



PSI GUIDANCE ON THE PROVISION OF SEASONAL INFLUENZA VACCINATION SERVICE BY PHARMACISTS IN RETAIL PHARMACY BUSINESSES (2012)

This guidance has been revised and updated for the 2012-2013 season and will be reviewed as necessary in the future. It has also been revised in light of the findings and recommendations of the report of the risk review group established to examine and report on the causes of underdosing of some patients with seasonal influenza vaccine by some pharmacists. This report is published on the PSI website at this link:

http://thepsi.ie/Libraries/Latest_News/Final_Report_of_the_Risk_Review_Group_26th_June_2012.sflb.ashx

INTRODUCTION

In October 2011, pharmacists in Ireland were enabled to participate in the national seasonal influenza vaccination campaign on the introduction of the Medicinal Products (Prescription of Control and Supply) (Amendment) Regulations 2011(S.I. No. 525 of 2011), which came into force on 14th October 2011. Under this legislation, pharmacists were enabled to lawfully supply and administer the seasonal influenza vaccine in the ordinary course of their professional practice, provided they fulfil the required conditions set out in those 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 seasonal influenza vaccine.

This guidance is intended to support pharmacists in providing a seasonal influenza vaccination service in line with the legislation. It is also intended to assist in the exercise of their knowledge, skills and professional judgement in the delivery of the service and thereby provide a service which meets the highest standards of patient safety, quality and best clinical practice.

NATIONAL IMMUNISATION AGENCIES

The National Immunisation Advisory Committee (NIAC) is a committee established with a view to advising the Department of Health in the area of immunisation procedures and related matters. This Committee prepares the *Immunisation Guidelines for Ireland*¹ which are updated regularly and are available through the Royal College of Physicians and on its website www.rcpi.ie (under the College Structure/Standing Committees section).

The HSE National Immunisation Office (NIO) oversees the day-to-day implementation of the national immunisation programme by the Health Service Executive (HSE). The NIO provides up to date information leaflets for the public and health care professionals and publishes the national guideline *A Practical Guide to Immunisation*². The most current information is available on their website www.immunisation.ie.

The NIO is also responsible for the procurement and distribution of vaccines for the national immunisation strategy within the cold chain.

Pharmacists should ensure that they are familiar with the most recent versions of both the NIAC and NIO national guidance documents on immunisations¹⁻²

One of the most important factors in ensuring the success of influenza vaccination programmes is ensuring a high level of uptake in the at-risk groups. Annual vaccination with the most recent strains is recommended and it is important that influenza vaccination uptake is maximised in order to improve patient outcomes nationally.

IMPLEMENTATION OF A VACCINATION SERVICE

This guidance sets out the legal and professional requirements which need to be fulfilled. It also describes the other related issues that need to be considered by pharmacists in ensuring the safe and proper provision of the seasonal influenza vaccination service to patients in their retail pharmacy businesses (pharmacies).

¹ Immunisation Guidelines for Ireland. Royal College of Physicians of Ireland National Immunisation Advisory Committee, www.rcpi.ie.

² A Practical Guide to Immunisation, HSE National Immunisation Office, www.immunisation.ie.

These requirements relate to:

1. Legislative Requirements
2. Professional Management (Role of Superintendent Pharmacist and Policies and Procedures)
3. Pharmacist Training
4. Premises and Facilities
5. Vaccine Stock Management
6. Patient Consultation and Vaccination (including follow-up care)
7. Recordkeeping
8. Pharmacovigilance

1 LEGISLATIVE REQUIREMENTS

The Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 provide for the administration of the seasonal influenza vaccine by pharmacists. These regulations amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003, primarily by inserting a new regulation 4B relating to the supply and administration of influenza vaccine by authorised persons (registered pharmacists), a new regulation 10A relating to the keeping of records, and the insertion of an Eighth Schedule. (The 2011 regulations also provide for a small number of other amendments to the 2003 regulations, including insertion of definitions.)

