

# National COVID-19 Vaccination Programme – Community Pharmacy

## Operational Guidance for COVID-19 Vaccination in Community Pharmacy (mRNA Vaccines)

V15

04/04/2024

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V4.0	22/11/21		<ul style="list-style-type: none"> <li>Update on administration to pregnant women</li> <li>Update on administration of booster programme</li> <li>Notification of clinical waste service</li> <li>Risk management considerations when COVID-19 vaccines and Flu vaccines are both in use in a pharmacy</li> <li>Update on HSE PharmaVax system</li> </ul>
V5.0	20/12/21		<ul style="list-style-type: none"> <li>Addition of Spikevax® (Moderna) COVID-19 vaccine</li> </ul>
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V8.0	10/5/22		<ul style="list-style-type: none"> <li>Update on second booster programme</li> <li>Updated guidance for vaccination in pregnancy</li> <li>Update on HSE PharmaVax system</li> </ul>
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V10	31/8/22		<ul style="list-style-type: none"> <li>Update to NIAC Guidelines</li> <li>Restoration of 15m observation post vaccination</li> </ul>
V11	03/10/22		<ul style="list-style-type: none"> <li>Addition of Comirnaty® (Pfizer BioNTech) and Spikevax® (Moderna) adapted booster vaccines</li> <li>Removal of operational security information in relation the HSE PharmaVax system</li> </ul>
V12.0	23/02/23		<ul style="list-style-type: none"> <li>Correction to vaccine equipment for community pharmacy</li> <li>Update to useful contacts</li> <li>Vaccine names updated throughout to adhere to standardised convention</li> <li>Detailed clinical information replaced with links to latest guidance</li> </ul>
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			<ul style="list-style-type: none"> <li>• Update on anaphylaxis</li> <li>• Update on the use of PPE</li> </ul>
V14.0	25/09/23		<ul style="list-style-type: none"> <li>• How to join the COVID-19 and Seasonal Influenza Vaccination Programme</li> <li>• HSE Pharmacy Finder update</li> <li>• Update on identifying immunocompromised status in PharmaVax</li> <li>• Update on delivery of patient vaccine information to Community Pharmacies</li> <li>• Vaccine removal from HSE PharmaVax</li> <li>• Importance of timely data returns</li> <li>• Where mRNA vaccines are contraindicated</li> <li>• Update on COVID-19 EU digital certificates</li> </ul>
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## 1. Overview and Introduction

COVID-19 is a highly infectious disease that can cause serious illness, hospitalisation and even death. COVID-19 vaccination gives the best protection against serious COVID-19 illness and reduces the risk of hospitalisation from illness. The aim of the Vaccination Programme is to ensure equitable access to safe and effective vaccines with the goals of limiting severe disease and death from COVID-19, protecting healthcare capacity and enabling social and economic activity<sup>1</sup>. The COVID-19 vaccine is free to all eligible persons of the State. It is not available privately. While the vaccine is not mandatory, it is recommended and vaccination depends on person's age and if they are at higher risk from COVID-19.

Community Pharmacists continue to play a key role in the delivery of the Vaccination Programme in accordance with the agreed national vaccination schedule, by offering accessibility and choice for those seeking vaccination.

This document sets out guidance in relation to the approach, logistical arrangements and processes established for the management of the vaccine programme to patients in Community Pharmacies.

## 2. Pharmacy Regulation and the Vaccination Programme

Community Pharmacies are regulated by the Pharmaceutical Society of Ireland (PSI) in accordance with the Pharmacy Act 2007 and Regulations made thereunder (the term used in the Act for pharmacies is "retail pharmacy business"). PSI views Community Pharmacies as an essential part of the healthcare system's response to COVID-19 and are keen to ensure that relevant and proportionate regulation plays an appropriate role in ensuring the safety and effectiveness of the National Vaccination Programme.

The PSI has developed "[COVID-19 Operational Standards for Pharmacies](#)" and are primarily intended for those in statutory governance and leadership positions in Community Pharmacies, i.e., pharmacy owners, superintendent and supervising pharmacists. The Standards set out clearly what the public can expect from pharmacies by way of safe services and a safe environment.

The legislative framework and the PSI's "COVID-19 Operational Standards" are also supported by a number of guidelines designed to support the safe delivery of particular services by pharmacies, including the delivery of [vaccination services](#) in pharmacies and [guidelines for retail pharmacy businesses \(pharmacies\)](#) relating to premises and equipment requirements and requirements on the storage of medicines.

In addition, the [Code of Conduct](#) supports all registered pharmacists in their practice; this is the public declaration of the principles and ethical standards which govern pharmacists in the practice of their profession, and which the public, patients, other healthcare professionals and society require and expect from pharmacists. The public and other healthcare professionals place significant trust in every pharmacist. He/she must maintain a high level of professionalism, competence, act with probity and integrity in order to earn and maintain that trust.

PSI is committed to working with all involved in the National Vaccination Programme to ensure the success of the overall programme. This includes working with the HSE and IPU to develop and refine the helpful and supportive guidance set out later in this document.

