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Rebalancing medicines legislation and pharmacy regulation programme

Responses to the public consultation on the draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order and the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order

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Laid before Parliament pursuant to paragraph 9(2) of Schedule 3 to the Health Act 1999

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Any enquiries regarding this publication should be sent to us at: mb.rebalancing@dhsc.gov.uk.

Executive summary

The health departments in England, Scotland, Wales and Northern Ireland are committed to delivering a modern approach to healthcare regulation, which promotes patient safety while 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.

On 19 June 2018, the Department of Health and Social Care, on behalf of the 4 UK health departments, published a UK-wide consultation seeking comments and views on a series of proposals linked to 2 draft orders:

- the draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2018

- the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

The consultation closed at 11.59pm on 11 September 2018.

The publication of this consultation report and laying of the above draft legislation before Parliament was deprioritised as the government faced the dual challenges of the coronavirus (COVID-19) pandemic and Brexit preparation.

These legislative changes are now being taken forward under the powers in Section 60 of the Health Act 1999, as:

- the draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022

- the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022

These draft orders will support wider work being taken by the government, the NHS and the devolved administrations to address medication errors, improve patient safety and strengthen and clarify governance arrangements in registered pharmacies.

This report provides a summary of the responses received to the consultation. The report summarises what we heard during the consultation and feedback from engagement events, and our response to points raised.

Overview of the consultation

The UK-wide consultation, which was run on behalf of the 4 UK health departments between 19 June and 11 September 2018, sought views on a series of proposals in relation to 2 draft orders:

- The draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2018 (now 2022)

- The draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018 (now 2022)

The draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order

The draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 seeks to extend defences for inadvertent preparation and dispensing errors made by registered pharmacists and pharmacy technicians (referred to throughout this document as 'pharmacy professionals'), to those working in hospitals and other relevant pharmacy services where appropriate governance arrangements are in place, such as care homes and prisons.

This follows on from the provisions contained in an earlier order entitled the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018, which introduced the defences for pharmacy professionals working at a registered pharmacy.

The aim of the draft legislation is to remove the threat of criminal sanctions for inadvertent preparation and dispensing errors and to provide a greater incentive for an increase in the reporting of these errors, which in turn affords greater learning opportunities – translating to improved patient safety. Such measures have already been brought forward for pharmacy professionals working at registered pharmacies, and this draft order would ensure there is parity across the pharmacy professions, regardless of where pharmacy professionals work.

The proposals did not address dispensing doctors, as GP practice dispensaries are unlikely to have the sort of governance arrangements that the draft order contemplates, that is 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. The order 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.

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

The draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 seeks to amend the Medicines Act 1968 to strengthen and clarify the organisational governance requirements of registered pharmacies – especially in relation to the roles and responsibilities of the responsible pharmacist (RP) - the pharmacist responsible for the safe and effective running of an individual registered pharmacy - and superintendent pharmacists (SP) – the pharmacist generally responsible for the safe and effective supply of medicinal products across all branches of a pharmacy business (body corporate).

The key aims of this draft order are to rebalance:

- criminal law and professional regulation, so that matters within the ambit of the pharmacy regulators, the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI), are dealt with by them and by registration sanctions, rather than by the criminal courts

- Ministerial powers and the powers of the regulators, so that pharmacy practice matters are more appropriately set by the 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: that is the safe and effective practice of pharmacy should be the required outcome rather than binding the professions to particular processes or ways of doing things; and

- the relationship between pharmacy owners, superintendent pharmacists and responsible pharmacists to ensure the safe and effective practice of pharmacy in a retail pharmacy context, making clear the accountability of each respective role

At the request of the Department of Health in Northern Ireland and the PSNI, there are also 2 technical changes that apply specifically to Northern Ireland:

- giving the Department of Health in Northern Ireland the power to appoint a deputy registrar, in respect of the registration requirements set out in the Pharmacy (Northern Ireland) Order 1976

- extending the requirement that a superintendent pharmacist must inform the relevant pharmacy regulator when they stop holding the role in a pharmacy business to include Northern Ireland and the Pharmaceutical Society of Northern Ireland

  This aims to align the law in Northern Ireland with that of Great Britain

Requirement for regulators to consult on draft rules and regulations

The draft order puts in place safeguards to ensure that the pharmacy regulators consult publicly on any proposed rules or regulations made under the new powers under section 72A of the Medicines Act (The Responsible Pharmacist), offering the opportunity for scrutiny and comment. It is proposed that before making rules, the GPhC must publish draft rules and invite representations from ministers and other appropriate persons. 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' procedure in the UK Parliament. Separately, any regulations made under section 72A by the PSNI would require consultation of appropriate persons and consultation of and approval by the Department of Health in Northern Ireland. This will ensure transparency in the use of these powers by the Regulators and ensure public debate ahead of any new rules entering into force.

The current regulations concerning the duties of responsible pharmacists - The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 - will be revoked but will remain in place until the GPhC and PSNI make their first rules or regulations.

Overview of responses received

This report responds to the consultation run in respect of the 2 draft orders outlined above.

The consultation was separated into 2 parts: Part 1 being in respect of the draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order, and Part 2 being in respect of the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order.

In total, 632 responses were received to the consultation. Responses were received from a mix of pharmacy professionals, representative groups, organisations and public-sector bodies. Of the total respondents, 473 answered questions on Part 1

and 558 answered questions on Part 2. A breakdown of respondents is provided at Annex A and a list of organisations or representative bodies that responded to the consultation can be found at Annex B.

For the purposes of this document, the responses received from organisations and from individuals are counted as single responses and no weighting has been applied.

Where respondents provided comments to accompany their response to each consultation question, these have been analysed and summarised into key themes. Detail on these key themes is pulled out for each of the consultation questions below. It should be noted that some respondents did not provide any comments against their responses to the consultation questions, and a few respondents provided comments against every consultation question that they answered.

The overwhelming majority of respondents responding to Part 1 of the consultation supported the proposals in relation to extending preparation and dispensing error defences to pharmacy professionals working in hospital and other pharmacy services. In respect of Part 2 of the consultation, most of the proposals also received a high level of support. However, several proposals were more contentious and a lower level of support was indicated by respondents. Where this was the case, the proposals were subject to further consideration by the Rebalancing Programme Board and action was taken to address relevant concerns, where it was deemed appropriate, as outlined in this document.

To support and encourage responses to the consultation, a number of engagement events were held during the consultation period with the aim of ensuring that stakeholders understood the proposals fully and had an opportunity to raise their comments and concerns for clarification. A Partners' Forum event was held on 24 July 2018, with approximately 60 attendees from a range of pharmacy organisations, as well as individuals with an interest in the proposed legislation. An event was also held at the Pharmaceutical Society of Northern Ireland (PSNI) in Belfast on 21 August 2018.

The department supported other activities, as requested – namely attending meetings of the Independent Sector Chief Pharmacists Group and the All England Chief Pharmacists Group to discuss the consultation.

In Scotland, the consultation was promoted by officials via communications directed through the network of Health Board Directors of Pharmacy, and the network of community pharmacies across Scotland.

In Wales, officials highlighted the consultation to Community Pharmacy Wales, the Welsh NHS Chief Pharmacist Peer Group and the Welsh Pharmaceutical Committee (a statutory advisory committee to ministers) to promote engagement with the consultation and offer opportunity for clarity to be provided.

In Northern Ireland, the chief pharmaceutical officer for Northern Ireland met with the Heads of Pharmacy from the Health and Social Care Trusts in August 2018 as part of engaging stakeholders on the consultation. This provided an opportunity to

discuss and respond to questions, in particular those relating to the proposals included in Part 1 of the consultation document. Further to this, the chief pharmaceutical officer for Northern Ireland also wrote to the Health and Social Care Board in Northern Ireland and the Pharmaceutical Society of Northern Ireland to ask that both organisations establish a Short Life Working Group to take actions during 2018 to 2019 that will raise awareness amongst pharmacists of the implications of the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 – with the aim of supporting increased error reporting and learning activity in the community pharmacy setting using existing systems.

Alongside this, members of the Rebalancing Programme Board's communications sub-group, which includes the pharmacy regulators and the pharmacy professional leadership bodies, set up and ran their own events and workstreams to explain the proposals and encourage participation and engagement in the consultation from their stakeholders and memberships.

Responses submitted to the consultation

As the consultation jointly sought views on 2 draft orders, and some respondents only answered questions in respect of one of the draft orders in their response, the consultation responses have been broken down to reflect responses received for each of the 2 draft orders separately.

Clarification has been provided in each section below in respect of comments received from respondents where there appears to have been a misunderstanding of the current or proposed situation.

In some cases, respondents shared comments in relation to the same or similar point for more than one of the questions answered. Where this is the case, clarification is only provided once with cross-referral as appropriate.

Responses to the draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022

The first of the draft orders consulted on proposals that are linked directly to and extend existing defences for inadvertent preparation and dispensing errors (offences of contravening section 63 (adulteration of medicinal products) or 64 (sale of any medicinal product which is not of the nature or quality demanded by the purchaser) of the Medicines Act 1968), which were introduced for pharmacy professionals working at registered pharmacies in April 2018. These initial defences are provided for in the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 – the 'Registered Pharmacies Order'.

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)?

What we proposed:

The proposal was to extend the defences to the criminal offences in sections 63 and 64 of the Medicines Act 1968, as provided for 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 or DHSC governed healthcare activities that exist in the 4 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 licensed aseptic preparation units, which will still be subject to the offences outlined in section 63 and 64 of the Medicines Act 1968.

The draft order proposed to amend 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' – including services in the course of the business of a hospital.

There is no generally recognised definition of what constitutes a 'hospital'. It was 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 Care Quality Commission (CQC) is sufficient to cover hospital pharmacy services because all the relevant pharmacy services are covered by CQC registration in some way and therefore English hospitals are not separately referred to in the legislation.

What we heard:

Responses	Agree	Disagree	Not indicated or not answered
Number	409	30	34
%	86.5	6.3	7.2

86.5% of respondents indicated agreement to the proposal to extend defences for inadvertent preparation and dispensing errors to pharmacy professionals working in hospital pharmacies, similar to those provided for pharmacy professionals working at or from registered pharmacies.

It was, however, mentioned in multiple responses, both agreeing and disagreeing with the outlined approach, that the extension of defences to preparation and dispensing error offences does not go far enough – and that the criminal offences associated with contravening section 63 or section 64 of the Medicines Act 1968 should be removed in their entirety. The primary argument given for removing these offences completely was that the extended defences would not remove sufficiently

the threat of prosecution associated with inadvertent preparation or dispensing errors.

Several other relevant themes arose in response to the question, and these were primarily around the need for guidance for state prosecutors on how the defences should be applied; the need for guidance documents on the defences for professional leadership bodies to share with their memberships; and the need for other streams of work to address and promote the reporting of preparation and dispensing errors, for example in relation to the work of professional leadership bodies and others to encourage use of reporting systems and the sharing of learning from when things have gone wrong.

In some responses, it appeared that there was confusion in understanding of how the defences would work in practice – for example, it was suggested that the defences should be extended to cover pharmacy technicians and other staff working under a pharmacist, when the defences enable that already.

Our response:

We will extend the legal defences that are provided for against offences that contravene sections 63 and 64 of the Medicines Act 1968 so that pharmacy professionals working in hospital and other pharmacy services will also be able to rely on the defences, assuming that all of the relevant conditions are met, as is currently the case for pharmacy professionals working at registered pharmacies.

Complete removal of preparation and dispensing error offences

Comments in relation to the complete removal of preparation and dispensing error offences from legislation were raised repeatedly throughout consultation responses. Where this is the case in respect of responses to other questions in Part 1 of the consultation, clarification is provided here.

As explained in the government response to the Registered Pharmacies Order, the government does not propose to remove the offences contained in section 67 of the Medicines Act 1968 in respect to contravening either section 63 or 64 of that Act. This is because the offences apply to all sales or supplies of medicinal products – not just those by pharmacy professionals working in community pharmacies, hospitals or other regulated settings.

They, for example, apply to the whole medicines supply chain – manufacturers, wholesalers, sales of medicines in shops and sales by herbalists – and there is no mandate to remove the offences in these other contexts. There are also 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 has occurred. To remove the offence altogether would not be in the interest of the public and patients.

Further to this, there are defences already available in section 64 itself, and also in sections 121 and 122 of the Act. In the past one of the key defences has been

section 121(2), which exonerates a defendant where the contravention was due to the default of another person and the defendant themselves exercised all due diligence to secure that the provision would not be contravened. This defence remains available.

