Gibraltar Health Authority

PATIENT GROUP DIRECTION (PGD)

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

for

HEXAVALENT VACCINE DTAP/IPV/HIB/HEPB (INFANRIX®-HEXA & Vaxelis®)

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority (GHA) St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	6th August 2025		
Date of expiry	6th August 2027		
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

[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.

With the consent of Minister	The Honourable Minister for Health Gemma Arias-Vasquez MP[2]		

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 (GNRB) • practitioners currently registered with the Gibraltar Medical Registration Board (GMRB) • Anyone deemed by the Director of Public Health to be competent who meets the additional requirements detailed 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, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book including national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training for registered Healthcare Practitioners (2018) • 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 delivering the vaccine using the licenced administration injection technique

[2] See footnote 1.

	• 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 and relevant online resources such as the Green Book • 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**
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 6 weeks (routinely 8 weeks) to under 10 years of age for the prevention of diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b and hepatitis B in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 16, Chapter 18, Chapter 24, Chapter 26, and Chapter 30 of Immunisation Against Infectious Disease: 'The Green Book'. • individuals who require immunisation in response to an outbreak of polio or are at high risk of an outbreak of polio, as risk assessed by the Director of Public Health and proposal ratified by GHA executive Team.

Criteria for inclusion	Individuals from 6 weeks to under 10 years of age who: • require a primary course of immunisation against diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b and hepatitis B (including those who do not have a complete or reliable vaccination history, see Special considerations / additional information section) • have a tetanus prone injury and primary immunisation is considered incomplete or immunisation status is not known or uncertain (see 'The Green Book' Chapter 30) In an outbreak situation, under written instruction from the Director of Public Health, specific additional groups of the population may be offered a vaccine as specified in the written instruction.
Criteria for exclusion[3]	Individuals for whom no valid consent has been received. Individuals who: • are less than 6 weeks of age • are aged 10 years and over • have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b or hepatitis B 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. Including formaldehyde, neomycin and polymyxin (see Name, strength and formulation plus relevant SmPC) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) [1] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

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Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). If the child has not been investigated by a specialist, then immunisation should be deferred until a specialist opinion is obtained. If a seizure associated with a fever occurred within 72 hours of a previous immunisation with any component of the vaccine, immunisation should continue as recommended except where a child has evidence of current neurological deterioration, as outlined above (see also special considerations and addition information section). The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination is still recommended. Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hours. If the premature infant was stable at discharge and has no history of apnoea and/or respiratory compromise, further vaccinations can be given in the community setting. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Infanrix®-hexa contains a source of phenylalanine. Though phenylalanine may be harmful to individuals with phenylketonuria (PKU), the parent or carer of the individual will be well versed as to the amounts of phenylalanine tolerable in their diet. The National Society for Phenylketonuria (NSPKU) advise the amount of phenylalanine contained in vaccines is negligible and therefore strongly advise individuals with PKU to take up the offer of immunisation.

Action to be taken if the patient is excluded	If aged less than 6 weeks advise to return for routine immunisation when the child is 8 weeks of age or over and give an appropriate appointment. Immunisation can be administered to infants from 6 weeks of age if required, for instance if travelling to an endemic country or at increased risk of hepatitis B virus and dose of HepB vaccine is due. If aged 10 years or over assess for immunisation with Td/IPV as appropriate. Individuals who have had a confirmed anaphylactic reaction to a previous dose of hexavalent vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity. Seek appropriate advice from the individual's clinician and/or Director of Public Health when a vaccine is indicated outside the remit of this PGD rather than delay immunisation. 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 in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local specialty policy

