

INSPECTORS' CHECKLIST – MONITORING AND INSPECTION VISITS



Royal
Pharmaceutical
Society
of Great Britain

Status of this document

This checklist is intended for use by the Society's Inspectorate; however pharmacists, pharmacy owners and superintendent pharmacists may find it of assistance when preparing for a monitoring and inspection visit. Pharmacists may also wish to use this document for the purposes of self audit at any other time.

The Society's Inspectorate also undertakes monitoring and inspection visits that specifically look at how controlled drugs are managed within the pharmacy. For a checklist relating to the controlled drug monitoring and inspection visit see: www.rpsqb.org/pdfs/inspformAES.pdf (England and Scotland) or www.rpsqb.org/pdfs/inspformAW.pdf (Wales).

The Inspector will often carry out the monitoring and inspection visit at the same time as the controlled drug monitoring visit.

Background

During a monitoring and inspection visit the Inspector will examine how the pharmacy operates with the aim of ensuring that the supply of medicines and the provision of pharmacy services to patients from a registered pharmacy are safe and do not pose a risk to patient safety.

Where a monitoring and inspection visit shows areas of risk and non-compliance with the legislation and/or professional standards expected of a registered pharmacy and/or registered pharmacist/pharmacy technician the Inspector will seek to secure compliance by providing advice and support. If compliance is not secured the registrant may be subject to professional disciplinary proceedings.

From the 1st October 2009 the concept of personal control will be replaced with the introduction of the responsible pharmacist. The responsible pharmacist now makes clear what the pharmacist in charge of a pharmacy (i.e. the responsible pharmacist) must do to ensure that he or she meets the legal duty of a pharmacist to secure the safe and effective running of a pharmacy. This is distinct from the role of the pharmacy owner and the superintendent pharmacist.

This is a significant change in pharmacy that will directly effect every registered pharmacy and therefore the Society has modified this checklist to incorporate a specific section on the responsible pharmacist. As with the other sections that make up this checklist, this is intended to be a guide to show what the Inspectorate may look for during a monitoring and inspection visit. To try and support pharmacists through the implementation of the responsible pharmacist requirements, this checklist now also includes specific comments on what the Inspectorate will be expecting to find in place during a monitoring and inspection visit to demonstrate compliance with the legislation and professional standards underpinning the responsible pharmacist.

General

Opening hours	
Telephone number	
Email address	

Responsible pharmacist requirements

From the 1st October 2009, every registered pharmacy premises will be required to have a responsible pharmacist appointed during the pharmacy's business hours. In this context "business hours" means the period during which the pharmacy business is operational on any day (between midnight and midnight).

The responsible pharmacist is responsible for the safe and effective running of the registered pharmacy.

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. The individual pharmacist should also be satisfied that he or she is competent and has the necessary skills to assume the role of the responsible pharmacist. In order to do this the responsible pharmacist will need to establish the scope of the role and take all reasonable steps to clarify any ambiguities or uncertainties with the pharmacist owner and/or superintendent pharmacist.

Appointment of a responsible pharmacist	
Is a notice conspicuously displayed on the registered pharmacy premises detailing the name and registration number of the responsible pharmacist and the fact that s/he is in charge of the registered pharmacy at that moment in time?	A notice must be conspicuously displayed stating the name and registration number of the responsible pharmacist and the fact that s/he is in charge of the registered pharmacy at that moment in time.
Pharmacy procedures	
<p>Are there adequate and up-to-date SOPs in place for the following:</p> <ul style="list-style-type: none"> • Arrangements to ensure that medicinal products are:- <ul style="list-style-type: none"> - ordered - stored - prepared - sold by retail - supplied in circumstances corresponding to retail sale - delivered outside the pharmacy and - disposed of in a safe and effective manner. • The circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products; • The identification of members of pharmacy staff who 	<p>Since the 1st October 2009 the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 require that the pharmacy procedures are in place and they must provide information on the following:</p> <ul style="list-style-type: none"> • Arrangements to ensure that medicinal products are:- <ul style="list-style-type: none"> - ordered - stored - prepared - sold by retail - supplied in circumstances corresponding to retail sale - delivered outside the pharmacy and - disposed of in a safe and effective manner.

<p>are, in the view of the responsible pharmacist, competent to perform specified tasks relating to the pharmacy business;</p> <ul style="list-style-type: none"> • The keeping of records about the matters mentioned above; • Arrangements which are to apply during the absence of the responsible pharmacist from the premises; • Steps to be taken when there is a change of responsible pharmacist at the premises; • The procedure which is followed if a complaint is made about the pharmacy business; • The procedure which is to be followed if an incident occurs which may indicate that the pharmacy business is not running in a safe and effective manner and; • The manner in which changes to the pharmacy procedures are to be notified to the staff. 	<ul style="list-style-type: none"> • The circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products; • The identification of members of pharmacy staff who are, in the view of the responsible pharmacist, competent to perform specified tasks relating to the pharmacy business; • The keeping of records about the matters mentioned above; • Arrangements which are to apply during the absence of the responsible pharmacist from the premises; • Steps to be taken when there is a change of responsible pharmacist at the premises; • The procedure which is followed if a complaint is made about the pharmacy business; • The procedure which is to be followed if an incident occurs which may indicate that the pharmacy business is not running in a safe and effective manner and; • The manner in which changes to the pharmacy procedures are to be notified to the staff.
<p>Is there evidence that the pharmacy procedures are reviewed?</p>	<p>Regulation 4 of the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 and Section 2 of the Professional Standards and Guidance for Responsible Pharmacists require that procedures are reviewed at least once every two years and following an incident or event which indicates that the pharmacy is not running safely and effectively.</p> <p>Section 2.5 of the Professional Standards and Guidance for Responsible Pharmacists requires that the pharmacy procedures are marked with the date of preparation and marked with the date the procedure is due for review.</p> <p>As a matter of good practice the reason why the pharmacy procedures were reviewed or amended should be recorded.</p>
<p>Pharmacy record</p>	
<p>Is there evidence that the pharmacy record is accurate and entries are made contemporaneously?</p>	<p>Failure to complete the pharmacy record is a criminal offence. The minimum information that must be recorded is:</p>

