Gibraltar Health Authority

PATIENT GROUP DIRECTION

Issued under Part 2 of the Medicines (Prescriptions Only) Regulations, 1987 by the Director of Public Health with the consent of the Minister
for

Diphtheria, Tetanus, acellular Pertussis and Inactivated Poliomyelitis vaccine: dTaP/IPV Repevax-Boostrix-IPV

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	1st September 2024		
Date of expiry	1st September 2026		
Staff characteristics	See below (section 1)		
Professional Authorisation		SIGNATURE	DATE
Lead Doctor	Dr Helen Carter Director of Public Health[1]		
In Consultation with		SIGNATURE	DATE
Lead Pharmacist	Ms Melanie Gordon Chief Pharmacist		
Lead Nurse	Ms Sandra Gracia Director of Nursing		
Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for[2] Health Gemma Arias-Vasquez MP		

[1] A Patient Group Direction issued shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.
[2] See footnote 1.

• Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV
• Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV
Authors: Dr Helen Carter, DPH and Mr Ian Bramble EN
Date effective from 11/04/2025 and expires 11/04/2027

1. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses or midwives currently registered with the Gibraltar Nursing Registration Board (NRB) • practitioners currently registered with the Gibraltar Medical Registration Board (MRB) Anyone deemed by the Director of Public Health to be competent who meets the additional requirements below.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC) • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must be familiar with, and alert to changes in the relevant GHA standard operating procedures (SoPs) • must have undertaken training appropriate to this PGD as required by local policy and national GHA standard operating procedures • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016) and to discuss issues related to vaccination • must be competent in the correct handling and storage of vaccines, and management of the cold chain • must be competent in the handling of the vaccine product, procedure for dilution of the vaccine and use of the correct technique for drawing up the correct dose • must be competent in the injection technique • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions • must have access to the PGD • should fulfil any other additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT**

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Continued training requirements	• Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). • Practitioners should be constantly alert to any subsequent recommendations from Public Health Gibraltar and/or the GHA and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals from 3 years for the prevention of diphtheria, tetanus, pertussis and poliomyelitis, in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 24, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: the 'Green Book' and associated disease management guidelines (see Dose and frequency of administration section)
Criteria for inclusion	Individuals for whom valid consent has been received. Individuals from 3 years 4 months to under 10 years of age who: • require a booster following a primary course of immunisation against diphtheria, tetanus, pertussis and poliomyelitis (this booster is usually offered from 3 years 4 months of age) Individuals from 3 years of age (see Additional information regarding individuals over 10 years) who: • have a tetanus-prone wound and tetanus immunisation is recommended in accordance with Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds or tetanus boosters are due soon and it is convenient to give now (see the 'Green Book' Chapter 30) • require vaccination in line with the national recommendations for the management of cases and contacts of diphtheria or polio (see dose and frequency) In an outbreak situation, under written instruction from the Director of Public Health, specific additional groups of the population may be offered an inactivated seasonal influenza vaccine as specified in the written instruction.

Criteria for exclusion [1]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis or poliomyelitis containing vaccine, including any conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate • have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture, these may include formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin and bovine serum albumin (refer to relevant SPC) • have not yet completed primary immunisation with three doses of diphtheria, tetanus, pertussis and poliomyelitis antigen unless recommended by an Outbreak Control Team • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

[1] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK. If a seizure associated with a fever occurred within 72 hours of a previous immunisation with pertussis containing vaccine, immunisation should continue as recommended if a cause was identified, or the child recovered within 24 hours. However, if no underlying cause was found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear. If a child has experienced encephalopathy or encephalitis within seven days of immunisation, it is unlikely that these conditions will have been caused by the vaccine and they should be investigated by a specialist. If a cause is identified or the child recovered within seven days, immunisation should proceed as recommended. In children where no underlying cause was found and the child did not recover completely within seven days, immunisation should be deferred until the condition has stabilized or the expected course of the condition becomes clear. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate. Individuals who are immunosuppressed may not be adequately protected against tetanus, despite having been fully immunised. In the event of an exposure they may require additional boosting and/or immunoglobulin (see the 'Green Book' Chapter 30 and Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds).

