Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses

Pharmaceutical Society of Ireland
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Key changes

- Section 2.3 Pharmacist and Staff Training
- Section 2.5.4 Other Storage and Stock Requirements
- Section 2.7.2 Post Vaccination Observation and Counselling
- Section 2.8 Record Keeping
- Section 2.9 Post Vaccination Communication
- Section 5 Requirements for Specific Vaccines

Further guidance documents have been published by the PSI to support pharmacists in providing vaccination services in line with the legislation:

- Guidance on the Provision of an Influenza Vaccination Service for Children Aged 6 Months and Older
- Practical Guidance when Providing a Pharmacy Vaccination Service During COVID-19
- Guidance to Support Pharmacies in Providing Safe Vaccination Services Offsite from the Pharmacy Premises

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1. Introduction

The purpose of this guidance is to support and assist pharmacists in delivering a vaccination service to patients in pharmacies. The guidance sets out the legal and professional requirements which need to be fulfilled in order to safely provide the service. It details the general requirements applicable to the provision of a vaccination service in a pharmacy (Section 2). Detailed clinical information and guidance is not provided as this is addressed during a pharmacist's vaccination training.

Since the introduction of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011), pharmacists in Ireland have been authorised to administer the seasonal influenza vaccine. Under this legislation, pharmacists are enabled to supply and administer the seasonal influenza vaccine in the course of their professional practice, provided they fulfilled the required conditions set out in the regulations for the delivery of this service. The legislation also provides for the supply and administration of adrenaline (epinephrine) injections at any place (i.e. within or outside the retail pharmacy business premises, as necessary) for the emergency treatment of anaphylaxis that may on rare occasions arise as a result of the administration of vaccines.

The Medicinal Products (Prescription and Control of Supply) (Amendment No.2) Regulations 2015 (S.I. No. 449 of 2015) authorised pharmacists to supply and administer the pneumococcal polysaccharide (PPV23) and herpes zoster (zoster/shingles) vaccines.

Pharmacists are authorised to administer adrenaline (epinephrine) injections presented as an ampoule or a prefilled syringe for the treatment of anaphylaxis.

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (S.I. No. 698 of 2020) allow for COVID-19 vaccinations to be supplied and administered by pharmacists. The HSE has produced a separate operational guidance document for the provision of COVID-19 vaccination services in pharmacies.

1.1 National Immunisation Agencies

The National Immunisation Advisory Committee (NIAC) of the Royal College of Physicians of Ireland (RCPI) is the national body established to advise the Department of Health (DoH) on evidence based immunisation related policy. This Committee prepares the *'Immunisation Guidelines for Ireland'*, which are updated regularly, and are available through the National Immunisation Office (NIO) website www.immunisation.ie.

The Health Service Executive (HSE) NIO oversees the day-to-day implementation of the national immunisation programmes. The NIO provides up to date information leaflets for the public and publications, guidelines and information leaflets for health care professionals. Current information is available on the NIO website.

The NIO is also responsible for the procurement and distribution of vaccines for the national immunisation programme, including distribution of the seasonal influenza vaccine. Pharmacists have participated in the national seasonal influenza vaccination campaign since 2011.

Pharmacists should ensure that they are familiar with the most recent versions of both the NIAC and NIO national guidance documents on immunisations and management of anaphylaxis.

2. Implementation of a Vaccination Service

Pharmacists have an important role to play in advising and educating the public about health protection measures such as immunisation, as well as an important role in implementing the national immunisation programme and providing vaccination services.

2.1 Legislative Requirements

The Medicinal Products (Prescription and Control of Supply) (Amendment No.2) Regulations 2015 and the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 provide for the supply and administration of particular vaccines by pharmacists, specifically seasonal influenza, pneumococcal polysaccharide and herpes zoster vaccines. Both of these regulations amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003.[1] The Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (S.I. No. 698 of 2020) allow for COVID-19 vaccinations to be supplied and administered by pharmacists. The HSE has produced a separate operational guidance document for the provision of COVID-19 vaccines.

A copy of the regulations is available on the PSI website www.psi.ie or www.irishstatutebook.ie

Pharmacists must be satisfied that their supply and administration of vaccines and provision of associated services is in full compliance with the requirements of these regulations and other relevant pharmacy and medicines legislation, including the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)(as amended).

