Pharmacy Supervision

The Pharmacists' Defence Association's response to the Department of Health and Social Care's consultation

February 2024

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Summary

To reflect changes in pharmacy practice since the introduction of the 1968 Medicines Act more than fifty years ago, it has been a long-standing ambition of successive Governments to amend the legislation surrounding the requirement for the supervision of individual transactions by a pharmacist involved in the preparation, assembly, sale and supply of medicines.

In general, pharmacists accept that a change in the supervision regime is needed but assert that the objective of such a change must be to give members of the public greater access to pharmacists in the community pharmacy setting and not less so, as was previously recommended through the remote supervision proposals being made by the government (2007-2015).

The benefit of creating greater access to the pharmacist should be through improved patient safety around the use of medicines. This becomes possible when pharmacists are enabled to apply their unique clinical knowledge and expertise around medicines; a discipline called pharmaceutical care.

The PDA also fully accepts that how supervision is exercised in practice, specifically in the context of community pharmacy, needs reform and that appropriate changes to the legislation and regulatory framework could support the benefits that may follow.

It should also be noted that with the support of the Department of Health and Social Care (DHSC), the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI), (the government and the UK regulators), the PDA together with others in the pharmacy sector constituted a Supervision Practice Group (Sector Group) of stakeholders.

It was intended that the recommendations from the Sector Group on supervision would provide a framework on which the government and the regulators could draft specifically worded revisions to legislation and regulatory rules and standards.[1]

The principal conclusion of this Sector Group report (which was published in August 2023), was that the presence of a pharmacist was the very cornerstone of community pharmacy practice. The PDA therefore cautiously welcomed the current DHSC consultation and especially the foreword by the four UK Chief pharmaceutical officers which stated:

> ***"These proposals are not a move towards allowing pharmacists to remotely supervise a community pharmacy."*** [2]

[1] Supervision in community pharmacy - Recommendations from the Supervision Practice Group
https://www.the-pda.org/wp-content/uploads/Supervision-in-community-pharmacy-FINAL-APPROVED.pdf
[2] Department of Health and Social Care Consultation - Pharmacy supervision
https://www.gov.uk/government/consultations/pharmacy-supervision/pharmacy-supervision#foreword

In broad terms, the PDA supports the thrust of the DHSC consultation document, however there are some departures from the sector group recommendations. One of significant concern and which could not be supported by the PDA is written in the Statutory Instrument explanatory notes, that a "pharmacist anywhere in the UK" could authorise individuals to undertake certain tasks in a community pharmacy.

This would be tantamount to remote supervision as it could mean that a pharmacist not in the pharmacy could authorise. The PDA has sought and received written confirmation from the DHSC that the 'pharmacist anywhere in the UK' extract is meant to indicate the territorial extent of the new authorisation provision (in proposal 2) and not to imply any form of remote supervision. In response to the concern raised by the PDA the Department has agreed that given the possibility of misinterpretation, they will be making drafting changes prior to consideration by Parliamentarians.

The ethos of the Sector Group report is that pharmacists should spend their time focussing on the parts of the supply function which rely on their unique clinical skills, around helping the public to use their medicines safely and effectively (which is where the greatest value of their work is delivered).

Through skill mix, pharmacy technicians would take much more responsibility for the mechanical and technical aspects of the preparation, assembly, sale and supply of prescription medicines, and this would include taking responsibility for the accuracy of the preparation and assembly. We welcome the acknowledgement in the consultation impact assessment that certain activities such as the clinical check (also known as clinical assessment) are reserved to a pharmacist and cannot be undertaken by a pharmacy technician. We also welcome the impact assessment acknowledging:

> *"…and it could be argued that the preparation and assembly of medicines is more aligned with the education and training of pharmacy technicians."*

The PDA firmly believes that any such clinical assessment(s) must only be undertaken by a pharmacist that is on the premises.

The PDA has long supported the role of pharmacy technicians as valuable colleagues, who are fully qualified to undertake the technical aspects of the preparation and assembly of prescriptions. The PDA published a comprehensive report on how skill mix could work within community pharmacies.[3]

This skill mix approach in freeing up time of the pharmacist from the preparation and assembly activity could enable the delivery of pharmaceutical care (including reducing adverse drug

[3] Pharmacy technicians: an assessment of the current UK landscape, and proposals to develop community pharmacist and pharmacy technician roles and skill mix to meet the needs of the public https://www.the-pda.org/wp-content/uploads/FINAL-PT-Report-28-02-19.pdf

reactions, medicines optimisation and addressing problems surrounding polypharmacy). This is discussed in detail later in the submission.

This is why the PDA supports the premise that “supervision” should, in the future be defined as being exercised when a responsible pharmacist (RP) or another physically present pharmacist is proximal and aware of the activities that are ongoing within that community pharmacy and, that this should not mean the “direct supervision” of each individual transaction.

During PDA focus groups and through member surveys held across all four countries of the UK, over many years, pharmacists articulated their concerns about being held personally accountable for the errors of a pharmacy technician to whom they have delegated the activities of preparation and assembly. The prosecution of some pharmacists in the past have occurred when the errors had been committed by pharmacy support staff. This is one of the main reasons why the delegation of tasks to pharmacy technicians has not received universal support from the community pharmacist workforce.

The PDA therefore welcomes the proposal for the creation of the new term “authorisation”, which allows for the accountability for the accuracy of the preparation and assembly and sale and supply of prescription medication to pass to the pharmacy technician once they have been authorised by the Responsible Pharmacist.

Authorisation of a pharmacy technician by the Responsible Pharmacist, following a situational assessment made of the prevailing conditions in the pharmacy premises, could also enable pharmacy technicians to supervise the preparation and assembly work of others.

As the most important patient safety measure, under the proposals of the Sector Group, no prescribed medicines could ever be handed out to the public without the clinical assessment of the pharmacist in the community pharmacy. This could mean that in future, whilst a pharmacist would be held accountable for the probity of the clinical assessment, the pharmacy technician would be held accountable for any accuracy or labelling issues (providing the authorisation has been made appropriately).

Without doubt, the transformational proposals being made in this consultation have the potential to redistribute the existing excessive workload and the current accountability in a safe and appropriate way. They could underpin a welcome direction of travel for pharmacy practice. The positioning of the pharmacist in the community pharmacy would become a pivotal component of practice in the short, medium and longer term.

