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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

June 2018

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Executive summary

- This UK-wide consultation, issued on behalf of the four UK Health Departments, seeks comments and views on two pharmacy-related draft Orders being made under the powers in section 60 of the Health Act 1999. 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 11 September 2018 and we are consulting on both draft Orders:

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

- The first draft 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 The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018, which came into force on 16 April 2018, and ensures that these professionals 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 dispensing errors, incentivising an increase in the reporting of dispensing 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, such as shops and garages.

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

- The second draft Order relates to the organisational governance arrangements for registered 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 SP and RP 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 an organisational and a professional standpoint.

- 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 – the appointment of a deputy registrar and a notification obligation of SPs.

Policy background

1. The Health Departments in England, Scotland, Wales and Northern Ireland are committed to delivering a modern approach to healthcare regulation, which promotes patient safety whilst supporting health professionals and the development of quality systems. In line with this, and with broader developments in the delivery of healthcare, the opportunity has been taken to examine the different systems underpinning the regulation of pharmacy.

2. Pharmacy practice is governed by medicines and pharmacy legislation and professional standards. In addition, National Health Service (NHS) and Health and Social Care Northern Ireland (HSC) legislation governs the provision of NHS and HSC pharmaceutical services.

Broader policy developments

3. The UK Government's Red Tape Challenge on medicines included consideration of the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 ("the RP Regulations")[i]. Those Regulations were also subject to an evaluation commissioned by the Royal Pharmaceutical Society and the Pharmacy Forum of the Pharmaceutical Society of Northern Ireland (PFPSNI) in 2011[ii]. In the course of reviewing the outcome from both initiatives, it became clear that there was a need to examine the broader landscape of arrangements for pharmacy governance in the round, rather than simply dealing with aspects in isolation. Additionally there is a need to take account of the activities being undertaken by others, including:
   - the pharmacy regulators' work programme, which includes registered pharmacy standards, inspection and new enforcement mechanisms;
   - work by the professional bodies on professionalism, professional leadership, quality systems and culture;
   - changes to NHS and HSC regulation;
   - work in relation to the Francis Inquiry report[iii], "Trusted to Care" (Wales)[iv], the Quality 2020 strategy (Northern Ireland)[v] and the Healthcare Quality Strategy for NHS Scotland[vi];
   - Scotland's "Achieving Excellence In Pharmaceutical Care"[vii];
   - the NHS Five Year Forward View[viii]; and
   - reform of professional regulation of healthcare professionals

4. Our aim is to ensure that legislative and regulatory arrangements support progress and developments in pharmacy practice whilst protecting, promoting and improving people's health through the safe management and use of medicines.

Policy, legislative framework and regulation

5. The main domestic legislation for medicines in the UK is the Human Medicines Regulations 2012[ix]. Certain elements of the Medicines Act 1968[x] that pertain to medicines supply and pharmacy regulation have been retained, although the Act was largely repealed by the 2012 Regulations.

6. The UK Health Departments are responsible for setting the overarching policy, whilst the role of the pharmacy regulators – the General Pharmaceutical Council (GPhC) and Pharmaceutical Society of Northern Ireland (PSNI) - is to safeguard the public and those who use or need the services of pharmacy professionals or registered pharmacies. To achieve this, the pharmacy regulators have legal functions and powers to set and require compliance with standards and to take action when these standards are not met.

Policy development

7. The Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board (RPB), chaired by Ken Jarrold CBE, was established to consider and review the legislation and regulation associated with pharmacy and to advise UK Ministers on policy. The RPB is tasked with examining the respective scope of legislation and regulation, and the interface between them, with a view to ensuring these are optimally designed to provide safety for users of pharmacy services, whilst facilitating and reducing the barriers to the responsible development of practice, innovation and a systematic approach to quality in pharmacy[xi].

8. Further information on the RPB can be accessed on the gov.uk website using this link: https://www.gov.uk/government/groups/pharmacy-regulation-programme-board. The programme addresses a number of key issues, set out in more detail below. This consultation is concerned with proposals relating to preparation and dispensing errors by registered pharmacy professionals working for hospitals and other pharmacy services – and proposals relating to pharmacy owners, superintendent pharmacists and responsible pharmacists.

   (a) **Registered Pharmacy Standards and Related Matters:** The Pharmacy (Premises Standards, Information Obligations etc.) Order 2016 comes into force in relation to Great Britain on 24 May 2018. The Order enables the GPhC to implement work related to registered pharmacy standards and changes to inspections, inspection reports and enforcement. Similar changes will apply in respect of Northern Ireland in the future.

   (b) **Preparation and Dispensing Errors - Registered Pharmacies:** A review of the criminal offences in sections 63 and 64 of the Medicines Act 1968 in relation to regulated pharmacy professionals operating from regulated pharmacy premises was undertaken. The review recommended the provision of a defence to sections 63 and 64 of the Medicines Act 1968 for inadvertent dispensing errors made in registered pharmacies, subject to the meeting of certain conditions. The section 60 Order entitled “The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018” sets out the provisions for these changes. The Order was approved by Parliament in December 2017 and came into effect on 16 April 2018.

   (c) **Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services:** A review of the legislative and regulatory arrangements for preparation and dispensing errors in hospitals and other pharmacy

services was undertaken. The review recommended the provision of a defence for inadvertent preparation and dispensing errors in such locations. These proposals are similar to, but separate from, those in the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 for registered pharmacies, as the provision of medicines to patients in hospitals and other settings with different oversight arrangements, such as care homes and prisons, largely does not require registration of pharmacy premises – although all of these pharmacy professionals are subject to professional regulation.

(d) **Pharmacy Owners, Superintendent Pharmacists and Responsible Pharmacists:** A review of the system which supports patient safety, in particular the role of pharmacy owners, SPs and RPs. The proposals aim to strengthen the organisational governance of registered pharmacies, and in particular provide greater clarity on the roles, responsibility and accountability for RPs and SPs.

(e) **The Supervision of the Preparation, Sale and Supply of Medicines:** The RPB's remit is "to address in parallel medicines and professional regulatory matters (e.g. supervision), which are considered to restrict full use of the skills of registered pharmacists and registered pharmacy technicians, impede the deployment of modern technologies and put disproportionate or unnecessary obstacles in the way of new models of service delivery by and/or involving pharmacy". No firm proposals have been agreed by the RPB and further stakeholder engagement is anticipated in due course.

Legislative process

9. These 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 means the two draft 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, a further "Commencement Order" will be drafted for each of the initial Orders, to enact the new provisions in the four nations.

10. There are also 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 health 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.

11. 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.

12. The draft Orders are only required to be laid 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.

Part 1: Extension of the preparation and dispensing error defences to pharmacy professionals working in hospitals or other pharmacy services

Background

13. The sale and supply of medicines is governed by the Medicines Act 1968 and the Human Medicines Regulations 2012, as well as a number of pharmacy specific matters being covered in the Pharmacy Order 2010[xii] and the Pharmacy (Northern Ireland) Order 1976[xiii].

14. The Medicines Act 1968 contains "strict liability" consumer protection offences concerning the sale and supply of medicines. Section 63 covers the adulteration of medicinal products, for example, an error by a pharmacy professional in preparing or "making-up" a medicine for a patient. Section 64 covers the sale of any medicinal product, or supply against a prescription, which is "not of the nature or quality demanded by the purchaser".

15. The proposals subject to this consultation are similar to, but separate from, those in the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 ("the Registered Pharmacies Order"), which was approved in Parliament in December 2017 and came into force on 16 April 2018. The Registered Pharmacies Order introduces defences for the offences in section 63 and 64 of the Medicines Act 1968 for inadvertent preparation and dispensing errors made by registered pharmacy professionals working at or from registered pharmacies, subject to certain conditions.

16. The proposed draft Order, published alongside this document, seeks to amend the Medicines Act 1968 to extend the defences to pharmacy professionals working in hospital pharmacy services (regardless of whether or not the activity is undertaken at or from a registered pharmacy), or indeed a unregistered pharmacy, and in other relevant pharmacy services.

17. The approach being taken in relation to this draft Order aligns with initiatives by the Secretary of State for Health and Social Care and Chief Pharmaceutical Officer for England to both reduce medication errors and build a culture of learning and safety across the NHS. The draft Order also follows recommendations/conclusions of the Healthcare Quality Strategy (and subsequent healthcare strategies) for NHS Scotland, "Trusted to Care" (Wales), the Quality 2020 strategy (Northern Ireland) and a review of hospital pharmacy governance arrangements undertaken by an RPB Expert Advisory Group[xiv].

What is a dispensing error?

18. There is no universal definition of a dispensing error. For this consultation, a dispensing error is viewed as an error which has been made at any point during the dispensing process from receipt of the prescription, or a decision to

dispense in accordance with a direction, through to the supply of the medicine, where the error means that the patient actually receives a medicine (referred to as a "product" in legislation) that they should not.

19. Errors can include but are not limited to:
    - the wrong medicine being dispensed;
    - a medicine intended for another patient being dispensed to the wrong patient;
    - an ingredient being 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.

Why is Government intervention required?

20. Throughout the United Kingdom, we estimate that there are around 52 million items supplied a year in secondary care. Whilst the number of dispensing errors in UK hospital pharmacy services is relatively small, it is estimated that around 523,000 dispensing errors occur each year, but only 5% of these errors (26,132) are reported. A number of factors are likely to contribute to this under-reporting, but it is estimated that one of the leading causes is the fear of prosecution.

21. Breaches of sections 63 and 64 of the Medicines Act 1968 are what are known as "strict liability" offences, notwithstanding that they are already subject to limited defences in sections 64(3) and (4), 121 and 122 of the Medicines Act 1968. This means that the prosecution does not have to prove a "mental element" – intention, recklessness or negligence – on the part of the defendant for the prosecution to succeed. This in turn means that prosecutions are relatively straightforward to bring, resulting in a "fear factor" amongst pharmacy professionals, who are reluctant to admit errors as it may mean that they will face prosecution. In fact, prosecutions have to date been rare and have largely only been brought in the most serious cases, for example, where the error has resulted in death.

