Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Service Specification:

Seasonal influenza Community Pharmacy Vaccination Service (Flu-CPVS)

7th October 2024 – 31st March 2025

This document is correct at the time of publishing however may be subject to change. Please ensure you are working to the most up to date version of documents. These can be found on BSO and PCI

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Change history

Version number	Change details	Date
V01.00	➢ 2024/25 service specification developed for use as part of Seasonal influenza Community Pharmacy Vaccination Service (Flu-CPVS)	13th September 2024

Contents

1. Service description and background

1.1 For most healthy people, influenza (flu) is an unpleasant but usually self-limiting disease. However, older people, pregnant women and those with underlying diseases are at particular risk of severe illness if they catch it.

1.2 The seasonal influenza vaccination programme is a key factor in HSC resilience. Influenza impacts on those who become ill, the HSC services that provide direct care as a result, and on the wider health and social care system.

1.3 The seasonal influenza vaccination programme in Northern Ireland (NI) aims to reduce population ill health, reduce GP consultations, unplanned hospital admissions, pressure on emergency departments and staff absence as a result of flu.

1.4 In order to improve access to flu vaccination for eligible individuals, the Department of Health (DoH), and Public Health Agency (PHA) have commissioned the Flu-CPVS.

1.5 Community pharmacies providing the Flu-CPVS will identify and vaccinate individuals eligible in line with PGD/VP during the 2024/25 programme.

Contractors will be notified of eligible cohorts that may be vaccinated under the CPVS by correspondence from the Strategic Planning and Performance Group (SPPG) and individuals eligible will be defined in the PGD/VP.

2. Service aims

2.1 The aims of this service are to:

- Assist in the delivery of the 2024/25 Seasonal Influenza Vaccination Programme in Northern Ireland.
- Provide increased accessibility and convenience for eligible individuals to access Influenza vaccinations.
- Lower the public health impact of Influenza morbidity and mortality especially for vulnerable people.
- Reduce Influenza related illness, primary care consultations, unplanned hospital admissions and deaths.

3. Service outline

3.1 Community pharmacies contracted to the Flu-CPVS service will offer seasonal flu vaccinations to specified patient cohorts.

3.2 The Flu-CPVS service will operate from 7th October 2024 to 31st March 2025. However, those administering the vaccine can choose to begin offering the vaccine earlier if they have received their first delivery of vaccine, provided a valid PGD or National Protocol is in place. There will be a focus on activity to ensure that a significant proportion of the eligible cohorts will have been vaccinated early in the programme.

3.3 The Flu-CPVS service must only be provided by community pharmacies where there is a contract in place with the SPPG. The community pharmacy must only administer those vaccines defined in the Patient Group Direction (PGD)/Vaccination Protocol (VP) and 2024/25 Flu- CPVS communications issued by PHA/SPPG.

This contract may be terminated by either the commissioner (SPPG) or the provider (Pharmacy contractor) by giving one week's notice.

3.4. This service is available to those individuals who meet all of the following criteria:

- Are aged 18 years and over

And

- Are in an eligible cohort as defined by PGD/VP and 2024/25 DoH seasonal influenza vaccination programme and SPPG correspondence

And

- Provide acceptable forms of identification (ID) - identity and eligibility for the service must be confirmed

Please refer to PGD/VP and CPVS support documents on BSO website and PCI.

It is not an essential requirement for patients to have their HCI number or GP registration to receive a vaccination and they must not be denied vaccination on this basis.

3.5 The seasonal flu vaccine(s) must be administered under this service in line with the relevant PGD/VP and "Immunisation against Infectious Disease" (The Green Book).

3.6 Pharmacy contractors must ensure that vaccination is offered in line with any JCVI guidance on the co-administration of vaccinations or the required interval

between any vaccinations, including where they have been administered by another provider.

3.7 If a prospective individual (or carer) enquires about eligibility for vaccination, the pharmacy contractor must be able to provide accurate and up-to-date information and signpost to another vaccination provider if needed.

