



Supervision in community pharmacy

Recommendations from the Supervision Practice Group



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Report summary

Community pharmacy is evolving, with an enhanced role in the care of patients and the health system. The Supervision Practice Group (a group of community pharmacy, pharmacist and pharmacy technician representative organisations) have held a series of workshops to discuss how this policy meets practice, and how legislation, regulatory rules and standards, and professional standards and guidance can facilitate this changing role. The aim is to enable enhanced patient access to the pharmacist while improving safety. This report summarises our discussions that have taken place through a series of facilitated workshops.

What is the current community pharmacy context?

Current primary and secondary legislation states that the preparation, assembly, sale and supply of medicines must be conducted under the “supervision” of a pharmacist. The current interpretation of the supporting case law requires pharmacists to supervise individual transactions. Whilst pharmacists are focussed on medicines supply, and this remains a core role, there is a policy shift to make the pharmacist more available to provide pharmaceutical care to their patients and to support the wider aims of the health system.

What is the future vision for community pharmacy?

The Supervision Practice Group first discussed a vision for community pharmacy to provide a framework for our discussions. The concepts below have guided our discussions and helped the group to contextualise our work within the bigger picture of future community pharmacy practice.

- Changes to the law must enhance patient experience and improve safety
- Community pharmacy must be enabled to provide care that is more holistic and integrated within the NHS
- Community pharmacy should have the opportunity to fully utilise technology to deliver safe, effective and efficient care for patients
- Changes to the law must recognise the skill mix required to deliver high-quality, person-centred care
- Community pharmacy must be an attractive and progressive career option for the whole pharmacy team
- Changes to the law must enable innovations in practice and care delivery

What did the Supervision Practice Group discuss?

Over the course of nine collaborative and positive workshop-style discussions the Supervision Practice Group covered the following topics with the aim of reframing legislation, regulatory rules and standards, and professional standards and guidance to achieve the vision outlined above.

- How can the legislation and regulatory rules and standards underpinning community pharmacy practice support our vision?
- Accountability, responsibility and delegation
 - Why is it important to consider these concepts?
 - What do they look like in practice?
 - What do they enable in future practice?

- Absence from the pharmacy premises
- Future practice – how do we future proof our recommendations?

What was the output from our discussions?

The whole group identified that the physical presence of the pharmacist in the pharmacy was an important and defining element of community pharmacy. It was important to all participating organisations that the pharmacist should be more accessible to patients and the public as a result of changes to legislation and regulatory rules and standards.

The NPA, PDA, PFNI & RPS felt that primary legislation should be amended to include a definition of “supervision” that required the physical presence of the pharmacist (for reasons explained in the report). AIMP, APTUK & CCA felt that including it in either secondary legislation, regulatory rules and standards, and/or professional standards and guidance would be more appropriate (for reasons explained in the report).

The whole group agreed that whilst the pharmacist should be present in the pharmacy and accessible to patients and the public, legislation should be clarified to reflect that “supervision” should no longer be interpreted to mean supervising individual transactions. Both the superintendent pharmacist (SP), who takes responsibility for the way in which a company carries out its professional pharmaceutical activities, and the responsible pharmacist (RP), whose role is to secure the safe and effective running of the pharmacy when they are signed in, must exercise professional oversight of the preparation, assembly, sale and supply of medicines to the extent required in legislation and be accountable for their actions while performing their distinct functions.

There may be situations that necessitate the RP’s absence from the pharmacy premises. The group agreed that these situations should be temporary and only where the benefits of absence outweigh the risks. Where absence is necessary, the group agreed clear delegation and mechanisms be put in place to enable continued access to the pharmacist and some pharmacy services (including certain medicines) which it is deemed safe to provide in their absence, subject to additional risk management measures being in place. There was a consensus that the two-hour time limit for absence should remain. It was recognised that even though this is defined in legislation, there is scope to change it in the future if practice requires, as this is now in the control of the GPhC/PSNI.

In relation to delegation, the group agreed that legislation should be amended to enable aspects of the preparation, assembly, sale and supply of medicines to be delegated in defined circumstances from the RP to appropriate members of the pharmacy team (including pharmacy technicians). The group agreed that it must be clear who has the power to delegate and to whom they can delegate. It must be a two-way conversation and the accountability for the delegated activity must be clear to all.

Finally, it was agreed that legislation be amended to enable the preparation and assembly of medicines to take place outside the opening hours of the pharmacy without a RP being signed in, with accountability for dispensing accuracy resting with SP. This was in recognition that this is associated with a lower risk profile providing the lines of accountability for those prescriptions prepared or assembled out-of-hours is clear. When the RP is signed in, they will be responsible for assessing the professional and clinical appropriateness and

assume accountability for the *clinical safety* of medicines prepared and assembled out-of-hours.

What happens next?