22. Despite the relative rarity of prosecutions, the evidence demonstrates that the "fear factor" persists. The fundamental premise on which this draft Order and the related Registered Pharmacies Order is based is that reduction in the risk of prosecution will increase the number of reported errors. Over time, learning from increased numbers of error reports should lead to improvements in training and practices, which should reduce the number of errors made. The consultation responses to the Registered Pharmacies Order have confirmed that this logic (i.e. a virtuous cycle of reporting, learning and improving) and the assumptions underlying it are reasonable.

23. The *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry*, chaired by Robert Francis QC (February 2013), highlighted the importance of putting patient safety at the heart of everything we do and taught us about the importance of achieving a careful balance between assuring accountability to

the patient and developing a culture of openness and transparency such that we learn from errors, improving practice and safety. The government commissioned six independent reviews to consider some of the key issues identified by the Inquiry, including one by the National Advisory Group on the Safety of Patients in England, chaired by Professor Don Berwick, to provide advice on next steps toward a better and safer NHS[xv]. The National Advisory Group's report, the "Berwick Report", entitled *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England*, was published in August 2013[xvi]. Professor Berwick stated in the report that "the most important single change in the NHS, in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care".

Criminal Sanctions - Sections 63 and 64 of the Medicines Act 1968

24. The consultation and Parliamentary debates on the Registered Pharmacies Order raised the question of whether the offences of contravening section 63 or 64 of the Medicines Act 1968 should be removed altogether. The Government has been clear that it is not de-criminalising the offence, and that the offences are retained because they apply to all sales or supplies on prescription, not just to those by 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 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. Such errors will continue to be subject to the offences under the Medicines Act 1968. All errors remain potentially the subject of sanctions from the pharmacy regulators, such as fitness to practise investigations, and general criminal law.

Proposals to provide defences to section 63 and 64 offences

25. The proposal is to extend the defences to the criminal offences in section 63 and 64 of the Medicines Act 1968, as provided by the Registered Pharmacies Order, to registered pharmacy professionals working in hospitals or other relevant pharmacy services against prosecution for inadvertent preparation and dispensing errors, subject to certain conditions. The proposals take account of the different governance and registration arrangements that may apply across the regulated and NHS/HSC governed healthcare activities that exist in the four home countries, compared to those seen in community pharmacy. The proposals do not cover errors made where medicines are supplied as part of licenced manufacturing activity wherever based, for example in aseptic preparation units, which will still be subject to the offences outlined in section 63 and 64 of the Medicines Act 1968.

Scope of defences

26. The draft Order, published alongside this document, amends the new defences created in sections 67A to 67D of the Medicines Act 1968, by the Registered Pharmacies Order, to apply them where an error occurs in the course of the provision of a "relevant pharmacy service". Article 8 of the draft Order defines

"relevant pharmacy service" and the associated conditions that must be met. It is proposed that a "relevant pharmacy service" includes services in the course of the business of a hospital, including clinic, nursing home or similar institutions; services and institutions where people are lawfully detained, for example prison, youth detention, mental health and immigration/asylum; and other services/activities subject to regulation i.e. by the Care Quality Commission (CQC), and equivalents across the UK. These services are explored further below.

Hospitals

27. There is no generally recognised definition of what constitutes a "hospital". It is proposed to use the definition of "hospital" from the Human Medicines Regulations 2012 –"hospital" includes a clinic, nursing home or similar institution. Generally, expressions used in the Medicines Act 1968 and the Human Medicines Regulations 2012 bear the same meaning by virtue of section 132 (general interpretation) of the Medicines Act 1968. For England, however, reference to the CQC is sufficient to cover hospital pharmacy services because all the relevant pharmacy services are covered by CQC registration in some way – so English hospitals are not separately referred to in the legislation. Hospital pharmacy services do not necessarily operate at premises that are recognisably "pharmacies" and reference is therefore made to pharmacy services of a hospital within the new condition. Thus, in the case of hospitals, the defence covers preparation and dispensing errors made by pharmacy professionals that occur within the pharmacy department or elsewhere in the hospital in the course of providing medicines in accordance with the directions of a prescriber.

Part 1 – Question 1:
Do you agree with the approach to provide a defence for registered pharmacy professionals working in a hospital pharmacy, similar to that implemented for registered pharmacies (predominately community pharmacy)?

Part 1 – Question 2:
Do you agree that in the case of hospital pharmacy services, this should be extended to include dispensing errors by registered pharmacy professionals which are made anywhere as part of a hospital pharmacy service, and so including elsewhere in the hospital, for example on a ward or in a hospital facility that does not have a recognisable pharmacy but supplies dispensed medicines in accordance with the directions of a prescriber?

Other relevant pharmacy services

28. It is proposed to extend the preparation and dispensing errors defences beyond hospital pharmacy services to include other relevant pharmacy services. Broadly, the defences will extend to:
    (a) accommodation used for the purposes of restricting the liberty of any person, i.e. a prison or youth detention accommodation, or those detained under mental health provisions or immigration and asylum legislation;
    (b) an activity in respect of which a legal person (e.g. a company) is registered with the CQC;

(c) independent health services registered with Healthcare Improvement Scotland under section 10P of the NHS (Scotland) Act 1978 and other care services registered under Chapter 3 of Part 5 of the Public Services Reform (Scotland) Act 2010 (e.g. in care homes);
(d) a legal person (e.g. a company) registered with Healthcare Inspectorate Wales; and
(e) a service in respect of which a legal person (e.g. a company) is registered by the Health and Social Care Regulation and Quality Improvement Authority in Northern Ireland.

Part 1 – Question 3:
Do you agree in principle with the proposal to extend the defences for registered pharmacy professionals making an inadvertent dispensing error to include other relevant pharmacy services?

Part 1 – Question 4:
Are there any other pharmacy services that you feel should be included within the scope of the new defences as specified in article 8 of the draft Order, i.e. that are not mentioned in the consultation document, and meet the criteria?

Governance of the hospital and other relevant pharmacy services

29. In developing the proposals for a defence to preparation and dispensing errors contained in the Registered Pharmacies Order, consideration was given to the system governance arrangements for registered pharmacies. Generally, pharmacies are required to be registered with one of the pharmacy regulators – the GPhC or the PSNI. This provides a consistent approach to system governance across the UK, which can be incorporated as a condition in the preparation and dispensing error defences for registered pharmacies, and in turn provides further public reassurance for the introduction of the defences.

30. Hospital pharmacies, however, do not routinely need to be registered with one of the pharmacy regulators. In addition, there is no uniform system of governance or registration and inspection regimes across the four UK countries in respect to health care. As the Medicines Act 1968 applies across the UK, any requirement that relies on governance would have to be capable of being applied in the various regimes.

31. As these proposals concern criminal law, it is essential that the system governance element of the defence is clearly understood. After significant consideration, including by the RPB of which membership includes the Chief Pharmaceutical Officers of the four home nations, it is proposed to include as part of the necessary system governance the role of a “Chief Pharmacist”, who is to be the person who is responsible for the safe and effective running of the pharmacy service.

32. The role that the Chief Pharmacist must have in the pharmacy service builds on existing concepts in general law and used in other areas of legislation. The proposed Chief Pharmacist should be a “senior manager” with “authority to make decisions that affect the running of the pharmacy service”. This reflects

the approach being taken for Superintendent Pharmacists, which will be detailed in Part 2 of this consultation. It should be noted that the statutory Chief Pharmacist role is specific to pharmacy services and they do not need to be a senior manager of the organisation as a whole – e.g. of the prison – although in some contexts they might well be.

33. If a pharmacy service that potentially is covered by the extension of the defences does not in fact have a Chief Pharmacist, registered pharmacy professionals working for that service will not benefit from the extension of the defences. Therefore, although having someone performing the role of Chief Pharmacist isn't mandatory for any broader purposes; there is a significant incentive for pharmacy services to have someone in that role – and to have the governance arrangements that go along with it.

34. In summary, it is proposed that the Chief Pharmacist should –
    (a) be a registered pharmacist;
    (b) play a significant role in the making of decisions about how all or a substantial part of the pharmacy services' activities is to be managed or organised; or alternatively manage or organise the whole or a substantial part of those activities; and
    (c) have authority to make decisions that affect the running of the pharmacy service so far as concerns the sale or supply of medicines and be responsible for securing the safe and effective running of the pharmacy service.

35. It is also proposed to enable the pharmacy regulators to set professional standards for Chief Pharmacists, including a description of their professional responsibilities. This is similar to the Superintendent Pharmacist proposals in Part 2 of this consultation, to give powers to the pharmacy regulators to set professional standards and professional responsibilities for SPs.

Part 1 – Question 5:
Do you agree with the proposals that a pharmacy service that potentially benefits from the extended defences must have a Chief Pharmacist in order to rely on the extended defences?

Part 1 – Question 6:
Do you agree that the pharmacy regulators should be enabled to set standards in respect of pharmacists who are Chief Pharmacists (or who are designated the responsibilities of a Chief Pharmacist), including a description of the professional responsibilities of a Chief Pharmacist?

Conditions of the defences

36. This draft Order amends the conditions for the preparation and dispensing error defences which were introduced by the Registered Pharmacies Order. There are differences between the defences for sections 63 and 64, essentially because the offences in section 64 only apply to sales and supplies in pursuance of a prescription, and the scope of the defences necessarily matches the scope of the offences to which they relate.

A summary of the conditions required to be met in order to rely on the proposed extended defences is provided below:

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
3. The registrant was acting in course of their profession*
4. 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 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 pharmacy service is overseen by a "Chief Pharmacist"

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

Part 1 – Question 7:
Do you agree that the conditions of the defences for pharmacy professionals working in hospitals and other pharmacy services should broadly align with those required to be met by pharmacy professionals working in registered pharmacies?

First condition - The person who dispensed the product was a registrant, or was acting under the supervision of a registrant

37. The first condition of the defences is that the person who dispensed the medicine was either a registrant or being supervised by a registrant. The defences therefore potentially apply to a wide range of pharmacy personnel, including pharmacy assistants, students and pre-registration trainees. This applies the same condition of the defence put in place for registered pharmacy professionals working at or from registered pharmacies (new section 67A (2)(b), 67B (2)(b) and 67C (2)(b) of the Medicines Act 1968, inserted by the Registered Pharmacies Order). These proposals do not in themselves change the existing position in medicines legislation as to who may or may not "supervise" the preparing, assembling, dispensing, sale or supply of pharmacy or prescription only medicines. However, as indicated above, "supervision" is being looked at as part of a separate strand of work by the RPB but no firm proposals have been agreed and further stakeholder engagement is anticipated in due course.