Guidance
Comments in relation to the need for guidance were raised repeatedly throughout consultation responses. Where this is the case in respect of responses to other questions in Part 1 of the consultation, clarification is provided here.

An FAQ document has been published on the Rebalancing Programme Board's website which provides information on the 2 draft orders, as well as clarity in respect of the policy intention, implications and requirements, for pharmacy professionals and interested others.

The pharmacy regulators, professional leadership bodies and other organisations may also produce further guidance and support for pharmacy professionals and their teams.

Pharmacy staff covered by the defences
The defences for pharmacy professionals working in hospitals and other pharmacy services would extend to registrants – pharmacists in the United Kingdom and pharmacy technicians in Great Britain – and other pharmacy staff working under the supervision of a pharmacist, assuming that all the conditions of defence have been met. This means that unregistered staff working under the supervision of a pharmacist, such as pharmacy technicians in Northern Ireland and dispensing assistants across the UK, would be covered by the defences.

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?

What we proposed:

It was proposed that in extending the preparation and dispensing error defences to hospitals, they should cover registered pharmacy professionals working anywhere as

part of the hospital pharmacy service – that is registered pharmacy professionals working outside of 'recognisable pharmacies'.

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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	366	48	59
%	77.4	10.1	12.5

77.4% of respondents indicated agreement to the proposal that in the case of defences being extended to cover inadvertent preparation and dispensing errors in hospital pharmacies, this should include errors made anywhere as part of a hospital pharmacy service, and so would include errors occurring elsewhere in the hospital to the recognisable pharmacy.

Similar to the responses for Part 1 – Question 1, the desirability of completely decriminalising preparation and dispensing error offences was highlighted as a reason for indicating disagreement with this proposal.

Aside from this, it was raised in several responses that greater guidance on the parameters of the 'hospital pharmacy service' would be useful in allowing pharmacy professionals to know whether specific errors would be covered under the defences. For example, the extent of the defined hospital pharmacy service was questioned – with a respondent querying whether a 'community team', based outside of the hospital premises, would be covered by the defences.

Clarity was also requested in respect of which errors would be captured under the defences – with incorrectly labelled medicine errors, transcription errors, errors involving more than one member of staff, and errors where a pharmacist or pharmacy technician was not physically present being listed as examples.

Furthermore, it was suggested that the differences in the definitions of 'providing' and 'dispensing' medicines need to be made explicitly clear in respect of availing of the defences.

One respondent suggested that defences should not be afforded where errors occur outside of a recognisable pharmacy.

Our response:

We will extend the legal defences that are provided for against offences that contravene sections 63 and 64 of the Medicines Act 1968 such that pharmacy professionals working in hospital pharmacy services will also be able to rely on the defences, assuming that all the relevant conditions are met. The defences will extend to dispensing errors which are made anywhere as part of the hospital pharmacy service.

Complete removal of preparation and dispensing error offences
Clarification in respect of the complete removal of preparation and dispensing error offences is provided in the section on Part 1 – Question 1 of the consultation.

Guidance
Clarification in respect of guidance is provided in the section on Part 1 – Question 1 of the consultation.

Errors captured under the defences
Guidance will be published by the appropriate pharmacy regulator to answer questions of detail relevant to each jurisdiction, but the government and Rebalancing Programme Board understands that in each country the standard 'hospital-related' places and services will all be covered by the provisions in the draft order.

Definitions of 'providing' and 'dispensing' medicine

For most practical purposes, what is or is not a dispensed medicine is understood, even if there is the debate which carries on as to when dispensing stops and 'sale or supply' takes over. On balance it was decided that it was impractical to define these terms for the purposes of these provisions, as these terms are widely used in other legislation concerning pharmacy and medicine.

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?

What we proposed:

It was proposed to extend the inadvertent preparation and dispensing errors defences beyond hospital pharmacy services to also include other relevant pharmacy services. Broadly, the defences would extend to:

- Accommodation used for the purposes of restricting the liberty of any person, that is a prison or youth detention accommodation, or those detained under mental health provisions or immigration and asylum legislation

- An activity in respect of which a legal person (e.g. a company) is registered with the CQC

- 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)

- A legal person (e.g. a company) registered with Healthcare Inspectorate Wales; and

- A service in respect of which a legal person (e.g. a company) is registered by the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	403	42	28
%	85.2	8.9	5.9

85.2% of respondents indicated agreement to the proposal to extend the defences for inadvertent preparation and dispensing errors to pharmacy professionals working in relevant pharmacy services.

Again, where disagreement to the proposal was indicated, comments primarily suggested that this was in relation to the need to go further than providing defences for inadvertent preparation and dispensing errors and to remove the criminal offences associated with contravening sections 63 or 64 of the Medicines Act 1968 entirely.

Accompanying this, comments raised that guidance should be developed and published to clarify which services would and would not be captured under the defences; and that guidance should highlight what the requirements are in order for pharmacy professionals working in specific relevant pharmacy services to avail

themselves of the defences, so as to ensure that they are aware of what they must do to secure potential utilisation of the defences.

Similar to several responses to Part 1 – Question 1, there appears to have been some confusion in the understanding of how the extended defences function, in that several respondents suggested that the defences should cover staff such as pre-registration pharmacists and student technicians.

Further to this, it was identified that pharmacy technicians in Northern Ireland are not currently registered with the PSNI and therefore could not avail themselves of the defences as registered pharmacy professionals. Nevertheless, they would be covered providing they were working under the supervision of a pharmacist and the other conditions were met. It was suggested that pharmacy assistants trained to NVQ level 2 in Northern Ireland are dispensing medicines, and legislation should take account of the new and extended roles for pharmacy support staff.

Our response:

We will extend the legal defences that are provided for against offences that contravene sections 63 and 64 of the Medicines Act 1968 such that pharmacy professionals working in other pharmacy services will also be able to rely on the defences, assuming that all of the relevant conditions are met, as is currently the case for pharmacy professionals working in registered pharmacies.

Complete removal of preparation and dispensing error offences

Clarification in respect of the complete removal of preparation and dispensing error offences is provided in the section on Part 1 – Question 1 of the consultation.

Guidance on captured services

Clarification in respect of guidance is provided in the section on Part 1 – Question 1 of the consultation.

Pharmacy technicians in Northern Ireland

Currently, pharmacy technicians working in Northern Ireland are not registered with the PSNI. They will however be covered by the defence if they were working under the supervision of a pharmacist, and the other conditions of the defence were met. Other unregistered pharmacy staff, like pharmacy assistants, would similarly be covered by the defence.

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, that is that are not mentioned in the consultation document, and meet the criteria?

What we proposed:

Consultation respondents were asked if there were any other pharmacy services that they felt should be included within the scope of the new defences, that were not included already (as described in Part 1 – Question 2 and Part 1 – Question 3).

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	115	124	234
%	24.3	26.2	49.5

24.3% of respondents indicated that they felt there are pharmacy services that are not currently included within the scope of the extended defences that should be considered.

Several respondents suggested that all pharmacy services should be covered under the extension of the defences, not just those specifically outlined in the consultation document.

Where specific services were referenced for inclusion within the scope of the defence, the most frequently suggested of these were service involving the preparation and manufacturing of medicines under an Medicines and Healthcare products Regulatory Agency (MHRA) licence, such as aseptic preparation and radio-pharmacy services. Reference was however also made to other specific services, some of which would already be captured under the current wording in the draft order – subject to the service meeting the specified governance requirements:

- Clinical screenings

- Directly funded and provided prison healthcare

- Dispensing doctors

- GPs and GP out of hours services
- Homecare providers
- Internet pharmacies (that is, distance selling pharmacies)
- Mass prophylaxis dispensing
- Medicine's reconciliation
- Military healthcare
- One stop dispensing or to take out (TTO) dispensing
- Pharmaceutical services at, for example, festivals and sporting events
- Pharmacy-supplied clinics
- Provision of emergency hormonal contraception
- Remote dispensing from pharmacy automated dispensing units
- Urgent care centres.

Alongside the above services, several respondents remarked that pharmacy professionals working at or from community pharmacies should also be covered by the defences. This is already the case, with defences being enacted in April 2018 by commencement of the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018.

It was also suggested that the defences be extended to preparation and dispensing errors made in respect of General Sale List (GSL) medicines.

Our response:

Following consideration by lawyers and the Rebalancing Programme Board on the responses received to this question, we will progress with the proposals as they are drafted in respect of what pharmacy services the inadvertent preparation and dispensing error defences cover.

Flagged services already covered in the drafting
The drafting of the order as proposed will already capture some of the services referred to by respondents.

Of those that aren't captured, some themes are readily identifiable. Firstly, in the area of primary care, where dispensing is done under the supervision of a doctor – or potentially a nurse – rather than a pharmacy professional. Importantly, the remit of the Rebalancing Programme Board is only to look at preparation and dispensing errors of pharmacy professionals and not to look into activities undertaken by other health care professionals. For example, there may be merit in covering GP dispensing and out of hours services, but consideration of that would be necessary in the context of errors by medical practitioners.

Secondly, services which are either unregulated or refer to activities undertaken by non-health care professionals this is something falling outside the scope of our enabling powers.

Thirdly, we have deliberatively focused on safe systems at the end of the supply chain in a pharmacy setting. Safe systems in the context of manufacturing requires consideration of the interplay with the manufacturers' licensing system and a different set of considerations that flow from that. Pharmacies may sometimes have manufacturing licenses, but our essential focus has been on pharmacy settings not manufacturing settings.

Defences to GSL medicine errors
In terms of GSL medicines, the defences as drafted would catch a GSL medicine (and indeed any medicinal product) that has been dispensed against a prescription, or directions of an authorised prescriber, a patient group direction or under arrangements for emergency supply. Retail sale of GSL medicines may of course happen in a number of retail settings outside a pharmacy with no involvement of a health professional so 'deregulating' in that area is not a matter for orders under the Health Act 1999.

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?

What we proposed:

It was proposed that in order to ensure the system governance element of the extended defences, there should be a chief pharmacist (CP) for the hospital or other relevant pharmacy service in order for registered pharmacy professionals to avail themselves of the extended defences.

The CP should be the person who is responsible for securing the safe and effective running of the pharmacy service, and tying in with existing concepts of general law, based around concepts in other legislation of who would be a 'senior manager' with 'authority to make decisions that affect the running of the pharmacy service'. The role is specific to pharmacy services, and the CP does not need to be a senior manager of the organisation as a whole – although in some circumstances this may be the case.

It was proposed that should a pharmacy service not have a CP, registered pharmacy professionals working for that service would not be able to avail themselves of the extended defences. The CP role is therefore not mandatory for broader purposes than the extension of the defences – although it is a significant incentive for a pharmacy service to have someone in that role and to have the associated governance arrangements in place that go along with it.

To summarise, it was proposed that the CP should:

- Be a registered pharmacist

- 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

- 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

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	254	139	80
%	53.7	29.4	16.9

53.7% of respondents indicated agreement to the proposal to require there to be a CP for the pharmacy service in order for the defences to be relied upon. 29.4% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the Association of Pharmacy Technicians UK (APTUK), GPhC, National Pharmacy Association (NPA), Pharmacy Forum of Northern Ireland (PFNI), PSNI and the Royal Pharmaceutical Society (RPS). The Association of Independent Multiple Pharmacies (AIMp) and Pharmacists' Defence Association (PDA) indicated general disagreement to the proposal.

Where disagreement was indicated, comments largely suggested that this was because it was felt that requiring a CP should not be a condition of the defence; or more fundamentally, it was felt that inadvertent preparation and dispensing error offences should be decriminalised or removed entirely instead of defences being introduced.

Conversely, some responses that indicated disagreement were on the basis that a CP should be mandatory for every hospital or pharmacy service, and that this requirement should be placed independently in legislation.

Comments also raised that the CP role is not applicable to a variety of settings, such as care homes and general practice, and pharmacy professionals working in these settings are therefore disadvantaged. Respondents also suggested that some settings are outside the scope of CPs' influence, such as aseptic manufacturing units; and it was also proposed that a CP should not always need to be a pharmacist.

Furthermore, queries were raised as to what happens in a situation where a CP is unable to work or the position is vacant. It was requested for it to be made clear that where the CP role is vacant, but someone is acting in that capacity, the condition for defence can be met. Alongside this, respondents also asked for it to be made clear to those without a CP that they would not be able to avail themselves of the defences and that wider guidance be made available on the CPs' role and responsibilities.