3. Description of treatment

Name, strength & formulation of drug	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated), *Haemophilus influenzae* type b (conjugate) and hepatitis B (rDNA) vaccine (adsorbed), DTaP/IPV/Hib/HepB: • Infanrix®-hexa, powder (Hib) in vial and suspension (DTaP/IPV/HepB) for suspension for injection in a pre-filled syringe or vial The vaccine may contain traces of formaldehyde, neomycin and polymyxin (see exclusion criteria). • Vaxelis® suspension for injection in a pre-filled syringe. The vaccine may contain traces of glutaraldehyde, formaldehyde, neomycin, streptomycin, polymyxin B and bovine serum albumi
Legal category	Prescription only medicine (POM)
Black triangle	No
Off-label use	Administration of Infanrix®-hexa to individuals born before 24 weeks of gestational age or to individuals who are over 36 months of age is off-label but is indicated until 10 years of age under this PGD in accordance with national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status guidance and the relevant chapters of 'The Green Book'. Administration of Vaxelis® to individuals who are over 15 months of age is off-label but is indicated until 10 years of age under this PGD in accordance with national guidance recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and the relevant chapters of the Green Book. Administration of DTaP/IPV/Hib/HepB to individuals who experienced an encephalopathy of unknown cause occurring within 7 days following previous vaccination with pertussis-containing vaccine is off-label. Individuals may be vaccinated under this PGD once the condition has stabilized or the expected course of the condition becomes clear (see Cautions), in line with the recommendations in the associated chapters of 'Green book'. Administration of Infanrix®-hexa by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 of 'The Green Book'. The SPC for Vaxelis® advises doses should not be administered by deep subcutaneous injection. Administration of either Vaxelis® or Infanrix®-hexa by deep subcutaneous injection to individuals with a bleeding disorder is appropriate where the intramuscular route is unsuitable and is in line with advice in Chapter 4 of the Green Book. The vaccine product SPCs do not make reference to use of DTaP/IPV/Hib/HepB for the management of outbreak, cases or contacts but do include use of the vaccine as a booster and state that the vaccine should be administered in accordance with official recommendations. Vaccination is

	therefore recommended under this PGD in accordance with the relevant chapters of the Green book, including guidance and written instruction from the Director of Public Health, Gibraltar. Vaccine should be stored according to the conditions detailed in the 'Storage section' below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Route / method of administration	Infanrix®-hexa is presented in two parts, as DTaP/IPV/HepB suspension for injection and Hib powder, which must be reconstituted in accordance with the manufacturer's instructions prior to administration. Vaxelis® is presented as a suspension for injection in a pre-filled syringe. Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under 1 year of age. The deltoid region of the upper arm may be used in individuals over 1 year of age. When administering at the same time as other vaccines, care should be taken to ensure 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. Check product name, batch number and expiry date prior to administration. The site at which each vaccine was given should be noted in the individual's records. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection in accordance with the recommendations in the Green Book Chapter 4. If the intramuscular route is not considered suitable, the individual may be offered either Infanrix®-hexa or Vaxelis® for administration by deep subcutaneous injection instead (see off-label use).

	Infanrix®-hexa Before reconstitution, the pre-filled syringe may contain a clear liquid with a white deposit, which should be well shaken to obtain a homogenous turbid white suspension. The powder in the vial is reconstituted with the entire contents of the pre-filled syringe, which should be well shaken until the powder has dissolved. The reconstituted vaccine appears as a cloudier suspension than the liquid component alone. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, discard the vaccine in accordance with local procedures. **Vaxelis®** Shake the pre-filled syringe gently prior to administration to obtain a homogeneous, whitish, cloudy suspension. The suspension should be inspected prior to preparation and administration, for foreign particulate matter and other variation of expected appearance . Should either occur, discard the pre-filled syringe in accordance with local procedures. Further guidance on preparation and administration of either vaccine may be found in the respective SPC.
Dose and frequency of administration	PGD updated in August 2025 to capture the changes to the childhood immunisation schedule from the discontinuation of production of Menitorix®. The change is that a new 4th dose of DTaP/IPV/Hib/HepB will be offered at 18 months instead. Single 0.5ml dose per administration **Routine Childhood Immunisation Schedule** The national recommendation for infants is for a 4-dose course of DTaP/IPV/Hib/HepB DTaP/IPV/Hib/HepB 0.5ml should ideally be given at the: • first primary immunisation visit (usually at age 8 weeks*) • second primary immunisation visit (usually at age 12 weeks) • third primary immunisation visit (usually at age 16 weeks) • fourth dose at 18 months (once supplies of Hib/Men C the Menitorix® vaccines are no longer available) *Note: immunisation may be brought forward to commence no earlier than 6 weeks of age, and an interval of not less than 3 weeks (for 1 dose only) when required, for instance due to impending travel to an endemic country. Children born on or before 30 June 2024 should continue to be offered a dose of Hib at one year of age, as Hib/MenC. Once Menitorix® is no longer available, these children should be offered their Hib dose as the hexavalent vaccine from one year of age.

