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

Q&A

The Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018; and

The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

June 2018

Title: Rebalancing Medicines Legislation and Pharmacy Regulation:

Consultation on draft Orders under section 60 of the Health Act 1999: Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018; and Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

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Consultation Frequently Asked Questions

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Target audience:

Pharmacy professionals, providers of pharmacy services, including registered pharmacies, pharmacy regulatory bodies, pharmacy professional and representative bodies, unions, patients and the public, and health organisations.

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About this consultation

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. These particular section 60 orders are subject to UK 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.

The consultation period will run between 19 June 2018 and 11September 2018 and we are consulting on both draft Orders:

Draft Order entitled "Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018"

- The first draft Order entitled Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018 seeks to bring in defences for inadvertent preparation and dispensing errors by pharmacy professionals (registered pharmacists and registered pharmacy technicians) occurring in hospitals and other settings with appropriate governance arrangements, such as care homes and prisons. This aligns with provisions contained in an earlier Order entitled Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 – the "first Preparation and Dispensing Errors Order" in respect of errors at registered pharmacies (i.e. predominantly retail pharmacies), which came into force on 16 April 2018. The draft Order will ensure that pharmacy professionals in these other settings can make use of the defences already afforded to pharmacy professionals operating in registered pharmacies.

- The aim of the legislation is to remove the threat of criminal sanctions for inadvertent preparation and dispensing errors, incentivising an increase in the reporting of errors, which will afford greater learning opportunities – translating to increased patient safety.

- This consultation does not address dispensing doctors, as GP practice dispensaries are unlikely to have the sort of governance arrangements that the draft Order contemplates, i.e. the pharmacy service being a separate entity under the direction of a Chief Pharmacist and being separately registered with or inspected by the relevant authorities. Medication errors by doctors and nurses is however a matter that is under broader consideration (the outcome of a review is pending in England), and further proposals are possible in due course. It also does not address regulated or unregulated professionals operating in non-pharmacy retail premises, for example herbalists or retail outlets selling medicines, like shops and garages.

Draft Order entitled "Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018"

- The second draft Order relates to the organisational governance arrangements for registered pharmacies (i.e. predominantly retail pharmacies), specifically in respect of Superintendent Pharmacists (SPs) and Responsible Pharmacists (RPs).

- The draft Order seeks to clarify and strengthen the organisational governance arrangements for registered pharmacies, specifically to define and clarify the core purpose of the Superintendent Pharmacist and Responsible Pharmacist in primary legislation with professional regulation defining how that purpose is fulfilled. The proposals take account of the interplay between the roles, responsibility and accountability from both organisational and professional standpoints.

- At the request of the Pharmaceutical Society of Northern Ireland, the draft Order also proposes to align Northern Ireland with Great Britain on a couple of technical matters - appointing a deputy registrar and a notification obligation of SPs.

The consultation document and draft Orders can be found here:

https://www.gov.uk/government/consultations/pharmacy-legislation-on-dispensing-errors-and-organisational-governance

Frequently Asked Questions (FAQ)

The Legislative Process

1. What is the legislative process for introducing changes to the Medicines Act 1968?

The legislative instruments are Orders under section 60 of the Health Act 1999. Section 60 Orders permit changes to primary legislation (i.e. Acts of Parliament) through secondary legislation, by an affirmative procedure. The affirmative procedure in question means the two Orders must be debated and approved by both Houses of the UK Parliament before they can be presented for approval at a meeting of the Privy Council. Following approval by the Privy Council, further "Commencement Orders" will be drafted for each of the initial Orders, to bring the new provisions into force in the four nations.

2. Is the process the same in each of the four countries of the United Kingdom?

There are constitutional, regulatory and operational differences in relation to pharmacy matters in the devolved administrations. In particular, pharmacy regulation and the subject matter of the Medicines Act 1968 are fully devolved matters as regards Northern Ireland, and the pharmacy regulator function is not separated legislatively from the professional body in the same way as it is in Great Britain. Additionally, pharmacy technicians are not a registered healthcare profession in Northern Ireland. The arrangements for the regulation of healthcare professionals are currently being considered by the Department of Health in Northern Ireland, and therefore Northern Ireland's position may be subject to change.

To reflect the distinct arrangements for pharmacy in Northern Ireland, provision is made that the changes made to the Medicines Act 1968 or an amendment of the Pharmacy (Northern Ireland) Order 1976 by the Orders will only be commenced in relation to Northern Ireland with the agreement of the Department of Health in Northern Ireland.

The Orders are only required to be laid in draft before the UK Parliament. It remains the case, however, that the draft Orders have the support of all four UK Health Departments – and indeed both the consultation and the legislative process are being undertaken on that basis.