In addition, pharmacists must ensure that their professional practice, in relation to these patients, is in compliance with the requirements and guidance of the PSI and the Code of Conduct for pharmacists.

2.2 Professional Management

2.2.1 Role of the Superintendent Pharmacist and Pharmacy Owner

A system for the professional management and clinical governance of vaccination services must be established for each pharmacy. The superintendent pharmacist has overall responsibility and accountability for the service provided in the pharmacy or pharmacies that are under his or her personal control. Pharmacy owners must facilitate superintendent pharmacists in carrying out their roles and responsibilities and have their own specified responsibilities.

The responsibilities of the pharmacy owners and superintendent pharmacist in relation to the provision of safe and effective vaccination services, include that:

- The premises, in particular the patient consultation area/vaccination services area, are of an appropriate standard for the nature and scale of the service provided.
- All necessary equipment and facilities are available on the pharmacy premises.
- Appropriate professional indemnity arrangements are in place.
- Adequate pharmacist and support staff are available to allow the service to be delivered in compliance with legislative and professional requirements and to ensure supervision of all other professional activities available in the pharmacy.

1 The regulations insert (2011) and replace (2015) regulation 4B relating to the supply and administration of specified vaccines by registered pharmacists, regulation 10A relating to the keeping of records, and the eighth schedule. There are also a number of other amendments. The term *'authorised person'* in these regulations means a *'registered pharmacist'*. The 2015 legislation also enables pharmacists to supply and administer specified prescription-only medicines in emergency situations and to supply specified medicines to 'listed organisations' notified to the Health Products Regulatory Authority (HPRA). Guidance for pharmacists on emergency medicine supply and administration is available on the PSI website www.psi.ie.

- The required training has been successfully completed by pharmacists delivering the service and that they hold the prescribed certificate(s).
- The requisite knowledge and skills are demonstrated by all pharmacists delivering the service in the pharmacies under their control.
- Robust documented policies and procedures are in place for the delivery of the service and that these documents are reviewed and updated regularly in accordance with best professional practice (see section 4 Policies and Procedures).
- Vaccination against Hepatitis B is offered to all pharmacist and pharmacy staff participating in the delivery of the service and other pharmacy staff, as appropriate, dependant on risk. Details of the completion of vaccination schedules (or vaccine refusal) should be maintained in the pharmacy.

In addition, the superintendent pharmacist's responsibilities include that:

- Supervised practice runs in the pharmacy are carried out regularly as part of an internal sign-off process. Practice runs assure that pharmacists are familiar with all aspects of delivering the service in the specific pharmacy environment. Practice runs should occur, at a minimum, annually for non-seasonal vaccinations and prior to the start of each vaccination season for seasonal vaccines. All relevant staff should be involved in practice runs, e.g. staff that would assist the pharmacist in the event of an emergency should practice emergency protocols. Details of internal sign off and the approval of pharmacists providing the vaccination service, including supervised practice runs, should be maintained in the pharmacy.
- The delivery of the service is reviewed on an ongoing basis.
- All pharmacists are aware of the adverse reactions that may arise and adequate follow up arrangements are in place.
- Systems are in place for the recording of errors, 'near misses', and relevant incidents, including sharps injuries.
- An effective and robust patient and interdisciplinary communication system has been established.

2.2.2 Interdisciplinary Communication

The establishment of interdisciplinary relationships, particularly between the pharmacist and any relevant GPs and nurses, involved in the provision of vaccination or associated services to the pharmacy's patients, are important to ensure adequate lines of communication are in place. These relationships will also enable pharmacists to ensure they are aware of all vaccine administrations and therefore provide patients with an appropriate standard of care.

A robust communication system will reduce the risk of a clinical error and the likelihood of a patient receiving a vaccine from more than one healthcare provider and subsequently the risk of adverse events. A pathway for the management of adverse reactions should also be agreed where adverse reactions are referred to the GP for management as appropriate. All communications should be adequately documented.

2.3 Pharmacist and Staff Training

In order to be authorised to administer a vaccine, pharmacists must have successfully completed the PSI approved training pathway[2] for each vaccine they will be administering. Certificates received and any other relevant

2 Training which meets the PSI's accreditation and quality assurance standards is provided by a body approved by the PSI Council and recognised by the PSI Registrar in line with the requirements of regulations (S.I. No. 449 of 2015 and S.I. No. 525 of 2011)

documents associated with the pharmacist's training should be available in the pharmacy. If a pharmacist is providing vaccination services in a number of pharmacies, a copy of their certificate(s) should be available in each pharmacy. Certificates may be displayed to the public in the vaccine services area or another public area of the pharmacy.

