Pharmacy Supervision Consultation

Royal Pharmaceutical Society response

The Royal Pharmaceutical Society (RPS) states that a pharmacist can only be the Responsible Pharmacist (RP) for one pharmacy at any one time. The pharmacist should be more accessible to patients and the public as a result of changes to legislation and regulatory rules and standards.

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 1: 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

The RPS is supportive of proposal 1, and believes this enabling legislation should be enacted. The RPS has long advocated for the expansion of the clinical role of pharmacists, fully utilising their skills for patient benefits. Our visions for pharmacy across England, Scotland and Wales highlight the upskilling of all members of the pharmacy team as a key way to release the capacity for pharmacists to utilise their clinical and prescribing skills. Beyond legislative change, pharmacists and pharmacy teams will require support, both in terms of workforce development and adequate investment, to enable the consistent provision of high-quality pharmacy services. One example of this support could be the introduction of protected learning time for pharmacists by employers; and expectations for such set out by the General Pharmaceutical Council.

We welcome the clarification that these proposals are not a move towards allowing pharmacists to remotely supervise a pharmacy. The physical presence of at least one pharmacist in a community pharmacy (apart from under responsible pharmacist (RP) regulations allowing a specified time of absence) and to only be responsible for one pharmacy at any given time are fundamental. Supporting regulations and guidance should continue to cement this principle.

Whilst RPS is in agreement with the overarching enabling legislative proposal, our members are concerned about the nature in which authorisation is provided and withdrawn. We believe authorisation should be mandated to be documented, and that this is set out in future regulations, ideally in a digital format, to facilitate audit and review. Such provision would protect both the pharmacist as the person issuing the authorisation, and the pharmacy technician who can demonstrate their agreement to that authorisation. Our members are concerned that undocumented oral authorisations could lead to greater ambiguity and a lack of clarity over accountability in the event of an error. We are also concerned that the draft Statutory instrument under 220A (2) (d) only allows the pharmacists that issued the authorisation to withdraw it, “may be varied or withdrawn by the pharmacist by whom it is given”. We believe there need to be wider circumstances where a different pharmacist, acting as the RP can withdraw the authorisation.

Currently, the proposed legislation states that ‘a pharmacist’ can authorise. This means it could either be the Superintendent pharmacist (SI) or the Responsible Pharmacist (RP) or another pharmacist working in the pharmacy. There needs to be more clarity provided in regulations as to who can provide authorisation and in which situations. For example, whether or not the Superintendent pharmacist (SI) could authorise a number of pharmacy technicians at any given time, across a number of pharmacies, or whether it can only be the Responsible Pharmacist (RP) working in the pharmacy on any particular day. Clarity is also needed as to whether the authorising pharmacist has to agree who the pharmacy technician can themselves supervise to undertake tasks.

Accountability for any authorised activity must be made very clear and should be set out in forthcoming regulations. The proposed changes are likely to blur current responsibilities across the pharmacy team. Clarity needs to be given as to the degree of accountability and how it will be shared in terms of Responsible Pharmacist, the authorising pharmacist (if different to the RP) and the pharmacy technician.

The authorisation must be a two-way conversation and decision, not something imposed by a pharmacist. A person accepting the authorisation must be confident, competent and willing to do so. The accountability for the authorised activity must be clear to all. If the Responsible Pharmacist authorises a registered pharmacy technician to undertake certain tasks, then accountability for those tasks should follow, with shared accountability. Where a RP authorises non-registered pharmacy team members to undertake tasks, the accountability for that task would remain with the RP.

In addition, there should be further responsibilities for pharmacy owners included in future regulations to ensure that pharmacists are able to exercise their professional judgement when working as a Responsible Pharmacist and are not pressurised into giving authorisations to pharmacy technicians.

Patients and the public must be assured of a pharmacy technician’s capability, capacity, confidence and willingness to undertake and accept the responsibility that authorisation brings. There is a historical variance in pharmacy technician training, and support will be needed for some pharmacy technicians, in terms of investment in training, to cover any notable skills gaps, to ensure a level of consistency to support authorisation.

One route could be a competency framework for pharmacy technicians, supported by professional guidance to help assure a pharmacist when authorising a pharmacy technician to undertake more responsibilities. This could be similar to the current declarations of competence that pharmacists complete for service provision within community pharmacies.

Although this legislation is enabling, it is important to understand any unintended consequences that such changes may potentiate. For example, the potential to disadvantage those community pharmacies who do not have a regular pharmacy technician

employed. These changes must be viewed holistically and supported by adequate workforce planning and appropriate sustainable funding, to reward and recognise pharmacy staff for their skills and responsibilities.

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 2: 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.

RPS believes that patients and the public should continue to have access to the professional knowledge and skills of a pharmacist when required.

RPS have strongly advocated for a member of the pharmacy team to be able to hand out prescriptions that have been checked and bagged, when a pharmacist is signed in as a Responible Pharmacist but absent, and it is safe to do so.

In our policy position statement, 'Strengthening Pharmacy Governance' we stated that *Legislation change is needed to enable appropriate medicines that have been clinically checked, dispensed, and accuracy checked, to be given to a patient or their representative when the pharmacist is signed in as RP but absent.*

This provides a balance between supporting patient expectations in terms of accessing their medicines and the safety required with medicines supply. However, implementation must ensure that patients can engage with pharmacists and receive advice and support when they need it.

We believe this could be a straight forward process for those medicines that a pharmacist has approved and they deem suitable to be given to the patient with no planned further intervention by the pharmacist. Future professional guidance could identify those medicines at increased risk that may require an intervention, such as new medicines or controlled drugs.