<sup>1</sup> COVID-19 Vaccine Allocation Strategy (2021) at [12], Department of Health & National Immunisation Advisory Committee

### 3. Clinical Governance and Guidance

Pharmacy owners, superintendent and supervising pharmacists have overall responsibility for the governance of Community Pharmacies and must ensure the delivery of a consistently high quality and safe vaccine service.

#### 3.1 Clinical Governance

The clinical governance for ensuring the patient is eligible for the vaccine in line with [NIAC Guidance](#) on eligibility and interval periods, administering the vaccine and managing the person post-vaccine, rests with the pharmacist and their existing governance and regulatory structures i.e. Superintendent Pharmacist and Supervising Pharmacists.

#### 3.2 Clinical Supporting Information

Guidelines and information are available for the COVID-19 vaccines and include information such as how to administer the vaccine, the possible side effects, the required post vaccination observation times, management of anaphylaxis and FAQs. Pharmacists should keep up to date with the latest HSE Clinical Guidance from the National Immunisation Office at [NIO Clinical Guidance](#).

Pharmacists should direct all clinical queries to the NIO via [immunisation@hse.ie](mailto:immunisation@hse.ie).

### 4. Vaccination Primary Care Contractors (VPCC)

The COVID-19 Vaccination Programme is supported by the HSE Vaccinations Primary Care Contractors (VPCC) team, who coordinate the service and provide Relationship Management Support to GPs and Community Pharmacists. For further details, please see [VPCC webpage](#).

### 5. Indemnity

Claims management in relation to claims and litigation initiated in connection with COVID-19 vaccination has been delegated to the State Claims Agency by means of Government Order.

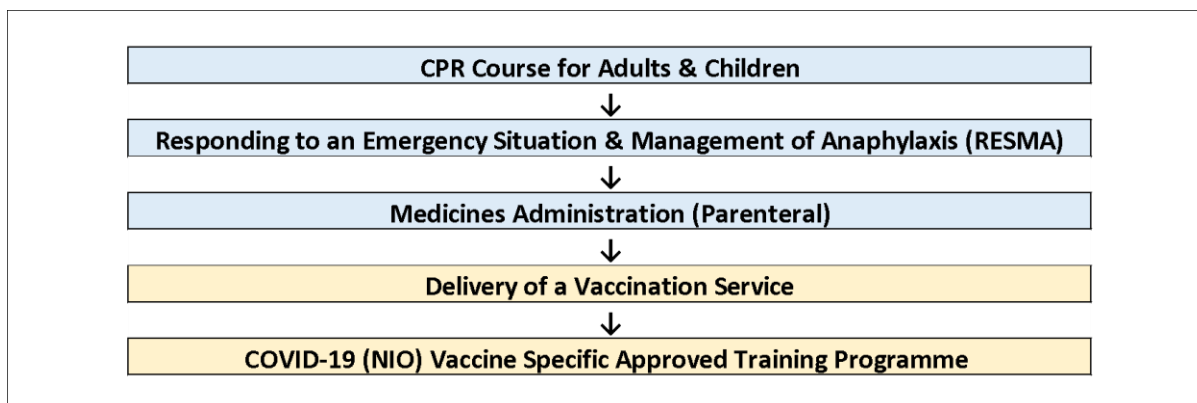
Registered medical practitioners (including GPs); nurses; pharmacists; and other health professionals in receipt of relevant training with regard to administration of the vaccine, who are administering vaccines on the direction of, or on behalf of, the HSE will be indemnified with regard to any adverse product liability-related events arising from their administration of the vaccine.

GPs, GP Practice Nurses and Community Pharmacists however, will not be indemnified in respect of malpractice events occurring during the administration of the vaccine. Such malpractice events will be indemnified by their professional insurers.

### 6. Training for Pharmacists on Vaccine Administration

The [Medicinal Products \(Prescription and Control of Supply\) \(Amendment\) \(No.7\) Regulations 2020 \(S.I. 698 of 2020\)](#) and subsequent amendments authorise a registered pharmacist to supply and administer a COVID-19 vaccine where they have received training approved by the PSI. This legislation also outlines the record keeping requirements for the COVID-19 Vaccination Programme.

The approved training pathway for vaccinating pharmacists for inclusion in the COVID-19 Vaccination Programme is outlined below. All training must be up to date, as per the validity periods published on the PSI website. You can check the validity for training programmes on the [Vaccination Training Requirements for Pharmacists](#).



You can contact the [Irish Institute of Pharmacy \(IIOF\)](#) to find out how to register and complete the required training programmes (other than training hosted on HSeLanD).

The relevant NIO COVID-19 vaccine training programmes are available through [HSeLanD](#). Extensive information and training on COVID-19 vaccines has been prepared by NIO and other clinical experts. This information is updated regularly and it is recommended you check this information often to ensure you have up to date and accurate information when vaccinating. This is in addition to ensuring you review the regular [vaccine bulletins](#) published by NIO on their website.

