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

Pharmaceutical Society of Ireland
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PSI vaccination guidance has been updated to reflect changes to record keeping requirements arising from the Medicinal Products (Prescription and Control of Supply) Amendment (no.4) Regulations 2024. These changes bring the record keeping requirements for all types of pharmacy vaccinations into closer alignment. Some pharmacy vaccination records that previously needed to be printed and endorsed, no longer require this, and the requirements to record and notify a patient's GP no longer apply.

Contents

1. Introduction

Pharmacists in Ireland have been authorised to supply and administer the seasonal influenza vaccine since 2011. Additions and amendments to pharmacy and medicines legislation in the intervening period, have expanded the range of vaccines that can be provided by pharmacists, the range of patients who can be vaccinated, and the locations where vaccination can occur.

Currently, pharmacists who have completed the necessary training can provide a pharmacy vaccination service for COVID-19 or influenza, either at the pharmacy or at another suitable and appropriate place, and in accordance with a HSE national vaccination programme. The HSE may add additional vaccines to the national programme, should a public health need arise.

Appropriately trained pharmacists are also authorised to supply and administer pneumococcal, herpes zoster (shingles), and influenza vaccines through private pharmacy vaccination services, should they choose to do so. The pneumococcal and shingles vaccines must be provided by the pharmacist at the pharmacy, while private influenza vaccination can be carried at the pharmacy, or at a suitable and appropriate offsite place on behalf of the pharmacy.

The purpose of this guidance is to support pharmacists and those in pharmacy governance roles in delivering vaccination services at or on behalf of a retail pharmacy business. The guidance therefore sets out the key legal and professional requirements which need to be fulfilled for all pharmacy vaccination services, whether private or part of the HSE vaccination programme.

Where pharmacies are providing HSE vaccination services, it will also be necessary that they adhere to the relevant operational guidance provided by the HSE.

All pharmacists involved in the provision of vaccination services will be required to complete the necessary training, ensure they have an understanding of the summary of products characteristics (SmPCs) of each specific vaccine(s) they use, and, ensure that they vaccinate in compliance with the legislation, PSI guidance, any relevant national guidance, the Code of Conduct and the pharmacy's procedures.

As this guidance focuses on pharmacy vaccination services, it does not fully address circumstances where an individual pharmacist provides vaccination services independent of a pharmacy (for example at an HSE-led vaccination centre). In such circumstances the guidance provided by the relevant employer, or organisation should also be referred to.

1.1 Role of PSI

The Pharmaceutical Society of Ireland (PSI) – The Pharmacy Regulator, is the statutory body responsible for regulating pharmacists and retail pharmacy businesses (commonly referred to as community pharmacies). PSI sets the quality standards for pharmacist vaccination training delivered by approved training providers, and produces guidance for the profession on the delivery of pharmacy vaccination services. To ensure regulatory compliance and protect patient safety, PSI conducts pharmacy inspections, during which authorised PSI personnel may request information relating to vaccination, such as policies and procedures, training records and patient records. Where pharmacy vaccination services are provided in line with a national HSE vaccination programme, the pharmacy may also be subject to relevant HSE probity and compliance assurance requests and inspections.

1.2 Role of National Immunisation Agencies

There are several agencies involved in the development of national immunisation policy, vaccination guidance, and the national HSE vaccination programme.

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 NIO is an office within the HSE with responsibility for overseeing the day-to-day implementation of the HSE's 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 vaccination programme.

Pharmacists should ensure that they are familiar with the most recent versions of both the NIAC and NIO national guidance documents on immunisation 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. The provision of vaccination services by community pharmacies is an integral part of the delivery of the national vaccination programme. The provision of private pharmacy vaccination services can improve accessibility and empower patients and the public to make informed choices on their vaccine options.

2.1 Legislative Basis

The Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2024 ("the regulations") authorise the supply and administration of specified vaccines by pharmacists, under specific circumstances and conditions. A copy of the regulations is available on the PSI website www.psi.ie or www.irishstatutebook.ie

Regulation 4B of the regulations authorises appropriately trained pharmacists acting during their professional practice, to administer vaccines listed in Schedule 8 of the regulations. These currently include vaccines for COVID-19, influenza, pneumococcal polysaccharide (PPV23) and herpes zoster (zoster/shingles). Schedule 8 stipulates that pneumococcal and shingles vaccinations must be provided by the pharmacist at the pharmacy premises. Schedule 8 also stipulates that influenza vaccines provided in this way (such as private vaccination) must be provided in connection with a pharmacy in which the pharmacist is employed or engaged.