Second condition - The medicine must be supplied in the course of the provision of a relevant pharmacy service

38. The pharmacy services that potentially benefit from the defences are discussed above in relation to questions 1, 2, 3 and 4.

Third condition - The registrant was "acting in the course of their profession"

39. Again, this aligns with the conditions inserted under the Registered Pharmacies Order. The new section 67D places an "evidential burden" on the defendant. This means the defendant (who may or may not be the registrant) must provide sufficient evidence to show that the registrant was "acting in the course of his or her profession" if they want to rely on the new defence. If the defendant discharges this "evidential burden", the burden of proof then shifts to the prosecution. To secure a conviction, the prosecution then has to prove beyond a reasonable doubt that the registrant was not "acting in the course of his or her profession".

Illustrative ground

40. Whilst it is not intended to be overly prescriptive, the new section 67D (inserted by the Registered Pharmacy Order) includes illustrative grounds that the prosecution might wish to rely on to demonstrate that the registrant was not "acting in the course of his or her profession".

41. The first of these illustrative grounds relates to the registrant "*using his or her professional skills for an improper purpose*". This ground might be used where a product is dispensed for improper and unprofessional reasons, for example relating to drug addiction.

42. The second illustrative ground relates to where the registrant "*deliberately failed to have due regard for patient safety*" whilst acting in the course of their profession. As with the first illustrative ground, this addresses the possibility that a registrant could be carrying out an "authorised activity" in what might be considered an "unauthorised mode". So, the registered pharmacist could be dispensing medicines (an authorised activity) but showing a deliberate disregard of patient safety, for example by deciding, because they were in a hurry, to ignore a clear dosage error that has been drawn to their attention (unauthorised mode). In cases of such fundamental failure to act professionally, we want it to be clear that the defences cannot be relied upon.

43. However, new section 67D(4) provides that where a registrant 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 the registrant is not acting in the course of his or her profession. This reflects the importance of professional autonomy as a key component of professional practice, linking in with professional accountability and professional judgement.

44. For example, a pharmacy may have a SOP that says that all supplies must be dispensed in accordance with prescriptions presented. A registrant may, for good reason, need to exercise their professional judgement to override what has been written on the prescription/direction by a prescriber. In such cases, the registrant, acting properly, may intentionally dispense in pursuance of a prescription in a manner that is not in accordance with the prescription, but nevertheless is appropriate to the specific patient in the circumstances.

Medicines legislation makes allowance for this and we are not proposing to make any changes which could have the effect of restricting the exercise of professional judgement in the interests of the patient.

Fourth condition - The medicine was dispensed in pursuance of a prescription/directions or under the recognised arrangements for emergency supply without a prescription/directions

45. The fourth condition is that the medicine is in fact a dispensed medicine. It is recognised that arrangements for the supply of medicines to patients by a hospital pharmacy or other relevant 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 is not generally engaged (because it only applies to sales and supplies in pursuance of a prescription) even though the offence in section 63 is (because it applies to any supply).

Fifth condition - 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

and

Sixth condition - The patient was promptly notified of the error, unless considered unnecessary

46. These two conditions are essentially unchanged from how they apply in a community pharmacy setting, although the concept of a “pharmacy owner” may not be relevant in quite the same way when it comes to the potential role of an “appropriate person”. These important provisions nevertheless should be reiterated in some detail. The sixth condition requires, in essence, 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. In many cases, it will be someone other than the dispenser who discovers a dispensing error, including the patient themself. So, it is only in some cases that the issue of notifying the patient of an error will arise.

47. As is already the case for errors in registered pharmacies, it is not proposed to provide a definition of “promptly”, to recognise that the circumstances of each case have to be examined on their own merits. In recognition of the difficulty in deciding whether or not a patient needed to be notified or action was taken promptly, there is what is known as an “evidential burden” on the defendant to demonstrate that the action taken might have been prompt. If there is sufficient evidence that it might have been prompt, the onus is then on the prosecution to prove that the notification was not “prompt” - beyond reasonable doubt - if the prosecution are to secure a conviction (new section 67D(6) inserted by the Registered Pharmacies Order).

48. To rely on the defence, a notification must be by an “appropriate person”, and the legislation identifies any of the following as people who could discharge this responsibility (new section 67B(6) and 67C(6)):

(a) the person who dispensed the product;
(b) the supervising registrant, if the product was dispensed under the supervision of a registrant rather than by a registrant;
(c) the person carrying on the pharmacy business or relevant pharmacy service; or
(d) a person acting on behalf of the person carrying on the relevant pharmacy service – which could be anyone with authority to act on that person's behalf.

49. Whereas it will always be obvious who is carrying on a retail pharmacy business, because they will be the person identified as the owner in the premises registers held by the GPhC and PSNI, it may be less obvious in the case of a relevant pharmacy service. However, who is carrying on the business will essentially be a question of fact, and the service provider should be easy to establish in the great majority of cases – i.e. it will generally be whoever is employing the Chief Pharmacist.

50. The combined result of the draft Order and Registered Pharmacies Order is that this recognises that both professional and corporate duties of candour are required once an error is discovered – and also that it is possible the error maker may not be the person who discovers the error. In some instances the error-maker may never find out about the error (for example, if they were a locum at the pharmacy just for the day), but another "appropriate person" could – e.g. someone else working in a hospital pharmacy –, and would then need to decide what action needed to be taken. It may also not always be appropriate or necessary to notify the patient. If an appropriate person reasonably forms the view that it is not necessary or appropriate to notify the patient in the particular circumstances of the case, the notification condition is met (section 67B(5)(a)(ii) and 67C(5)(a)(ii) inserted by the Registered Pharmacies Order).

51. For example, a registered pharmacist who, on notice of an error, might reasonably form the view that notification is not appropriate as a result of having regard to guidance on standards of conduct, ethics and practice of the relevant regulator (the GPhC or the PSNI) or other advice. These instances might include:
(a) the patient already knows of the error;
(b) the type of error is generally accepted to be too trivial to merit contact with a patient;
(c) where notification to the patient would do more harm than good (a patient with a nervous disposition, for example, might be better off hearing of the error from their named consultant or GP, and the registrant may have agreed this with the patient's named consultant or GP); or
(d) where another individual may be the most appropriate person to notify about the error, most obviously in the case of a young child or someone lacking mental capacity.

52. Not all "appropriate persons" can reasonably form the view that the patient does not need to be notified of a preparation or dispensing error. For example, a pharmacy student could not "reasonably" take such a view on their own account

– even if they made the error. They would need to refer the matter to the supervising registrant. In essence, the view has to be taken by someone who can reasonably be responsible for that decision not to notify, having regard to their professional or corporate duty of candour – or both.

53. If it is appropriate to notify the patient, the requirement is to take all reasonable steps to notify the patient – it is not necessary for the patient to have been located to rely on the defence. If all reasonable steps have been taken, but it has not proven to be possible to contact the patient – for example, they have become untraceable because they have gone abroad – the defendant can still rely on the defence.

54. Importantly, the notification provisions only apply once a responsible person becomes aware that there is a problem (sections 67B(5)(a) and 67C(5)(a) inserted by the Registered Pharmacies Order). Awareness, rather than suspicion, is required before notification of the patient necessarily has to be considered. This is because the professional and corporate obligations are subtly different in the case of suspicion of a problem and actually knowing about a problem (the immediate task, on suspecting that there is a problem, may be investigating that suspicion rather than contacting the patient) – and the intention is not to add a further level of complexity by attempting to deal with "suspicion" as well. Knowledge, one way or the other, is therefore the key to this part of the defences, and is the key to understanding its structure (sections 67B(3) to (5) and 67C(3) to (5) inserted by the Registered Pharmacies Order). Generally speaking, if, before the defendant is charged they did not know about the problem, the notification obligation is irrelevant.

55. There are, however, two important exceptions to this – one that applies to pharmacy owners/service providers and another which applies where a pharmacist has supervised someone other than a registered pharmacy technician dispensing a product.

56. Essentially, in both cases, the person who makes an error cannot rely on their ignorance of an error if the person supervising them or the pharmacy owner/service provider knows about the error but fails to discharge their duty of candour. That is, if any appropriate person knows of the error but does nothing about it, the 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. The policy behind this approach, which is inherited from the Registered Pharmacies 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.

57. Although "knowledge" is linked to the moment that a defendant is charged, to avoid defendants needing to do something after they have been contacted as part of a criminal investigation, defendants are deemed to be ignorant of things that they find out about as a result of a criminal investigation (section 67D(5) inserted by the Registered Pharmacies Order).

58. If the evidence of knowledge is contested – for example, if the pharmacist said something to a colleague that indicated that they suspected that the wrong product had been dispensed – then the pharmacist would have to show from the surrounding circumstances that their suspicion never became knowledge, for example, by showing that they had sought to confirm or refute their suspicion, but had not been able to do so before the police contacted them.

Seventh condition – The pharmacy service is overseen by a "Chief Pharmacist"

59. As outlined earlier in this document, it is proposed that a pharmacy service must have a "Chief Pharmacist", who is responsible for securing that the pharmacy service is carried on safely and effectively. This provides patients and the public assurance that there is someone in charge with responsibility for the safe and effective running of the pharmacy service. It is also proposed to enable the pharmacy regulators to set professional standards for the Chief Pharmacist role, including a description of their professional responsibilities.

60. Pharmacy services without a Chief Pharmacist will not be able to rely on the defence. We recognise the diversity of governance arrangements across the UK and the need for flexibility. As such, organisations do not need to adopt the statutory term "Chief Pharmacist" as a job title. However, they should ensure that the statutory functions of the Chief Pharmacist are included in the job responsibilities of the individual appointed to fulfil the role. A parallel can be drawn with controlled drugs legislation[xvii] where "Accountable Officers" can have a range of official job titles, not least because in that case the statutory role can be fulfilled by a number of different health professionals.