The National Immunisation Office has developed SOPs as guidance for COVID-19 vaccinators, which can be accessed here: [NIO developed SOPs](#)

## 7. How to join the Vaccination Programme for COVID-19

For information on joining the Vaccination Programme, please see the [VPCC Vaccination Programme](#).

## 8. Communications

The HSE has comprehensive information available on COVID-19 vaccinations available at [HSE COVID-19](#).

### 8.1 Access to COVID-19 Information Materials

COVID-19 booklets and record cards are available to order on the [Health Promotion Website](#). For further information on COVID-19 resources, see [VPCC FAQs](#). Patient information leaflets and resources are available at [COVID-19 Vaccine Materials](#).

### 8.2 Pharmacy Finder

It is important that the information available to the public remains accurate and up to date. Pharmacists are reminded to review their details on the [pharmacy finder](#) webpage and update their participation status to reflect the vaccination services they are providing during the autumn/winter campaign and any spring/summer campaigns. To amend, temporarily suspend, or delete your details please use this [form](#).

## 9. Vaccine Updates

### 9.1 Vaccine Type

The adapted vaccines are expected to increase the breadth of immunity against current dominant and emerging variants. For guidance on vaccine selection for primary doses or booster doses please refer to NIO [clinical guidance](#).

For the most up to date information on the administration of COVID-19 vaccines please see vaccine specific information available on [www.immunisation.ie](http://www.immunisation.ie) and also follow the pharmacy specific SOPs.

For a quick reference table on the different types of COVID-19 vaccines currently available, please see [Clinical Information on COVID-19 Vaccines](#).

Please see **Appendix 1** for Risk Management Considerations when Multiple Vaccines are in Use.

Frequently Asked Questions for Vaccinators on the administration of COVID-19 Vaccines can be accessed at [NIO FAQs for Vaccinators](#).

### 9.2 Vaccine Interval

Pharmacists should be aware of changes in the recommended intervals for vaccines used in primary and booster courses for some cohorts, as well as updated guidance on the recommended COVID-19 vaccine intervals in pregnancy.

### 9.3 Eligibility

The vaccine programme is informed by [NIAC Guidance](#) with regards to the provision of primary course and the ongoing roll out of booster doses. Clinical guidance and supporting information on current eligibility for primary course or booster doses can be found [here](#).

Pharmacists are required to familiarise themselves with the updated clinical guidance to aid with correct vaccine selection.

### 9.4 Pregnancy and Breastfeeding

Pregnant women can also receive the vaccine in pharmacies and this includes the adapted booster vaccines. The updated information on interval selection for COVID-19 mRNA vaccines for women who are pregnant or breastfeeding and their healthcare professionals can be found in the [clinical guidance](#) and the HSE webpage [pregnancy, breastfeeding and fertility: COVID-19 vaccination](#).

### 9.5 Immunocompromised

It is important that the correct vaccination course type is selected for the correct patient. Please do not enter regular booster doses (vaccines given based on age eligibility criteria) as immunocompromised (additional doses).

### 9.6 Where mRNA Vaccines are Contraindicated

Alternative pathways are in place for patients where mRNA vaccines are contraindicated - please refer to VPCC [Guidance Note 6](#)



## 10. Vaccine Stock and Consumables

The vaccine supply chain is managed by the NIO and the HSE National Cold Chain Service (NCCS).

Pharmacies order online through [www.ordervaccines.ie](http://www.ordervaccines.ie).

See National Immunisations Office for comprehensive information on [Vaccine Ordering and Storage](#).

### 10.1 Ordering Vaccine

The HSE National Cold Chain Service ([NCCS](#)) will deliver COVID-19 vaccines.

Appointments should be scheduled based on the expected vaccine delivery as per NCCS delivery calendar.

### 10.2 Vaccine Consumables for Community Pharmacy

A national distribution service (JMC Logistics) will deliver consumables to pharmacies participating in the COVID-19 programme.

When ordering COVID-19 vaccine stock on [NCCS](#), the system will ask you if you require COVID-19 clinical consumables. Tick the “YES” box to receive packs in line with your order volume.

If sufficient packs are available in your site tick the “NO” box and none will be delivered. For further information, please refer to [VPCC Guidance Note 1](#) on COVID-19 vaccine consumables.

### 10.3 Storage of Vaccines in Community Pharmacies

See [HSE Guidelines](#) (Section 12.3) and **Appendix 2** for maintenance of Cold Chain in vaccine fridges and management of vaccine stock. Community pharmacy must have a pharmaceutical grade fridge and must be able to certify that the fridge meets required requirements as outlined in the [PSI guidelines on the storage of medicinal products within a retail pharmacy business](#).

### 10.4 HSE Removal of Waste from Community Pharmacy Sites

Stericycle Services will be providing a COVID-19 clinical waste service on behalf of the HSE.

Pharmacies should contact [serviceireland@stericycle.com](mailto:serviceireland@stericycle.com) or 1800 937 628 for removal of waste, quoting account number 9607596. Stericycle will only accept those sharps bins supplied by the HSE for this service.