Some respondents requested clarity on certain situations in respect of the CP's responsibility – for example, it was asked who the most senior person would be in a situation where an NHS Trust or Health Board has both a registered pharmacy, requiring a superintendent pharmacist (SP), and a relevant pharmacy service, requiring a CP for the dispensing error defence to be made out, who may, but may not necessarily, be the same person. Further to this, clarity was also sought on how the provision of homecare would sit within the CPs' responsibilities.

It was also suggested that a register of the CP for each relevant pharmacy service, which the public and pharmacy professionals could access, would be beneficial.

Our response:

We will extend the legal defences that are provided for against offences that contravene sections 63 and 64 of the Medicines Act 1968 such that pharmacy

professionals working in hospital pharmacy services will also be able to rely on the defences, assuming that all of the relevant conditions are met. One of these conditions will be that the pharmacy service must have a CP in order for pharmacy professionals to benefit from the defences.

Consideration has been given to the transparency requirements as regards CPs, especially in respect of pharmacy professionals working in a pharmacy service being assured that their organisation has a CP in place for them to be able to benefit from the potential defences. The government and Rebalancing Programme Board is of the view that the pharmacy regulators could use their regulatory standards for CPs to ensure staff know who occupies the CP role in their organisation. The pharmacy regulators have agreed to consider this in producing relevant standards for CPs.

Requirement for a CP

There will be a requirement for there to be a CP overseeing the pharmacy service in order for the defences to be available to pharmacy professionals.

This is so that there is an assurance that the system governance requirement of the extended defences is made out where an inadvertent error has occurred, and also keeps the conditions of defence in relevant pharmacy services in line with that of registered pharmacies. The CP role is intended to mirror that of the SP in registered pharmacies, in respect of ensuring that medicines are being safely and effectively sold and supplied within the pharmacy service.

CP in services outside of a hospital

The CP will have a duty in respect to ensuring the safe and effective running of the pharmacy service for which they are responsible, to provide the certainty and clarity necessary for the defences to be relied upon.

'Relevant pharmacy service' is not bounded by premises. It can reflect the scope of the organisation of which it is part, for example spanning hospital and community services. For homecare services, the medicines are likely to be supplied from a registered pharmacy and so pharmacy professionals working in such a service can avail themselves of the defence in the Registered Pharmacies Order. The contracting for homecare services by a hospital CP and the assurance of quality is not within the remit of this draft order. The licensed manufacture of medicines is also outside the scope of the draft order and so the requirement to have a CP, who is a pharmacist, does not become an issue.

Pharmacy services without a CP will not be able to rely on the defences. We recognise the diversity of governance arrangements across the UK and the need for flexibility. As such, organisations do not need a specific role or person called a CP, but should ensure that statutory functions of a CP are included in the relevant individual's job responsibilities, if they want to benefit from the defences.

Vacancy of CP role

The CP role is an important role for a pharmacy service. Where the CP post becomes vacant, it would be expected that arrangements would be made to cover

the role, albeit on a temporary or acting basis until a permanent replacement is in place, such that the statutory functions, which are a condition of the dispensing error defence, would be met.

CP and SP interplay
The draft order allows for an individual to be both the CP of the pharmacy service and the SP of the retail pharmacy business at the same time in a situation where an organisation has both – there is no restriction in relation to this.

Where an organisation has both a registered pharmacy, requiring a SP, and a relevant pharmacy service, requiring a CP for the dispensing error defence to be made out, it is likely that the most senior pharmacist in the organisation would hold both the role of the CP and the role of the SP. This does not necessarily need to be the case however, and in such circumstances, it would be for the organisation to decide the seniority of both positions and how they should interact.

Register of CPs
Ensuring the role of CP is transparent, so that pharmacy professionals and others reliant on there being a CP to meet this condition of the defence, is important. The pharmacy regulators have agreed to consider this in producing relevant standards for CPs.

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?

What we proposed:

Alongside the requirement for there to be a CP for a pharmacy service in order for registered pharmacy professionals to potentially avail themselves of the extended defences, it was proposed that the pharmacy regulators be enabled to set the professional standards for a CP.

This could include a description of their professional responsibilities, and ties in with the proposals for SPs in Part 2 of the consultation.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated

Number	255	146	72
%	53.9	30.9	15.2

53.9% of respondents indicated agreement to the proposal to enable the pharmacy regulators to set standards in respect of CPs (or those who are designated their responsibilities), which can include a description of the CPs' professional responsibilities. 30.9% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, GPhC, NPA, PFNI, PSNI and RPS.

Where disagreement to the proposal was indicated, comments received suggest that this was mainly because it was felt that the professional leadership bodies should lead on the setting of professional standards for CPs rather than the pharmacy regulators. There was a view that the pharmacy regulators should only regulate and enforce standards set by the professional bodies and there was a proposal that an advisory body should be established to scrutinise and review any standards proposed by the professional leadership bodies.

Further to this, it was raised by some respondents that they did not trust the pharmacy regulators to undertake and use the proposed powers effectively. It was also suggested that the potential introduction of a new multi-professional healthcare regulator that may encompass the current regulators' role in the near future could lead to inappropriate and unrealistic standards being set for CPs.

Alongside these comments, respondents raised that it needs to be made clear that the pharmacy regulators would consult with the profession on any standards that they set in respect of the CP; and that standards should be produced in a profession-driven manner.

The role of the CQC in respect of the setting of standards for CPs was considered, with it being suggested that the CQC should set the standards for CPs working in CQC-registered services rather than the pharmacy regulators; or alternatively that the CQC should at least closely feed into the setting of these standards.

Our response:

We will enable the pharmacy regulators to set standards in respect of pharmacists who are CPs (or who are designated the responsibilities of a CP). This may include a description of the professional responsibilities of a CP.

Standards being set by the pharmacy regulators

The pharmacy professional leadership bodies play an important role in ensuring that registrants continue to develop and improve their professional skills, that pharmacists and pharmacy technicians feel supported, and that the professions continue to advance. This includes setting good practice and aspirational professional standards.

However, the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976 sets out the legal basis through which the pharmacy regulators can set standards for registered pharmacy professionals in relation to conduct, ethics and performance. This is a legal framework to which registered pharmacists and pharmacy technicians must comply. Through affording the pharmacy regulators powers to set standards for CPs, under the provisions set out in the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976, there is an assurance that these standards would be required to be adhered to, and there is a firm basis of expectation of the CP's responsibilities and thus what a CP should be capable of doing within their role.

Nothing in these proposals would change the respective roles of the professional bodies and the regulatory bodies. Essentially, what is being proposed is that what the regulatory bodies will be doing in relation to RPs and SPs, they should also be doing in relation to CPs.

Multi-professional regulator
The Department of Health and Social Care, along with the health departments in Scotland, Northern Ireland and Wales, has consulted on proposals to reform health and care professional regulation in the UK.

The Promoting professionalism; reforming regulation consultation ran from 31 October 2017 to 23 January 2018. It sought views on making regulation more proportionate, flexible and effective. The government published its response to the consultation on 15 July 2019. A further consultation on Regulating Healthcare professionals, protecting the public ran from 24 March 2021 to 16 June 2021.

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?

What we proposed:

It was proposed that the conditions required to be met in order for a registered pharmacy professional working in a hospital or other relevant pharmacy service to avail themselves of the extended defences should generally align with those required of registered pharmacy professionals working in registered pharmacies.

There are 2 main deviations from the initial approach, however, in that the medicines must have been supplied 'in the course of the provision of a relevant pharmacy service' rather than 'at or from a registered pharmacy', and that there is a

requirement for the pharmacy service to be overseen by a CP, mirroring the role of the SP.

A summary of the conditions required to be met in order for registered pharmacy professionals working in hospitals and other relevant pharmacy services to potentially rely on the extended defences is set out below:

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

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

- The registrant was acting in course of their profession*

- 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*

- At the time of the alleged contravention, the defendant did not know that the product had been adulterated or was not of the required nature or quality*

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

- The pharmacy service is overseen by a 'chief pharmacist'

*denotes commonality with the defence for registered pharmacies

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	383	35	55
%	81.0	7.4	11.6

81.0% of respondents indicated agreement to the proposal that the conditions of the defences to inadvertent preparation and dispensing error offences for pharmacy professionals working in hospitals and other relevant pharmacy services should broadly align with those required to be met by pharmacy professionals working at or from registered pharmacies – a view supported in responses to earlier questions in Part 1.

Where disagreement was indicated to the proposal, comments were similar to those received for earlier questions in Part 1, suggesting the defences did not go far enough and that preparation and dispensing error offences should be completely removed from legislation.

Linked to the above, it was suggested that in hospital pharmacies, to meet patient need, the supply of medicines is often made with the prescription being written retrospectively – and the extension of the defences in respect of this was queried. It was also proposed that the conditions should be further tailored to account for the differences in each sector and service, and the different conditions and roles which pharmacy professionals are working to.

Further clarity on the definition of supervision was requested, in respect of whether, for example, non-registered staff working in an aseptic clean room without a registered pharmacy professional present could rely on the defence; and whether supervision is to be interpreted as direct, physical supervision. Similarly, further definition of dispensing was requested in order to resolve the ambiguity around the extent of the defences – with it being suggested that currently the term 'dispensing' is open to interpretation.

Our response:

We will extend the legal defences that are provided for against offences that contravene sections 63 and 64 of the Medicines Act 1968 such that pharmacy professionals working in hospital and other pharmacy services will be able to rely on the defences, assuming that all of the relevant conditions are met. The conditions of these defences will broadly align with those required to be met by pharmacy professionals working in registered pharmacies.

Medicine supplied without prescription in a hospital

Where an error has occurred in a case where a medicine has been supplied without a prescription having been written first, the defences would still apply so long as the medicine was supplied under the directions of a prescriber, which could be verbal initially, followed up in writing.

Definition of 'supervision'

As to the meaning of supervision, these proposals will not add any references to 'supervision' into the legislation, but will build on existing references. So, the question about the level of supervision required to amount to supervision is the same legal question as arises in relation to 'supervision' at a retail pharmacy.

This will be the subject of further consideration in the context of the work to make more efficient use of the rich skill mix in pharmacy teams, as envisaged under the Community Pharmacy Contractual Framework, and work of the Cross-Sector Supervision Practice Group.

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?

What we proposed:

In keeping with good professional practice, it is exceptional for a pharmacist to dispense a prescription they have written themselves, but it does occur, especially when justified to meet patient need.

It was decided therefore that the Registered Pharmacies Order should allow for registered pharmacists working in registered pharmacies to potentially avail themselves of the defences where a preparation or dispensing error has occurred and the pharmacist was both the prescriber and the dispenser.

It was therefore proposed that in extending the defences for registered pharmacy professionals working in hospitals and other relevant pharmacy services, this point should also be extended.

As part of this, however, it is important to remember the broader safeguards within the defences – including the system governance element. Indeed, prescribing and dispensing by the same person should only in practice be happening where the service provider, and particularly its CP, is satisfied that this can be done safely and effectively.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	337	65	71
%	71.2	13.7	15

71.2% of respondents indicated agreement to the proposal that the extended defences should apply where an inadvertent preparation or dispensing error occurred in a situation where the pharmacist was both the prescriber and dispenser.

Where disagreement was indicated to the proposal, comments suggest that this was largely because respondents, at the time of the consultation, felt that pharmacists should never be in a situation where they should both prescribe and dispense a medicine, as this may impinge on patient safety. The need to completely remove preparation and dispensing error offences from legislation was also referenced.

Linked to the above, some respondents suggested that the government should restrict the practise of a pharmacist prescribing and dispensing the same medicine – either completely, or in cases where this is occurring and there is a vested financial interest or where profit can be made.

Other comments raised in respect of responses to this question remarked that the pharmacy regulators should produce and publicise guidance and or standards stating that this practise should occur only in exceptional circumstances, and if other staff are available then an accuracy check should always be performed.

Some respondents commented that the practise of a pharmacist prescribing and dispensing the same medicine is unlikely to ever happen in their organisation; although conversely to this it was also suggested by other respondents that reductions in funding has meant that pharmacy teams are smaller and it is therefore more difficult to avoid this practise.

It was proposed by several respondents that where pharmacists are prescribing and dispensing the same medicines, particular arrangements should be made – for example the undertaking of a risk assessment by the pharmacy service's CP – to ensure this is safe, and that the arrangements should be reviewed if an error occurs.

Our response:

We will extend the legal defences that are provided for against offences that contravene sections 63 and 64 of the Medicines Act 1968 such that pharmacy professionals working in hospital pharmacy services will be able to rely on the defences, assuming that all of the relevant conditions are met. The defences will extend to preparation and dispensing errors which are made where the pharmacist was both the prescriber and dispenser.

