# **Guidance to Support Pharmacies in Providing Safe Vaccination Services Offsite from the Pharmacy Premises**

Addendum to the PSI's Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses.

Pharmaceutical Society of Ireland

Version 4 September 2023

Contents	
1. Purpose of this Guidance	2
2. Introduction	2
3. Legislation Authorising the Provision of this Service	
4. Requirements when Implementing a Vaccination Service	
5. Additional Considerations when Implementing a Vaccination Service Offsite from the Pharmacy Premises	4
5.1 Planning for a Vaccination Service Offsite from the Pharmacy Premises	4
5.2 Choosing a Suitable Location and Vaccination Services Area	5
5.2 Choosing a Suitable Eocation and Vaccination Services Area	
5.3 Governance and Staffing	6
	6
5.3 Governance and Staffing	
<ul><li>5.3 Governance and Staffing</li><li>5.4 Training</li></ul>	6
<ul><li>5.3 Governance and Staffing</li><li>5.4 Training</li><li>5.5 Equipment and Facilities, and Medicines Management</li></ul>	6
<ul> <li>5.3 Governance and Staffing</li> <li>5.4 Training</li> <li>5.5 Equipment and Facilities, and Medicines Management</li> <li>5.6 Infection Prevention and Control</li> </ul>	6 6 8

# 1. Purpose of this Guidance

The purpose of this guidance is to support those who have governance responsibilities for pharmacies, i.e., pharmacy owners, superintendent pharmacists and supervising pharmacists, in providing a safe vaccination service at any suitable and appropriate place offsite from the pharmacy premises.

It is important to note that currently this only applies to COVID-19 and influenza vaccination services.

### 2. Introduction

While vaccination services are available onsite in many pharmacies, the extension of the service to offsite locations has the potential to greatly increase access to vaccines, and in turn increase vaccine uptake. Increasing access to the influenza vaccine and COVID-19 vaccines is a high priority to protect society, especially those most vulnerable in the community, and to help mitigate the impact on healthcare services over the winter period.

Offsite vaccination enables pharmacies to provide vaccination services to a greater number of patients by providing greater flexibility for service planning, and removing some potential practical barriers which may be in place due to public health advice.

Where 'you' is referenced throughout the guidance, this refers to pharmacy owners, superintendent pharmacists and supervising pharmacists.

# 3. Legislation Authorising the Provision of this Service

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.5) Regulations 2020 came into effect in October 2020 (S.I. No. 401 of 2020). These amending Regulations now permit:

An appropriately trained pharmacist to supply and administer the influenza vaccine suspension for injection presented as a pre-filled syringe and the influenza vaccine nasal spray suspension, at any suitable and appropriate place (i.e. within or offsite from the retail pharmacy business premises) having regard to the public convenience and the need to protect the health and safety of the public.

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.7) Regulations 2020 came into effect in December 2020 (S.I. No. 698 of 2020), this amendment and subsequent amendments made to the legislation as new COVID-19 vaccines became authorised and as the National COVID-19 vaccination programme progressed, permit:

 An appropriately trained pharmacist to supply and administer COVID-19 vaccines at any suitable and appropriate place, having regard to public convenience and the need to protect the health and safety of the public.

Any vaccination service provided offsite under this legislation <u>must</u> be carried out in connection with a named registered retail pharmacy business, in which the vaccinating pharmacist is employed or engaged.

# 4. Requirements when Implementing a Vaccination Service

Along with the legislation, Code of Conduct, and mandatory training, there are a number of guidance documents (listed below) which support the provision of a pharmacy vaccination service. This ensures that this service is provided to a consistently high standard in all pharmacies.

When planning a vaccination service offsite from the pharmacy premises the same guidance will apply and must be read and adapted to the chosen setting. This will ensure that the vaccination service is provided to the same high standards of patient safety and quality regardless of the setting:

- Relevant legislation<sup>1</sup>, which includes the condition that administration of a vaccine is in accordance with the summary of product characteristics of the product administered and the <u>Immunisation Guidelines for Ireland</u>, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland and the advice and guidance of the <u>National Immunisation Office (NIO)</u>.
- The PSI's Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses (September 2023) (PSI's Vaccination Guidance).
- The PSI's Guidance on the Provision of an Influenza Vaccination Service for Children Aged 6 Months and Older (September 2023).
- HSE-PCRS National COVID-19 Vaccination Programme Community Pharmacy: Operational Guidance for Vaccination in Community Pharmacy.