Our recommendations provide a framework on which the Department of Health and Social Care and the regulators can draft specifically worded revisions to legislation and regulatory rules and standards. These legislative and regulatory changes that are proposed by government and regulators will be subject to a full consultation process. Professional standards and guidance will then be updated to reflect these changes and provide further support to pharmacists and pharmacy technicians.

We would encourage all colleagues to read the whole document to understand our discussions and reasoning for the recommendations made above. We hope that this document will inform individual responses to the forthcoming consultations.

1.0 Introduction

This report represents the discussions surrounding “supervision” that have taken place between community pharmacy, pharmacist and pharmacy technician representative organisations (see appendix 1 for list) between December 2022 and July 2023. The Department of Health and Social Care (DHSC), General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI) were present as observers for all discussions.

Dr Michael Twigg, Associate Professor of Primary Care Pharmacy, University of East Anglia and Head of Research Design and Evaluation, NHS Norfolk and Waveney, was asked in Autumn 2022 to Chair the group and facilitate discussions. Carolyn Ruston, Policy Director, Association of Optometrists was asked to provide the secretariat. An outline of the topics discussed at each workshop are listed in appendix 1.

Discussions were positive, collaborative and focussed on a need to find solutions that centred on enhancing patient experience, improving safety, enabling the community pharmacy workforce to maximise their skills and professional roles and promoting integration within the wider NHS. Discussions also strongly focussed upon the need for pharmacy teams to be available to deliver a new and exciting range of increasingly clinical services to include independent prescribing by pharmacists. Consequently, the group discussed ways in which the public expectation of pharmacist availability in a community pharmacy setting could be achieved and that they are empowered to play an ever-increasing role in the community pharmacy as part of the multi-disciplinary health care team. The group recognised the importance of ensuring that all members of the pharmacy team are available to the public within their scope of practice to ensure patients are supported appropriately.

This report starts by providing an overview of the law relating to “supervision” followed by a brief explanation of why it was necessary to convene this group at this time. The report then outlines a group vision for community pharmacy practice that helped to provide a framework for our discussions. Finally, key recommendations are described for consideration. The group was invited to share their recommendations with the DHSC and the pharmacy regulators. The DHSC, GPhC and PSNI will consult broadly on their interpretation of these recommendations and the implications for legislative and regulatory changes.

The report represents a collaborative effort from all participating organisations. This is not a report that has been written solely by the Chair but one that has been co-produced with each organisation contributing text to the final document. Whilst complete agreement amongst the contributing organisations could not always be established, it seeks to accurately reflect the views of the pharmacy bodies that participated in the workshops and to articulate a consensus position.

2.0 The current community pharmacy context

This section outlines the law on “supervision” and goes on to discuss why it is important to review this now in the context of current and future community pharmacy practice.

2.1 The law relating to “supervision”

Historically, there has been a requirement for certain medicines to be sold only by, or under the supervision of, a pharmacist. This was the form of words used in section 18 of the Pharmacy and Poisons Act 1933. This requirement came to be considered by the courts in two cases:

- Roberts v Littlewoods Mail Order Stores and Pharmaceutical Society v Boots Cash Chemists (Southern) Limited (1943).
- Pharmaceutical Society v Boots Cash Chemists (Southern) Limited (1953).

In summary, the effect of the judgments in these cases was that “supervision” in the 1933 Act required a pharmacist to know what was being sold (supervise each transaction) and be in a position to intervene to prevent a sale, if needed. The wording of the legislation has evolved over the decades with the Pharmacy and Poisons Act 1933 replaced by the Medicines Act 1968 and then largely replicated in the Human Medicines Regulations 2012. The current legislative position is described below. This is not a detailed list but a summary of the main primary and secondary legislation in force in July 2023.

Medicines Act 1968

Section 69 of the Medicines Act 1968 provides that a retail pharmacy business may only be carried on by a pharmacist, a partnership of pharmacists or a body corporate.

Each premises where the retail pharmacy business is carried on and medicinal products (other than medicinal products on a general sale list) are sold or supplied must have a responsible pharmacist in charge of those premises (sections 70 and 71 of the Medicines Act 1968). Currently, Section 72A of the Medicines Act 1968 reads:

“72A The responsible pharmacist

(A1) Nothing in this Part is to be taken as requiring there to be a responsible pharmacist in respect of premises at or from which a retail pharmacy business is carried on at a time when no medicinal products (whether they are on a general sale list or not) are being—

- (a) offered or exposed for sale by retail or supply in circumstances corresponding to retail sale at or from the premises, or
- (b) assembled, prepared or dispensed at or from the premises with a view to such sale or supply.

(1) It is the duty of the responsible pharmacist mentioned in sections 70, 71 and 72 of this Act to secure the safe and effective running of the pharmacy business carried on at or from the premises in question so far as concerns—

- (a) the retail sale at or from those premises of medicinal products (whether they are on a general sale list or not), and
- (b) the supply at or from those premises of such products in circumstances corresponding to retail sale.

