



Medicine Protocol for the Administration of REVAXIS (Td/IPV) (Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)) 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 REVAXIS (Td/IPV), to Refugees and Applicants Seeking Protection in Ireland (hereafter referred to as vaccine recipients) and in the event of an outbreak by registered nurses and registered midwives. This medicine protocol is valid for the 2024/2025 Health Service Executive (HSE) Schools Immunisation Programme (SIP) and for National Immunisation Advisory Committee (NIAC) recommended catch up immunisation and in the event of an outbreak as advised by public health.


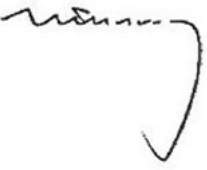

This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the HSE including HSE community vaccination clinics who have undertaken the required education and training programmes to administer REVAXIS (Td/IPV) , with reference to and guidance from Nursing & Midwifery Board of Ireland (NMBI), National Immunisation Working Group, National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for REVAXIS (Td/IPV) vaccine as detailed by the Health Products Regulatory Authority (HPRA) at www.hpra.ie

- 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/
- 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 (2024/2025) *Supporting Information for Staff: Schools Immunisation Programme* available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf>
- National Immunisation Office (2024) *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 (2024) *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/NMBI/media/NMBI/NMBI-Practice-Standards-for-Midwives.pdf?ext=.pdf>
- 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/nmbi/media/NMBI/Publications/recording-clinical-practice-professional-guidance.pdf?ext=.pdf>
- 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 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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| Document reference number | Version3-NIO-TdIPV-December 2024 |
| 1.0 Critical Elements | |
| Name of Organisation /Setting where medicine protocol applies | 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">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 |
| Date the medicine protocol comes into effect | December 2024 |
| Date for review of medicine protocol | December 2025 |
| Document prepared by | HSE 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> | Name: Dr. Eamonn O’Moore , Director of National Health Protection, HSE Signature:  Name: Dr Colm Henry , Chief Clinical Officer, HSE Signature:  Name: Dr Geraldine Shaw , Nursing and Midwifery Services Director, HSE Signature:  |



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| 2.0 Clinical Criteria | |
| Clinical condition for use of the medicine protocol | The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of diphtheria, tetanus and poliomyelitis (polio) disease. |
| Circumstances in which the medicine protocol applies | To provide REVAXIS (Td/IPV) 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. |
| Inclusion criteria for vaccine recipients receiving the REVAXIS (Td/IPV) (Diphtheria, tetanus and poliomyelitis (inactivated) vaccine under this medicine protocol | <p>For catch-up vaccine in those aged 10 years of age and older with no history of receipt of the recommended course of these antigens previously.</p> <ol style="list-style-type: none"> 1. First give a Tdap vaccine x1 2. Followed by REVAXIS (Td/IPV) x 3 at ≥ 4 weeks apart (Leave a 4 week gap after Tdap vaccine) <p>For outbreak response: As advised by public health</p> <p>Precautions</p> <ul style="list-style-type: none"> • Acute severe febrile illness, defer until recovery • Type III (Arthus) hypersensitivity reaction to a previous dose (see adverse reactions in NIAC Chapter 6). Persons experiencing these reactions usually have very high serum diphtheria or tetanus antitoxin levels; they should not be given further routine or emergency booster doses of tetanus or diphtheria containing vaccines more frequently than every 10 years. <p>Note: COVID-19 vaccines and other vaccines may be administered at the same time or at any interval.</p> |
| Exclusion criteria for vaccine recipients receiving the REVAXIS (Td/IPV) (Diphtheria, tetanus and poliomyelitis (inactivated) vaccine under this medicine protocol | <ul style="list-style-type: none"> • A known history of anaphylactic or hypersensitivity reaction to REVAXIS (Td/IPV) or any of the vaccine's constituents. |
| Actions to be taken for those who are excluded from the medicine protocol | <p>All vaccine recipients meeting exclusion criteria must be referred to the clinical lead for an individual clinical assessment.</p> <ul style="list-style-type: none"> • Document action in clinical notes • Where REVAXIS (Td/IPV) is prescribed following clinical assessment, the nurse or midwife may administer REVAXIS (Td/IPV) within their scope of practice. <p>Note: 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> |
| Description of circumstances and referral arrangements when further advice or consultation is required | <p>Discuss the vaccine recipient with the clinical lead in the event of:</p> <ul style="list-style-type: none"> • Previous adverse reaction • Other clinical concerns |
| Documentation required for the implementation of this medicine protocol | <p>A consent form must be completed by the parent/legal guardian for all children who receive the REVAXIS (Td/IPV) vaccine. Children aged 16 years and over consent on their own behalf, 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> |



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| | <ul style="list-style-type: none"> • Vaccination session report form • Blank vaccine consent forms • Vaccine Information Leaflets • Patient held record cards/ Vaccine passport • HPRA Adverse Reaction Reporting forms • HSE Incident/near miss report forms • Post vaccination advice <p>It is the responsibility of each registered nurse or midwife to be familiar with the appropriate documentation to support the safe administration of REVAXIS (Td/IPV) which includes the following:</p> <ul style="list-style-type: none"> • Medicine Protocol for the administration of REVAXIS (Td/IPV) (Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)) by registered nurses and midwives to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak • NIAC (2023) <i>Anaphylaxis: Immediate Management in the Community</i> available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ |
| <p>3.0 Name of Medicine</p> | <p>REVAXIS, Suspension for injection in pre-filled syringe Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) Dose: 0.5ml</p> <p>Route: Intramuscular injection</p> <p>Site: Deltoid muscle</p> |
| <p>Link to Medicine</p> <p>Details of product information and other data including instructions for supply and administration is available from the HPRA at www.hpra.ie</p> | <p>Link to Summary of Product Characteristics: https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2131-007-001_13042023121308.pdf</p> <p>Link to Patient Information Leaflet: http://www.hpra.ie/img/uploaded/vaccines/PIL_PA2131007001.pdf</p> |
| <p>Procedure for the reporting and documentation of errors and near misses involving the medicine</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 documentation/notes and the relevant National Incident Management Report Form completed: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf</p> <p>For children, the child's 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 medications/not directly involving the vaccine recipient (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. Refer to https://www.hpsc.ie/a-z/emi/algorithms/EMISharpsAlgo.pdf</p> |



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www.HSELand.ie

- 4) An approved *Basic Life Support for Health Care Providers Course* within the last two years (i.e. Irish Heart Foundation (IHF))
- 5) Initial *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELand.ie followed by a two hour classroom based skills workshop. Recertification is required every two years by completing the on-line *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELand.ie
- 6) Children having vaccinations and healthcare procedures: Clinical Holding (Professor Lucy Bray/ONMSD, 2023) available at www.HSELand.ie
- 7) 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



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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

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/

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 (2024/2025) *Supporting Information for Staff: Schools Immunisation Programme* available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf>

National Immunisation Office (2024) 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>

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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>

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Sanofi Pasteur REVAXIS (Td/IPV) *Summary of Product Characteristics and Patient Information Leaflet*, available at www.hpra.ie