

Community Pharmacy Assurance Visit Protocol 24/25

Contractor number:

Contractor name & address:

PART 1: Review of Community Pharmacy Assurance Declaration

Prior to the visit, the most recent Community Pharmacy Assurance Declaration, practice leaflet and complaints procedure, as submitted by the contractor, will be reviewed and any issues requiring follow up will be discussed.

Date declaration was received: [Click here to enter a date.](#)

Topic	Reviewed	Comments
1. Hours of Provision of Pharmaceutical Services	<input type="checkbox"/>	Click here to enter text.
2. Business Continuity	<input type="checkbox"/>	Click here to enter text.
3. Complaints Procedure	<input type="checkbox"/>	Click here to enter text.
4. Dispensing	<input type="checkbox"/>	Click here to enter text.
5. Pharmacy Services	<input type="checkbox"/>	Click here to enter text.
6. Palliative Care	<input type="checkbox"/>	Click here to enter text.
7. Consultation Area for Additional Services	<input type="checkbox"/>	Review during visit
8. Practice Leaflet	<input type="checkbox"/>	Click here to enter text.
9. Record keeping	<input type="checkbox"/>	Click here to enter text.
10. Current Medicine Safety Issue - Valproate	<input type="checkbox"/>	Click here to enter text.
11. Medicines Adherence	<input type="checkbox"/>	Click here to enter text.

Date practice leaflet was received: [Click here to enter a date.](#)

Practice leaflet includes:	
• Name, address and telephone number of the premises	<input type="checkbox"/>
• List of pharmaceutical services provided	<input type="checkbox"/>
• Opening hours	<input type="checkbox"/>
• Out of hours arrangements	<input type="checkbox"/>
• Complaints/comments information	<input type="checkbox"/>
Notes	
Click here to enter text.	

Date complaints procedure was received: [Click here to enter a date.](#)

Complaints procedure includes:	
• A specified complaints contact (name or job title)	<input type="checkbox"/>
• All complaints must be recorded in writing	<input type="checkbox"/>
• All complaints must be acknowledged within 3 working days	<input type="checkbox"/>
• All complaints must be properly investigated	<input type="checkbox"/>
• A written summary of the investigation and conclusions must be provided to the complainant within 10 working days	<input type="checkbox"/>
• Records must be kept of all complaints and associated correspondence	<input type="checkbox"/>
Notes	
Click here to enter text.	

PART 2: Core Essential Service – Dispensing

Dispensing is described as the supply of medicines and appliances¹ ordered on HSC prescriptions, together with information and advice, to enable safe and effective use by patients and carers, and maintenance of appropriate records.

The requirements for dispensing are set out in the [Terms of Service](#) and the [HSC Dispensing Service Specification](#). Pharmacists are also expected to work in line with the. [Pharmaceutical Society of Northern Ireland \(PSNI\) Code of Professional Standards of Conduct, Ethics and Performance](#).

The service specification sets out the aims and intended outcomes for dispensing:

- To ensure patients receive ordered medicines and appliances safely and appropriately by the pharmacy:
 - performing appropriate legal, professional, clinical and accuracy checks
 - having safe systems of operation
 - having systems in place, in line with Code of Ethics, to guarantee the integrity of products supplied
 - maintaining a record of all medicines and appliances supplied which can be used to assist future patient care
 - maintaining a record of advice given, and interventions and referrals made, where the pharmacist judges it to be clinically appropriate
- To ensure patients are able to use their medicines and appliances effectively by pharmacy staff providing:
 - information and advice to the patient or carer on the safe use of their medicine or appliance
 - when appropriate, broader advice to the patient on the medicine, for example its possible side effects and significant interactions with other substances

¹ Pharmacies are required to supply any drugs ordered via a prescription. With regards appliances, they are only required to supply those that they supply in the normal course of their business.

2.1. Dispensing Standard Operating Procedures (SOPs)

The [Responsible Pharmacist Regulations 2008](#) require the responsible pharmacist to establish pharmacy procedures designed to ensure the safe and effective running of the pharmacy. These procedures need to be maintained and regularly reviewed. The PSNI guidance in relation to the Responsible Pharmacist Regulations can be found [here](#).

Note: SPPG does not need or want to check SOPs in detail, as it is for the contractor to ensure they are fit for purpose and provide adequate direction to staff to enable safe working practices.

Does the pharmacy have dispensing SOP(s), which cover all aspects of the prescription journey and the staff work in accordance to it?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
Do dispensing SOPs cover the following processes?	
<input type="checkbox"/> Assembling & labelling prescriptions <input type="checkbox"/> Clinical assessment <input type="checkbox"/> Accuracy check <input type="checkbox"/> Hand out of prescriptions <input type="checkbox"/> Stock control & record keeping	<input type="checkbox"/> Owing prescriptions <input type="checkbox"/> Repeat dispensing <input type="checkbox"/> Instalment dispensing <input type="checkbox"/> Controlled drugs <input type="checkbox"/> Monitored Dosage Systems (MDS)
<i>Further comment</i> Click here to enter text.	

