National COVID-19 and Influenza Vaccination Programme Operational Guidance for Community Pharmacy

Version 1

11/09/2024

Version	Date	Prepared by	Version Updates
V1.0	11/9/2024	Vaccinations	
		Primary Care	
		Contractors	

Table of Contents

1.	Overview and Introduction	5	
2.	Pharmacy Regulation and the Vaccination Programme	5	
3.	Clinical Governance and Guidance	6	
3	3.1 Clinical Governance	6	
3	3.2 Clinical Supporting Information	6	
4.	Vaccinations Primary Care Contractors (VPCC)	6	
5.	Indemnity	6	
6.	Training for Pharmacists on Vaccine Administration	7	
7.	How to join the Vaccination Programme	8	
8.	Communications	8	
8	3.1 Access to COVID-19 and Influenza Information Materials	8	
8	3.2 Pharmacy Finder	8	
9. V	/accine Updates	8	
ç	9.1 Vaccination and Eligibility	8	
ç	9.2 Sequencing of vaccination in PharmaVax	9	
10.	Vaccine Stock and Consumables	9	
1	10.1 Ordering Vaccine	9	
1	10.2 Vaccine Consumables for COVID-19 in Community Pharmacy	9	
1	10.3 Storage of Vaccines in Community Pharmacies	9	
1	10.4 Removal of COVID-19 Sharps from Community Pharmacy Sites	10	
1	10.5 Return of expired vaccine stock	10	
11.	Preparing for a Vaccination Service	10	
1	11.1 Community Pharmacy Premises Requirements	10	
1	11.2 Observation Post Vaccination	10	
1	11.3 Record Keeping	11	
1	11.4 Data Quality	11	
12.	Reporting of Incidents during a Vaccination Session	11	
1	12.1 Adverse Reaction Reporting	12	
1	12.2 Management of Injuries	12	
13.	Consent	12	
14.	PharmaVax	12	
1	14.1 Vaccine Removal from HSE PharmaVax	13	
1	14.2 Individual Health Identifier	13	
15. Technical Support and Other Contact Details			
16.	Fees and Reimbursement	13	
1	16.1 Fees	13	

16.2 Reimbursement	13
Appendix 1 - Risk Management Considerations when Multiple Vaccines are in use in a Pharmacy	14
Appendix 2 - Workflow Considerations	15
Appendix 3 - Useful Links & Resources	16

1. Overview and Introduction

The Seasonal Vaccination Programme is developed based on the recommendations issued by the National Immunisation Advisory Committee (NIAC), available at <u>www.rcpi.ie/Healthcare-</u><u>Leadership/NIAC/Immunisation-Guidelines-for-Ireland</u>

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 and Influenza, protecting healthcare capacity and enabling social and economic activity. The COVID-19 and HSE Influenza vaccines are free to all eligible persons of the State.

The National Immunisation Advisory Committee (NIAC) provides evidence-based advice to the Chief Medical Officer and the Department of Health on vaccines, immunisation and related health matters to inform health policies in Ireland, which includes COVID-19 and influenza vaccination.

Pharmacies continue to play a key role in the delivery of the vaccination programmes in accordance with the agreed national vaccination schedule.

This operational guidance provides best practice for the implementation of the programmes, including logistical arrangements and processes established for the management of the vaccine programme to patients in Community Pharmacy.

The programmes are integrated maximising available resources, promoting uptake and providing those eligible with the opportunity to receive both COVID-19 and Influenza vaccinations together.

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"). The PSI views Community Pharmacies as an essential part of the delivery of national vaccination programmes and are keen to ensure that relevant and proportionate regulation plays an appropriate role in ensuring the safety and effectiveness of these national vaccination programmes.

The legislative framework is also supported by <u>Guidance and Guidelines for Pharmacists and</u> <u>Pharmacies.</u>

In addition, the <u>Code of Conduct</u> 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.