Pharmacists prescribing and dispensing the same medicine

It is exceptional for a situation to occur where a pharmacist both prescribes and dispenses a medicine – not withstanding recent changes to pharmacist initial education and training to become independent prescribers at the point of registration - and this usually arises in a situation where it is felt that patient need surpasses normal practise.

The proposal does not aim to address the validity of this practice, but to provide a defence where it does occur and an error is made. However, it is important to note that there are broader safeguards within the defence in consideration of the exceptionality of a pharmacist doing so. This includes the system governance element – in that prescribing and dispensing by the same person should in practice

only be happening where the service provider, and in particular the CP, is satisfied that this can be done safely and effectively.

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?

What we proposed:

It was proposed to extend the defences to also cover registered pharmacy professionals working in hospitals and other pharmacy services where a preparation or dispensing error occurs in relation to the sale or supply of a medicine against a patient group direction. This aligns with the approach taken in the Registered Pharmacies Order.

Supplies against a patient group direction 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. It is therefore likely that most cases of supply against patient group directions would only be considered in relation to the offence of contravening section 63.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	373	64	36
%	78.9	13.5	7.6

78.9% of respondents indicated agreement to the proposal that the extended defences should apply where an inadvertent preparation or dispensing error occurred in a situation where a pharmacy professional sold or supplied a medicine against a patient group direction.

Again, where disagreement to the proposal was indicated, comments suggest this was largely around respondents feeling that preparation and dispensing error offences should be removed completely from legislation – as was raised in respect of comments to earlier questions in Part 1.

Other comments suggested that there should be safeguards in place where medicines are being supplied under patient group directions; that the defences should cover where an error has occurred in the administration of a medicine; and

that guidance should make clear that use of patient group directions is only intended for exceptional circumstances.

Furthermore, comments suggested that the supply of General Sale List (GSL) and Pharmacy (P) medicines, such as those sold or supplied under a minor ailment scheme, should be captured; and that the defences should only be able to be availed where a pharmacy professional can demonstrate that they have been trained and approved in the use of patient group directions.

Several respondents raised that pharmacy professionals would be subject to prosecution under regulation 233 of the Human Medicines Regulations 2012 where an inadvertent preparation or dispensing error occurred in respect of medicine sold or supplied under a patient group direction, and the defences should cover this.

Our response:

We will extend the legal defences that are provided for against offences that contravene sections 63 and 64 of the Medicines Act 1968 such that pharmacy professionals working in hospital pharmacy services will also be able to rely on the defences, assuming that all of the relevant conditions are met. The defences will extend to preparation and dispensing errors which are made where the pharmacist sells or supplies a medicine against a patient group direction.

CP responsibility in relation to patient group directions

In being responsible for the safe and effective running of the pharmacy service, the CP would be expected to ensure that processes such as the provision of medicine under a patient group direction meet the relevant legal requirements, are risk-managed and undertaken safely.

Defences to GSL medicines errors

Clarification that the defences apply to GSL medicines (and also applying to P medicines) is provided in the section on Part 1 – Question 4 of the consultation.

Patient Group Directions

A patient group direction is not required for GSL medicines or P medicines to be supplied from a pharmacy, but is not precluded. Clarification in that the defences apply to GSL medicines (and also applying to P medicines) is provided in the section on Part 1 – Question 4 of the consultation.

Defences for erroneous administration of a medicine

The draft order as proposed provides defences only to section 63 and 64 of the Medicines Act 1968. Offences of making an error in relation to the administration of a medicinal product are covered under a separate area of legislation, and do not fall within the scope of this work.

Regulation 233 of the Human Medicines Regulations 2012
Central to this question is the issue of whether preparation and dispensing errors could be prosecuted in the alternative as breaches of Part 12 of the Human Medicines Regulations – essentially a question of whether prosecuting authorities, once they will no longer be able to use the 'obvious' offences, will try to squeeze the facts of dispensing errors into other offences.

The history of enforcement in respect of prosecution of dispensing error cases is that to date they have not been considered under Part 12 of the Human Medicines Regulations – or the preceding provisions in the Medicines Act 1968. By prosecuting under part 12 of the Human Medicines Regulations, prosecuting authorities could be argued to be going against Parliament's intentions to decriminalise dispensing errors. Prosecuting authorities around the UK will no longer be able to bring a relatively simple prosecution for a strict liability offence. This is necessary to help remove the 'fear factor' of an easy to prove prosecution.

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.

What we proposed:

A proportionate economic analysis was undertaken of the costs to businesses of introducing defences for preparation and dispensing errors in hospital pharmacy services and other relevant pharmacy services.

Ten central assumptions were made, and the associated estimated costs and benefits published in the consultation document. Views were sought on whether the assumptions were accurate, and whether any additional significant impacts or benefits could be identified.

The ten central assumptions are listed below:

- 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

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	58	110	305
%	12.3	23.3	64.5

12.3% of respondents indicated that additional significant impacts or benefits could be identified in relation to the cost benefit analysis associated with the draft Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018.

Where additional evidence and or estimates were provided by respondents in response to the question, relevant comments raised that consideration should be given to:

- Costs associated with creating and maintaining the CP role in situations where it is not already present

- Costs associated with more preparation and dispensing error cases being referred to the pharmacy regulators rather than the legal system

- Decreased employment in pharmacy services which are not covered by the proposed extension of defences, such as licensed aseptic preparation and manufacturing units

- Indemnity insurance premium costs being higher for pharmacy professionals working in, for example, GP practices and care homes than those working in hospitals and other similar services

- Indemnity insurance premium costs being unlikely to reduce, and more likely to increase as the more complex legal defences will take longer to manage and the associated costs likely to rise

- The Department of Health and Social Care commissioning an independent cost-benefit analysis of the proposals

- The indemnity insurance premium figures, referencing the prices of the National Pharmacy Association, being incorrect

- These proposals not leading to a decrease in the risk of prosecution, and therefore not leading to an increase in the reporting of errors

- Training costs associated with familiarisation

Our response:

Following consideration of the evidence presented to us during the consultation, and in line with taking a proportionate approach to estimating the cost-benefits

associated with these policies, we have identified 2 main areas to update on in respect of our assessment on the cost-benefit impacts of this policy - the cost of indemnity and the impact of a smaller deduction in the dispensing error rate.

Comments during the consultation suggested that insurance premiums for pharmacy professionals may in fact rise rather than fall, and as such indemnity costs are likely to vary. We tested the sensitivities of these assumptions. Analysis showed that if there was no fall in indemnity costs to pharmacy professionals the benefits would still far outweigh the costs. When testing for higher average indemnity costs, we found that the average indemnity costs would have to be prohibitively higher for the costs to offset the benefits. Therefore, this assumption has limited impact on the policy.

Comments also suggested that the dispensing error rate reduction may be lower than presumed. However, even if the reduction in the dispensing error rate is much lower than presumed in the initial cost benefit analysis, further assessment indicates that the benefits of the policy will still outweigh the costs.

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?

What we proposed:

An assessment of the impact of these proposals on equality was produced and published alongside the consultation document. Views were sought on whether any additional information could be considered in relation to how the proposals may impact on equality, both in relation to patients and public who use pharmacy services and pharmacy teams providing pharmacy services.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	25	215	233
%	5.3	45.5	49.3

5.3% of respondents indicated that additional evidence could be considered in relation to the assessment of the impact of this policy on equality.

Where additional evidence was provided by respondents in response to the question, relevant comments suggested that consideration should be given to the impact on the equality protected characteristics including:

- That by not including licensed aseptic preparation and manufacturing units and activities not within the scope of the extended defences, a two-tier hierarchy of pharmacists is likely to be created within the NHS

- Disparity between the rules and regulations of doctors that dispense medicines, community-based pharmacy professionals and hospital-based pharmacy professionals, and their treatment in relation to preparation and dispensing errors – and that not enough is being done in respect of addressing this

- Extending the defences to cover any member of pharmacy staff, regardless of registration status

Our response:

Following consideration of the evidence presented to us during the consultation, we do not intend to update our assessment of the impact of this policy on equality.

Responses to the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order

The second of the draft orders consulted upon regards the organisational governance requirements of registered pharmacies. Particularly focusing on the roles and responsibilities of RPs and SPs and how they interconnect.

The draft order seeks to amend the Medicines Act 1968 to strengthen and clarify the organisational governance requirements of registered pharmacies – especially in relation to the roles and responsibilities of the responsible pharmacist (RP) - the pharmacist responsible for the safe and effective running of an individual registered pharmacy - and superintendent pharmacists (SP) – the pharmacist generally responsible for the safe and effective supply of medicinal products across all branches of a pharmacy business (body corporate).

Two Northern Ireland-specific legislative changes, in relation to the appointment of a deputy registrar and a notification requirement for SPs working in Northern Ireland, were also proposed.

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?

What we proposed:

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

It was proposed to change this so that the SP is required to be 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, for the purpose of the draft order, 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.

Furthermore, it was proposed that there be a requirement for 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 GSL 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 relating to the wider business.

It was 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 responsible pharmacist (RP) beyond what already exists – although there is an important new definition of their 'function', which is explained in relation to Part 2 – Question 3 later in this paper.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	390	102	66
%	69.9	18.3	11.8

69.9% of respondents indicated agreement to the proposal to require the SP to be a senior manager of the retail pharmacy business, who has 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. 18.3% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the APTUK, GPhC, NPA, PDA, PFNI, PSNI and RPS. The AIMp indicated general disagreement to the proposal.

Comments received in relation to this question varied in content – with comments raising points relevant specifically to the question as well as comments on wider points of pharmaceutical service provision.

Respondent's comments that were relevant to this question were primarily around the need to ensure that the SP's authority must not impair or impinge on the RP's professional autonomy and professional judgement. Linked to this, some respondents suggested that RPs should make decisions that affect running of the retail pharmacy business rather than the SP.

It was reflected by several respondents that it was felt that the SP should be concerned with accountability and reflective process when things have gone wrong; that the SP should be there to support the RP, but the ultimate duty for the preparation, sale and supply of medicines should fall to the RP; and that the SP could only be made accountable for organisational shortcomings if they had the authority and ability to make meaningful changes to the running of the retail pharmacy business.

Alongside the above comments, respondents suggested that the proposal may impact on patient safety and lead to the needs of the business outweighing what is best for patients, particularly in respect of the conflict between making profit and the safety procedures. It was also remarked that changing the SP's statutory role would mean that body corporates may have to convene a General Meeting and amend their articles in association to include the additional SP responsibilities, and also update the associated job descriptions etc.

It was queried whether the proposed authority of the SP would include influence on budgetary control; and concerns were shared that if an SP is currently self-employed, the new authority requirements would mean that companies could no longer employ them in this capacity.

Our response:

We will amend legislation such that the Medicines Act 1968 will require an SP to be a senior manager of the retail pharmacy business, with the authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale and supply of medicinal products.

This will ensure that SPs have the seniority and influence required of their role, to allow for them to appropriately make decisions about how the retail pharmacy business is run, in the best interests of patients and the public.

SP role and duties

The aim of the proposals is to expand upon the SP's role and responsibilities. The intention is to introduce a statutory requirement that the SP is to be a 'senior manager' – a term already recognised in legislation – with the authority to make decisions that affect the retail pharmacy business so far as concerns the sale and supply of medicinal products; a significant role in making decisions about how the retail pharmacy business is to be managed or organised; and to introduce a statutory duty for the SP to secure the safe and effective running of the retail pharmacy business so far as concerns the sale and supply of medicinal products. It should be noted that, under the Medicines Act 1968, SPs are already required to be managers within their body corporates.

The draft order is purposely non-specific in respect of defining the position that the SP must hold within the wider body corporate, to allow for differences in organisational structures. The statutory requirements of the SP role do ensure that an SP must have sufficient seniority within the retail pharmacy business and authority to make decisions that affect the running of the pharmacy business, so far as concerns the sale and supply of medicinal products.

Some of the concerns reflect one of the common misapprehensions about the way Part 4 of the Medicines Act 1968 currently operates. A retail pharmacy business may be only one part of a wider business – and indeed many retail businesses are an aggregate of a number of different types of 'business', e.g. a retail pharmacy business, a grocery business, a café business etc. There is some confusion around whether or not these should truly be considered separate businesses if they are not also separate corporate entities. Critically, for the purposes of the Medicines Act 1968, the 'retail pharmacy business' does not need to be. So, a supermarket chain may carry on a 'retail pharmacy business' at some or all of its supermarkets – and that retail pharmacy business may not have a separate corporate identity – but under the Medicines Act 1968 it will be classed as a separate business.

