Medicine Protocol for the Administration of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) 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 Boostrix 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, Boostrix vaccination during pregnancy in line with the NIAC recommendations 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 Boostrix 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 Boostrix 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
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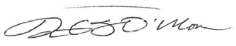
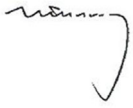
Note: This medication protocol does not enable registered nurses and registered midwives employed in the capacity of vaccinator in the voluntary and statutory services of the HSE including vaccination clinics, to provide routine antenatal or postnatal care. Vaccine recipients with any pregnancy related concerns beyond vaccination concerns, should be referred to the GP/hospital obstetrician.

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 (AnBord Altranais, 2007, page 37).

Document reference number	Version3-NIO-Tdap-December2024
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	December 2024
Date for review of medicine protocol	December 2025
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 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. Eamonn 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 tetanus, diphtheria, and pertussis disease.
Circumstances in which the medicine protocol applies	To provide a Boostrix (Tdap vaccine) to Refugees and Applicants Seeking Protection in Ireland (hereafter referred to as vaccine recipients), or in the event of an outbreak as advised by public health.
Inclusion criteria for vaccine recipient of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) under this medicine protocol	A booster dose of Boostrix (Tdap vaccine) should be given to children aged 10 years of age and older (routinely given to students in 1st year of second level school and age equivalent in special schools and home schooled students). **Catch up vaccination** **Tdap/IPV (IPV Boostrix) vaccine is no longer available in Ireland.** Therefore NIAC have issued new guidelines for catch-up vaccination. For people aged 10 years of age and older the following vaccines are now recommended: a) First give a **Boostrix** (**Tdap vaccine) x1** b) followed by Revaxis (Td/IPV) x 3 at ≥4 weeks apart (Leave a 4 week gap after Boostrix (Tdap vaccine)) **Outbreak vaccination** Vaccination as advised by public health **Pregnancy** **Pregnant Women:** Maternal antibodies from women immunised before pregnancy wane quickly and the concentration of pertussis antibodies is unlikely to be high enough to provide passive protection to their infants prior to primary vaccination. Pregnant women should be offered Tdap as early as possible after 16 weeks and up to 36 weeks gestation in each pregnancy, to protect themselves and their infant. Tdap can be given at any time in pregnancy after 36 weeks gestation although it will be less effective in providing passive protection to the infant. **Post-partum women, including those breastfeeding:** Tdap should be offered in the week after delivery to those women who were not vaccinated during their pregnancy; this is to prevent maternal infection so she will not be a source of infection to her baby. **Precautions** • Acute 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.
Exclusion criteria for vaccine recipient of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) under this medicine protocol	A known history of anaphylactic or hypersensitivity reaction to Boostrix (Tdap Vaccine) or to any of the Boostrix (Tdap vaccine) constituents.

Actions to be taken for those who are excluded from this medicine protocol	All recipients meeting exclusion criteria must be referred to the clinical lead for an clinical assessment. • Document action in clinical notes. • Where Boostrix (Tdap vaccine) is prescribed following clinical assessment, the nurse or midwife may administer Boostrix (Tdap vaccine) within their scope of practice. **Note**: In determining their scope of practice, nurses and midwives must make judgements about their competence to carry out a role or activity (NMBI, 2015).
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 completed by the parent /legal guardian for children who receive the Boostrix (Tdap vaccine) vaccine, once understood and 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 • HPRA Adverse Reaction Reporting forms • HSE Incident/Near Miss report forms • Post vaccination advice It is the responsibility of each registered nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Boostrix (Tdap vaccine) vaccine which includes the following: • Medicine Protocol for the Administration of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) 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. • NIAC (2023) *Anaphylaxis: Immediate Management in the Community* available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
3.0 Name of Medicine	Boostrix suspension for injection in pre-filled syringe Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) **Dose:** 0.5ml **Route:** Intramuscular injection **Site:** Deltoid muscle (right arm recommended for children aged 10-14yrs only as they may receive the other school vaccines in Left arm) Note: Adults including Pregnant women can receive the vaccine in either arm.
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:** http://www.hpra.ie **Link to Patient Information Leaflet:** https://www.hpra.ie

Procedure for the reporting and documentation of errors and near misses involving the medicine	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 medical practitioner. 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 For children, 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/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
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 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.
Resources and equipment required for the administration of Boostrix Diphtheria, tetanus and pertussis (acellular, component) vaccine	• Boostrix 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 material • Alcohol hand sanitiser • Handwashing facilities • Access to telephone • Resuscitation equipment and drugs in accordance with the NIAC (2023) *Anaphylaxis: Immediate Management in the Community* available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • Safe storage areas for medicines and equipment • Current medicine protocol for Boostrix vaccine.
Audit process to identify appropriate use of the protocol or unexpected outcomes	All documentation will be held for review and audit purposes as per local policy

4.0 Information for the vaccine recipient/parent/legal guardian	
Advice to be given to vaccine recipient/parent/ legal guardian before treatment	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.
Advice to be given to 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 nurse/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 *Schools Immunisation Programme* 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 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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GlaxoSmithKline, Ireland Limited Boostrix *Summary of Product Characteristics and Patient Information Leaflet,* available at: www.hpra.ie

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National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/.

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