Independent prescribing by a pharmacist

61. Following feedback from the earlier consultation on the Registered Pharmacies Order, it was decided that where a dispensing error is made in a situation where a pharmacist was both the prescriber and dispenser, it should come within the defence. Whilst a pharmacist dispensing a prescription they have written themselves happens exceptionally, in keeping with good professional practice, it does occur and provision was made for it in the Registered Pharmacies Order. On this point, the defences have been extended without any modification. However, in a case where a pharmacist is both prescriber and dispenser, it is important to remember the broader safeguards within the defence, 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.

Part 1 – Question 8:
Do you agree that the defences should apply where an inadvertent preparation or dispensing error is made in a situation where a pharmacist was both the prescriber and dispenser?

Sale of a medicine against patient group directions

62. Supplies against a patient group direction will only come within section 64 of the Medicines Act 1968 if the medicine is actually sold. However, NHS supply against a patient group direction would be caught by section 63. Where a medicine is sold or supplied to a patient against a patient group direction, the Registered Pharmacies Order already covers the possibility of the defences applying if the dispensing is by registered pharmacy professionals working in registered pharmacies. It is proposed to extend the defences to also cover registered pharmacy professionals working in hospitals and other pharmacy services.

63. As indicated above, supplies that are neither sales nor in pursuance of a prescription are not covered by section 64 of the Medicines Act, although they are covered by the adulteration offence in section 63. It is therefore likely that most cases of supply against patient group directions or under, say, a minor ailment service would only be considered in relation to the offence in section 63 or the general criminal law.

Part 1 – Question 9:
Do you agree that the defences should apply where an inadvertent error is made in a situation where a pharmacist sells or supplies a medicine against any patient group direction?

Business and equality impact

64. Government rules dictate that an Impact Assessment be produced where the equivalent Annual Net Direct Cost to Business (EANDCB) is greater than +/- £5m. Where measures are likely to fall below this threshold, Departments should undertake a proportionate cost benefit analysis to inform decision-making and establish that the business impacts fall below the +/- £5m EANDCB threshold.

65. It is estimated that the proposed Order will fall below this threshold. Initial analysis suggests likely costs to business of around £26,000 and benefits of around £284.000, giving an estimated Net Present Value (for business) of -£258,000 over ten years. Costs will be mainly one-off familiarisation costs in year 1 and increases in the number of errors reported as a result of these proposals. Benefits are largely long-term savings calculated on the assumption that additional error reporting leads to improved learning that in turn reduces dispensing errors and costs/harm resulting from these proposals.

66. A summary of the cost benefit analysis is provided in this section. While the estimates in this analysis are derived from NHS settings in England, it is assumed that these are broadly equivalent to that in the Devolved Administrations relative to their populations. However, we would particularly welcome any additional information in relation to how the proposals might differentially impact settings in the other countries of the United Kingdom and outside the NHS.

67. A proportionate economic analysis has been undertaken of the costs to business of introducing a defence for preparation and dispensing errors in hospital pharmacy services and other relevant pharmacy services. In order to assess the likely impact of this policy, it is necessary to make a number of assumptions. Broadly, these fall into two categories:
    (a) General assumptions that underpin the proposal:
    These assumptions describe the likely direct and indirect effects of the policy. *An example of these general assumptions is that an excessive fear of prosecution deters appropriate reporting of inadvertent dispensing errors.*
    (b) Specific assumptions that inform any quantitative analysis:
    These assumptions detail estimates that are used to model the likely effects described above. *An example of these specific assumptions is that it will take approximately 20mins for a pharmacy professional to familiarise themselves with the new legislation.*

68. These classifications are not exclusive, and a summary of the estimated costs and benefits and full list of assumptions is presented below, together with references to published sources where these are available – see Table 1 and 2.

Assumption 1:	Inadvertent dispensing errors are underreported, in part due to an excessive fear of prosecution
Assumption 2:	Introducing a defence that reduces this excessive fear will thus decrease underreporting
Assumption 3:	There are costs associated with an increased rate of error

reporting

Assumption 4: Increased reporting will improve learning and thus reduce the number of inadvertent dispensing errors

Assumption 5: There are cost savings (benefits) to hospitals and other relevant pharmacy services from reduced errors

Assumption 6: There are health benefits to patients from reducing the number of dispensing errors, including a reduction in the number of deaths.

Assumption 7: There are further cost savings (benefits) from the reduction of prosecution risk

Assumption 8: There are costs associated with familiarisation

Assumption 9: A proportion of these effects will be felt by private businesses

Assumption 10: The nature of the proposal mitigates any risk of an increased number of inadvertent dispensing errors

Table 1 Summary of estimated costs of extending legal defences for inadvertent dispensing errors in hospital pharmacy

£, thousands

	Year 1	Year 2	10-yr appraisal period (undiscounted)	10-yr appraisal period (discounted)
NHS				
Total costs	£141.1	£11.6	£249.8	£242 (£241.9)
Total benefits		£501.4	£4,690.1	£4,353 (£4,352.8)
Private				
Total costs	£15.7	£1.3	£27.8	£26 (£25.9)
Total benefits		£36.0	£336.4	£284 (£283.8)
Total				
Total costs	£156.8	£12.9	£277.5	£268 (£267.8)
Total benefits		£537.4	£5,026.6	£4636 (£4636.6)

Source: See assumptions in Table 2

1 Familiarisation costs are assumed to be one-off costs occurring in year 1 only. Benefits start in year 2, and for NHS figure only include costed impact of QALY gains due to mortality reductions.

2 Discounting of 1.5% applied for NHS, and 3.5% for private sector.

Table 2 Inputs into calculations to estimate cost impacts of extending legal defences for inadvertent dispensing errors in hospital pharmacies

Inputs and calculations	Value	Estimate or Assumption	Data source
Incidence & costs of dispensing errors			
Annual no. of prescription items dispensed in hospitals in UK	52,263,713	Extrapolated from figure for England – assumed to increase at 2% per annum.	Elliott et al. (1)
No. of dispensing errors in UK hospitals in year 1	522,637	Estimated rates of dispensing errors in UK hospitals, max rate of 1%	James et al. (2)
Cost per error associated with increased bed-days due to avoidable Adverse Drug Reactions (ADRs) in UK	£0.98	Estimate from: a) £17.6m extrapolated costs of increased bed-days due to ADRs linked to medication errors (£14.8m for England); b) 2.9% of medication errors are dispensing errors; and c) no. of dispensing errors	Elliot et al. (1) – page 4, and page 142 for b)
Costs per error associated with 10 Quality Adjusted Life Years (QALYs) lost due to deaths resulting from ADRs	£3.36	Estimate from: a) extrapolated 101 deaths due to ADRs linked to medication errors (85 for England); b) 10 QALYS lost per death; and c) £60k cost per QALY, then multiplied by 2.9% and divided by 522,637 as above	Elliot et al. (1) – page 4
Reporting rates and costs			
No. of dispensing errors that are reported in year 1	26,132	Assumption – 5% of 522,637 dispensing errors detected & reported	
Costs of reporting an error, based on pharmacy staffing costs	£5.43	Indirect estimate from: a) assumed time taken to report error (15 mins); b) weighted hourly salary costs of pharmacists & pharmacy technicians plus 30% overheads (£26.65 x 60% + £14.29 x 40% = £21.71 per hour) based on composition of	GPhC workforce figures (3)

		hospital pharmacy workforce	and ONS earnings data (4)
Assumed impact of extending legal defences			
Relative reduction in number of dispensing errors due to learning from reporting	10%	Assumption – relative reduction of 10% from 1% to 0.9% occurs in year 1 and then persists for next 10 years resulting in approx. 495,000 avoided errors in total	
Relative increase in reporting of errors	10%	Assumption – relative increase of 10% in reporting from 5% to 5.5% of all errors resulting in approx. 25,000 total additional reports over 10 years	
One-off familiarisation time per staff member	20 minutes	Assumption –	IA for Registered Pharmacies Order 2018 (5)
Reduction in professional indemnity insurance	£22,000	Assumption – Cost of insurance of around £100. Cost of insurance premium expected to reduce by 1%. Estimated total saving to pharmacy professionals of £22,000 per year (after a 1 year lag).	National Pharmacy Association – professional indemnity insurance premium (6)

Table 2 references

(1) Elliott RA, Camacho E, Campbell F. et al. Prevalence and economic burden of medication errors in the NHS in England., Table 29, link http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf

(2) James LK, Barlow D, McArtney R, et al. Incidence, type and causes of dispensing errors: a review of the literature. International Journal of Pharmacy Practice 2009;17:9-30.

(3) Overall numbers from GPhC Annual Report 2016/17. https://www.pharmacyregulation.org/resources/corporate-publications. Description of hospital pharmacy workforce. General Pharmaceutical Council Registrant survey 2013. http://www.pharmacyregulation.org/sites/default/files/gphc_registrant_survey_2013_main_report_by_natcen.pdf

(4) Office of National Statistics; Annual Survey of Hours and Earnings (ASHE); 2017 Provisional; Table 14.5a

(5) DHSC Impact assessment: Rebalancing medicines legislation and pharmacy regulation programme: Dispensing errors, November 2014. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/403865/IA.pdf

(6) National Pharmacy Association, Professional indemnity insurance – hospital pharmacists. https://www.npa.co.uk/insurance/professional-indemnity-insurance/hospital-pharmacists/

69. This economic analysis follows Department of Health and Social Care (DHSC) and HM Treasury (HMT) guidance in using a 1.5% and 3.5% discount rate for NHS and private business impacts respectively. 10% of estimated impacts are attributed to private businesses[18].

70. Whilst the vast majority of benefit and cost impact will occur in hospitals, this draft Order extends to other pharmacy services. Due to the limited availability of data in regard to dispensing errors in these, albeit small number of, services, the cost benefit analysis is based on hospital pharmacy dispensing only.

71. Furthermore, all analyses have been considered in the context of the recently published, DHSC-commissioned, Policy Research Unit in Economic Evaluation of Health & Care Interventions (EEPRU) report entitled "*Prevalence and Economic Burden of Medication Errors in the NHS in England"*[19].