### 10.5 Return of expired vaccine stock

Any expired stock should be returned to NCCS using the normal process – see

<https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/vaccreturn.pdf>

## 11. Preparing for a Vaccination Service

Pharmacists should conduct a risk assessment and capacity assessment to determine if their site is appropriate (premises and staffing levels) for the preparation and administration of the COVID-19 vaccines and to determine the number of vaccinations that they can administer safely. Please see **Appendix 3** for a sample checklist for preparing for COVID-19 vaccination clinics within your community pharmacy.

### 11.1 Community Pharmacy Premises Requirements

The premises standards as set out in the *Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended)* and in *guidelines on the Premises Requirements of a Retail Pharmacy Business (Oct 2017)*. These can be accessed [here](#).

In order to provide the COVID-19 vaccines in a safe and efficient manner, Community Pharmacies will require the following:

- Sufficient number of pharmacists, trained in the relevant vaccines, to ensure that all activities involved in drawing-up and administering the vaccine are carried out in a safe and timely manner by a pharmacist.
- Registration/reception area for patients.
- Preparation of vaccine and refrigeration area.
- Vaccination area for patients.
- Observation area for patients – this need not be within the community pharmacy building.

In the interest of safety and accountability, the pharmacist must personally carry out all of the activities involved in drawing-up and administering the vaccine.

Please also refer to the [PSI guidance on providing a pharmacy vaccination services](#) including guidance on providing vaccination services off site from the pharmacy premises. Particularly in relation to children, superintendent pharmacists and pharmacy owners are reminded of obligations under [the Children First Act 2015](#).

Risk Management Considerations are outlined in **Appendix 1** when COVID-19 vaccines and flu vaccines are both in use in a pharmacy.

See section 10.3 on Storage of Vaccines in Community Pharmacy.

## 11.2 Community Pharmacy Staff Requirements

The community pharmacy should have the following personnel available for the Vaccination Programme:

- One staff member available for registration\*
- One staff member for observation area\*
- Pharmacist vaccinator

\*Depending on the size of the vaccination clinic, the registration staff member could also be the observation staff member. The supervising pharmacist together with the superintendent pharmacist and pharmacy owner should use their professional judgement to ascertain the appropriate staffing levels to provide a safe service. In determining the staffing levels, they should be cognisant on the need to gather patient details at registration, have appropriately trained staff available for the recommended observation period, and be able to comply with all the infection control standards and the demands of the vaccination service in addition to the requirements of their ongoing service to patients.

For workflow considerations when setting up a COVID-19 clinic please see **Appendix 4**.

Patients are required to bring photographic ID and this must be validated, for further guidance see **Appendix 5**.

## 11.3 Observation Post Vaccination

Scheduling of people should allow for a safe space to observe the person for **15 minutes** after the vaccine (30 minutes if they have a history of allergic reactions in line with NIAC advice). NIAC in a letter to the CMO on October 6, 2022, noted that “Vaccine recipients should be observed for at least

15 minutes after vaccination. If this is not practicable, vaccine recipients should wait in the vicinity for 15 minutes”.

NIAC recommends the following post vaccination observation periods:

- Those with no history of anaphylaxis: 15 minutes
- Those with a history of mastocytosis: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated.

The Pharmacist must be aware of signs and symptoms of adverse reactions and manage any that arise. For more information regarding anaphylaxis, please refer to [Immunisation Guidelines](#).

Pharmacists should be aware of the risk of fainting particularly in hot weather and in younger patient cohorts. Advice to minimise the risk can be found [here](#).

#### 11.4 Record Keeping

It is important that pharmacists enter records of vaccination as soon as possible onto HSE PharmaVax to ensure a timely update of the patient vaccination history, which may be accessed by other vaccine providers. This will reduce the risk of inadvertent duplicate vaccination by different providers accessed by the same patient. There are a number record keeping requirements that apply to the supply and administration of a COVID-19 vaccination.

It is a legal requirement to forward to the Health Service Executive, within 7 days, by electronic means, the following particulars in respect of such administration:

- a) the date of administration;
- b) the name, address, contact number(s), email address(es), ethnicity, pregnancy status, date of birth and sex of the person to whom the product was administered, to the extent that the person can provide such particulars;
- c) Consent (see further information in section on consent);
- d) the patient’s PPSN number;
- e) the name and batch number of the product (not serial number);
- f) expiry date / use before date (and/or time) of the product;
- g) the name, business address, email and telephone number of the person who administered the vaccine and the number of his/her professional registration;
- h) the name, address and telephone number of the general practitioner (if any) of the person to whom the product was administered to the extent that the person can give such particulars; and
- i) such other relevant and necessary information as may be specified by the Minister.

Once this data has been recorded on HSE PharmaVax these particulars will be transferred to the HSE and the patient records updated on the COVAX system.

For a full list of vaccine record requirements in Community Pharmacy please refer to the [PSI website](#).

A record of the vaccination with batch level detail, must be provided to the patient.