(2) A person may not be the responsible pharmacist in respect of more than one set of premises at the same time, except in circumstances specified by the General Pharmaceutical Council in rules in relation to premises in Great Britain or the Council of the Pharmaceutical Society of Northern Ireland in regulations in relation to premises in Northern Ireland, and then only if such conditions as may be so specified are complied with.”

In essence, this section means that a responsible pharmacist must be signed in whenever certain medicines are being prepared, assembled, sold or supplied and that their duty is to ensure the safe and effective operation of the business. The effect of this is to imply that when a RP is not signed in, the registered pharmacy must remain closed to the public. This section was updated significantly in 2022 with The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 in which the power to make changes to the rules surrounding responsible pharmacists was moved from Ministers to the GPhC and PSNI.

The concept of “supervision” is also referenced in Section 10 of the Act in relation to the preparation and assembly of medicines which must be undertaken under the supervision of a pharmacist.

Human Medicines Regulations 2012

Section 220, a direct replication from Section 52 of the Medicines Act 1968, reads:

“220.— (1) Unless paragraph (2) applies, a person (“P”) may not sell or supply, or offer for sale or supply, a medicinal product that is not subject to general sale.

(2) This paragraph applies if—

- (a) P is a person lawfully conducting a retail pharmacy business;
- (b) the product is sold, supplied, or offered for sale or supply, on premises that are a registered pharmacy; and
- (c) P or, if the transaction is carried out on P’s behalf by another person, that other person is, or acts under the supervision of, a pharmacist.”

The courts have not been asked to consider the meaning of the requirement for “supervision” based on the wording in either section 52 of the Medicines Act 1968 or regulation 220 of the Human Medicines Regulations 2012. Even though Parliament chose to adopt different wording in the Medicines Act 1968 to the wording of the 1933 Act, an assumption appears to have been made over the years that the 1943 and 1953 cases are still applicable. In the absence of further court rulings on the subject of “supervision”, treating the 1943 and 1953 rulings as if they were applicable in the current legislative and professional context has a potentially constraining effect on community pharmacy practice.

Other relevant legislation and guidance

In addition to the Medicines Act 1968 and Human Medicines Regulations 2012, further reference is made to “supervision” in the various NHS Terms of Service from each of the UK’s constituent countries.

The relevant section of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (England-only) reads:

“Providing ordered drugs or appliances

8.—(1) Where an NHS pharmacist (P) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, P must only provide the drugs or appliances so ordered—

...

(2) Drugs or appliances so ordered shall be provided either by or under the direct supervision of a registered pharmacist.”

In Scotland, this reference occurs through the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009:

“Dispensing of medicines

7.—(1) The dispensing of medicines shall be performed either by or under the direct supervision of a pharmacist.”

In Wales, through the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020:

“Providing ordered drugs or appliances

9.—(1) Where an NHS pharmacist is presented with a prescription form or a repeatable prescription, the NHS pharmacist must only provide the drugs or appliances so ordered—

...

(2) Drugs or appliances so ordered must be provided either by or under the direct supervision of a registered pharmacist.”

In Northern Ireland, through the Pharmaceutical Services Regulations (Northern Ireland) 1997:

“Supply of drugs and fitting of appliances

5. - (1) Drugs shall be supplied either by or under the direct supervision of a pharmacist.”

On a UK wide basis, there is a further legislative anomaly. Although the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 expressly permit the responsible pharmacist to be absent from the premises for up to two hours a day, a range of activities to include the sale of P medicines and the handing out of pre-checked and bagged prescription medicines from the pharmacy in their temporary absence, are not permitted, unless another pharmacist is present on the premises.

In 2005, The Royal Pharmaceutical Society of Great Britain (at the time the combined regulator and professional body) issued guidance in the form of a Law and Ethics Bulletin which stated “If a pharmacist is involved in a consultation with a patient in a private area or room of a registered pharmacy premises, pharmacy medicines can be sold and dispensed prescriptions that have been checked for clinical appropriateness and accuracy can be supplied, provided that robust standard operating procedures are in place. The pharmacist will still have professional responsibility for any sales or supplies of medicines that take place

while they are involved in the consultation and it is essential the SOPs clearly identify when a pharmacist's intervention in such medicine sales or supplies is required and that systems provide for this intervention."

Interaction between legislation, regulatory rules and standards, and professional standards and guidance

The interaction between the legislation, regulatory rules and standards, and professional standards and guidance can often be confusing. The diagram below describes how legislation works with regulatory rules and standards and professional standards and guidance to ensure high quality patient and public outcomes and experience. Legislation is found in the Medicines Act 1968 and the Human Medicines Regulations 2012 (described above), regulatory rules and standards emanate from the rules, standards and guidance produced by the GPhC and PSNI with professional standards and guidance being delivered by the professional bodies. The underpinning principle behind the "onion" is one in which the further you move towards the patient at the centre, the more detailed it becomes i.e. legislation provides a broad framework with professional guidance providing detailed examples and interpretation that can be more readily updated as practice advances.