In practical terms, the 'retail pharmacy business' part of the business is the part that is carried on at the registered pharmacy premises. To a certain extent, therefore, the scope of the retail pharmacy business is at the discretion of the pharmacy owner. If the owner choses to register the entirety of their retail outlet as a registered pharmacy, the retail pharmacy business is everything carried on at that outlet. If they only register part of the outlet, the retail pharmacy business is what happens at the registered part.

In the course of developing the proposals the government and Rebalancing Programme Board concluded that it was not appropriate to seek to clarify this further on the face of the legislation, although there may be a role for doing so in guidance. This indeed is in keeping with the underlying approach of the changes, which is to move things away from legislation.

Another main area of concern from respondents reflects another policy decision taken in the course of the preparation of the order. The new general duty of the superintendent, at first reading, appears to make them solely responsible for the business being carried on in ways that ensure its safe and effective running so far as concerns medicines sale or supply, but this is not the case.

The provision is based on the pre-existing general duty in relation to RPs, who have the responsibility to ensure the safe and effective running of the business at particular premises, when they are signed in, so far as concerns medicines sale or supply.

The 2 duties are deliberately complementary: one relating to particular premises on a particular day (the RP), and the other relating to the business as a whole, and applying 24 hours a day (the SP). The Medicines Act 1968 as a whole, it is clear that neither duty is absolute and the duties of both the RP and SP are qualified by the existence of the other.

SP relationship with the RP

The SP is intended to be the professional lead within a body corporate and is responsible for the safe and effective running of all pharmacy premises under their control. The RP on the other hand, is the pharmacist in charge of each individual pharmacy on a given day, and they have a statutory duty to ensure the safe and effective running of that pharmacy.

There is interplay between the 2 roles, and where the proposals set out that SPs should be responsible for ensuring the safe and effective running of the whole retail business, sufficient flexibilities are also reserved for RPs to divert from organisational-wide procedures and processes where this would benefit patients. For example, where a certain standard operating procedure (SOP) may not be in the best interest of a patient, the RP would have autonomy to be able to temporarily adjust or choose not to follow the procedure. This is also in keeping with good professional practise.

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?

What we proposed:

Alongside the proposal in respect of the SP being required 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…', it was also proposed that there should no longer be a requirement for an SP to be on the board of the pharmacy business, if the business wants to have 'chemist' in its name.

As matters stand, the requirement does not necessarily ensure the SP is of appropriate seniority and has sufficient authority. The purpose of retaining this restriction is therefore unclear, and as with any burden on business that does not have a clear purpose, there is an expectation that it should be removed.

In keeping with this, it was 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).

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	89	336	133
%	15.9	60.2	23.8

Only 15.9% of respondents indicated agreement to the proposal to remove the restriction for body corporates with 'chemist' in their title to have to have an SP as a member of their board, while 60.2% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, Company Chemists' Association (CCA), GPhC, NPA, PFNI, PSNI and RPS. The PDA indicated general disagreement to the proposal.

Comments suggest that several respondents were confused by the wording of this question, and seemed to have considered that this proposal was to remove the SP from the board of all retail pharmacy body corporates, rather than just removing the requirement on body corporates with 'chemist' in their title.

Where disagreement was indicated, comments suggest that this was largely because it was felt by respondents that all retail pharmacy businesses that are body corporates are required to have the SP as a member of the board.

Some respondents were not sure how the SP would be able to effectively influence the retail pharmacy business body corporate if they were not a member of the board; and that removing the requirement for the SP to sit on the board would devalue the profession. Some respondents considered that the SP should be required to sit where the relevant authority is held – and that if this requires them to be on board of the body corporate, then that is where they should sit, but that this is not necessarily the case.

Our response:

We will amend legislation such that the SP is no longer required under the Medicines Act 1968 to sit on the board of the body corporate where that body corporate has chosen to have 'chemist' in its title.

SP presence on pharmacy body corporate board

Currently, there is no legislative requirement for an SP to be a member of the board of a retail pharmacy body corporate – unless that body corporate's business title contains 'chemist'. It was proposed that to remove this restriction on body corporates with 'chemist' in their title would be fitting, as the appropriate seniority and authority required of the SP is not necessarily captured through them being a member of the board, but would be met by the requirement for them to be a 'senior manager' within the organisation.

The removal of the requirement for an SP to be a member of the board of a body corporate with 'chemist' in the business title does not however mean an SP is restricted from being a member of the board. This is true of any retail pharmacy body corporate – regardless of whether 'chemist' is in the business title or not. There is no remit under these proposals to change this.

Responses indicate a clear misunderstanding of the implications of this provision and gave no good reason why it should be maintained. The Board agreed that there is no impediment to proceeding with the proposal.

Part 2 – Question 3:

Do you agree with the proposed general duty for the role of the superintendent pharmacist?

What we proposed:

The new general duty that was proposed for the SP is for them 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).

This reflects the general duty that already exists for the RP (in section 72A of the Medicines Act 1969) 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.

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. 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.

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.

The proposals seek to provide an appropriate balance between the respective roles of an SP and RP, as well as coherence and clarity.

In summary, the following are proposed in relation to the statutory duty of the SP:

- 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

- The duty of the SP refers to the ways in which the business is carried on, rather than specifying elements such as procedures

- The duty of the SP covers all medicines: GSL, in addition to P and POM medicines, to align with the RP's duties

- 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

- 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

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	259	129	170
%	46.4	23.1	30.5

46.4% of respondents indicated agreement to the proposed general duty of the SP, while 23.1% of respondents indicated disagreement to the proposal and 30.5% of respondents did not provide a view. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, GPhC, NPA, PDA, PFNI, PSNI and RPS.

Where disagreement was indicated, comments largely suggest that it was felt that the RP should still have the authority and ability to make temporary changes to SOPs – using professional judgement to suit local need, and that this proposal may impinge on this.

It was also suggested that the proposed duty does not go far enough, and that the SP's duty should extend to all aspects of retail pharmacy business – not just the retail sale and supply of medicines, but also pharmaceutical services. It was also proposed that duties in relation to pharmaceutical care and advice and clinical care be prescribed for SPs.

Some respondents raised that further clarification was required on the duties of the SP, and that the general duties should be consulted on with the profession separately. It was suggested by some respondents that there should also be training and education requirements and or a minimum level of practice for SPs.

Our response:

We will amend legislation such that the proposed general duty of the SP is provided for under new section 72AA of the Medicines Act 1968. This will include the establishment of all 5 general points outlined above.

RP making temporary changes to SOPs

The SP is responsible for securing the safe and effective running of the retail pharmacy business, and as such would be expected to issue and review organisation-wide SOPs. In keeping with good professional practise however, RPs

are able, and will still be able under the draft order, to temporarily adjust or choose not to follow a procedure where following it would be detrimental to the patient. See also clarification in respect of Part 2 – Question 14, which concerns removing the requirement for the RP to establish, maintain and keep procedures from the face of statute.

SP duties extending to cover services
The extension of SP duties beyond just the retail sale and supply of medicines is proposed later on in the consultation, and is addressed in Part 2 – Question 10.

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?

What we proposed:

Alongside proposals in respect of the SP general duty, it was also proposed to address an anomaly for the SP's statutory role, and for it to now also cover GSL medicines (in line with the current duty for RPs). Thus, the duty of the SP would cover all medicines.

Alongside this, it was proposed that 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	359	126	73
%	64.3	22.6	13.1

64.3% of respondents indicated agreement to the proposal that the SP general duty should extend to all medicines – GSL, P and POMs. 22.6% of respondents indicated disagreement to this proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, GPhC, NPA, PDA, PFNI, PSNI and RPS.

Where disagreement was indicated, comments suggest that this is primarily because it was felt that as GSL medicines can be sold outside of a retail pharmacy business, which is not overseen by a SP, it would not be fair for an SP's role to extend to have to cover them in a retail pharmacy business.

Several respondents also considered that SPs would have little control over the sale and supply of GSL medicines, and some made the point that this proposal is not consistent with the defences provided to section 64 of the Medicines Act 1968 against dispensing error offences. It was also suggested that SPs should be responsible for ensuring that all staff are trained in GSL medicines.

Respondents sought clarity on how far the responsibility for GSL medicines would extend – with queries and comments being submitted around how this would work in settings such as a supermarket, where GSL medicines may be being sold as part of the grocery business rather than from a registered pharmacy, which is part of the retail pharmacy business. It was stressed that an SP's responsibility should not extend to GSL medicines for areas outside of the immediate recognisable pharmacy in this situation, and it would be disproportionate if this was to be the case.

Some respondents raised that instead of the SP, the responsibility for GSL medicines should rest with the RP in charge at the time.

Our response:

We will amend legislation such that the SP general duty, as outlined in the Medicines Act 1968, extends to all medicines – including GSL medicines, as well as POMs and P medicines.

GSL medicines sold within a retail pharmacy business but outside the registered pharmacy area

The draft order specifies that the SP's role in relation to securing the safe and effective sale and supply of GSL medicines extends only to the 'retail pharmacy business'. This may be only part of a larger business.

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?

What we proposed:

It was proposed that the role of the SP extends beyond just the sale and supply of medicines from the retail pharmacy business, to include other services – such as clinical and public health services.

The proposed way of achieving this was to give the 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 PSNI would need to consult on any such standards but initial views were sought on whether in principle it is appropriate to proceed in this direction.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	365	107	86
%	65.4	19.2	15.4

65.4% of respondents indicated agreement to the proposal that the role of the SP should extend to other services, such as clinical and public health services. 19.2% of respondents indicated disagreement with this proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, NPA, PDA, PFNI, PSNI and RPS.

Respondents shared a range of comments in relation to this proposal. It was suggested that each case (that is service) should be considered on its own merit; and that there should be a requirement for stating in standards that the SP is responsible for ensuring that each pharmacy service that they have authority for is defined – in a similar fashion to a statement of purpose.

Furthermore, some respondents considered that the generalist SP may not be the best person to oversee services; or that it may be better placed for the RP present on the day to manage these services, as they are the ones that provide them; or that the SP's role should not extend to making contractual decisions – for example in respect of certain NHS contracts, such as those commissioned locally by Clinical Commissioning Groups or local authorities.

Respondents raised that services should be further defined, in respect of the SP's scope of authority – for example, questioning whether this would extend to the provision of pharmaceutical advice or the administration of medicines.

Several respondents suggested that regulatory guidance would be preferred to changing legislation in respect of the proposal.

Our response:

We will amend legislation such that the pharmacy regulators are empowered, through the Pharmacy Order 2010 in respect of Great Britain and the Pharmacy (Northern Ireland) Order 1976, in respect of Northern Ireland, to include in their standards a description of the professional responsibilities of SPs where SPs take on responsibilities in areas not specifically covered by the Medicines Act 1968 – such as clinical and public health services.

SP role extending to services

In keeping with the direction of travel in relation to the provision of pharmaceutical services in the United Kingdom, it was proposed that the SP role extends to cover services other than just the sale and supply of medicines.

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

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?

What we proposed:

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 2 or more pharmacy businesses and thus 2 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 was proposed that the current restriction on an SP holding the role for only one retail pharmacy business at a time should be removed from primary legislation and left as a matter for the pharmacy regulators.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	144	348	66
%	25.8	62.4	11.8

Only 25.8% of respondents indicated agreement to the proposal that the restriction whereby an SP can only hold the role for one business at a time should be removed from primary legislation and the issue be left to the pharmacy regulators. 62.4% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, NPA, PDA, PFNI, PSNI and RPS.

Where disagreement was indicated, comments suggest that this is largely because it was felt that the proposals would serve no benefit or might lead to an increased risk to patient safety. Respondents proposed that an SP should continue to be only able to run one business at a time; that there may be conflicts of interest or collusion occurring if an SP holds the role for more than one business at a time; that different businesses work to different models; and some questioned whether an SP could manage more than one retail pharmacy business at a time effectively.

Alternatively, respondents recommended that if an SP is to hold the role for more than one business at a time, that there should be limits to the number of businesses an SP can do this for, as well as limits on the number of individual registered pharmacies that they can be the SP for. It was also suggested that the decision to be SP for more than one business at a time should lie with the individual SP, who should use their professional judgement to decide whether they would have the sufficient authority in each business to discharge their role effectively.

Comments in relation to the role of the pharmacy regulators were shared, with some respondents stating that they would not trust the pharmacy regulators to implement the proposal effectively; that the regulators should consult on their plans in more detail; and that there should be restrictions on the proposal and that each case should be considered individually.

Our response:

We will amend legislation such that the restriction whereby an SP can only be the SP for one retail pharmacy business at a time is removed from the Medicines Act 1968. The rules relating to this matter may be further addressed by the pharmacy regulators in establishing standards describing the professional responsibilities of SPs.