3.8 The service must be provided by an appropriately trained, registered healthcare professional, authorised under the PGD/VP.

3.9 The pharmacy contractor must have a standard operating procedure (SOP) in place governing this service.

3.10 Prior to vaccination, consent must be sought from each patient. Patients should be provided with information to allow them to make an informed decision about having the vaccine. This consent should cover:

- the administration of the vaccine
- sharing of information as per privacy notice
- Sharing of information that will take place for the appropriate recording of the vaccination in their GP practice record, if applicable.
- Information resources can be found at the BSO and PCI

Should a patient decline the vaccination during the consultation, this should be recorded in VMS.

Where an individual lacks capacity to provide consent (e.g. care home resident), vaccinators should consider if vaccination is in the patient's "best interests" having taken account of information available and record this decision. See support document on BSO or PCI.

3.11 For the management of individuals with a known history of allergies vaccinators should refer to the Green Book Chapter 19 and PGD/VP.

The pharmacy contractor must ensure vaccinators have a protocol in place for the management of anaphylaxis and access to the contents of an anaphylaxis pack details of which can be found within Chapter 8 of the Green Book (for more anaphylaxis guidance see Resuscitation Council UK (RCUK) guidance on Management of Anaphylaxis in the Vaccination Setting and the PHA Management of Anaphylaxis in the Vaccination Setting).

3.12 Patients should be observed post vaccination as directed by the PGD/VP.

3.13 Each patient must be given appropriate post vaccination advice and a copy of the manufacturer's patient information leaflet. A copy of the PHA leaflet "*Flu is more serious than you think*" could also be provided prior to vaccination.

3.14 The pharmacy contractor is required to report any patient safety or adverse incidents in line with SPPG clinical governance arrangements.

Where a patient experiences a clinically significant adverse drug reaction following vaccination this information should be shared with the GP practice [where identified] as soon as possible. In addition, this should be reported through the MHRA yellow card reporting website.

3.15 The pharmacy contractor must ensure that it has in place appropriate indemnity and/or insurance arrangements that provide adequate cover, including but not limited to clinical negligence cover, in relation to the delivery of this service, and that the indemnity and/or insurance arrangements provide such cover for all clinical professionals and other staff working in connection with the delivery of the service.

3.16 HSC seasonal flu vaccines supplied for use within this service **cannot be used** for any private service. HSC vaccines should be segregated from any private vaccine stock. Private stock should not be used for NHS vaccinations.

4. Premises requirements

4.1 Vaccinations can be offered in any area of the pharmacy or in any other appropriate location where suitable facilities are available and patient confidentiality can be maintained. The patient's home is not considered a suitable location under the Flu-CPVS, with the exception of residents of are homes.

4.2 The service must be provided from an area of the pharmacy or location where infection control standards can be maintained. The pharmacy contractor must ensure Flu-CPVS is provided in line with PHA Infection Prevention and Control manual and the IPC recommendations, including relevant appendices and PPE section.

4.3 There must be a suitable area where patients can be observed post vaccination when appropriate. This area must have:

- Any appropriate social distancing or IPC requirements as defined by current public health guidance.
- Access to appropriate equipment such as adrenaline/anaphylaxis kits.
- Individual(s) suitably trained in basic life support techniques, and in recognising and responding to anaphylaxis.

4.4 The Resuscitation Council UK published information for use in any vaccination setting. On 4th January 2021, they also published an additional guidance document that clarifies guidance on the provision of oxygen within the vaccination setting. As part of this guidance a local Risk assessment should be made in all vaccination settings considering the following:

- Remoteness of location.
- Ability to call for help (e.g. presence of a phone signal, landline).
- Access to an emergency ambulance or resuscitation team.
- Access and parking for ambulances, and ability of local ambulance service to respond to a 999 call.
- Location of people being vaccinated (e.g. small rooms, narrow doors, stairs for accessing or moving individuals).