#### 11.5 Data Quality

Data quality errors or inconsistencies identified within COVAX are followed up by the HSE data

quality team. The data quality team may contact the Pharmacist to clarify information in order to amend the record.

Amendments to vaccine records in COVAX may not reflect in the vaccination history search (VHS). For queries about VHS or to make amendments in vaccination records please contact the HSE data quality team on 01 240 8786 (Pharmacy direct line only).

## 12. Reporting of Incidents during a Vaccination Session

In the case of medication errors that directly involve the vaccine recipient, i.e., wrong medication/dose/route being administered or another medication error, the incident must be recorded in your pharmacy incident records and a full investigation should be undertaken to identify the root cause of the incident. The vaccine recipient and/or significant others should be informed of the incident. The NIO will be able to advise on required follow up contact using [immunisation@hse.ie](mailto:immunisation@hse.ie) do not use patient identifiers in this communication.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA.

### 12.1 Adverse Reaction Reporting

The Health Products Regulatory Authority (HPRA) is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the EMA. Adverse reaction reporting is an important part of the EMA intensive monitoring plan for COVID-19 vaccines, so that any changes in benefit risk balance can be promptly detected and acted upon. This enables the EMA to continue to safeguard public health safety. The HPRA must be informed using the [Adverse Reaction Report](#) (Yellow Card System).

### 12.2 Management of Injuries

In the event of a sharps injury the local procedure must be followed. This will require immediate first aid and follow-up. For further information on the Emergency Management of Injuries (EMI) and Post-Exposure Prophylaxis (PEP) please see [Health Protection Surveillance Centre Website](#)

## 13. Consent

For specific information on consent, please see [Consent for Vaccination for COVID-19: Guiding Principles](#).

Written consent forms are available [here](#).

A module on HSeLand has been developed to provide advice and guidance on the process for gaining consent from parents and legal guardians of 12-15 year olds to support the programme. We strongly recommend that any pharmacist offering vaccine to this age group views this module on [www.hseland.ie](http://www.hseland.ie) (search for COVID-19 Vaccine Training Programmes and complete the programme).

Pharmacists must be aware of how [consent](#) is obtained for a young person aged 12-15 years.

The Pharmacist should keep a note if a patient does not consent and the reason for non-consent in their local records.

## 14. PharmaVax

HSE PharmaVax allows pharmacies to record details of, and claim reimbursement for, COVID-19 vaccinations that are administered. HSE PharmaVax also facilitates the recording of administration records for flu and pneumococcal vaccinations. The portal is used to record vaccination events. It is not a tool to be used to support clinical decision making. It does not have scheduling functionality.

**Note:** Please do not enter any “test” vaccinations on the system as these will be treated as bona fide records.

For information on how to register for HSE PharmaVax please contact the support team at [a2ihids.support@hse.ie](mailto:a2ihids.support@hse.ie). Please refer to the most recent version of the HSE PharmaVax User Guide, which is circulated to all registered users via Healthmail after each update.

HSE PharmaVax enables pharmacists to:

- Register people for the COVID-19 Vaccination Programme and record required patient identifiers as outlined in the legislation.
- Record their PPSN and contact details.
- Record their eligibility and consent.
- Record the batch number and 'use by' and time (if required for individual vaccines) date of each vaccine administered.
- Record vaccination course for eligible individuals.
- Automatically communicate electronic vaccination details to the COVID Immunisation System (COVAX).
- Automatically communicate electronic payment claims to PCRS.
- Vaccination History Lookup to allow you to search for vaccination records on COVAX.

The Vaccination History Lookup portal should be checked by the pharmacist, prior to COVID-19 vaccination, to identify a patient's current eligibility. This portal is available through the PharmaVax system.

#### **Browser**

- Google Chrome, Firefox and MS Edge (latest version) are the recommended browsers.
- Internet Explorer is not recommended. Chrome is preferred.

PharmaVax will not permit you to enter booster vaccine details unless there has been at least a three-month period since last dose administered. Always refer to the latest clinical guidance for recommended intervals between doses.

### **14.1 Vaccine Removal from HSE PharmaVax**

Vaccines and any batches that are no longer available for use, will be periodically communicated to pharmacies prior to removal from the HSE PharmaVax system.

It is important that all vaccinations related to products being removed are input into HSE PharmaVax prior to the relevant dates, to ensure that patient records are up to date and payment issued. There will be no facility for retrospective entry once the vaccines are removed from the HSE PharmaVax system.

### **14.2 Individual Health Identifier**

An Individual Health Identifier (IHI) is a number that identifies each person who has used or may use a health or social care service in Ireland. Each individual will be assigned their own personal number which is unique to them. The main benefit of having an IHI is to uniquely identify each service user and therefore, improve patient safety by reducing errors that might happen, such as ensuring patients receive the correct medication, vaccinations, and treatment. The IHI is established first and foremost as a patient safety mechanism. See VPCC Webpage, [Guidance Note 2](#).

## 15. Technical Support and Other Contact Details

Support teams are available within business hours unless otherwise stated.

