# Guidance on the Provision of an Influenza Vaccination Service for Children Aged 6 Months and Older

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

Pharmaceutical Society of Ireland Version 4 September 2023

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# **1. Introduction**

Since the 2020/2021 influenza vaccination season, appropriately trained pharmacists are authorised to:

- supply and administer influenza vaccines to children from the age of 6 months<sup>1</sup>.
- supply and administer the influenza vaccine (live attenuated) nasal spray suspension to children and adolescents from 24 months, in accordance with the summary of product characteristics of the product administered and the Immunisation Guidelines for Ireland<sup>2</sup>.

The requirements set out in the PSI's *Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses* (available on the PSI website) must be met when providing an influenza vaccination service for children. In addition, recommendations set out in the National Immunisation Advisory Committee (NIAC)'s Immunisation Guidelines for Ireland<sup>3</sup> and the advice and guidance of the National immunisation Office (NIO) must be met. These Guidelines are updated regularly, and pharmacists should ensure that they are familiar with the most recent versions.

Additional guidance specific to providing a vaccination service to children is set out in this guidance document and must be read and considered by all pharmacy owners, superintendent pharmacists and supervising pharmacists who wish to provide this service.

# 2. Implementation of a Vaccination Service for Children

# 2.1 Pharmacist and Staff Training

The training requirements to provide a pharmacy vaccination service are set out on the PSI website. These are reviewed on an ongoing basis and are subject to change, therefore all pharmacists should check the training requirements each year in their preparation for providing an influenza vaccination service. Each pharmacist should carry out a self- assessment of their own skills to ensure that they are competent and confident to provide this service safely and to a high standard to children or upskill where needed. The PSI have developed a self-declaration form available on the **PSI website**, which can help pharmacists to review the requirements for a vaccination service and determine their competency to deliver this service.

The Medicines Administration (Parenteral) (PAMT) course<sup>4</sup>, which is accredited by the PSI, includes training on administration of injections to infants from 6 months of age. When offering a vaccination service for children for the first time, pharmacists should carefully reflect on their skills, self-assess and evaluate whether they need to refresh their training with this programme. Pharmacists who have not completed the PAMT training programme, which commenced in 2016, must undertake this training programme in order to be able to administer influenza vaccinations to children from 6 months of age.

The seasonal influenza vaccine training programme<sup>4</sup>, which is accredited by the PSI, must be completed by all pharmacists each year, prior to the commencement of the influenza season.

- 1 Approved by PSI Council at their meeting on 20 June 2019.
- 2 Medicinal Products (Prescription and Control of Supply) (Amendment) (No.4) Regulations 2020.
- 3 Immunisation Guidelines for Ireland
- 4 You can enrol for this course at <u>www.iiop.ie</u>.

This module includes information on vaccinating children from 6 months old as well as training on how to administer the influenza vaccine, nasal spray suspension.

All staff members should be trained on policies and procedures as relevant to their role in relation to the operation of an influenza vaccination service for children, and be clear on which age groups the pharmacy offers a vaccination service.

Pharmacists and pharmacy staff are in a key position in the community to provide factual information about the benefits and evidence base relating to the use of vaccinations. They should signpost anyone concerned about vaccinations to trusted sources of information, for example, the HSE's National Immunisation Office<sup>5</sup>.

## 2.2 Assessment of Suitability of the Pharmacy Premises and Facilities

The pharmacy owner, superintendent pharmacist and supervising pharmacist should carefully assess whether the vaccination services area<sup>6</sup> is of an appropriate size and layout, and can provide the required level of privacy, to be able to provide a vaccination service to children, keeping in mind that the child has to be accompanied by a parent or guardian at all times.

From a practical point of view, the layout of the vaccination area should be carefully considered, with all medicines and sharps bins kept well out of the reach of children, and adequate space for prams or push chairs provided if needed.

A risk assessment of the vaccination services area may indicate that the facilities are not appropriate to provide the service to infants but would be sufficient to provide the service to older children. The pharmacy owner and superintendent pharmacist may set their own minimum age limit, above 6 months of age, at which they are satisfied that they can safely provide the influenza vaccination service, for each pharmacy that they are in charge of. Any age limit set should be clearly communicated to staff members, customers and patients.

# 2.3 Considerations when Administering a Vaccine to a Child

The information set out in the Patient Consultation section of the PSI's *Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses* also applies in the context of providing a vaccine to a child.

This includes, prior to vaccination, carrying out a documented risk assessment of the child's suitability for vaccination and ensuring that the precautions and contraindications, provided in the Immunisation Guidelines for Ireland and specified in the Summary of Product Characteristics (SmPC) of the vaccine, are appropriately addressed<sup>7</sup>. Records of these assessments should be maintained in the pharmacy.

In addition to the required training that must be carried out to ensure best practice in administration technique, the Immunisation Guidelines for Ireland provide information on how to hold an infant or child during immunisations. The guidelines also provide useful information on pain reduction for injections, including distraction techniques which may be useful to include in the pharmacy's Standard Operating Procedures (SOPs).

5 HSE's National Immunisation Office: <u>www.immunisation.ie</u>.

<sup>6</sup> The PSI's Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses details Requirements for a Vaccination Services Area.