Ultimately, the provisions of the draft Orders that amend the Medicines Act 1968 will apply to the whole of the UK – England, Wales, Scotland and Northern Ireland.

Consultation Process

3. Why are you consulting on draft Orders?

The 4 UK Health Departments are consulting on the draft Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018 and the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018. 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 consultation 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

4. Who can respond to the consultation?

The public consultation is open to input from anyone who is interested. The primary target audiences of the consultation however are: pharmacy professionals; providers of pharmacy services, including owners of registered pharmacies; pharmacy regulatory bodies; pharmacy professional and representative bodies; unions; patients and the public; and health organisations.

5. How can I respond to the consultation?

Responses should be submitted by 23:59 on 11 September 2018 via the on-line survey, which can be accessed using the following link:
https://consultations.dh.gov.uk/pharmacy/two-pharmacy-related-draft-section-60-orders/

If you have additional evidence you wish to submit, this can be sent to MB-Rebalancing <21@dh.gsi.gov.uk> quoting the reference number you will be provided with after submitting your consultation response in the on-line survey.

If you wish to receive a paper copy of the consultation form, please contact the Pharmacy Team at MB-Rebalancing <21@dh.gsi.gov.uk> or by mail at:

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Draft Pharmacy (Preparation and Dispensing Errors - Hospitals and Other Pharmacy Services) Order 2018

6. What does the draft Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018 do?

The proposal is to extend the defences that already apply to registered pharmacy professionals working in registered pharmacies, which for the most part are retail pharmacies. The defences were introduced by the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018, and relate to offences under section 63 (adulteration of medicinal products) and section 64 (sale of any medicinal product which is not of the nature or quality demanded by the purchaser) of the Medicines Act 1968. The draft Order extends these defences to registered pharmacy professionals working in hospital pharmacy services and other relevant pharmacy services, such as for care homes and prisons.

7. Does the draft Order apply to the whole UK?

This draft Order extends to England, Wales, Scotland and Northern Ireland.

8. Why introduce these defences?

Currently, registered pharmacy professionals working outside of a registered pharmacy are at risk of prosecution under section 63 (adulteration of medicinal products) and section 64 (sale of any medicinal product which is not of the nature or quality demanded by the purchaser) of the Medicines Act 1968 in the event that they prepare or dispense medicines erroneously.

Aligning the defences available for registered pharmacy professionals working beyond registered pharmacies will support increased reporting of errors, without the fear of prosecution, and allows for individual and shared learning from those mistakes, leading to improved patient safety.

9. Will a preparation or dispensing error committed by a pharmacy professional still be a criminal offence?

This draft Order does not remove completely the criminal offences for preparation or dispensing errors made by registered pharmacy professionals, and those supervised by them. What it does do, is extend the recent defences to strict liability offences for inadvertent preparation and dispensing errors in retail pharmacies, where certain criteria are met, so that they also apply potentially to registered pharmacy professionals working in hospitals and other pharmacy services.

10. Why doesn’t the Order go further and remove the offences altogether?

The offences are retained because they apply to all sales or supplies on prescription, not just to those by registered pharmacy professionals in community pharmacies, hospitals or other regulated settings – for example they apply to sales of medicines in shops and to sales by herbalists. There is no mandate to sweep away the offence in these other contexts.

There are also still circumstances where pharmacy professionals should not benefit from a defence, for example where they have shown a deliberate disregard for patient safety or have not discharged their professional “duty of candour” to advise patients promptly of any error that occurs.

11. Does the draft Order totally remove the risk of prosecution for preparation or dispensing errors?

No. The risk of prosecution cannot realistically be totally removed. This draft Order, along with the previous one for pharmacy professionals working at or from registered pharmacies, is expected to lead to a decrease in the risk of prosecution.

The draft Order extends already existing defences to section 63 (adulteration of medicinal products) and section 64 (sale or supply in pursuance of a prescription of any medicinal product which is not of the nature of quality demanded by the purchaser) of the Medicines Act 1968, and prior to 2018 there were defences already available in section 64 itself, and also in sections 121 and 122 of the Act. In the past one of the key defences has been section 121(2), which exonerates a defendant where the contravention was due to the default of another person and the defendant themselves exercised all due diligence. This defence is also still available.

In enacting the earlier preparation and dispensing errors Order, Parliament has already made clear its intention that pharmacy professionals in registered pharmacies should not be prosecuted for genuine inadvertent preparation or dispensing errors – provided the conditions of the defence are met.