5. Training, educational and other staff requirements

5.1 The pharmacy contractor must ensure that all individuals involved in providing this service are competent to do so.

5.2 The Flu-CPVS service should be provided in line with the requirements set out in the PGD/VP and service specification. The pharmacy contractor must ensure all registered individuals vaccinating complete the Flu Vaccinator Competency Assessment Tool. Any training needs identified by vaccinator competency assessment tools should be addressed. Copies of the assessments should be held in the pharmacy.

5.3 The pharmacy contractor must ensure that individuals providing the service are working in line with National Minimum Standards and core curriculum for immunisation training and are compliant with the training requirements within those standards that apply, the PGD/VP and service specification.

5.4 The pharmacy contractor must ensure all vaccinators have completed face to face training and refresher training for injection technique and basic life support (including administration of adrenaline for anaphylaxis). Annual updates should be undertaken to ensure knowledge and practice remain current.
Periodic face to face refresher training for vaccinators should be considered to ensure consistency of practice, peer support and to discuss any clinical issues that are arising in practice.

5.5 Vaccinators must be familiar with Resuscitation Council UK (RCUK) guidance on Management of Anaphylaxis in the Vaccination Setting and information in Chapter 8 of the Green Book. A protocol must be in place for the management of anaphylaxis

5.6 The pharmacy contractor must ensure that individuals involved in the provision of the service are familiar with the latest relevant information from the PHA/VP on influenza immunisation. The PHA will produce information to support the delivery of the programme, which will be available on the PHA website:

- Seasonal flu vaccination programme training slides
- Influenza factsheet
- E-learning for healthcare
- Influenza weekly surveillance bulletins

5.7 The pharmacy contractor must oversee and keep a record to confirm that all staff have undertaken the required training prior to participating in administration of the vaccination.

5.8 The pharmacy contractor must ensure that any pharmacy staff providing the Flu-CPVS within a care home have completed an AccessNI check.

5.9 The pharmacy contractor must ensure that individuals involved in the provision of this service are advised that they should consider being vaccinated against Hepatitis B and be advised of the risks should they decide not to be vaccinated.

5.10 It is best practice for individuals providing the service to also be vaccinated against COVID-19 and seasonal influenza.

6. Clinical Waste

6.1 Equipment used for immunisation, including used vials, ampoules, expired stock, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste , Department of Health2013). See Table below. See support document.

Item	Waste Categorisation	Waste Sub-Category	Management Route	Packaging
Fully discharged Needles Syringes Vials	Clinical	Waste whose collection and disposal is subject to special requirements in	Alternative treatment	**Orange lidded yellow sharps box**

		order to prevent infection		
Partially discharged or full: Syringes Vials	Medicines	Medicines (excluding cytotoxic/cytostatic)	Incineration	**Purple lidded yellow sharps box**

6.2 Any blood-stained gauze or cotton wool should be placed in a clinical waste bag.

6.3 Local policy should be followed for disposal of PPE.

7. Vaccine ordering and storage

7.1 Vaccine orders and consumables should be placed with Movianto using the online ordering system. For support in using this system, contact Movianto Customer Services on 02890 795799 or info.ni@movianto.com.

7.2 The pharmacy contractor must ensure upon delivery, the seasonal influenza vaccine is immediately transferred to a fridge and stored as per manufacturer's instructions.

7.3 All refrigerators in which vaccines are stored are required to record maximum/ minimum temperatures. Readings are to be taken and recorded twice daily on all working days. Records should be kept for a period of 5 years. All CPVS providers must use a fridge data logger meeting the requirements (as specified in the Community Pharmacy Infrastructure Vaccination Fridge Data Logger Grant Funding Allocation December 2021).

7.4 Vaccine availability and supply may be constrained and is subject to change over time. The SPPG may need to make allocation decisions regarding the vaccine during the term of this service. Allocation decisions may include prioritising vaccine to particular sites or localities or the use of a particular type of vaccine.