<sup>7</sup> In some circumstances, advice in the SmPC may differ from the Immunisation Guidelines for Ireland. When this occurs, the recommendations in the Immunisation Guidelines for Ireland, which are based on current expert advice, should be followed.

#### 2.3.1 Parent or Guardian Consultation and Obtaining Informed Consent

Prior to administering an influenza vaccination to a child aged under 16 years old, informed consent must be obtained from the child's parent or legal guardian.

The adult should confirm that they are the child's parent or guardian, and this should be documented. If they are not the parent or guardian, contact must be made with the appropriate person in order to seek appropriate consent. Further information and a description of who can give consent for a child is provided in the HSE National Consent Policy<sup>8</sup>.

Informed consent must include providing clear, evidence-based, easy to understand information about the vaccine being administered, including:

- vaccine choice i.e., intra-muscular injection or nasal spray suspension (depending on the child's age and any contraindications),
- its purpose,
- number of doses to be administered,
- benefits and risks, including common side effects, and
- information on how long the child (and parent or guardian) will be required to remain in the pharmacy following administration of the vaccine in line with NIAC guidelines.

The parent or guardian must be given the opportunity to ask questions and receive further information as needed. It should also be confirmed with the parent or guardian that the child has not received the influenza vaccine already from another healthcare provider, during the current influenza season.

While there are no legal provisions in Ireland for children under 16 years old to give consent on their own behalf, it is nonetheless good practice to involve them in the decision-making process and to give them information about their care, including the procedure for vaccination if they are old enough to understand. Language should be tailored to their age and level of understanding. Additional time may be needed in order to provide information to the child's parent or guardian compared to when administering a vaccine to an adult. This should be taken into account when making bookings and assessing the staffing levels needed to provide this service. You may wish to consider providing this information in advance, for the parent or guardian to read prior to them arriving with the child for the vaccination service.

The pharmacist must record that consent for the vaccine administration was obtained.

When vaccinating a child, it is expected that the parent or legal guardian must be present at all times during vaccination. An exception to this is when administering the LAIV (Live Attenuated Influenza Vaccine) nasal influenza vaccine to children in a school setting, where informed consent has been obtained from a parent or guardian in advance, Further information is provided in the PSI *Guidance to Support Pharmacies in Providing Safe Vaccination Services Offsite from the Pharmacy Premises.* 

#### 2.3.2 Vaccine Choice

The HSE provides updated information each year on who is eligible for a free influenza vaccine, as well as specific information on the influenza vaccine(s) procured for the national immunisation programme. This generally includes information on the vaccine's composition, who should and should not receive the vaccine, as well as guidance for administering to a patient with a confirmed egg allergy etc.

Pharmacists should be familiar with the most up to date guidance from NIAC and NIO. The <u>Immunisation Guidelines for Ireland</u> provide up to date information on contraindications and precautions for all influenza vaccines which pharmacists must be aware of and apply when deciding on the suitability of a vaccine.

The <u>National Immunisation Office</u> provides information for healthcare professionals on the relevant clinical information for influenza vaccination for children and should be consulted for the most up to date information. In addition, always check the SmPC for the vaccine prior to vaccination to confirm that it is suitable and licensed for administration for the age of the child being vaccinated, and any precautions and contraindications are appropriately addressed. The <u>HPRA website</u> provides product information for each vaccine.

#### 2.3.3 Required dose

The NIO and NIAC provide guidance on the relevant clinical information for influenza vaccination for children, including up to date information on the dose(s) required to provide protection.

## 2.4 Post Vaccination Counselling

Before leaving the pharmacy, the child's parent or guardian should have received all necessary information and counselling, including whether they need to return for a second dose, potential side effects, as set out in the Immunisation Guidelines for Ireland and the product's SmPC, and how these should be managed. They should be provided with the patient information leaflet from the vaccine and any other support material deemed necessary. 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.

It is also important to remind the parent or guardian of other appropriate infection prevention and control measures to prevent the spread of viruses, for example, regular hand washing and respiratory hygiene.

# 2.5 Treating an Adverse Event in a Child

All pharmacists involved in the vaccination service must be trained and competent to respond quickly and appropriately should an adverse event occur post-immunisation, particularly an event which requires the administration of adrenaline (epinephrine) or the provision of basic life support to a child.

Guidance on treating anaphylaxis, including anaphylaxis in children, is provided by NIAC. The dose of adrenaline (epinephrine) to be administered to treat anaphylaxis varies with age, and a reference containing the recommended dosage by age, as per current guidance from NIAC, should be readily available in the pharmacy as part of an Anaphylaxis Kit.

# 2.6 Record Keeping and Notifying the HSE and Patient's GP

The legal requirements for record keeping and notification to the HSE and patient's GP, following administration of a vaccination, are the same when immunising a child or an adult. These requirements are set out in the *Record Keeping* and *Post Vaccination Communication* sections of the *PSI's Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses.* If the child's parent or guardian has an 'immunisation passport' available, it may also be useful to fill it in with a record of the administration of the vaccine for their own records.

# 3. Policies and Procedures

SOPs must clearly set out the procedure to be followed when vaccinating a child in the pharmacy. They should be specific to the pharmacy and the age from which the service is offered.

The SOPs should be reviewed regularly, in particular at the start of each new influenza season, to ensure that they are specific to each pharmacy and take account of the information set out in this guidance and best practice provided by NIAC and NIO.

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.

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