

COMMUNITY PHARMACY ASSURANCE FRAMEWORK

Guidance Update

March 2024

The purpose of the assurance framework is to monitor compliance of community pharmacy contractors with Terms of Service, service specifications and related professional standards to ensure that patients and members of the public receive safe, effective and high-quality pharmaceutical services.

The CPAF consists of two components:

- an annual declaration, to be completed and signed by all community pharmacy contractors and
- a programme of visits undertaken by SPPG staff

The following reflective questions are designed to encourage and support contractors to review and update current practice where necessary, to comply with the HSCB assurance framework.

1. Hours of Provision of Pharmaceutical Services

- The pharmacy's contracted hours are those detailed in the pharmaceutical list: [here](#)
- Is your pharmacy open its contracted hours?
- Contractors are free to open over and above their contracted hours and many operate longer commercial opening hours. However, to be considered compliant with Terms of Service, SPPG expect your pharmacy to be open, at the very least, during the contracted hours as stated on the pharmaceutical list.
- Any requests to permanently change contracted hours should be submitted in writing to mark.nelson@hscni.net at BSO detailing the proposed changes and the reason for the changes.
- For more information see [BSO website](#)

2. Business Continuity

- Community pharmacies should have up-to-date arrangements for business continuity in the event of unforeseen service pressures.
- Template business continuity plans have been developed by CPNI. The templates are intentionally generic and individual pharmacies will need to tailor the sample plan to their own exact requirements.
- Available on CPNI's website [here](#)

3. Complaints Procedure

- Do you have a complaints procedure (SOP) in place to include details of the following?
 - A specified person who deals with complaints.
 - Management of complaints - all complaints must be:
 - Recorded in writing
 - Acknowledged within 3 working days
 - Properly investigated and a written summary of the investigation and conclusions provided to the complainant within 10 working days
 - Keep records of all complaints and associated correspondence.
- How do you make your patients aware of your complaint's procedure?

- SPPG template complaints leaflet and poster are available: [here](#)
- These should be displayed and easily accessible.
- See [CPNI Factsheet - Complaints](#).

Note. A copy of the pharmacy complaints SOP is required when returning annual declaration to your local HSCB office

4. Dispensing

- Are there up-to-date SOPs in place to cover dispensing processes?
- Are the SOPs easily accessible and signed by relevant staff?
- Do all staff fully understand the SOPs and work in accordance with them?
- SOP Review
 - Are the SOPs reviewed every 2 years or sooner if needed? e.g. following an incident
 - What was the date of last review?
 - What is the process for review?
 - Good Practice: Are all relevant members of staff involved in the review of SOPs, where possible?
- See [CPNI SOP template](#)

5. Falsified Medicines Directive

- The [EU Falsified Medicines Directive \(2011/62/EU\)](#) (FMD) was implemented in 2019 and relates to safety features on the packaging of medicinal products intended for human use, to ensure that medicines are safe and that trade in medicines is properly controlled. This remains a requirement in NI in the post-EU exit regulatory framework.
- There are processes and equipment in place in your pharmacy to support ongoing compliance with FMD?
- See [CPNI Falsified Medicines Directive \(FMD\)](#) for supporting resources

6. Additional services

- What services is your pharmacy contracted to provide?
- Additional pharmaceutical services are commissioned in line with strategic priorities and may be provided by all Community Pharmacies provided relevant service specification requirements are met.
- Locally required services are commissioned for delivery against a specified local need and are therefore only provided by certain Community Pharmacies.
- For all service-related info see [BSO website](#)

7. Consultation Area

- Does your consultation area meet the following requirements?
 - the consultation area should be where both the patient and the pharmacist can sit down together;
 - the patient and pharmacist should be able to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff);
 - the consultation area should be clearly designated as an area for confidential consultations, distinct from the general public areas of the pharmacy;
 - (Do you have a 'Consultation Area/Room' sign in place)?