The PDA has carefully considered the consultation document and has taken account of extensive member feedback, and comprehensive legal counsel relating to the proposals, the Statutory Instrument (SI), explanatory notes and the impact assessment. The PDA has also received helpful written clarifications from the DHSC on the intentions behind some of the statements made.

Logic dictates that because the connected consultations of the pharmacy regulators (GPhC and PSNI) have not yet occurred, some of the DHSC's proposals cannot receive unqualified support, because, depending on how the regulator consultations emerge, they could yet lead to unintended and potentially damaging consequences as detailed later in this consultation submission.

The PDA has therefore identified these areas as proposals which it cannot currently either agree or disagree with and has qualified its responses to this consultation with conditional requirements.

The PDA seeks clarification and urges caution in the following areas

The PDA was disappointed that certain recommendations and detailed considerations made by the Sector Group were not included (or discounted as detailed in the impact assessment) as part of this consultation.

The Sector Group made a series of interlinked recommendations which would have resulted in a safe framework for how supervision is exercised within community pharmacy.
It is not tenable to discount some significant recommendations made by the Sector Group whilst half adopting others. Disturbing the checks and balances put in place by the Sector Group could introduce levels of risk not envisioned when the recommendations were developed.

1. **P Medicines**
   The PDA's response to this consultation relates only to prescribed medicines and not to P medicine sales. When the Sector Group considered supervision issues, it agreed that such was the complexity and importance of the P medicines issue, that it deserved careful consideration and a separate consultation altogether. In effect, it would be a mistake to consider the P medicines issue within the remit of the supervision consultation.

2. **Authorisation**
   The consultation cites that the ability to authorise a pharmacy technician can be made by (any) pharmacist, (such as a second pharmacist, a superintendent pharmacist or an Area Manager pharmacist) whereas that Sector Group report was explicit in that this needed to be the Responsible Pharmacist.

   The Sector Group's reasoning was that the RP was best placed to fully understand the exact operational environment of that community pharmacy at any given time. Furthermore, the current governance regime places the statutory responsibility for the safe and effective operation of the pharmacy with the RP. So, any decision to authorise a pharmacy technician that is made by any pharmacist other than the RP undermines the current safety regime of the community pharmacy. This could create potential

governance and control conflicts which inevitably would lead to the diminution of patient safety.

The DHSC has indicated that it believes that this decision is better left for the regulators in their forthcoming consultation on Responsible Pharmacists and Superintendent Pharmacists. The PDA believes that this should have been done in the statute, even though the DHSC have stated that they expect the GPhC to take into account the recommendations of the Sector Group:

> *"The GPhC will take account of recommendations from the Supervision Practice Group as it develops standards and rules, including its recommendations in relation to responsible pharmacist absence from the premises and maintaining the current 2-hour limit."*

Response to Questions

Proposal 1

Proposal 1 is to amend the Medicines Act 1968 and Human Medicines Regulations 2012 to enable **pharmacists** (should they wish) to **authorise** a registered pharmacy technician to carry out, or **supervise** another person to carry out, the preparation, assembly, dispensing, sale and supply of POMs and P medicines.

Question:
Do you agree or disagree with proposal 1?

- Agree
- **Neither agree nor disagree ✓**
- Disagree

If you have any additional information to support your answer, please provide details (maximum 350 words).

The Statutory Duty of the Responsible Pharmacist

The physical presence of the pharmacist in a community pharmacy is the bedrock of community pharmacy practice. The PDA is of the firm view that this must be explicitly stated in legislation and not merely be inferred as is currently the case.

The terminology of "Responsible Pharmacist" (RP) is relatively new in pharmacy legislation. It was introduced specifically to remove the "personal control" element of case law and regulatory precedent which meant that a pharmacist always had to be on the pharmacy premises to exercise "personal control". Section 72A of the Medicines Act 1968 specifically places the duty to secure the safe and effective operation of the registered pharmacy with the RP.

In this context the PDA has concerns about certain elements of the DHSC's proposals. In busy pharmacies, the prevailing circumstances can often change multiple times during the working day and the proximal pharmacist (who is usually also the RP) is able to make unfettered decisions to secure conditions that allow for the continued safe and effective operation of the pharmacy in real time.

Given this busy and ever-changing situation, we welcome the first part of this statement in the consultation stating:

> *"The responsible pharmacist may only be responsible for one premises (which includes any associated premises), at any one time, and the pharmacy regulators have a power to introduce an exception to this rule. No provisions have been introduced to date to allow an exception."*

This is why it is not possible for one RP to secure the safe and effective operations of multiple pharmacies given the high intensity workload prevalent in community pharmacy which has imposed considerable strain on the existing workforce.[4]

The PDA is of the firm view that wording in the Statutory Instrument must be sufficiently robust to exclude the possibility of either extant SOPs or remote authorisations given by others, as this would diminish the role of the RP to a meaningless title.

Following the RP regulations 2008 coming into force in October 2009, some employers interpreted the RP regulations in a way where they took the 2-hour absence decision away from the RP by using an Advanced Declaration Template for the purposes of reducing their operational costs. This specific experience, recent in history around how preparation and assembly of prescription medicines is undertaken, serves as an excellent example why the draft Statutory Instrument needs to be appropriately worded.[5] [6]

The PDA contends that the only way to secure the safe and effective operations of the pharmacy is by a physically present pharmacist assessing the contemporaneous situation (for example staff ringing in sick or unexpected outage to the pharmacy telephone/internet system) before considering signing in as the RP. This is a critical patient safety step in the overall governance system.

Once signed in, it must then be the RP who chooses to make authorisations and similarly, they must be able to revoke them according to any prevailing conditions within the pharmacy. In all cases authorisations must always cease at the point when they sign off as the RP.

Authorisations for the preparation, assembly, sale and supply of medicines

The DHSC has recognised that the Sector Group expressed a preference for the RP to be cited as the pharmacist who should be in charge of the authorisation process, however, they have indicated that they would prefer for this level of detail to be delivered by the regulator in their forthcoming supervision consultation.

The PDA feels that such is the importance of the RP safety and governance regime, that this should be a matter covered in the statute and not left to the regulators' rules and standards.