If you already provide a vaccination service in your pharmacy, many of the requirements will be the same as when providing this service offsite from the pharmacy premises, for example, the equipment needed, the training requirements for the vaccinating pharmacist, the required patient consultation, vaccine administration and record

keeping requirements. Whilst the guidance and legislation set out above is comprehensive, we have identified some *additional* considerations to assist you when planning and carrying out a vaccination service at other locations.

# 5. Additional Considerations when Implementing a Vaccination Service Offsite from the Pharmacy Premises

# **5.1** Planning for a Vaccination Service Offsite from the Pharmacy Premises

A vaccination service carried out under this legislation<sup>2</sup> can only be provided by a pharmacist employed or engaged by a registered retail pharmacy business<sup>3</sup>.

It is important to note that where a pharmacy is part of a chain or symbol group this service must be provided by an individual pharmacy within that chain or group, and not the corporation as a whole. This ensures appropriate governance and procedures are in place for the safe and appropriate sourcing, storage, supply and disposal of medicines, record keeping requirements and provision of suitable equipment, and trained staff to carry out this service.

Where a locum pharmacist is employed by a retail pharmacy business specifically to provide an offsite vaccination service, the superintendent pharmacist is responsible for ensuring that the locum pharmacist has completed all the required training and he/she is competent to provide this service in line with the pharmacies policies and procedures.

When providing a vaccination service in a location offsite from the pharmacy, there may be additional challenges and risks depending on the purpose, size and chosen setting of the service that you are planning. The aim should be

to increase access to vaccinations for as many people as possible, in a controlled and safe manner.

Each year prior to the influenza vaccination season, the HSE provides a list of those people considered to be in an 'at risk group' and other people who should get the influenza vaccine to protect themselves, their families and those they care for. Special consideration should be given to increasing access for these groups. For more information on who is in these categories please see:

- HSE's Seasonal Influenza Vaccination Programme
- NIO Immunisation Bulletins

It should be noted that influenza vaccines provided free under the National Immunisation Programme, must only be used for eligible patients as defined by the HSE and not diverted for private vaccination services.

The needs of your patients and local community should be taken into account when you are planning the service, for example the times the service will be available and where it will be held. You should also take account of how accessible it is for older people and those with disabilities and mobility issues.

When planning a vaccination service offsite from the pharmacy premises you must ensure the same high standards of patient safety and quality service, as would be provided on the pharmacy premises.

You must also ensure that appropriate professional and public indemnity arrangements are in place for the provision of this service at the chosen location.

It is recommended that patients are provided with appointment times, in order to reduce the risk of overcrowding, to ensure safe patient flow can be maintained, and to adequately inform patients of what to expect before they attend for their vaccination. This also helps with planning

<sup>2</sup> The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.5) Regulations 2020 (S.I. No. 401 of 2020) and the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.7) Regulations 2020 (S.I. No. 698 of 2020).

<sup>3</sup> The name and registration number of the specific pharmacy which is providing the service should be clearly displayed, for all patients attending for vaccination to see.

with regard to how many vaccines will be needed as well as the required amount of adrenaline (epinephrine) in case of an anaphylactic reaction.

Completing the required patient consultation and documentation should be factored into the amount of time needed for each vaccination to ensure this service is provided safely and in line with the guidance.

If you intend to administer more than one type and/or brand of vaccine from the offsite location, it is most important that you assess the associated risks and implement the required safety processes at this site. For example, vaccine stock must be stored so that the different types and/or brands are clearly segregated either by shelf or if an additional fridge is available, in separate fridges. All vaccinating pharmacists must be alerted that more than one type and/ or brand is on site. The administration of different types and/or brands of vaccine should be separated in time and space, for example a morning session with vaccine A and an afternoon session with vaccine B.

See **Checklist 5.1** for further considerations to help you plan your service **(Appendix A)**.

# 5.2 Choosing a Suitable Location and Vaccination Services Area

Once you are clear on the purpose of the vaccination service, you should identify a location that is suitable for the patient cohort you wish to vaccinate, the needs of the local community and the facilities available. When deciding on a suitable location for this service, it is important to bear in mind the requirement that it should facilitate the same level of professional service as that provided at the pharmacy premises. A thorough risk assessment should be conducted before setting out your service plan.