Query	Service	Telephone	Email	Commentary
Vaccine ordering & delivery issues	National Cold Chain Service (NCCS)	01 463 7770	<a href="mailto:vaccines@udd.ie">vaccines@udd.ie</a>	Any queries relating to quantity/allocation should be raised through the email address
Queries relating to order / delivery of vaccine consumables	Consumables Support	081 800 88 11	<a href="mailto:vaccine.support@jmc.ie">vaccine.support@jmc.ie</a>	Must be emailed from a non Healthmail account
Clinical queries any queries relating to cold chain maintenance or breakdown	National Immunisation Office (NIO)		<a href="mailto:immunisation@hse.ie">immunisation@hse.ie</a>	
Data quality errors support	HSE Data Quality Team	01 240 8786		
Payment queries / claims regarding any vaccines	HSE Primary Care Reimbursement Service (PCRS)	01 864 7100	<a href="mailto:PCRS.PPUQueries@hse.ie">PCRS.PPUQueries@hse.ie</a>	Reimbursement of vaccinations only
General queries / information & relationship management	Relationship Management	081 800 8811	<a href="mailto:pharmacyvaccines@vision.com">pharmacyvaccines@vision.com</a>	
PharmaVax, any technical queries, usability or system issues	PharmaVax Support	01 7784998	Healthmail contact: <a href="mailto:a2ihids.support@healthmail.ie">a2ihids.support@healthmail.ie</a>  Email contact: <a href="mailto:a2ihids.support@hse.ie">a2ihids.support@hse.ie</a>	Monday to Saturday 9am to 5pm
Healthmail issues	Healthmail Support	061 203 779	<a href="mailto:ictsupport@three.ie">ictsupport@three.ie</a>	Any queries relating to your Healthmail account including the secondary email address attached to your account
Vaccines outside cold chain temperature parameters	National Immunisation Office (NIO)		<a href="mailto:pharmacynio@hse.ie">pharmacynio@hse.ie</a>	If vaccines are exposed to temps outside parameters, please contact NIO pharmacist immediately

For contract queries	National Contracts Office	044 9395519	natcontractsoffice@hse.ie	
Contact HSE	HSELive	1800 700 700	You cannot contact HSE Live by email See <a href="#">HSELive</a>	Monday to Friday, 8am to 8pm, Saturday, 9am to 5pm

## 16. Fees and Reimbursement

### 16.1 Fees

Following a process of consultation involving the Department of Health, the HSE and the Irish Pharmacy Union, the Minister for Health, with the consent of the Minister for Public Expenditure, pursuant to **Section 42** of the Public Service (Pay and Pensions) Act, 2017 has determined a schedule of fees rates be paid to pharmacists for the delivery of the COVID-19 Vaccination Programme. Any update regarding fees will be communicated with campaign information.

### 16.2 Reimbursement

The Primary Care Reimbursement Service (PCRS) will receive, process, and integrate electronic COVID-19 vaccination payment claims from HSE PharmaVax to ensure that Community Pharmacists are paid promptly for services provided with minimal administration overhead. Payments will be based on the electronic claims, which are submitted by the vaccinations recorded in HSE PharmaVax. Payment claims will be validated, loaded, reimbursed, and included on the pharmacies monthly statement.

Each patient will be asked to provide their PPSN (if they have one) when attending for vaccination, so that a valid PPSN can be submitted with each electronic claim to facilitate automated payment by the PCRS. Claims for individuals that do not have a PPSN will be processed by PCRS using an exceptional reimbursement process. Any queries regarding the exceptional reimbursement process can be directed to [pcrs.ppuqueries@hse.ie](mailto:pcrs.ppuqueries@hse.ie).



## Appendix 1 - Risk Management Considerations when Multiple Vaccines are in use in a Pharmacy

### Introduction

The introduction of Adapted Booster Vaccines for COVID-19 coincided with the Seasonal Flu Vaccination Programme. Internationally, there have been multiple reports of administration mix-ups between COVID-19 vaccines and flu vaccines<sup>2</sup>.

Note that vaccine requirements for recipients may vary:

- Some may require COVID-19 vaccine only.
- Some may require flu vaccine only.
- Some may require both COVID-19 vaccine and flu vaccine.

Note the different types of COVID-19 vaccines in use. See clinical [guidance](#).

There are also different doses, different age cohorts, different intervals and there are also different types of flu vaccines in use, increasing the complexity of the process.

Effective planning for safe and robust workflow practices is required. No one single step will eliminate the risk and an active approach to risk reduction is required at all steps in the process from scheduling, to arrival/ registration at the pharmacy, to vaccination and record keeping.

### Key Steps to Reduce Risk

- Ensure consistent use of approved terminology (NCCS/SmPC) for the names of each vaccine.
- Schedule vaccine-specific days or sessions where possible.
- Training to ensure awareness of the risks of multiple vaccines being in use is required for all staff involved in any of the steps in the process, even if not working as a vaccinator.
- Avoid the use of the term 'booster' without specifying which vaccine.
- A second independent check on the vaccine(s) to be administered.
- and/or ask the vaccine recipient to read the syringe label / vial aloud to confirm the correct vaccine.

