



## Medicine Protocol for the administration of Nimenrix (MenACWY) vaccine by registered nurses and registered midwives to students in primary/second level school through a School Immunisation Programme.

This medicine protocol is a specific written instruction for the administration of Nimenrix (MenACWY) Vaccine to students in second level school by registered nurses and registered midwives. This medicine protocol is valid for the 2023/2024 Health Service Executive (HSE) School Immunisation Programme (SIP).


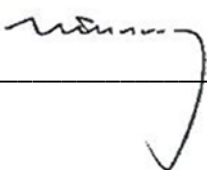

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Nimenrix (MenACWY) vaccine with reference to and guidance from Nursing & Midwifery Board of Ireland (NMBI), National Nursing and Midwifery Immunisation Working Group, National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Nimenrix (MenACWY) vaccine as detailed by the European Medicines Agency (EMA) at <https://www.ema.europa.eu/en/medicines>

- 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://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 Office (2023/2024) *Supporting Information for Staff: Schools Immunisation Programme* available at:  
<https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.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>
- 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/nmbi/media/NMBI/Publications/Scope-of-Nursing-Midwifery-Practice-Framework.pdf?ext=.pdf>

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)

**Medicine Protocol for the administration of Nimenrix (MenACWY) vaccine by registered nurses and registered midwives to students in primary/second level school through a School Immunisation Programme**

Document reference number	ONMSD 2023-002
<b>1.0 Critical Elements</b>	
Name of Organisation where protocol applies	Health Service Providers across the voluntary and statutory services of the HSE. This Medicine Protocol applies to: Registered nurses and midwives involved in the supply and administration of the Nimenrix (MenACWY) vaccine to students in second level school through a School Immunisation Programme.
Date the protocol comes into effect	September 2023 (For the school year September 2023 to 2024)
Date for review of protocol	May 2024
Document prepared by	Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration NIO at the request of Dr Éamonn O’Moore, Director of National Health Protection.
<p><b>Names and Signatures of the employing authority who is authorising the implementation of the protocol</b></p> <p><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>	<p>Name: <b>Dr Éamonn O’ Moore</b>, Director of National Health Protection, HSE</p> <p style="text-align: center;"></p> <p>Signature: _____</p> <p>Name: <b>Dr Colm Henry</b>, Chief Clinical Officer, HSE</p> <p style="text-align: center;"></p> <p>Signature: _____</p> <p>Name: <b>Dr Geraldine Shaw</b>, Nursing and Midwifery Services Director, HSE</p> <p style="text-align: center;"></p> <p>Signature: _____</p>

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<b>2.0 Clinical Criteria</b>	
<b>Clinical condition for use of the protocol</b>	The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of Meningococcal Group ACWY (Men ACWY) disease.
<b>Circumstances in which the medicine protocol applies</b>	<p>The School Immunisation Programme (SIP) will be delivered annually by the HSE.</p> <p>The aim of this immunisation programme is to protect children against four types of meningococcal disease which can cause meningitis (inflammation of the lining around the brain) and /or septicaemia (blood poisoning).The Meningococcal ACWY vaccine will boost child’s protection against group C meningococcal disease. It will also provide additional protection against meningococcal groups A, W and Y. In addition, this vaccine also reduces the risk of carrying the disease so can help protect other people too.</p> <p>The Nimenrix (MenACWY) vaccine is given as a vaccination for first year students in second level schools (or age equivalent)</p> <p><a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/">https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/</a></p>
<b>Inclusion criteria for students receiving the vaccine under the medicine protocol.</b>	<p>Students in first year of second level school and age equivalent in special schools and home schooled students.</p> <p><a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/">https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/</a></p> <p>Students with valid consent.</p> <p>If Men C vaccine has recently been received, defer Nimenrix (MenACWY) vaccine until at least 2 months after Men C vaccine.</p>
<b>Exclusion criteria for students receiving the vaccine under the medicine protocol.</b>	<p>A known history of anaphylactic or hypersensitivity reaction to Nimenrix (MenACWY) vaccine or any of its components including Sucrose and Trometamol.</p> <p>Already received a dose of conjugated Nimenrix (MenACWY) vaccine at the age of 10 years or older.</p> <p><b>Precaution</b></p> <ul style="list-style-type: none"> <li>• Acute severe febrile illness, defer until recovery</li> </ul> <p><b>Note:</b> The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation.</p> <p><b>Note:</b> COVID-19 vaccines and other vaccines may be administered at the same time or at any interval.</p>
<b>Actions to be taken for those who are excluded from the Protocol</b>	<ul style="list-style-type: none"> <li>• All students meeting exclusion criteria must be referred to the medical practitioner for an individual assessment, except where excluded due to receipt of Nimenrix (MenACWY) vaccine at 10 years or older who therefore do not require further vaccination.</li> <li>• Document action in clinical notes</li> <li>• Where Nimenrix (MenACWY) vaccine is prescribed following medical assessment, the nurse or midwife may administer Nimenrix (MenACWY) vaccine within their scope of practice.</li> </ul>

	<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).
<b>Description of circumstances and referral arrangements when further advice or consultation is required</b>	Discuss the student with the Medical Practitioner or lead nurse in the event of: <ul style="list-style-type: none"> <li>• Previous adverse reaction</li> <li>• Other clinical concerns</li> </ul>

<b>Documentation required for the implementation of this medicine protocol</b>	<p>Consent form must be completed by the parent/legal guardian for all students who receive the vaccine. Appropriate details including the batch number must be recorded on the consent form following vaccination.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> <li>• Vaccination session report forms</li> <li>• Blank Vaccine consent forms</li> <li>• Vaccination 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>• Tear pads post vaccination and advice</li> </ul> <p>It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Nimenrix (MenACWY) vaccine which includes the following:</p> <ul style="list-style-type: none"> <li>• Supporting Information for Staff: SIP 2023/2024</li> <li>• Medicine Protocol for the administration of Nimenrix (MenACWY) vaccine</li> <li>• NIAC (2023) Anaphylaxis: Immediate Management in the Community</li> </ul> <p><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></p>
<b>3.0 Name of Medicine</b>	<p>Nimenrix (MenACWY) Vaccine</p> <p><b>Dose:</b> 0.5ml</p> <p><b>Route:</b> Intramuscular injection</p> <p><b>Site:</b> Deltoid (Right arm recommended)</p> <p><b>Vaccine must be reconstituted</b></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.ie">www.ema.ie</a>	<p><b>Link to Summary of Product Characteristics and Patient Information Leaflet:</b></p> <p><a href="https://www.ema.europa.eu/en/documents/product-information/nimenrix-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/nimenrix-epar-product-information_en.pdf</a></p>

<p><b>Procedure for reporting and documentation of errors and near misses involving the medication</b></p>	<p>In the case of medication errors that directly involve the student, i.e. wrong medication/patient/dose/route being administered or another medication error, the registered nurse or registered midwife must remain with the student and closely monitor them for any adverse reactions.</p> <p>Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible.</p> <p>The incident and all actions taken must be promptly recorded 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>The student’s parent and/or legal guardian must be informed of the incident. Any suspected adverse reactions associated with medication errors must be reported to the HPRA as outlined below.</p> <p>Any errors and near misses not involving medication, (i.e. needle stick injury) 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 ‘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 Health Products Regulatory Authority (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 on-line 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</b></p>	<ul style="list-style-type: none"> <li>• Nimenrix (MenACWY) Vaccine</li> <li>• Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C)</li> <li>• Vaccination cool packs</li> <li>• Disposable kidney dishes/coloured trays</li> <li>• Gauze swabs/Plasters</li> <li>• Sharps bins and bags for disposal of healthcare risk and non-risk waste material</li> <li>• HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022). <a href="https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management-of-sharps-and-prevention-of-sharp-injuries.pdf">https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management-of-sharps-and-prevention-of-sharp-injuries.pdf</a></li> <li>• Alcohol hand sanitizer</li> <li>• Face masks</li> <li>• Access to telephone</li> <li>• NIAC (2023) Anaphylaxis: Immediate Management in the Community <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> </ul>

	<ul style="list-style-type: none"> <li>• Current medicine protocol for Nimenrix (MenACWY) vaccine.</li> </ul>
<b>Audit process to identify appropriate use of the protocol or unexpected outcomes</b>	All documentation will be held for review and audit purposes as per local policy.

#### 4.0 Information for Student/Parent/ Legal Guardian

<b>Advice to be given to the student/parent/legal guardian before treatment</b>	HSE first year vaccination programme information leaflet must have been supplied with the consent form to each student/parent/legal guardian prior to administration of the vaccine.
<b>Advice to be given to the student/parent/guardian after treatment</b>	<p><b>After Treatment</b></p> <p>An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/guardian's attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination.</p> <p>The student 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.</p>

#### 5.0 Staff authorised to use this medicine protocol

<b>Professional qualifications, training, and competence required prior to using this medicine protocol</b> <b>Professional Qualifications</b>	<p>Registered nurse or registered midwife must have completed all of the following:</p> <ol style="list-style-type: none"> <li>1. Be a Registered Nurse or Registered Midwife, on the active register maintained by the NMBI</li> <li>2. Education programme for nurses and midwives on <i>School Immunisation Programme</i> and any updates for nurses and midwives accessible on <a href="http://www.HSELand.ie">www.HSELand.ie</a></li> <li>3. An approved <i>Basic Life Support for Health Care Providers Course</i> within the last two years (i.e. Irish Heart Foundation (IHF))</li> <li>4. 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 Programme for Health Care Professionals</i> accessible on <a href="http://www.HSELand.ie">www.HSELand.ie</a></li> <li>5. Immunisation Foundation Programme: accessible on <a href="http://www.HSELand.ie">www.HSELand.ie</a></li> <li>6. The registered nurse/midwife must complete the Competency Self-Assessment Form available at <a href="http://www.immunisation.ie">www.immunisation.ie</a></li> </ol>
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## References

European Medicines Agency available at: [www.ema.ie](http://www.ema.ie)

Health Service Executive (2010) Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste. Dublin: Health Service Executive.

HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022).

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 Consent Policy (2022)

<https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/hse-national-consent-policy.pdf>

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<https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice>

Pfizer Nimenrix (MenACWY) *Summary of Product Characteristics and Patient Information Leaflet*, available at: [www.hpra.ie](http://www.hpra.ie)