12. Are pharmacists potentially liable under the law of gross negligence manslaughter for dispensing errors?

Potentially, yes. The new statutory defences have no direct impact on the common law offence of gross negligence manslaughter, as it applies in healthcare settings. It is important to emphasise however that the legal bar for conviction for gross negligence manslaughter, clarified by the Court of Appeal in 2017, is high. For there to be a conviction, the circumstances of the breach of the duty of care that caused the death have to be “truly exceptionally bad and so reprehensible as to justify the conclusion that it amounted to gross negligence and required criminal sanction.”

This offence, although it applies in healthcare settings, is not specific to healthcare settings. However, it is an example of how the general criminal law continues to apply to pharmacy professionals, and of how broader issues of how errors by healthcare professionals are investigated do necessarily impact on pharmacy professionals. The review by Sir Norman Williams of gross negligence manslaughter in healthcare, published in June 2018, included a number of recommendations in relation to investigations of gross negligence manslaughter, and the implementation of these recommendations is likely to have an impact on the criminal investigation of errors by healthcare professionals more generally.

13. What are the conditions of the draft defences?

This draft Order extends the defences for inadvertent preparation or dispensing errors to registered pharmacy professionals working in hospitals and other relevant pharmacy services.

In order to qualify for the defences, certain conditions must be satisfied:

1. The person who dispensed the product was a registrant, or was acting under the supervision of a registrant*

2. The medicine must be supplied in the course of the provision of a relevant pharmacy service (in essence, “relevant pharmacy services” are pharmacy services registered with or subject to inspection by relevant authorities such as the CQC, Regulation and Quality Improvement Authority (NI), Healthcare Improvement Scotland or Healthcare Inspectorate Wales)
3. The registrant was acting in course of their profession*
4. The medicine was a dispensed medicine, that is the sale or supply was in pursuance of a prescription or directions or was of a prescription only medicine (POM) that was sold or supplied in circumstances where there is an immediate need or could not otherwise have been obtained without undue delay*
5. At the time of the alleged contravention, the defendant did not know that the product had been adulterated/was not of the required nature or quality*
6. The patient was promptly notified of the error, unless considered unnecessary*
7. The relevant pharmacy service is overseen by a “Chief Pharmacist”.

*** denotes commonality with the existing defence for registered pharmacies**

14. What are preparation and dispensing errors?

Errors include for example:

- a medicine intended for another patient being dispensed to the wrong patient;
- the wrong medicine being dispensed;
- an ingredient is inadvertently omitted or added when making up a medicine;
- the medicine being dispensed at the wrong strength or in the wrong dosage form; or
- the supply of an out of date medicine.

15. Why do dispensing errors occur?

Pharmacy professionals have listed multiple explanations for the occurrence of dispensing errors, including:

- Similar medicine names and the same branding on packaging for different products;
- Incorrect selection of medication from a drop down list on an electronic system - i.e. a "picking error";
- Workload, interruptions and distractions;
- Physical environment, e.g. lighting.

16. If we relax the rules, won’t this negatively impact on patient safety?

We are not relaxing the rules in the sense of taking errors any less seriously. We expect that this Order will have a positive impact because of an increase in the reporting of dispensing errors, which will afford greater learning opportunities – translating to improved patient safety. It is important to recognise that pharmacy professionals may still be subject to prosecution, under the Medicines Act 1968, where the conditions of the defence are not fulfilled e.g. a pharmacist showing deliberate disregard for patient safety would not benefit from the defence, as such a person would not be “acting in the course of his or her profession”.

In addition, under general criminal law, pharmacy professionals may be prosecuted on the same basis as any other health care professional for the normal range of offences against the person and professional sanctions can also be administered, if warranted, by the General Pharmaceutical Council or the Pharmaceutical Society of Northern Ireland where errors occur.

Responses to the Government’s consultation on similar measures for registered pharmacies highlighted considerable support from patient and service-user groups and

recognition of the potential for increased learning to help prevent dispensing errors and improve patient safety.

17. What is being done to increase learning from preparation and dispensing errors?

Government, regulatory and professional bodies expect pharmacy teams to be pro-active and engaged in improving patient safety.

To encourage and foster a culture of learning and improvement in registered pharmacies, the regulatory and professional pharmacy bodies across the UK have:

- Published professional standards to support increased reporting, learning, changing practice and sharing learning from dispensing errors and near misses;
- Run patient safety and quality roadshows and medicines safety conferences to promote the standards and engage the professions; and
- Published a range of tools and resources to support the further improvement to systems and procedures - for example www.pharmacyqs.com

In each of the four nations, there are also a number of system wide initiatives to support learning and improvement at a local, regional and national level and help to better identify and address system errors. For example, in England there has been the introduction of medication safety officers and improvement reporting systems (the National Reporting and Learning System – also in Wales), and in Northern Ireland a team of Medicines Governance Pharmacists has been established to promote incident reporting and identify learning at a regional and local level.