Is there a process for regular review of SOPs?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Can you describe the process e.g. who conducts, frequency, reviewed following incidents?</i> Click here to enter text.	

2.2. Clinical assessment of prescriptions

As detailed in [HSC Dispensing Service Specification](#) and [PSNI Professional Standards & Guidance for the Sale and Supply of Medicines](#), a clinical assessment of every prescription should be undertaken by a pharmacist, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient. Where appropriate, records of clinical interventions and referrals should be made.

Guidance notes

Clinical check guidance has been produced by the Pharmacy Forum and is available here: <https://www.pfni.org.uk/development/professional-guidance/>

Where concerns or queries arise in respect of a prescription, [best practice guidance](#) from SPPG is that communication is directly between the pharmacist and the prescriber.

Pharmacists should keep a record of significant clinical checks and interventions made, including communication or discussions with the prescriber and other healthcare professionals, and decisions agreed.

Are all prescriptions clinically assessed prior to dispensing?

☐ Yes

☐ No

Can you describe the process for undertaking a clinical assessment of a prescription?

Click here to enter text.

Does the pharmacist address clinical queries with an appropriate healthcare professional?

☐ Prescriber

☐ Other GP in the practice

☐ General Practice pharmacist

☐ Other

Further comment

Click here to enter text.

Do you keep a record of clinical interventions and referrals?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
Where do you keep records of interventions and referrals?	
<input type="checkbox"/> Patient Medication Record <input type="checkbox"/> Separate computer record <input type="checkbox"/> Paper record <input type="checkbox"/> Other	
<i>If other, please provide further detail</i> Click here to enter text.	
Please provide an anonymised example for discussion. Is there a record of:	
<input type="checkbox"/> Date and time <input type="checkbox"/> Patient details <input type="checkbox"/> Summary of the query and outcome <input type="checkbox"/> Name of the pharmacist and GP/healthcare professional involved	
<i>Further comment</i> Click here to enter text.	

2.3. Accuracy of dispensing

The [HSC Dispensing Service Specification](#) states that pharmacists must perform appropriate accuracy checks as part of the dispensing process. Patients are entitled to expect the dispensing service provided to be accurate and pharmacists must adhere to this standard ([PSNI Professional Standards & Guidance for the Sale and Supply of Medicines](#), section 3).

Are all prescriptions accuracy checked as part of dispensing?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Can you describe the process for undertaking an accuracy check of a prescription?</i> Click here to enter text.	

Is there a double check built into your dispensing process where possible?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Consider all prescriptions e.g. acute, repeat, instalment, for care homes or those supplied in MDS. If no, what mitigating factors are in place? For example, use of pharmacy scanners, mental breaks etc.</i> Click here to enter text.	

2.4. Provision of patient information leaflets (PILs)

A PIL must be issued with a medicine at the time of dispensing. This applies even if the medicine is dispensed, sold or supplied outside its original packaging. The only exceptions are where packing includes all the information that would otherwise be in the leaflet. The regulations for supply of PILs are set out in [The Human Medicines Regulations 2012 – Part 13](#).

Guidance notes

Extra copies of leaflets should be available for supply with split packs or stock pots. These could be provided by the manufacturer or by downloading a leaflet from one of the following websites:

- EMC: <https://www.medicines.org.uk/emc/>
- MHRA: <http://www.mhra.gov.uk/spc-pil/>

Do you routinely issue a PIL with each full and part pack of medicine at the time of dispensing?

☐ Yes

☐ No

Further comment

Click here to enter text.

If a PIL is not supplied with every dispensing, e.g. instalment dispensing, do you have a process in place which considers the risk and includes appropriate measures to account for this?

☐ Yes

☐ No

Points to consider include: patients are advised of supply arrangements for PILs and consent to this, record keeping of supply or non-supply where appropriate, an individual pharmacist can choose to supply at each dispensing, patients are advised that they can request a PIL at any time.

Click here to enter text.

2.5. Assembly of prescriptions

Every dispensed item must have a label affixed to aid patients and carers in safe and correct usage of the product. As detailed in [PSNI Professional Standards and Guidance for the Sale and Supply of Medicines](#) paragraph 3.11, pharmacist must ensure that labelling of dispensed products is clear and legible, computer-generated and where appropriate includes any cautionary and advisory labelling recommended by the BNF. This includes medicines supplied in MDS. Possible exceptions to this may be the supply of dietetic products or surgical products where outer packaging could be labelled once.

