

INSPECTORS' CHECKLIST MONITORING AND INSPECTION VISITS

About this document

This document is a guide to show what the Inspectorate may look for during an inspection visit. It is intended for use by the GPhC's Inspectorate; however pharmacists, pharmacy owners and superintendent pharmacists may find it of assistance when preparing for a visit. Pharmacists may also wish to use this document for the purposes of self audit.

The GPhC's Inspectorate also undertake controlled drug monitoring to specifically look at how controlled drugs are managed within the pharmacy. For a checklist relating to controlled drug monitoring see: Controlled Drug Self Assessment Form (England and Scotland).

The Inspector will often carry out controlled drug monitoring as part of a monitoring and inspection visit.

This document will next be reviewed in September 2011.

Introduction

During an 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 appropriate.

Where an inspection visit shows areas of risk and non-compliance with the legislation and/or 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 pharmacy professional may be subject to professional disciplinary proceedings.

General

Registered address	
Opening hours	
Telephone number	
Email address	

Responsible pharmacist requirements

Every registered pharmacy premises is 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 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.

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

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 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>	

Pharmacy record	
Is there evidence that the pharmacy record is accurate and entries are made contemporaneously?	
Is the pharmacy record maintained for at least 5 years?	
Absence	
Is the responsible pharmacist ever absent from the registered pharmacy?	
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?	

Service provision	
Are SOPs available where required?	
Do service provisions comply with best practice? (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	
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?	
Are emergency supply records legally compliant?	
Are poison records legally compliant (including permits and other documentation where necessary)?	
Are records of sales of veterinary medicines legally compliant (Veterinary Medicines Regulations)?	
Are specials records legally compliant?	
Are there appropriate records of extemporaneously prepared products (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 care 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	