Within the chosen location, an area should be set aside that has both visual and auditory privacy for the administration of the vaccine. This area should meet the requirements for a 'vaccination services area' (as relevant to offsite vaccination) set out in the PSI's Vaccination Guidance.

When deciding on the location and vaccination services area, you must consider the patient's privacy and dignity and ensure that confidential and personal information cannot be overheard or seen by others.

Some potential locations where pharmacists may wish to provide this service include:

- A community centre, parish or church hall or sports centre
- A residential care home or day care facility
- A school or other childcare facility<sup>4</sup> (please refer to Checklist 6.2 (Appendix A) of this guidance document, and the PSI's Guidance on the Provision of an Influenza Vaccination Service for Children Aged 6 Months and Older, for further guidance for this cohort)
- A business premises

The examples provided above are not an exhaustive list and any potential offsite location should be viewed in the context of any current public health advice.

See **Checklist 5.2** for further considerations to help you to decide on an appropriate location **(Appendix A)**.

<sup>4</sup> It must be clear that this service is provided by a named pharmacy and not part of the national school's Immunisation Programme.

#### 5.3 Governance and Staffing

It is important that robust documented policies and procedures are in place for all aspects of this service to ensure that it is provided safely and effectively. As the same requirements for a vaccination service apply regardless of the setting, if you already provide a pharmacy based vaccination service, you may be able to adapt your current policies and procedures to the provision of this service at the new location (with the addition of any extra measures needed to ensure the safety of patients and staff in line with current public health advice).

For oversight of the service, it will generally be necessary to have additional members of staff assisting the vaccinating pharmacist(s) for example, someone should be available to greet and register patients on arrival and direct patients where to go. The number of staff needed will depend on the size of the venue, and the number of people you intend to vaccinate. Assigning clear roles and responsibilities in advance will assist with the smooth and safe management of the service and will help provide accountability.

When a patient is attending an offsite vaccination service, the name and registration number of the specific pharmacy which is providing the service should be clearly displayed for all patients to see, along with the vaccinating pharmacist's name and registration number. Patients should be informed that they can contact the pharmacy directly if they have any follow up questions or concerns following vaccination. Staff members and those managing the service should be clearly identifiable to patients on arrival and a record of staff on duty should be maintained.

Staff and patients should be encouraged to provide feedback on the provision of the service. All concerns or queries should be addressed, and the superintendent pharmacist should ensure that relevant procedures are regularly reviewed and updated following feedback from staff and patients, to continually improve the quality and safety of the service.

See **Checklist 5.3** for further considerations to help you when putting governance arrangements in place and planning for additional staff **(Appendix A)**.

#### 5.4 Training

The same training requirements for pharmacists apply when providing a vaccination service at locations offsite from the pharmacy premises as those carried out in the pharmacy. Current training requirements are set out on the PSI website

Vaccinating pharmacists and all other staff members involved in the provision of a vaccination service must also be trained on the pharmacy's policies and procedures regarding the operation of this service at the chosen location.

See **Checklist 5.4** for further considerations to help ensure that all members of staff are appropriately trained **(Appendix A)**.

# 5.5 Equipment and Facilities, and Medicines Management

The PSI's Vaccination Guidance sets out the equipment required for a vaccination service on a pharmacy premises. These requirements must also be met when a vaccination service is provided offsite. You should also refer to the **HSE-PCRS** Operational Guidance for Vaccination in Community Pharmacy which sets out the specific equipment required for the delivery of a COVID-19 vaccination service. Consideration should be given to the appropriate number of sharps bins and clinical waste bins that will be needed for the scale of service being provided, and a protocol should be in place for the safe transport of these to and from the vaccination site. An exemption under the regulations for the carriage of dangerous goods is provided for pharmacists when carrying clinical waste for a vaccination service, in their private vehicles.

To avail of this exemption, measures must be taken to prevent any leakage of contents under normal conditions of carriage<sup>5</sup>.

When providing a vaccination service at a location offsite from the pharmacy, particular consideration must be given to the safe handling of medicines, which must be under the control of the pharmacist at all times. You will need to have adequate supplies of vaccine for the number of people you intend to vaccinate and also an adequate supply of adrenaline (epinephrine) (as part of an anaphylaxis kit<sup>6</sup>).