All solid dose and all oral and external liquid preparations should be dispensed in suitable re-closable child resistant containers unless it has specifically been requested otherwise, the patient has been assessed as requiring a compliance aid or the medicine's original pack makes this inadvisable ([PSNI Professional Standards and Guidance for the Sale and Supply of Medicines](#) paragraph 3.10). All liquid medicines should be supplied with a 5ml plastic measuring spoon or oral syringe measure, depending on prescribed dose, as per NI Drug Tariff specifications ([NI Drug Tariff Part V](#)).

Guidance notes

Information on the stability of medicines prior to dispensing in MDS can be accessed using the Specialist Pharmacist Service [Medicines in Compliance Aids Stability Tool](#). Enter the drug name in the search bar, click on the specific medicine from the search results and review the advice on medicine compliance aid stability for that particular medicine.

Do you ensure a label is supplied with each pack/container?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does MDS packaging contain a label for every item supplied in the compliance aid?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
Do you ensure each item is dispensed in a suitable re-closable child resistant container where appropriate?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
Do you supply a measuring spoon or oral syringe and bottle adapter where appropriate, with each liquid medicine dispensed?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Further comment</i> Click here to enter text.	

2.6. Handing out of prescriptions

Procedures must be in place within the pharmacy to minimise the risk of dispensing errors ([PSNI Standards and Guidance for the Sale and Supply of Medicines](#), paragraph 3.14). As part of this, there must be an appropriate procedure to ensure dispensed items are handed out to the correct patient, carer or appropriate representative.

Guidance notes

The HSC Community Pharmacy 'Right Person' poster is available on the Primary Care Intranet here: [HSC Community Pharmacy Right Person Poster](#)

The Pharmacy Forum has produced guidance entitled 'Children collecting medicines from a pharmacy' which is available here: <https://www.pfni.org.uk/development/professional-guidance/>

Do you check name, address and, if necessary, date of birth with the patient before handing out medicines?

☐ Yes

☐ No

Consider scenarios with similar patient names, or where a patient's representative e.g. family member, neighbour, volunteer is collecting on their behalf.

Click here to enter text.

Is there a process for confirming patient details when medicines are delivered?

☐ Yes

☐ No

Further comment

Click here to enter text.

Do you have any additional measures in place when handing out any of the following?

☐ Instalment dispensing

☐ Controlled drugs

☐ Medicines to children

☐ None of the above

Further comment

Click here to enter text.

2.7. Provision of advice to patients

As per [HSC Dispensing Service Specification](#), information and advice must be provided to the patient or carer to ensure the safe and effective use of the prescribed medicine. It may also be appropriate to provide broader advice to the patient on the medicine in order to meet their personal need for general information on the item, for example its possible side effects and significant interactions with other substances. Patients should also be advised on the safe storage and keeping of medicines and of the recommendation that unwanted medicines should be returned to the pharmacy for safe destruction.

If a medicine is delivered as part of a delivery service, the pharmacist must ensure that the delivery mechanism used enables any necessary information relating to the medicine to be communicated ([PSNI Standards and Guidance for the Sale and Supply of Medicines](#), section 6).

Guidance notes

A range of patient information is available on the Patient Area of the NI formulary website, available at: <https://niformulary.hscni.net/patient-area/>

Pharmacy stationery including steroid cards, lithium booklets, methotrexate booklets are available to order from BSO by emailing pharmacystationeryorders@hscni.net

Do you ensure that appropriate advice is given to patients (or their representatives) on their prescribed medicines?

☐ Yes

☐ No

Do you have any additional measures in place to ensure appropriate advice is given when handing out any of the following?

☐ New medicines or changes in dose or formulation

☐ Controlled drugs

☐ Insulin

☐ High risk medicines

☐ Antibiotics

Further comment

Click here to enter text.

How do you remind patients to store their medicines safely?

- ☐ Verbally
- ☐ Dispensing bags
- ☐ Dispensing label
- ☐ Posters
- ☐ Practice leaflet
- ☐ No reminder given
- ☐ Other

Consider advice on safe storage for items such as fridge lines, controlled drugs.

[Click here to enter text.](#)

How do you remind patients to return unwanted medicines to the pharmacy for safe disposal?

- ☐ Verbally
- ☐ Dispensing bags
- ☐ Dispensing label
- ☐ Posters
- ☐ Practice leaflet
- ☐ No reminder given
- ☐ Other

Consider medicines with special advice for disposal.

[Click here to enter text.](#)

PART 3: Clinical Governance

3.1. Patient safety

Patient safety is essential and lies at the heart of quality patient care. The [PSNI Code for Professional Standards of Conduct, Ethics and Performance](#), Principle 2 requires pharmacists to provide a safe and quality service, with Standard 2.2 focusing on Managing Risk. This requires pharmacists to:

- **2.2.1** Undertake a regular risk assessment in relation to your professional practice and the procedures that you follow.
- **2.2.2** Apprise staff of medication safety issues, identify areas of high-risk practice and implement procedures and processes to minimise medication safety risks or associated issues arising.
- **2.2.3** Where any risk, issue or problem is identified, arises, or occurs in your practice, take prompt action to prevent, minimise, follow up and resolve any such risk, issue or problem, and this includes risks, issues or problems relating to medicines and appliances.
- **2.2.4** Keep abreast of medication safety alerts and other publications to ensure the safety and quality of pharmacy services.
- **2.2.5** Contribute appropriately to 'near-miss' and error reporting systems.

