



## **Medicine Protocol for the Administration of Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) 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 Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) to refugees and applicants seeking protection in Ireland (hereafter referred to as vaccine recipients aged 16 years and above) in the event of an outbreak by registered nurses and registered midwives. This medicine protocol is valid for the 2025/2026 Health Service Executive (HSE) vaccination programme in the event of an outbreak as advised by public health.


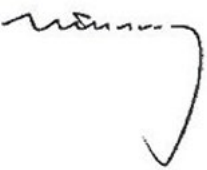

This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the HSE including HSE community vaccination clinics who have undertaken the required education and training programmes to administer Havrix Monodose Vaccine, (Hepatitis A Vaccine (inactivated, adsorbed)) with reference to and guidance from the 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 Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) as detailed by the Health Products Regulatory Authority (HPRA) at [www.hpra.ie](http://www.hpra.ie)

- 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://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/anaphylaxis>
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* available at: <https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland>
- National Immunisation Office (2025) *Children Who Have Come To Ireland From Another Country: Information For Healthcare Professionals On Catch-Up Vaccination* available at <https://www.hse.ie/eng/health/immunisation/hcinfo/botpipa/hcwcatchupothercountries.pdf>
- National Immunisation Office (2025/2026) *Supporting Information for Staff: Schools Immunisation Programme* available at: <https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/supportingdoc-2025.pdf>
- National Immunisation Office (2025) *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 (2025) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives incorporating the Scope of Practice and Professional Guidance*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Code-of-Professional-Conduct-and-Ethics.pdf?ext=.pdf>
- 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.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/NMBI/media/NMBI/NMBI-Practice-Standards-for-Midwives.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 registered nurse or midwife in identified clinical situations. A medication protocol involves the authorisation of the nurse or midwife to supply and administer a medication to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment (An Bord Altranais, 2007, page 37).



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<b>Document reference number</b>	Version4-NIO-HepA-November 2025
<b>1.0 Critical elements</b>	
<b>Name of organisation /setting where medicine protocol applies</b>	Health Service Providers across the voluntary and statutory services of the HSE including HSE community 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 HSE community vaccination clinics, congregated settings, temporary clinics and mobile units</li></ul>
<b>Date the medicine protocol comes into effect</b>	November 2025
<b>Date for review of medicine protocol</b>	November 2026
<b>Document prepared by</b>	National Immunisation Office (NIO) in collaboration with the Office of the Nursing and Midwifery Services Director (ONMSD) HSE.
<b>Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol</b>  <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. Éamonn O 'Moore</b>, Director of National Health Protection, HSE</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> <p> Signature: _____</p>



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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 Hepatitis A virus infection.
<b>Circumstances in which the medicine protocol applies</b>	Active immunisation with Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) for vaccine recipients aged 16 years and above and in the event of an outbreak as advised by public health (hereafter referred to as vaccine recipients). It applies to those <b>aged 16 years and older</b> at-risk of Hepatitis A infection (See Section 8.5 of NIAC Immunisation Guidelines for Ireland), close contacts of cases of Hepatitis A virus infection, or in the case of an outbreak identified by public health as part of outbreak management.
<b>Inclusion criteria for vaccine recipients receiving Havrix Monodose Vaccine (Hepatitis A Vaccine) under this medicine protocol</b>	<p>For those aged 16 years and above</p> <p><b>Precautions</b></p> <ul style="list-style-type: none"><li>• Acute severe febrile illness, defer until recovery</li><li>• All monocomponent Hepatitis A vaccines contain phenylalanine, which may be harmful to patients that have phenylketonuria (PKU)</li></ul> <p><u>Pregnancy</u></p> <p>Hepatitis A Virus (HAV) containing vaccines may be given to pregnant women if clinically indicated. Safety data in pregnant women are not available, but the risk is considered to be low or non-existent because the vaccines contain inactivated purified viral proteins.</p> <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>
<b>Exclusion criteria for vaccine recipients receiving Havrix Monodose Vaccine (Hepatitis A Vaccine) under this medicine protocol</b>	<ul style="list-style-type: none"><li>• A known history of anaphylaxis to Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) or to any of its constituents</li></ul>
<b>Actions to be taken for those who are excluded from the medicine protocol</b>	<p>All recipients meeting exclusion criteria must be referred to the clinical lead for an individual clinical assessment.</p> <ul style="list-style-type: none"><li>• Document action in clinical notes</li><li>• Where Havrix Monodose Vaccine, (Hepatitis A Vaccine (inactivated, adsorbed)) is prescribed following clinical assessment, the registered nurse or registered midwife may administer Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) within their scope of practice.</li></ul> <p><b>Note:</b> In determining their scope of practice, registered nurses and midwives must make judgements about their competence to carry out a role or activity (NMBI, 2025).</p>
<b>Description of circumstances and referral arrangements when further advice or consultation is required</b>	<p>Discuss the vaccine recipient with the Clinical lead in the event of:</p> <ul style="list-style-type: none"><li>• Previous severe adverse reaction</li><li>• Other clinical concerns</li></ul>
<b>Documentation required for the implementation of this medicine protocol</b>	<p>Young people aged 16 years and over consent on their own behalf as per the HSE National Consent Policy (2022). Informed consent should be obtained prior to vaccination once understood and translation of consent is undertaken with support of translator if required. Relevant details including the batch number of the vaccine 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>• Vaccine Information Leaflets</li><li>• Patient held record cards/vaccine passport</li></ul>