Figure 1: The pharmacy "onion"

2.2 The importance of "supervision" in the context of current and future practice

From the legal precedent test cases, the view of "supervision" has been that a pharmacist must directly observe the preparation, assembly, sale and supply of all pharmacy-only (P) and prescription-only (POM) medicines. The current *regulatory* framework argues that whilst a pharmacist should be physically present in the pharmacy, they are not required to involve themselves in each individual transaction. This is something that is not explicit in primary or secondary legislation or from the current case law.

The context in which pharmacy teams operate has changed significantly since the 1968 Act and 2012 Regulations. In 2023, compounding in a community pharmacy is no longer undertaken and pharmacists have rightly come to rely on the supplies of original packs that they receive from the wholesaler. Additionally, since 1968, community pharmacy has embraced technological advances, expanded the workforce and has had the benefit of the

introduction and regulation of pharmacy technicians¹. The workload has also increased significantly over this time period with community pharmacies now dispensing in excess of one billion prescription items per year.

The significant contextual changes to the operation of community pharmacy and the 'modern needs' of the public brought about by polypharmacy and an ageing population means there is now a need to reconsider the meaning of "supervision" and its impact on the care of patients and professional practice. If this could be achieved, it would be beneficial for the public, the NHS and the profession.

Over the last 20 years there has been significant discussion about the changing role of pharmacists and embracing the skills and expertise of other members of the pharmacy team. The overarching aim of this is to enable the pharmacist to provide a much more ambitious and necessary role in a wider range of clinical and patient facing services related to pharmaceutical care and their unique skills around medicines.

¹ Terminology surrounding pharmacy technicians. Pharmacy technicians are part of the pharmacy team in all countries of the United Kingdom. However, they are only a registered professional in England, Wales and Scotland (General Pharmaceutical Council). In Northern Ireland, pharmacy technicians are not registered at present and therefore it is important throughout the report to make it explicit when referring to registered/non-registered professionals as this has an impact on concepts such as accountability.

3.0 Our future vision for community pharmacy

Whilst it is important to maintain the protections to the public that are delivered by the Medicines Act 1968 (and subsequent Regulations) it is evident that a forward-looking view of community pharmacy practice should be considered. This should go beyond consideration of what current practice should or should not be permitted in the physical presence or absence of the pharmacist. It should consider what legal and regulatory framework could deliver the benefit of holistic pharmaceutical care (not just focussed on medicines supply but also the appropriate use of medicines); with pharmacists and their teams seeking to ensure that medicines exert a beneficial effect on patients. Consequently, the role of pharmacists as the experts in medicines is an important objective of the Supervision Practice Group. This review is an opportunity to consider how the future of pharmacy practice with regards to pharmaceutical care could be supported by updated legislation and regulatory rules and standards.

At the outset of our discussions, the group agreed to describe a vision for community pharmacy in 10-15 years' time to provide a framework for our conversations. The vision described below is not intended to replace other visions/roadmaps that have been articulated by various organisations (including those part of this group) over recent years. The concepts below have guided our discussions and helped the group to contextualise our work within the bigger picture of future community pharmacy practice.

Changes to the law must enhance patient experience and improve safety

Community pharmacy teams already provide a high-quality, safe environment for patients and members of the public. The group recognised at the outset of our discussions that any changes to legislation, regulatory rules and standards, and professional standards and guidance must not just maintain, but enhance, patient experience and satisfaction. Additionally, with approximately 7% of hospital admissions related to medicines harm, it was central to our discussions that the issue of medicines use and safety be improved as a result of our proposals.

Community pharmacy teams must be enabled to provide care that is more holistic and integrated within the NHS

Community pharmacies are recognised across the NHS as an integral part of primary care provision. Relationships with primary care colleagues are constructive and support seamless person-centred care. These relationships are enhanced by the integration of commissioned services into community pharmacy; working with patients to support them with their long-term condition management and providing acute care for minor illnesses.

Community pharmacy should have the opportunity to fully utilise technology to deliver safe, effective and efficient care for patients

Technology will be deployed to streamline operational and clinical workflows, enhancing safety and enabling pharmacists and pharmacy technicians to deliver more patient-facing care. Digital systems will readily interface, allowing teams to provide patients with safe and seamless access to healthcare across the NHS. Accessible and secure digital communications will support greater access for patients, at locations and times that best suit them.

Changes to the law must recognise the skill mix required to deliver high-quality, person-centred care

The physical presence of the responsible pharmacist in the pharmacy is key to their role, as ultimately, they are accountable for the safe and effective operation of the pharmacy. Within this, the responsible pharmacist should be able to delegate tasks to members of their team. The lines of accountability for such delegation should be clear to all members of the pharmacy team.