Regulation 4F of the regulations includes registered pharmacists in a wider list of health professionals who are authorised to administer vaccines (and other medicinal products) in accordance with a national vaccination programme, coordinated, overseen and implemented by the HSE. The vaccinations which can be provided in this way are listed in Schedule 12 of the regulations and include COVID-19 and influenza.

Vaccination for COVID-19 and influenza can be provided either at a pharmacy or at any suitable and appropriate place, having regard to public convenience and the need to protect the health and safety of the public and safely administer the product.

Further Guidance to Support Pharmacies in Providing Safe Vaccination Services Offsite from the Pharmacy Premises is available on the PSI Website www.psi.ie.

Pharmacists are also authorised to supply and administer adrenaline (epinephrine) 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. 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* is available on the PSI website www.psi.ie.

While the current HSE vaccination programme for community pharmacy includes COVID-19 and influenza, the regulations allow for national

programmes to be established for other infectious diseases such as Varicella, Smallpox, Monkeypox, Tuberculosis, and Measles, Mumps and Rubella (MMR), should they be required or where a public health emergency is declared.

2.2 Professional Management

2.2.1 Roles and Responsibilities

Where a retail pharmacy business is providing a vaccination service it is the responsibility of the pharmacy owner and superintendent pharmacist to ensure that appropriate policies, procedures, equipment, indemnity and governance arrangements are in place and staff are appropriately trained and supported to ensure the vaccination service complies with the legislation, PSI guidance and other relevant national guidance.

The supervising pharmacist will have responsibility for ensuring that vaccination policies and procedures are always implemented and adhered to while vaccination services are in operation.

All pharmacists involved in the provision of vaccination services must ensure they are suitably trained and competent to do so, and must take personal responsibility for ensuring their professional practice complies with the legislative requirements, the service policies and procedures, PSI guidance, any other relevant guidance, and the Code of Conduct for pharmacists.

2.2.2 Clinical Governance and Vaccination Service Oversight

In establishing a pharmacy vaccination service, the pharmacy owner and superintendent pharmacist are responsible for ensuring that robust clinical governance and professional management procedures are in place. Essential considerations include:

- The premises where vaccination will be provided, in particular the patient consultation area/vaccination services area, is of an appropriate standard for the nature and scale of the service provided.
- All necessary equipment and facilities are available on the pharmacy premises, or where relevant the offsite vaccination premises.
- Appropriate professional indemnity arrangements are in place for all aspects of the vaccination service, including any offsite provision.
- Adequate and suitably trained 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.
- 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, dependent 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 ensuring that:

- Supervised practice runs in the pharmacy are carried out regularly as part of an internal sign-off process. Practice runs ensure 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.

2.2.3 Communication

The establishment of effective communication between the pharmacist and patient, (and where applicable their carer, parent or representative), and any relevant health professionals involved in their care will be an essential aspect of the pharmacy's vaccination service. Clear and effective communication will ensure patients are provided with accurate information, in a manner which they can understand and use to base their informed choices.

Pharmacists should make appropriate use of shared patient information systems such as CoVax and PharmVax where relevant to reduce 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

To be authorised to administer a vaccine, pharmacists must have successfully completed the PSI approved training pathway[1] for each vaccine they will be administering.Certificates received and any other relevant 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.

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. It should include training on Infection Prevention and Control (IPC) measures such as, hand hygiene, respiratory hygiene, cough etiquette, and environmental cleaning to minimise the risk of infection in the pharmacy[2].

The training should enable all staff to play their part in helping to ensure a safe and effective service.