72. As referred to above, there currently is very little evidence of the number of dispensing errors occurring in hospitals and other pharmacy services in the United Kingdom. The EEPRU report considered medication errors across not only primary care, but also care homes, secondary care and various stages of the medication pathway through reviewing 36 studies.

73. The EEPRU report comments '*there were no UK prospective studies of dispensing errors in secondary care that reflected how many errors would leave the pharmacy. A UK retrospective incident reporting was considered to underestimate dispensing errors. Therefore we assumed that secondary care dispensing error rates were equivalent to primary care'* – therefore predicting the error rate in secondary care (relating to all potential types of error) to be 3.1%.

74. As the report does not just review medication errors relating to pharmacy, the findings are considered under the caveat that the overall number of dispensing errors occurring in hospital pharmacy services reported in the EEPRU paper is a reflection of the extrapolation of the dispensing error rate in primary care to the number of items dispensed in secondary care in England.

75. Furthermore, the number of medication items dispensed annually in secondary care in England is not reported in the paper, and the figure is determined to be approximately equivalent to the number of items prescribed in secondary care – at 44,724,144 items in England. Assuming that the number of issues in Scotland, Wales, and Northern Ireland are broadly equivalent to their respective populations, we estimate there are 52,263,713 prescription items issued in secondary care in the UK.

76. The EEPRU report estimates the rate of dispensing errors (of all prescription items issued) at 3.1%, but does not report an estimate of the rate or number of dispensing errors that make it through to patients. We have thus assumed that 1% of all prescription items issued include a dispensing error that is not rectified.

Part 1 – Question 10:
Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.

Equality assessment

77. An initial assessment of the impact on equality has been produced alongside this consultation document. We would welcome any additional information in relation to how the proposals on which we are consulting might impact on equality, both in relation to patients and the public who use pharmacy services and the pharmacy teams providing pharmacy services.

78. We intend to update this equality analysis to include information received as part of this consultation.

Part 1 – Question 11:
Do you have any additional evidence which we should consider in developing the assessment of the impact of this policy on equality?

Part 2: Superintendent Pharmacists and Responsible Pharmacists

Introduction

79. This part of the consultation document is concerned with elements of the organisational governance arrangements for pharmacies in medicines legislation. There are two distinct concepts in medicines legislation in regard to the sale and supply of medicines:
    - organisational level governance; and
    - individual transaction governance, for the sale or supply of prescription only medicines (POMs) or pharmacy (P) medicines.

80. Pharmacy owners, Superintendent Pharmacists (SPs) and Responsible Pharmacists (RPs) are part of the organisational level governance, alongside the registration of pharmacy premises. While the RP and pharmacist supervising the sale and supply of medicines is often the same pharmacist, these are distinct roles and the two governance concepts have been given separate consideration by the RPB.

81. This consultation addresses the RP appointed by the pharmacy owner, who 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 concept that is clarified through the proposals). An operational pharmacy cannot function without one. An RP cannot be responsible for more than one premises at any one time.

82. The consultation also considers the SP, who is intended to be the professional lead within a body corporate and responsible for the safe and effective running of all pharmacy premises under their control. At present the law does not elaborate on the SP's roles and responsibilities, whereas the roles and responsibilities of the RP are outlined in detail in the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 ("the RP Regulations").

83. The proposed draft Order is published alongside this document.

Key aims of rebalancing in respect of pharmacy owners, Superintendent Pharmacists and Responsible Pharmacists

84. The overarching approach is for the essential role and responsibilities of the SP and RP to be outlined 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 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:
  (a) the RP, who is in charge of a particular pharmacy on a given day;
  (b) the SP, who is intended to be the professional lead within a company; and
  (c) the pharmacy owner.

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

Pharmacy owners

86. Pharmacies may be owned by an individual pharmacist, a partnership, where, depending on jurisdiction, one or more of the partners is a pharmacist, or a body corporate. In the case of the first two instances, there is a pharmacist as an owner (potentially in partnership with others), who is subject to professional regulation. We do not propose any change to the position in respect of ownership. However, the use of standards as the basis for the regulation of registered pharmacies, rather than rules, has already been enabled through the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016, which comes into force, as regards England, Wales and Scotland, on 24 May 2018.

Superintendent Pharmacist and Responsible Pharmacist – general

87. The roles of RPs and SPs have been reviewed together in order to clarify the purpose of the roles, responsibility, accountability and interplay of both from an organisational and professional perspective. As part of the review we have sought to define the roles to reflect their obligations not just in relation to the supply of medicines but also for the quality of care provided through pharmacies. This has also included attributes of the roles such as professionalism, leadership, clinical and corporate governance. We have also taken into account the GPhC's and the PSNI's guidance on the responsibilities of pharmacy owners, RPs and SPs and the key findings from the independent evaluation of the RP Regulations, commissioned by the Royal Pharmaceutical Society and the Pharmacy Forum of the Pharmaceutical Society of Northern Ireland (PFPSNI)[ii].

88. It is proposed to retain the requirement for a body corporate to have an SP and for every pharmacy to have an RP when it is operating.

Superintendent Pharmacist

Current position

89. Broadly speaking, and subject to various exceptions, three criteria have to be met in order to sell or supply medicines that are not on a general sale list (GSL). These are:
    - the seller/supplier must be lawfully conducting a retail pharmacy business;
    - the transaction must be on premises that is a registered pharmacy; and
    - the transaction must be by or under the supervision of a registered pharmacist.

90. The Medicines Act 1968 requires that a corporate body lawfully conducting a retail pharmacy business must:
    - have an SP who is a pharmacist; and

- organise itself so that the keeping, preparing and dispensing of POMs and P medicinal products by that business is under the management of that SP.

91. The Medicines Act 1968 does not provide any further detail about the role of an SP, which has allowed for diverse interpretations of the law. While variation can be helpful, a common framework may provide a more consistent basis for on-going development of the SP role.

92. The requirement for the SP to be a pharmacist is to protect the public from unscrupulous and negligent suppliers of medicines, reflecting that medicines are not ordinary items of commerce. The requirement also indicates a professional aspect to the role, the need to continue to have a duty to adhere to the standards and ethics of the profession and to give due regard to this aspect of the role in discharging his/her duties.

Retain requirement for a Superintendent Pharmacist

93. It is proposed to retain the requirement to have an SP for a body corporate and leave the structure of section 71 of the Medicines Act 1968 (dealing with a retail pharmacy business carried on by a body corporate) broadly as it is now. However, amendments are proposed to clarify the role of the SP, which will reflect at a corporate level the role of the RP in a particular pharmacy on a particular day. The current situation is unchanged in so far as an SP is only required for a body corporate. Therefore, a business run by a pharmacist or partnership (where one or more of the partners is a pharmacist) would only require an RP.

Superintendent Pharmacist seniority and authority

94. Legislation currently refers to certain types of retail sale or supply of medicines (i.e. of POM and P medicines) as being "under the management" of the SP, but this is not defined. In practice, this lack of clarity has allowed some pharmacy companies to confer the role on someone nominally and not necessarily with sufficient seniority or authority.

95. It is proposed to change this so the SP is a senior manager in the retail pharmacy business (which may only be one part of the company), who has the authority to make certain types of decision. An advantage of using the concepts of "senior manager" and "authority to make decisions" is that these are well established in general law. A "senior manager" is defined as such if he or she plays a significant role (irrespective of whether others also do) in the making of decisions about how the whole or a substantial part of the activities of the retail pharmacy business are operated. The SP cannot simply be any senior manager. The proposal is to require the SP to be a senior manager *"…who has authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale of medicinal products (whether they are general sale list or not) and the supply of such products in circumstances corresponding to retail sale…*" This will mean the SP is a person with decision making authority that affects the running of the retail pharmacy business so far as concerns medicines, rather than specific management functions.

96. It is not proposed to further define the nature of the "authority" of the SP, for example, in terms of their relationships with other individuals such as the RP beyond what already exists – although there is an important new definition of their "function", which is explained below. It is also proposed that it should no longer be a requirement for a SP to be on the board of the pharmacy business, or for an SP to report to a member of that

board. Such a requirement would not necessarily ensure the SP is of appropriate seniority and has sufficient authority. As such, it would not add to the proposal for the SP to be a senior manager with authority to make decisions in respect to the retail pharmacy business, and is not being pursued. In keeping with this, it is proposed to remove the restriction for companies with "chemist" in their title such that the SP does not have to be a member of the board of the body corporate (section 78(3)(b) of the Medicines Act 1968).

Part 2 – Question 1:
Do you agree that the Superintendent Pharmacist should be a senior manager of the retail pharmacy business (which may be just one part of the company for which they work) with the authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale of medicinal products and the supply of such products?

Part 2 – Question 2:
Do you agree with the removal of the restriction for companies with "chemist" in their title such that the Superintendent Pharmacist no longer has to be a member of the board of the body corporate?

Superintendent Pharmacist general duty

97. An important consequence to the fact that there is some flexibility over the nature of the "authority" of the SP is the fact that the SP will nevertheless be expected to have sufficient "authority" to discharge their new general duty in draft section 72AA of the Medicines Act 1968. The new general duty proposed for the SP is to secure the safe and effective running of the retail pharmacy business so far as concerns the retail sale of all medicines by that business and the supply of medicines by that business in circumstances corresponding to retail sale (e.g. on NHS prescription).

98. This reflects the general duty that already exists for the RP (in section 72A of the Medicines Act 1968) to secure the safe and effective running of the pharmacy business at a particular pharmacy premises so far as concerns the retail sale of medicines by that business and the supply of medicines by that business in circumstances corresponding to retail sale. Thus, the SP's duty relates to the whole of the pharmacy business, and not just an individual pharmacy. The duty would relate to an "outcome", which is the safe and effective running of the pharmacy business so far as concerns the supply of medicines rather than the performance of specific tasks, leading to that outcome.

99. It is considered unnecessary to duplicate the duty of the RP for the safe and effective running of their particular premises with a similar duty on the SP. Conversely, there are issues with expecting the RP to have an overarching responsibility for what in practice are likely to be organisation-wide policies – such as SOPs – responsibility for which would sit more appropriately with the SP (provided the RP is able to exercise professional judgement in respect of the individual pharmacy for which they are responsible). The proposals seek to provide an appropriate balance between the respective roles of an SP and RP, as well as coherence and clarity. The SP will of course have other duties, more on which is explained below, but it is proposed that this will be the core statutory duty.