Limits associated with SPs holding the role for more than one retail pharmacy business at a time

The organisational structure of retail pharmacy businesses and their body corporates across the UK is diverse. In consideration of this, the proposal was left purposely flexible to ensure that businesses are not restricted by arbitrary limitations on the extent to which an SP can operate within their role.

Ultimately, it is for an SP and pharmacy owners or body corporates to decide whether an SP can manage their professional responsibility and undertake their role safely and effectively if they chose to do so for more than one retail pharmacy business at a time.

The role of regulatory standards and guidance

The new powers of the pharmacy regulators to describe the role of SPs will give them some scope for saying what SPs should not be doing, as well as what they should be doing. The statute only provides a legal baseline beyond which it should be impossible to go in any situation. Given the diverse organisational structures under consideration, it seems appropriate to deal with this issue in that way rather than by statutory restrictions. In particular, in cases where there are corporate mergers or business aggregations falling short of full merger, the current rule can seem somewhat arbitrary.

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?

What we proposed:

It is the case currently that SPs in Great Britain must tell the GPhC when they stop being the SP of a particular pharmacy business. It was not proposed to remove this requirement.

It was however proposed to expand this requirement to Northern Ireland and require notification to the PSNI.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	433	42	83
%	77.6	7.5	14.9

77.6% of respondents indicated agreement to the proposal to retain the requirement for SPs to notify the GPhC when they stop being SP for a particular pharmacy business, and to extend this requirement to Northern Ireland and the PSNI. 14.9% of respondents did not express a view.

Alongside respondents generally commenting that there should be consistency across the whole of the UK, it was suggested that there should be a similar process in place for CPs in hospitals and other pharmacy services; and that there should be a requirement for a new SP to be in place within 30 days after the previous has left the business (although note that, in fact, a retail pharmacy business always needs an SP – there should never be a gap).

Our response:

We will retain the requirement, as provided for in the Medicines Act 1968, that SPs working in Great Britain are required to notify the GPhC when they stop holding the role for a particular retail pharmacy business.

In order to align the law across the UK, we will amend legislation such that the Medicines Act 1968 also sets out a requirement for SPs working in Northern Ireland to notify the PSNI when they stop holding the role for a particular retail pharmacy business.

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?

What we proposed:

It was proposed to provide the pharmacy regulators with a new power that makes it clear that they can set the professional standards specifically for SPs.

This new power would also enable the pharmacy regulators to set out descriptions of an SP's professional responsibility, and how they should be achieved (that is 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 – tying in with the approach outlined in respect of Part 2 – Question 5.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	268	212	78
%	48.0	38.0	14.0

48% of respondents indicated agreement to the proposal to provide the pharmacy regulators with powers to set professional standards for SPs and describe their role. 38% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, NPA, PFNI and PSNI. The PDA and RPS indicated general disagreement to the proposal in their response – with the RPS suggesting that the pharmacy regulators should produce regulatory standards instead of professional standards.

Where disagreement to the proposal was indicated, comments received suggest that this was mainly due to a fundamental disagreement on who should set professional standards. There was a view that the professional leadership bodies should lead on the setting of professional standards for SPs rather than the pharmacy regulators – and that the pharmacy regulators should only regulate and enforce these standards, and a proposal that an advisory body should be established to scrutinise and review the standards proposed by the professional leadership bodies. Alongside this, several respondents proposed that the regulators should collaborate with the professional leadership bodies on producing standards for SPs if they are to be the ones to set professional standards.

Alongside the above, it was also raised by some respondents that the pharmacy regulators were not trusted to undertake and use the proposed powers effectively, and that it should be clear that the regulators would consult on any standards and review these regularly.

Our response:

We will amend legislation such that the Pharmacy Order 2010, in respect of Great Britain and the Pharmacy (Northern Ireland) Order 1976, in respect of Northern Ireland sets out powers for the pharmacy regulators to set standards of conduct, ethics and performance for SPs. This may include detail of their professional responsibilities, and how these should be achieved.

Standards being set by the pharmacy regulators
The pharmacy professional leadership bodies play an important role in ensuring that registrants continue to develop and improve their professional skills, that pharmacists and pharmacy technicians feel supported, and that the profession continues to advance itself.

However, the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976 set out the legal basis through which the pharmacy regulators can set professional standards in relation to conduct, ethics and performance of registrant pharmacists and pharmacy technicians (in GB). There is nothing in the proposals that changes the existing boundaries between what the professional leadership bodies do, and what the pharmacy regulators do. There is understandable sensitivity around terminology, but it is important to focus on the substance of the relevant provisions, and the relatively limited nature of the extension of those provisions that is proposed.

Without these changes, the pharmacy regulators will set standards for all pharmacy professionals, including SPs and RPs, and as part of that standard setting they will necessarily need to have regard to the roles that SPs and RPs are expected to perform. This proposal gives the pharmacy regulators a positive responsibility to do something that they would have difficulty avoiding doing anyway, and makes that process transparent and proactive.

Requirements for the pharmacy regulators to consult on any new standards
The draft order ensures pharmacy regulators must consult on any proposed standards, offering the opportunity for sufficient scrutiny and comment.

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?

What we proposed:

It was 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.

Building on this however, it was proposed to refine legislation 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	476	39	43
%	85.3	7.0	7.7

85.3% of respondents indicated agreement to the proposal that the statutory duty of the RP should be engaged only for the time when the RP is actually designated the RP role for that pharmacy, and is therefore in charge.

The primary comments received from respondents in respect of this proposal were around there being the need to ensure that the RP is required to be physically present at the pharmacy during the time they are engaged in the role – and how this links with ensuring the safety of patients, and decreased criminal liability for pharmacists.

It was suggested by some respondents that it needs to be clear that the RP should still be responsible for any issues that arose during their time as RP, even when they no longer hold the role, until the issues are either resolved or handed over to an appropriate other person.

Our response:

We will retain the general rule in legislation, specifically within the Medicines Act 1968, that there must be a RP in charge of each pharmacy, with a statutory duty in relation to the safe and effective running of that pharmacy.

We will amend legislation such that it is clear in the Medicines Act 1968 that the RP's statutory duty is only engaged when they are actually designated the role of RP, and therefore in charge of the pharmacy.

RP responsibility for issues

In keeping with their professional responsibilities, pharmacists and pharmacy technicians are expected to ensure that issues and concerns are appropriately resolved either by themselves or another suitable person. Nothing in these proposals would change that, including in respect of the RP's responsibility for resolving issues.

RP responsibility for handling medicines

See clarification under Part 2 – Question 10.

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?

What we proposed:

It was 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.

Building on this however, it was proposed to refine legislation 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 (that is, 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	464	50	44
%	83.2	9.0	7.9

83.2% of respondents indicated agreement to the proposal 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.

Where disagreement was indicated to this proposal, comments suggest that this was primarily in relation to it being felt that the RP does not need to be in charge of the premises during the handling, assembly, preparation and dispensing of medicines – so long as they perform a final check of the medicines before they are sold or supplied to the patient. It was suggested by some respondents that if this was the case, it should be the responsibility of the SP to ensure that systems are in place to ensure the safe and effective handling, assembly, preparation and dispensing of medicines where an RP is not physically in charge of a premises.

Conversely, however, some respondents suggested that there should be an RP physically present and or in charge of a pharmacy premises at all times it is functioning, whether open to the public or not. The need for an RP for the sale of all GSL medicines was also proposed.

Alongside this, respondents sought clarity on whether the proposal's scope meant that the RP was required to be present in order for the provision of pharmaceutical services or pharmaceutical advice; and how this proposal would interact with the business model of 'internet pharmacies' – that is, distance selling pharmacies.

It was remarked that this proposal may work suitably for community pharmacy, but it doesn't fit as well for hospital pharmacy – where the supply of medicines and clinical functions are different.

A query was also raised in relation to the extent to which 'handling' applies within the context of requiring an RP to be in charge for this, and whether, for example, the placing of medicines on shelves would be captured under this activity or whether this can be done without an RP being required to be in charge.

Our response:

We will amend legislation such that it is clear in the Medicines Act 1968 that there needs to be an RP in charge of the registered pharmacy premises when medicines are being sold or supplied, or assembled, prepared or dispensed at or from the premises with a view to sale or supply.

Following consideration of the responses received to the consultation and deliberation by the Rebalancing Programme Board, the government has explored the removal of 'handled' from the legal drafting setting out when an RP must be in charge of the pharmacy. The Rebalancing Programme Board and DHSC felt there was merit in concerns expressed around the inclusion of 'handling' in the draft order being too restrictive on currently ongoing procedures being carried out in some registered pharmacies – including, but not limited to, the stacking of shelves. It was felt that these activities would not require an RP to be in charge of the pharmacy.

The department has removed 'handling' from the legislation.

RP presence at a registered pharmacy: general observation

The proposal to require there to be an RP in charge of a pharmacy premises when medicines are being sold or supplied, or being assembled, prepared or dispensed with a view to sale or supply, stems from the need to ensure that these processes are safely managed and governed – with the safety of patients being the top priority. The current legislation and The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 (RP Regulations) already enable the RP to be absent from the pharmacy, albeit for a limited period, and that ability for the RP to be absent is not changed by the proposals in the draft order.

RP in charge and the provision of pharmaceutical advice and other services
The drafting of the order does not require an RP to be in charge of the pharmacy premises for a pharmacy service other than for the sale and supply of medicines to be undertaken. That is when a medicinal product is offered for sale or if a medicine is being assembled, prepared or dispensed with a view to being sold or supplied.

The pharmacy regulators will be able to address this matter in setting standards of conduct, ethics and performance for the RP, and are able to set out professional responsibilities for RPs in respect of ensuring these services are being carried on safely and effectively, including in respect to an RP being in charge of the pharmacy premises.

RP responsibility and GSL sales
The RP Regulations already provides for GSL medicines to be sold without an RP being present in the pharmacy. It is merely the aim of these proposals to ensure that this requirement is clear on the face of legislation, therefore ensuring the requirements on pharmacies in respect of GSL medicines are in keeping with those of other retail outlets, which do not require a pharmacist. That said, the public visit a pharmacy for advice on medicines to be used to treat a particular condition. As such, it is right the sale of GSL medicines from a pharmacy requires there to be an RP in charge, albeit that the RP does not need to be physically present. This therefore is being carried forward.

RP responsibility for the handling of medicines
As drafted, the proposals envisaged 4 activities requiring an RP to be in charge of a pharmacy, even if not physically present: handling, assembling, preparing or dispensing medicines with a view to their sale or supply.

As indicated above, concern has been expressed that this goes too far, and in particular that the restocking of shelves – an activity that most people would see as ‘handling’ of medicines, should be allowed to happen while a RP is not in charge (whether present or absent). As outlined above in response to Part 2 – question 10, ‘handling’ has been removed from the draft order. Thus, only the activities that touch and concern an individual prescription require an RP to be in charge of a pharmacy.

Remote supervision
Comments in relation to objection to ‘remote supervision’ were raised repeatedly throughout consultation responses. Where this is the case in respect of responses to other questions in Part 2 of the consultation, clarification is provided here.

The proposals on which we have consulted concern the RP. The role of the RP is a distinct and different role from the supervising pharmacist, albeit that they may be undertaken by the same pharmacist at the same time. The RP role is concerned with the organisational governance of the pharmacy, whereas supervision by a pharmacist concerns individual transactions. The current legislation and RP Regulations already enable the RP to be absent from the pharmacy, albeit for a limited period. The consultation did not raise proposals in relation to remote supervision.

Supervision will be the subject of further consideration in the context of the work to make better use of the rich skill mix in pharmacy teams, as envisaged under the Community Pharmacy Contractual Framework, and work of the Cross-Sector Supervision Practice Group.

Nothing within this draft order would impact upon the requirement for there to be a pharmacist, or someone working under their supervision, to carry out the sale or supply of a medicine not subject to general sale in a registered pharmacy – as outlined in regulation 220 of the Human Medicines Regulations 2012.

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)?

What we proposed:

It was 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.

Building on this however, it was proposed to refine legislation 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	454	47	57
%	81.4	8.4	10.2

81.4% of respondents indicated agreement to the proposal that the RP's duties should be clarified so that it is clear that these are related to the operation of the pharmacy business 'at or from' the particular premises (e.g. including home deliveries of medicines).

Comments received from respondents suggest that this proposal may blur the line between the responsibility of the RP and the SP; and that consideration needs to be given to the increasingly blurred lines between the provision of primary and secondary care – in respect of increasingly integrated care.