18. What is being done to tackle medication errors more generally?

In February 2018, at the Patient Safety Movement Foundation Summit, the Secretary of State for Health and Social Care outlined the results of a recent evidence based review that indicated the prevalence, scale and economic burden of medication errors in the NHS. New research estimates that some 237 million medication errors occur in England per annum. He also set out a number of areas where we could do better to tackle prescribing and medication errors: from improving how we use technology, such as electronic prescribing and medicines administration systems, to understanding how best to educate and inform patients about their medicines.

As part of this package of work, NHS Improvement are working with the Medicines and Healthcare products Regulatory Agency (MHRA) to analyse the root cause of medication errors and where appropriate ask for changes to medicines labelling, where changes could be beneficial for both clinical staff and patients.

19. Why is this draft Order separate to the previous one for registered pharmacies?

This draft Order applies only to registered pharmacy professionals (pharmacists and pharmacy technicians) making inadvertent preparation and dispensing errors in hospitals or other pharmacy services - outside of a registered pharmacy. Hospital pharmacies are generally not registered and do not have the same governance arrangements. It was therefore decided to produce two separate draft Orders, with the first – the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 – coming into effect on 16 April 2018 and dealing with registered pharmacies (i.e. predominantly retail pharmacies) where the content of the defences is more straightforward. This allowed progress to be made in some areas while the policy was being worked through in others.

20. When a dispensing error occurs, patients should be told about it. How does the draft Order address this?

It is a requirement of the defence for the patient to be advised promptly of any error that occurs. This builds on the "duty of candour" of health care professionals where they make a mistake, and the corporate "duty of candour" of pharmacy owners.
This is a key part of the new thinking. Pharmacy professionals will move from a position of having a reason not to report their errors (fear of prosecution) to a position of having a clear additional reason to report them (helping to make out a possible defence to a prosecution).

The Explanatory Memorandum accompanying the finalised Order will have examples to illustrate how these notification obligations will work in practice.

21. This draft Order does not go far enough and should mandate the reporting of errors?

The defences have been drafted to incentivise the reporting of errors – and not just by the error maker but also by others in a position of responsibility. In addition, pharmacy professionals are already subject to professional standards set out by the pharmacy regulators – the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland.

These standards include a "duty of candour", which includes an obligation to be open and honest when things go wrong and report and raise concerns.
This is in line with other healthcare professionals.

22. A condition of the defence is that the patient was promptly notified of an error, what constitutes 'promptly'?

An appropriate person should take all reasonable steps, on becoming aware of the error, that the person to whom the product was intended to be administered, i.e. the patient, is informed as soon as possible. Depending on the severity of the error, the expected response of a pharmacy professional may differ. Recognising this, we have not put specific time limits in the legislation.

In many cases, it will be someone other than the dispenser who discovers a dispensing error, including the patient themselves. Where the patient recognises the error, clearly there is no requirement to inform the patient – as they already know.

23. The burden of proof for acting promptly to notify the patient is in the wrong place?

We have put the burden of proof on the prosecution to show that the defendant did not act "promptly" in notifying the patient of an error. In practice, this means that if there is genuine doubt about whether the notification was sufficiently prompt, given the circumstances, the benefit of that doubt will go to the defendant.

On balance, we have opted in favour of making prosecutions difficult to bring rather than making it difficult for defendants to show they come within the defence. The benefit of doubt should generally be with the defendant – which of course is a general presumption in criminal law.

24. “Acting in the course of his or her profession” is a condition of the defences. How will it be judged whether a registered pharmacy professional is “acting in the course of his or her profession”?

The burden of proof on this issue will be for the prosecution to show otherwise beyond reasonable doubt.

In general, if a registered 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 the course of their profession.

Illustrative grounds of what is not considered as “acting in the course of his or her profession” are provided for in the Medicines Act 1968, having been inserted by the first Preparation and Dispensing Errors Order. The illustrative grounds provided are, a registrant “misusing his or her professional skills for an improper purpose” and a registrant “acting in a manner that showed deliberate disregard for patient safety”.

25. This draft Order makes it more difficult for the Crown Prosecution Service and other prosecuting authorities to bring successful prosecutions?

This is true and deliberate. As regards mistakes by pharmacy professionals, the prosecuting authorities around the UK will no longer be able to bring a relatively simple prosecution for a strict liability offence. This is necessary to help remove the “fear factor” of an easy to prove prosecution.

26. Can a pharmacy professional benefit from this defence if they have not followed Standard Operating Procedures (SOPs)?

Yes. This is because occasionally a pharmacy professional must use their professional judgement to put the benefit of a patient above strictly following an SOP. This is why not following a SOP does not of itself contribute proof that the pharmacy professional was not “acting in the course of their profession”. The prosecution still has to prove that beyond a reasonable doubt.