Community pharmacy must be an attractive and progressive career option for the whole pharmacy team

Community pharmacy should have plenty to offer both pharmacists and pharmacy technicians in terms of job satisfaction and professional fulfilment. It should also offer a rewarding and interesting career for other members of the pharmacy team. Through skill mix and working in a collegiate fashion to address the needs of patients, the supply of medicines to the public continues to be a core service whilst at the same time the pharmaceutical care of patients is significantly developed.

Changes to the law must enable innovations in practice and care delivery

Community pharmacies will have the capacity and capability to engage in innovation and have access to mentorship and training as well as having protected time for such activities. Ultimately, the innovation that pharmacists and pharmacy technicians explore will inform future practice and ensure that high-quality, cutting-edge care is at the heart of community pharmacy.

4.0 Recommendations from the Supervision Practice Group

4.1 Overview

Currently, legislation provides safeguards in terms of medicines preparation, assembly, sale and supply, but it does not focus upon the safe *use* of medicines. It does not facilitate the exciting possibilities offered by future innovation and technology in enabling the development of pharmaceutical care in community pharmacy. The group believes that any changes to legislation must continue to prioritise patient safety, enhance the delivery of pharmaceutical care and at the same time be responsive to patients' and health system needs.

If the profession has an ambition to adapt and evolve in the future, to take advantage of a developing healthcare landscape, then legislation needs to be enabling. In the context of "supervision" this means that in most cases legislation should define principles with regulatory rules and standards and professional standards and guidance providing the detail. No one can fully predict how pharmaceutical care will be delivered in a community pharmacy in the future, but our group aims to identify the guiding principles to make this a reality.

There is an expectation amongst the public that they can find a pharmacist in the community pharmacy. In the future, community pharmacists will be independent prescribers and the public will inevitably need even greater access as they will require them to assess their condition and prescribe medicines. Throughout its work, the whole group was keen to ensure that any changes in legislation had the effect of making the pharmacist more available to the public in a community pharmacy than is currently the case.

At this stage, we do not know whether this will lead to there being more than one pharmacist working in each pharmacy; although this was something that the group discussed as an aspirational possibility. Regardless, the capacity and capability of the whole pharmacy team will need to be comprehensively developed so that the availability of services in a community pharmacy can be increased. For pharmacy technicians in community pharmacy, this is an opportunity for a greater level of professional recognition and with it comes added responsibility and accountability. It is also an opportunity to strengthen training and competencies for the rest of the pharmacy team and to involve them in a more comprehensive range of activities.

4.2 Recommendations relating to "supervision" specifically

The whole group identified that the physical presence of the pharmacist in the pharmacy was an important and defining element of community pharmacy to ensure the safe and effective operation of the pharmacy. The group agreed that current references to "supervision" in legislation, regulatory rules and standards, and professional standards and guidance alongside the NHS contractual frameworks need to be reviewed and aligned in the context of future practice.

All agreed that both the superintendent pharmacist (SP), who takes responsibility for the way in which a company carries out its professional pharmaceutical activities, and the responsible pharmacist (RP), whose role is to secure the safe and effective running of the pharmacy when they are signed in, must exercise professional oversight of the preparation, assembly, sale and supply of medicines to the extent required in legislation and be accountable for their actions while performing their distinct functions.

One of the problems that was identified very early on in our discussions was that because “supervision” was not defined in legislation, it meant that a number of historic test cases were, in effect, providing the current interpretation. This was based on the premise that there was a requirement to supervise each individual transaction. The whole group agreed that this was no longer suitable for modern practice. The whole group agreed that whilst the pharmacist should be present in the pharmacy and accessible to patients and the public, primary and secondary legislation should be clarified to reflect that “supervision” should no longer be interpreted to mean supervising individual transactions. A clarifying statement or direction in legislation or regulatory rules and standards to remove the case law precedent would be a helpful step forward.

The group understands that the requirement for the physical presence of the pharmacist is already identified in various places in legislation and regulatory rules and standards. However, physical presence is not mentioned within the specific context of defining “supervision”. To provide clarity on the role of the pharmacist in relation to “supervision”, there was consensus that “supervision” requires a pharmacist to be present in the pharmacy.

The National Pharmacy Association (NPA), Pharmacists’ Defence Association (PDA), Pharmacy Forum of Northern Ireland (PFNI) and Royal Pharmaceutical Society (RPS) felt that primary legislation should be amended to include this definition of “supervision” and also require the physical presence of the pharmacist. This would not only deal with the outdated concept of supervision and remove the previous case law precedent but importantly make it clear to all pharmacists, employers and patients that the community pharmacy is the place in which a pharmacist should be found. Embedding this concept in the Medicines Act 1968 would give confidence to pharmacists and the public in the future and inform the nature and style of commissioning going forward. Any future innovation and technological advances such as artificial intelligence, would then be developed to beneficially support (rather than replace) pharmacists in their face-to-face dealings with the public and in their delivery of pharmaceutical care. Secondary legislation and regulatory rules and standards would continue to have the agility to be reviewed and respond to changes in practice and define the exceptions to primary legislation.