### COVID-19 Vaccines

Confirm vaccine type with recipient at check-in, consent and immediately prior to administration; and please check before each vaccination:

- Is this a primary course, an additional dose for a person who is immunocompromised or a booster dose?
- What is the age of the person?
- What is the recommended vaccine for this age-group?
- What is the recommended dose?
- What is the recommended interval since the last dose?
- Has the person had COVID-19 infection? What is the recommended interval since COVID-19 infection?

Ensure the correct patient information is available for the vaccine in use for the Primary Vaccination Programme and/or the Booster Programme as appropriate.

<sup>2</sup> [Institute of Safe Medication Practices](#)

### **COVID-19 Vaccines and Flu Vaccines**

If provision is being made to administer both COVID-19 and flu vaccines at the same appointment ensure that:

- Only the required vaccine(s) for the individual recipient are taken into the vaccination area.
- Vaccines should be administered in different arms.

## Appendix 2 – HSE Guidelines for Maintenance of Cold Chain in Vaccine Fridges and Management of Vaccine Stock

Definitions and the guidance around “expiry date”, “use before” and “discard time” for COVID-19 vaccines are detailed within the [Clinical Guidance](#).

[HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock](#)



### Appendix VIII: Report following breakdown in Cold Chain

(Please fill this form separately for each fridge and email to the immunisation@hse.ie)

<b>Name of Site</b>		<b>Phone</b>	
<b>Account no.</b>	300.....	<b>Email</b>	
<b>Contact person</b>		<b>Mobile</b>	

#### Date and time “Cold Chain” breach occurred (noticed)

<b>Date (DD/MM/YYYY):</b>	<b>Time (use 24 h clock):</b>
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#### FRIDGE temperature at time of breach in “Cold Chain” identification

Fridge ID	Current (°C)	Minimum (°C)	Maximum (°C)

**Description of incident:**

#### Last recorded temperature of fridge and reset

Fridge ID	Date last record (DD/MM/YYYY):	Time last record (use 24 h clock):	Date last reset (DD/MM/YYYY):	Time last reset (use 24 h clock):

#### Current Fridge temperature at present (if vaccines moved to another fridge - indicate by recording in the Fridge ID\*)

Fridge ID*	Date (DD/MM/YYYY):	Time (use 24 h clock):	Current (°C)	Minimum (°C)	Maximum (°C)

#### DATA LOGGER details

Fridge ID	Time when reading exceeded +8°C or dropped below +2°C (use 24 h clock):	Time when reading became normal i.e. between +2°C and 8°C (use 24 h clock):	Duration (when fridge outside of +2 and + 8 °C) - (use 24 h clock): ___ hour ___ min

#### ROOM TEMPERATURE (where fridge is located)

Minimum room temperature during the excursion period (°C)	Maximum room temperature during the excursion period (°C)

- Note:**
1. Please do not use or dispose of any vaccines unless advised by the NIO.
  2. Quarantine all vaccines within cold chain conditions and notify relevant staff.
  3. Temperature excursions are cumulative and if some of the vaccines were exposed to previous breaches please specify and give details.
  4. HSE sites only - please fill the National Incident Report Form (NIRF-04 Complaint/Dangerous occurrence).

## Appendix 3 – Sample Checklist for COVID-19 Vaccination Clinics

This is a support document for the safe practices for COVID-19 vaccination.

This sample checklist should be used in conjunction with the PSI [COVID-19 Operational Standards](#)

Before the Vaccine Clinic		
Physical Environment / Layout of the Vaccine Clinic		
YES	NO	A designated space for registration
YES	NO	Awaiting area for patients to be called for vaccination. This may be the same space as for registration
YES	NO	A designated clean area for vaccine storage and preparation in the pharmacy
YES	NO	A designated area for vaccine administration
YES	NO	Area for post vaccine observation for 15 minutes (30 minutes if they have a history of allergic reactions) with adequate space for physical distancing and a private space for medical emergencies (anaphylaxis management)
Documentation (Check for most up to date version of documents <a href="http://www.immunisation.ie">www.immunisation.ie</a> )		
YES	NO	Clinical and administrative guidance for vaccinators
YES	NO	National immunisation Advisory Committee Immunisation Guidelines for Ireland. <a href="https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland">https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</a>
YES	NO	Copy of a relevant COVID-19 vaccine standard operating procedure
YES	NO	Anaphylaxis management in the community - copy of an algorithm ( <a href="https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland">https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland</a> )
YES	NO	Copy of information on cold chain management or access to the same <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/">https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/</a>
YES	NO	Vaccination record cards and HSE advice leaflets for after vaccination for the recipients (if hard copies are available)
YES	NO	Current up to date copies of: HSE vaccine information leaflets <a href="https://www.hse.ie/eng/services/covid-19-resources-and-translations/covid-19-vaccine-materials/">https://www.hse.ie/eng/services/covid-19-resources-and-translations/covid-19-vaccine-materials/</a>
Infection Prevention & Control Precautions:		
YES	NO	Posters in relation to COVID-19/ Cough etiquette/respiratory hygiene/hand hygiene are available from the HSE website <a href="http://hsenet.hse.ie/">http://hsenet.hse.ie/</a>
YES	NO	Hand sanitiser (alcohol gel/foam sanitiser) for staff and patients
YES	NO	PPE for the vaccinator if required as per latest <a href="#">HPSC guidance</a>
YES	NO	Disposable tissues available for patients and a foot pedal bin for disposal
YES	NO	Disinfectant wipes for worktops and other areas
YES	NO	Sharps waste bin, clinical and nonclinical risk waste bins
Clinical equipment		