100. In summary, the following are proposed in relation to the statutory duty of the SP:
    (a) establishment of a new general duty for the SP to secure that the retail pharmacy business is carried on in ways that ensure its safe and effective running so far as concerns the retail sale of medicinal products and the supply of medicinal products in circumstances corresponding to retail sale;
    (b) the duty of the SP refers to the ways in which the business is carried on, rather than specifying elements such as procedures;
    (c) the duty of the SP covers <u>all</u> medicines: GSL, in addition to P and POM medicines, to align with the RP's duties;
    (d) the statutory duty of the SP is 'just' in respect of the retail pharmacy business (the body corporate may be the aggregate of a number of businesses); and
    (e) the duty on the RP to establish, maintain and keep procedures under review is removed and instead is subsumed in the general duty of the SP, more on which below.

101. The aim of the general duty is to ensure the objectives of SPs are the same, but will provide companies with flexibility to comply with the duty in ways most appropriate to their pharmacy business.

102. As indicated above, there are no plans to make specific mention of procedures in relation to the SP's duty. Instead it is proposed that the duty refers to the ways in which the business is carried on – with "procedures" being just one part of the ways in which a business is carried on. In general, it is expected that SOPs should be the responsibility of the SP. However, that should not inhibit the RP from their responsibility to contribute to the development and operation of SOPs and to act in the best interests of the patients, notwithstanding the SOP.

103. The SP would, however, become responsible for systemic errors in the business. In judging the SP's responsibility, it would need to be clear that such errors are due to demonstrable systemic failings, which could have been reasonably foreseen and did not align with good professional practice.

104. If the SP was failing to discharge their duty, both the SP and the business would risk fitness to practise sanctions from the relevant pharmacy regulator. However, it would not mean the pharmacy owner had ceased to be someone who was lawfully operating as a retail pharmacy business – potentially compromising the legality of all supplies of POMs and P medicines by that business. It is important that the sanctions regime is proportionate. A sanctions regime more reliant on regulatory action by the relevant regulator than criminal sanctions is more likely to support transparency of identifying problems, a collaborative approach to seeking solutions, and where necessary swifter action.

105. As indicated above, it is also proposed to address an anomaly for the SPs statutory role, and for it to now cover GSL medicines (in line with the current duty for RPs). Thus, the duty of the SP would cover all medicines.

106. Also as indicated above, the statutory duty of the SP is "just" in respect of the retail pharmacy business. Where the retail pharmacy business is part of a larger undertaking, for example a supermarket chain, GSL medicines sold outside of a pharmacy, for

example through general grocery or a petrol outlet, will not be covered by the SP's statutory duty.

Part 2 – Question 3:
Do you agree with the proposed general duty for the role of the Superintendent Pharmacist?

Part 2 – Question 4:
Do you agree that the Superintendent Pharmacist general duty should extend to all medicines – general sale list (GSL) medicines, as well as prescription only medicines (POM) and pharmacy (P) medicines?

107. The RPB has also recommended the role of the SP extends beyond the sale and supply of medicines from the retail pharmacy business to other services, such as clinical and public health services. The proposed way of achieving this is to give the relevant pharmacy regulators the powers to include in their standards a description of the professional responsibilities of SPs, rather than by attempting to set out this extended role in primary legislation, which would be a far less flexible way of covering the issue. The GPhC and the PSNI would need to consult on any such standards but initial views are sought on whether in principle it is appropriate to proceed in this direction.

Part 2 – Question 5:
Do you agree that the role of the Superintendent Pharmacist should extend to other services, such as clinical and public health services?

Superintendent Pharmacist for more than one business

108. At present, a pharmacist cannot be the SP for more than one retail pharmacy business at the same time. So, 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 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. It is proposed that the current restriction should be removed from primary legislation and left as a matter for the pharmacy regulators.

Part 2 – Question 6:
Do you agree that the restriction whereby a Superintendent Pharmacist can only be a Superintendent Pharmacist for one business at any given time should be removed from primary legislation and the issue be left to the pharmacy regulators?

Superintendent Pharmacist notification of the pharmacy regulators

109. It is already the case that SPs in Great Britain must tell the GPhC when they stop being the SP of a particular pharmacy business – and we do not propose to remove that requirement. We do however propose expanding this requirement to Northern Ireland and requiring notification to the PSNI.

Part 2 – Question 7:
Do you agree with the proposal to retain the requirement for Superintendent Pharmacists to notify the General Pharmaceutical Council when they stop being Superintendent Pharmacist for a particular pharmacy and to extend the requirement to Northern Ireland and the Pharmaceutical Society of Northern Ireland?

Professional standards for Superintendent Pharmacists

110. It is proposed to provide the pharmacy regulators with a new power that makes it clear that they can set professional standards specifically for SPs. This new power would also enable the pharmacy regulators to set out descriptions of an SP's professional responsibilities and how they should be achieved (outcome standards). It is expected that the pharmacy regulators would use these powers to make it clear that the professional responsibilities of SPs extend beyond the sale and supply of medicines from the retail pharmacy business to other services, such as clinical and public health services, as indicated above.

111. The standards would not be set in rules or regulations. However, failure to meet the standards could be taken into account in fitness to practise proceedings, although as article 48 of the Pharmacy Order 2010 makes clear, it does not in itself constitute misconduct.

Part 2 – Question 8:
Do you agree with the proposal to provide the pharmacy regulators with power to set professional standards for Superintendent Pharmacists and describe their role?

Responsible Pharmacist

Current position

112. The provisions in respect of the RP and associated regulation making powers are contained in Part 4 of the Medicines Act 1968, and in particular section 72A. Section 72A(1) contains the RP's statutory duty in relation to securing the safe and effective running of a pharmacy business at particular premises so far as concerns the retail sale of medicines and the supply of medicines in circumstances corresponding to retail sale (e.g. on NHS prescription). Section 72A also contains provisions relating to how that duty is to be fulfilled and more general Ministerial regulation making powers to add further detail. Developments in professional leadership and regulation since the RP Regulations came into force, as well as evolving government policy on better regulation, in the context of the overall aims for the "rebalancing" programme, have encouraged a review and impetus to reduce the level of detail in the 1968 Act and in current Ministerial legislation in respect to the RP role.

Statutory duty of the Responsible Pharmacist

113. It is proposed to retain the requirement for an RP to be in charge of each pharmacy, along with the current statutory duty in relation to the safe and effective running of that pharmacy. However, three further refinements are proposed:

- to make clear that the statutory duty is engaged only for the time when the RP is actually designated the RP role for that pharmacy, and is therefore in charge – in contrast to the duty of the SP, which is not time limited;
- to clarify the nature of the activities that trigger the need for an RP. Essentially, this is when either the pharmacy is actually open to the public for business (i.e. medicines are actually being offered for sale etc., even if in the case for example of an online pharmacy the transactions are being handled without public access to the premises) or when medicines are being handled, assembled, prepared or dispensed at or from the premises with a view to sale or supply, for example the preparation of medicines outside of opening hours; and
- to clarify that the RP's duty relates to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines) for which the RP is in charge.

Part 2 – Question 9:
Do you agree that the statutory duty of the Responsible Pharmacist should be engaged only for the time when the Responsible Pharmacist is actually designated the RP role for that pharmacy, and is therefore in charge?

Part 2 – Question 10:
Do you agree that the trigger for when there needs to be an RP in charge of the premises is when medicines are being sold or supplied, or handled, assembled prepared or dispensed at or from the premises with a view to sale or supply?

Part 2 – Question 11:
Do you agree that Responsible Pharmacist's duties should be clarified so that it is clear these are related to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines)?

General approach to the Responsible Pharmacist's responsibilities and transitional provisions

114. It is proposed that it should be for the pharmacy regulators to set out the detail of the RP's statutory responsibilities (apart from their general duty in section 72A(1)) in rules of the GPhC and regulations of the PSNI, instead of in primary legislation or in Ministerial regulations. Transitional provisions would be made to preserve the current RP Regulations until each pharmacy regulator has made their first set of rules or regulations under section 72A of the Medicines Act 1968.

Part 2 – Question 12:
Do you agree that the pharmacy regulators rather than Ministers should set out the detail of the Responsible Pharmacist's statutory responsibilities?

Responsible Pharmacist in charge of one pharmacy - power to make exception

115. Current powers allow for an exception to the general rule that a RP can only be in charge of one pharmacy at one time, for example, to enable such developments as pharmacist controlled dispensing machines. The proposal is to replace the Ministerial regulation making power to make an exception with a pharmacy regulator rule/regulation making power to do this instead.

Part 2 – Question 13:
Do you agree that the pharmacy regulators should have the power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time?

Procedures

116. It is proposed that the duty on RPs to establish, maintain and keep the procedures, generally known as SOPs, under review is removed. As set out above, the accountability for establishing and maintaining SOPs will be subsumed into the general duty of SPs with regard to the ways in which the retail pharmacy business is run. The pharmacy regulators will have the option of saying more about establishing and maintaining SOPs in standards, but it is proposed that there will be no legislative reference to this activity.

Part 2 – Question 14:
Do you agree that the duty on the Responsible Pharmacist to establish, maintain and keep procedures under review is removed and instead is subsumed into the general duties of Superintendent Pharmacists?

Record keeping

117. It is proposed the record keeping duties that fall on both the RP and the pharmacy owner in respect of the RP in charge of the pharmacy, as well as the related offences, are removed. The pharmacy regulators will be able to address such matters, as necessary, through their rules/regulations and a proposed consequential amendment to section 72B of the 1968 Act means that failure to comply would essentially be treated as a professional misconduct matter.

Part 2 – Question 15:
Do you agree that the duties relating to record keeping should be set out by the pharmacy regulators, rather than in Ministerial legislation, and be enforced where appropriate via fitness to practise procedures?

Rule and regulation making powers

118. It is proposed to remove from the face of legislation (from section 72A (7) of the Medicines Act 1968) most of the express matters about which further details can be added through Ministerial regulations and replace with a new general rule/regulation making power for the pharmacy regulators in respect of the RP. One of the powers it is proposed to remove is the power to make provision in regulations about the qualification and experience of RPs as we would expect these to be dealt with through standards rather than rules/regulations.