The Association of Independent Multiple Pharmacies (AIMP), Association of Pharmacy Technicians UK (APTUK) and Company Chemists’ Association (CCA) felt that including the concept of physical presence in either secondary legislation, regulatory rules and standards and/or professional standards and guidance would be more appropriate to enable future innovation. These organisations felt that if the physical presence of the pharmacist was already a requirement in the Human Medicines Regulations 2012, then an additional reference in the Medicines Act 1968 was not necessary, and if it did occur it could restrict flexibility in the future as making changes to primary legislation would be difficult. As practice evolves, supported by technology, and that technology becomes peer reviewed, widely accepted and regulated, seeking to amend regulatory rules and standards as opposed to amending primary legislation, feels more appropriate. This, more iterative approach, will create more opportunities for pharmacists, pharmacy technicians and pharmacies in the future and would bring pharmacists in line with other professionals.

4.3 Recommendations relating to the temporary absence of the RP

The group agreed that the default expectation should be that the RP is present to ensure the pharmacy is operating safely and effectively. It was recognised that the absence of a pharmacist from a community pharmacy increases risk (particularly in relation to sale and supply of medicines). There will be situations where the RP needs to be absent and it was felt that certain activities should be allowed to continue for the duration of their absence. The group agreed that the following questions were important for RPs to justify their absence from the pharmacy:

- Has the RP made a professional decision that an absence is necessary for a defined, and limited, period of time?
- Is the risk of absence less than the risk of physical presence? Such as when fatigue requires a rest break to be taken.
- Is it temporary or sustained?
- Are there appropriate risk management processes in place to facilitate absence, including ensuring the continued provision of patient care and access to a pharmacist?

The group agreed that these situations should be temporary and where the benefits of absence outweigh the risks. Where absence is necessary, the group agreed clear delegation and mechanisms be put in place to enable continued access to the pharmacist and some pharmacy services (including certain medicines) which it is deemed safe to provide in their absence, subject to additional risk management measures being in place. The group discussed the need for the decision regarding absence to be undertaken by only the RP and that it can only be taken once they are signed in; it cannot be undertaken retrospectively. It was discussed that only the RP can decide what activities are undertaken in their absence and that this must be a two-way conversation between the RP and those remaining in the pharmacy.

In terms of what could take place in the absence of the RP, the group discussed the supply of checked and bagged prescriptions and agreed that those assessed as professionally and clinically appropriate by the RP and not requiring a further pharmacist intervention, could be given to the patient in their absence. Those requiring a further pharmacist intervention must not be supplied until the RP has returned. This is a risk-based decision undertaken by the RP at the time of assessing the professional and clinical appropriateness.

In relation to the supply of P medicines, the group agreed that further work would need to be undertaken in consultation with the Medicines and Healthcare Products Regulatory Authority (MHRA). This was discussed as a large and wide-ranging subject area that required in-depth discussion and debate to consider the ramifications for various future scenarios. That discussion is outside the remit of the Supervision Practice Group in the time available.

There was a consensus that the two-hour time limit for absence should remain. It was recognised that even though this is defined in legislation, there is scope to change it in the future, if practice requires, as this is now in the control of the GPhC/PSNI.

4.4 Recommendations relating to delegation

There was consensus amongst organisations that pharmacy technicians and other pharmacy team members should be enabled to play a greater role in the preparation, assembly, sale and supply of medicines thereby releasing pharmacist time to undertake a wider range of pharmaceutical care services. This should be achieved through the formal delegation of tasks.

The group agreed that aspects of the preparation, assembly, sale and supply of medicines could be delegated in defined circumstances from the RP to any member of the pharmacy team. The group agreed that it must be clear who has the power to delegate and to whom they can delegate. It must be a two-way conversation and the accountability for the delegated activity must be clear to all.

The extent of accountability is an important concept the group felt it was important to clarify. If the RP delegates a task to a registered pharmacy technician or another pharmacist, then accountability for that task should follow. Where RPs are delegating tasks to non-registered pharmacy team members, the accountability for that task remains with the RP. It was also an important feature of our discussions that a person accepting the delegation must be confident, competent and willing to do so. Delegation must be a two-way conversation and not something that is imposed by the RP.

Professional guidance to support professionals with this approach to delegation should be produced by the professional leadership bodies.

4.5 Recommendations relating to when a RP is not signed in

When a RP is signed in and the pharmacy is therefore open to the public (and involved in the preparation, assembly, sale and supply of medicines) it is the RP who remains responsible and accountable for the safe and effective operation of the pharmacy. This involves accountability for the accuracy check and assessing the professional and clinical appropriateness of prescriptions. It is fully anticipated that some activities, primarily related to preparation and assembly, will be delegated to suitable pharmacy team members (as outlined above) or be delivered through reliance upon automation.