YES	NO	Access to pharmaceutical grade fridge with a display of current temperature
YES	NO	An anaphylaxis medical kit as per <a href="#">Guidelines</a> .
YES	NO	Gloves <input type="checkbox"/> Sharps boxes <input type="checkbox"/> Alcohol gel <input type="checkbox"/> Clinical tray <input type="checkbox"/> Cotton wool <input type="checkbox"/> Tape <input type="checkbox"/> Clinical waste bags <input type="checkbox"/> 70% Alcohol swabs <input type="checkbox"/> Needles <input type="checkbox"/> Syringes
<b>After the vaccination</b>		
YES	NO	Post-vaccination monitoring (recommended for 15 minutes or 30 minutes if patient has a history of allergic reactions): Allocation of staff for post vaccine observation for 15 -30 minutes. The IPU has designed a time to leave ticket to enable Community Pharmacists to manage this process.
YES	NO	Post vaccine documentation Vaccinations administered recorded in HSE COVID-19 Vaccination Management System via HSE PharmaVax
YES	NO	All patient medical information placed in a secured storage location for data protection. Provide patient with record of the vaccine, including batch, that they received, and any follow up if required.

## Appendix 4 – Workflow Considerations

*It is envisaged that Community Pharmacies will:*

- Identify patients are within designated group for receiving vaccine in line with the immunisation guidelines. Determine previous COVID-19 vaccination history via HSE vaccination history search portal.
- Where possible facilitate patient appointments for the co-administration of COVID-19 vaccines and seasonal influenza vaccines.
- Set up initial and follow-on vaccination timeslots with patients (*e.g., Monday 10:00-11:30am as per vaccination schedule for the individual vaccine and patient cohort guidance*).
- Be informed of the vaccine that has been allocated by the HSE based on available supply ETA (*e.g., 60 doses to arrive next Monday*).
- Contact patients to confirm appointment times and run through eligibility criteria, including any recent history of COVID-19 infection.
- Receive vaccines from the NCCS as per agreed delivery schedule.
- Check, verify and accept the vaccine delivery.
- Store correctly in fridge and monitor fridge temperature.
- Enter patient details and vaccine specific data (as relevant) on HSE PharmaVax (COVID-19 vaccine manufacturers, batch numbers and expiry date are now pre-populated in the HSE PharmaVax system. Pharmacists are required to input the use before date and time).
- Pre-clinic setup (*e.g., stock control, patient/clinic list*).
- Patient arrival/reception.
- Patient registration (ID checks Please see **Appendix 5** for guidance) ensure details are on HSE PharmaVax (*e.g., verify and update PPSN, mobile phone number and email address*). *Note patient must have photographic ID in order to complete ID checks.*
- Verify patient consent and eligibility, ensure consent is provided by parent or legal guardian in case of young person aged 12-15 years and record assent to vaccination of young person on consent form.
- Vaccinate patient.
- Record and save details on the pharmacy record as soon as possible to ensure patient vaccination history is up to date.
- Submit final details on HSE PharmaVax.
- Patient waits 15 minutes if required in line with NIAC advice (or 30 minutes if clinically needed) ensure that they receive patient information leaflet.
- Treat and record any immediate adverse reactions (Report to HPRA).
- Complete HSE patient vaccination record card.
- If required, opportunistically vaccinate other patients – contingency list utilisation in line with HSE implementation strategy (*e.g., make use of vaccines that will otherwise expire*).
- Treat and/ or refer as appropriate and record any later adverse reactions (Report to HPRA).
- Complete post-clinic wrap up (*e.g. number of patients vaccinated, stock used/cannot be used*).
- Print daily audit of vaccinations completed using the report function in HSE PharmaVax – stamp, date, and signed by vaccinating pharmacists. Retain this record within the pharmacy.

## Appendix 5 – Guidance on Photographic ID

Patients are required to bring photographic ID and this must be validated. The HSE acceptable forms of identification are provided below:

- Passport - book or card
- Driving Licence
- Public Services Card
- Travel Pass
- National Age Card - issued by the Gardaí
- Identification Form - with a photograph signed by a member of the Gardaí - get this from a Garda station

For those aged 12-15 years old where photo ID is not available a birth certificate is sufficient as proof of age.