If a prescription requires an intervention by the pharmacist prior to handing out, then there should be agreed procedures for these to be identified, that is understood by all pharmacy team members. In such cases the patient / carer should be asked to return to the pharmacy once the pharmacist is present. This would be following a risk-based decision undertaken by the RP at the time of assessing the professional and clinical appropriateness of the prescription for the individual person.

Standard operating procedures will need to ensure a robust process is in place to enable a patient to speak with the pharmacist, using technology or in person, within a reasonable timescale if they so wish.

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 3: 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.

We agree with this proposal to support the vitally important role that pharmacists and pharmacy teams play in providing technical services.

Technical Services is a highly skilled area of practice, where historically, pharmacists have been accountable for the preparation of high-risk medicines, in a controlled environment for vulnerable patients. Quality Management Systems within aseptic units describe roles, responsibilities and accountabilities of key personnel and will be critical when new accountable pharmacy technician roles emerge. Aseptic dispensing unit teams are already supported by skilled and knowledgeable pharmacy technicians.

We recognise that the necessary knowledge, skills and experience for these accountable pharmacy job roles will need to be clearly described in person specifications.

The competency of the individual responsible for the aseptic unit must be validated through a consistency of experience, education and training, irrespective of title.

We are aware that the initial education and training for pharmacy technicians no longer includes mandatory training on aseptic dispensing due to the reducing number of aseptic dispensing units in Great Britain. To ensure a sustainable pipeline of both pharmacists and pharmacy technicians moving into this career pathway, there must be access to relevant accredited training programmes.

The Chief Pharmacist must continue to be ultimately responsible for the aseptic unit in line with other responsibilities they have in this role, and ensure that where any pharmacy professional is responsible for a unit they have the adequate knowledge, skills, confidence and competence to carry out their duties.

Regulations will be required to describe any exclusions for products that may sit outside of this provision, such as radiopharmaceuticals and advanced therapeutic medicinal products.

‘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 4: 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:

We support the amendment concerning the supply of medicines from ‘on premises’ to ‘at or from’ and welcome it at this stage.

This will reflect current practice and support patients in accessing medicines in the most appropriate and convenient way for themselves.

This will help to remove any ambiguity that may exist around supply, in terms of home delivery of medicines, and also to align with other methods patient choose in which to access regular medicines, for example, locker box collection points.

Legislative barriers

Question 5: Do you think there any other barriers to modernising pharmaceutical practice in government legislation that we should consult on removing in the future?

Yes

No

Don’t know

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

- In line with the sector wider proposals set out by the Pharmacy Supervision Practice Group, legislation needs to 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 the SP. This is 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.

- In order to optimise the benefits of these legislative changes, pharmacists and pharmacy teams will require time to put in place the necessary procedures and training. The Royal Pharmaceutical Society recognises the importance of protected time for pharmacists as described in the Protected Learning Time Policy document.

- 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.

- NHS regulations will need to be updated following any changes to legislation and regulations to ensure consistency and standardisation, removing the position where the NHS regulations place a higher supervision requirement onto pharmacy teams.

- Given the current challenges pharmacists and pharmacy team face in addressing medicines shortages, we would welcome changes to the Human Medicines Regulations 2012 to enable pharmacists to make minor amendments to prescriptions without referring to a GP to support timely supply, in line with the RPS substitution policy.

Impact assessment

Question 6: 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.

Patients and the public expect a consistency in service from a community pharmacy. This legislative change could, unintentionally, cause confusion amongst patients and the public as to the difference between the regulated professions in pharmacy. Within an individual pharmacy, there will potentially be different processes in terms of authorisation arrangements being enacted on different days. These could be dependent on skill mix on any given day and the decision of the RP whether to authorise, or not. As a result, consideration should be given to the investment to be made into the public awareness campaign to support this change in legislation which has not been adequately captured in the impact assessment. For example, patients will require information to explain why on some occasions they may be able to collect medication when the pharmacist is not present but on other occasions this won't be possible.

Whilst the impact assessment suggests that there is a potential for an increase in errors, we note this is mitigated by the fact that pharmacy technicians are a registered and regulated healthcare professional in their own right.

Evidence shows that the current error rate in community pharmacy in low and we do not believe that these proposals alone represent a significant increase in patient safety risk. It is essential that good governance, regulatory standards, professional guidance and operational procedures are in place to support this change and mitigate against any perceived increased risk.

The monitoring of voluntary error reporting through the National Reporting and Learning system should highlight any change in patterns, positive or negative, which can then be evaluated.

Draft statutory instrument

Question 7: If you have any further comments on any aspect of the draft statutory instrument, please provide it here (maximum 350 words).

Under “Sale or supply of items dispensed by a pharmacist who is absent or treated as absent”

220B. (1) A person (P1) acts in accordance with this regulation where— (a) the transaction relates to a medicinal product that has been dispensed by or under the supervision of a pharmacist (P2) and is ready for sale or supply to the person for whom it has been dispensed;

While we have not sought legal expertise, we are concerned that the wording a “*medicinal product that has been dispensed by or under the supervision of a pharmacist*” may prohibit a member of staff being authorised to issue a bagged and checked item that has been prepared under the supervision of a different pharmacist. i.e. a medication that has been prepared and bagged the day before under the supervision of a different pharmacist to the Responsible Pharmacist on the day. We would want to ensure that the proposed wording enables supply and doesn’t present a further barrier to it.