8. Cold-chain breaches

8.1 Cold chain must be maintained in line with PGD/VP and SPPG guidance. Please refer to the 'cold chain' guidance on PCI and BSO on actions to be taken when dealing with one-off temperature excursions, significant cold chain breaches and potential off-label use. The affected vaccines should be quarantined in the fridge whilst awaiting advice on their suitability for use.

8.2 If vaccines have been administered to patients prior to discovery of cold chain breach, this should also be reported to the PHA Duty Room pha.dutyroom@hscni.net (0300 555 0119) for further risk assessment including whether or not patients need revaccination following a cold chain breach.

8.3 Any cold chain breaches that result in the loss of vaccine should be reported immediately to SPPG local office.

9. Regional Vaccine Management System (VMS) reporting

9.1 The pharmacy contractor must maintain accurate and contemporaneous vaccination records.

9.2 All patients vaccinated via this service must be recorded on the Vaccine Management System (VMS) on the same day as vaccine administration or at earliest convenience soon after. This is a record that the vaccine has been administered in line with the PGD/VP.

Additionally records for specific cohorts are to be recorded appropriately within VMS (e.g. care home residents should have the correct RQIA code attributed to their vaccination record).

Contractors should only add records for vaccines they have administered i.e. **do not record vaccines administered by other providers.**

For data quality purposes, contractors will be asked to correct inaccuracies in VMS records.

VMS entries made more than 15 calendar days post vaccination may not be paid by SPPG.

9.3 In exceptional circumstances if VMS is not accessible (for example due to a planned upgrade or an access issue), a paper based record form can be

downloaded from the PCI or BSO website. This can be used to record the details of the vaccination and must be added to VMS as soon as possible after the VMS becomes available again. Any paper based record forms should be disposed of in the confidential waste. The paper based record form **will not be accepted** for payment.

9.4 Upon vaccination record entry onto the VMS:

- Data will be collated and sent to the BSO for pharmacy payment purposes.
- If the patient is registered with a GP
  - A copy of the vaccination record will automatically be sent to the patient's registered GP within 24hrs
- If the patient is recorded as "unregistered" on VMS
  - The vaccination record will not be shared/ viewed with other providers (GP, Trust, etc.)
  - The person may not be included in any call or recall for future vaccinations/boosters

9.5 SPPG would remind community pharmacies to review their information governance arrangements if additional devices (e.g. tablets/laptops etc.) are used. As data controllers, community pharmacies must process data in line with data protection principles outlined in GDPR. Further guidance on this can be found on the ICO website.

9.6 If the use of additional devices introduces additional risks in terms of storage or processing of personal data (e.g. using an unencrypted device or unsecure means of data transfer) then pharmacies may need to amend their privacy notice to allow the patient make an informed decision.

9.7 Records must be retained securely in line with Department of Health Retention Policy 'Good management, Good Records' and outlines the requirements for retention and disposal of community pharmacy held records.

9.8 Should SPPG request access to vaccination records, the pharmacy contractor will be required to submit all records within 14 days of receipt of the request.

10. Vaccine wastage

10.1 The pharmacy contractor must plan clinics to maintain low levels of vaccine wastage.

Appropriate procedures must be in place to ensure stock rotation, monitoring of expiry dates and appropriate use of vaccines to ensure that wastage is minimised.

10.2 The pharmacy contractor may be requested report wastage as detailed by the SPPG to allow reporting to PHA.

11. Service availability

11.1 The pharmacy contractor should aim to ensure that locums, relief pharmacists are adequately trained, so as to ensure continuity of service provision where possible. **If the pharmacy temporarily or permanently ceases to provide the service, they must notify the SPPG immediately via their local office**.

11.2 The pharmacy contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible individual shall be excluded or experience particular difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy and maternity, or age.

Consideration should be given to those individuals with communication needs and those who may experience difficulty accessing vaccination elsewhere.