	See the Hib/MenC PGD and the routine childhood vaccination schedule letter for further information. Other diphtheria, tetanus, pertussis and polio-containing vaccines are recommended for subsequent routine boosters to complete immunisation, in accordance with national recommendations. **Vaccination of individuals with incomplete immunisation status** When primary vaccination has been delayed, the individual should be immunised at the earliest opportunity. If the primary course is interrupted it should be resumed but not repeated, allowing an interval of 4 weeks between remaining doses. When supplies of Menitorix® are exhausted and the new 4 dose schedule commences, an interval of 4 weeks should be observed between the first 3 primary doses, with the fourth dose offered at 18 months of age. If the individual presents late for their fourth dose, the hexavalent dose should be offered to ensure the individual receives a dose of Hib over the age of one year. If they have received at least one of their primary doses of hexavalent vaccine over one year of age, the additional hexavalent dose offer at 18 months is not needed. Provided it has been at least one year since the last hexavalent dose and that at least one hexavalent dose has been given over the age of one year, the routine dTaP/IPV booster may be given at the scheduled 3 years 4 month visit. Refer to the dTaP/IPV PGD. Individuals who commenced but did not complete a course of multivalent DTaP-containing vaccine (or equivalent) should be managed in line with vaccination of individuals with uncertain or incomplete immunisation status. Note it may be appropriate to discount any previous doses given in countries other than the UK and transfer the individual onto the UK schedule, as appropriate to their age. **Management of tetanus prone wound** Individuals with incomplete or uncertain history of tetanus immunisation should be vaccinated in accordance with the recommendations in the 'The Green Book' Chapter 30 Table 30.1. Individuals may also require human tetanus immunoglobulin (see 'The Green Book' Chapter 30). This PGD does not cover the administration of immunoglobulin. **Immunisation of infants at risk of hepatitis B** Infants born to women living with hepatitis B infection should receive monovalent hepatitis B (HepB) vaccine (see HepB PGD) at birth and at 4 weeks of age, followed by 3 doses of DTaP/IPV/Hib/HepB vaccine at 8, 12 and 16 weeks of age. A dose of hexavalent vaccine should be offered at 18 months. The Dried Blood Spot (DBS) test should be carried out at any time between 12 months to 18 months of age to check for hepatitis B infection. Where such infants have received doses of monovalent hepatitis B vaccine scheduled for 0 and 4 weeks late, but before 6 weeks of age, routine primary immunisations should still continue to be scheduled at 8 weeks of age,

	irrespective of the timing of the late monovalent hepatitis B vaccine dose. This is necessary in order not to delay protection against the other infections. If an infant born to a woman with hepatitis B infection attends after the age of 6 weeks for their first or second dose of hepatitis B vaccine, DTaP/IPV/Hib/HepB should be administered along with the primary immunisation series, with subsequent immunisation visits scheduled at 4-week intervals. In this situation it is very important that the child is tested, from 12 months of age, to check whether they were infected early in life as they missed an early dose of HepB vaccine. Following the recommendation for a fourth dose of hexavalent vaccine at 18 months, there is no longer the requirement for an additional dose of monovalent hepatitis B vaccine at the age of 12 months. Where the child is at risk of acquiring hepatitis B infection but was born on or before 30 June 2024, the child remains eligible for a dose of hepatitis B vaccine at 12 months. DBS testing should also be carried out at the same time. See the HepB PGD for more information. **Management of cases and contacts of polio outbreak or where there is a high risk of an outbreak** Cases and contacts of polio should be managed under the direction of the Director of Public Health, Gibraltar. 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	The primary course usually consists of 3 doses with an interval of 1 month between each dose with a 4th dose at 18 months old. Other diphtheria, tetanus, pertussis and polio containing vaccines are routinely recommended for subsequent boosters to complete immunisation in accordance with national recommendations.
Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book, Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. From a microbiological point of view, vaccines should be used as soon as practicably possible once opened and prepared for administration. For Infanrix®-hexa, stability has been demonstrated for up to 8 hours at 21°C. Where the contents have remained unopened throughout, data indicates that for Infanrix®-hexa the vaccine components are stable at temperatures up to 25°C for 72 hours. For Vaxelis®, data indicates the vaccine is stable at