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

(It should be noted that the term '*authorised person*' in these regulations means a '*registered pharmacist*')

Pharmacists must be satisfied that their supply and administration of the influenza vaccine is in full compliance with the requirements of the regulations. Pharmacists must also be satisfied that the provision of associated services, fully comply with all relevant requirements of pharmacy and medicines legislation, including the Pharmacy Act 2007, the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), and the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) which includes the 2011 amendment.

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

2 PROFESSIONAL MANAGEMENT

ROLE OF THE SUPERINTENDENT PHARMACIST

A system for the professional management and clinical governance of the vaccination service must be established for each pharmacy. The superintendent pharmacist is the pharmacist who holds 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.

The particular responsibilities of the Superintendent Pharmacist in relation to the provision of vaccination services would include the following:

- That the premises, in particular the patient consultation area (or room where the consultation will occur), are of an appropriate standard, and that the pharmacy has all necessary equipment and facilities to provide the influenza vaccination service
- That the provision of the service is covered by appropriate professional indemnity arrangements
- That there are adequate pharmacist staff available to allow for the vaccination service to be appropriately delivered in compliance with the requirements of the legislation while at the same time facilitating the appropriate supervision of all other professional activities being undertaken within the pharmacy
- That the pharmacists delivering the service have successfully completed the appropriate training and are the holders of the prescribed Certificate as evidence of that fact
- That as the superintendent pharmacist, he or she is satisfied that all pharmacists delivering the service in the pharmacies under his or her control have the requisite knowledge and skills and are fit to perform the service. The process for assuring this should include an

internal sign-off process by each superintendent/supervising pharmacist prior to the formal introduction of the service, and following appropriate practice runs within the pharmacy environment. This should also be done for every new pharmacist joining the practice who intends to be involved in providing the vaccination service. In addition, there should be ongoing monitoring of the delivery of the service.

- That appropriate and robust documented policies and procedures are in place for the delivery of the service, and that these policies and procedures are reviewed and updated regularly in accordance with best professional practice.(see section below on policies and procedures).
- That all pharmacists participating in the delivery of the service are aware of the pharmacovigilance issues that may arise and that adequate arrangements are in place for appropriate follow-up with patients.
- That appropriate systems are in place for the recording of errors, 'near misses' and relevant incidents, including sharps injuries
- That appropriate infection control measures are in place, including in relation to hand hygiene, observation of universal precautions (whereby all blood and bodily fluids are treated as if infectious) and provision of appropriate personal protective equipment for staff. All pharmacists participating in the delivery of the service and all other pharmacy staff, as appropriate, should be offered vaccination against Hepatitis B, and the receipt or refusal of the vaccination appropriately documented.

POLICIES AND PROCEDURES

Policies and procedures developed for the provision of a vaccination service should take into account and comply with: relevant legislation, relevant guidance, including that of NIAC and NIO, 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:

- Providing information to patients and gaining informed consent
- Patient inclusion/exclusion criteria
- Preparation and administration of the vaccine

- Patient counselling and monitoring post-vaccination, including information on adverse reactions and their management
- Management of adverse reactions or medication error
- Management of anaphylaxis (including administration of adrenaline and provision of basic life support measures)
- Prevention and management of needlestick Injuries
- Disposal of sharps and clinical waste
- Management of patient data and confidentiality

Some of the policies and procedures already in existence in the pharmacy may also be relevant (e.g. those relating to cold chain management, dealing with patient complaints, or for dealing with a product recall) and these should be reviewed, updated or cross-referenced where necessary.

Superintendent and supervising pharmacists should ensure that all pharmacists providing vaccination services within the particular pharmacy are appropriately trained in the relevant policies and procedures, and re-trained where necessary following any review and update of a relevant policy or procedure.

3 PHARMACIST TRAINING AND CONTINUING PROFESSIONAL DEVELOPMENT

Pharmacists administering seasonal influenza vaccine must have successfully completed appropriate training, which meets the PSI's accreditation and quality assurance standards³ and which is approved and recognised by the PSI Council in line with the requirements of regulations (i.e. S.I. No. 525 of 2011). Certificates received and any other relevant records associated with the pharmacist's training should be retained in the pharmacy³ and certificates may be displayed to the public in the consultation area.