Action to be taken if the patient is excluded	Individuals who have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis and poliomyelitis vaccine, or any components of the vaccine, should be referred to a clinician for specialist advice and appropriate management. If the individual has not yet completed primary immunisation with three doses of diphtheria, tetanus, pertussis and poliomyelitis antigen provide priming doses of DTaP/IPV/Hib/HepB as required (see DTaP/IPV/Hib/HepB PGD). In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the Director of Public Health or the individual's clinician where appropriate. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform, or refer to, the GP or a prescriber as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2018, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of 'The Green Book'. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given, and the decision reached. Inform, or refer to the GP or a practitioner as appropriate.
Arrangements for referral for medical advice	As per local GHA policy

• Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV
• Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV

3. Description of treatment

Name, strength & formulation of drug	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed): • Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV • Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV
Legal category	Prescription Only Medicine (POM)
Black triangle	no
Off-label use	Administration of Infanrix-IPV by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 of "The Green Book" . Note: Repevax SPC includes consideration of administration by deep subcutaneous injection to individuals with bleeding disorders. Administration to individuals who have experienced an encephalopathy of unknown origin within 7 days of previous vaccination with a pertussis-containing vaccine is off-label but may proceed once the cause is identified or the condition has been stabilized in accordance with the recommendations in Chapter 24 of Immunisation Against Infectious Disease: the 'Green Book'. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Route / method of administration	Administer by intramuscular injection, preferably into deltoid region of the upper arm. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4 or the product's SPC. The vaccine's normal appearance is a uniform cloudy, white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine. The vaccine should not be used if discoloured or foreign particles are present in the suspension. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.

Dose and frequency of administration	Single 0.5ml dose per administration **Routine childhood immunisation schedule** The dTaP/IPV booster should ideally be given three years after completion of the primary course of diphtheria, tetanus, pertussis and polio vaccination as the first booster dose and is recommended as a pre-school vaccine at around 3 years and 4 months of age though it may be used until 10 years of age. When primary vaccination has been delayed, this first booster dose may be given at the scheduled visit provided it is at least 12 months since the last primary dose was administered. Where children have had a fourth dose of tetanus, diphtheria and polio containing vaccine at around 18 months of age, this dose should be discounted as it may not provide satisfactory protection until the time of the teenage booster. Additional doses of DTaP-containing vaccines given under 3 years of age do not count as a booster to the primary course in the UK. The routine pre-school and subsequent boosters should be given according to the UK schedule. **Individuals with unknown or incomplete immunisation status**

	Children coming from developing countries, from areas of conflict, or from hard-to-reach population groups may not have been fully immunised. Where there is no reliable history of previous immunisation, it should be assumed that they are unimmunised and the full UK recommendations should be followed (see Chapter 11 on vaccine schedules). Where children coming to the UK from some countries may have had a fourth dose of tetanus, diphtheria and polio containing vaccine at around 18 months of age, this dose should be discounted as it may not provide satisfactory protection until the time of the teenage booster. Additional doses of DTaP-containing vaccines given under 3 years of age do not count as a booster to the primary course in the UK. The routine pre-school and subsequent boosters should be given according to the UK schedule. **Management of tetanus prone wounds** Individuals with incomplete or uncertain history of tetanus immunisation should be vaccinated in accordance with the recommendations in the 'Green Book' Chapter 30 Table 30.1 and Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds. In accordance with those recommendations, individuals who are immunosuppressed may require additional boosting. Individuals may also require human tetanus immunoglobulin. Administration of tetanus immunoglobulin is not covered by this PGD. **Management of cases and contacts of diphtheria** Cases and contacts of diphtheria should be managed in accordance with Public health control and management of diphtheria (in England and Wales) guidelines and recommendations from the Director of Public Health. Individuals who are fully immunised but have not received diphtheria containing vaccine in last 12 month may be given a single booster dose of diphtheria containing vaccine. **Management of pertussis outbreak in a school/nursery** Cases and contacts of pertussis in a school/nursery outbreak should be managed in accordance with Guidelines for the Public Health Management of Pertussis in England and recommendations from the Director of Public Health. **Management of cases and contacts of polio** Cases and contacts of polio should be managed in accordance with National polio guidelines: Local and regional services guidelines and recommendations from the Director of Public Health. Management will depend on the level of exposure but may include the administration of a single dose of IPV containing vaccine, regardless of vaccine history.
Duration of treatment	A single booster dose. Other diphtheria, tetanus, pertussis and polio vaccines are recommended for primary immunisation (that is DTaP/IPV/Hib/HepB) and subsequent boosters (that is the Td/IPV adolescent booster) to complete immunisation in accordance with national recommendations.