119. There are also currently regulation making powers in respect of the RP and supervision, specifically the supervision of individual medicine sale and supply transactions when an RP is not present on the pharmacy premises and in relation to supervising activities for which they are not the RP. It is also proposed to remove these powers in keeping with removing detailed regulation making powers. Supervision of sale and supply of medicines, as a general issue, is covered by Part 12 of the Human Medicines Regulations 2012, and nothing in this Order will impact upon the requirements in Part 12 of those Regulations.

120. Legislation also specifically provides for Ministers to make regulations in respect of the RP's absence from the pharmacy (i.e. at times when they are in charge of the pharmacy). This provision has been used to limit the absence of the RP from the pharmacy to a maximum of two hours per day. In line with the general approach to rebalancing, we propose amendments to enable the pharmacy regulators to address this matter in future rules/regulations.

121. However, it is proposed to qualify the rule and regulation making powers in section 72A in two ways:
- to make clear on the face of the legislation that if the pharmacy regulators' rules/regulations do allow the RP to be absent from the premise, they must also provide that the retail sale of GSL medicines may continue at the pharmacy while the RP is absent. This will ensure the requirements on pharmacies in respect of GSL medicines are in keeping with those of other retail outlets, which do not require a pharmacist; and
- for pharmacy regulators to consider the burden of any rules/regulations on business and to have regard to the principle that these should be kept to a minimum, consistent with other obligations.

122. It is proposed that before making rules under 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 and approval by the Department of Health in Northern Ireland.

Part 2 – Question 16:
Do you agree that the pharmacy regulators should be provided with a new general rule/regulation making power in respect to the Responsible Pharmacist and remove the specific Ministerial regulation making powers in respect of:
(a) the qualification and experience of Responsible Pharmacists;
(b) the Responsible Pharmacist and supervision;
(c) procedures; and
(d) the record-keeping of the Responsible Pharmacist

Professional standards for Responsible Pharmacists

123. As for SPs, it is proposed to provide the pharmacy regulators with a new power that makes it clear that they can set professional standards specifically for RPs. This new power would also enable the pharmacy regulators to set out a description of the RPs professional responsibilities, as well as setting standards in respect of those responsibilities. The standards would not be set in rules or regulations. However, failure to meet those standards could be taken into account in fitness to practise proceedings, although as with the equivalent powers being proposed in relation to SPs, failure to meet the standards does not in itself constitute misconduct.

Part 2 – Question 17:
Do you agree that the pharmacy regulators should be given new powers to set professional standards for Responsible Pharmacists and describe their role?

Deputy Registrar

124. The Pharmacy (Northern Ireland) Order 1976 currently provides for the role of the registrar in Northern Ireland, who holds and maintains the professional registers in relation to pharmacy in Northern Ireland. The Order affords powers to the Department of Health in Northern Ireland to appoint this registrar.

125. It is proposed that further powers are given to the Department to appoint a deputy registrar who may be authorised by the registrar to act on their behalf in any matter. This will enhance public safety by ensuring that important functions can be performed in the absence of the registrar. The amendment will bring the legislation closer to the rest of the United Kingdom, as already established by the Pharmacy Order 2010.

Part 2 – Question 18:
Do you agree that the Pharmacy (Northern Ireland) Order 1976 should be amended to provide for the appointment of a Deputy Registrar and to provide that the Deputy Registrar may be authorised by the Registrar to act on their behalf in any matter?

Business and equality impact

126. Government rules dictate that an Impact Assessment be produced unless the equivalent Annual Net Direct Cost to Business (EANDCB) is less than +/- £5m. Where measures are likely to fall below this threshold, Departments should undertake a proportionate cost benefit analysis to inform decision-making and establish that the business impacts fall below the +/- £5m EANDCB threshold.

127. It is estimated that the proposed Order will fall below this threshold. A summary of the cost benefit analysis is provided in this section.

128. This analysis finds that the benefits of the policy, conservatively estimated at £516,000 over the next ten years, are likely to outweigh any costs, which we believe to be limited to a one-off cost of £379,000 (as pharmacy staff take time to familiarise themselves with the changes). This gives an estimated Net Present Value (for business) of £137,000 over ten years. Put another way, benefits are likely to be around £3.63 per pharmacy, per year; costs are likely equivalent to £2.67 per pharmacy per year over the ten year timeframe.

129. In order to assess the likely impact of this policy, it is necessary to make a number of assumptions. Broadly, these fall into two categories:

(a) General assumptions that underpin the proposal

These assumptions describe the likely direct and indirect effects of the policy. *An example of these general assumptions is that relevant pharmacy professionals will need to familiarise themselves with the changes in respect to SPs and RPs.*

(b) Specific assumptions that inform any quantitative analysis

These assumptions detail estimates that are used to model the likely effects described above. *An example of these specific assumptions is that it will take 30 minutes of familiarisation time to implement the policy, and an average of two staff per pharmacy will need to familiarise themselves.*

130. These classifications are not exclusive, and a full list of assumptions is presented below, together with references to published sources where these are available.

Assumption 1: There will be familiarisation costs associated with changing the legislation in regard to SP and RP

(a) It is normal for pharmacy professionals to routinely keep up to date with changes in legislation. They will also receive communications about the changes in the course of their normal engagement with their professional bodies.

(b) To the extent that some members of staff do not familiarise themselves with changes in legislation, costs for their employers may arise. They may therefore have to give staff time to ensure they are fully informed of the changes.

(c) It is assumed that each pharmacist will, on average, take 30 minutes (0.5 hours) extra to familiarise themselves with the new legislation. This estimate only refers to the additional time required, while at work, beyond the familiarisation those professionals would be expected to have already incurred through engagement with professional bodies and other means.

(d) The Office for National Statistics 2017 (Provisional) Annual Survey of Hours and Earnings (ASHE) indicates earnings for pharmacists of £20.50 per hour[20]. This is the wage level that forms the basis for the calculation of familiarisation costs. Assuming that employment overheads add an extra 30% to total labour costs, we estimate of the hourly employment cost of a pharmacist at £26.65 per hour.

(e) To calculate the total familiarisation costs to businesses, an estimate is required of the numbers of staff affected. Data suggest that there are 11,699 pharmacies in the England[21], 1,255 pharmacies in Scotland[22], 716 pharmacies in Wales[23] and 548 pharmacies in Northern Ireland[24] for a total of 14,218 in the UK.

(f) If, on average, two pharmacists needed to familiarise themselves with the policy changes per pharmacy (including SPs and RPs), the total cost to business of familiarisation is estimated to be 0.5h x ([14,218] x 2 x £26.65]) = £378,910. This is a one-off cost, which represents a cost of approximately £2.67 per pharmacy per year a 10 year period.

Assumption 2: There are benefits to be had from the deregulatory elements of the draft Order

(a) This section provides a logical framework to determine how burdensome each change to the legislation is likely to be relative to the provision it replaces. Table 2 below summarises the likely impacts of key legislative changes under this draft Order.

Table 2 - Current and proposed replacement regulation in regard to the potential benefits from deregulatory elements of the draft of Order

Current regulation	Replacement regulation	Likely impact on businesses
Superintendent Pharmacists (SP) restricted to working for one and only one pharmacy business	Remove restriction on SP being SP for more than one pharmacy business	**Positive:** Deregulatory and less burdensome on businesses. Cost-savings as SPs can be allocated in a more efficient manner according to the business' needs, avoiding unnecessary duplication.
Pharmacy business with 'chemist' in the title are required to have SP on the Board	Remove the requirement for pharmacy business with the word 'chemist' in its title to have an SP on the Board	**Positive:** Deregulatory and removes the need to have an SP on the board for the single purpose of avoiding changes to a pharmacy business' title. Board composition will be determined mainly by the individual's potential to support corporate responsibilities and governance.

SP to provide continuous update to regulator on their status regarding their role on the Board	Remove requirement for SP to notify regulators if they are on the Board or not	**Positive:** Deregulatory: reduces cost to businesses of SP devoting time and resources to routine regulatory procedures.
RP to make a record of the RP in charge and failure to do so can be a criminal offence	Removes the criminal offence for failure to make a record of the RP in charge	**Positive:** Reduces any fear of prosecution for non-compliance.
Ministers have specific regulation making power to make provision about the qualifications and experience a pharmacist must have to be the RP and the associated criminal offence. Power not used to date	Remove so that pharmacy regulators may address this through their professional standards	**Positive:** Businesses will be able to have more ownership over who they see as having the appropriate skills to be an RP, instead of being instructed through regulations as to the necessary qualities of the RP. Cost-savings are likely to arise through the more efficient and flexible deployment of the affected work-force. Reduces burdens for business and any fear of prosecution for non-compliance. Failure to meet the standards could instead be taken into account in fitness to practise proceedings undertaken by the pharmacy regulators.

(b) Table 2 suggests that a variety of benefits will be realised through individual policy changes. In particular, the decrease in the overall volume of regulation will give businesses more freedom to decide how to allocate their resources in the most efficient way. Over a 10 year period, these efficiency gains would be consolidated.