[4] Pharmacy Pressures Survey confirms impact on teams, businesses and patients
https://cpe.org.uk/our-news/pharmacy-pressures-survey-confirms-impact-on-teams-businesses-and-patients/
[5] The Boots Advance Declaration for the RP; the PDA view
https://www.the-pda.org/the-boots-advance-declaration-for-the-rp-the-pda-view/
[6] The response by Boots to PDA website article on Boots' responsible pharmacists' advance declaration template
https://www.the-pda.org/pdf/boots_rp_20100820.pdf

It is equally important that any authorisation which seeks to transfer accountability for an activity must always be a decision which is the subject of an agreement following a two-way conversation.

Whilst the PDA supports the proposal that a pharmacy technician may be authorised to undertake the preparation, assembly, sale and supply of prescriptions or supervise others doing so, the pharmacy technician can only supply the dispensed medicines when there is a pharmacist physically present on the pharmacy premises, and after the pharmacist has undertaken the clinical assessment.
Whilst the two conditions are likely to be described by the regulators in their forthcoming consultations, currently, neither of these two conditions are detailed in the DHSC consultation.

Robust written processes and procedures

Whilst accountability may follow authorisation for undertaking activities, it can only do so if the framework around how that authorisation is given is robust and fit for purpose.

To ensure clear and auditable lines of accountability, every authorisation which is given must always be properly documented in writing (electronic or hand) and retained to ensure that accountability and liability is appropriately apportioned in case of errors which result in patient harm.

The PDA fully accepts that a written and documented authorisation may be ***communicated*** verbally or orally, but this is distinct and separate to it solely being made verbally or orally.

Similarly, to ensure safe and effective governance, any additions, revocations or changes to authorisations made by a RP can only be made by the RP or by another physically present pharmacist with the RP's consent. This must be contemporaneously and fully documented.

To summarise;

- When the Responsible Pharmacist is present, they **may choose** to authorise a pharmacy technician to undertake the preparation, assembly, sale and supply of medicines or to supervise others doing so**.**
- Such an authorisation must **only** operate in the presence of the RP, it **must not be given remotely**, **nor be the subject of an overriding Standard Operating Procedure**.
- Authorisations given by a RP during their duty period **must cease at any point as determined by the RP** during the opening hours of the pharmacy, and they always cease when the pharmacist signs off as being the RP for those premises.
- Any authorisation given **must always be documented digitally or in writing** and retained to maintain full records and provide an audit trail in case of an error which results in patient harm.

- Authorisation, should it be given by the RP, **must be a two- way conversation, it must be agreed and not be imposed**.
- The **clinical assessment of every prescription must be undertaken only by a pharmacist who is physically present in the pharmacy**. This must be recognised by the GPhC when formulating any new Rules and Standards.
- Under such circumstances, a prescribed medicine may **only** be supplied to the patient **if the pharmacist has undertaken and is responsible for the clinical assessment**, leaving the pharmacy technician to take responsibility for the technical activity for which they have been authorised.

The points above outline key aspects concerning Proposal One. There are several interlinked issues that need consideration. This is especially important as the term ***'authorisation'*** is not a term used within any regulations, standards or guidance of the non-pharmacy UK healthcare regulators.

Authorisation

A clear definition of the word 'authorisation' used in these proposals has not been provided and this introduces the risk of ambiguity. This ambiguity must be removed as it could lead to unintended consequences, difficulties in future practice situations and potentially unhelpful future case law arguments.

Legal convention dictates that when a word is included in legislation without definition, then the Oxford English Dictionary definition applies.

The Oxford English Dictionary definition of authorisation is;

> *The action of authorising a person or thing; formal permission or approval; an instance of this. Also: the action of making legally valid* [7].

In light of these definitions, to avoid confusion in what DHSC intend authorisation to mean, and to ensure that this is not simply delegation; which could be a form of permission or approval (and which keeps the accountability linked to the pharmacist), the PDA would expect that it is made clear that authorisation is the '*action of making legally valid'*, as this is the activity that supports the full transfer of accountability for activities that have been authorised to a pharmacy technician.

[7] OED Dictionary - 1 result authorisation
https://www.oed.com/search/dictionary/?scope=Entries&q=authorisation&tl=true

Proposal 2

Proposal 2 will enable a pharmacist to authorise any member of the pharmacy team to hand out checked and bagged prescriptions to patients or patient representatives. This is to align 'bricks and mortar' pharmacy premises with current practice for home delivery, locker box and other delivery services.

Question

Do you agree or disagree with proposal 2?

- Agree
- **Neither agree nor disagree ✓**
- Disagree

If you have any additional information to support your answer, please provide details (maximum 350 words).

Balancing safety and assurance with patient convenience

The Sector Group fully understood the concerns expressed by the DHSC that patients were confused as to why prescriptions, which were checked and bagged on the shelf, and which had been cleared for handing out to patients, could not be given to them in the temporary absence of a pharmacist.

However, it is important to recognise that there are significant patient safety considerations to be made. The Sector Group's recommendations addressed this and are based on the 2005 RPSGB provisions which are detailed in the December 2005 Law and Ethics Bulletin.[8]

The 2005 guidance, which was put in place with the explicit support of the then Departments of Health for each home nation, has allowed the physically present pharmacist to delegate to appropriately trained staff the sale and supply of checked and bagged medicines whilst the pharmacist was in a consulting room (and therefore interruptible) within the pharmacy.

The proposal in the current consultation would facilitate these same activities being conducted in the temporary ***physical absence*** of the pharmacist and the RP, and we believe seek to strike a sensible balance between convenience and patient safety.

[8] Law and Ethics Bulletin - The Pharmaceutical Journal - Vol 275 No 7380 p756-758 - 17 December 2005 Interim guidance for pharmacist supervision and private consultation areas

In recognising that safety is critically important, the PDA proposes that the following safeguards must be put into place:

- If a signed in RP decides that they need a rest break (or is otherwise uninterruptible or absent for a brief period) they may **choose** to authorise any suitably trained member of staff to include a pharmacy technician to hand out **only those prescribed medicines that have already been clinically assessed and deemed safe to supply to patients without any further involvement of the pharmacist.** Such medicines would already be bagged and awaiting collection.