It was raised by some respondents that it was felt that the RP should not be responsible where staff have not followed SOPs – for example in the case of delivery drivers; or alternatively that home deliveries should not fall under the responsibility of RPs at all.

One respondent commented that it would be useful to make specific mention of distance selling pharmacies in the responsibilities of RPs.

Our response:

We will amend legislation such that it is clarified in the Medicines Act 1968 that the RP's duties relate to the operation of the pharmacy business 'at or from' the particular premises for which the RP is in charge.

RP responsibility 'at or from' the pharmacy
Notwithstanding what is actually in the legislation, the common interpretation of the legislation is that this extends to both activities 'a' and 'from' the pharmacy. This proposal merely clarifies the current position and understanding of RP responsibility in respect of 'at or from' in primary legislation.

RP responsibility for delivery drivers
Current interpretation is that the RP's responsibility extends to the completion of a transaction by way of home deliveries and thus to delivery drivers. In the context of the Registered Pharmacies Order, it has been made clear that if a delivery driver makes an inadvertent error in supplying a dispensed medicine, the defence can be made out if all of the conditions are met.

Where a delivery driver, or indeed any member of staff, purposely ignores SOPs and this leads to deleterious consequences, a due diligence defence exists in legislation whereby the RP (or supervising pharmacist) can make the case that the fault lies solely with the staff member (section 121 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?

What we proposed:

It was 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	280	204	74
%	50.2	36.6	13.3

50.2% of respondents indicated agreement to the proposal to allow the pharmacy regulators rather than ministers to set out the detail of the RP's statutory responsibilities. 36.6% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, PFNI, PSNI and RPS. The PDA indicated general disagreement to the proposal.

Where disagreement was indicated, comments suggest this was largely felt in relation to a lack of trust of the pharmacy regulators to undertake and use their proposed powers effectively. Similarly, it was suggested that professional standards should be set by professional leadership bodies not the pharmacy regulators, and that the pharmacy regulators should only regulate and enforce these standards - with an advisory body being established to scrutinise and review the standards proposed by the professional leadership bodies. It is assumed that respondents commenting with this view were meaning to refer to statutory responsibilities rather than professional standards in respect of their response to this question.

Some respondents commented that the setting of statutory responsibilities for RPs should remain with ministers – although some took the opposite view that the powers should instead be afforded to the pharmacy regulators. It was proposed by some respondents that the specific standards around length of absence from the registered pharmacy premises should remain with ministers.

Furthermore, respondents raised that should the pharmacy regulators be enabled to set the statutory responsibilities for RPs, they should be required to consult on these with the profession. It was also remarked by one respondent that any responsibilities set by the pharmacy regulators would have to be in guidance rather than standards, as the pharmacy regulators do not have the power to determine the scope and interpretation of statute – and that this is instead a matter for the courts.

The possibility of the GPhC and the PSNI going in separate directions in respect of the responsibilities they may set for RPs was queried; and the potential introduction of a new multi-professional healthcare regulator that may encompass the current regulators' role in the near future was also flagged as a requirement for consideration going forward.

It was commented that the terms of service for NHS pharmaceutical services do not align with the current RP responsibilities, in respect of allowing clinical services to be provided away from the pharmacy premises.

Our response:

We will amend legislation such that the pharmacy regulators are enabled, under the Medicines Act 1968, to set out the detail of the RP statutory responsibilities in their rules or regulations rather than ministers in regulations.

These powers will be qualified by a new duty to have regard to the principle that the burdens imposed on businesses by rules or regulations are the minimum necessary to secure the benefits expected to result from them – and by new consultation obligations. The current Ministerial regulations will be transitionally saved until the 2 pharmacy regulators have published their first rules or regulations on the matter.

Statutory responsibilities being set by the pharmacy regulators

The pharmacy professional leadership bodies play an important role in ensuring that registrants continue to develop and improve their professional skills, that pharmacists and pharmacy technicians feel supported, and that the profession continues to advance itself.

However, the pharmacy regulators are statutorily responsible for protecting the public, and giving assurance to patients that they will receive safe and effective care when using pharmacy services. As part of this, the pharmacy regulators set standards for pharmacy professionals and pharmacies to remain registered, promote professionalism and support continuous improvement, and assure the quality and safety of pharmacy. They are therefore best placed to ensure that the responsibilities of the RP fit within that wider context and provide assurance that the organisational governance arrangements in respect to RPs remain appropriate and effective. It is the pharmacy regulators which can set out the requirements for RPs through their rule or regulations and standards. Fundamental to the Rebalancing Programme is using professional regulation rather than criminal law, addressing pharmacy practice matters through pharmacy regulator powers rather than ministerial powers, which are more flexible and enable complaints to be dealt with through registrations sanctions – rather than through the criminal courts.

The professional leadership bodies, and wider, will of course have an important role to play in ensuring that the pharmacy regulators set responsibilities for RPs that work both for the profession and in the best interests of patients and the public, through engaging and providing feedback on any proposals.

In respect to the comment raising that the pharmacy regulators would have to produce guidance rather than standards, there appears to have been some misunderstanding. The proposal is to give the pharmacy regulators powers to set out RP requirements. It is not about interpreting statute.

Requirements for the pharmacy regulators to consult on proposed statutory responsibilities

The pharmacy regulators must consult on any proposed rules or regulations, including proposed statutory responsibilities for RPs, offering the opportunity for scrutiny and comment.

It was proposed that before making rules under the new powers in 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' procedure in the UK Parliament. Separately, any regulations made under section 72A by the PSNI would require consultation of appropriate persons and consultation of and approval by the Department of Health in Northern Ireland.

Differing approaches of the GPhC and PSNI to RP statutory responsibilities

There is a potential issue in the regulation of pharmacy professionals and pharmacies in general where there are 2 pharmacy regulators for the UK. The GPhC and PSNI have been consulted throughout the development of this policy and both regulators are committed to taking a collaborative approach in exercising their new powers.

NHS pharmaceutical services terms of service

These proposals are in relation to medicines legislation and pharmacy professional regulations. NHS pharmaceutical services, which are regulated separately by devolved administrations, are not within the scope of these proposals.

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?

What we proposed:

Current powers allow for an exception to the general rule that an RP can only be in charge of one pharmacy at one time, for example, to enable for example, such developments as pharmacist controlled dispensing machines.

It was proposed to replace the Ministerial regulation making power to make an exception with a pharmacy regulator rule or regulation making power to do this instead.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	74	457	27
%	13.3	81.9	4.8

Only 13.3% of respondents indicated agreement to the proposal to move from ministers to the pharmacy regulators powers to make an exception to the general rule that an RP can only be in charge of one pharmacy at a time. 81.9% of respondents indicated disagreement to this proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, PFNI, PSNI and RPS. The NPA and PDA indicated general disagreement to the proposal.

Where disagreement was indicated to the proposal, comments suggest that this was largely the case because it was felt that the proposal would lead to increased risks to patient safety, through not requiring there to be an RP present and in relation to enabling 'remote supervision', as well as this unfairly exposing pharmacists to criminal and civil prosecution and regulatory sanctions. A large number of responses received stating this reasoning were identical, and are likely to have stemmed from a coordinated campaign. Linked to this concern, some respondents argued that the unique selling point of a pharmacy is that there is always access to a pharmacist – and this should not be infringed upon.

Further to the above, multiple respondents suggested that the 'one RP for one pharmacy' rule should never be exempted and that provisions allowing for this – either by ministers or the pharmacy regulators – should be removed entirely. Related to this, it was argued that the difficulties associated with being in charge of premises on which they are not physically present would mean that the RP could not fulfil their responsibility in the case of fulfilling the role for more than one pharmacy at a time. It was also considered that there is no situation where it would be necessary for the exception to the general rule to be made.

Comments were voiced by some respondents that the pharmacy regulators were not trusted to use this power effectively; that it should be made clear that the exemption would apply in only certain exceptional circumstances – and that it would not occur regularly; and that the pharmacy regulators would consult further on the exemption. Concerns were raised by some respondents as to how far the pharmacy regulators would take the exceptions.

It was considered by some respondents that the proposed legislative requirements for the pharmacy regulators to consider minimising the costs on business in respect of any rules or regulations made by the pharmacy regulators were inappropriate, and instead that there should be a requirement for legislation to stipulate that the pharmacy regulators should be required to consider patient safety.

Several respondents' comments suggested that the example used in the consultation document of exemption potentially applying to pharmacy-controlled dispensing machines outside of the registered pharmacy was flawed.

Our response:

We will amend legislation such that the pharmacy regulators rather than ministers may use an existing power under the Medicines Act 1968 to set out an exception to the general rule that a RP may only be in charge of one pharmacy at a time. The pharmacy regulators will be able to address such matters through their rules or regulations, following the appropriate consultation and then approval from the Privy Council and Parliament.

Remote supervision

Clarification in respect of remote supervision is provided in the section on Part 2 – Question 10 of the consultation.

Exceptions to the general rule

The power to permit an exception to the general rule that an RP must hold the role for only one registered pharmacy at a time already exists in legislation. The draft order does not remove that exception from legislation and so is not part of the proposals on which we are consulting. The proposal was to move this exception-making power from ministers to the pharmacy regulators, in keeping with the general principle of rebalancing.

Should the pharmacy regulators seek to exercise the power to permit an exception, the same consultation requirements outlined above in respect to Part 2 – Question 12 would apply.

RP holding the role for more than one pharmacy at a time

Should an exception be made to the general rule, it is for an RP to decide whether they can manage their professional responsibility and undertake their role safely and effectively if they chose to do so for more than one registered pharmacy at a time.

Pharmacy regulators to consider minimising the costs on business associated with the exemption

The pharmacy regulators are required to consider the health, safety and well-being of members of the public and pharmacy users as part of their core functions. When ministers make changes to regulations they are required to consider the impacts, both costs and benefits, including on business. In moving Ministerial regulation making powers to the pharmacy regulators in making rules or regulation this

provision maintains the requirement to consider the impact on business and to be proportionate.

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?

What we proposed:

It was proposed that the duty on RPs to establish, maintain and keep the procedures, generally known as SOPs, under review is removed.

As set out in respect of Part 2 – Question 3, the accountability for establishing and maintaining SOPs was proposed to be subsumed into the general duty of SPs, with regard to the ways in which the retail pharmacy business is run. The pharmacy regulators would have the option of saying more about establishing and maintaining SOPs in standards, but it was proposed that there will be no reference to this activity in primary legislation.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	220	264	74
%	39.4	47.3	13.3

39.4% of respondents indicated agreement to the proposal for the duty on the RP to establish, maintain and keep procedures under review to be subsumed into the general duties of the SP. 47.3% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, PFNI, PSNI and RPS. The PDA indicated general disagreement to the proposal.

Where disagreement was indicated, comments suggest this is largely because it was felt that RPs should still be allowed to make changes to and revise procedures in

everyday practice, with an aim to improve patient safety, and that moving the duty to SPs would impinge on this.

Linked to the above, respondents suggested that there should be shared responsibility for procedures between SPs and RPs, and the 2 should work together to ensure procedures are appropriate. It was remarked by several respondents that the SP should ensure procedures are in place, and agree these with the RP of each pharmacy.

It was considered that each pharmacy is different and therefore it should be for the RP, who is more informed, to make decisions in respect of procedures for that pharmacy on this basis – and it should subsequently be them who has responsibility to establish, maintain and review procedures. Several respondents also argued that an RP should not be responsible for SOPs designed by someone other than themselves.

Where it was agreed that SPs should have responsibility for establishing, maintaining and reviewing procedures, it was flagged that the SP should be required to ensure staff can follow these procedures – and that any training and qualification requirements associated with achieving this are ensured by the SP.

Our response:

We will amend legislation such that in the Medicines Act 1968 the duty to establish, maintain and keep procedures under review is removed from the RP and subsumed into the general duty of the SP.

SP and RP relationship in respect to procedures

The SP is intended to be the professional lead within a body corporate and is responsible for the safe and effective running of all pharmacy premises under their control. The RP on the other hand, is the pharmacist in charge of each individual pharmacy on a given day and has a statutory duty to ensure the safe and effective running of that pharmacy.

There is interplay between the SP and RP roles, in respect to SOPs. While the proposal is that the accountability for establishing and maintaining SOPs will be subsumed in the general duty of the SPs with regard to the ways in which the retail pharmacy is run, this 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 patients, notwithstanding the SOP. It is proposed that there is no longer any specific reference to SOPs in legislation. However, the pharmacy regulators have the option of saying more about SOPs in standards, including in respect to SPs and RPs.

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?

What we proposed:

It was proposed that 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 from legislation.