It is important that pharmacists maintain their competence in the administration of vaccines, and that they continue to update their knowledge and skills as necessary as part of their on-going continuing professional development (CPD) and re-certification requirements. Pharmacists should regularly review their training materials, be aware of updates to relevant national guidance and should carry out an assessment of their needs to help identify any particular training or CPD requirements they may have.

All pharmacy staff should be familiar with the provision of vaccination services and be trained according to their level of involvement in the process. All staff should be trained, appropriate to their role, to be aware of the potential for an adverse reaction to occur (e.g. an anaphylactic reaction), to alert the pharmacist immediately if they are concerned about a patient and to assist the pharmacist in attending to the patient as quickly as possible.

Staff training should also ensure familiarity with all relevant policies and procedures, e.g. management of the cold chain and management of patient queries or complaints.

2.4. Premises and Facilities

Pharmacies providing vaccination services must have appropriate and adequate premises and facilities.

2.4.1 Vaccination Services Area

The requirements for a vaccination services area exceed those specified in the PSI's *Guidelines on Patient Consultation Areas in Retail Pharmacy Businesses,* particularly in relation to the size, privacy and equipment requirements of the area. The patient consultation area may be a suitable area provided it meets the additional requirements.

A separate vaccination services area within the pharmacy which meets the minimum requirements and is designated for the provision of vaccination and/or clinical services should be established if:

- The patient consultation area does not meet the minimum requirements for a vaccination services area, or
- A pharmacy is engaged in vaccinations and/or other clinical services on a large scale or volume. It is important to ensure the patient consultation area is available when needed for its primary function, i.e. as a private area where the pharmacist and patient can discuss medication therapy.

2.4.2 Requirements for a Vaccination Services Area

Vaccination services areas must meet the minimum requirements set out in the PSI's patient consultation area guidelines and in addition must be:

- Located close to the dispensary to facilitate a convenient workflow. Direct access for pharmacists from the professional services area of the pharmacy is preferable.
- Adequately private. The area should be enclosed to ensure the dignity and privacy of the patient. Doors or shutters may be used to enclose the area and where necessary, blinds, opaque glass or other visual barriers to provide additional visual privacy.
- Of an appropriate professional finish for the delivery of a clinical service.
- Of sufficient size and of an appropriate layout to facilitate the pharmacist carrying out vaccinations and to allow for a comfortable, safe and efficient workflow, to accommodate the required

fittings, consumables, documentation and equipment, and to adequately manage an adverse reaction.

- Contain adequate fixtures and fittings, including comfortable seating for the patient, their chaperone or carer and the pharmacist, an adequate work surface with a smooth impervious finish and any facilities required for managing potential adverse events following vaccination, e.g. a patient fainting or a serious adverse event. Facilities must also be available to ensure items, including sharps bins, are stored privately, safely and securely when not in use.

Pharmacy owners must also ensure the vaccine services area is located within the registered retail pharmacy business premises[3], accessible from the public area of the pharmacy and accommodate all patients, including patients with a disability, e.g. be wheelchair accessible.

In line with NIAC guidance on the management of anaphylaxis, patients must be observed post- vaccination in case they have an allergic reaction. Consideration should be given as to whether the patients will wait in the vaccination services area, or whether another area with seating is provided for this purpose. If this is not practicable, patients should be asked to wait in the vicinity of the pharmacy.

2.4.3 Equipment

All the equipment required for the provision of the service should be available and either stored in the consultation area or in another area easily accessed by the pharmacist. If stored in a publicly accessible patient consultation area, the equipment must be appropriately secured.

The required equipment includes:

- Infection prevention and control equipment, such as alcohol hand gel and hard surface wipes.
- Administration equipment, including latex-free gloves and gauze swabs/cotton wool.
- Waste bins, including sharps bin(s), clinical waste bin(s)/bag(s) and confidential waste bins.
- Emergency equipment, including a CPR (cardiopulmonary resuscitation) mask.
- Personal protective equipment for dealing with sharps spillage, such as puncture-proof/'turtle skin' gloves, forceps and protective clothing (apron etc.).
- Any other equipment deemed necessary.

Drinking water must be available as well as access to hot water for hygiene purposes.

2.5 Vaccine Stock Management

The general requirements for the management of the sourcing, storage and disposal of medicinal products, as set out in PSI guidelines, must be adhered to. The relevant requirements in the NIAC Immunisation Guidelines for Ireland and the NIO's guidelines should also be adhered to.

2.5.1 Sourcing

Pharmacists should be familiar with the process involved in the sourcing of vaccines from wholesalers and through the HSE National Cold Chain Delivery Service as applicable. The sourcing of vaccines must be carried out in accordance with the requirements of PSI *Guidelines on the Sourcing of Medicinal Products for Sale or Supply by a Retail Pharmacy Business.*

Pharmacists must ensure they order and receive the correct vaccine for the service provided, this is particularly important where similar vaccines are available. Vaccines should be checked immediately on receipt and stored in accordance with the Summary of Product Characteristics (SmPC) provided. Pharmacists should also satisfy themselves that vaccines have been transported under appropriate 'cold chain' conditions.

3 Changes made in respect of the floor plan of the registered premises must be notified to the PSI to ensure that the registration of the pharmacy remains valid. These changes can be made on the PSI online portal. More information here.

2.5.2 Storage

Medicinal products, including vaccines and adrenaline (epinephrine) must be stored securely under the control of the pharmacist and must be managed in accordance with PSI *Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business*. The maintenance of the cold chain as set out in the storage guidelines is particularly important for vaccines. The cold chain must be maintained through the use of a pharmaceutical grade refrigerator of adequate capacity and by monitoring and reviewing the fridge temperature to ensure it is maintained in the 2-8°C range.

2.5.3 Disposal

Waste products such as sharps and clinical waste, used injections and blood-stained gauze, must be placed immediately into specialised waste bins. Sharps and other waste bins should be easily accessible when a vaccine is being administered, i.e. in the vaccination services area. After a vaccine consultation, the pharmacist must ensure that waste bins are stored securely and not accessible to members of the public, either by storing them in a locked cupboard in the vaccine services area or in another designated area of the pharmacy that is inaccessible to members of the public.

Waste bins should be of an adequate capacity and should be securely sealed when full, pending prompt removal for destruction. Detailed records on the disposal of sharps and other clinical waste should be maintained in the pharmacy. Further information on requirements for safe disposal are set out in the PSI *Guidelines on the Disposal of Medicinal Products for a Retail Pharmacy Business* and additional information can be obtained from the pharmacy's waste management company.

The HSE National Cold Chain Service should be consulted as to their arrangements for the collection and destruction of any unused, unopened, damaged or expired HSE provided vaccines.

2.5.4 Other Storage and Stock Requirements

The supervising pharmacist should ensure that adequate stock of vaccines and any other required products for provision of this service are available in the pharmacy at all times.

In addition, adequate stock of adrenaline (epinephrine) injections, designated for emergency use only, must be maintained in the pharmacy.

Where pharmacists ensure that there is an adequate time interval between the administration of the vaccine to each patient, the pharmacy needs only to have sufficient stock of adrenaline (epinephrine) injections for administration to one patient (per vaccinating pharmacist), in line with NIAC guidance on the management of anaphylaxis. In all other circumstances, there must be sufficient stock of adrenaline (epinephrine) injections for administration to a minimum of two patients available. Pharmacists should ensure that the adrenaline (epinephrine) injections they stock are authorised for the administration of adrenaline (epinephrine) in accordance with legislation and current NIAC guidance for the management of anaphylaxis.

2.6 Patient Consultation

Prior to vaccine administration, the pharmacist must first carry out a documented assessment of the patient's suitability for vaccination in line with established protocols and checklists and ensure that the precautions and contradictions, particularly those specified in the SmPC of the vaccine, are appropriately addressed. Records of these assessments should be maintained in the pharmacy. Relevant SmPCs are available from the Health Product Regulatory Authority (HPRA) website www.hpra.ie and copies of all relevant SmPCs should be readily accessible or available within the pharmacy.

Pharmacists should also be cognisant of the vaccines they are trained to administer and the patient cohorts they are trained, competent and confident to vaccinate.