- Prescribed medicines that the RP has indicated as requiring the pharmacist to speak to the patient on a clinical matter upon their return **will not be authorised to be handed out.**

- If a patient comes in to collect a medicine that has previously been cleared for collection, but introduces an unexpected clinical query or complication, for example notifying the pharmacy staff of a worrying side effect, allergy or new diagnosis, **the patient would need to wait for the return of the pharmacist to discuss the implications.**

- **Authorisations given by an RP during their duty period may be ceased by them** during the opening hours of the pharmacy, and they always cease when the RP signs off as being the RP for those premises.

- Any **authorisation given must always be documented digitally or in writing** and retained to maintain full records and provide an audit trail in case of an error which results in patient harm.

- Authorisation, should it be given by the RP, **must be a two- way conversation, it must be agreed and not be imposed**. It should neither be given remotely, nor become a default because of operational SOPs.

Summary of PDA position on proposals one and two

- There must be **no dilution of the existing Responsible Pharmacist's (RP) authority regime**.

- There must be **no advanced authorisations** – authorisation can only be given during a signed in presence of an RP.

- Authorisations can **never be given by any pharmacist remotely** (from anywhere in the UK).

- Authorisations **must not be simply given orally**; they must be fully documented and retained to enable a clear audit trail.

- The **clinical assessments of a prescription cannot be undertaken remotely or by anyone other than a pharmacist present in the pharmacy**; the proximity to the patient or their representative and the possibility of consulting with them is one of the important components of the ability to assess safely.

- Authorisations **must never be the subject of an overriding Standard Operating Procedure**.

Proposal 3

Proposal 3 is to allow a registered pharmacy technician to be responsible for a hospital aseptic facility in the same way that a pharmacist is under the current law.

Question

Do you agree or disagree with proposal 3?

- Agree
- Neither agree nor disagree
- **Disagree** ✓

If you have any additional information to support your answer, please provide details (maximum 350 words).

Whilst proposals one and two are predicated on skill mix and an appropriate separation of technical and clinical activities, proposal three introduces simple role substitution which does not take into account the important clinical considerations that need to be undertaken in aseptic facilities.

In considering its response, the PDA consulted widely with members working in this area of practice, including one-to-one conversations, events, and inviting feedback by email. The feedback received from experienced pharmacists including those of 30 years standing in this this specialised area, raised serious concerns about proposal 3 which are reflected in this response.

Appropriateness for inclusion in this consultation

Quite differently from that of a community setting, pharmacy practice in hospital is undertaken within a NHS management structure, where certain aspects have entirely different governance frameworks and skill mix. Proposal 3 deserves to be considered in comprehensive detail and as part of a whole system approach in an entirely separate consultation. The PDA firmly believes that this proposal is not suitable for consideration as part of the consultation on supervision.

The Carter Reviews of 2015 and 2016[9] were seminal moments for hospital practice in that they led to the initiation of the Hospital Pharmacy Transformation Plans. It is outside of the scope of this submission to consider these plans, their subsequent implementation and the impact that they have had on hospital practice.

What is important to understand is that in 2020, a further review of aseptic services was requested by Government Ministers, and which asked Lord Carter:

[9] Productivity in NHS hospitals - Lord Carter's review of efficiency in hospitals shows how large savings can be made by the NHS.
https://www.gov.uk/government/publications/productivity-in-nhs-hospitals

" .. to review the quality, safety and resilience of the hospital-pharmacy, aseptic service"[10]

In 2022/23, the cost to NHS commissioners in England for medicines was approximately £19.2 billion (pre-rebates). Of this the cost of medicines issued in hospitals was approximately £9.5 billion.[11]

Within this, the cost of aseptic medicines makes up a substantial portion of the overall medicine spend of hospitals in England (with likely similar proportions in all 4 home nations).
It is in this financial context that Lord Carter, working closely with the then Chief Pharmaceutical Officer for England, in the 2020 review proposed:

> *"I am proposing the transformation of the aseptic services production model across England. It will need considerable investment but will yield significant returns in quality and cost. A national network of regional hubs with the capacity to produce high volume products on an industrialised scale using automated systems in off-hospital sites will free up nursing staff for the business of care, enable care closer to home and allow space for the aseptic facilities in hospitals to deliver the more complex, individualised medicines much closer to the patient."*

It is important to recognise and acknowledge that in the review of transforming aseptic services in England the *Carter review did not recommend any change in the existing supervision requirements* operating within aseptic units. Specifically, the report recognised

> *"Aseptic services are the highest risk area in NHS provider pharmacy supply provision. Therefore, the systems of quality assurance and governance processes are critical. Facilities producing aseptic medicines are subject to strict regulations. The UK regulates compounding facilities (and other medicines related activities) via two legislative routes:*
>
> *1.1 Under the direct supervision of a pharmacist who takes personal responsibility for quality..."*

Lack of clarity as to nature of problem that is being addressed

It is unclear as to the nature of the problem that the proposal 3 is seeking to solve. The impact assessment accompanying the consultation states that:

[10] Transforming NHS pharmacy aseptic services in England
https://www.gov.uk/government/publications/transforming-nhs-pharmacy-aseptic-services-in-england
https://assets.publishing.service.gov.uk/media/5f9afdbdd3bf7f1e405d9a23/aseptic-pharmacy.pdf
[11] Prescribing Costs in Hospitals and the Community - England 2018/19 to 2022/23
https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202122/prescribing-costs-hospitals-and-community-england-201819-202223

"The roles of pharmacists in hospitals are changing with more time spent in patient-facing clinical roles"

The PDA fully supports the evolution and growth of the patient facing clinical roles which make the best use of the 5-year underpinning clinical training for all UK registered pharmacists. However, this can never be a binary choice – an either / or.

Pharmacists in highly specialised wards such as cancer or paediatrics work hand in hand with their colleagues in aseptic units. Some may have dual roles – i.e. they may be able to undertake activities in both the patient facing ward and in overseeing or being involved in the production of specialised products within a hospital aseptic unit.