It is important that pharmacists maintain their competence in the administration of seasonal flu vaccines, and that they continue to update their knowledge and skills as necessary as part of their on-going continuing professional development and re-certification requirements.

³ PSI Revised Interim Accreditation Standards for Seasonal Influenza Vaccination Training Programmes for Pharmacists (updated for 2012-2013)

All other pharmacy staff should be familiar with the provision of the vaccination service and be trained appropriate to their level of involvement in the process. Staff training should ensure familiarity with all relevant policies and procedures, e.g. management of the cold chain and management of patient queries or complaints.

4 PREMISES AND FACILITIES

4.1 Patient consultation and vaccination service delivery area requirements:

Pharmacies providing or intending to provide vaccination services must have appropriate and adequate facilities. The requirements for the patient consultation/clinical services area to be used for vaccinations exceed those specified in the PSI's *Guidelines on Patient Consultation Areas in Retail Pharmacy Businesses* (May 2010), particularly in relation to the size of the area required, the degree of privacy required, and the equipment requirements.

The patient consultation area can be a suitable area provided that the area meets the additional requirements outlined below. However, pharmacists should be aware that a patient consultation area that complies with the minimum requirements to allow for a conversation or discussion on medicines to be undertaken in private may not be adequate to allow for a vaccine service to be delivered.

A second separate area within the pharmacy designated for the provision of clinical services may also be used, particularly where a pharmacy is engaged in vaccinations and other clinical services on a large scale or volume, provided that it meets the requirements outlined below.

Superintendent pharmacists must be satisfied that the area and facilities within the pharmacy, or pharmacies under their control, meet the necessary requirements prior to commencing a new clinical service.

Vaccination services should not be provided in any area of the pharmacy which does not meet these requirements.

REQUIREMENTS FOR PATIENT CONSULTATION/CLINICAL SERVICES AREA

- All such areas must be part of the registered retail pharmacy business premises and any changes made in respect of the floor plan of the registered premises must be notified to the PSI in order that the registration of the pharmacy remains valid.
- In all cases the area used should be fit for purpose, appropriately private, and be of sufficient size and an appropriate layout to facilitate a safe and efficient workflow, a comfortable consultation for the pharmacist and patient, and to allow for the safe and effective management of any incidents, such as a patient fainting, or additional patient care that may arise.
- **Designated area:** It is necessary that a designated area is available within the pharmacy for the provision of the vaccination services. Pharmacists should consider the adequacy of the patient consultation area currently available in the pharmacy and be mindful of the expected volume of activity that the vaccination service will demand in addition to the other clinical services that may be provided in the pharmacy.
- **Space:** The area available must be of sufficient size and of an appropriate layout to facilitate the pharmacist carrying out vaccinations and to allow for a comfortable and safe workflow. The area should accommodate a work bench and comfortable seating for the patient, their carer or chaperone and the pharmacist. Sufficient space is also required to accommodate the consumables, documentation and equipment required, including bins for the safe disposal of sharps, clinical and non-clinical waste and confidential information. Pharmacists should also consider the space available to them for dealing with potential adverse events following vaccination. As patients must be asked to remain within the pharmacy for at least 15 minutes post-vaccination, consideration should be given as to whether the patients will wait in this designated area or whether another area with seating is available for this purpose.
- **Privacy:** The area provided for vaccination service delivery should ensure the dignity and privacy of the patient. Additional privacy requirements are required for a clinical services patient consultation area, particularly visual privacy requirements. The area should be enclosed, where a door or shutters can be closed to enclose the area. Blinds, opaque glass or other visual barriers can be used to provide visual privacy, as necessary depending on the design of the area.

