Medicine Protocol for the Administration of Tetravac (Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine, (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 Tetravac 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 2025/26 Health Service Executive (HSE) Primary Childhood Immunisation Programme (PCIP), Schools Immunisation Programme (SIP) and for National Immunisation Advisory Committee (NIAC) recommended catch up vaccination programme/s 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 Tetravac, 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 Tetravac vaccine as detailed by the Health Products Regulatory Authority (HPRA) at 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/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland
- 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/hcpinfo/botpipa/hcwcatchupothercountries.pdf
- National Immunisation Office *Supporting Information for Staff: Schools Immunisation Programme 2025/2026* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.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).

Document reference number	Version4-NIO-DTap/IPV-September 2025
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: • 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	September 2025
Date for review of medicine protocol	September 2026
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 ***"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"***	Name: **Dr Éamonn O'Moore,** Director of National Health Protection Signature:_____ _____ Name: **Dr Colm Henry**, Chief Clinical Officer, HSE Signature: Name: **Dr Geraldine Shaw**, Nursing and Midwifery Services Director, HSE Signature: _____

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, pertussis (whooping cough) and poliomyelitis (polio) disease.
Circumstances in which the medicine protocol applies	To provide Tetravac to vaccine recipients as recommended in the Immunisation Guidelines for Ireland, or in the event of an outbreak as advised by public health.
Inclusion criteria for vaccine recipients receiving Tetravac (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine using this medicine protocol	• **Primary childhood immunisation for children born on or after October 2024:** If the third dose of 6 in 1 vaccine is delayed to 12 months or more, the 4th 6 in 1 which is recommended at 13 months in the schedule, should be replaced by the Tetravac. The Tetravac should be given after an interval of 6 months after the 3rd dose of the 6 in 1 vaccine has been administered • To provide catch up vaccine for Inactivated Poliovirus Vaccine (IPV) as Tetravac for those coming to Ireland, from countries using Oral Poliovirus Vaccine (OPV), **vaccinated since April 2016** • A booster dose of Tetravac is recommended at 4-5 years of age (usually given in junior infants) • There should be an interval of at least 6 months between booster doses of Tetravac and the completion of a primary course of DTaP containing vaccines (i.e. 6 in 1 vaccine) • Tetravac can be given at any interval following an inappropriately administered Tetanus and diphtheria (Td) vaccine as per the NIAC guidelines • Children who have received four doses of diphtheria, pertussis, polio and tetanus vaccines before the age of 3 yrs and 4 months should receive a Tetravac booster at least 6 months after the 4th dose. **Catch-up vaccination and outbreak response:** **This vaccine is not recommended for those aged 10 years and olde**r. (See NIAC chapter 2 Table 2.4a regarding immunisation schedule of those aged 10 years and older) **Precautions** • 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. **Note:** COVID-19 vaccines (except for COVID-19 vaccine given to children aged 6 months to 4 years where a 14-day interval is recommended) and other vaccines may be administered at the same time or at any interval.

Exclusion criteria for vaccine recipients receiving Tetravac (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine under this medicine protocol	• Children under 10 years of age who have not commenced a primary immunisation course of DTaP containing vaccines • Children aged 10 years and above should not receive Tetravac. Refer to the NIAC Chapter 2 Table 2.4. • Previous Anaphylactic reaction to any of the vaccine constituents.
Actions to be taken for those who are excluded from the medicine protocol	All recipients meeting exclusion criteria must be referred to the clinical lead for an individual clinical assessment. • Document action in clinical notes • Where Tetravac vaccine is prescribed following clinical assessment, the registered nurse or midwife may administer Tetravac vaccine within their scope of practice. **Note**: In determining their scope of practice, registered nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2025).
Description of circumstances and referral arrangements when further advice or consultation is required	Discuss the vaccine recipient with the clinical lead in the event of: • Previous adverse reaction • Other clinical concerns
Documentation required for the implementation of this medicine protocol	A consent form must be understood and completed by the parent /legal guardian for children who receive the Tetravac vaccine. Translation of consent is undertaken with support of translator if required. Relevant details including the batch number must be recorded on the consent form. The following documents will be required at each vaccination session: • Vaccination session form • Blank vaccine consent forms • Vaccine Information Leaflets • Patient held record cards /vaccine passport • Post vaccination advice should be provided. It is the responsibility of each registered nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Tetravac which includes the following: • This medicine protocol • NIAC (2023) *Anaphylaxis: Immediate Management in the Community* available at: https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland
3.0 Name of Medicine	Tetravac, suspension for injection in prefilled syringe Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine, (adsorbed). **Dose:** 0.5 ml **Route:** Intramuscular injection **Site:** Deltoid muscle (left arm recommended)