- ensures equal service provision for all patients or able to facilitate equal service provision for all patients through reasonable adjustment.
- If you provide remote consultations, they should meet the confidentiality requirements detailed above.
- See also [PSNI Premises Standards](#)

8. Practice Leaflet

- Is your practice leaflet up-to-date and include the following?
 - The name, address, and telephone number of the pharmacy
 - Opening hours
 - List of contracted pharmaceutical services
 - Provision of oxygen is a pharmaceutical service which should be included in the leaflet if listed on the pharmaceutical list
 - Out of hours arrangements e.g. display of rota key, rota information on BSO website or in local press, details of NI direct website e.g. When this pharmacy is closed, please visit www.nidirect.gov.uk/choosewell for details of local pharmacy rotas, Out of Hours GP services and other health services
 - Details of how a person can complain or comment on the pharmacy's pharmaceutical services e.g. If you have any comments, suggestions, or complaints, please speak to any member of our staff
- Your leaflet should not contain any references not applicable to N. Ireland e.g. NHS.
- Is the practice leaflet on display in an easily accessible part of the pharmacy?
- See [CPNI practice leaflet template](#)

Note. A copy of the pharmacy complaints SOP is required when returning annual declaration to your local HSCB office

- Do you have at least 8 health promotion leaflets on display?
- For additional leaflets see [PHA website](#)

9. Record Keeping

- What is the process used for keeping records of all HSC prescriptions dispensed in your pharmacy?
- Do you know if your PMR back-up arrangements are secure?
- Does your pharmacy maintain records relating to additional services, in line with service specifications?
- The [Department of Health](#) (section M) outlines the requirements for retention and disposal of community pharmacy held records.
 - Patient medication records have a minimum retention period for:
 - Adults: six years after the conclusion of treatment.
 - Children and young people: until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment or eight years after death.

10. Current Medicine Safety Issue – Valproate

- Valproate must no longer be used in any woman or girl able to have children unless she has a pregnancy prevention programme (PPP) in place, due to the risk of birth defects and developmental disorders.

- When a valproate medicine is dispensed to a woman or girl of childbearing potential, pharmacists should
 - Ensure the Patient Card is provided every time valproate is dispensed and they have received the Patient Guide.
 - Dispense valproate in the original package. In situations where repackaging cannot be avoided always provide a copy of the package leaflet and add a sticker with the warning to the outer box.
 - Remind patients of the risks in pregnancy, the need for highly effective contraception and annual specialist review.
 - Refer patient to GP if they are unaware of the risks associated and need for contraception whilst on this medication.
- Has the pharmacy an SOP in place which outlines the specific requirements for dispensing valproate to women and girls?
- Resources: • [MHRA Guidance: Valproate use by women and girls](#) • [Pharmacy Forum NI Valproate guidance](#)
- Template SOPs are available from NPA and Numark

CPNI Assurance Framework

<https://www.communitypharmacyni.co.uk/services/assurance-framework/>

HSCB Terms of Service, Pharmaceutical Service Regulations (NI) 1997

<http://www.hscbusiness.hscni.net/services/2539.htm>

HSCB Assurance Framework documentation and guidance

<http://www.hscbusiness.hscni.net/services/2693.htm>

Complaints Procedure - HSCB complaints leaflet and poster

[Complaints - Business Services Organisation \(BSO\) Website \(hscni.net\)](#)

PSNI standards, guidance and code of ethics

<http://www.psni.org.uk/publications/code-of-ethics-and-standards/>

CPNI can visit your pharmacy to provide practical support ranging from SPPG visit preparation to finalising and implementing action plans. If you feel you would benefit from a support visit to facilitate the process and assist you in receiving the SPPG letter of compliance with CPAF, please contact: Clare Hunter Drug Tariff and Services Support Pharmacist.

Email: chunter@communitypharmacyni.co.uk

Contact Details for Local Integrated Care Offices:

| Belfast | South Eastern | Southern | Northern | Western |
|--|--|--|--|--|
| 12-22 Linenhall Street Belfast BT2 8BS | 12-22 Linenhall Street Belfast BT2 8BS | Tower Hill Armagh. BT61 9DR | County Hall 182 Galgorm Road Ballymena BT42 1QB | Gransha Park House 15 Gransha Park Clooney Road Londonderry BT47 6FN |
| Tel: 028 9536 3926 | Tel: 028 9536 3926 | Tel: 028 9536 2104 | Tel: 028 9536 2812 | Tel: 028 9536 1082 |
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