In line with best practice identified by the NIO, prior to the administration of the vaccine the pharmacist should:

- Verify the patient's name, date of birth and previous vaccination history.
- Provide the patient with information on the disease that they are being vaccinated for.
- Outline the process of vaccination and how to deal with common side effects.
- Ensure that informed consent for vaccination has been given by the patient.
- Ensure that there are no contraindications or precautions to the vaccine being given.
- Carry out a 'double check' of the vaccine details.

The pharmacist should provide information to the patient in a manner that is clear and easily understood by the patient and provide adequate time to answer any questions that the patient may have.

The pharmacist must ensure that the patient has full knowledge and provides voluntary informed consent both to the vaccination and the recording and keeping of data and understands what this entails. The pharmacist must record that consent for vaccine administration was obtained.

2.7 Vaccine Administration

2.7.1 Administration of Vaccines

The legislation[4] details certain administration requirements for the vaccines pharmacists are authorised to supply and administer, including the form and presentation of the products that can be administered, the authorised routes of administration, the indications for which they may be administered, the dosage and methods of administration and the authorised place of administration.

- Vaccines should be prepared and administered/injected in a safe and effective manner, in accordance with the current Immunisation Guidelines for Ireland, the SmPC of the vaccine and current best practice in injection technique.
- The vaccines colour and composition must be examined to ensure that it conforms to the description in the SmPC and the expiry date on the vaccine should be checked. Once the vaccine has been drawn up it must be used within any timeframe specified in the SmPC or, if not, discarded.
- Pharmacists must ensure they are administering the correct dose, of the correct vaccine, to the correct patient via the correct route, with an appropriate double-checking procedure and that they have assessed and documented all required information (see Record Keeping Section 2.8).
- The current principles of infection prevention and control should be followed when assessing and preparing the injection site and administering the vaccine.

2.7.2 Post Vaccination Observation and Counselling

In line with NIAC guidance on the management of anaphylaxis, following administration of a vaccine, the patient should be observed in case they have an allergic reaction. If it is not practicable for the patient to remain in the pharmacy for the duration of the observation period, they should be advised to wait in the vicinity. The reason for this requirement should be explained to the patient.

The pharmacist should be competent in responding quickly and appropriately should an adverse event occur post injection, particularly an event which requires the administration of adrenaline (epinephrine) or the provision of basic life support. The response should be in line with the pharmacist's training, NIAC guidance on the management of anaphylaxis

4 The Eighth Schedule of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

and the pharmacy's documented policies and procedures, which should have been subjected to practice runs within the pharmacy.
If the pharmacy only has sufficient stock of adrenaline (epinephrine) injections for administration to one patient, pharmacists must ensure that recommended time elapses between the administration of vaccines to patients.

Before they leave the pharmacy, patients should have received all necessary information and counselling, including the package leaflet from the vaccine and any other information material deemed necessary, e.g. applicable information provided by the HSE. Patients should be advised of the potential side effects and how these should be managed. They should be given contact details for the pharmacy and their contact details should be recorded in an appropriate place where they can be easily retrieved.

2.7.3 Follow-up and Referral

Superintendent pharmacists should ensure a policy is in place for patients returning to and/or contacting the pharmacy with suspected adverse events or any other concerns of a clinical nature. This policy should include referral to a healthcare professional for further treatment, if required. Information on adverse events should be communicated to healthcare professionals and agencies as appropriate. Follow-up contacts with patients and any interventions or referrals should be recorded.

A policy for the handling of patient complaints should also be in place and all staff should be familiar with the appropriate procedure for dealing with complaints or concerns of patients and the public.

2.8 Record Keeping

The legislation outlines a number of record keeping requirements in relation to the supply and administration of vaccines and the supply and administration of adrenaline (epinephrine) injection for the emergency treatment of anaphylaxis arising as a result of the administration of vaccines[5].

2.8.1. Administration Records

The regulations require that the pharmacist who has administered the vaccine, records the following particulars in respect of each such administration:

- Date of administration.
- Name, address, date of birth and sex of the patient to whom the vaccine was administered.
- Personal public service number (PPSN) of the patient to whom the vaccine was administered (unless the patient fails to provide one).
- Name, dosage, marketing authorisation number, batch number and expiry date of the product.
- Their own name and PSI registration number.
- Address of the retail pharmacy business where the vaccine was supplied and administered.
- Name, address and contact particulars of the patient's GP (unless the patient fails to provide this information).
- Confirmation that consent was obtained from the patient prior to the administration of the product.