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

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 vaccination in line with the <u>HSE</u> <u>Guidance</u> on eligibility and interval periods, administering the vaccine and managing the person postvaccine, rests with the pharmacist and their existing governance and regulatory structures i.e. Superintendent Pharmacist and Supervising Pharmacists.

3.2 Clinical Supporting Information

The HSE make Guidelines and information available for the COVID-19 and Influenza vaccines preferred within the national vaccination programme. These resources 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 <u>NIO Clinical Guidance</u>.

Pharmacists should direct all clinical queries to the NIO via immunisation@hse.ie .

4. Vaccinations Primary Care Contractors (VPCC)

The National Vaccination Programme is supported by the HSE Vaccinations Primary Care Contractors (VPCC) team, who co-ordinate the service and provide Relationship Management Support to GPs and Community Pharmacists. For further details, please see <u>VPCC webpage</u>.

There are a number of operational resources to support vaccinators in the provision of COVID-19 and Influenza vaccines, including <u>FAQs</u> and <u>guidance notes</u>.

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 COVID-19 vaccine.

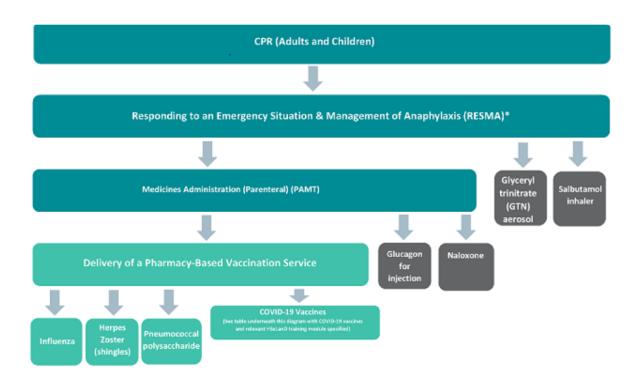
GPs, GP Practice Nurses and Community Pharmacists however, will not be indemnified in respect of malpractice events occurring during the administration of the COVID-19 vaccine. Such malpractice events will be indemnified by their professional insurers.

For further information, see Professional Indemnity Insurance for Pharmacists | PSI (thepsi.ie).

6. Training for Pharmacists on Vaccine Administration

The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended) authorise a registered pharmacist to supply and administer a certain vaccines and/or emergency medicines where they have received training approved by the PSI. This legislation also outlines the record keeping requirements for the supply and administration of vaccinations and/or emergency medicines.

The approved training pathway for vaccinating pharmacists is available on the PSI website. 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 <u>Vaccination Training Requirements for Pharmacists</u>.



You can contact the <u>Irish Institute of Pharmacy (IIOP)</u> to find out how to register and complete the required training programmes (other than training hosted on HSeLanD). The IIOP have developed a new vaccination resource to guide and support pharmacists in identifying their training requirements for the supply and administration of vaccines. It can be accessed at; <u>Training for the Supply and Administration of Emergency Medicines and Vaccinations | IIOP Portal.</u>

The relevant NIO COVID-19 vaccine training programmes are available through <u>HSeLanD</u>. The relevant Influenza Vaccine training module is available on the IIOP website.

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 <u>Immunisation bulletins</u> published by NIO on their website.

In addition, NIO have developed a number of resources to support vaccinators in the provision of Influenza which are available on the <u>immunisation</u> website.

7. How to join the Vaccination Programme

For information on joining the Vaccination Programme, please see the <u>VPCC Vaccination</u> <u>Programme</u>.

8. Communications

The HSE has comprehensive information available on COVID-19 and Influenza vaccinations.

8.1 Access to COVID-19 and Influenza Information Materials See Guidance Note 1 – <u>Guidance on COVID-19 and Influenza Vaccine Consumables and Information</u> <u>Resources.</u>

Additional resources are available at COVID-19 Vaccine Materials and at Flu Vaccine Information.

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 <u>pharmacy finder</u> webpage and update their participation status to reflect the vaccination services they are providing during the autumn/winter programme and any spring/summer programme. It is recommended that Pharmacies, when not in active campaign, suspend their account details on pharmacy finder. To amend, temporarily suspend, or delete your details please use this <u>form</u>.