27. Will the defences provided by this draft Order apply if the pharmacist that dispenses the medicine also prescribed it?

Yes. However, it is currently exceptional for a situation like this to occur, usually arising in situations where it is felt that patient need surpasses normal practice.
There are broader safeguards within the defence in consideration of the exceptionality of a pharmacist dispensing a medicine they also prescribed, including the system governance element. Prescribing and dispensing by the same person should in practice only be happening where the service provider, and in particular its Chief Pharmacist, is satisfied that this can be done safely and effectively.

28. Will the defences provided by this draft Order apply if an error occurs in the process of fulfilling a patient group direction?

Supplies against a patient group direction will only come within section 64 at all if the medicine is actually sold. However, NHS supply against patient group directions would be caught by section 63 (adulteration offence). Where a medicine is sold or supplied to a patient against a patient group direction, the first Preparation and Dispensing Errors Order already addressed the possibility of the defences applying in these circumstances if the dispensing is by registered pharmacy professionals working in registered

pharmacies. It is proposed to extend these aspects of the defences to also cover registered pharmacy professionals working in hospitals and other pharmacy services.

29. Will this draft Order cover the preparation and sale/supply of “aseptic products”?

The defences already cover preparation and dispensing of aseptic products at or from registered pharmacies and the draft Order will extend this to the preparation and dispensing of aseptic products in the course of a hospital or other pharmacy services. It will not, however, cover licensed activity occurring in licensed premises (i.e. licensed manufacturing), including the preparation and sale/supply of aseptic products occurring in licensed premises (i.e. undertaken under a manufacturing license).

30. What happens if an error is someone else’s fault?

A due diligence defence already exists where an error is the result of someone else’s actions – section 121(2) of the Medicines Act 1968. So, it is possible that a pharmacy owner or corporate entity responsible for a hospital or other pharmacy service, which might otherwise be held liable for the actions of a member of their staff, may be able to benefit from the due diligence defence even if they are not able to benefit from the new defence – if for example all the fault lies clearly with their employees.

31. I run a hospital pharmacy service - could I potentially be prosecuted for not notifying a patient of an error if the registered supervising pharmacist I employ knew about the error?

If any appropriate person knows of the error but does nothing about it, the new defence is lost to all the potential defendants. The decision on who to charge, if anyone, in those circumstances may of course take account of the behaviour of all the potential defendants. In addition, if the person running the hospital pharmacy service can show that they exercised all due diligence and actually the offence was due to the act or default of another person, they are in the clear, although it may admittedly be difficult to show “all” due diligence. The policy behind this approach, which is inherited from the first Preparation and Dispensing Errors Order, is to create a powerful incentive for owners and supervisors to remain on top of what is happening in their business or under their supervision.

32. Does this draft Order mean all hospitals and other pharmacy services are required to have a Chief Pharmacist?

No. It is proposed to introduce a statutory term of 'Chief Pharmacist', together with a statutory duty in respect of the safe and effective running of the pharmacy service, for which they are responsible, to provide the certainty and clarity necessary for the defences to be relied upon.

Pharmacy services without a Chief Pharmacist will not be able to rely on the defences, but beyond that there is no jeopardy to them. We also recognise the diversity of governance arrangements across the UK and the need for flexibility. As such, organisations do not need a specific Chief Pharmacist role, but should ensure that statutory functions of a Chief Pharmacist are included in the relevant individual’s job responsibilities, if they do want to benefit from the defences.

33. Between this draft Order and the previous one for registered pharmacies, will all settings at which medicines are being sold or supplied be offered defences for inadvertent preparation and dispensing errors?

No. Some hospitals and other regulated pharmacy services may chose not to go down the chief pharmacist route and some supplies, e.g. by herbalists, simply fall outside the scope of the defences. The aim is that between the two Orders virtually all registered pharmacy professionals will be able to avail themselves of the defences to offences for inadvertent preparation and dispensing errors. The public consultation offers the opportunity to highlight in the responses areas that may not be covered by either Order as currently drafted but which people wish to see covered.

34. How does this draft Order relate to smaller independent hospitals?

In smaller independent hospital pharmacies, there is more likely to be an interface between the activity of a registered pharmacy, within the remit of the pharmacy regulators, and activity which is regulated by the CQC, Regulation and Quality Improvement Authority (NI), Healthcare Improvement Scotland or Healthcare Inspectorate Wales. A medicine may be dispensed under dual registration, and where this happens an inadvertent preparation or dispensing error should be covered by one of the two Orders, assuming the conditions are met.