5 The Medicinal Products (Prescription and Control of Supply) Regulations 2003 and the amendments, in particular the Medicinal Products (Prescription and Control of Supply) (Amendment No.2) Regulations 2015 and the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011.

In line with best practice identified by the NIO, the pharmacist should also record the injection site used. These record keeping requirements also apply to the supply and administration of adrenaline (epinephrine) injection for anaphylaxis under these regulations[6].

All of the required details must be maintained for each day vaccines are administered. If records are maintained electronically, a printout of the record must be certified as true and correct by the pharmacist who administered the vaccines. If vaccines were administered by more than one pharmacist, each pharmacist must certify the records for the vaccines they administered. Certification must occur within 24 hours of making the daily printout.

2.8.2 Record Retention and Confidentiality

- All records relating to the administration of vaccines and, if applicable, adrenaline (epinephrine) following an anaphylactic reaction to a vaccine must be kept for two years at the pharmacy premises concerned and be available for inspection.
- Vaccine administration records and if applicable, adrenaline (epinephrine) administration records, must also be preserved by the pharmacy owner for at least eight years.
- If the ownership of a pharmacy changes within that time period, the new owner will be responsible for preserving the records for the remainder of the designated time period.
- All other records should be retained for a minimum of two years.
- The pharmacist and the pharmacy owner must ensure the confidentiality of patient records in accordance with the requirements of Data Protection legislation.

2.9 Post Vaccination Communication

2.9.1 Notifying the HSE

The regulations require that a copy of the particulars in the vaccine administration record is forwarded, by electronic or other means, to the HSE within seven days of the administration. All vaccinations, whether with HSE-supplied vaccine stock or other stock, must be notified to the HSE. Details of contact with the HSE should be accessible and easily retrieved in the pharmacy.

2.9.2 Notifying the Patient's GP

The regulations require that a copy of the particulars in the vaccine administration record is forwarded to the patient's GP, unless the patient fails to provide the name and contact details of a GP. The relevant information must be forwarded to the GP, by electronic or other means, within seven days of the administration. Details of contact with GPs should be accessible and easily retrieved in the pharmacy.

All administrations of adrenaline (epinephrine) for the emergency treatment of anaphylaxis arising as a result of the administration of the specified vaccines, must also be notified to the patient's GP where GP details have been provided.

6 Further details on record keeping and other requirements for the supply and administration of adrenaline (epinephrine) are available in the *PSI Guidance for Pharmacists on the Safe Supply and Administration of Prescription-Only Medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency.*

3. Pharmacovigilance

As with all medicines, any suspected adverse reactions, including cases of suspected anaphylaxis, should be promptly reported to the HPRA, preferably online via the HPRA website www.hpra.ie. The reporting of adverse effects resulting in patient harm are particularly important. Reports should be as detailed as possible and should include the product brand name and vaccine batch number.

4. Policies and Procedures

Policies and procedures should be in place in the pharmacy to ensure that vaccination services are consistently carried out safely and effectively, in line with legislation and good practice. They should take into account and comply with relevant legislation, relevant guidance, including that of NIAC and the NIO as applicable, health and safety requirements and patient needs.

A documented policy should be developed to include the following key aspects of the service and of the vaccination process:

- Ordering and storing vaccines.
- Patient inclusion/exclusion criteria.
- Providing information to patients and gaining informed consent.
- Infection prevention and control measures, including hand hygiene, observation of universal precautions and provision of personal protective equipment for staff.
- Preparation and administration of the vaccine.
- Patient counselling and monitoring post-vaccination, including information on adverse reactions and their management.
- Management of adverse events.
- Management of anaphylaxis, including administration of adrenaline (epinephrine) and provision of basic life support measures.
- Prevention and management of needle stick injuries.
- Management, storage and disposal of sharps and clinical waste.
- Management of patient data and confidentiality.

Vaccination procedures should also be developed and should outline the specific vaccination processes for the relevant pharmacy. Some of the policies and procedures already in existence in the pharmacy may also be relevant, e.g. those relating to cold chain management, managing patient complaints or medication errors or managing a product recall, and these should be reviewed, updated and cross-referenced where necessary.