9. Vaccine Updates

9.1 Vaccination and Eligibility

The vaccine programme is informed by <u>NIAC Guidance.</u> Clinical guidance and supporting information including eligibility for COVID-19 and Influenza is available from National Immunisation Office (NIO) at <u>www.hse.ie/eng/health/immunisation/hcpinfo/</u>

For a quick reference table on the different types of COVID-19 vaccines currently available, please see <u>Quick Reference Guide COVID-19 Vaccines</u>

Influenza programme materials are available here.

Frequently Asked Questions for Healthcare Professionals can be accessed at <u>Frequently Asked</u> <u>Questions about Immunisation</u>.

See Appendix 1 for Risk Management Considerations when Multiple Vaccines are in Use.

The VPCC have developed a range of resources to support Pharmacists in the delivery of the programmes, see <u>Information and Resources for Vaccination Programme</u> including vaccination programme guidance notes and FAQ's.

Pharmacists are required to familiarise themselves with the updated clinical guidance including appropriate vaccine selection in pregnancy and breastfeeding, and for immunocompromised individuals. For further information on inputting immunocompromised status in PharmaVax,

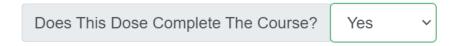
see <u>Guidance Note 10.</u> See also, Guidance Note 3 <u>Guidance on Repeat Primary Course COVID-19</u> <u>Vaccination</u>.

Note: Alternative pathways are in place for patients where mRNA COVID-19 vaccines are contraindicated, refer to <u>Guidance Note 6</u>.

9.2 Sequencing of vaccination in PharmaVax.

For COVID-19 vaccinations, dose sequence should follow Primary Course Dose 1, Primary Course Dose 2 (where clinically indicated), and additional dose (where clinically indicated). Booster doses should only be recorded after a primary course/additional dose record. It is important that the dose sequence is correct on entry to ensure that clinical records are up to date and that payment is issued from PCRS.

For Influenza vaccines, if an individual is clinically eligible for a single dose of Influenza vaccine, the 'course complete' box in PharmaVax should indicate yes.



For individuals that clinically require a second dose of Influenza vaccine during the season, the 'course complete' box should indicate no on the <u>first</u> dose.

Does This Dose Complete The Course? No ~

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 <u>www.ordervaccines.ie</u>. See National Immunisations Office for comprehensive information on <u>Vaccine Ordering and Storage</u>.

10.1 Ordering Vaccine

The HSE NCCS will deliver COVID-19 and Influenza vaccines.

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

10.2 Vaccine Consumables for COVID-19 in 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 <u>NCCS</u>, 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 <u>VPCC Guidance Note 1</u> on COVID-19 vaccine consumables.

10.3 Storage of Vaccines in Community Pharmacies

See <u>HSE Guidelines</u> (Section 12.3) 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 <u>PSI guidelines on the storage</u> of medicinal products within a retail pharmacy business.

10.4 Removal of COVID-19 Sharps from Community Pharmacy Sites

Stericycle Services will be providing a COVID-19 sharps disposal service on behalf of the HSE. Pharmacies should contact <u>serviceireland@stericycle.com</u> or 1800 937 628 for removal of sharps containers, 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 www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/vaccreturn.pdf

11. Preparing for a Vaccination Service

In preparation for the ongoing rollout of the vaccines, 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 and influenza vaccines, and to determine the number of vaccinations that they can administer safely.

For workflow considerations when setting up a vaccination clinic please see **Appendix 2**.

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 <u>here</u>.

In order to provide the COVID-19 and influenza 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 the preparation and administration of 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.

Please also refer to the <u>PSI guidance on providing a pharmacy vaccination services</u> including guidance on <u>providing vaccination services off site from the pharmacy premises</u> and <u>PSI Guidance on the</u> <u>Provision of an Influenza Vaccination Service for Children Aged 6 months and Older</u>. Particularly in relation to children, superintendent pharmacists and pharmacy owners are reminded of obligations under <u>the Children First Act 2015</u>.

