



**Draft Guidance on the Provision of Vaccination Services by
Pharmacists in Retail Pharmacy Businesses 2016
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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 two) and additional considerations specific to the provision of each vaccination service, i.e. seasonal influenza, pneumonia and shingles vaccines (section three). Detailed clinical information and guidance is not provided as this is addressed during a pharmacist's vaccination training.

Since October 2011, with the introduction of the Medicinal Products (Prescription of Control and Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011), pharmacists in Ireland have been authorised to administer the influenza vaccination. Under this legislation, pharmacists were 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 an anaphylactic shock that may on rare occasions arise as a result of the administration of vaccines.

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

1.1 National Immunisation Agencies

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

The HSE National Immunisation Office (NIO) oversees the day-to-day implementation of the national immunisation programme. The NIO provides up to date information leaflets for the public and publications, guidelines and information leaflets for health care professionals, including "*A Practical Guide to Immunisation*". Current information is available on the immunisation section of the HSE website.

The NIO is also responsible for the procurement and distribution of vaccines for the national immunisation programme, including distribution of the seasonal influenza and the PPV23 vaccines for 'at risk' patients. Pharmacists have participated in the national seasonal influenza vaccination campaign since 2011. Pharmacists are not currently included in the national

programme for the PPV23 vaccine. The shingles vaccine is not currently included in the national immunisation programme.

Pharmacists should ensure that they are familiar with the most recent versions of both the NIAC and NIO national guidance documents on immunisations¹.

2. Implementation of a Vaccination Service

Pharmacists have an important role to play in advising and educating the public about the public 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 shingles vaccines. Both of these regulations amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003.² A copy of the regulations is available on the PSI website www.thePSI.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). 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.

¹ Royal College of Physicians of Ireland NIAC Guidelines, the Immunisation Guidelines for Ireland and HSE NIO Guidelines, including A Practical Guide to Immunisation, www.hse.ie

² 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 Product Regulatory Authority (HPRA). Guidance and explanations for pharmacists on emergency medicine supply and administration have been issued by 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* and an *Explanatory Note for Pharmacists, on the Supply of 'emergency' Prescription-only Medicines to a Listed Organisation* are available on the PSI website www.psi.ie.

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 within the pharmacy.
- 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 2.11 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 regimes (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 the 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. Details of internal sign off and the approval of pharmacists providing the vaccination service including supervised practice runs should be maintained in the pharmacy.
- On-going monitoring of the delivery of the service occurs

- 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, is important to ensure adequate lines of communication are in place. These relationships will also help pharmacists ensure they are aware of all vaccine administrations and therefore ensure patients receive 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 PSI approved training³ for each vaccine they will be administering. Certificates received and any other relevant records 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 and should carry out an assessment of their needs to help identify any particular training or CPD requirements they may have.

All other pharmacy staff should be familiar with the provision of vaccination services and be trained appropriately according to their level of involvement in the process. All staff should be trained, appropriate to their role, to be aware of the service being provided by the pharmacy, the potential for an adverse reaction, e.g. an anaphylactic reaction, to alert the pharmacist

³ 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).

immediately if they are concerned about a patient and to assist the pharmacist in attending to the person 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 Requirements

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 service areas must meet the minimum requirements set out in the PSIs 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 blinds, opaque glass or other visual barriers can be used to provide additional visual privacy, where necessary.
- 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, the pharmacist and their chaperone/carer, 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 to ensure items, including sharps bins, are stored privately, safely and securely when not in use must also be available.

Pharmacy owners must also ensure the vaccine services area is located within the registered retail pharmacy business premises⁴, accessible from the public area of the pharmacy and accessible to all patients, e.g. wheelchair accessibility.

As patients must be asked to remain in the pharmacy for at least 15 minutes post-vaccination in case they have an allergic reaction patients, 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.

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 accessible to the pharmacist. If stored in a publicly accessible patient consultation area, the equipment must be appropriately secured.

The required equipment includes:

- Infection 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 and there must be 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.

⁴ 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.

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 within 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). Pharmacists should also satisfy themselves that vaccines have been transported under appropriate 'cold chain' conditions.