1 Training which meets the PSI's 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)

2 National Clinical Guidelines: Infection Prevention and Control (IPC)

2.4 Premises and Facilities

Where vaccination services are provided at a pharmacy, the pharmacy must have appropriate and adequate premises and facilities in place. Where a pharmacy is providing vaccination services offsite, for example at a school or community centre, pharmacy owners and superintendent pharmacists should refer to the Guidance to Support Pharmacies in Providing Safe Vaccination Services Offsite from the Pharmacy Premises which is available on the PSI Website www.psi.ie.

2.4.1 Vaccination Services Area

The requirements for a vaccination services area in a pharmacy 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 pharmacy's patient consultation area may be a suitable vaccination area provided it meets the additional requirements.

However, a separate, suitable vaccination services area 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 in a Pharmacy

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

- Located in an area of the pharmacy which facilitates a convenient vaccination 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 personnel, consumables, documentation and equipment, and to adequately manage an adverse reaction.
- Include 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.

Where vaccination is being provided at the pharmacy, the vaccination area must be located within the area registered as the retail pharmacy business premises3, The area must also be accessible from the public area of the pharmacy and be capable of accommodating all patients, including patients with a disability, e.g. be wheelchair accessible.

Consideration should also be given as how and where patients can be accommodated for any necessary post-vaccination observation.

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 registration portal. More information here

2.4.3 Equipment

All the equipment required for the provision of the service should be available and either stored in the vaccination services 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 with respect to vaccine and adrenaline (epinephrine) stock. 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 or 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 comply with any relevant obligations under the Falsified Medicines Directive (2011/62/EU) (commonly referred to as FMD) in relation to vaccines received into the pharmacy, as well as checking the tamper proof seal and authenticating and/or decommissioning prior to supply, as appropriate. Further information on compliance with the FMD is available from the Irish Medicines Verification Organisation website www.imvo.ie. Pharmacists should also satisfy themselves that vaccines received at the pharmacy are the correct product for the service being provided and have been stored and transported under appropriate 'cold chain' conditions prior to receipt.

2.5.2 Storage

Medicinal products, including vaccines and adrenaline (epinephrine) must be stored appropriately, in accordance with the product SmPC, and under the supervision and control of the pharmacist, in accordance with PSI *Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business.* Appropriate storage conditions must be maintained throughout the set-up, operation and conclusion of pharmacy vaccine services and offsite clinics. Products requiring cold chain conditions 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.

Ensuring that separate areas of the pharmaceutical fridge are identified for each vaccine (particularly those which look-a-like or sound-a-like) may reduce the risk of error, as would separating HSE stocks from any private stocks, where both are held.

2.5.3 Disposal

Waste products such as sharps and clinical waste, used injections and 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.

Records of the disposal of sharps and other clinical waste should be maintained in the pharmacy and in accordance with the PSI *Guidelines on the Disposal of Medicinal Products for a Retail Pharmacy Business.* Additional information may be available from the pharmacy's waste management company and/or the relevant company assigned for HSE associated collection.

The HSE 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 maintained in the pharmacy and, where applicable, brought to any offsite vaccination location.

In addition, adequate stock of adrenaline (epinephrine), designated for emergency use only, must be maintained in the pharmacy, and adequate stocks should be brought to any off-site location where vaccines are planned to be provided.

Where pharmacists ensure that there is an adequate time interval between the administration of the vaccine to each patient, the pharmacy (or relevant offsite location) needs only to have sufficient stock of adrenaline (epinephrine) 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) for administration to a minimum of two patients available. Pharmacists should ensure that the adrenaline (epinephrine) they stock is authorised for use 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 thevaccines 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 (or parent in the case of a child under 16) or, where they are unable to provide consent, their will and preferences have been established and the administration is in their benefit.

- Ensure that there are no contraindications or precautions to the vaccine being given.
- Carryout 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 they may have. The pharmacist must ensure that the consent provided by the patient (or where applicable, by their parent), includes informed consent to the recording and keeping of data and understands what this entails. The pharmacist must record the nature of consent provided by the patient .

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, by an appropriately trained pharmacist, in accordance with the legislation and with the current Immunisation Guidelines for Ireland, the SmPC of the vaccine and current best practice in injection technique.
- The colour and composition of each vaccine dose 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 (as applicable) it must be used within any timeframe specified in the SmPC or, if not, disposed of appropriately.
- 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 may require observation in case they have an allergic reaction. If such observation is required it should be conducted in a designated area as described in the pharmacy procedures. If it is not practicable for the patient to remain in the pharmacy or in the premises where vaccination was provided 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 adequately trained and competent in responding quickly and appropriately should an adverse event occur post vaccination, 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 and the pharmacy's documented policies and procedures, which should have been subjected to practice runs within the pharmacy.