11.3 Where a community pharmacy is unable to vaccinate a patient, they should be signposted to an alternative provider.

11.4 Where there is reduced patient demand contributing to significant potential for wastage (in the reasonable view of the commissioner) and/or the pharmacy does not wish to continue providing the CPVS, the SPPG may agree a temporary suspension of the CPVS.

12. Payment arrangements

12.1 Claims for payments for the CPVS will be based upon VMS data entry. The paper based record form **will not be accepted** for payment.

The fees payable will be processed monthly by BSO. The pharmacy contractor should monitor and record the number of vaccinations completed on a monthly basis for verification against BSO payments.

12.2 Where the record of the vaccination event is not created within 15 days of the vaccination being administered, SPPG reserves the right to not pay an IoS fee and any associated domiciliary visit fee.

Only in exceptional circumstances will late submissions be accepted for payment by the BSO up to six months post administration of the vaccination. Claims or submissions after this date will not be processed.

12.3 Payment for the Flu-CPVS in the 2024/25 year, is set out in the fees and reimbursement document on the PCI and BSO.

12.4 The pharmacy contractor will not be reimbursed, under CPVS, for vaccines administered to individuals who are not eligible to be vaccinated as part of flu-CPVS as defined by PGD/VP or for vaccines administered that were not provided by PHA for the 2024/25 programme.

12.5 The SPPG will be monitoring compliance with the requirements of the contract. Where the SPPG identifies failure to comply, the SPPG reserves the right to recover all, or part of, the funding.

13. Other terms and conditions

13.1 The responsible pharmacist at the registered pharmacy premises is professionally responsible for the safe delivery of this service. If the responsible pharmacist is unable to provide sufficient supervision, for example due to workload or where vaccinations are undertaken off the pharmacy premises, an on-site pharmacist supervising delivery of the service must be linked and work closely with the responsible pharmacist and superintendent pharmacist through an appropriate governance framework.

13.2 Where vaccinations are undertaken off the pharmacy premises, the pharmacy contractor must ensure there is an on-site pharmacist supervising delivery of the service (or delivering the vaccination service themselves) and that vaccinators:

- are administering vaccines in accordance with a valid, up to date PGD/VP.
- Ensure that vaccinators have professional indemnity that covers off-site vaccinations.
- Continue to adhere to all professional standards relating to vaccinations.
- Follow appropriate cold-chain measures for transfer and storage of vaccines.
- Ensure appropriate security measures of vaccines are in place.

- Ensure that the setting used to administer the vaccinations is appropriate (including ensuring patient confidentiality).
- Ensure appropriate anaphylaxis arrangements are in place including a protocol for management of anaphylaxis and an anaphylaxis pack.
- Appropriately dispose of any clinical waste or PPE.
- Comply with any COVID-19 testing protocols in place at the site of vaccination.
- Comply with any relevant IPC guidance and PPE requirements for the vaccination setting.
- Ensure that a risk assessment has been undertaken to allow the management of vaccinations to occur at any site which is in or post outbreak e.g. care homes.
- Ensure appropriate record keeping of vaccinations.

13.3 Materials and resources for use as part of the service are available from PHA and should be used to promote the service to the public.
SPPG communications and other resources to assist contractors can be found on the PCI and BSO.

13.4 The pharmacy contractor shall not publicise the availability of the service, other than using any materials specifically provided by the SPPG/PHA (unless with the prior agreement of the SPPG) or publicise in any way which is inconsistent with the professional nature of the service.

13.5 The pharmacy contractor shall not give, promise or offer to any person any gift or reward as an inducement to or in consideration of his/her registration with the service.

13.6 The pharmacy contractor shall ensure that service provision is in accordance with relevant professional standards and guidelines.

13.7 The pharmacy contractor should cooperate with any request from SPPG to submit data necessary to gauge progress of the vaccination programme.

13.8 SPPG Supporting documents can be found at the BSO and PCI.