2.5.2 Storage

Medicinal products, including vaccines and adrenaline 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*. In particular, the cold chain must be maintained as set out in the guidelines, 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, for example 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 not be overfilled. Waste bins 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 within 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 injections, designated for emergency use only, must be maintained in the pharmacy. Where pharmacists ensure that a time interval of at least 20 minutes elapses between the administration of the vaccine to each patient, the pharmacy needs only to have sufficient stock of adrenaline injections for administration to one patient (per vaccinating pharmacist). In all other circumstances, there must be sufficient stock of adrenaline injections for administration to a minimum of two patients available.

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 HPRA's 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 that 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 document that consent for vaccine administration was obtained. This should include obtaining the patient's signature and consent forms should be retained in the pharmacy.

2.7 Vaccine Administration

2.7.1 Administration of Vaccines

The legislation⁵ 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 and the dosage and methods of administration. For further detail see *Appendix*.

- Vaccines should be prepared and administered/ injected in a safe and effective manner, in accordance with the current Immunisation Guidelines for Ireland¹, 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.
- 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).
- 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

Following administration of a vaccine, the pharmacist should observe and monitor the patient for at least 15 minutes in case they have an allergic reaction. The reason for this requirement should be explained to the patient.

The pharmacist should be competent in responding quickly and appropriately should an adverse reaction or event occur post injection, particularly an event which requires the administration of adrenaline or the provision of basic life support. The response should be in line with the pharmacist's training 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 injections for administration to one patient, pharmacists must ensure that a time interval of at least 20 minutes 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 the patient medication record (PMR).

⁵ Schedule eight of the Medicinal Products (Prescription and Control of Supply) (Amendment No.2) Regulations 2015

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 reactions should be communicated to healthcare professionals and agencies as appropriate. Follow-up contacts with patients and any interventions or referrals should be recorded in the PMR.

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

2.8 Record Keeping

Adequate and appropriate records of the supply and administration of vaccines and, if applicable, adrenaline must be kept in the pharmacy.

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 injection for the emergency treatment of anaphylactic shock arising as a result of the administration of vaccines⁶.

2.8.1. Administration Records

The regulations require that the pharmacist who has administered the vaccine record 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).

⁶The 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.

- Confirmation that prior to the administration of the product consent was obtained from the patient

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 injection for anaphylaxis under these regulations.⁷

All of the required details must be maintained for each day vaccines are administered. If records are maintained as a computerised printout they 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 Supply Records:

A record of the supply of the vaccine should be kept with the supply of all other prescription medicines in the individual patient's PMR and included in the daily audit report for the pharmacy.

2.8.3 Other Records:

Additional records, as outlined throughout the document, should also be maintained and available for review in the pharmacy, e.g. pharmacist and staff training records, patient consultation and consent records and records of communications with patients, healthcare professionals and agencies.

2.8.4 Record Retention and Confidentiality:

- All records relating to the administration of vaccines and, if applicable, adrenaline 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 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. The management of data or information collected, recorded or retained in relation to the vaccination service must be in accordance with the requirements of the Data Protection Acts 1988 and 2003.

⁷ Further details on record keeping and other requirements for the supply and administration of adrenaline 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*.

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 retained in the pharmacy for review.

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 when this information is requested by the pharmacist. 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 maintained in the pharmacy.

All administrations of adrenaline, for the emergency treatment of anaphylactic shock 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.

2.10 Pharmacovigilance

As with all medicines, any suspected adverse reactions should be promptly reported to the HPRA, preferably online via the HPRA website, www.hpra.ie.

2.11 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 control measures, including hand hygiene, observation of universal precautions⁸ 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.

⁸ whereby all blood and bodily fluids are treated as if infectious

- Management of adverse reactions.
- Management of anaphylaxis, including administration of adrenaline 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 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 involved in the process 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 so that learnings and any new issues can be appropriately addressed and incorporated.

3. Requirements for Specific Vaccinations

This section sets out additional requirements and guidance for each of the vaccines pharmacists are authorised to supply and administer. NIAC and the NIO provide detailed recommendations for the administration of each vaccine.¹ 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.

3.1 Seasonal Influenza Vaccination Requirements

Pharmacists have been authorised to supply and administer the seasonal influenza vaccine, both privately and as part of the national immunisation programme, once appropriately trained, since October 2011.⁹

One of the most important factors in ensuring the ongoing success of the influenza vaccination programme is ensuring a high level of uptake in those aged over fifty and in the at-risk groups.

⁹ Since the introduction of the Medicinal Products (Prescription of Control and Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011)

This includes front-line healthcare workers, such as pharmacy staff, who should be encouraged to be vaccinated against influenza both for their own protection, as they are likely to come in contact with influenza during outbreaks, and for the protection of their patients.

3.1.1 Seasonal Influenza Vaccine Management and Administration

Annual vaccination with the most recent influenza strains is necessary and the ideal time for vaccination is before the influenza season, i.e. from September to October, but the vaccine can be given until the end of April. Injectable influenza vaccines are inactivated (non-live) and cannot cause influenza. Following vaccination, influenza antibodies take from ten to fourteen days to reach protective levels.

The influenza vaccine is administered via intra-muscular (IM) injection. During storage the vaccine should be protected from light. The vaccine should be allowed to reach room temperature, shaken and visually inspected prior to administration.

The influenza vaccine may be given at the same time, but at a different site, as any other vaccine and if indicated it can be administered at the same time as the pneumococcal polysaccharide vaccine.

Vaccines from the HSE national stock are supplied with accompanying patient vaccination record cards. These cards, or an equivalent card developed by the pharmacy, should be completed and given to the patient.

3.2 Pneumococcal Vaccination Requirements

Pharmacists have been authorised to supply and administer the pneumococcal polysaccharide (PPV23) vaccine, once appropriately trained, since October 2015.¹⁰ While the PPV23 vaccine is administered to patients by GPs as part of the national immunisation programme, currently pharmacists are not included in the programme for this vaccine. Pharmacists may administer this vaccine to patients as a private service, outside of the national immunisation programme.

There are two types of pneumonia vaccines, the PPV23 vaccine and the pneumococcal conjugate vaccine. The first vaccine is for use in patients over two years of age and the second for patients under two years of age and in other specific circumstances. Pharmacists are authorised to supply and administer the PPV23 vaccine only.

One of the most important factors in the success in preventing pneumococcal infections is ensuring a high level of uptake in those aged over sixty five and in the at-risk groups.

¹⁰ Since the introduction of the Medicinal Products (Prescription of Control and Supply) (Amendment No.2) Regulations 2015 (S.I. No. 449 of 2015)

3.2.1 Pneumococcal Vaccine Management and Administration

Due to the availability of two types of pneumococcal vaccines, the PPV23 vaccine and the pneumococcal conjugate vaccine, pharmacists are reminded to be particularly vigilant when checking vaccines at the points of receipt and administration. Pharmacists must ensure they order, receive and administer the correct vaccine.

The scheduling of both types of pneumococcal vaccines (PPV23 vaccine and the pneumococcal conjugate vaccine) for patients is complex and it is important that pharmacists are familiar with when it is appropriate to administer the PPV23 vaccine.

- A once only dose of the PPV23 vaccine is recommended for those aged sixty five years and older.
- The vaccine is recommended for those aged two to sixty four years with specific long term medical conditions. They may also require pneumococcal conjugate vaccine (pharmacists are not authorised to administer this vaccine).
- A once only booster vaccination is recommended five years after the first vaccination for those aged sixty five years and older if they received the vaccine more than five years before and were less than sixty five years of age at the time of the first dose.
- A booster is also recommended for those whose antibody levels are likely to decline rapidly, e.g. immunosuppressed patients.
- There are specific dosing requirements and intervals recommended for those with specific conditions or receiving specific treatments, e.g. HIV patients, patients whose spleen is being removed and those receiving chemotherapy or radiotherapy.

The PPV23 vaccine is administered by IM injection. The vaccine should be visually inspected prior to administration.

Re-immunisation with the pneumonia vaccine can produce severe local reactions especially if given within three years of the previous injection, therefore accurate vaccine medication histories are particularly important for patients receiving this vaccine. A robust communication system between pharmacists and GPs is necessary in order to avoid a patient receiving a double dose of the vaccine.

The shingles vaccine can't be administered at the same time as the PPV23 vaccine as there have been reports of reduced efficacy of the PPV23 vaccine following concurrent administration. Administration of the two vaccines must be separated by a minimum of four weeks. If indicated, the pneumococcal vaccine may be administered at the same time as the seasonal influenza vaccination.

3.3 Shingles Vaccination Requirements

Pharmacists have been authorised to supply and administer the herpes zoster (shingles) vaccine, once appropriately trained, since October 2015.¹¹ The shingles vaccine is not currently included in the routine national immunisation schedule¹². Pharmacists may administer this vaccine to patients who require it as a private service.

The vaccine is indicated for administration to patients over fifty years of age for the prevention of shingles or zoster-related post-herpetic neuralgia (nerve pain). It is not indicated for the treatment of zoster or post-herpetic neuralgia.¹³

3.3.1 Shingles Vaccine Management and Administration:

Due to the availability of herpes zoster (shingles) and varicella zoster (chicken pox) vaccines, pharmacists are reminded to be particularly vigilant when checking vaccines at the points of receipt and administration. Pharmacists must ensure they order, receive and administer the correct vaccine.

Counselling patients on the efficacy of the vaccine is important, i.e. that vaccination may not result in all vaccine recipients being protected from shingles. The duration of protection after vaccination is unknown and the need and timing of a booster dose has not yet been defined.¹⁴

The shingles vaccine is administered by sub-cutaneous (SC) injection. During storage, the vaccine should be protected from light. This vaccine (in its current formulation) needs to be reconstituted by the pharmacist before administration to a patient. After reconstitution the vaccine should be used immediately and any unused vaccine discarded.

The shingles vaccine is a live attenuated vaccine. Following vaccination there have been reports that the shingles virus may be transmitted rarely between those that have received the vaccination and susceptible contacts, such as chicken pox susceptible infant grandchildren.¹⁴ Pharmacists should ensure they counsel patients following administration of this vaccine regarding aftercare in this regard.

There is a requirement to separate the PPV23 and shingles vaccination administration by a minimum of four weeks due to a reduction in the response to the PPV23 vaccine when they are administered simultaneously.

¹¹ Since the introduction of the Medicinal Products (Prescription of Control and Supply) (Amendment No.2) Regulations 2015 (S.I. No. 449 of 2015)

¹² NIAC Guidelines, the Immunisation Guidelines for Ireland

¹³ Zostavax SmPC

4. 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
Professional Management				
Are all pharmacists familiar with the <i>PSI Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses 2016</i> and is a copy readily available in the pharmacy?				
Are all pharmacists familiar with the National Immunisation Advisory Committee's (NIAC) current ' <i>Immunisation Guidelines for Ireland</i> ' and all relevant information from the HSE National Immunisation Office (NIO), including ' <i>A Practical Guide to Immunisation</i> ' and are copies of relevant documents readily available in the pharmacy?				
Are all pharmacists familiar with the Summary of Product Characteristics (SmPCs) for the relevant vaccines and adrenaline injections, and are copies readily available in the pharmacy?				
Is the vaccination service covered by appropriate professional indemnity arrangements?				
Have effective and robust patient and interdisciplinary communication systems been established for the management of the vaccination service?				
Training				
Have all pharmacists participating in delivery of the service successfully completed the approved training?				
Have all pharmacists participating in delivery of the service had their knowledge and skills ensured via an internal sign-off process, which includes practice runs?				
Are all training certificates (including the required vaccination training certificates) and other relevant training records up-to-date and retained in the pharmacy?				
Staffing				
Are adequate pharmacist staff available in the pharmacy to allow for the appropriate supervision of all professional activities, including providing the vaccination service?				

