



**Royal  
Pharmaceutical  
Society**  
of Great Britain

## **Responsible pharmacist requirements: What activities can be undertaken?**

### **Status of this document**

This guidance is intended to assist the profession in implementing the responsible pharmacist requirements within registered pharmacy premises.<sup>1</sup>

Appendix A provides more information as background to this document.

### **Purpose of this document**

In preparing for the implementation of the responsible pharmacist requirements the profession has had to carefully review current working practices.

One of the consequences of this work is that the profession has identified some activities which registered pharmacies undertake when a pharmacist may not be present in the pharmacy. This document aims to set out a list of key relevant activities and clarify whether they:

- 1) Require a responsible pharmacist to be in charge of the premises (s/he may be absent for up to two hours per day), and need to take place under the supervision of a pharmacist and the supervising pharmacist will need to be physically present at the premises;
- 2) Require a responsible pharmacist to be in charge of the premises (s/he may be absent for up to two hours per day) and take place under the supervision of a pharmacist but who may not need to be physically present at the premises;
- 3) Require a responsible pharmacist to be in charge of the premises (s/he may be absent for up to two hours) but does not require the supervision of a pharmacist;
- 4) Do not require a responsible pharmacist to be in charge of the premises but does require the pharmacy support staff undertaking the activity to be appropriately trained and for the activity to be done under standard operating procedures.

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<sup>1</sup> This guidance is intended to assist in understanding the requirements of the Medicines Act 1968. However, it does not represent an authoritative statement on the law. There is no substitute for reference to the law itself or for seeking professional legal advice as to what the law says or how it applies in particular circumstances.

**1) Activities which require a responsible pharmacist to be in charge of the premises (s/he may be absent for up to two hours per day), and need to take place under the supervision of a pharmacist and the supervising pharmacist will need to be physically present at the premises.**

*(This is not an exhaustive list).*

Activity	Underpinning legislation	Who is accountable?	Other regulatory considerations
Professional check (clinical and legal check) of a prescription.	The professional check is not required under the Medicines Act 1968.  The responsible pharmacist / superintendent responsibilities covered by Sections 70, 71, 72 and 72A of the Medicines Act 1968.	1) Pharmacist undertaking the activity; 2) Responsible pharmacist accountable for the SOPs being in place; 3) Superintendent / pharmacy owner responsible for the overarching governance framework.	The check is required under NHS pharmaceutical services legislation and under the Code of Ethics and Professional Standards for pharmacists.
Sale/supply of pharmacy medicines.	Sections 52, 70, 71, 72 and 72A of the Medicines Act 1968.	1) Pharmacist undertaking or supervising the activity; 2) Responsible pharmacist accountable for the SOPs being in place; 3) Superintendent / pharmacy owner responsible for the overarching governance framework.	'Supervision' in this context requires physical presence and a pharmacist being able to advise and intervene.
Sale/supply of prescription-only medicines (e.g. handing dispensed medicines over to a patient, patient representative or a delivery person).	Sections 52, 58, 70, 71, 72 and 72A of the Medicines Act 1968.	1) Pharmacist undertaking or supervising the activity; 2) Responsible pharmacist accountable for the SOPs being in place; 3) Superintendent / pharmacy owner responsible for the	'Supervision' in this context requires physical presence and a pharmacist being able to advise and intervene.

		overarching governance framework.	
Supply of medicines under a patient group direction.	Sections 52, 58, 70, 71, 72 and 72A of the Medicines Act 1968.  Articles 12A-12E of the Prescription Only Medicines (Human Use) Order 1997.	1) Pharmacist undertaking or supervising the activity; 2) Responsible pharmacist accountable for the SOPs being in place; 3) Superintendent / pharmacy owner responsible for the overarching governance framework.	'Supervision' in this context requires physical presence and a pharmacist being able to advise and intervene.
Wholesale of medicines.	Section 10(7) of the Medicines Act 1968.	1) Pharmacist undertaking or supervising the activity; 2) Responsible pharmacist accountable for the SOPs being in place; 3) Superintendent / pharmacy owner responsible for the overarching governance framework.	'Supervision' in this context requires physical presence and a pharmacist being able to advise and intervene.
Emergency supply of a medicine(s) at the request of a patient or healthcare professional.	Sections 52, 58, 70, 71, 72 and 72A of the Medicines Act 1968.  Article 8 of the Prescription Only Medicines (Human Use) Order 1997.	1) Pharmacist undertaking or supervising the activity; 2) Responsible pharmacist accountable for the SOPs being in place; 3) Superintendent / pharmacy owner responsible for the overarching governance framework.	'Supervision' in this context requires physical presence and a pharmacist being able to advise and intervene.

**2) Activities which require a responsible pharmacist to be in charge of the premises (s/he may be absent for up to two hours per day) and take place under the supervision of a pharmacist but who may not need to be physically present at the premises.**

*(This is not an exhaustive list).*

Activity	Underpinning legislation	Who is accountable?	Other regulatory considerations.
<p>The assembly process (including assembly of monitored dosage systems):</p> <ul style="list-style-type: none"> <li>• Generating a dispensing label;</li> <li>• Taking medicines off the dispensary shelves;</li> <li>• Assembly of the item (e.g. counting tablets);</li> <li>• Labelling of containers with the dispensing label;</li> <li>• Accuracy checking.</li> </ul>	<p>Section 10(1)(a) of the Medicines Act 1968.</p>	<p>1) Responsible pharmacist is accountable for the SOPs being in place, operated effectively and kept under review; 2) Superintendent / pharmacy owner is responsible for the overarching governance framework.</p>	<p>‘Supervision’ in this context may not require the physical presence of a pharmacist. The level of supervision required of the suitably trained staff who undertake this work will depend on what is regarded as good practice within the pharmacy profession (see the note in the Appendix below).</p>

**3) Activities which require a responsible pharmacist to be in charge of the premises (s/he may be absent for up to two hours) but does not require the supervision of a pharmacist.**

*(This is not an exhaustive list).*

<p>Sale of general-sale list medicines.</p>	<p>Sections 51, 70, 71, 72 and 72A of the Medicines Act 1968.</p>	<p>1) Responsible pharmacist is accountable for the SOPs being in place and operated effectively; 2) Superintendent / pharmacy owner is responsible for the overarching</p>	<p>Undertaken by suitable trained staff and operating within an agreed documented operating procedure.</p>
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		governance framework.	
Processing waste stock medicines or patient returned medicines (excluding controlled drugs).	<p>Regulation 4 of the Medicines (Pharmacies)(Responsible Pharmacist) Regulations 2008 requires this to be addressed in pharmacy procedures.</p> <p>The Hazardous Waste (England and Wales) Regulations 2005.</p> <p>The Waste Management Licensing Amendment (Scotland) Regulations 2006.</p>	<p>1) Responsible pharmacist is accountable for the SOPs being in place and operated effectively;</p> <p>2) Superintendent / pharmacy owner is responsible for the overarching governance framework.</p>	<p>Undertaken by suitable trained staff and operating within an agreed documented SOP.</p> <p>There are also medicines disposal obligations in NHS pharmaceutical services legislation.</p> <p>Responsible pharmacists and superintendents should give consideration to processing stock or patient returned medicines which are controlled drugs.</p>
<p><b>4) Activities which do not require a responsible pharmacist to be in charge of the premises but does require the pharmacy support staff undertaking the activity to be appropriately trained and for the activity to be done under standard operating procedures.</b></p> <p style="text-align: right;"><i>(This is not an exhaustive list).</i></p>			
<b>Activity</b>	<b>Underpinning legislation</b>	<b>Who is accountable?</b>	<b>Other regulatory considerations</b>
Ordering stock from pharmaceutical wholesalers.	Regulation 4 of the Medicines (Pharmacies)(Responsible Pharmacist) Regulations 2008 requires this to be addressed in pharmacy procedures.	<p>1) Superintendent / pharmacy owner is responsible for the overarching governance framework.</p> <p>2) Responsible pharmacist is accountable for the safe and</p>	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.

		effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	
Receiving stock from pharmaceutical wholesaler into the building (excluding controlled drugs).	Not covered by legislation.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.  Responsible pharmacists and superintendents should give consideration to how the pharmacy receives orders containing controlled drugs taking in to account the Misuse of Drugs Regulations 2001
Putting medicinal stock received from the wholesaler away onto the pharmacy shelves (GSL, P and POMs, excluding CDs).	Regulation 4 of the Medicines (Pharmacies)(Responsible Pharmacist) Regulations 2008 requires this to be addressed in pharmacy procedures.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.  Responsible pharmacists and superintendents should give consideration to how the pharmacy handles controlled drugs in accordance with the Misuse of Drugs Regulations 2001

Date checking (excluding controlled drugs).	Not covered by legislation.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.  Responsible pharmacists and superintendents should give consideration to how the pharmacy date checks controlled drugs in accordance with the Misuse of Drugs Regulations 2001
Stocking pharmacy with consumables.	Not covered by legislation.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.
Cleaning of the pharmacy	Not covered by legislation.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.  Responsible pharmacists and superintendents

		effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	should give consideration to how access to the registered pharmacy premises is controlled, especially if cleaning of the pharmacy takes place overnight when the pharmacy is closed and/or if cleaning services are contracted out.
Responding to enquiries (about medicine issues).	Regulation 4 of the Medicines (Pharmacies)(Responsible Pharmacist) Regulations 2008 requires this to be addressed in pharmacy procedures.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.
Accessing the PMR.	Not covered by legislation.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.  Responsible pharmacists and superintendents should give consideration to how access to confidential information is protected in

		operation of SOPs.	accordance with Data Protection and confidentiality requirements.
Receiving prescription directly from patients or collecting from a surgery	Not a mandatory requirement but should be addressed in the pharmacy procedures.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.  Obligations under NHS pharmaceutical legislation to ensure that prescriptions are dispensed with reasonable promptness.
Processing of prescription forms that have been dispensed (e.g. counting number of items dispensed, sorting prior submission for reimbursement).	Not covered by legislation.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.  NHS reimbursement covered under NHS legislation.
Delivery person conveying medicines to the patient.	Regulation 4 of the Medicines (Pharmacies)(Responsible Pharmacist) Regulations 2008 requires this to be addressed in pharmacy procedures.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.

		2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Responsible pharmacists and superintendents should give consideration to what will happen to undelivered medicines especially relating to controlled drugs.
Receiving patient returned medicines (excluding controlled drugs).	Not covered by legislation.	1) Superintendent / pharmacy owner is responsible for the overarching governance framework. 2) Responsible pharmacist is accountable for the safe and effective operation of the pharmacy, once they are in charge, including the operation of SOPs.	Undertaken by suitable trained staff and operating within an agreed documented operating procedure.  Obligations under NHS pharmaceutical services legislation are engaged so it is advisable that this activity is only undertaken in opening hours.  Responsible pharmacists and superintendents should give consideration to how the pharmacy handles receipt of patient returned medicines which are controlled drugs in accordance with the Misuse of Drugs Regulations 2001

## **Appendix A – Background information on the responsible pharmacist requirements within the context of this document.**

The responsible pharmacist requirements set the quality framework for registered pharmacy premises to safeguard patients and the public in relation to the sale and supply of medicines. They support the pharmacist in exercising professional responsibilities and accountability. Legislation makes clear what the pharmacist in charge of a registered pharmacy must do to ensure that he or she meets the legal duty to secure the safe and effective running of the pharmacy – as distinct from the role of the pharmacy owner and the superintendent pharmacist.

Some registered pharmacy premises may operate with more than one pharmacist working in the pharmacy at the same time. In these circumstances, only one pharmacist can be the responsible pharmacist. The other pharmacist(s) are still responsible and accountable for their actions but they are not the 'responsible pharmacist' at any given time.

The owner and/or superintendent pharmacist has an obligation to be satisfied that the person they appoint as a responsible pharmacist is competent to take on the role of ensuring the safe and effective running of a pharmacy.

Currently, Sections 70 to 72 of the Medicines Act 1968 require each pharmacy business to be under the personal control of a pharmacist. The personal control requirement relates to the sale and supply of **all** medicines, including those on the general sale list (GSL medicines).

To define more clearly the role of the pharmacist in charge of the pharmacy, Sections 27, 28 and 29 of the Health Act 2006 amend sections 70, 71 and 72 of the Medicines Act 1968 to remove the "personal control" requirement and to provide for a new requirement for a responsible pharmacist to be in charge of each registered pharmacy. Like "personal control", the new requirement relates to all registered pharmacy premises both in the community and in some hospitals

In addition, section 72A makes provision for Regulations concerning the responsible pharmacist to be made. These Regulations are the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008.

The Society has also consulted on and published Professional Standards and Guidance for responsible pharmacists.

After 1<sup>st</sup> October 2009, if a pharmacy does not have a responsible pharmacist, it will be operating illegally in relation to the retail sale and supply of all medicines.

### **Explanation of 'assembly'**

One issue that has been frequently raised with the Society is that of the 'assembly' of medicines against a prescription. The assembly of medicines against a prescription is controlled by Section 10 of the Medicines Act 1968. In relating to a medicinal product 'assembly' is defined by the Medicines Act 1968 as:

*"enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it."*

Section 10 of the Medicines Act 1968 requires that the assembly process takes place under the 'supervision' of a pharmacist.

Supervision is not defined in the Act, and since the time the legislation was written the nature of assembly has changed in many instances. The introduction of patient packs has reduced the need to pack down or break bulk and the act of assembly often involves 'picking' the product rather than creating the final package or extemporaneously preparing medicines. The skills and competencies of staff undertaking dispensing activities have been developed and there is more emphasis of making full use of support staff releasing time for the pharmacist to provide a wider range of services. However, the legal definition remains the same.

The courts have considered the issue of the nature of 'supervision' required for the purposes of sale or supply of medicines and have concluded that, where supervision by a pharmacist is required, the actual transaction cannot take place without the physical presence of a pharmacist who is able to advise and intervene, even though s/he will not need to carry out the transaction themselves. However, the level of supervision required for assembly activities is less clear, and so for these activities, reference has to be made to more general case law of what 'supervision' means in the context of professional supervision. The general position (derived from the Court of Appeal's judgment in *Summers v Congreve Horner & Co* [1992] 2 EGLR 152) is that supervision, in the context of professional supervision, means the degree of supervision required by what is regarded as good practice within the profession, having regard to the qualifications and experience of the person being supervised, but actual physical presence may not be necessary.

Applying that to the present context, it means that if the pharmacist responsible for supervising assembly of a medicinal product is absent, pharmacy support staff may continue to carry out activities which are considered to be "assembling" activities for the purposes of the definition set out above, without breaching the legislation, provided it is recognised good practice within the pharmacy profession that they be allowed to do so. The Society has published its good practice guidance separately, but it is important to emphasise that no single solution fits all circumstances. What may be good practice for one type of assembling activity may not be good practice for other types of assembling activities, and all such activities must be "supervised" at an appropriate level.

It is also important to emphasise that this does not affect the position that the **supply** of assembled medicines against a prescription is prohibited unless the pharmacist is physically present in the registered pharmacy and in a position to advise and intervene. However, 'supervision' is not a 'one size fits all circumstances' legal concept, and the courts have recognised this.

### **Explanation of the 'Pharmacy Record'**

The pharmacy record is an important legal document. It documents who was accountable for the safe and effective running of the pharmacy (the responsible pharmacist) on any given date and at any time. This audit trail is very important in the event of any incident or error as it documents who was accountable. The record must be accurate and made contemporaneously by the responsible pharmacist. The record must also accurately record any absence.

It is important to remember that the pharmacy record is a 'record' of who has been the responsible pharmacist (and any absences) and it is not a case that a pharmacist 'signs in' and 'signs out' as being the responsible pharmacist.

For example, a registered pharmacy which has the same responsible pharmacist Monday to Friday may decide to make the record at the end of the week (i.e. on Friday evening) or they may like to make the record as they go along (e.g. making the record each day). The pharmacist must be able to justify that the record is contemporaneous.

If the pharmacy wishes to undertake activities at the start or at the end of the working day which requires a responsible pharmacist to be in charge of the pharmacy premises but does not require the physical presence of a pharmacist the responsible pharmacist may be absent for up to two hours during these times. The pharmacy record must reflect this.