Superintendent and supervising pharmacists should ensure that all pharmacists providing vaccination services and other relevant staff within a particular pharmacy are trained in the relevant current policies and procedures, and re-trained where necessary following any review and update. Compliance with policies and procedures should be regularly evaluated. Training records should be maintained.

Superintendent and supervising pharmacists should ensure that all relevant policies and procedures are reviewed regularly and if applicable prior to the start of each new vaccination season. This is important in order to ensure learnings and any new issues can be appropriately addressed and incorporated.

5. Requirements for Specific Vaccines

NIAC and the NIO provide detailed recommendations for the administration of each vaccine. Pharmacists should refer to these guidelines, the vaccine's SmPCs and vaccination training materials for the relevant vaccine for clinical information on supplying and administering each vaccine, including precautions and contraindications.

Pharmacists should consult relevant legislation for further information on medicinal products which may be supplied and administered by Authorised Persons pursuant to regulation 4B of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

A copy of the regulations is available on the PSI website www.psi.ie or www.irishstatutebook.ie.

6. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Are all pharmacists familiar with the PSI Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses and is a copy readily available in the pharmacy?				
Are all pharmacists familiar with the National Immunisation Advisory Committee's (NIAC) current *'Immunisation Guidelines for Ireland'* and all relevant information from the HSE National Immunisation Office (NIO) and are copies of relevant documents readily available in the pharmacy?				
Are all pharmacists familiar with the Summary of Product Characteristics (SmPC) for the relevant vaccines and adrenaline (epinephrine) injections, and are copies readily available in the pharmacy?				
Is the vaccination service covered by appropriate professional indemnity arrangements?				
Have infection prevention and control precautions, including staff Hepatitis B vaccination and measures for the prevention and management of needle stick injury and the spillage of bodily fluids been implemented in the pharmacy?				
Have effective and robust patient and interdisciplinary communication systems been established for the management of the vaccination service?				
Have all pharmacists participating in delivery of the service successfully completed the approved training, and are training certificates and other relevant training records up-to-date and available in the pharmacy?				
Have all pharmacists participating in delivery of the service had their knowledge and skills assured via an internal sign-off process, which includes practice runs?				
Are adequate pharmacist staff available in the pharmacy to allow for the appropriate supervision of all professional activities, including providing the vaccination service?				
Are the pharmacy premises in particular the vaccination services area, of an appropriate standard for the provision of a vaccination service?				

Ask Yourself	Yes	No	N/A	Required Action
Does the pharmacy have all appropriate equipment and facilities for the provision of the vaccination service, and is the equipment stored appropriately?				
Are all pharmacists familiar with the requirements of the PSI's Guidelines on the sourcing, storage and disposal of medicinal products in a Retail Pharmacy Business that relate to the provision of a vaccination service?				
Is a pharmaceutical grade refrigerator, of adequate capacity and appropriately temperature monitored, which meets all requirements of PSI guidelines used to store vaccines?				
Is adequate stock of vaccines and adrenaline (epinephrine), designated for emergency use, maintained in the pharmacy at all times?				
Is all waste generated by the vaccination service managed appropriately and disposed of in a manner which assures the safety of patients and the public?				
Are records of each administration recorded by the pharmacist administering the vaccine and maintained in the pharmacy?				
Are records of patient consultation and patient consent maintained in the pharmacy?				
Are all patient vaccination records forwarded to the HSE, and the patient's GP (if name and contact details supplied), within seven days of the administration?				
Are documented policies and procedures relating to all aspects of the provision of vaccination services available in the pharmacy, are all staff trained in their content and are they reviewed regularly?				
Do the pharmacy's vaccination procedures address vaccine administration, including patient inclusion/exclusion criteria, post vaccination monitoring, management of anaphylaxis and patient counselling, including the provision of package leaflets?				
If applicable, are all pharmacists familiar with specific requirements relating to the management and administration of the seasonal influenza vaccine?				
If applicable, are all pharmacists familiar with specific requirements relating to the management and administration of the pneumococcal polysaccharide vaccine?				
If applicable, are all pharmacists familiar with specific requirements relating to the management and administration of the herpes zoster vaccine?				

Name	Version Number	Date Issued
Guidance on the Provision of Seasonal Influenza Vaccination Service by Pharmacists in Retail Pharmacy Businesses	1 2 3	July 2012 May 2013 July 2014
Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses	4 5 6 7 8	April 2016 October 2018 April 2019 October 2021 September 2022