Guidance notes

Examples of safety communications include: Drug recall notices, Safety & Quality Learning Letters, Medicines Management newsletter, Learning Matters newsletter, Pharmacy Regional Newsletter, Counter Fraud notices & alerts, Public health advice, professional letters. These will be sent to your secure email and can also be found on the BSO website under [Communications](#) or on the Community Pharmacy section of the [Primary Care Intranet](#).

Community pharmacists are encouraged to report incidents, including near misses, via the Online Anonymous Incident Reporting System, so that learning and good practice advice can be shared without any concerns for the reporting pharmacist. The link to the website is: <https://cpincidents.hscni.net/>.

Where an incident or concern involves controlled drugs, the Controlled Drug Accountable Officer should be notified, by reporting online at <http://www.cdreporting.co.uk/>.

Do you have a process for disseminating patient safety communications from the SPPG to dispensing staff?

☐ Yes

☐ No

Further comment e.g. team meeting, individual briefing, group email, staff noticeboard

Click here to enter text.

Do you keep records to show safety alerts have been dealt with?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Do the records include date received, name of responsible person, record of actions taken, sign off when actions complete?</i> Click here to enter text.	

Do you keep a record of medicines incidents and near-misses?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>What electronic patient safety incident reporting system do you have?</i> Click here to enter text.	
Please provide an anonymised example of an incident or near miss record for discussion.	
Click here to enter text.	
Do you review practice with the whole pharmacy team in light of any incidents, e.g. in the pharmacy or one highlighted in a patient safety communication, in order to reduce risk of recurrence?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Further comment</i> Click here to enter text.	

Are you aware of the process for reporting of anonymous incidents?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No

Have you made any changes in your pharmacy in response to any incidents to reduce the risk of dispensing errors?

- ☐ Physical separation of stock
- ☐ Staff awareness raising
- ☐ Tags or labels on shelving
- ☐ Enhanced checking procedures for certain medicines
- ☐ IT warnings
- ☐ Other
- ☐ None necessary

Further comment

[Click here to enter text.](#)

3.2. Current Medicine Safety Issue – Valproate

Pharmacists are reminded they must continue to follow strict precautions for dispensing of valproate medicines. Valproate has a high teratogenic potential and reproductive risks are now known to apply to males and females. Information about these risks and the measures in place to reduce potential harm can be found on the [MHRA website](#). In females of childbearing potential, valproate in any indication must only be prescribed and dispensed in accordance with the [Pregnancy Prevention Programme](#). Precautionary measures are now also in place for males, with advice to use effective contraception throughout the treatment period and for 3 months after stopping.

The MHRA have published materials to support the implementation of these measures. These materials are all available on the [MHRA website](#) and include:

- [Pharmacy poster](#) - Provides important actions for pharmacists dispensing valproate.
- [Patient card](#) - Provides key information for patients receiving valproate on contraception and pregnancy prevention.
- Patient guide for [female](#) and [male](#) patients - Provides those taking valproate (or their parent, caregiver, or responsible person) with information on the risks and what they need to do.
- [Healthcare Professional Guide](#) - Provides information for healthcare professionals and includes actions for pharmacists when dispensing valproate.

For more information, please see: <https://www.pharmacyregulation.org/pharmacists/standards-and-guidance-pharmacy-professionals/guidance-pharmacy-professionals/sodium-valproate-resources-and-information>

Are all staff involved in the dispensing process aware of the specific requirements for valproate dispensing to male and female patients?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are the requirements for valproate medicines considered and acted upon when a valproate medicine is dispensed?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Are there any barriers to implementing these requirements? What could improve the safety of valproate dispensing?</i> Click here to enter text.	
Dispensing processes for valproate will be reviewed regularly in response to any further safety updates.	
<input type="checkbox"/> Yes	<input type="checkbox"/> No

PHARMACY REPRESENTATIVE

Name
Click here to enter text.
Position
<input type="checkbox"/> Contractor
<input type="checkbox"/> Superintendent
<input type="checkbox"/> Pharmacy Manager
<input type="checkbox"/> Pharmacist
<input type="checkbox"/> Other (Please specify)

STRATEGIC PLANNING & PERFORMANCE GROUP (SPPG) REPRESENTATIVE

Name
Click here to enter text.
Position
Pharmacy Adviser

Date of visit: