



## Medicine Protocol for the Administration of Prevenar 13 vaccine (PCV13) by registered nurses and registered midwives to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak

This medicine protocol is a specific written instruction for the administration of Prevenar 13 vaccine (PCV13) to Refugees and Applicants Seeking Protection in Ireland (hereafter referred to as vaccine recipients) and in the event of an outbreak as advised by public health, by registered nurses and registered midwives. This medicine protocol is valid for the 2023/2024 Health Service Executive (HSE) Primary Childhood Immunisation Programme (PCIP), Schools Immunisation Programme (SIP) and National Immunisation Advisory Committee (NIAC) catch up Immunisation Programme, and in the event of an outbreak as advised by public health.

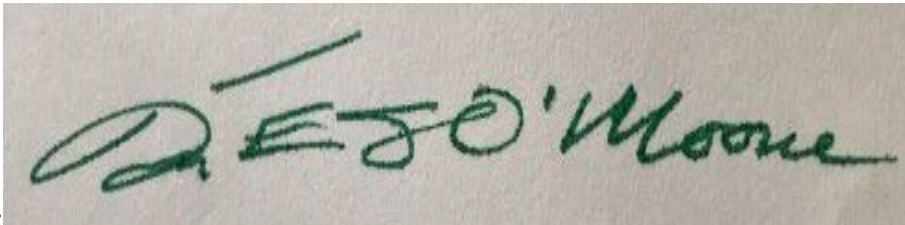

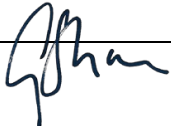
This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the HSE including Mass vaccination clinics who have undertaken the required education and training programmes to administer Prevenar 13 vaccine (PCV13) with reference to and guidance from Nursing & Midwifery Board of Ireland (NMBI), National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Prevenar 13 vaccine (PCV13) as detailed by the European Medicines Agency (EMA) at [www.ema.eu](http://www.ema.eu)

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management*. Dublin: An Bord Altranais
- National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community* available at: [https://rcpi.access.preservica.com/uncategorized/IO\\_a36f9e4b-4c80-432d-8264-546089359925/](https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/)
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: Royal College of Physicians of Ireland National Immunisation Advisory Committee available at: <https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland>
- National Immunisation Office (2023/2024) *Supporting Information for Staff: Schools Immunisation Programme* available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf>
- National Immunisation Office (2023) *Clinical information to support healthcare staff to deliver catch-up vaccination for Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak* available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/clinicalinfobotpipa.pdf>
- National Immunisation Office (2022) *Supporting Information for Vaccinations in General Practice* available at: <https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf>
- Nursing and Midwifery Board of Ireland (2021) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/NMBI/media/NMBI/Code-of-Professional-Conduct-and-Ethics.pdf>
- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration* available at: <https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf>
- Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/MidwivesStandards>
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice>
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/StandardsGuidance/Scope-of-Practice/Nursing-Practise-Scope-Definition>

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect” (An Bord Altranais, 2007).



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Document reference number	NIO 2023
<b>1.0 Critical elements</b>	
Name of Organisation where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the HSE including Mass vaccination clinics. This Medicine Protocol applies to: <ul style="list-style-type: none"><li>registered nurses and registered midwives employed in the voluntary and statutory services of the HSE including Mass vaccination clinics, congregated settings, temporary clinics and mobile units</li></ul>
Date the medicine protocol comes into effect	December 2023
Date for review of medicine protocol	December 2024
Document prepared by	National Immunisation Office (NIO) in collaboration with the Office of the Nursing and Midwifery Services Director (ONMSD) HSE.
Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol <i>“On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation”</i>	<p>Name: <b>Dr. Eamonn O’Moore</b> Director of National Health Protection</p>  <p>Signature: _____</p> <p>Name: <b>Dr Colm Henry</b>, Chief Clinical Officer, HSE</p>  <p>Signature: _____</p> <p>Name: <b>Dr Geraldine Shaw</b>, Nursing and Midwifery Services Director, HSE</p> 



**Medicine Protocol for the Administration of Prevenar 13 vaccine (PCV13) by registered nurses and registered midwives to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak**

	Signature: _____
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<b>2.0 Clinical Criteria</b>							
<b>Clinical condition for use of the medicine protocol</b>	The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of Pneumococcal disease caused by the serotypes included in the Prevenar 13 vaccine (PCV13).						
<b>Circumstances in which the medicine protocol applies</b>	To provide a Prevenar 13 vaccine (PCV13) to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak (hereafter referred to as vaccine recipients).						
<b>Inclusion criteria for vaccine recipient receiving Prevenar 13 vaccine (PCV13) under this medicine protocol</b>	<p><b>Primary immunisation</b> The primary schedule consists of 3 doses at 2, 6 and 13 months of age.</p> <p><b>For catch up programme</b> Unvaccinated children up to 2 years of age should be vaccinated as per the NIAC catch up schedule as below.</p> <table border="1"> <thead> <tr> <th>Vaccine</th> <th>4 months to &lt; 12 months</th> <th>1 to &lt; 2 years</th> </tr> </thead> <tbody> <tr> <td>PCV13</td> <td>2 doses ≥ 8 weeks apart</td> <td>1 dose</td> </tr> </tbody> </table> <p>Children who are aged 2yrs and above do not require PCV vaccine unless they are in “at risk group” as per the NIAC guidelines.</p> <p><b>Pneumococcal (PCV13) vaccination for those at increased risk of IPD</b> As advised by public health</p> <p><b>For outbreak response</b> As advised by public health</p> <p><b>Precautions</b></p> <ul style="list-style-type: none"> <li>• Acute severe febrile illness, defer until recovery</li> <li>• If Prevenar 13 vaccine (PCV13) vaccine is given to children aged 12-23 months of age, it should be separated from influenza vaccine by at least 1 week. This is because of a slightly increased risk of febrile convulsions if the vaccines are given at the same time in this age group.</li> <li>• If Prevenar 13 vaccine (PCV13) vaccine has been given during chemotherapy or radiotherapy, revaccination ≥3 months after treatment is recommended.</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• The presence of a minor infection such as a mild upper respiratory infection or low-grade fever is not a contraindication to immunisation.</li> <li>• COVID-19 vaccines (except for COVID-19 vaccine given to children aged 6 months 4 years where a 14-day interval is recommended) and other vaccines may be administered at the same time or at any interval.</li> <li>• For children aged 6 - &lt;24months, if PCV and seasonal Influenza Vaccine are given at the same time, Parent/Carers/legal Guardians should be advised of a small increased risk of fever and febrile convulsions. Separating the vaccines by <u>one week</u> may be advisable.</li> </ul>	Vaccine	4 months to < 12 months	1 to < 2 years	PCV13	2 doses ≥ 8 weeks apart	1 dose
Vaccine	4 months to < 12 months	1 to < 2 years					
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<b>Exclusion criteria for</b>	Anaphylaxis to any of the vaccine constituents						



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<p><b>vaccine recipients receiving Prevenar 13 vaccine (PCV13) under this medicine protocol</b></p>								
<p><b>Actions to be taken for those who are excluded from the medicine protocol</b></p>	<p>All vaccine recipients meeting exclusion criteria must be referred to the medical practitioner for an individual assessment.</p> <ul style="list-style-type: none"> <li>• Document action in clinical notes</li> <li>• Where Prevenar 13 vaccine (PCV13) is prescribed following medical assessment, the nurse or midwife may administer Prevenar 13 vaccine (PCV13) within their scope of practice.</li> </ul> <p><b>Note:</b> In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).</p>							
<p><b>Description of circumstances and referral arrangements when further advice or consultation is required</b></p>	<p>Discuss the vaccine recipient with the Medical Practitioner or clinical lead in the event of:</p> <ul style="list-style-type: none"> <li>• Adverse reaction</li> <li>• Other clinical concerns</li> </ul>							
<p><b>Documentation required to support implementation of the medicine protocol</b></p>	<p>A consent form must be completed by the parent /legal guardian for all children who receive the Prevenar 13 vaccine (PCV13) once understood and translation of consent is undertaken with support of translator if required. Appropriate details including the batch number must be recorded on the consent form.</p> <p>The following documents will be required at each vaccination session:</p> <ul style="list-style-type: none"> <li>• Vaccination session form</li> <li>• Blank vaccine consent forms</li> <li>• Vaccine Information Leaflets</li> <li>• Patient held record cards/ Vaccine passport</li> <li>• HPRA Adverse Reaction Reporting forms</li> <li>• HSE Incident/Near Miss Report Forms</li> <li>• Post vaccination advice</li> </ul> <p>It is the responsibility of each registered nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Prevenar 13 vaccine (PCV13) which includes the following:</p> <ul style="list-style-type: none"> <li>• Medicine Protocol for the administration of Prevenar 13 vaccine (PCV13) by registered nurses and registered midwives to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak</li> <li>• NIAC (2023) <i>Anaphylaxis: Immediate Management in the Community</i> available at: <a href="https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/">https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/</a></li> </ul>							
<p><b>3.0 Name of medicine</b></p>	<p>Prevenar 13 vaccine (PCV13)</p> <p><b>Dose:</b> 0.5ml</p> <p><b>Route:</b> Intramuscular injection</p> <table border="1" data-bbox="448 1834 1498 2125"> <thead> <tr> <th data-bbox="448 1834 799 1910">Patients Age</th> <th data-bbox="799 1834 1150 1910">Site</th> <th data-bbox="1150 1834 1498 1910">Needle length &amp; Size</th> </tr> </thead> <tbody> <tr> <td data-bbox="448 1910 799 2125">Birth to &lt;12 months</td> <td data-bbox="799 1910 1150 2125">Vastus lateralis muscle</td> <td data-bbox="1150 1910 1498 2125">25 mm (Use a 16 mm needle in infants under 2.5 - 3 kg)  23-25 gauge</td> </tr> </tbody> </table>		Patients Age	Site	Needle length & Size	Birth to <12 months	Vastus lateralis muscle	25 mm (Use a 16 mm needle in infants under 2.5 - 3 kg)  23-25 gauge
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	12 to <36 months	Vastus lateralis or deltoid muscle (depending on muscle mass)	25 mm 23-25 gauge
	3 years and older	Deltoid muscle	25 mm 23-25 gauge
<p><b>Link to Medicine</b> Details of product information and other data including instructions for supply and administration is available from the EMA at <a href="http://www.ema.eu">www.ema.eu</a></p>	<p><b>Link to Summary of Product Characteristics:</b> <a href="https://www.ema.europa.eu/en/documents/product-information/prevenar-13-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/prevenar-13-epar-product-information_en.pdf</a> <b>Link to Patient Information Leaflet:</b> <a href="https://www.ema.europa.eu/en/documents/product-information/prevenar-13-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/prevenar-13-epar-product-information_en.pdf</a></p>		
<p><b>Procedure for reporting and documentation of errors and near misses involving the medicine</b></p>	<p>In the case of medicine errors that directly involve the vaccine recipient, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the vaccine recipient and closely monitor them for any adverse reactions.</p> <p>Vital signs should be recorded and the vaccine recipient should be reviewed by the registered nurse/midwife and/or medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible. The incident and all actions taken must be promptly recorded in the recipient’s notes and the relevant National Incident Management Report Form completed: <a href="https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf">https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf</a></p> <p>For infant/child, their parent and/or legal guardian must be informed of the incident.</p> <p>Any suspected adverse reactions associated with medicine errors should be reported to the HPRA as outlined below.</p> <p>Any errors and near misses not involving medication e.g. needle stick injuries, the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager as per local policy. Refer to ‘EMI Tool Kit’ (<a href="https://www.hpsc.ie/a-z/EMIToolkit/">https://www.hpsc.ie/a-z/EMIToolkit/</a>)</p>		
<p><b>Procedure for reporting Adverse Drug Reactions to the HPRA</b></p>	<p>The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out online at <a href="https://www.hpra.ie">https://www.hpra.ie</a> or through use of the yellow card system which is available in the downloadable format from the HPRA website, or on request from the HPRA.</p>		
<p><b>Resources and equipment required for the administration of Prevenar 13 vaccine (PCV13)</b></p>	<ul style="list-style-type: none"> <li>• Prevenar 13 vaccine (PCV13)</li> <li>• Fridge/cooler box with minimum/maximum thermometer to maintain cold chain temperature between (+2° to +8°C)</li> <li>• Disposable kidney dishes/coloured trays</li> <li>• Gauze swabs/Plasters</li> </ul>		