Vaccines must be authenticated under the Falsified Medicines Directive. Authentication involves the scanning and decommissioning of each 2D barcode and checking the tamper proof seal on the outer packaging. For any vaccines that are provided in multipack, the outer pack only needs to be scanned and decommissioned once, upon first opening.

You must ensure the handling, storage and transportation of vaccines is safe and in accordance with the manufacturer's instructions (as set out in the product's Summary of Product Characteristics (SmPC) or Package leaflet (PL)), and that the cold chain is maintained as required. This includes transport of the vaccines from the pharmacy to the chosen site, while at the chosen site, and then for any excess vaccines to be returned to the pharmacy.

The HSE has published <u>Guidelines for</u> maintenance of cold-chain in vaccine fridges and management of vaccine stock and <u>Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes</u>. A procedure must be drawn up and followed based on this guidance, as relevant to the provision of the service at the chosen location.

As set out in the HSE Guidelines: If there are any unused vaccines remaining at the end of a vaccination session, **providing that the cold chain has been maintained**, the vaccines can

be returned to the vaccine fridge. They must be marked and should be used first on their next vaccination session.

It should also be noted that the HSE guidelines state: SOPs should allocate overall responsibility for cold chain management to a designated person(s). However, each vaccinator is responsible for ensuring that the vaccines they administer have been correctly stored and are in date.

The HSE have also produced an e-learning training module to update and train staff involved in handling vaccines, which is available to all pharmacists on HSELanD (www.hseland.ie/dash/Account/Login).

Adequate vaccine stock and adrenaline (epinephrine) must be available at the service. The amount of stock needed will be dependent on how quickly you intend to vaccinate patients, and the number of patients receiving vaccines at any one time. The anaphylaxis kit containing adrenaline (epinephrine) must be stored securely, but also readily available if needed in an emergency.

A designated area must be available for the patient to wait for post-vaccination observation in line with NIAC guidelines and a designated area must also be available should an adverse event occur post injection, particularly an event which requires the administration of adrenaline (epinephrine) or the provision of basic life support.

See **Checklist 5.5** for further considerations to help you manage medicines and decide on what equipment and facilities are needed at your chosen location **(Appendix A)**.

<sup>5</sup> Further information can be found in: <u>ADR Carriage of Dangerous Goods by Road; A Guide for Business</u>

<sup>6</sup> Suggested Anaphylaxis Kit is provided in the Chapter on Anaphylaxis; NIAC Immunisation Guidelines: Anapyhlaxis

## 5.6 Infection Prevention and Control

When you are preparing the vaccination services area in a location offsite from the pharmacy you must ensure the area meets the same standard of infection prevention and control as you would provide in your pharmacy. This should be based on routinely applying basic infection prevention and control strategies, to minimise risk to both patients and your staff. In particular, hand hygiene, respiratory hygiene and cough etiquette, appropriate use of personal protective equipment, regular cleaning, and safe handling and disposal of sharps<sup>7</sup>.

See **Checklist 5.6** for further considerations in relation to infection prevention and control **(Appendix A)**.

# 6. Carrying out the Vaccination Service

Due to the potential to vaccinate many more patients per day at a dedicated vaccination service provided at an offsite location, it is essential that good information management is in place. In particular, ensuring the correct information/patient record is reviewed for the correct patient.

The section on patient consultations in the PSI's Vaccination Guidance should be read and applied in the context of providing a vaccination service at the chosen location. This includes, prior to vaccination, carrying out a documented risk assessment of the patient's suitability for vaccination and ensuring that the precautions and contraindications, provided in the Immunisation Guidelines for Ireland and specified in the Summary of Product Characteristics (SmPC) of the vaccine, are appropriately addressed<sup>8</sup>.

The patient consultation must be carried out in an area which is compliant with current public health advice, while still maintaining patient confidentiality. Alternatively, the patient consultation can be carried out in advance (with their consent) by telephone, online or using other eHealth measures such as video consultation.

If the patient consultation has been carried out in advance (including providing consent for the vaccination and the recording and keeping of data), when the patient attends for vaccination, the pharmacist must confirm that:

- the information they have in front of them relates to the correct patient,
- the patient has read all relevant information about the vaccine (that should have been provided to them to ensure informed consent),
- the patient has the opportunity to ask any questions, and
- the patient confirms consent for the vaccine verbally, prior to vaccination.