As stated above, section 72A of the Medicines Act 1968 effectively implies that a pharmacy must be closed to the public when a RP is not signed in. Currently, in situations where the RP is not signed in, the preparation, assembly, sale and supply of medicines cannot take place.

The group discussed that the inherent risks seen in a pharmacy when it is closed to the public are far lower than when it is open. In such a situation the group proposes that preparation and assembly could be undertaken without an RP being signed in, but instead under the supervision of an absent superintendent pharmacist (SP). Such activity could be undertaken by suitably qualified staff or by reliance on automation.

Under such an arrangement, the responsibility and accountability for the accuracy of the preparation and assembly would rest with the SP. The advantage of such a proposal is that there is a much greater probability that the SP can put in place suitable structural arrangements in the pharmacy than an RP who might be covering an out-of-hours

pharmacy. The SP is much better positioned within the business than the RP to put in place the most appropriate solutions and in turn this further reduces the operational risks. They are more able to make decisions on the correct staffing levels, the quality of the dispensing robot as well as the overall training and competency levels of the staff, for example.

When the RP signs in again, the pharmacy would revert to business as usual, with the RP taking responsibility and accountability for the preparation, assembly, sale and supply of prescriptions that come in whilst signed on and therefore open to the public. When an RP is signed in and assesses the professional and clinical appropriateness of medicines prepared and assembled under the SP's oversight, they will assume accountability only for the *clinical safety* of those medicines. They will not assume the responsibility for the accuracy of those medicines (the SP retains this accountability). Importantly, this proposal relies on a robust process to be able to identify which medicines had been assembled under the SPs oversight (when the RP is not signed in) and which under the RPs oversight (assembled whilst they were signed on) as this information would be needed to hold to account the right individual in the event of a dispensing error.

As part of this proposal, it is also important to provide the opportunity for the SP to delegate tasks when the RP is not signed in, if appropriate. If the SP delegates a task to a registered pharmacy technician or another pharmacist in the pharmacy, then accountability for that task should follow. Where SPs are delegating tasks to non-registered pharmacy team members or relying on automation, the accountability for that task remains with the SP. As discussed above, it was also an important feature of our discussions that a person accepting the delegation must be confident, competent and willing to do so. The group recognised that the SP should be able to delegate to a deputy or suitably qualified registrant to cover for situations like holidays or sickness. That person, like the SP, could be outside of the pharmacy. It is expected that the SP will establish a framework for such delegation to ensure it is clear to what extent and to whom various tasks are delegated.

5.0 Conclusions

Our recommendations provide a framework on which the Department of and Social Care and the regulators can draft specifically worded revisions to legislation and regulatory rules and standards. These specific legislative and regulatory changes that are proposed by government and regulators will be subject to a full consultation process. Professional standards and guidance can then be updated to reflect these changes and provide further support to pharmacists and pharmacy technicians.

Throughout this process, discussions between the organisations have remained positive, collaborative and focussed on finding a consensus way forward. All organisations have shown a pragmatic willingness to engage in the conversations and have recognised that with the nature of collective work involving those representing differing memberships and mindsets, they would never reach a position which represents 100% of what they would like to see. At all times, views have been respected and challenged in a constructive manner.

The whole group agree on the vast majority of recommendations, and we have articulated throughout the report how these will benefit patient care, the NHS and the community pharmacy profession. Where different opinions have been voiced, these have also been described in a way that the reader can follow the differing approaches. We hope that this document provides further detail of our discussions to inform individual responses to the respective consultations.

Note of thanks from the Chair

I would like to thank all organisations for their commitment to this process and the honesty with which they have approached the discussions and their interaction with Carolyn and me. When faced with an alternative viewpoint, all organisations have worked together to find a way forward in the spirit of collaboration. This report would not have been possible without this commitment to build a positive future for community pharmacy practice.

Appendix 1: Approach to discussions

Once appointed the Chair explained that his role was to facilitate discussions and not bring a particular perspective to the discussions. For context, the Chair is a registered pharmacist but no longer practices in community pharmacy. Each of the group sessions were framed as workshops in order to facilitate collaboration and understanding. As such, minutes were not taken.

Membership

The Supervision Practice Group is made up of the following members:

Association Independent Multiple Pharmacies (AIMP)
Association of Pharmacy Technicians UK (APTUK)
Company Chemists' Association (CCA)
National Pharmacy Association (NPA)
Pharmacists' Defence Association (PDA)
Pharmacy Forum Northern Ireland (PFNI)
Royal Pharmaceutical Society (RPS)

The observers of the group are:

Department of Health and Social Care (DHSC)
General Pharmaceutical Council (GPhC)
Pharmaceutical Society of Northern Ireland (PSNI)

Each group was invited to field two representatives for each workshop. If they were unavailable, they were able to send deputies. The number of representatives in attendance at each workshop is listed below:

Workshop	Number of representatives present						
	AIMP	APTUK	CCA	NPA	PDA	PFNI	RPS
1	1	2	2	2	2	2	2
2	1	2	2	2	2	1	1
3	0	2	2	2	2	1	1
4	1	2	2	2	2	1	2
5	1	2	2	1	2	1	2
6 (virtual, short notice)	1	2	1	2	2	1	2
7	0	2	2	2	2	1	2
8 (virtual)	2	2	2	2	2	1	2
9 (virtual, short notice)	1	1	1	1	1	0	1
10 (virtual, short notice)	0	2	2	2	2	1	2

The secretariat was provided by the Association of Optometrists (Carolyn Ruston, Director of Policy).