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	<ul style="list-style-type: none"><li>• Sharps bins and bags for disposal of healthcare risk and non-risk waste materials</li><li>• Alcohol hand sanitiser</li><li>• Face masks (as per local guidelines)</li><li>• Access to telephone</li><li>• Resuscitation equipment and drugs in accordance with the NIAC (2023) <i>Anaphylaxis: Immediate Management in the Community</i> available at: <a href="https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/">https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/</a></li><li>• Access to medical support</li><li>• Safe storage areas for medicines and equipment</li><li>• Current medicine protocol for Prevenar 13 vaccine (PCV13).</li></ul>
<b>Audit process to identify appropriate use of the medicine protocol or unexpected outcomes</b>	All documentation will be held for review and audit purposes as per local policy.
<b>4.0 Information for vaccine recipient /parent/guardian</b>	
<b>Advice to be given to the vaccine recipient/parent/ legal guardian before treatment</b>	Reiterate the information provided in the HSE patient information leaflet for the vaccine in the appropriate language and translator support if required.  For children, Patient Information Leaflet/Fact Sheet must be supplied with the consent form to each parent/legal guardian prior to administration of the vaccine as above.
<b>Advice to be given to the vaccine recipient/parent/ legal guardian after treatment</b>	<b>After Treatment</b> The vaccine recipient must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife who is present.
<b>Details of any necessary follow-up, action and referral arrangements</b>	In the event of an adverse reaction the registered nurse or midwife must ensure that all procedures are adhered to as outlined in Section 3.
<b>5.0 Staff authorised to use this medicine protocol</b>	
<b>Professional qualifications, training, experience and competence required prior to working under this medicine protocol</b>	Registered nurse or registered midwife must have completed all of the following:  1) Be a Registered Nurse or Registered Midwife, on the active register maintained by the NMBI  2) <i>Immunisation Foundation Programme</i> accessible on <a href="http://www.HSELand.ie">www.HSELand.ie</a>  3) Education programme for nurses and midwives on <i>Primary Childhood Immunisation Programme</i> and any updates for nurses and midwives accessible on <a href="http://www.HSELand.ie">www.HSELand.ie</a>  4) Education programme for nurses and midwives on <i>Schools Immunisation Programme</i> and any updates for nurses and midwives accessible on <a href="http://www.HSELand.ie">www.HSELand.ie</a>  5) NIO education programme on <i>Catch up vaccination for Refugees and Applicants Seeking Protection in Ireland</i> accessible on <a href="http://www.HSELand.ie">www.HSELand.ie</a>  6) An approved <i>Basic Life Support for Health Care Providers Course</i> within the last two years (i.e. Irish Heart Foundation (IHF))  7) Initial <i>National Anaphylaxis Education Programme for Health Care Professionals</i> accessible on <a href="http://www.HSELand.ie">www.HSELand.ie</a> followed by a two hour classroom based skills workshop. Recertification is required every two years by completing the on-line <i>National Anaphylaxis Education</i>



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Programme for Health Care Professionals accessible on [www.HSEIreland.ie](http://www.HSEIreland.ie)

8) The registered nurse/midwife must complete the Competency Self-Assessment Form to vaccinate\* Refugees and Applicants Seeking Protection in Ireland \*Health Service Executive (HSE) Primary Childhood Immunisation Programme (PCIP), Schools Immunisation Programmes (SIP) and the National Immunisation Advisory Committee (NIAC) Catch Up Immunisation Programme available at [www.immunisation.ie](http://www.immunisation.ie).

### References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management*. Dublin: An Bord Altranais

Health Products Regulatory Authority available at: [www.hpra.ie](http://www.hpra.ie)

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)

<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community* available at: [https://rcpi.access.preservica.com/uncategorized/IO\\_a36f9e4b-4c80-432d-8264-546089359925/](https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/)

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: Royal College of Physicians of Ireland National Immunisation Advisory Committee available at: <https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland>

National Immunisation Office (2023/2024) *Supporting Information for Staff: Schools Immunisation Programme* available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf>

National Immunisation Office (2023) Clinical information to support healthcare staff to deliver catch-up vaccination for Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/clinicalinfobotpipa.pdf>

National Immunisation Office (2022) *Supporting Information for Vaccinations in General Practice* available at: <https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf>

Nursing and Midwifery Board of Ireland (2021) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Code>

Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Registered Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020>

Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives* Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Midwives-Standards>

Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Scope-ofPractice/Nursing-Practise-Scope-Definition>

Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives*.



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Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice>

Pfizer Prevenar 13 vaccine (PCV13) *Summary of Product Characteristics and Patient Information Leaflet*, available at [www.ema.eu](http://www.ema.eu)