If vaccinating a child, the parent or legal guardian must provide informed consent on the child's behalf. The parent or guardian must also be present at all times during vaccination, except when administering a LAIV (Live Attenuated Influenza Vaccine) nasal influenza vaccine in a school setting.

See **Checklist 6.2** for considerations in relation to the administration of the LAIV nasal influenza vaccine in a school setting **(Appendix A)**.

<sup>7</sup> National Clinical Guidelines: Infection Prevention and Control (IPC)

<sup>8</sup> In some circumstances, advice in the SmPC may differ from the Immunisation Guidelines for Ireland. When this occurs, the recommendations in the Immunisation Guidelines for Ireland, which are based on current expert advice, should be followed.

It is recommended to carry out practice runs prior to the start of the service.

Practice runs help to ensure that pharmacists are familiar with all aspects of delivering the service in the specific environment, for example, setting up the vaccination services area, proper storage and handling of the vaccines and anaphylaxis kit, patient flow through the service and procedure to be followed in the event of an emergency etc.

Support staff should also carry out practice runs to ensure that they are clear on how the service will operate and ensure that current public health advice is followed.

See **Checklist 6** for further considerations in relation to the patient consultation and recommended practice runs **(Appendix A)**.

# **6.1 Safe Management of Medicines, Records and Waste**

All medicines (vaccines and those in the anaphylaxis kit), sharps and clinical waste must be kept under the direct supervision of the pharmacist at all times and removed from the venue and returned to the pharmacy at the end of the service for appropriate storage or disposal.

The legal requirements for record keeping and notification to the HSE and patient's GP, following administration of a vaccination, are the same whether the pharmacy is vaccinating offsite from the pharmacy premises or on the pharmacy premises. These requirements are set out in the PSI's Vaccination Guidance. At all times patient information must be kept secure and in line with Data Protection legislation, so that confidentiality can be assured.

See **Checklist 6.1** for considerations in relation to the management of patient information, medicines and waste **(Appendix A)**.

## **Appendix A: Checklist**

This checklist provides points for consideration to help you plan and carry out your vaccination service.

# **5.1 Planning for a Vaccination Service Offsite from the Pharmacy Premises**

- Ensure the vaccination service will be provided by a trained pharmacist in connection with a named registered retail pharmacy business.
- Consider the needs of your patients and the local community when deciding on which vaccinations will be offered, opening hours of the service, the location of the service, including access for those with disabilities, mobility issues or those who may not have access to transport.
- Consider the additional safety processes that need to be implemented if providing more than one type and/or brand of vaccine from the offsite location.
- Contact your indemnity provider to ensure that provision of this service is fully covered, including the vaccinating pharmacist and support staff.
- Consider the public liability indemnity arrangements in place at the chosen vaccination site.
- Consider taking bookings for the service and providing appointment times to ensure patients are adequately informed and safe patient flow can be maintained.
- Read and consider how the requirements set out in the following guidance will be met:
  - Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses (September 2023)
  - Guidance on the Provision of an Influenza Vaccination Service for Children Aged 6 Months and Older (September 2023)
  - HSE-PCRS National COVID-19 Vaccination Programme Community Pharmacy: Operational Guidance for Vaccination in Community Pharmacy
- · Some further considerations:
  - How many people do you estimate can be vaccinated in the allocated time?
  - Do you have sufficient adrenaline (epinephrine) on hand to enable the planned rate of vaccinations, in line with the recommendations set out in the Anaphylaxis chapter of the <u>Immunisation Guidelines for Ireland</u>?
  - How will patient flow be managed to ensure movement through the relevant parts of the service as
    efficiently as possible? (For example, using signage and members of staff to help guide people).
  - Is there availability of recommended personal protective equipment for all vaccinating pharmacists and staff members relevant to their roles and the chosen location of the service?
  - How will confidentiality be maintained, including visual and auditory privacy?

- How can you work with other local healthcare professionals to increase access to vaccination, especially for those people in the HSE 'at-risk groups'?
- How will patients be informed about this service, including information on how to book an appointment and what they can expect when they arrive for vaccination?

