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

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Contents

1. Introduction

Commencing in 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[1].

- 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[2].

The requirements set out in the Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses 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[3] 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 below 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, 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[4], which is accredited by the PSI, includes training on administration of injections to infants from 6 months of age. As pharmacists would not routinely administer vaccines to children, they 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[4], which is accredited by the PSI, must be completed by all pharmacists each year, prior to the commencement of

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: http://bit.ly/NIACGuideline.
4 You can enrol for this course at www.iiop.ie.

the influenza season. This module has been updated to include 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 new procedures regarding the operation of this service for children, including the age from which the pharmacy is now providing 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[5].

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[6] (which may be the patient consultation area or another part of the pharmacy) 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 the parent/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 *Section 2.6 Patient Consultation* of the PSI's Pharmacy Vaccination Guidance should be read and applied 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[7]. Records of these assessments should be maintained in the pharmacy. Informed consent for vaccination must also be obtained from the child's parent or guardian.

2.3.1 Parent/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 on the consent form. If they are not the parent/guardian, contact must be made with the appropriate person in order to seek appropriate consent. Further information

5 HSE's National Immunisation Office: www.immunisation.ie.

6 Section 2.4.2 of the PSI's Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses details *Requirements for a Vaccination Services Area*.

7 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.

and a description of who can give consent for a child is provided in the HSE's document 'Consent: A guide for health and social care professionals'[8].

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 (see Table 1 and Table 2),
- benefits and risks, including common side effects, and
- information on how long the child (and parent/guardian) will be required to remain in the pharmacy following administration of the vaccine.

The parent/guardian must be given the opportunity to ask questions and receive further information as needed. It should also be confirmed with the parent/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 minors 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/guardian compared to when administering a vaccine to an adult. This should be taken into account when assessing the staffing levels needed to provide this service. You may wish to consider providing this information in advance, for the parent/guardian to read prior to them arriving for the vaccination.

The pharmacist must document that consent for the vaccine administration was obtained. This should include the parent/guardian's signature and consent forms should be retained in the pharmacy.

2.3.2 Vaccine Choice

The HSE provide 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[9] (whether anaphylactic or non-anaphylactic) etc. Please consult their website[10] for further information.

There are two types of vaccine licensed for influenza:

1. Live attenuated influenza vaccines (LAIV), given by nasal application. These vaccines are only licensed from 2 to <18 years old. LAIV should not be used in children below 2 years of age because of safety concerns regarding increased rates of hospitalisation and wheezing in this population[11]. LAIV is supplied as a nasal spray suspension in a single use, pre-filled, nasal applicator. LAIV must not be injected.
2. Inactivated (non-live) influenza vaccines, given by injection. The licensed age for the administration of these vaccines starts at 6 months of age but can vary between products. All parenteral influenza vaccines

8 Additional information on consent is available on the HSE's website: www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/.

9 Chapter 11, Section 11.4.1 *Precautions*; Immunisation Guidelines for Ireland: http://bit.ly/NIACGuideline, also provides information on administering the influenza vaccine to a person with confirmed egg anaphylaxis or egg allergy.

10 HSE Flu Vaccination, Information Materials: www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/information/.

11 Chapter 11, Section 11.4 *Influenza vaccines;* Immunisation Guidelines for Ireland: http://bit.ly/NIACGuideline.

are supplied in a prefilled syringe for intra-muscular (IM) injection into either the anterolateral thigh or deltoid muscle (depending on the age of the child).

The Immunisation Guidelines for Ireland[12] recommend:

- LAIV for all children aged 2 to < 18 years old.
- The inactivated quadrivalent influenza vaccine (QIV)[13] for those children aged 2 to <18 years where LAIV is contraindicated.
- QIV for those children aged 6 months to <2 years at increased risk of influenza related complications[14].

The Immunisation Guidelines for Ireland provide up to date information on contraindications and precautions for all influenza vaccines which you must be aware of and apply when deciding on a suitable vaccine. 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 HPRA's website provides product information for each vaccine.

Please note, in some circumstances, advice in the SmPC may differ from that in 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.

It should be noted that LAIV has a shelf life of 18 weeks, this is much shorter than the inactivated influenza vaccine. It should also be noted that the expiry date is day specific and may not be the last day of the month. The expiry date on all vaccines must always be checked prior to administration.

Appropriate training must be carried out to ensure best practice in administration technique[15]. The Immunisation Guidelines for Ireland[16] provide information on how to hold a child during intramuscular vaccine administration. The Guidelines[17], 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).

2.3.3 Required dose

Table 1 and Table 2 sets out the number of doses of influenza vaccine required for protection, which is dependent on age, whether the child is in an at risk group and whether they have had the influenza vaccine before.

