Medicine Protocol for the administration of Boostrix (Tdap -Tetanus, Diphtheria, and Pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives to students in second level schools through a School Immunisation Programme.

This medicine protocol is a specific written instruction for the administration of Boostrix (Tdap) vaccine to students in second level school by registered nurses and registered midwives. This medicine protocol is valid for the 2024/2025 Health Service Executive 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 Boostrix (Tdap) vaccine with reference to and guidance from Nursing & Midwifery Board of Ireland, National Nursing and Midwifery (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 Boostrix (Tdap) 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

- 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/Standards-Guidance/Scope-of-Practice/Nursing-Practice-Scope-Definition

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, pg35, 2007)

Medicine Protocol for the administration of Boostrix (Tdap, Tetanus, Diphtheria, and Pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives to students in second level schools through a School Immunisation Programme.

Document reference number	**ONMSD 2024-006**
1.0 Critical Elements	
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 Boostrix (Tdap) vaccine to first year students in second level school through a School Immunisation Programme.
Date the protocol comes into effect	September 2024 (For the school year of September 2024 – September 2025)
Date for review of protocol	May 2025
Document prepared by	Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the NIO at the request of Dr Éamonn O'Moore, Director of National Health Protection.
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 Éamonn O'Moore**, Director of National Health Protection, HSE Signature: Dr Éamonn O'Moore (Aug 12, 2024 15:24 GMT+1) 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 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. Boostrix (Tdap) vaccine is given as a booster dose to protect against tetanus, diphtheria, and pertussis vaccine to children in first year in second level school.
Circumstances in which the medicine protocol applies	The School Immunisation Programme (SIP) will be delivered annually by the HSE. The aim of the immunisation programme is to offer a booster dose of the Boostrix (Tdap (tetanus, diphtheria and pertussis (acellular) vaccine, to all first year students in second level schools and age equivalent in special schools and home schooled students as recommended by NIAC in the Immunisation Guidelines for Ireland https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
Inclusion criteria for student/service user treatment using the medicine protocol	Students in first year of second level school and age equivalent in special schools and home schooled students. https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/ Students with valid consent given while in 1st year of secondary school and missed the opportunity to attend the vaccination clinic due to illness or other personal circumstances.
Exclusion criteria for student/service treatment using the medicine protocol	Anaphylaxis to any of the Boostrix vaccine constituents. **Precautions** • Acute febrile illness, defer until recovery • Type III (Arthus) hypersensitivity reaction to a previous dose (see adverse reactions in NIAC chapters 6 and 21). 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 and other vaccines may be administered at the same time or at any interval as Boostrix (Tdap) vaccine.
Actions to be taken for those who are excluded from the Medicine Protocol	• All students meeting exclusion criteria must be referred to the medical practitioner for an individual assessment • Document assessment and action in clinical notes • Where Boostrix (Tdap) vaccine is prescribed following medical 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 competency to carry out a role or activity (NMBI, 2015).
Description of circumstances and referral arrangements when further advice or consultation is required	Discuss the student with the Medical Practitioner or lead nurse in the event of: Confirmed or suspected anaphylactic reaction to the vaccine itself or to constituents of that vaccine or other clinical concerns.

Documentation required for the implementation of this medicine protocol	Consent form must be completed by the parent /legal guardian for all students who receive the Boostrix (Tdap) vaccine. Appropriate details including the batch number must be recorded on the consent form following vaccination The following documents will be required at each school vaccination session: • 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 • Tear pads for post vaccination and advise It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Boostrix (Tdap) vaccine which includes the following: • Supporting Information for Staff: School Immunisation Programme 2024/2025 and Medicine Protocol for the administration of Boostrix (Tdap) vaccine Tetanus, Diphtheria, and Pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives to students in second level schools through a School Immunisation Programme. • NIAC (2023) Anaphylaxis: *Immediate Management in the Community* https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
3.0 Name of Medicine	Boostrix (Tdap) Vaccine: **Dose:** 0.5ml **Route:** Intra Muscular **Site:** Deltoid (right side recommended)
Link to Medicine **Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at www.hpra.ie**	**Link to Summary of Product Characteristics:** http://www.hpra.ie/img/uploaded/vaccines/SPC_PA1077020001.pdf **Link to Patient Information Leaflet** https://www.hpra.ie/img/uploaded/vaccines/PIL_PA1077020001.pdf
Procedure for the reporting and documentation of errors and near misses involving the medication	In the case of medicine errors that directly involve the student, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the student and closely monitor them for any adverse reactions. Vital signs should be recorded and the student 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 student's documentation/notes and the relevant incident report form completed:

	https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf The student's parent and/or legal guardian should be informed of the incident. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below. 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 form and forwarded to the relevant line manager as per local policy. Refer 'EMI Tool Kit' https://www.hpsc.ie/a-z/EMIToolkit/.

Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (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 in line 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	• Boostrix (Tdap) Vaccine (pre-filled syringe) • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) • Vaccination cool pack • Disposable kidney dishes/coloured trays • Gauze swabs/Plasters • Sharps bins and bags for disposal of healthcare risk and non-risk waste material. HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022). https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management-of-sharps-and-prevention-of-sharp-injuries.pdf • Face masks If required • Alcohol hand sanitizer • 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/ • Access to medical support • Safe storage areas for medicines and equipment • Current medicine protocol for Boostrix (Tdap) Vaccine.
Audit process to identify appropriate use of medicine protocol or unexplained outcomes	All documentation will be held for review and audit purposes as per local policy.
4.0 Information for the student/parent/legal guardian	
Advice to be given to the student/parent/legal guardian before treatment	HSE first year vaccination programme information booklet must have been supplied with the consent form to each student's parent or legal guardian prior to administration of the vaccine.

Advice to be given to the student/parent/legal guardian after treatment	**After Treatment:** An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/legal 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. 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.
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. Education programme for nurses and midwives on *Schools Immunisation Programme* and any updates for nurses and midwives accessible on www.HSELanD.ie 3. An approved *Basic Life Support for Health Care Providers Course* within the last two years (i.e. Irish Heart Foundation (IHF)) 4. 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 Note: The Immunisation Foundation Programme will be replaced with Primary Childhood Immunisation Programme (PCIP) accessible on www.HSELanD.ie 5. The registered nurse/midwife must complete the Competency Self-Assessment Form available at www.immunisation.ie

References

GlaxoSmithKline, Ireland Limited Boostrix *Summary of Product Characteristics and Patient Information Leaflet,* available at: www.hpra.ie

Health Products Regulatory Authority available at: www.hpra.ie

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

https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management- of-sharps-and-prevention-of-sharp-injuries.pdf

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

6. D1Tdap(Boostrix) 060824

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