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Pharmacy and the Law

Getting to grips with “supervision”

Richard Hough, a practitioner in pharmacy law, takes a look at the complicated subject of supervision in pharmacies



An unnecessarily complicated mixture of case law and legislation currently governs the supervision by pharmacists of the assembly, sale and supply of medicinal products. The main source of legislation, the Medicines Act 1968, was drafted in an age when advanced and enhanced services had not been widely contemplated, if at all, and many of its ambiguities and deficiencies have been addressed through case law, to leave us with a patchwork quilt of rules and guidance which are unacceptably uncertain.

Community pharmacists are providing a wider range of services than ever, but, unfortunately, the law governing supervision has not kept pace with pharmacy's evolution and, due to this unacceptable uncertainty, is now considered as being no longer suitable for modern pharmacy practice.

An opportunity to amend the law governing supervision arose in 2009 when, after a period of extensive consultation, the Responsible Pharmacist Regulations came into force. It was envisaged at the time of their implementation that they would support the development of a more flexible clinical role for community pharmacists and create a need to place greater reliance and responsibility on pharmacy support staff.

To support the development of this evolving role, the RP Regulations allow for the responsible pharmacist to be absent from pharmaceutical premises for a maximum period of two hours during the pharmacy's business hours. However, being held accountable for acts undertaken from the pharmacy during temporary absence has understandably proved to be a cause for concern to many pharmacists.

Tasks

Central to this concern is the degree of supervision which must be exercised by pharmacists over certain tasks being undertaken by pharmacy staff during any period of absence from a pharmacy during opening hours.

More fundamentally, a significant proportion of respondents (66 per cent) to the Royal Pharmaceutical Society's (RPS) recent consultation on supervision believe that a community pharmacy cannot be open safely to the public in the absence of a pharmacist

and that to do so would compromise patient safety.

Clearly, therefore, the opportunities for community pharmacists to develop a more flexible, clinical role away from the pharmacy, as envisaged by the RP Regulations, are considered by a significant number of pharmacists not to be worth pursuing due to the perceived risk to patient safety. In light of this prevailing unease amongst many pharmacists, it is evident the opportunity to consult on supervision alongside the RP Regulations was a missed one, which is why the RPS consulted its members on the issue.

A previous article of mine (*ICP*, October 2010, p12) has covered the main areas of uncertainty surrounding the law governing supervision. Briefly, “supervision” is not defined in the Medicines Act. Case law provides some guidance but somewhat unhelpfully has ascribed different meanings to supervision in relation to, firstly, the sale or supply of medicinal products (physical presence is required) and secondly, their assembly (physical presence may not be required, as long as good practice within the profession is adhered to).

access medicines (including POMs, Ps and GSLs), quality assured medicines information and pharmaceutical services

2. Patient safety and wellbeing is paramount and this needs to be ensured via quality systems and processes

3. Patients should have their medicines supply overseen by a pharmacist and they should have a right to counselling about their medicines

4. Patients have a right to expect that a pharmacist will perform a professional check on every prescription dispensed

5. The need and respect for the pharmacy profession must be protected

6. Any changes to supervision should not lead to an increase in risk and any changes in workload must be at an acceptable level for the profession

7. A pharmacist can only be responsible for one pharmacy at any one time

8. Supervision models may differ in different settings but there must be adequate staffing levels to deliver the services required.

Position statements

Further to consulting its members, the RPS has now published five position statements, upon which its official response to the Department of Health's consultation on supervision will be based, which are as follows:

- There should be common overarching principles which derive from standards of pharmaceutical care that describe what patients should expect from all pharmacists. However, the requirements of supplying patients with medicines differ significantly depending upon the sector of practice, so this will mean that the operational implementation of any changes to supervision requirements (or regulations) will need to reflect this diversity.

- The supply of prescribed medicines to the public requires a clinical check by a pharmacist to ensure that the medicine is appropriate, and this should comply with professional and regulatory standards.

- Pharmacists hold patient safety at the centre of their practice and they must have sufficient autonomy to guarantee that their pharmaceutical care of patients is delivered in a way that is as safe as possible for their patients. Changes to supervision requirements (or regulations) must further empower individual pharmacists to exert their professional duty on behalf of their patients.

- Pharmacy has always been at the forefront of technological advance. Future technological

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The RPS has sought the views of its members on the following principles, which it has identified as being integral to the concept of supervision and how the future of supervision, insofar as it relates to community pharmacy, should be shaped:

1. Patients and the public have a right to

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advances may provide better, safer and cheaper processes for assisting with the assembly of prescriptions and any changes to supervision requirements (or regulations) should enhance patient safety. Innovations should allow the pharmacist to concentrate upon patient care and ensure continuity of, and enhance the quality of, pharmaceutical care.

● Changes to the role of pharmacists towards increasing clinical and public health service provision are to be promoted. Supervision requirements (or regulations) should be amended so that direct hands-on supervision of the assembly of prescriptions can be delegated to a registered pharmacy technician. With suitable support in place, this delegation can be effective and safe when the pharmacist is readily accessible within the healthcare facility. This ready accessibility of the pharmacist will enable progressive, high quality, pharmaceutical care for patients. The public rightly expect a pharmacist to be present within the healthcare facility whenever the pharmacy is open.

If the RPS's recommendations are adopted, supervision requirements will be based on certain core principles which have patient welfare at their centre, but which should be sufficiently flexible to adapt to operational differences in different sectors of the profession and also to anticipate future technological advances. Improved clarity of regulation concerning the delegation by pharmacists of direct supervision of the assembly of prescriptions to registered pharmacy technicians, but only when the pharmacist is readily accessible within the pharmacy, should be sufficient to appease the fears of the many pharmacists who believe that assembly of medicines should not occur in a pharmacy in the absence of a pharmacist.

Influential

The RPS will undoubtedly be influential in shaping any future changes to supervision regulation, which will need to ensure that a balance is struck between maximising the opportunities afforded to pharmacists to provide our patients with a greater range of services, ensuring patient safety and confidence in the profession, and ensuring that we remain accessible to our patients.

This increased engagement will not happen though if, through uncertain regulation, we remain tied to our dispensary benches.

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