Retention, recruitment and banding

The PDA understands the issue around recruitment and retention in pharmacy roles. However, this includes the problems faced in recruiting at all levels and especially at the lower bandings. Specifically, our pharmacist members (many who have extensive experience of working within aseptic units) have indicated that the problems around retention are especially notable at the lower banding. The PDA has been informed that on completion of their training programme, these junior staff often leave seeking higher banded roles. This has led to staff being appointed to higher bandings which are not reflective of their experience nor their skills. This needs a system wide and joined up solutions which are outside the scope of this submission.

Summary of the PDA position in relation to proposal three

In summary, as the production of aseptic products become more specialised, more personalised and more complex, it becomes even more critical that there is a person supervising the units who has not only the underpinning clinical knowledge but also knowledge and expertise of aseptic production – a dual role in effect.

This is the big picture context reason why the PDA cannot support proposal three.

- Pharmacy Technicians ***may*** be the most experienced individuals for the technical aspects of a ***technical process*** in an aseptic unit, but this can ***never*** substitute for the clinical knowledge, understanding and decision-making skills of the pharmacist. The proposal fails to address the systemic problem around recruitment and retention of staff and a more holistic approach to pharmacy staffing within hospital settings is required.

- The proposed governance system with **the Chief Pharmacist overseeing the activities of an aseptic unit is inherently unsafe**. The Chief Pharmacist is too far removed from the day-to-day activities of an aseptic unit to exercise any meaningful oversight role. Removing multiple stages of oversight and Governance is therefore inherently dangerous for patients.

- The proposal will over time **reduce overall capacity in the system as rotational pharmacist training in aseptic units** will diminish or disappear altogether. Pharmacists working within aseptic units work hand in hand with specialist treatment wards (for example in cancer treatment) and many prepared treatments are specialised, bespoke and made by manipulating products within the aseptic unit using a pharmacists clinical knowledge and expertise.

- The **risk of catastrophic clinical error will increase as pharmacy technicians do not have the underlying clinical knowledge of a pharmacist**. A clinically trained pharmacist will exercise judgement and clinical knowledge to make or suggest changes to clinician colleagues in the wards – for example when a product is in short supply and an urgent substitute is required. A pharmacy technician does not have the clinical knowledge to do this.

- The proposal **may over time lead to a total loss of pharmacist involvement in aseptic production**. This valuable dual-aspect (clinical and technical) unique knowledge and involvement of the pharmacist (especially in specialist wards such as cancer or paediatrics) may be lost forever. This cannot be in the patient interest or in the longer-term interest of the NHS.

"At or From"

We propose that Regulation 220 of the Human Medicines Regulations 2012 is brought into line with the changes already made to other legislation concerning the supply of medicines 'at or from' a registered pharmacy premises. This is to better reflect current practice, particularly in the provision of delivery services from a registered premises.

Question

Do you agree or disagree with this proposal?
- Agree
- Neither agree nor disagree
- **Disagree ✓**

If you have any additional information to support your answer, please provide details (maximum 350 words).

The consultation document states that the reason for the proposal to make this amendment "At or From" in Regulation 220 of HMR 2012 is because:

> *"It also reflects current practice, particularly where delivery services are used, which has led to strained readings of the legislation – including strained understandings of when supply takes place – in order to ensure that current standard practices are*

understood to have a proper legal base. ***This change may be made in other legislation in the pipeline****, but in case it is not, the possibility of it being in this order has been provided for to ensure that regulation 220 is brought into line with the changes already made."*

Collection and Delivery services from pharmacies have been made with the approval of professional and regulatory bodies for many decades. The Medicines, Ethics and Practice Guide for pharmacists has, for many decades, included professional guidance around delivery of medicines to patients. We are not aware of any current issues arising which strains understanding of this long standing and existing practice.

We can accept at face value that this may need clarification but cannot support a proposal which may have wider unknown implications due to "other legislation in the pipeline". This is especially as there is no information on what that other legislation is and how it fits in with the ongoing multiple changes in the legislation and regulations concerning pharmacy practice.

Legislative Barriers

Question

Do you think there any other barriers to modernising pharmaceutical practice in government legislation that we should consult on **removing in the future**?

- **Agree** ✓
- Neither agree nor disagree
- Disagree

If you answered yes, please provide details of these barriers to support your answer (maximum 350 words).

Supervision and direct supervision – removing case law

The sector group highlighted that 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" 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.

Additionally, the NHS pharmaceutical services regulations in all four home nations contains the term “direct supervision” with slight variation in exact wording. In the England regulations this is described as;

> *“Drugs or appliances so ordered shall be provided either by or under the direct supervision of a registered pharmacist”*

It has long been recognised that such provisions do not support modern pharmacy practice. Within community pharmacy, long-standing accepted professional practice is that the pharmacist will usually only be involved in the clinical assessment of the prescription, but when required (for example due to lack of support staff) will get involved in any or every aspect of the preparation, assembly checking and bagging of the prescription. **S*upervision has not*** involved pharmacists standing over the shoulder of support staff and directly observing the preparation and assembly of individual prescriptions.

The Sector Group recommended that one way of ending the reliance upon historic case law which leaned towards the supervision of individual transactions, was to introduce a supportive definition of supervision into the statute.

The PDA suggests that the definition of supervision that could be introduced is ***“supervision occurs when a pharmacist, who is proximal and aware of the wider activities within the pharmacy premises, has undertaken and completed a clinical assessment of the prescription for each supply and is able to intervene.***

The consultation however, omitted to provide a definition of supervision, meaning that the case law definition still exists. The problem of ‘direct supervision’ of individual transactions has merely been moved to a pharmacy technician (if authorised to prepare and assemble by a RP). The PDA urges the DHSC to address this problem to avoid courts in future relying on outdated case law and also, to amend the NHS regulations accordingly.

A total system approach

The Sector Group report recognised the importance of a total system governance approach, which must be in place to ensure patient safety.

The layers of legislation, regulations, standards and professional guidance must be robust, align seamlessly and developed after **all** registrants have been consulted on the proposals.

In the UK we have two pharmacy regulators, in Northern Ireland the professional leadership body membership of PFNI is coterminous with the regulator PSNI and therefore has all registrants in membership, whereas in Great Britain (GB), the organisation that is the professional body for pharmacists (Royal Pharmaceutical Society - RPS), and a body that represents pharmacy technicians (association of Pharmacy Technicians UK – APTUK) do not have membership of all pharmacists and pharmacy technicians as they are separate from the regulator.