The aim is for both this draft Order and the first Preparation and Dispensing Errors Order to cover virtually the whole of the pharmacy professional workforce, regardless of where they work. This public consultation offers an opportunity for registered pharmacy professionals who feel they will not be covered under either Order to raise their concerns.

35. The pharmacy in my hospital is a registered pharmacy. Which defences can be used by pharmacy professionals in this instance?

Generally hospital pharmacies in England, Scotland and Wales are not registered with the General Pharmaceutical Council, although some are. The position in Northern Ireland is different with 10 out of the 17 Trust pharmacies being registered with the Pharmaceutical Society of Northern Ireland. However, what follows applies equally throughout the United Kingdom.

The intention is that, in due course, virtually all pharmacy services, both from registered pharmacies and non-registered, will be covered by one of the two Orders. In the interim, we recognise that there will be cases of uncertainty about whether a dispensing error that has occurred in the course of non-retail dispensing at a registered hospital pharmacy can benefit from the defences. Arguably, the defences are only engaged if the sale or supply is in the course of the carrying on of a retail pharmacy business (see for example section 67C(4)(c) and (6)(c)). Because our intention has always been to address the issue of hospital pharmacies, we decided it was better to live with this uncertainty than to address the issue head on and add another level of complexity to the first version of the defences. However, the whole point is that we are seeking to move away from prosecution for inadvertent preparation and dispensing errors, so if the first version of the defences already covers some non-retail dispensing in hospitals, that is not in itself a concern because of all the other elements to the defences.

36. Are pharmacy professionals operating in GP practices covered by the proposed defences?

The draft Order does not in practice address dispensing doctors, as GP practice dispensaries are unlikely to have the sort of governance arrangements that the draft Order contemplates, i.e. the pharmacy service being a separate entity under the direction of a Chief Pharmacist and being separately registered with or inspected by the relevant authorities. Medication errors by doctors and nurses is however a matter that is under (the Professor Sir Norman Williams Review in England).

It also does not address regulated or unregulated professionals operating in non-pharmacy retail premises, for example herbalists or retail outlets selling medicines, such as shops and garages.

37. Is the dispensing of a medicine for named patients taking place on a ward, regardless of whether the hospital's pharmacy is registered or not, covered by this draft Order?

Yes. The proposal is for the draft Order to cover the "relevant pharmacy services" – i.e. all pharmacy services provided in a hospital. This is to take account of the full range of services that may be provided in hospitals, as regards the sale and supply of medicines.

It is recognised that arrangements for the supply of medicines to patients by a hospital pharmacy or other pharmacy service is generally made on the direction of a prescriber, and so for example in the case of NHS in-patient supply, the offence in section 64 of the Medicines Act 1968 is not generally engaged (because it only applies to sales and supplies in pursuance of a prescription), whereas the offence in section 63 applies to any supply.

38. This draft Order provides pharmacy technicians with a defence. Have you enabled supervision of medicine sales and supply by pharmacy technicians?

No. Only pharmacists can supervise the sale and supply of prescription only medicines (POMs) and pharmacy (P) medicines, under Regulation 220 of the Human Medicines Regulations 2012. This has not changed and any proposals to do so will be publicly consulted on.

Currently, pharmacy technicians are not legally able to supervise the sale and supply of prescription only medicines (POMs) and pharmacy (P) medicines. If they attempted to do so, they would not be "acting in the course of their profession" so the defences would not apply.

39. Why do pharmacy technicians in Northern Ireland not benefit from these defences?

Pharmacy technicians in Northern Ireland do not benefit from the defences being extended by this draft Order because they are not subject to professional regulation. Pharmacy technicians do not have to be registered in Northern Ireland.

40. CQC has recently published a report that highlights patient safety concerns in independent acute hospitals. How will this draft Order contribute to remedying the issue?

The extended defences will be available to registered pharmacy professionals working in independent hospitals, and in order to avail themselves of the defences they will have to

demonstrate that where an error occurs they were acting in the course of their profession and meet the other conditions of the defences. A key requirement of the defence is that a hospital or other pharmacy service will have a Chief Pharmacist, who is responsible for the ensuring the safe and effective running of the pharmacy service. This provides public reassurance that there is a governance framework in place for ensuring that medicines are being safely prepared and dispensed.

Registered pharmacy professionals, working in either the public or private sector, should be open and honest with patients when things go wrong, and candour is an essential duty for all healthcare professionals. The proposed draft Order is expected to remove the fear of prosecution and encourage improved reporting and learning from errors. This learning will improve patient safety, and reduce the risk of errors occurring in the future.

The Draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacist etc.) Order 2018

41. What is a Responsible Pharmacist (RP)?

A RP is appointed by the pharmacy owner. S/he is a registered pharmacist, in charge of the registered pharmacy on a given day for the safe and effective running of the registered pharmacy for the sale and supply of all medicines when it is operational. A pharmacy cannot operate without one. A responsible pharmacist cannot be responsible for more than one pharmacy premises at any one time.