If the pharmacy (or relevant offsite location) only has sufficient stock of adrenaline (epinephrine) for administration to one patient, pharmacists must ensure that recommended time elapses between the administration of vaccines to patients.

4 Regulations 4B and 4F, and Schedules 8 and 12 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

Before they leave the pharmacy or premises where vaccination was provided, patients (or their parents or carers) 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 concerns relating to vaccination and should outline the necessary steps, including 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, which should include those arising in relation to vaccination services. All staff should be familiar with the appropriate procedure.

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) for the emergency treatment of anaphylaxis[5].

2.8.1. Administration Records

In all circumstances where a pharmacist provides a vaccination service on behalf of a pharmacy, the regulations require that the pharmacist who has supplied and administered the vaccine must record the following particulars:

- 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 vaccine being supplied and administered.
- The pharmacist's own name and PSI registration number
- Address of the retail pharmacy business where the pharmacist practices and where (or on behalf of which) the vaccine was provided.
- Confirmation that consent was obtained from the patient (or their parent in the case of a child under 16) prior to the administration of the vaccine, or, where the patient was unable to give such consent, their will and preferences were established, and the administration was for their benefit.

In addition to the particulars above, where the pharmacy's vaccination service is provided in line with a HSE vaccination programme, the record must also include:

- The patient's contact number, email address, ethnicity and pregnancy status, in so far as the patient can provide the information.
- Where a PPS number is not provided by the patient, the details of any other/alternative form of ID provided, as required by the national programme.
- The pharmacy's email and telephone number. Note: These details may be automatically recorded within the pharmacy's PharmaVax account.

5 Regulations 10A, 10C and 10D of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

- Any other such relevant or necessary information as required within the terms of the HSE vaccination programme, as specified by the Minister.

In line with best practice identified by the NIO, the pharmacist should also record the injection site used.

Relevant record keeping requirements will also apply to the supply and administration of adrenaline (epinephrine) for anaphylaxis, and pharmacists should refer to 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*[6].

Those in governance roles must ensure that all vaccinations, whether they are provided as part of HSE vaccination programme or as a private service, are recorded in a manner which satisfies the regulations. Pharmacies may use the HSE PharmaVax system for the purposes of recording vaccination, and for notifying vaccinations to the HSE in line with any guidance provided by the HSE on the use of PharmaVax.

2.8.2 Record Retention and Confidentiality

- If the ownership of a pharmacy changes within that time period, the new owner will be responsible for preserving the relevant vaccination records for the remainder of the designated time period.
- Other relevant vaccination records such as records of patient consultations, 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

In all circumstances, the regulations require that a copy of the particulars recorded in respect of each patient vaccination administered by a pharmacist are forwarded, by electronic or other means, to the HSE within seven days of the administration. This includes all vaccinations which may be provided by a pharmacy service, whether these have been provided privately or in line with a HSE vaccination programme.

3. Pharmacovigilance

As with all medicines, any suspected adverse reactions arising from the administration of vaccinations, 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.

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

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. Polices should consider and refer to PSI and other relevant guidance, including that of NIAC and the NIO as applicable, health and safety requirements, and patient needs.

At a minimum, documented policies should cover 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.

In addition to specific vaccination policies, 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, managing a product recall, and pharmacy record keeping, 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 newvaccination 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 continue to consult relevant legislation for further information on medicinal products which may be supplied.

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) products, 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 within a pharmacy 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 vaccination administration recorded and maintained in the pharmacy in accordance with the relevant requirements?				
Are records of patient consultation and patient consent maintained in the pharmacy?				
Are all patient vaccination records forwarded to the HSE 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?				
Are all pharmacists familiar with specific requirements relating to the management and administration of the specific vaccination services offered at the pharmacy?				

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 9 10	April 2016 October 2018 April 2019 October 2021 September 2022 September 2023 September 2024