Community Pharmacy England's response to the Department of Health and Social Care's consultation on supervision

February 2024

About Community Pharmacy England

We are the voice of community pharmacy in England, representing all of the c.10,800 community pharmacies across the country.

We champion community pharmacies across the country – representing our members and giving them the support they need, negotiating the best deal with the Government and NHS, and influencing positive change.

We represent community pharmacy businesses of all sizes in England and are responsible for negotiating the NHS Community Pharmacy Contractual Framework (CPCF) under which all community pharmacies operate.

We work closely with everyone in the community pharmacy sector, including the Local Pharmaceutical Committees (LPCs), to meet our goals and to promote the value of community pharmacy.

Because everyone in society needs community pharmacy to thrive.

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Community Pharmacy England is the operating name
of the Pharmaceutical Services Negotiating Committee.

Supervision

Consultation 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.

Community Pharmacy England supports this proposal, but on the basis that:

- in addition to a pharmacist authorising a pharmacy technician to dispense and supervise dispensing,
- a pharmacist's supervision of dispensing can and will be interpreted in the context of current good pharmacy practice.

As the Department of Health and Social Care's (DHSC) Impact Assessment indicates, there are relatively few pharmacy technicians available to pharmacies, and therefore many pharmacies will be unable to benefit from pharmacy technician dispensing, or may not be able to afford to employ a pharmacy technician. These pharmacies should still be able to benefit from the rebalancing of medicines legislation.

Our understanding is that the interpretation of pharmacist supervision in the context of current good practice is assisted and progressed by the following:

- The clarification of the current interpretation of supervision, and
- Recognition in judicial precedent that supervision was '…a matter of degree…' and would vary depending as to what the profession deemed best practice (Summers v Congreve Horner [1992]), and
- The recognition that *this* '… allows for a body such as the Royal Pharmaceutical Society (RPS) … to provide guidance as to what is good practice in the profession …', and

- The commitment by the Royal Pharmaceutical Society (RPS) to issue new professional guidance on the interpretation of supervision, and
- The extent of that interpretation must be within the '… presumed limits to how far a professional body could go with issuing this sort of guidance, even though there are no legal bright lines to say when these limits would be reached…'.
  (DHSC's consultation on supervision, in particular, Annex B)

Supporting comments

1. Community Pharmacy England accepts that supervision of the preparation, dispensing and supply of medicines should only be carried out by a suitably quantified and regulated healthcare professional who is a member of the pharmacy team and, therefore under pharmacist oversight from the Responsible Pharmacist (RP) and any Superintendent Pharmacist (SP).

2. There are insufficient pharmacy technicians available for all community pharmacies and some would be unable to afford one in any event. Therefore, this consultation must enable the interpretation of pharmacist supervision (and authorised pharmacy technician supervision) to be clarified and developed so that it applies to current good pharmacy practice.

3. Annex B of the consultation provides helpful guidance on the current interpretation of supervision – which enables a pharmacist having checked a prescription to then provide clinical consultations from the consultation room while still supervising the dispensing and supply process (with the use of protocols etc.) The full extract from annex B is set out at the end of this response.

4. It was noted that a supervising pharmacist is not required by legislation to be physically presence in the pharmacy (unlike the RP, subject to the RP Rules), but such physical presence is required as part of good pharmacy practice.

5. There was agreement that the legislation should remain flexible on the manner of authorisation, and that guidance on this, should be a matter of professional standards or guidance. The appropriate records that should be maintained of such authorisations should also be a matter of professional standards or guidance.

6. It was considered that any appropriate pharmacist should be able to authorise, or withdraw any previous authorisation, from a pharmacy technician, otherwise, there could be concurrent and conflicting authorisations.

7. It was noted that legislation provides for the sale and supply of GSL medicines at the pharmacy premises, but not from the pharmacy premises (reg 221 of the HMRs). Whether an amendment is required is debatable, and there was no wish to encourage sales of GSL medicines from (meaning, for example, by post) any retail premises.

8. There was support for the proposals relating to unsafe dispensing, in particular, that this may be considered to be misconduct for the purposes of the relevant disciplinary committee (in Great Britain the GPhC Fitness to Practise Committee).

9. There is a need to support pharmacy technician training, including financially, and to consider fast-tracking, to varying degrees, of other pharmacy staff who are appropriately qualified or experienced, so that they can qualify as pharmacy technicians.

10. The following clarification was noted, that '… GP practice dispensaries (dispensing doctors) generally fall outside the scope of this consultation. In these locations, the dispensing of medicines is done under the authority of a doctor, rather than a pharmacist …'

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.

Broadly, Community Pharmacy England supports this proposal.

This support is based on changes to, and clarification of, the draft legislation to ensure that bagged and checked medicines at the pharmacy can be:

- dispensed or prepared by or under the supervision of any pharmacist at the pharmacy, and
- dispensed or prepared by or under the supervision of any duly authorised pharmacy technician …
- dispensed or prepared by a hub pharmacy in the same pharmacy business (with relevant pharmacist supervision in the hub and spoke pharmacy). (In due course this is likely to include hub and spoke dispensing between different pharmacy businesses or organisations, for example, other registered pharmacies in the community or hospital.)

and at that pharmacy, can be:

- handed out to a patient or the patient's representative by any authorised member of the pharmacy team, and
- collected from an automatic locker box or equivalent that is located at or on the registered pharmacy premises (i.e. the locker box does not have to be outside the registered pharmacy premises which is the current practice).

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.

Community Pharmacy England has no comments in relation to this proposal.

Supervision

Additional questions

'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 registered premises.

Community Pharmacy England accepts this change on the basis that:

- 'at' means the sale or supply, or offer of the sale or supply, by a person, or as a statement etc, as appropriate, situated or located, at or on, the registered pharmacy premises, and premises (in terms of good practice) any supervision required takes place by a person at, or on, the pharmacy premises; and
- 'from' means the same as 'at' but, in addition, the sale or supply having been made and supervised at the registered pharmacy premises, the dispensed medicine is then transported or taken to the patient, or the patient's representative, at a location other than the pharmacy – and any offer of any sale or supply may communicated more widely but is about a sale or supply at the pharmacy premises with the medicine delivered etc. i.e. from the pharmacy.

Legislative barriers

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

There are some topics that Community Pharmacy England will bring to the DHSC for discussion.

Impact assessment

- 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).

This is noted.

Draft statutory instrument

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

Comments have been provided in the responses to proposals 1 and 2.

Supporting comments in relation to Responsible Pharmacists, noting the GPHC consideration of new RP Rules and RP standards

Community Pharmacy England considered that:

- Any appropriate pharmacist should be able to authorise a pharmacy technician and there is no need to restrict this to the RP.
- The time an RP should be allowed to be absent from the pharmacy should remain at 2 hours, even though this appears to be an arbitrary time. In due course, consideration could be given to a risk-based assessment, to consider the appropriate length of time the RP may be away from the pharmacy premises.
- The ability to sell or supply GSL medicines from a pharmacy in the absence of a pharmacist remains important in practice.
- There was support for the preparation and assembly of medicines before an RP is signed into a pharmacy – with the RP after arrival, to make appropriate checks of all relevant

work carried out before the RP's arrival. Such activity to be subject to the oversight of the SP.

Supporting comments in relation to Serious Shortage Protocols (SSPs) and Original Pack Dispensing (OPD)

SSPs

Community Pharmacy England considered that:

- SSPs for a substitute or alternative medicine are not appropriate for supply by or under the supervision of an authorised pharmacy technician.

OPD

Community Pharmacy England considered that:

- OPD +/- 10% more or less of the prescribed POM should remain subject to the relevant amendments to the Human Medicines Regulations (regulation 217A) and as stated should not take place:
  '… in circumstances where a pharmacist is carrying out or supervising the sale or supply and the pharmacist considers, in the exercise of their professional skill and judgement, that the sale or supply of a different quantity to that ordered on the prescription may mean that the patient does not, or is not able to, follow the medication regimen as intended by the prescriber…'
- However, after a pharmacist …
  - has made the above professional decision, and overall has decided that it is appropriate to supply 10% more or less of the POM to the patient in an OP, or

- in the case of a POM where there is an exemption to supply an OP (these are set out in the HMRs but for NHS dispensing and reimbursement are known as 'special containers'), or
- in the case of P or GSL medicines, where similar principles apply and the pharmacist has decided that the supply of an OP is appropriate for the patient; and
- any of the above is appropriate in the context of NHS supply (currently NHS supply does not include OPD +/- 10% supply etc),

… the pharmacist should be able to authorise the supply to be made by or under the supervision of a pharmacy technician.

Summary

In summary, we support proposals 1 and 2 as outlined above.

We are grateful to the sector's Supervision Working Group, which indicated a desire for change on the issue of supervision.

We are also grateful to the DHSC team managing this consultation for their assistance and to the DHSC teams that have considered the issue in previous years.

Annex

'… What this means, when compared to the terms of the original Roberts definition of 'supervision' is as follows:

- in the case of a POM or P supply of a dispensed medicine:
    - as regards the 'awareness' requirement, the pharmacist will be aware of the supply (having done the earlier checks), but will not be aware of the actual supply at the moment to supply
    - the 'in a position to intervene' requirement is met by the pharmacist being on the premises and interruptible, and procedures or protocols ensuring that the supply

will not ahead if the threshold for a pharmacist's intervention is met but the pharmacist was not interrupted

- in the case of a P sale:
    - the 'awareness' requirement no longer applied because it was not considered professionally necessary
    - the 'in a position to intervene' requirement was again met by the pharmacist being on the premises and interruptible, and procedures or protocols ensuring that the supply will not go ahead if the threshold for a pharmacist's intervention was met but the pharmacist was not interrupted

This clearly put most strain on the Roberts position in the case of supply of P medicines – because of the difficulty in arguing that a pharmacist was aware, in any but the most general terms, of the transactions in question. However, DHSC and the devolved administrations have supported the RPS approach, recognising that the approach taken by the Court of Appeal in Summers does allow for a body such as RPS or PSNI to provide what amounts to a determination of what good practice in the profession would regard as necessary – and the 2005 guidance amounts to a reasonable determination, updating Roberts, in this case.

That said, there are presumed limits to how far a professional body could go with issuing this sort of guidance, even though there are no legal bright lines to say when these limits would be reached. It is not thought that the proposals covered in this consultation document could not simply be achieved by RPS or PSNI simply issuing even more flexible guidance on the meaning of 'supervision', for example. Some consistency with the courts' historic approach is necessary, even if the updating of that approach that has happened to date properly uses tools that the courts' themselves have given to provide such an update.

That said, it is important to emphasise that the proposed changes to legislation will not, in themselves, redefine 'supervision' – and supervision by a pharmacist will continue as before as one route to lawful preparation, assembly, dispensing and final sale or supply. New routes to the lawful undertaking of these activities are being established, which add to what is there at the moment, but conventional supply by or under the supervision of a pharmacist will remain an option. …'