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Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	The pharmacy at the GHA purchased vaccines for the national immunisation programme Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to Vaccine Incident Guidance
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.

Identification & management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site. Common adverse reactions include fever, irritability, headache, nausea, diarrhoea, vomiting, rash, arthralgia, appetite loss, malaise, fatigue/asthenia, dermatitis, bruising and pruritus. Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store and send a copy of the Yellow card to the Director of Public Health Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. **INFORM GIBRALTAR DIRECTOR OF PUBLIC HEALTH IMMEDIATELY IF SEVERE ADVERSE REACTION IS SUSPECTED**
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. GHA website for further information: https://www.gha.gi/public-health/ Immunisation promotional material may be provided as appropriate, such as Pre-school immunisations: guide to vaccinations (2 to 5 years)

Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes. The dTaP/IPV (Repevax® or Boostrix®-IPV) vaccine contains a lower dose of pertussis antigen, as well as a lower dose of diphtheria antigen, compared to DTaP/IPV (Infanrix®-IPV) or DTaP/IPV/Hib/HepB. It is important that primary vaccination in children is undertaken using a product with higher doses of pertussis, diphtheria and tetanus antigens (currently that is DTaP/IPV/Hib/HepB) to ensure that adequate priming occurs. Therefore, individuals immunised as part of an outbreak response but who have not completed primary immunisation should be referred to their GP for immunisation in accordance with Vaccination of individuals with uncertain or incomplete immunisation status algorithm. Where a dTaP/IPV vaccine has been administered to an individual who has not completed primary immunisation the dose of dTaP/IPV should be discounted. Individuals over 10 years of age should preferably be vaccinated using Td/IPV (Revaxis®) where protection against pertussis is not required. However, dTaP/IPV may be offered to individuals with a tetanus prone wound and cases or contacts of diphtheria or polio where Td/IPV (Revaxis®) is either not available or dTaP/IPV is recommended for a cohort identified by an Outbreak Control Team. Pertussis vaccination may be recommended for individuals over 10 years of age under inclusion criteria not covered by this PGD (see Pertussis PGD). Tetanus vaccine given at the time of a tetanus-prone injury may not boost immunity early enough to give additional protection within the incubation period of tetanus. Therefore, tetanus vaccine is not considered adequate for treating a tetanus-prone wound. However, this provides an opportunity to ensure that the individual is protected against future exposure. Individuals

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Special considerations / additional information continued	may also require human tetanus immunoglobulin (see the 'Green Book' Chapter 30). If a person has received vaccination for a tetanus-prone wound, or as a case or contact of diphtheria, tetanus or polio, with the same vaccine as due for routine immunisation and it was administered at an appropriate interval then the routine immunisation dose may not be required.

Records	Record: •that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2018 1. name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) 2. name of vaccinator 3. name and brand of vaccine 4. date of administration 5. dose, form and route of administration of vaccine 6. quantity administered 7. batch number and expiry date 8. anatomical site of vaccination 9. advice given, including advice given if excluded or declines vaccination 10. details of any adverse drug reactions and actions taken 11. supplied via PGD Records should be signed and dated (or a password-controlled vaccinator's record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

• Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV
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Key references	The dTaP/IPV vaccine • Immunisation Against Infectious Disease: The Green Book Chapter 15, Chapter 26 updated 19 April 2013, Chapter 30 updated 22 January 2020 and Chapter 24 updated 7 April 2016 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Repevax®, Sanofi Pasteur. 13 August 2021. http://www.medicines.org.uk/emc/medicine/15256 • Summary of Product Characteristic for Boostrix®-~IPV, GlaxoSmithKline UK. 16 November 2020. https://www.medicines.org.uk/emc/product/5302 • Vaccination of individuals with uncertain or incomplete immunisation status. Updated 26 August 2021. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • Public health control and management of diphtheria (in England and Wales) guidelines. Published 24 March 2015. https://www.gov.uk/government/publications/diphtheria-public-health-control-and-management-in-england-and-wales • Guidelines for the Public Health Management of Pertussis in England. Published May 2018. https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management • National polio guidelines: Local and regional services. UKHSA. 26 September 2019. https://www.gov.uk/government/publications/polio-national-guidelines General • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

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5. Practitioner authorisation sheet

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Valid from 11/04/25 to 11/04/27

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the **GHA** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.