#### 5.2 Choosing a Suitable Location and Vaccination Services Area

- When choosing a suitable location consider:
  - The size and layout needed for the number of people you intend to vaccinate (taking account of current public health advice).
  - The accessibility of the location for the patient group that will be using the service.
  - How you would implement recommended public health measures to help minimise the risk of and spread of infections.
  - The facilities and equipment that are available on-site. This should include equipment to maintain
    the cold-chain of vaccines as required in the products SmPC and set out in the HSE <u>Guidelines for
    maintenance of cold-chain in vaccine fridges and management of vaccine stock</u> and <u>Guidelines for
    maintaining the vaccine cold-chain in vaccine cool boxes</u>.
  - The area that can be used as the vaccination services area. Will this meet the requirements set out in the PSI's Vaccination Guidance (as relevant to offsite vaccination)?
  - How you will ensure that the patient's privacy and dignity is respected, and that confidential and personal information cannot be overheard or seen by others.
  - The area for patients to wait before being vaccinated. Any potential queues must maintain recommended physical distancing (if required), or patients could be asked to wait in their cars, outside or at another location until called.
  - The area where patients can wait following their vaccination to be observed for adverse reactions. This could include the patient's car or elsewhere in the vicinity that provides for the recommended physical distancing (if required) if safe to do so, and they (or their parent/guardian) are given post vaccination advice and the vaccinated person is accompanied by an adult<sup>9</sup>.
  - The area where patients with urgent medical problems could be managed (e.g., fainting or anaphylaxis).
  - Patient flow, from arrival to departure.

#### 5.3 Governance and Staffing

- Carry out a risk assessment on providing a vaccination service at the identified location and take
  actions where possible to mitigate identified risks. This should include appropriate transportation and
  storage of vaccines, the management of adverse events, infection prevention and control measures,
  fire safety and the overall safety of both patients and staff.
- Ensure up-to-date policies and procedures are in place for all aspects of the service so that it is provided safely and effectively and follows national public health advice.
- Ensure the name and registration number of the specific pharmacy which is providing the service is clearly displayed for all patients to see, along with the vaccinating pharmacist's name and registration number.
- Ensure that sufficient and appropriately trained staff are in place to run the vaccination service safely and to a high standard, taking into account the size and nature of the location, the number of people you intend to vaccinate and infection prevention and control.
- Actively encourage feedback on the quality and safety of the vaccination service from both patients
  and staff. Ensure all concerns and queries are addressed, and in response to these, that the service is
  reviewed and improvements made where necessary.

#### 5.4 Training

- Ensure all vaccinating pharmacists meet the <u>PSI's training requirements</u> for providing a vaccination service, including having a valid CPR certificate.
- Ensure all vaccinating pharmacists and other staff members involved in the provision of the vaccination service are trained on the pharmacy's policies and procedures regarding the operation of this service at the chosen setting.
- Give an overview in advance to all vaccinating pharmacists and staff members on how the service will operate at the specific site.

#### 5.5 Equipment and Facilities, and Medicines Management

- Ensure that all equipment required for a vaccination service on a pharmacy premises is available for staff at the offsite location, as set out in the PSI's Vaccination Guidance. In addition, you should also refer to the HSE-PCRS Operational Guidance for Vaccination in Community Pharmacy which sets out the specific equipment required for the delivery of a COVID-19 vaccination service. This should include equipment and facilities needed if a patient has an adverse event such as an anaphylactic reaction and needs CPR, adequate facilities for good hand hygiene, and items such as sharps bin and clinical waste bin etc.
- Ensure that there is adequate stock of both the vaccine and adrenaline (epinephrine) for the age and number of people you intend to vaccinate. Ensure that the adrenaline (epinephrine) is stored securely and yet readily available if needed in an emergency.
- Scan and decommission all vaccines before leaving the pharmacy. For vaccines that are provided in multipack, the outer pack only needs to be scanned and decommissioned once, upon opening.