- **Location:** The location should be convenient to the dispensary to facilitate a convenient workflow for the pharmacist delivering the service, including access to the vaccine storage refrigerator and for fulfilling the necessary record keeping requirements. The location chosen must minimise the risks to health and safety of the staff and the patients, and be accessible to all patients.
- **Fixtures and fittings:** It is important that the area is suitable and of an appropriate professional finish for the delivery of a clinical service. Comfortable seating must be provided for patient and chaperone/carer. An adequate work surface must be available which should have a smooth impervious finish. If consumables, sharps or records are to be stored in the area, there must be sufficient space to accommodate these and all equipment and records must be kept in a locked storage cupboard when not in use.

4.2 Equipment

All the equipment required for the provision of the service should be readily available.

The required equipment includes alcohol hand gel, hard surface wipes, sharps bin(s) clinical waste bin(s)/bag(s), latex-free gloves, water, gauze swabs/cotton wool, CPR (cardiopulmonary resuscitation) mask, and personal protective equipment for dealing with sharps spillage, such as puncture-proof/'turtle skin' gloves, forceps, apron, goggles and any other equipment deemed necessary.

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

5 VACCINE STOCK MANAGEMENT

The general requirements for the management of the sourcing, storage and disposal of medicinal products are set out in the *PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business* should be adhered to.

The relevant requirements in the NIAC *Immunisation Guidelines for Ireland* and the HSE NIO's *A practical guide to Immunisation* should also be adhered to.

5.1 Sourcing

Pharmacists should be familiar with the process and timelines involved in the sourcing of vaccines, including through the HSE National Cold Chain Delivery Service. The sourcing of vaccines from suppliers must be carried out in accordance with the relevant *PSI Guidelines*.

Vaccines should be checked immediately on receipt and placed in a refrigerator.

The person responsible for receiving delivery of the vaccines should also satisfy themselves that the medicinal products have been transported under appropriate 'cold chain' conditions, i.e. between 2^o-8^oC.

5.2 Storage

A purpose-built pharmaceutical grade refrigerator(s), of adequate capacity, must be used for the storage of all cold chain medicinal products, including the seasonal influenza vaccine.

It is necessary to ensure that the 2-8°C temperature range required for the storage of the vaccines has been maintained throughout and that appropriate temperature monitoring records are in place in demonstration of this.

5.3 Disposal

Waste medicinal products, e.g. partially used injections, sharps, e.g. needles/ glass, and clinical waste, e.g. used needles, blood stained gauze, should be placed immediately into specialised waste bins. Clinical and sharps waste should be disposed of in correctly labelled United Nations (UN) approved containers.

Waste bins should not be overfilled. They should be securely sealed when filled to the manufacturer's fill line or, if no fill line is present, when three-quarters full. They should then be appropriately secured pending prompt removal from the pharmacy by an appropriately authorised waste management company.

Further information on how to safely dispose of waste should be obtained from the pharmacy's waste management company.

Waste bins should be of an adequate capacity and be stored securely under the control of the pharmacist, in a designated area of the pharmacy that is inaccessible to members of the public.

Sharps bins may be brought into the consultation area when providing a vaccination consultation but should be removed after each consultation or stored in locked cupboards in the consultation area.

Detailed records for the disposal of waste medicinal products and other clinical waste should be retained in every pharmacy, as per *PSI Guidelines*.

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 vaccines.

5.4 Other storage and stock requirements

The supervising pharmacist should ensure that adequate stock of vaccines, other medicinal products, medical devices, and any other required products are available in the pharmacy for the provision of the service at all times, and that these stock levels are frequently checked and maintained at appropriate levels. In addition, adequate stock of adrenaline injections, designated for vaccination service use only, must be maintained in the pharmacy at all times. There must be sufficient stock of adrenaline injections for administration to a minimum of two patients available at all times.

6 PATIENT CONSULTATION AND VACCINE ADMINISTRATION

6.1 Patient consultation

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 the information to the patient in a manner that is clear and easily understood by the patient and be in a position to confidently address questions that are commonly asked by patients.

The pharmacist should document that consent was obtained, including the patient's signature (or that of a parent or guardian in the case of a child under the age of 16), and retain this information in the pharmacy.