The pharmacy regulators will be able to address such matters, as necessary, through their rules or 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	282	188	88
%	50.5	33.7	15.8

50.5% of respondents indicated agreement to the proposal for the pharmacy regulators to set out and enforce record keeping duties rather than Ministerial legislation. 33.7% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, PDA, PFNI, PSNI and RPS.

Comments received in respect of the proposal suggest that some respondents felt that they could not trust the pharmacy regulators to undertake and use the proposed powers effectively. If the pharmacy regulators are afforded these duties, it should be ensured that they consult on any proposed requirements.

It was the view of some respondents that these requirements should remain as currently specified in legislation; and that the links to other requirements around record keeping needed to be considered – for example legislative requirements in respect of controlled drugs.

It was also considered that the pharmacy regulators do not have ‘teeth’ to secure record keeping requirements in comparison to legislative requirements.

Our response:

We will amend legislation such that the record-keeping requirements currently set out in the Medicines Act 1968 in relation to duties on the RP and pharmacy owner are removed from legislation. The matter can then be dealt with more appropriately by the pharmacy regulators through standards.

This would result in the legal offence of contravening record-keeping requirements, in relation to duties on the RP and pharmacy owner, being removed from legislation and empower the regulators to establish such obligations under rule or regulations. The pharmacy regulators will then be enabled to enforce record-keeping requirements through fitness to practice procedures.

Requirements for the pharmacy regulators to consult on rules or regulations
Clarification in respect of the requirements of the pharmacy regulators to consult on any proposed rules or regulations is provided in the section on Part 2 – Question 12 of the consultation.

Part 2 – Question 16:

Do you agree that the pharmacy regulators should be provided with a new general rule or regulation making power in respect to the responsible pharmacist and remove the specific Ministerial regulation making powers in respect of:

the qualification and experience of responsible pharmacists

the responsible pharmacist and supervision

procedures; and

the record-keeping of the responsible pharmacist

What we proposed:

It was 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 or regulation making power for the pharmacy regulators in respect of the RP.

One of the powers it was 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 or regulations.

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 was 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 the draft order would impact upon the requirements in Part 12 of those Regulations.

Legislation also specifically provides for ministers to make regulations in respect of the RP's absence from the pharmacy (that is, 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 2 hours per day. In line with the general approach to rebalancing, amendments to legislation were proposed to enable the pharmacy regulators to address this matter in future rules or regulations.

Linked to this however, it was proposed to qualify the rule and regulation making powers of the pharmacy regulators in section 72A in 2 ways:

- to make clear on the face of the legislation that if the pharmacy regulators' rules or 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 or regulations on business and to have regard to the principle that these should be kept to a minimum, consistent with other obligations

It was proposed therefore 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 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	124	385	49
%	22.2	69.0	8.8

Only 22.2% of respondents indicated agreement to the proposal to provide the pharmacy regulators with new rule or regulation making powers in respect of the RP, and remove specific Ministerial regulation making powers in relation to RP qualification and experience, the RP and supervision, the RP and procedures and RP record-keeping. 69.0% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, NPA, PFNI, PSNI and RPS. The PDA indicated general disagreement to the proposal.

Where disagreement was indicated, comments suggest this was largely in relation to respondents feeling this proposal would lead to increases in the occurrence of remote supervision of pharmacy premises by the RP.

The above view was accompanied by concerns on how the pharmacy regulators would use any rule or regulation making powers in respect of remote supervision.

There also appeared to be some misunderstanding of the intent of the proposal (that is, respondents appeared to read the question to mean that restrictions around remote supervision were being removed rather than powers relating to the role of the RP, and not supervision, being transferred from ministers to the pharmacy regulators). Similarly, some respondents argued that the unique selling point of a pharmacy is that there is always access to a pharmacist – and this should not be infringed upon.

Alongside the concerns expressed above, it was suggested by respondents that the pharmacy regulators were not trusted to undertake and use their proposed powers effectively; and that the pharmacy regulators should only regulate and enforce rule or regulation making powers – not enact them.

Our response:

We will remove from legislation most of the express matters about which further details can be added through Ministerial regulations, in respect of the RP, and replace this with a new general rule or regulation-making power for the pharmacy regulators.

As part of this, the pharmacy regulators will be required to have regard to ensuring that GSL medicines are able to continue to be sold or supplied in the RPs absence

from the pharmacy, if they allow for the RP to be absent, and be required to consider the burden of any rules or regulations on business and to have regard to the principle that these should be kept to a minimum.

Remote supervision
Clarification in respect of remote supervision is provided in the section on Part 2 – Question 10 of the consultation.

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?

What we proposed:

It was proposed, as for SPs, 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	190	290	78
%	34.1	52.0	14.0

34.1% of respondents indicated agreement to the proposal to afford the pharmacy regulators new powers to set professional standards for RPs and describe their role. 52.0% of respondents indicated disagreement to the proposal. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, GPhC, NPA, PFNI and PSNI. The PDA and RPS indicated general disagreement to the proposal in their response – with the RPS suggesting that the pharmacy regulators should produce regulatory standards instead of professional standards.

Where disagreement was indicated, comments suggest this is because respondents felt that the professional leadership bodies should lead on the setting of professional standards for RPs rather than the pharmacy regulators – and that the regulators should only regulate and enforce these standards, with an advisory body being established to scrutinise and review the standards proposed by the professional leadership bodies. Alongside this, several respondents considered that the pharmacy regulators should collaborate with the professional leadership bodies on producing standards for RPs if they are to be the ones to set professional standards.

Respondents commented that it should be clear that the pharmacy regulators would consult on any proposed professional standards for RPs; and that any professional standards for RPs must complement those of SPs.

It was highlighted that the landscape in respect of professional standards is already detailed, and no more professional standards should be produced.

Our response:

We will amend legislation such that the Pharmacy Order 2010 as regards Great Britain and the Pharmacy (Northern Ireland) Order 1976 as regards Northern Ireland, sets out powers for the pharmacy regulators to set standards of conduct, ethics and performance for RPs. This may include detail of their professional responsibilities, and how these should be achieved.

Standards being set by the pharmacy regulators
Clarification in respect of standards being set by the pharmacy regulators is provided in the section on Part 2 – Question 8 of the consultation.

Furthermore, clarification in respect of requirements for the pharmacy regulators to consult on proposed standards is provided in the section on Part 2 – Question 8 of the consultation.

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?

What we proposed:

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.

It was 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.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	144	108	306
%	25.8	19.4	54.8

25.8% of respondents indicated agreement to the proposal 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. 19.4% of respondents indicated disagreement to the proposal, and 54.8% of respondents did not express a view. It should be noted that general agreement to the proposal was indicated by the AIMp, APTUK, CCA, PDA, PFNI and PSNI.

No comments were submitted by respondents that indicated disagreement to the proposal.

Where agreement was received, it was suggested that the proposal would be useful in ensuring the functions of the Registrar can be performed in their absence.

Our response:

We will amend legislation such that the Pharmacy (Northern Ireland) Order 1975 sets out provision in respect of the appointment of a Deputy Registrar in Northern Ireland, who 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.

What we proposed:

A proportionate economic analysis was undertaken of the costs to businesses of introducing defences for preparation and dispensing errors in hospital pharmacy services and other relevant pharmacy services.

Four central assumptions were made, and the associated estimated costs and benefits published in the consultation document. Views were sought on whether the assumptions were accurate, and whether any additional significant impacts or benefits could be identified.

The 4 central assumptions are listed below:

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

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

- 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

- 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

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	44	133	381
%	7.9	23.8	68.3

7.9% of respondents indicated that additional significant impacts or benefits could be identified in relation to the cost benefit analysis associated with the draft Pharmacy (Responsible Pharmacist, Superintendent Pharmacist etc.) Order.

Where additional evidence and or estimates were provided by respondents in response to the question, relevant comments raised that consideration should be given to:

- Costs to the professional leadership bodies and others of informing and publicising changes to legislation

- Familiarisation costs associated with the whole pharmacy team in respect of RP and SP changes, not just pharmacists

- Increased employment costs associated with the increased responsibility proposed for RPs and SPs

- Increased employment costs associated with the responsibility of the RP being extended to 'from' the registered pharmacy

- Increased employment costs associated with the RP working for more than one pharmacy at a time

- Increased potential costs associated with increases in indemnity insurance premiums for RPs working for more than one pharmacy at a time

- The assumption that benefits can be gleaned in relation to the RP working at more than one pharmacy at a time being inaccurate

- The costs associated with remote supervision

- The registration fees of the pharmacy regulators and how these may change in the future

Our response:

Following consideration of the evidence presented to us during the consultation, and in line with taking a proportionate approach to estimating the cost-benefits associated with these policies, we do not intend to update our assessment on the cost-benefit impacts of this policy.

Part 2 – Question 20:

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

What we proposed:

An assessment of the impact of these proposals on equality was produced and published alongside the consultation document. Views were sought on whether any additional information could be considered in relation to how the proposals may impact on equality, both in relation to patients and public who use pharmacy services and pharmacy teams providing pharmacy services.

What we heard:

Responses	Agree	Disagree	Not answered or not indicated
Number	20	226	312
%	3.6	40.5	55.9

3.6% of respondents indicated that additional evidence could be considered in relation to the assessment of the impact of this policy on equality.

Where additional evidence was provided by respondents in response to the question, comments suggested that consideration should be given to the impact on the equality protected characteristics, including:

- Applying the assessment of the impact of equality of these proposals to pharmacy technicians

- The current working conditions of pharmacy professionals

- The proportion of people from ethnic minority backgrounds in senior positions within the pharmacy profession

Our response:

Following consideration of the evidence presented to us during the consultation, we do not intend to update our assessment of the impact of this policy on equality.

Next steps

Following consideration of the consultation responses and deliberation by the Rebalancing Programme Board, the department has agreed the amendments to the draft RP and SP Order in respect of the removal of ‘handled’ from the legal drafting setting out when an RP must be in charge of the pharmacy.

Subject to approval by ministers and Parliamentary time, the draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 and the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 together with this report on the consultation will be laid before the UK Parliament in accordance with the affirmative resolution procedure.

Annex A: Breakdown of consultation respondents (by category, as self-recorded on consultation response)

Type of respondent	Number of respondents
Charity or third sector	1
Government or civil service	2
NHS or health service delivery	482
Other	23
Other public sector	10
Private sector	71
Regulatory or professional or representative body	13
Retired	3
Student	18
Not answered	9

Annex B: Organisations that responded to the consultation (as self-recorded on consultation response)

- AIMp Ltd (Association of Independent Multiple Pharmacies)
- Association of Pharmacy Technicians United Kingdom
- Becton Dickinson
- BLM
- Bolton CCG
- Care Quality Commission
- Celesio UK
- Chief Pharmacist Group of NHS Wales
- Community Pharmacy Lincolnshire
- Community Pharmacy Northern Ireland
- Community Pharmacy Scotland
- Community Pharmacy South Central
- Community Pharmacy Wales
- Company Chemists' Association
- Cononbridge Pharmacy Ltd and Cill Chuimein Pharmacy Ltd (joint)
- Director of Pharmacy group for Scotland
- Dispensing Doctors' Association
- The University of Manchester (Division of Pharmacy and Optometry – School of Health Sciences)

- Dmpharma
- General Pharmaceutical Council
- Greater Manchester Local Pharmaceutical Committee
- Guild of Healthcare Pharmacists
- Guy's and St Thomas' NHS Foundation Trust
- Health Education England
- Kent LPC
- King's College Hospital
- L. Rowland and Co (Retail) Ltd - Rowlands Pharmacy
- London Chief Pharmacists' Network
- MediCare Pharmacy Group, Northern Ireland
- National Pharmacy Association
- National Pharmacy Technician Group Scotland
- NHS City & Hackney CCG
- NHS England
- NHS Grampian Area Pharmaceutical Committee
- NHS Pharmaceutical Quality Assurance Committee
- NHS Pharmacy Production Committee
- Numark Ltd
- Pharmaceutical Services Negotiating Committee
- Pharmaceutical Society of Northern Ireland
- Pharmacy Eastern Network
- Pharmacy Forum of Northern Ireland

- Pharmacy Law & Ethics Association
- Professional Standards Agency
- Queen's Hospital
- Royal College of Physicians
- Royal National Orthopaedic Hospital NHS Trust
- Royal Pharmaceutical Society
- Semcare Pharmacy Ltd
- South of England Mental Health Chief Pharmacists'
- South West London & St George's Mental Health Trust
- The Pharmacists' Defence Association
- UK Radiopharmacy Group
- University Hospital Southampton NHS Foundation Trust
- Welsh Pharmaceutical Committee