- Ensure the safe handling, storage and transportation of vaccines to and from the location, in accordance with HSE <u>Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock</u> and <u>Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes</u>, guidance and the manufacturer instructions, and that the cold chain is maintained as required.
- Ensure that all medicines are under the control of a pharmacist at all times.
- Designate, in writing, overall responsibility for cold chain management to an appropriate person(s) and confirm that each vaccinating pharmacist is aware that they are also responsible for ensuring the vaccines they administer have been correctly stored and are in date.
- Ensure that there are arrangements in place for the safe disposal of clinical waste and sharps, including transportation from the vaccination site back to the pharmacy for safe disposal.
- Consider what IT equipment will be required on site.
- Consider how you will make the necessary records for supply and administration of each vaccination (as set out in the PSI's Vaccination guidance) and how this information will be kept secure and confidential at all times, in line with Data Protection legislation.

#### 5.6 Infection Prevention and Control

- Ensure that the chosen site is clean and complies with infection prevention and control best practices as per HSE and HPSC advice. This should include hand hygiene, respiratory hygiene and cough etiquette, appropriate use and provision of personal protective equipment, regular cleaning, and safe handling and disposal of sharps<sup>10</sup>.
- Make reasonable adjustments to ensure current public health advice on physical distancing is followed (if required), and where this is not possible, implement mitigating/control measures.

#### 6. Carrying out the Vaccination Service

- Where a patient consultation is carried out in advance (including providing consent both to the vaccination and the recording and keeping of data), ensure that when the patient attends for vaccination, that the pharmacist confirms that:
  - The patient records match the correct patient,
  - The patient has read all relevant information provided to them (to ensure informed consent),
  - Where the patient is a child, the parent or legal guardian has provided informed consent on their behalf,
  - The patient/parent or legal guardian, has the opportunity to ask any questions, and
  - The patient/parent or legal guardian, confirms their consent for the vaccine verbally, prior to vaccination, except when administering a LAIV nasal influenza vaccine in a school setting (See Checklist 6.2 for considerations in relation to the administration of the LAIV nasal influenza vaccine in a school setting).

Carry out practice runs prior to the start of the service to ensure that:

- Pharmacists and other staff members are familiar with all aspects of delivering the service in the specific setting.
- There is a clear and appropriate patient journey from when they arrive at the vaccination site to when they leave.
- Administration of the vaccine can be carried out safely and all equipment is present and easily accessible for the pharmacist in the given space.
- The pharmacist and other staff members are prepared and ready to manage an anaphylactic reaction or other adverse reaction.
- The pharmacist and other staff members are clear on measures to minimise the risk of spread of any infections.

#### 6.1 Safe Management of Medicines, Records and Waste

- Ensure that all medicines, sharps and clinical waste are removed from the location, returned to the pharmacy at the end of the service, and safely stored or disposed of as appropriate.
- Ensure maintenance of vaccination records is to the same high standard as if the service were provided on the pharmacy premises.
- Ensure patient information is kept secure and confidential at all times, in line with Data Protection legislation.

# **6.2 Administration of the LAIV nasal vaccine to children in a school setting**

- The provision of a vaccination service in a school setting is currently limited to the LAIV nasal influenza vaccine
- When providing a school vaccination service to children using the LAIV nasal influenza vaccination, the following must be considered regarding patient consent:
  - In general, parents or guardians must be present when a vaccination is being administered to a child. However, an exemption to this is permitted when pharmacists are administering the LAIV nasal influenza vaccine to children in a school setting, and informed consent has been obtained from the parent or guardian in advance of the vaccination<sup>11</sup>.
  - Pharmacists must assure themselves that informed consent has been obtained, using relevant guidance, toolkits and templates provided by the HYPERLINK <u>HSE</u> to support communication with schools, parents and guardians in advance of delivering a vaccination service in a school setting.
  - Pharmacists must inform parents and guardians that they can ask questions about the vaccine in advance, be present when the vaccine is being administered, and withdraw their consent at any time up to the vaccine being administered.

- The behaviour of the child at the time of vaccine administration is important and should be considered, particularly if the child is not accompanied by a parent or guardian.
- The pharmacist providing the vaccination service should be satisfied that the parent or guardian has provided informed consent.
- Appropriate after care and follow up should be facilitated by the pharmacist administering the vaccination, including ensuring contact details for the pharmacy providing the vaccination service are provided to facilitate any queries before or after the vaccination.

Version Number	Date Issued
1	October 2020
2	October 2021
3	September 2022
4	September 2023

#### Questions or queries on this Guidance?

If you have questions or queries on this Guidance, please contact us at Info@PSI.ie