The DHSC Consultation on Pharmacy Supervision

The PDA position and key points for members to consider

Introduction

For around 20 years the legal framework around pharmacy supervision has been debated, and finally, the DHSC is consulting on proposals around the future of this important subject.

The PDA has been highly active in this area and, in advance of this consultation was invited to be part of a sector practice group which was formed to try and find a way forward.

The Supervision Practice Group report was published in August 2023 and it forms the policy platform that the PDA is now using to respond to the DHSC consultation. This is one of the most important government consultations for pharmacists in decades and, because it is proposing to change the legal framework, it will determine the responsibilities of pharmacists and their accountabilities far into the future.

The PDA wants pharmacists to practice with professional fulfilment and job satisfaction and for the most appropriate respective responsibilities for pharmacists and pharmacy technicians to be defined in law. This should ultimately result in pharmacists being held responsible and accountable for medicines related issues, such as clinical assessments (the clinical check) and clinical patient interactions, and pharmacy technicians being held responsible and accountable for the technical and assembly elements of pharmacy practice – i.e. the accuracy of dispensing.

The PDA believes that the DHSC could provide a framework for the safe delivery of pharmaceutical care and pharmacy services from the UK-wide network of community pharmacies as outlined in the Supervision Practice Group Report. However, on their own, these proposals will not be enough; it will be important to ensure that the rules and standards produced by the GPhC/PSNI (following consultation) are relevant and supportive of our profession.

The GPhC/PSNI will hold their consultation later in the year and the PDA will provide further insights for members.

The PDA is providing a summary of key points for members to consider. These have been informed by legal counsel and a series of member engagement events, which have assisted the PDA to arrive at the positions described in this document.

The position statements are based on a foundation of long-standing PDA policies which were developed over many years through member surveys, focus groups, defence cases (including the case of Elizabeth Lee), and numerous conferences and events.

The PDA will be submitting a detailed organisational response which will be published in due course. Because of the important nature of these proposals which will shape the future of pharmacy practice for many years to come, the PDA is also appealing to as many members as possible to participate by responding, in their own words, to the online consultation which closes on 29th February 2024 Pharmacy supervision - Department of Health and Social Care (dhsc.gov.uk).

The PDA position on the consultation proposals

Key points to consider when responding to the consultation

Points found in the consultation that are not supported by the PDA

- 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.
- No authorisations can be given by any pharmacist remotely (from anywhere in the UK).
- Authorisations must not be simply given orally; they must be fully documented to enable a clear audit trail.
- Authorisations cannot be irrevocable.
- The clinical assessments of a prescription cannot be undertaken remotely or by anyone other than a pharmacist present in the pharmacy.
- Authorisations must not be the subject of an overriding Standard Operating Procedure.

Conditions required by the PDA

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

Proposal 1: introducing authorisation of a pharmacy technician by a pharmacist

- 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**.**

- Under such circumstances, a prescribed medicine may **only** be supplied to the patient **if the pharmacist first undertakes and is responsible for the clinical assessment**, leaving the pharmacy technician to take responsibility for the technical activity for which they have been authorised.

- 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** 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 with the pharmacy technician, 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 should be recognised by the GPhC and PSNI when formulating any new Rules and Standards.

Proposal 2: the handing out of pre-checked and bagged medicines to patients in the absence of a pharmacist

- 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 by 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 will not be authorised to be handed out in this **scenario.**

- **Authorisations given by an RP during their duty period cease at any point** as determined by the RP 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** 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, to a member of staff **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.

PDA comments on absence

The criteria for the absence of a pharmacist are not covered in the current consultation being held by the DHSC, however they are vitally important when considering supervision. The PDA position is as follows;

- Maintaining the two-hour maximum absence limit of the responsible pharmacist is now being passed from legislation to the rules of the GPhC/PSNI. The DHSC has acknowledged the Supervision Practice Group's recommendation about maintaining the current two-hour absence limit.
- When the GPhC/PSNI consultation occurs around rules and standards for the RP and Superintendent Pharmacist (SP), the PDA will seek to limit the impact on patient safety by strongly advocating that the two-hour absence period must not be extended
- Any prescription which is prepared and assembled out of hours or off site must not be supplied to a patient before it has been clinically assessed by a pharmacist present in the pharmacy where the supply will be made.

Not covered in the DHSC proposals

- To try and alleviate the consistently elevated levels of workload at a time when new clinical pharmacy services are emerging, the Supervision Practice Group recommended a mechanism for out of hours preparation and assembly of prescriptions when the pharmacy is closed.

- In this scenario, the accuracy of the items assembled when the pharmacy is closed with no RP signed in would fall under the accountability of the Superintendent Pharmacist. The RP would undertake and be held accountable for the clinical assessment prior to handing any medicines out to patients.

- The PDA recognises that the ongoing impact of workload on members is critical, and it is disappointing that this proposal, which was agreed through consensus by the pharmacy bodies on the Group, was not considered as part of the DHSC consultation.

Proposal 3: supervision by pharmacy technicians at hospital aseptic facilities

The PDA firmly believes that this proposal is not suitable for consideration as part of the consultation on supervision.

Quite differently from in 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 as part of a whole system consultation and in an entirely separate consultation.

Notwithstanding that, the PDA cannot support proposal 3 for the following reasons:

- 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 called for.

- 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.

If you have any detailed comments on the consultation or the positions outlined in this paper prior to the closing date of 29th February 2024, please email the PDA at supervision2023@the-pda.org