A Memorandum of Agreement was signed by all parties (except observers), the Chair and Secretariat.

Process

Individual meetings (November and December 2022)

Prior to the group workshops, the Chair invited organisations to an individual meeting to better understand their perspective on the concept of “supervision”. These meetings took place in November and December 2022.

It was noted how positive everyone has been engaging with this process, one of the main themes arising from discussions was a shared purpose to develop a strong, patient focussed future vision for community pharmacy acknowledging that if at the end of this project all we have done is redefine ‘supervision’ then we have ended up in the wrong place. The current problems surrounding supervision were discussed with collective views including:

- Multiple interpretations (not a good position for legislation)
- Not representative of community pharmacy practice today (or in the future)
- Does not enable innovation; limits policy makers
- Can result in poor patient experience
- Reinforces the parental relationship between pharmacists and pharmacy technicians

Workshop 1: Friday 13th January 2023

The Chair set out the following thoughts for the conduct of the workshops.

- i) Ensuring that the activity is co-produced based on the outcomes and thinking from this group
- ii) What is finally produced should look and feel like we have all had a hand in producing so when DHSC go out to consultation there should be no surprises
- iii) What is produced in terms of the future vision for community pharmacy should ultimately be clearly driven by patient benefit and experience
- iv) Everyone has the right to be heard. We must be respectful of everyone’s opinion and give everyone the space and time to contribute.

Over the course of the workshop, the group worked through the following questions:

- What does community pharmacy practice look like in 2035?
- How can the rules and regulations underpinning community pharmacy practice support this vision?
- Output and outcomes from the group
- Process for agreeing output and outcomes

Workshop 2: Thursday 9th February 2023

Over the course of the workshop, the group worked through the following topics:

- Reviewed the output from previous workshop (vision)
- Accountability, Responsibility and Delegation
 - Why is it important to consider this?
 - What does it look like in practice?

- What does it enable in future practice/hold back in current practice?

At the end of this session each organisation agreed to contribute to writing the vision statements at the start of this report.

Workshop 3: Thursday 2nd March 2023

Over the course of the workshop, the group worked through the following topics:

- To what does supervision apply?
- What aspects of community pharmacy practice should supervision apply to? What are the principles underpinning supervision that we need to consider?
- Why is it important to consider this?

The group also worked through a number of scenarios in order to clarify their thinking in this space.

Workshop 4: Thursday 23rd March 2023

At the end of the workshop, the group agreed to send the Chair a set of ideas surrounding “supervision”. These were collated in advance of workshop four and formed the basis of the discussion. The DHSC, GPhC and PSNI also gave a brief presentation on the legislation, regulation and guidance surrounding “supervision”.

At the end of this workshop, the Chair agreed to combine the ideas discussed and form into one proposal on which each organisation could provide their thoughts in advance of workshop five.

Workshop 5: Thursday 4th May 2023

Workshop five started with a general discussion of the comments from the proposal circulated at the end of the last workshop. The group then agreed 4-5 areas on which to focus during the session. These were:

- General framework versus more specific list of rules
- The issue of one pharmacist per pharmacy
- Absence
- Delegation and accountability
- Future practice – how do we future proof these recommendations.

At the end of the workshop, the Chair agreed to capture the discussion thus far in a revised set of recommendations. The group also agreed to meet two further times to finalise the discuss on absence and delegation.

Workshop 6: Monday 15th May 2023

This was a virtual workshop for two hours that focussed on the concept of physical presence in the pharmacy and whether this should sit within legislation or regulatory rules and standards.

Workshop 7: Friday 26th May 2023

The final workshop focussed on the following concepts:

- Articulation of the various viewpoints on physical presence in the pharmacy
- Out of hours provision
- Absence from the pharmacy and the general rules underpinning this
- The concept of delegation and how this might work in practice

The Chair agreed to capture the outputs from the discussion in a revised set of recommendations for the group to review remotely.

Workshop 8: Monday 5th June 2023

The group met virtually to hear from the DHSC about their thoughts following the workshops and how this aligned with the proposals being developed. As discussion then took place between the group to think about the impact of this on our proposals and further next steps.

Workshop 9: Friday 7th July 2023

A small sub-group (one person from each organisation) met to discuss final amendments to the report centred on physical presence, absence, delegation and out-of-hours.

Workshop 10: Monday 17th July 2023

Final queries and report dissemination discussed.