For a pharmacy business carried on by a body corporate, the RP must be the superintendent pharmacist (SP) or a pharmacist subject to the directions of the SP.

42. What is a Superintendent Pharmacists (SP)?

The SP is intended to be the professional lead within a body corporate and responsible for the safe and effective running of all pharmacy premises under its control. At present the law does not elaborate on the SP's roles and responsibilities.

43. Why are you introducing these changes in legislation?

The overarching approach is for the role and responsibilities of the RP and SP to be defined in primary legislation and for professional regulation/standards to define how that role and those responsibilities are to be fulfilled. The key aims of this are to rebalance:

- criminal law and professional regulation, so that matters within the ambit of the pharmacy regulators, the GPhC and the PSNI, are dealt with by them and by registration sanctions, rather than by the criminal courts;
- Ministerial powers and the powers of the pharmacy regulators, so that pharmacy practice matters are more appropriately set by pharmacy regulators and less by government Ministers;
- Legislation and standards, so that pharmacy practice standards are set and enforced by pharmacy regulators and less by inflexible legislation. Underpinning this is an "outcomes"-based approach: i.e. the safe and effective practice of pharmacy should be the required outcome rather than binding the pharmacy professions to particular ways of doing things; and
- the relationship between pharmacy owners, RPs and SPs to ensure safe and effective practice of pharmacy in a retail pharmacy context, making clear the accountability of:
  - the RP, who is in charge of a particular pharmacy on a given day;
  - the SP, who is intended to be the professional lead within a company; and
  - the pharmacy owner.

If standards set by the pharmacy regulators are not met, the regulators can take action such as fitness to practise proceedings and/or registration sanctions.

44. Does the draft Order apply to the whole UK?

This draft Order extends to England, Scotland, Wales and Northern Ireland.

45. What does the draft Order change in relation to SPs?

The Order

- Clarifies that the SP should be a senior manager with the authority to make decisions that affect the running of the whole retail pharmacy business (which may only be one part of a bigger retail business);
- Removes the requirement for the SP to be a member of the body corporate's board, where this is currently required;
- Sets out a general duty for the SP to secure the safe and effective running of the retail pharmacy business – making clear the SP is always responsible, even when retail premises are not open;
- Removes the restriction that states that an SP can only be an SP for one retail pharmacy business; and
- Empowers the pharmacy regulators to set regulatory standards for SPs, which extend beyond the sale and supply of medicines (POMs, Ps and general sale list (GSL)) to other pharmacy services, if they decide to describe their role in these terms.

46. What does the draft Order change in relation to RPs?

The Order

- Retains the requirement for an RP to be in charge of each pharmacy, with the current statutory duty to ensure the safe and effective running of the particular pharmacy, but only when the RP is actually designated the RP role for that pharmacy and the pharmacy is either open to the public for business or handling, assembling, preparing or dispensing medicines with a view to their sale or supply to the public;
- Clarifies that an RP's duty extends to a pharmacy business 'at or from' the premises for which the RP is in charge e.g. home deliveries;
- Retains the general rule that a pharmacist can only be the RP for one pharmacy at the same time, with the power to specify an exception transferred to pharmacy regulators;
- Continues the current position that GSL medicines can be sold when the RP is absent from the premises;
- Removes from legislation the duty for an RP to establish, maintain and keep procedures under review;
- Removes from legislation the record keeping duties in respect of the RP in charge of a pharmacy;
- Transfers, from Ministers to the pharmacy regulators, general powers to set out the detailed requirements/statutory responsibilities of the RP in rules/regulations , e.g. record-keeping in respect to the RP, qualification and experience of RPs; and
- Empowers the pharmacy regulators to set regulatory standards for RPs, and describe the RPs' professional responsibilities.

47. Why does the draft Order refer to "retail pharmacies" rather than "community pharmacies"?

The draft Order refers to the "retail pharmacy business" rather than "community pharmacies" as this is the phraseology already utilised in the relevant legislation – e.g. section 70 and 71 of the Medicines Act 1968.

48. The SP is defined as being responsible for the running of retail sale, as concerns medicines. What about pharmacy services?

This draft Order affords greater powers to the pharmacy regulators, allowing them to set regulatory standards for SPs and to describe their professional responsibilities. It will be

for the pharmacy regulators, in describing the role of the SP, to clarify their professional responsibilities beyond the sale and supply of medicines from the retail pharmacy business, and to say what that role is in respect of other services – such as clinical and public health services.