	<ul style="list-style-type: none"> • The responsible pharmacist's name; • Their registration number; • The date and time at which the responsible pharmacist became the responsible pharmacist; • The date and time at which the responsible pharmacist ceased to be the responsible pharmacist; • In relation to absence from the premises by the responsible pharmacist: <ul style="list-style-type: none"> - The date of absence - The time at which the absence commenced - The time at which they returned.
Is the pharmacy record maintained for at least 5 years?	The pharmacy owner or superintendent must ensure that the pharmacy record is maintained for at least five years. (In the case of a record in electronic form, the day on which it is created and in the case of a written record, the last day to which the record relates).
Absence	
Is the responsible pharmacist ever absent from the registered pharmacy?	The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 allow the responsible pharmacist to be absent from the pharmacy <u>only for a maximum of two hours</u> during the operational hours of the pharmacy between midnight and midnight.
When absent does the responsible pharmacist remain contactable or arrange for another pharmacist to be contactable and be available to provide advice?	

Staff training

Are staff appropriately trained for the tasks undertaken or undergoing appropriate training?	
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Service provision

Are SOPs available where required?	
Do service provisions comply with Professional Standards or any guidance issued by the Society? (Please indicate which service provisions were checked).	

Dispensing

Examine a random sample of medicines awaiting collection to ensure, for example, the use of appropriate advisory and cautionary warning labels, appropriate container. Do they comply with the Medicines Act 1968?	
Is there an adequate audit trail to identify the pharmacist responsible for the supply?	
Is there an adequate audit trail to identify other staff involved in the dispensing process?	
In addition for MDS only: Is medication identifiable? e.g. descriptions/IDs of drugs included on labelling e.g. white, bevelled tablet marked BZ5	
Is there an adequate audit trail to identify personnel involved in assembly and checking of MDS?	
Are there adequate procedures in place for handling medication or dosage changes occurring mid-cycle?	
Are medicines supplied in MDS for domiciliary patients? If so, approximately how many?	
Are medicines supplied in MDS for patients in care homes? If so, approximately how many?	

Medicine stock, containers and storage

Are medicines stored appropriately? (i.e. in original boxes, fully labelled, no loose blisters, mixed batches and in an organised fashion).	
Are unlicensed medicines in stock?	
Are Medicines stored in appropriate conditions? (e.g. temperature, humidity etc.).	

Are there adequate date checking procedures in operation?	
Are dispensing containers appropriately stored?	

Record keeping

Are private prescription records legally compliant and in accordance with Society guidance?	
Are emergency supply records legally compliant and in accordance with Society guidance?	
Are poison records legally compliant and in accordance with Society guidance? (including permits and other documentation where necessary)	
Are records of sales of veterinary medicines legally compliant and in accordance with Society guidance? (Veterinary Medicines Regulations)	
Are specials records legally compliant and in accordance with Society guidance?	
Extemporaneously prepared product records (incl. Methadone)	
Does the pharmacy maintain an error log and systems for documenting and auditing dispensing errors that have reached the patient?	
Does the pharmacy maintain incident or near miss logs and systems for documenting and auditing errors picked up during the dispensing process?	
Does the pharmacy maintain records of clinical interventions / significant events?	

Waste disposal

Are procedures in place for the safe disposal of returned medicines from individuals or households (includes residential homes), including hazardous waste?	
Are patient returned medicines clearly segregated?	
Are there procedures for the management of date expired pharmacy stock?	
Are staff trained to deal with waste and is appropriate protective equipment available (including gloves, overalls and materials to deal with spillages)?	

Chemicals

Are chemicals stored, labelled and supplied in compliance with the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002?	
Are COSHH assessments available for hazardous chemicals stocked or supplied?	

Information sources

Are main information services and/or reference sources available and up to date?	
Is there a system for dealing with Drug Alerts?	
Is an information pack available for locums?	

Computer

Is computer software regularly updated?	
Is the use of data registered in accordance with Data Protection Act 1998?	

Are patient confidential computer records accessible only to staff who need access?	
Are computer records regularly backed up?	

General premises check

Fascia and front access to premises	
Shop Area	
Dispensary area(s)	
Consultation Room	
Security	
Stock rooms	
Other e.g. toilets, external stores	