The PDA believes that any consultation which is undertaken by the pharmacy regulator, and which requires complementary guidance to be issued by the RPS or APTUK, must be consulted upon together and facilitated via the GPhC consultation process. In GB, this is the only mechanism by which all registrants can have a meaningful and fair opportunity to take part in the consultation process, unlike in Northern Ireland.

Therefore, a provision must be made for the full and meaningful consultation of all registrants on any guidance which may be made by the RPS or APTUK because of this draft statutory instrument.

Contract negotiations – embedding a new statutory obligation to involve the PDA in pharmacy contract developments

There is an important rationale upon which these changes to supervision have been built. It recognises that it is the considerations and decisions of the RP that will establish and secure the safe and effective operation of the pharmacy for the benefit of patient safety. The RP is the most appropriate decision maker in these circumstances as they are the closest to the patient interface.

Pharmaceutical care and pharmaceutical services are provided by individual pharmacists and not by business entities. Despite the important safety and governance role of the RP, and the fact that it is pharmacist practitioners who will be expected to deliver the services directly to patients, there is no involvement or influence of those individual pharmacists in the specification and development of new services being introduced by the NHS.

Discussions on the design and commissioning of new services have historically involved only the governments commissioners and business owners through their respective four country negotiating bodies.

Most community pharmacists are employees or locums rather than holding their own pharmacy contract. The PDA believes that in the future, to assist with the safe and effective development of pharmaceutical care services, the PDA as an independent organisation representing pharmacist employees and locums throughout the UK, must be included in the formative discussions.

Impact Assessment
Question If you have any further information to inform the consultation-stage impact assessment on the costs and benefits of each option, please provide it here (maximum 350 words).

The impact assessment (IA) states that these proposals would enable pharmacists "*to operate at the top of their competence*". The IA looks at errors and the impact on patient safety in a way which is falsely reassuring. It states:

> *"There is a potential risk to patient safety. The reduced pharmacist supervision could increase the number of errors made. However, this is mitigated by the fact that a pharmacy technician is a registered and regulated healthcare professional in their own right, with education and training to undertake dispensing of medicines."*

Pharmaceutical care, medication errors and reconfiguring the role of the pharmacist

The IA notes the reported error rates *as reported* to the NRLS at 1,921 for over 1 billion prescriptions. This is distinct to actual error rates and what should be described or classified as an error. This figure of 1,921 is grossly simplistic and stands in a marked contrast to the error rates identified in independent research papers over many decades.

The UK has an aging population with widespread polypharmacy and multi-morbidity. This introduces risks to patients in ways that were unimagined in the 1968 Medicines Act. Accurate dispensing of unadulterated medicines was the primary concern of pharmacists at that time –

ensuring the quality and accuracy of dispensing was at that time considered operating at the top of your license within community settings.

In the 21st century, the role of the pharmacist has evolved. Operating at the top of your competence now should mean reducing the incidence of harm and hospitalisations caused by medicines use through pharmaceutical care.

A rapid review report published in 2018 found 36 research studies and from these estimated the prevalence of prescribing error rates in primary care in England at:

> *".. We estimated that 66 million potentially clinically significant errors occur per year, 71.0% of these in primary care. This is where most medicines in the NHS are prescribed and dispensed. Prescribing in primary care accounts for 33.9% of all potentially clinically significant errors."* [12]

The report also noted that there are 237m medication errors at some point of the medication process and an unknown number are picked up before they reach the patient. Similarly, a 2022 research paper published in the BMJ estimated the cost to the NHS in England of hospitalisations due to adverse drug reactions, polypharmacy and multimorbidity at £2.2 billion.[13]

It is beyond the scope of this submission to discuss in huge detail these peer reviewed research papers. However, it is important to understand how missed opportunities to correct errors in prescribing has huge potential in improving patient outcomes and significant financial and capacity benefits to the NHS.

The PDA believes that making the best use of pharmacists, who have a unique 5 years of clinical training around the prescribing and use of medicines, must be the driver for any proposed change.

Within community pharmacy settings, only pharmacists have the ability to marry what is prescribed and what is dispensed. NHS England itself recognises that between 30% to 50% of all medicines prescribed for long term conditions are not taken as intended.

In 2005 Medicine Use Reviews were introduced as the first advanced service from community pharmacies in England. However, this service was stopped in April 2021. Re-

[12] Prevalence and Economic Burden of Medication Errors in The NHS in England: Rapid evidence synthesis and economic analysis of the prevalence and burden of medication error in the UK. https://pure.york.ac.uk/portal/en/publications/prevalence-and-economic-burden-of-medication-errors-in-the-nhs-in

[13] BMJ Open - Adverse drug reactions, multimorbidity and polypharmacy: a prospective analysis of 1 month of medical admissions https://bmjopen.bmj.com/content/bmjopen/12/7/e055551.full.pdf

introduction of a properly constructed “pharmaceutical care service” based within community pharmacy could have significant impact on patients.

Underpinning this opportunity is the benefit of the pharmacist in the community pharmacy now having read and write access to patient records, existing access to the pharmacy dispensing record, and because of minor ailments services being introduced in many parts of the UK – also has a significant knowledge of over-the-counter medicines purchased by patients. This unique and holistic view of medicines use must be leveraged for the patient benefit.

The issue around the impact of prescribing errors which are not identified before the patient is hospitalised or has come to harm has not been factored into the impact assessment.

The specialised underlying training of a pharmacist, the experts on medicines, is being diminished by a head long rush to deploy them to simply ease the burden on primary care and GP time. The PDA accepts that community pharmacies are accessible and that pharmacists can often resolve patient health concerns and provide treatment for many common conditions. However, the PDA passionately believes that to make the best use of the pharmacist workforce, a second pharmacist within every pharmacy offering clinical services other than full clinical assessments should become mandatory.[14]

To date there has been no consideration of the wider whole system cost – primary and secondary care – and the benefit of enabling pharmacists based within community pharmacies the time within a properly constructed framework to facilitate the use of their expertise in medicines to carry out detailed clinical assessments of a patients medicines and to provide pharmaceutical care.

Re-investing the time released for pharmacists

The Impact Assessment calculates the net benefit of “released pharmacist time” to be £386m.