Note: Prior to vaccine administration, the pharmacist must first assess 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 Summary of Product Characteristics (SmPC) of the vaccine, are appropriately addressed. Relevant SmPCs are available from the Irish Medicine Board's (IMB's) website www.imb.ie or from www.medicines.ie and copies of all relevant SmPCs should be readily accessible and available within the pharmacy.

Pharmacists should also be cognisant of the patient cohorts that they are trained to vaccinate (e.g. adults or children) and for which they are competent and confident to vaccinate.

Additional considerations may be required when vaccinating children in respect of obtaining informed consent, managing the consultation and administration of the vaccine and patient counselling and follow-up. The pharmacy's policy should also reflect relevant responsibilities under *Children First: National Guidance for the Protection and Welfare of Children* (available on www.dcyh.ie)

6.2 Vaccine administration

- The vaccine should be prepared and administered in a safe and effective manner, in accordance with the current Immunisation Guidelines for Ireland¹⁻². Particular attention should be paid to the information included in the SmPC of the vaccine, and, in particular, having regard to any contraindications, special precautions or warnings for use which may be specified.
- The vaccine's appearance and colour must be examined to ensure it conforms to the description in the vaccine's SmPC. The vaccine should be allowed to reach room temperature prior to administration.

- 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 below under Record Keeping).
- The current principles of infection prevention and control should be followed when assessing and preparing the injection site and administering the vaccine.
- The vaccine should be injected in accordance with current best practice in injection technique and in line with the vaccine's SmPC.

6.3 Post vaccination observation, follow-up and referral

Following the administration of the vaccine, the pharmacist should observe and monitor the patient, as appropriate, and explain to the patient the reason for requiring that he or she remain in the pharmacy for at least 15 minutes.

Before they leave the pharmacy, patients should have received all necessary information and counselling, including the Patient Information/Package Leaflet from the vaccine that had been administered, any relevant information material provided by the HSE and any other appropriate information material deemed necessary. 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. Patients should be advised of the potential side-effects and how these should be managed. They should be given contact details for the pharmacy should they have any queries or issues they need to discuss with the pharmacist after they leave the pharmacy. Patient contact details should be recorded in the Patient Medication Record (PMR).

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 to such events should be in line with the pharmacist's training and the pharmacy's documented policies and procedures, which have been subjected to practice runs within the pharmacy.

Superintendent and supervising pharmacists should ensure they have a policy 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 of a patient for further treatment, as

appropriate. Pharmacists should ensure that any communication and liaison with a patient's General Practitioner (GP), other appropriate healthcare professionals or agencies is carried out appropriately, as necessary.

Follow-up contacts with patients, and any interventions or referrals should be recorded in the PMR, as appropriate.

Superintendent pharmacists should also ensure that a patient complaint handling policy is in place and that all staff are familiar with the appropriate procedure for dealing with complaints or concerns of patients and the public.

7 RECORD KEEPING

Adequate and appropriate records of the patient consultation, and the supply and administration of the vaccine, and any other medicinal products, must be kept.

The keeping of records in relation to the supply and administration of the influenza vaccine, and the supply and administration of adrenaline injection for the emergency treatment of anaphylactic shock arising as a result of the administration of seasonal influenza vaccine, must be carried out in accordance with the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011.

These regulations require that the pharmacist who has administered the vaccine shall record the following particulars in respect of each such administration:

- the date of administration
- the name, address, date of birth and sex of the patient to whom the vaccine was administered
- the Personal Public Service Number (PPSN) of the patient to whom the vaccine was administered (unless the patient fails to provide one)
- the name, dosage, marketing authorisation number, batch number and expiry date of the product
- their own name and PSI registration number

- the address of the retail pharmacy business where the administration was carried out
- the name, address and contact particulars of the patient's GP (unless the patient fails to provide this information).

This information may be kept in the form of computerised records provided there is a print-out containing the details above for each day the pharmacy is open, and which is certified, by each of the pharmacists who on that day had administered the vaccine, that the record is true and correct. This certification must be made within 24 hours of the making of the daily print-out.

All records relating to the supply and administration of the vaccine must be kept for two years at the pharmacy premises concerned and be available for inspection. Furthermore, the records must 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.

A record of the supply of the vaccine must be kept with all other prescription medicines in the individual patient's PMR and included in the Daily Audit report for the pharmacy. In line with best practice identified by the NIO, the pharmacist should also record the injection site used.

These general record-keeping requirements also apply to the supply and administration of adrenaline injection under these regulations.

The patient consultation and patient consent record, signed by the patient or a parent/guardian in the case of a child under 16, should be kept in hard copy form. The pharmacist must ensure that the patient has full knowledge and consents to the recording and keeping of data and understands what this entails. The pharmacist and the pharmacy owner must ensure the confidentiality of patient records, and the management of data or information collected, recorded or retained in relation to the provision of the vaccination service, is in accordance with the requirements of the Data Protection Acts 1988 and 2003.

7.1 *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. The HSE are providing an online system to facilitate pharmacists in recording and transmitting this data. It is important for the appropriate monitoring of public health protection that data pertaining to all patients vaccinated against seasonal influenza is made available to the HSE as required by the regulations.

All vaccinations, whether with HSE-supplied vaccine stock or other stock, must be notified to the HSE.

All administrations of adrenaline, for the emergency treatment of anaphylactic shock arising as a result of the administration of seasonal influenza vaccine, must also be notified to the HSE.

7.2 *Notifying the patient's GP*

The regulations also 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.

All administrations of adrenaline, for the emergency treatment of anaphylactic shock arising as a result of the administration of seasonal influenza vaccine, must also be notified to the patient's GP.

8 PHARMACOVIGILANCE

As with all medicines, any suspected adverse reactions should be reported to the Irish Medicines Board (IMB), preferably online via the IMB website www.imb.ie.

Reports should be as detailed as possible and include the vaccine batch number. All administrations of the vaccine which result in suspected anaphylactic shock should be urgently reported to the IMB.

The Provision of Seasonal Influenza Vaccination Service by Pharmacists in Retail Pharmacy Businesses: Self-assessment Checklist for Pharmacists

This self-assessment checklist is a practical tool intended to aid compliance with the important elements of this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and procedures.

The checklist captures the most critical elements of the guidelines; it is not exhaustive and should only be used to assess pharmacy practice in combination with these guidelines and all other relevant guidelines 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 the Seasonal Influenza Vaccination Service by Pharmacists in Retail Pharmacy Businesses</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 all relevant Summary of Product Characteristics (SmPCs) for the influenza vaccines and adrenaline injections, and are copies readily available in the pharmacy?				
Is the vaccination service covered by appropriate professional indemnity arrangements?				
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 Certificate) 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?				

Premises and Equipment				
Are the pharmacy premises in particular the patient consultation/clinical services area, of an appropriate standard for the provision of a vaccination service, taking account of the requirements for space, privacy, and fixture 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, e.g. the management of product recalls?				
Are all pharmacists familiar with the process and timelines involved in ordering vaccines through the HSE National Cold Chain Delivery Service?				
Are all vaccinations checked immediately on receipt and placed in a pharmaceutical grade refrigerator?				
Is the pharmaceutical grade refrigerator of adequate capacity and appropriately temperature monitored and does it meet all requirements of PSI guidelines?				
Is adequate stock of vaccines, adrenaline, medical devices and other required products and equipment maintained in the pharmacy at all times, and is all relevant stock subject to effective stock rotation and date checking?				
Is all waste generated by the vaccination service disposed of in a manner which assures the safety of patients and the public and doesn't cause a risk to the environment?				
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?				
Policies and Procedures				
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?				
Do all policies and procedures contain an implementation and review date and are these documents 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 verbal and written 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, sanitisation and the use of personal protective equipment, the prevention and management of needlestick 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?				
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 and for reporting a suspected adverse reaction to the IMB?				

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