Table 1: Dose of inactivated influenza vaccine[18] i.e. intramuscular injection

Age Group	Dose
Children aged 6 months to under 9 years of age	Two doses, 4 weeks apart, if: • receiving influenza vaccine for the first time or • vaccination history is unknown
Children aged 6 months to under 9 years of age	One dose, if: • previously received at least one dose of influenza vaccine in their lifetime
9 years of age and older	One dose

12 Chapter 11, Section 11.4.1 *Recommendations*; Immunisation Guidelines for Ireland: http://bit.ly/NIACGuideline.

13 See individual SmPC for licensed age for administration, as this can vary between products.

14 See Chapter 11, Section 11.4.1.2 (iii) for additional information.

15 You can enrol for relevant courses at www.iiop.ie.

16 Chapter 2, Section 2.7 *How to hold an infant or child during immunisations;* Immunisation Guidelines for Ireland: http://bit.ly/NIACGuideline.

17 Chapter 2, Section 2.8 *Pain reduction*; Immunisation Guidelines for Ireland: http://bit.ly/NIACGuideline.

18 Taken from Chapter 11, Table 11.1, Immunisation Guidelines for Ireland, which also provides additional information for a child who is post haematopoeitic stem cell transplant or post solid organ transplant or who is a cancer patient who receives the vaccine while on chemotherapy.

Table 2: Dose of live attenuated influenza vaccine (LAIV)[19] i.e. nasal spray suspension

Age Group	Dose
Children aged 2 to under 18 years of age	One dose
Children aged 2 to under 9 years of age in a clinically at-risk group[20]	Two doses*, 4 weeks apart, if: • receiving influenza vaccine for the first time, or • vaccination history is unknown

* If a second dose of vaccine is required and an in-date LAIV is not available, the QIV can be given for the second dose.

2.4 Post Vaccination Counselling

Before leaving the pharmacy, the child's parent/guardian should have received all necessary information and counselling, including whether they need to return for a second dose in 4 weeks' time, potential side effects, as set out in the Immunisation Guidelines for Ireland[21] and product's SmPC, and how these should be managed, the package leaflet from the vaccine and any other information material deemed necessary, e.g. information provided by the HSE. They should be given contact details for the pharmacy, and their contact details should be recorded in the patient medication record (PMR).

The parent/guardian can be informed that an age-appropriate dose of either paracetamol or ibuprofen may be considered for the treatment of a fever above 39^{O}C, for a significant reaction at the site of vaccination, or if a child remains significantly distressed[22].

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

2.5 Treating an Adverse Event in the Pharmacy

All pharmacists involved in the vaccination service must be competent to respond quickly and appropriately should an adverse event occur post-immunisation, particularly an event which requires the administration of epinephrine or the provision of basic life support to a child. All pharmacists must complete the 'Responding to an Emergency Situation including the Management of Anaphylaxis' training programme[23] as per the PSI training algorithm, in order to be able to deliver the vaccination service.

Remember that the dose of epinephrine needed is dependent on age (see Table 3). Adequate stock of epinephrine 150mcg, 300mcg or 500mcg injections, designated for emergency use only, must be maintained in the pharmacy. Where pharmacists ensure that a time interval of at least 20 minutes elapses between the administration of the vaccine to each patient, the pharmacy needs only to have sufficient stock of epinephrine injections for administration to one patient (per vaccinating pharmacist), i.e. at least three doses of the relevant strength of epinephrine in line with the Immunisation Guidelines for Ireland. In all other circumstances, there must be sufficient stock of epinephrine injections for administration to a minimum of two patients available.

19 Taken from Chapter 11, Table 11.2, Immunisation Guidelines for Ireland-note these recommendations differ from those in the SmPC for these vaccines.

20 See Chapter 11, Section 11.4.1.2

21 Chapter 11, Section 11.4.1 *Adverse reactions*; Immunisation Guidelines for Ireland: http://bit.ly/NIACGuideline.

22 Chapter 2, Section 2.9 A*ntipyretics and Vaccination*; Immunisation Guidelines for Ireland: http://bit.ly/NIACGuideline.

23 You can enrol for this course at www.iiop.ie.

Table 3: Dose of Epinephrine required for effective treatment of anaphylaxis[24]

Epinephrine 1:1000 (1mg/ml) IM	
0-5 years	0.15ml (150micrograms)
6-12 years	0.3ml (300 micrograms)
>12 years	0.5ml (500 micrograms)

Repeat dose every 5-10 minutes, up to 3 doses, and phone an ambulance immediately.

The *Anaphylaxis* chapter of the Immunisation Guidelines for Ireland provides a useful flow chart setting out anaphylaxis treatment in the community (including the dose of epinephrine needed per age category), as well as a suggested anaphylaxis kit that should be readily available and checked prior to each vaccination session.

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 *Section 2.8 Record Keeping* and *2.9 Post Vaccination Communication* of the PSI's Pharmacy Vaccination Guidance. 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 for vaccinating a child in the pharmacy relevant to the age limit, above 6 months of age, at which the pharmacy's vaccination service will be provided.

The SOPs should be reviewed regularly, in particular at the start of each new influenza season, to ensure that they are specific to each individual pharmacy and take account of the information set out in this guidance and best practice provided in the Immunisation Guidelines for Ireland, and by the National Immunisation Office[25].

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.

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1	July 2020

24 Chapter on *Anaphylaxis*; Immunisation Guidelines for Ireland: http://bit.ly/NIACGuideline.
25 www.immunisation.ie