The purported aim of the proposed changes to “pharmacy supervision” is to free up pharmacist time to enable them to deliver more clinical services. The core clinical service that potentially adds most value to the patients and the NHS is pharmaceutical care (medicines optimisation, reducing adverse drug reactions and ensuring that medicines are taken as intended by the prescriber) and the PDA would fully support the reinvestment of released pharmacist time for this purpose as the emphasis should be on using the net present benefit to derive the value of pharmacists delivering pharmaceutical care.

[14] PDA welcomes the Pharmacy First service and calls for a second pharmacist in the pharmacy https://www.the-pda.org/pda-calls-for-second-pharmacist-in-the-pharmacy/

Case Law – the case law on the duties of a pharmacist

The duty of a pharmacist extends to more than just the supplying accurately assembled medicines against a prescription written by a doctor (and now increasingly written by professionals other than doctors).

Questions that need to be addressed include how accuracy and accurately are defined in the context of current pharmaceutical practice. The PDA suggest that the question "is it appropriate for this patient" or "can this be taken safely by this patient" are more relevant in the context of 21st century community pharmacist practice.

It is beyond the scope of the response to this consultation to undertake a full consideration of this. The authoritative guide to Pharmacy and Medicines Law lists several cases where the courts have found that pharmacists have a duty of care in the context of professional negligence.[15]

These cases revolve around the clinical obligations of a pharmacist rather than supervision (and it is important to remind ourselves that the case law around supervision remains despite this consultation) as already highlighted.

The case law around clinical obligations provide a steer that the duty of pharmacist when dispensing extends to more than accurately supplying what is written on the prescription and must also have due regard to the appropriateness of what is requested.

The 2006 case where a prescription was dispensed as prescribed by the doctor. This was not a case of a "dispensing error" but was in essence a clinical error. The Judgement noted:

> *"The accepted wisdom is that whenever pharmacists dispense a prescription, they should consider whether the medication being prescribed is suitable for the patient. That is what the Royal Pharmaceutical Society of Great Britain's Code of Medicines, Ethics and Practice requires pharmacists to do. Para. 4.1(b) includes the following:*
>
> *"Every prescription must be professionally assessed by a pharmacist to determine its suitability for the patient."* [16]

However, the very fact that this aspect of case law has not been considered in the consultation or the impact assessment is concerning. Pharmacists have a duty of care, and this extends to beyond mere technical supply. There are multiple other examples

[15] Dale and Appelbe's Pharmacy and Medicines Law - TENTH EDITION
Pharmaceutical Press, 1 Lambeth High Street, London SE1 7JN
[16] Cathy Bosworth Horton Vs (1) Timothy Evans and (2) Lloyds Pharmacy Limited
https://www.bailii.org/ew/cases/EWHC/QB/2006/2808.html

where the courts have specifically noted that the duty of a pharmacist extends to more than the simple accuracy of robotically supplying what is written on a prescription.

The PDA believes that the NHS must look at how the 5-year clinical training of pharmacists can be utilised to reduce the £2.2 billion cost burden of adverse drug reactions on secondary care while giving considerable benefit to patients.

The need for a holistic Equality Impact assessment

There is no explanation as to why no Equality Impact Assessment undertaken as part of the impact assessment. There are significant demographic weightings and divergences with the pharmacy technician register and the pharmacist register and there is a real possibility that the proposals will have a disproportionate impact on persons sharing certain protected characteristics.

The Pharmacy Workforce Race Equality Standard (PWRES) indicates widespread inequality and substitution of level 7 master's graduates with level 3 educated staff, as could occur with proposal three, may embed some aspects of inequality. Legislation should not embed inequalities.[17] and it is remiss of the DHSC to not have undertaken a full equality impact assessment as part of this consultation.

Draft Statutory Instrument (SI)
Question If you have any further comments on any aspect of the draft statutory instrument, please provide it here (maximum 350 words)

It is important to recognise the difference between pharmacists and pharmacy technicians

The House of Lords Scrutiny committee recently noted that a proposed statutory instrument for the regulation of physician associates and anaesthesia associates assumed that parliamentarians and others would be aware of their educational qualifications and their suitability to undertake the proposed roles.[18]

This is why the educational qualifications of pharmacists and pharmacy technicians must be added to the explanatory note in the statutory instrument so that parliamentarians are fully aware

[17] Pharmacy Workforce Race Equality Standard report
https://www.england.nhs.uk/long-read/pharmacy-workforce-race-equality-standard-report/
[18] HOUSE OF LORDS - Secondary Legislation Scrutiny Committee - 10th Report of Session 2023–24
Drawn to the special attention of the House: Draft Anaesthesia Associates and Physician Associates Order 2024
https://committees.parliament.uk/publications/43065/documents/214166/default/

of the distinct and different level of qualification which pharmacy technicians and pharmacists are equipped with to undertake their respective and distinct roles.

A pharmacist must complete 4 years of full-time education and a one-year full time foundation year (with a requirement to pass a robust UK wide registration exam set by the regulator). This is a full 5 years after completing their A levels. As an example of the robustness of the registration exam the pass rate at first sitting i.e. after 5 years of full-time education and training is still only around 80%.[19]

In stark contrast, the level 3 training of pharmacy technician at the endpoint is equivalent to A level standard (or equivalent), and disappointingly the regulator has chosen not to set a national registration exam for pharmacy technicians.

Mandatory registration for pharmacy technicians with the GPhC was introduced in July 2011 (and there are similar plans for the PSNI to regulate pharmacy technicians in Northern Ireland.

For context, even in 2024 around 50% of the current pharmacy technician workforce is present on the register through a grandparenting provision and that the underlying education and training of that 50% is not clear. Even the current Initial Education and Training for Pharmacy Technicians (IETPT) is a basic level 3 qualification which gets pharmacy technicians to a A level standard of knowledge at the end of the course.

So as not to mislead parliamentarians, the PDA asks the DHSC to ensure that the explanatory note which supports the draft SI is more explicit about the difference in educational levels between pharmacists and pharmacy technicians as they consider the proposals on supervision to ensure that their scrutiny is appropriate.