Ask Yourself	Yes	No	N/A	Required Action
Premises and Equipment				
Are the pharmacy premises in particular the vaccination services area, of an appropriate standard for the provision of a vaccination service, taking account of the requirements for space, privacy, and fixtures and fittings?				
Does the pharmacy have all appropriate equipment and facilities for the provision of the vaccination service, and is the equipment stored appropriately?				
Sourcing, Storage and Disposal				
Are all pharmacists familiar with the requirements of the <i>PSI's Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business</i> and all relevant requirements therein?				
Are all pharmacists familiar with the process involved in ordering vaccines (HSE and wholesaler)?				
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 designated for emergency use maintained in the pharmacy at all times?				
Is all waste generated by the vaccination service (sharps, clinical and confidential) managed appropriately and disposed of in a manner which assures the safety of patients and the public?				
Record Keeping				
Are records of each administration, as required by the regulations, recorded by the pharmacist administering the vaccine and maintained in the pharmacy?				
If these records are maintained in computerised format, are they appropriately certified by the relevant pharmacist(s)?				
Are records of all vaccine and adrenaline injection supply maintained in the PMR and included in the pharmacy's daily audit?				
Are hard copies of patient consultation and patient consent records 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?				

Ask Yourself	Yes	No	N/A	Required Action
<i>Policies and Procedures</i>				
Are documented policies and procedures relating to all aspects of the provision of vaccination services available in the pharmacy?				
Are all relevant staff aware of, and trained in, the pharmacy's vaccination policies and procedures?				
Are these policies and procedures reviewed regularly, in accordance with best practice, when any element of the process changes, or at a minimum annually?				
Have all relevant policies and procedures already in existence in the pharmacy been reviewed, updated and cross-referenced with vaccination documents, as necessary?				
<i>Do the pharmacy's policies and procedures address:</i>				
All issues in the PSI, NIAC and the NIO guidance and all relevant legal and Code of Conduct issues?				
The vaccination service patient inclusion and exclusion criteria?				
Informed patient consent, including providing patients with all necessary information prior to administering the vaccine?				
The assembling of equipment, and the preparation and administration of the vaccine?				
Providing patients with all necessary written information and counselling, including providing information on potential side effects and their management, post-vaccination?				
Observing and monitoring the patient post vaccine administration?				
Maintaining confidentiality throughout the process?				
Standard precautions, including staff Hepatitis B vaccination, infection control, the prevention and management of needle stick injury and the spillage of body fluids?				
The management of adverse reactions and medication errors?				
The management of anaphylaxis, including the administration of adrenaline and the provision of life support?				
The disposal of sharp and clinical waste, including the maintenance of appropriate records, and the management of unused vaccines?				

Ask Yourself	Yes	No	N/A	Required Action
The maintenance of records and related data protection requirements?				
Patient complaints and patients returning to the pharmacy with suspected adverse events or other clinical concerns?				
The arrangements in place for follow up with patients, health care professionals and for reporting a suspected adverse reaction to the HPRA?				
<i>Specific Vaccines</i>				
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 shingles vaccine?				

Appendix

EIGHTH SCHEDULE MEDICINAL PRODUCTS WHICH MAY BE SUPPLIED AND ADMINISTERED BY AUTHORISED PERSONS PURSUANT TO REGULATION 4B

Medicinal Product	Form and presentation of product administered	Route of administration	Indication for which the medicinal product may be administered	Dosage and conditions of administration
Column 1	Column 2	Column 3	Column 4	Column 5
Epinephrine (adrenaline) injection	Epinephrine (adrenaline) injection presented as a pre-filled syringe or ampoule	Intramuscular or subcutaneous injection	Adults and Children: For the emergency treatment of anaphylactic shock	In accordance with the summary of product characteristics of the product administered and relevant national guidelines
Influenza vaccine of a composition that has been approved for use in the European Union for the season in question	Influenza vaccine suspension for injection presented as a pre-filled syringe	By intramuscular injection only	Prevention of seasonal influenza	0.5ml or less for single administration. In accordance with the summary of product characteristics of the product administered and Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland
Pneumococcal Polysaccharide Vaccine solution for injection	Pneumococcal Polysaccharide Vaccine solution for injection 25mcg/0.5ml in a pre-filled syringe or vial	By intramuscular injection only	Active immunisation against disease caused by the pneumococcal serotypes included in the vaccine	0.5ml for single administration, in accordance with the summary of product characteristics of the product administered and the specific timing of, and need for re-vaccination as determined by the Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland
Herpes zoster vaccine for injection	Live attenuated varicella-zoster virus powder and solvent for suspension for injection	By subcutaneous injection only	Prevention of zoster and zoster-related post-herpetic neuralgia	0.65ml for single administration in accordance with the summary of product characteristics of the product administered and Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland