchester Hospital University NHS Foundation Trust

Community Pharmacy

Community Pharmacy NI

Community Pharmacy Scotland

Community Pharmacy Wales

Crown Prosecution Service

Derby Teaching Hospitals NHS FT

Dispensing Doctors Association

East & South East Specialist Pharmacy Services

General Pharmaceutical Council

Great Western Hospital NHS FT

Guild of Healthcare Pharmacists

Health and Social Care Board, Northern Ireland

Health Education England

Health Education Kent, Surrey and Sussex

Health Education Thames Valley

Health Foundation

Healthcare Improvement Scotland

HMP Swansea Pharmacy

Hywel Dda University Local Health Board

ICHT

Integritas Registered Charity

Kettering General hospital

King's College Hospital NHS FT

Law Society of Scotland

Leeds Teaching Hospitals NHS Trust

LETB Pharmacy Leads Group (Health Education England)

MEHT

Mid Essex Healthcare Services Trust

Mid Essex Hospital Services NHS Trust

Morgannwg Local Practice Forum Steering Group of the RPS

National Pharmacy Association

NHS Ayrshire and Arran

NHS Borders

NHS England

NHS Greater Glasgow and Clyde

NHS Lanarkshire

NHS Lothian

NHS Orkney/Shetland

NHS Pharmacy Education and Development Committee

NHS Scotland Directors of Pharmacy

NHS Sheffield CCG

NHS Shetland

NHS Wales

NICE

North East Senior Pharmacy Managers Group - Workforce Training and Development Group

North of Tyne Local Pharmaceutical Committee

Northern Health and Social Care Trust

Northumbria Healthcare NHS Foundation Trust

Oxford University Hospitals NHS Trust

Papworth Hospital NHS FT

Parkinson's UK

Patients First

Pharmaceutical Services Negotiating Committee

Pharmaceutical Society of Northern Ireland

Pharmacists Defence Association

Pharmacy and Prescribing Support Unit, NHS Greater Glasgow and Clyde

Pharmacy Forum NI

Pharmacy Schools Council

Pharmacy Voice

Professional Standards Authority for Health and Social Care

Royal Pharmaceutical Society

Royal Wolverhampton NHS Trust

Sandwell and West Birmingham NHS Trust

Scottish Prescribing Advisers Association

Sheffield Teaching Hospitals NHS FT

South Eastern Health and Social Care Trust

South Staffordshire Local Pharmaceutical Committee

South Warwickshire NHS FT

Suffolk LPC

Sussex Community NHS Trust

Thames Valley and Wessex Chief Pharmacists Group

The Luton & Dunstable University Hospital

University Hospital of South Manchester

University Hospital Southampton NHS FT

University Hospitals Bristol NHS FT

University of Wolverhampton

Wales Centre for Pharmacy Professional Education

Walsall Healthcare NHS Trust

Western Health & Social Care Trust

Wexham Park Hospital

Wye Valley NHS Trust

Business:

Asda Pharmacy

B K Kandola Ltd

Bannside Pharmacy Ltd

BLM

Boots Pharmacists Association

Boots UK & Manchester Pharmacy School

Boots UK / Walgreens Boots Alliance

Charles Russell Speechlys LLP

Intrahealth

L. Rowland and Co. (Retail) Ltd. t/a Rowlands Pharmacy

Medicare

Mounts health centre pharmacy

Nuffield Health

Numark

PCT Healthcare

SKF Lo (Chemists) Ltd

The Co-operative Pharmacy

Weldricks

Well - Bestway Group

Well Pharmacy

WR Evans (Chemist) Ltd