49. Why does this draft Order make it possible for a person to be SP for more than one large pharmacy business?

This draft Order removes the restriction on SPs only being able to hold the role for one pharmacy business at a time. This is because, for example, an SP of a body corporate with multiple branches may be the SP for hundreds or even thousands of pharmacies, but if a small independent takes over another small independent, the businesses will have to merge into a single corporate body if one person is to be the SP for both (a merger which may be disadvantageous for other reasons).

Similarly, there are examples in existing large multiples where a single corporate body has two or more retail pharmacy businesses and thus two or more SPs. As it becomes clearer that being an SP cannot simply be a nominal role, it may be a challenge in particular for some smaller companies to fill the role or for some smaller company groups to fill the role by multiple individuals, so there needs to be greater flexibility in the system. SP's have a statutory duty in respect of the safe and effective running of the retail pharmacy business. It is therefore for the SP to ensure this is occurring, regardless of the number of pharmacies they manage.

50. By referring to an SP as a "senior manager" this is likely to give them lower standing within the body corporate than the role requires?

The term "senior manager" is one the draft Order uses due to the phrase's connotations with previously defined law – specifically criminal law around corporate manslaughter. The phrase "senior manager" does not necessarily need to be used in common parlance.

The statutory duties of the SP role ensure that an SP must have sufficient seniority within the retail pharmacy business and authority to make decisions that affect the running of the pharmacy service.

51. Why are you removing the requirement for an SP to be the member of the body corporate's Board if the body corporate wants to use the title of chemist?

The requirement for an SP to be on the Board of a body corporate, if the body corporate wants to use the title of chemist, does not necessarily ensure the SP is of appropriate seniority and has sufficient authority to make decisions in respect to the retail pharmacy business. It is therefore proposed that this requirement is removed. The removal of this requirement does not however mean an SP is restricted from being a member of the Board, if that is decided to be appropriate.

52. What safeguards are there regarding the extra powers being afforded to the pharmacy regulators by this draft Order?

The pharmacy regulators must consult on the proposed rules/regulations, offering the opportunity for scrutiny and comment.

It is proposed that before making rules under the new powers (section 72A), the GPhC must publish draft rules and invite representations from Ministers and other appropriate

persons to consult on the draft rules. In Great Britain, the resultant rules cannot enter into force until approved by the Privy Council and will then be subject to the "negative resolution" scrutiny procedure in the UK Parliament. Separately, any regulations made under section 72A by the PSNI would require consultation of appropriate persons and consultation of and approval by the Department of Health in Northern Ireland.

53. This draft Order allows General Sale List medicines to be dispensed without a Responsible Pharmacist being present?

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 already provides for General Sale List medicines to be dispensed without an RP being present in the pharmacy. It is merely the aim of this draft Order to ensure that this requirement is clear on the face of legislation, therefore ensuring the requirements on pharmacies in respect of GSL medicines are in keeping with those of other retail outlets, which do not require a pharmacist.

54. Why has the Government consulted on changing the structure of healthcare professional regulation (including the regulation of pharmacy professionals) at a time when this draft Order is putting increased reliance on professional regulation?

The UK's model of professional regulation for healthcare professionals has become increasingly complex and outdated. It needs to change to protect patients better, to support our health services and to help the workforce meet future challenges. Government is committed to a flexible model of professional regulation which secures public trust, fosters professionalism and improved clinical practice, while also being able to adapt swiftly to future developments in health care. This needs to be complemented by a culture that enables professionals to learn from their experiences, including from their mistakes

The changes this draft Order makes are fully in line with the Government's proposals on professional regulation.

55. This draft Order is paving the way for supervision of the preparation, sale and supply of prescription only medicines by non-pharmacists?

This is not the case. The Government has no proposals in relation to supervision, and any proposals would be subject to a full public consultation and Ministerial approval.

56. Why are you extending the requirement for a Superintendent Pharmacist to inform their pharmacy regulator when they stop holding that role for a particular pharmacy business?

At the moment, SPs in Great Britain must inform the GPhC when they stop being the SP for a particular pharmacy business. It is proposed to extend this requirement to SPs in Northern Ireland to inform their regulator, the PSNI, in order to promote parity across the UK.

57. Why are you proposing there be a deputy registrar in Northern Ireland?

Currently there is a registrar in Northern Ireland who holds and maintains the professional registers in relation to pharmacy in the country, as provided for in the Pharmacy (Northern Ireland) Order 1976. The Department of Health in Northern Ireland appoints this registrar, and it is proposed that a further power for the Department to appoint a deputy registrar is introduced. This is to enhance public safety by ensuring that

important functions can be performed in the absence of the registrar and bring legislation in line with the rest of the United Kingdom (as already set out in the Pharmacy Order 2010).