See also section 10.3 on Storage of Vaccines in Community Pharmacy.

Patients are required to bring photographic ID and this must be validated.

11.2 Observation Post Vaccination

Scheduling of people should allow for a safe space to observe the person in line with NIAC advice.

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 <u>Immunisation Guidelines</u>.

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 <u>here</u>.

11.3 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.

Additionally, there is a requirement for pharmacists to forward to the Health Service Executive, within 7 days, by electronic means, specific details relating to a vaccine administration. The following details are recorded on HSE PharmaVax and transferred to the HSE automatically and satisfy that requirement:

- 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.

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.

11.4 Data Quality

Sometimes the data messages coming from the source systems may not communicate correctly or the data entered may not be fully complete. In order to clarify and address the data issue, the National Immunisation Office, (NIO) will work with HSELive to seek clarification. This will mean that vaccinators may receive a phone call from HSELive to clarify data items. HSELive is part of the HSE and the team work closely with the NIO and contracting office to seek clarification to resolve DQ issues. There is dedicated line for Pharmacies to ring HSELive, in relation to DQ issues which is: 01 2408786.

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 <u>immunisation@hse.ie</u> 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. This enables the EMA to continue to safeguard public health safety. The HPRA must be informed using the <u>Adverse Reaction Report</u> (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 <u>Health Protection Surveillance Centre Website</u>

13. Consent

For specific information on consent, please see:

- Consent for Vaccination for COVID-19: Guiding Principles.
- Healthcare professional information for flu including consent

Pharmacists must be aware of how consent is obtained for a young person.

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 and influenza vaccinations that are administered. 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 <u>a2ihids.support@hse.ie</u>. 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.

The Vaccination History Lookup portal should be checked by the pharmacist, prior to 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, <u>Guidance Note 2</u>.

15. Technical Support and Other Contact Details

See Pharmacy - Contact Details

For further useful contacts and links, see Appendix 3.

16. Fees and Reimbursement

16.1 Fees

Any update regarding fees will be communicated with campaign information on circulars. Previous HSE Circulars can be accessed <u>here</u>.

16.2 Reimbursement

The Primary Care Reimbursement Service (PCRS) will receive, process, and integrate electronic COVID-19 and influenza 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. A valid PPSN is required for the administration of HSE Influenza vaccines. COVID-19 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.

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

The introduction of 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 vaccines¹.

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.

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 or a booster dose?
- What age is 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 confirmed COVID-19 infection?

COVID-19 Vaccines and Flu Vaccines

If co-administering 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 - 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 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
- Pre-clinic setup (e.g., stock control, patient/clinic list).
- Patient arrival/reception.
- Patient registration (ID checks) Please 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.
- Vaccinate patient.
- Record and save details on PharmaVax as soon as possible to ensure patient vaccination history is up to date.
- Patient observation period 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 (<u>Report</u> 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 (<u>Report</u> to HPRA).
- Complete post-clinic wrap up (e.g. number of patients vaccinated, stock used/cannot be used).
- Complete any record keeping requirements as per PSI guidance

Appendix 3 - Useful Links & Resources

Immunisation Guidelines for Ireland www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

Clinical Guidelines for COVID-19 vaccines COVID-19 Vaccine Information for Health Professionals - HSE.ie

Anaphylaxis management

www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool box www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdfation/hcpinfo/vaccine ordering/sopnio02.pdf

Reporting adverse reactions to the Health Products Regulatory Authority (HPRA). Details of the brand name and batch number of the vaccine must be included.

Online reporting at www.hpra.ie

Using a downloadable report form also accessible from HPRA website, which may be completed manually and submitted to the HPRA via "freepost" available from the HPRA website

Summary of Product Characteristics (SmPC) for the COVID-19 vaccine used in the HSE COVID-19 Vaccination Programme available at <u>www.ema.europa.eu/en</u>

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 www.hpsc.ie/a-z/emi/