Assumption 3: There are benefits to be had from the increased involvement of the pharmacy regulators, in respect to the role and responsibilities of the SP and RP

Table 3 – Current and proposed replacement regulation in regard to potential benefits from increased involvement of the pharmacy regulators

Current regulation	Replacement regulation	Likely impact on businesses
Criminal law currently used to address the SP's failure to meet statutory duty.	Failure by SP to meet statutory duty to be dealt with through professional regulation and registration sanctions.	**Positive/Zero Net Cost:** Pharmacy regulators are legally required to take into account business impact. This is likely to avoid overly costly penalties. In the long-term it can be expected that the pharmacy regulator will develop expertise, which will lead to efficiency gains and time savings. However, uncertainty about the way the regulators will operate makes the overall impact harder to assess.
Ministerial regulation-making powers in respect of the RP, including (i) any exception to the "one RP, one pharmacy" rule; and (ii) absence of the RP from the pharmacy premises	Replace with a general power for the pharmacy regulators to agree professional standards and requirements for the RP and to do so with regard to the desirability of ensuring any resulting burdens on businesses are kept to a reasonable minimum. Replace with a power for the pharmacy regulators to make rules or regulations in relation to (i) any exception to the "one RP, one pharmacy, and (ii) the RP's absence from the pharmacy premises, where it is made clear that any such rules/regulations must provide that	**Positive:** As the pharmacy regulators focus solely on issues related to business (as opposed to Ministers) this is likely to speed up businesses' related processes. As a result, the cost to businesses of dealing with any issue that involves the regulator would be reduced. Also, making new rules/regulations has the potential to support continuity of business trading, in the absence of the RP (for example, where an RP is necessarily absent to provide clinical services off-site). This eliminates unnecessary delays in business trading and transactions, saving time and costs for business.

	the sale of GSL medicines may continue when the RP is absent from the pharmacy premises.	
	New power for the pharmacy regulators to set out descriptions of SP and RP professional responsibilities and how they should be achieved.	**Clarification:** Gives businesses further certainty on the respective roles of the RP and SP.

(a) These elements also suggest that the pharmacy sector as a whole could function in a more efficient way as a result of the changes. The pharmacy regulators, in setting new standards and new rules/regulations, will take into account any potential excessive burdens that these might place on business. Over time, the regulator will further develop its understanding of how its actions can impact on business and ensure that any such concerns are fully taken into account in the development process. The clarity and increased flexibility regarding the role of the SP and RP also benefits business planning.

Assumption 4: If it was possible to monetise some of the other direct benefits, it is likely that this policy would show overall positive net benefits to businesses

(a) A key issue in assessing the overall impact of this policy is to evaluate whether these benefits can be expected to be at least equal or higher than the familiarisation costs.
(b) The benefits from the removal of the restriction on an SP being the SP for more than one pharmacy business are important. This is an example of how increased flexibility is likely to result in a more efficient allocation of resources and cost-savings to businesses.
(c) Given an SP holds a senior managerial position, we assume their salary to be in the 75th percentile among pharmacists, or £46,132 per year. We then adjust this number to reflect employment overheads ('on-costs'), increasing it 30% to £59,972 per year. Thus, if the number of SPs was to be reduced by the equivalent of only one full-time SP across the whole sector, this would result in cost-savings of £59,972 per year. Over a period of 10 years (and using a discount rate of 3.5%), this would result in total cost-savings to businesses of approximately £516,217, or £3.63 per pharmacy per year.
(d) This analysis considers cost-savings from only one of the many elements of the policy option, which have been identified as providing direct benefits. Hence, under the conservative assumption that this would be the only direct benefit obtained from adopting this option, the results suggest this will represent, at least, a zero net cost (ZNC) to business.
(e) However, if it was possible to monetise some of the other direct benefits, it is likely that this policy would show overall positive net benefits to businesses. Our partial analysis suggests a net benefit of £516,217 (in benefits) - £378,563 (in costs) = £137,654 to businesses over a 10 year period. Further details on these other potential cost and benefits to be quantified will be collected during the consultation period.

Part 2 – Question 19:
Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.

Equality Assessment

131. We have also published an initial assessment of the impact on equality alongside this consultation document and we welcome any additional information in relation to how the proposals on which we are consulting might impact on equality, both in relation to patients and the public who use the services available through pharmacies and the pharmacy teams within pharmacies.

132. We intend to update the analysis of each assessment to include information received as part of this consultation. Additionally, any information received in this way will be included in the analyses to be published as part of the Department's response to the consultation.

Part 2 – Question 20:
Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?

Responding to this consultation

133. The consultation questions set out in this are document are summarised at **Annex A**. The consultation will run from 19 June 2018 to 11 September 2018. We welcome responses from any interested person, business or organisation.

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

135. 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 form.

136. 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:

Pharmacy Team
Medicines and Pharmacy
Department of Health and Social Care
Floor 3
39 Victoria Street
London
SW1H 0EU

Please note that, although hard copy responses will be accepted, electronic responses via the on-line form are preferred. We ask that hard copies are therefore only submitted by those unable to use the on-line form.

Criteria for consultation

137. 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

Next steps

138. Following the closing date of this consultation, policy officials at the Department of Health and Social Care will analyse the replies and publish a response document within 12 weeks of the consultation, or provide an explanation as to why this is not possible. The consultation response will set out the main findings resulting from the submissions made to the consultation, and will be available at: https://www.gov.uk/government/publications?departments%5B%5D=department-of-health-and-social-care&publication_filter_option=consultations

139. If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator
Department of Health and Social Care
2E08 Quarry House
Leeds
LS2 7UE
consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Annex A – Consultation Questions

Part 1 – The draft Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018

Part 1 – Question 1:
Do you agree with the approach to provide a defence for registered pharmacy professionals working in a hospital pharmacy, similar to that implemented for registered pharmacies (predominately community pharmacy)?

Part 1 – Question 2:
Do you agree that in the case of hospital pharmacy services, this should be extended to include dispensing errors by registered pharmacy professionals which are made anywhere as part of a hospital pharmacy service, and so including elsewhere in the hospital, for example on a ward or in a hospital facility that does not have a recognisable pharmacy but supplies dispensed medicines in accordance with the directions of a prescriber?

Part 1 – Question 3:
Do you agree in principle with the proposal to extend the defences for registered pharmacy professionals making an inadvertent dispensing error to include other relevant pharmacy services?

Part 1 – Question 4:
Are there any other pharmacy services that you feel should be included within the scope of the new defences as specified in article 8 of the draft Order, i.e. that are not mentioned in the consultation document, and meet the criteria?

Part 1 – Question 5:
Do you agree with the proposals that a pharmacy service that potentially benefits from the extended defences must have a Chief Pharmacist in order to rely on the extended defences?

Part 1 – Question 6:
Do you agree that the pharmacy regulators should be enabled to set standards in respect of pharmacists who are Chief Pharmacists (or who are designated the responsibilities of a Chief Pharmacist), including a description of the professional responsibilities of a Chief Pharmacist?

Part 1 – Question 7:
Do you agree that the conditions of the defences for pharmacy professionals working in hospitals and other pharmacy services should broadly align with those required to be met by pharmacy professionals working in registered pharmacies?

Part 1 – Question 8:
Do you agree that the defences should apply where an inadvertent preparation or dispensing error is made in a situation where a pharmacist was both the prescriber and dispenser?
Part 1 – Question 9:

Do you agree that the defences should apply where an inadvertent error is made in a situation where a pharmacist sells or supplies a medicine against any patient group direction?

Part 1 – Question 10:
Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.

Part 1 – Question 11:
Do you have any additional evidence which we should consider in developing the assessment of the impact of this policy on equality?

Part 2 – The draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

Part 2 – Question 1:
Do you agree that the Superintendent Pharmacist should be a senior manager of the retail pharmacy business (which may be just one part of the company for which they work) with the authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale of medicinal products and the supply of such products?

Part 2 – Question 2:
Do you agree with the removal of the restriction for companies with "chemist" in their title such that the Superintendent Pharmacist no longer has to be a member of the board of the body corporate?

Part 2 – Question 3:
Do you agree with the proposed general duty for the role of the Superintendent Pharmacist?

Part 2 – Question 4:
Do you agree that the Superintendent Pharmacist general duty should extend to all medicines – general sale list (GSL) medicines, as well as prescription only medicines (POM) and pharmacy (P) medicines?

Part 2 – Question 5:
Do you agree that the role of the Superintendent Pharmacist should extend to other services, such as clinical and public health services?

Part 2 – Question 6:
Do you agree that the restriction whereby a Superintendent Pharmacist can only be a Superintendent Pharmacist for one business at any given time should be removed from primary legislation and the issue be left to the pharmacy regulators?

Part 2 – Question 7:
Do you agree with the proposal to retain the requirement for Superintendent Pharmacists to notify the General Pharmaceutical Council when they stop being Superintendent Pharmacist for a particular pharmacy and to extend the requirement to Northern Ireland and the Pharmaceutical Society of Northern Ireland?

Part 2 – Question 8:
Do you agree with the proposal to provide the pharmacy regulators with power to set professional standards for Superintendent Pharmacists and describe their role?

Part 2 – Question 9:
Do you agree that the statutory duty of the Responsible Pharmacist should be engaged only for the time when the Responsible Pharmacist is actually designated the RP role for that pharmacy, and is therefore in charge?

Part 2 – Question 10:
Do you agree that the trigger for when there needs to be an RP in charge of the premises is when medicines are being sold or supplied, or handled, assembled prepared or dispensed at or from the premises with a view to sale or supply?

Part 2 – Question 11:
Do you agree that Responsible Pharmacist's duties should be clarified so that it is clear these are related to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines)?

Part 2 – Question 12:
Do you agree that the pharmacy regulators rather than Ministers should set out the detail of the Responsible Pharmacist's statutory responsibilities?

Part 2 – Question 13:
Do you agree that the pharmacy regulators should have the power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time?

Part 2 – Question 14:
Do you agree that the duty on the Responsible Pharmacist to establish, maintain and keep procedures under review is removed and instead is subsumed into the general duties of Superintendent Pharmacists?

Part 2 – Question 15:
Do you agree that the duties relating to record keeping should be set out by the pharmacy regulators, rather than in Ministerial legislation, and be enforced where appropriate via fitness to practice procedures?

Part 2 – Question 16:
Do you agree that the pharmacy regulators should be provided with a new general rule/regulation making power in respect to the Responsible Pharmacist and remove the specific Ministerial regulation making powers in respect of:
(e) the qualification and experience of Responsible Pharmacists;
(f) the Responsible Pharmacist and supervision;
(g) procedures; and
(h) the record-keeping of the Responsible Pharmacist

Part 2 – Question 17:
Do you agree that the pharmacy regulators should be given new powers to set professional standards for Responsible Pharmacists and describe their role?

Part 2 – Question 18:
Do you agree that the Pharmacy (Northern Ireland) Order 1976 should be amended to provide for the appointment of a Deputy Registrar and to provide that the Deputy Registrar may be authorised by the Registrar to act on their behalf in any matter?

Part 2 – Question 19:
Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.

Part 2 – Question 20:
Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?

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