The vagaries of using the phrase 'pharmacy professionals'

Through skill mix, pharmacy technicians and pharmacists have important roles to play in together delivering a quality service in a community pharmacy. The PDA has produced a detailed report on how these two groups could work in a supportive skill mix model for the benefit of the NHS and patients.

However, taking into account the significant difference between the training and formation of these two distinct groups, the services that each perform must be properly constructed and when receiving a service or advice in a pharmacy, patients deserve to know the difference, and whether they are dealing with a pharmacist or a pharmacy technician.

[19] GPhC announces results for June 2023 registration assessment
https://www.pharmacyregulation.org/news/gphc-announces-results-june-2023-registration-assessment

In a recent oral evidence session given at the Health and Social Care Committee on 16th January 2024 William Pett, the Head of Policy and Public Affairs and Research for the patient advocacy group Healthwatch, made some important contributions about this very point.

He said;

> "*Broadly, it is very understandable why some of the workforce challenges could be alleviated by expansion of what pharmacy technicians could offer. From a patient perspective, our sense from our research is that patients would welcome the increased use of pharmacy technicians, but only on the basis that they feel informed and aware of the difference between a pharmacy technician and a pharmacist.*
>
> *We would be concerned about patients seeing a pharmacy technician thinking that they are seeing a pharmacist. Our evidence shows that, when patients are taken through who they are seeing and what the role is of that professional, there is generally a good experience of care. The point around patient education and awareness is really important"*[20].

Since the creation of the register of pharmacy technicians in 2011, the government, the NHS, the pharmacy regulators, the Royal Pharmaceutical Society and the Association of Pharmacy Technicians UK have increasingly used the term 'pharmacy professional' to collectively describe pharmacists and pharmacy technicians.

Whilst this homogenisation or blurring of the lines between these two groups may well serve a broader agenda to expand the range of services being provided by pharmacy technicians, and give it a veneer of normality and acceptability, the increasing use of the phrase distinctly gives the impression of parity of these two occupational groups.

However, use of the term 'pharmacy professionals' confuses patients, policy makers and Members of Parliament, especially when the NHS, in its attempts to fix the workforce shortages seeks to enthusiastically develop new roles and services for pharmacy technicians that are way beyond their NVQ level 3 capability.

An example of this is the recent consultation on enabling NVQ level 3 pharmacy technicians to use Patient Group Directions (PGDs) at a time when the nearest comparator for PGD delivery in other healthcare areas is at NVQ level 5 or 6 and even at level 7.

In reference to the comments made by a senior representative of Healthwatch, members of the public deserve not to be exposed to 'parity of esteem' approach currently being taken by the NHS.

[20] Health and Social Care Committee - Oral evidence: Pharmacy, HC 140 - Tuesday 16 January 2024 https://committees.parliament.uk/oralevidence/14087/pdf/

The PDA urges the government to ensure that this practice ceases and that this homogenised approach is not reflected in the explanatory notes to the SI provided to Parliament.

The novel approach to this consultation

The establishment of a Sector Group has not been seen before, and this positive development has gone some way in dispelling the concerns and suspicions of pharmacists historically linked to how the government has handled supervision previously. It will be vital for the regulators to follow through and engage with this sector inclusive approach when they come to develop the forthcoming supervision regulatory rules and standards.

Managing prescription workload - out of hours assembly

It is possible to develop further the concept that the preparation and assembly of prescribed medicines is a technical activity that could be undertaken by pharmacy technicians and that the clinical assessment is a role that is reserved solely for the physically present pharmacist in a way that further assists with the reduction of the excessive community pharmacy workload.

One recommendation of the Sector Group that built upon this principle, recognised that the risks associated with the preparation and assembly of prescribed medicines when the pharmacy is not open to the public (for example in an out of hours situation) are far lower than when the pharmacy is open for business.

Currently, preparation and assembly can only occur when a RP is signed in, however, the Sector Group proposed that preparation and assembly could occur in a pharmacy that is closed with no RP signed in, but under the supervision of a superintendent pharmacist.

With the Superintendent taking responsibility for the accuracy of the dispensing, this would leave the RP responsible for undertaking the clinical assessment to enable the supply to be made. It is recognised that this would alter the approach to dispensing and possibly even the working patterns of RPs, however, with the resultant redistribution of the workload, this could release more time and create capacity for the RP to deal with pharmaceutical care.

Such an approach could encourage innovation in IT systems that support pharmacists in the undertaking of clinical assessments, as opposed to the current trend which is to replace clinical decision making by pharmacists with unregulated Artificial Intelligence.

The PDA supports such a proposal as the Superintendent Pharmacist is the person with the overall responsibility for the provision of resources, any IT systems and technology, as well as the oversight of pharmacy business operations. They should have accountability for assembly activity and the accuracy which happens when a pharmacy is not open to members of the public.

Systems to establish a clear separation of accountability between the SP for accuracy and RP for clinical assessment would need to be in place. This proposal puts a clear focus upon the RP as the clinician responsible for the safe use of medicines.

The PDA was disappointed that this transformational proposal was not contained within the current DHSC consultation and will be making continued representations with the DHSC as well as during the forthcoming RP/SP consultation of the GPhC and PSNI.

About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for profit defence association and trade union for pharmacists. It is the only organisation that exclusively looks after the interests of employee and locum pharmacists across all sectors of pharmacy. Currently with a membership of more than 37,000, the PDA is the largest representative membership body for pharmacists in the UK and this membership continues to grow.

Delivering more than 5,000 episodes of support provided to members who have found themselves in a critical incident situation in the last year alone, provides the PDA with a rich vein of up-to-date experiences which have informed policies and future strategy.

This experience has recently been informed by the very considerable number of Covid-19 related issues being faced by members. The practical experience gained in supporting member issues from the coal face is further enhanced by regular member surveys and focus group interactions. The information in this document is largely built upon the experience of our 37,000 members.

The primary objectives of the PDA are to:

- To advance and protect good health by promoting proper standards and best practice in pharmacy.
- To support the safe and effective practice of pharmacists at every stage of their career.
- To provide leadership and representation for employed pharmacists, and those in training.
- To protect, defend, lobby for and support the interests and reputations of pharmacists.
- To work with and support local, national and international organisations with similar objectives.
- To facilitate professional indemnity insurance, arrange benefits and undertake any other activities that can support the wider objectives.