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	<ul style="list-style-type: none"> <li>Post vaccination advice should be provided</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 Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) which includes the following:</p> <ul style="list-style-type: none"> <li>This medicine protocol</li> <li>NIAC (2023) <i>Anaphylaxis: Immediate Management in the Community</i> available at: <a href="https://www.higa.ie/reports-and-publications/niac-immunisation-guideline/anaphylaxis">https://www.higa.ie/reports-and-publications/niac-immunisation-guideline/anaphylaxis</a></li> </ul>
<b>3.0 Name of medicine</b>	<p>Havrix Monodose Vaccine Hepatitis A Vaccine (inactivated, adsorbed) 1440 ELISA units/1 ml Suspension for Injection in a pre-filled syringe <b>Dose:</b> 1 ml The recommended schedule is two doses, 6 -12 months apart <b>Route:</b> Intramuscular Injection <b>Site:</b> Deltoid muscle</p>
<b>Link to Medicine</b> <b>Details of product information and other data including instructions for supply and administration is available from the HPRA at <a href="http://www.hpra.ie">www.hpra.ie</a></b>	<p>Link to Summary of Product Characteristics: <a href="https://assets.hpra.ie/products/Human/24462/Licence_PA1077-026-002_21032025145112.pdf">https://assets.hpra.ie/products/Human/24462/Licence_PA1077-026-002_21032025145112.pdf</a> Link to Patient Information Leaflet: <a href="https://assets.hpra.ie/products/Human/24462/562c4212-fc90-411a-a637-f6c7cc7f9df8.pdf">https://assets.hpra.ie/products/Human/24462/562c4212-fc90-411a-a637-f6c7cc7f9df8.pdf</a></p>
<b>Procedure for the reporting and documentation of errors and near misses involving the vaccine</b>	<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 clinical lead.</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 vaccine recipients documentation/notes and the relevant National Incident Management Report Form completed, available at: <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> 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 medications (Needle stick injuries etc.), 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.</p>
<b>Procedure for reporting Adverse Drug Reactions to the HPRA</b>	<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></p>
<b>Resources and equipment required for the administration of Havrix Monodose Vaccine (Hepatitis A Vaccine)</b>	<ul style="list-style-type: none"> <li>Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed))</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>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 material</li> <li>Alcohol hand sanitiser</li> <li>Handwashing facilities</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://www.higa.ie/reports-and-publications/niac-immunisation-guideline/anaphylaxis">https://www.higa.ie/reports-and-publications/niac-immunisation-guideline/anaphylaxis</a></li> <li>Safe storage areas for medicines and equipment</li> <li>Current medicine protocol for Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)).</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</b>	
<b>Advice to be given to the vaccine recipient before treatment</b>  <b>Advice to be given to the vaccine recipient after treatment</b>	<p>Patient Information Leaflet/Fact Sheet <b>must</b> be supplied with the consent form to vaccine recipient prior to administration of the vaccine. Reiterate the information provided in the HSE patient information leaflet for the vaccine in the appropriate language and translator support if required.</p> <p><b>After Treatment</b></p> <p>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.</p>
<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 and competence required prior to using this medicine protocol</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) <i>Primary Childhood Immunisation Programme</i> accessible on <a href="http://www.HSeLanD.ie">www.HSeLanD.ie</a></li> <li>3) Education programme for nurses and midwives on <i>National Vaccination Education Programme for Registered Nurses/Midwives/Public Health Nurses: 2025/2026</i> and any updates for nurses and midwives accessible on <a href="http://www.HSeLanD.ie">www.HSeLanD.ie</a></li> <li>4) 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>5) 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>6) Children having vaccinations and healthcare procedures: Clinical Holding (Professor Lucy Bray/ONMSD, 2023) available at <a href="http://www.HSeLanD.ie">www.HSeLanD.ie</a></li> </ol> <p>The registered nurse/midwife must complete the Competency Self-Assessment Form to vaccinate Refugees and Applicants Seeking Protection in Ireland available at <a href="http://www.immunisation.ie">www.immunisation.ie</a></p>



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### References

GlaxoSmithKline (Ireland) Limited Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) *Summary of Product Characteristics and Patient Information Leaflet*, available at [www.hpra.ie](http://www.hpra.ie)

HSE National Policy on the Management of Sharps and Prevention of Sharp Injuries (2025), available at: <https://www2.healthservice.hse.ie/files/191/>

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC), available at: <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://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/anaphylaxis>

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* available at: <https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland>

National Immunisation Office (2025/2026) *Supporting Information for Staff: Schools Immunisation Programme* available at: <https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/supportingdoc-2025.pdf>

National Immunisation Office (2025) *Children Who Have Come To Ireland From Another Country: Information For Healthcare Professionals On Catch-Up Vaccination* available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/hcwcatchupothercountries.pdf>

National Immunisation Office (2025) *Supporting Information for Vaccinations in General Practice* available at: <https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf>

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