Link to Medicine **Details of product information and other data including instructions for supply and administration is available from the HPRA at www.hpra.ie**	**Link to Summary of Product Characteristics:** https://assets.hpra.ie/products/Human/30356/Licence_PA23458-007-001_06012025182548.pdf **Link to Patient Information Leaflet:** http://www.hpra.ie/img/uploaded/vaccines/PIL_PA2131009001.pdf https://assets.hpra.ie/products/Human/30356/447ac8d6-c81f-493c-8fa8-d59f864d2ab6.pdf
Procedure for the reporting and documentation of errors and near misses involving the vaccine	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. Vital signs should be recorded and the vaccine recipient should be reviewed by the registered nurse/midwife and/or clinical lead. 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, available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf The child's parent and/or legal guardian must be informed of the incident. Any suspected adverse reactions associated with medicine errors should be reported to the HPRA as outlined below. 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. Refer to https://www.hpsc.ie/a-z/emi/algorithms/EMISharpsAlgo.pdf
Procedure for reporting Adverse Drug Reactions to the HPRA	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 https://www.hpra.ie
Resources and equipment required for the administration of Tetravac (Diphtheria, Tetanus, Pertussis and Poliomyelitis) Vaccine	• Tetravac vaccine • Fridge/cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) • Disposable kidney dishes/coloured trays and covering • Gauze swabs/plasters • Sharps bins, and bags for disposal of healthcare risk and non-risk waste materials • Alcohol hand sanitizer • Handwashing facilities • Access to telephone • Resuscitation equipment and drugs in accordance with the NIAC (2023) *Anaphylaxis: Immediate Management in the Community* available at: https://www.hiqa.ie/sites/default/files/NIAC/Immunisation_Guidelines/Anaphylaxis.pdf • Safe storage areas for medicines and equipment • Current medicine protocol for Tetravac vaccine.

Audit process to identify appropriate use of the medicine protocol or unexpected outcomes	All documentation will be held for review and audit purposes as per local policy.
4.0 Information for vaccine recipient/parent/legal guardian	
Advice to be given to the vaccine recipient/parent/legal guardian before treatment	Patient Information Leaflet/Fact Sheet **must** be supplied with the consent form to each parent/legal guardian prior to administration of the vaccine. Reiterate the information provided in the HSE patient information leaflet for the vaccine and translator support if required.
Advice to be given to the vaccine recipient/parent/legal guardian after treatment	**After Treatment** 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.
Details of any necessary follow-up, action and referral arrangements	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.
5.0 Staff authorised to use this medicine protocol	
Professional qualifications, training, and competence required prior to using this medicine protocol	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) *Primary Childhood Immunisation Programme* accessible on www.HSeLanD.ie 3) Education programme for nurses and midwives on *National Vaccination Education Programme for Registered Nurses/Midwives/Public Health Nurses: 2025/2026* and any updates for nurses and midwives accessible on 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 The registered nurse/midwife must complete the Competency Self-Assessment Form to vaccinate Refugees and Applicants Seeking Protection in Ireland available at www.immunisation.ie

References

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

HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022), available at: https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management- of-sharps-and-prevention-of-sharp-injuries.pdf

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/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland

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 *Supporting Information for Staff: Schools Immunisation Programme 2025/2026* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.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

Nursing and Midwifery Board of Ireland (2025) *Code of Professional Conduct and Ethics for Register 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

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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

Sanofi-Pasteur, Ireland Tetravac *Summary of Product Characteristics and Patient Information Leaflet,* available at www.hpra.ie