	temperatures up to 25°C for up to 228 hours. By the end of these periods, the vaccines must be used immediately or discarded. These data are only intended to guide healthcare professionals in case of temporary inadvertent temperature excursions. In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
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 Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. This is not a reason to withhold vaccination, but the individual/parent/carer should be advised. May be given at the same time as other vaccines (see below – Identification and management of adverse reactions). A detailed list of interactions is available in the SPCs, which are available from the electronic Medicines Compendium website.
Identification & management of adverse reactions	When hepatitis B vaccine is added to DTaP/IPV/Hib vaccine the frequency and type of adverse reactions experienced remain similar. Prophylactic paracetamol is routinely recommended with co-administered infant doses of DTaP/IPV/Hib/HepB and 4CMenB (see the information about MenB vaccine and paracetamol and the What to expect after vaccinations leaflet on the Immunisation collection webpage for more information). Increased reporting rates of convulsions (with or without fever) and hypotonic hyporesponsive episode (HHE) were observed with concomitant administration of DTaP/IPV/Hib/HepB and PCV13. Prophylactic administration of paracetamol is not routinely recommended where PCV13 and DTaP/IPV/Hib/HepB are co-administered in the absence of 4CMenB. Administration of paracetamol concomitantly with PCV13 vaccination may reduce the immune response to some pneumococcal serotypes in PCV13 in infancy, although this reduction is unlikely to be clinically significant; this effect is not seen when also co-administered with the 4CMenB vaccine. If post immunisation fever does occur after any vaccination visit, then symptoms may be managed with paracetamol. Local reactions following vaccination are very common such as pain, bruising, induration, swelling or redness at the injection site. A small painless nodule may form at the injection site.

	Other common adverse reactions include fever, abnormal crying, irritability, restlessness, appetite loss, fatigue, diarrhoea, vomiting and nervousness. Hypersensitivity reactions, such as bronchospasm, angioedema, rash, dysponea, erythema ultiforme, urticaria, and anaphylaxis reaction (such as urticaria, angioedema, oedema, face oedema, shock) can occur but are very rare. A detailed list of adverse reactions is available in the SPCs, which are available from the electronic Medicines Compendium website. **IMMEDIATE ACCESS TO OXYGEN IS NOT A NECESSITY UNDER THIS PGD. BASIC LIFE SUPPORT & CALLING EMERGENCY SERVICES IS SUFFICIENT FOR IMMEDIATE RESUSUSCITATION**
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. Immunisation promotional material may be provided as appropriate: • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies • What to expect after vaccinations • Using paracetamol to prevent and treat fever after MenB vaccination • Public Health Gibraltar: Vaccines and Immunisations • Infanrix®-Hexa PIL
Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site. Advise the parent/carer about administering prophylactic paracetamol with routine immunisations scheduled at 8 weeks and 16 weeks of age when DTaP/IPV/Hib/HepB is co-administered with MenB vaccine (see Identification and management of adverse reactions). 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. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. A family history of seizures is not a contraindication to immunisation. (see Green Book Chapter 26 and SPCs). When there is a personal or family history of febrile seizures, there is an increased risk of these occurring after any fever, including that caused by immunisation. Seizures associated with fever are rare in the first six months of life and most common in the second year of life. After this age the frequency falls and they are rare after five years of age (see Green Book Chapter 26). Children coming to the Gibraltar who have a history of completing immunisation in their country of origin may not have been offered protection against all the antigens currently used in the Gibraltar. They may not have received Hib-containing vaccines in their country of origin. 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 individuals are unimmunised and the full Gibraltar recommendations should be followed. Un- or incompletely immunised children require 1 dose of Hib over the age of 1 year. It does not matter if the child receives additional Hib at subsequent appointments if the DTaP/IPV/Hib/HepB vaccine is given. If an individual has received vaccination for a tetanus-prone wound with the same vaccine as due for routine immunisation and it was administered at an appropriate interval then the routine immunisation is not required; refer to advice in 'The Green Book' Chapter 30. 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 the individual is protected against future exposure. Individuals may also require human tetanus immunoglobulin which is not covered by this PGD (see 'The Green Book' Chapter 30).
Records	Record: 1. that valid informed consent was given 2. name of individual, address, date of birth and GP with whom the individual is registered 3. name of immuniser 4. name and brand of vaccine 5. date of administration 6. dose, form and route of administration of vaccine

	7. quantity administered 8. batch number and expiry date 9. anatomical site of vaccination 10. advice given, including advice given if excluded or declines immunisation 11. details of any adverse drug reactions and actions taken 12. supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record and parent held records. Where vaccine is administered outside the GP setting appropriate health records should be kept including in the parent held record 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

Key references	**DTaP/IPV/Hib/HepB vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 15, Chapter 16 and Chapter 26 last updated 19 April 2013; Chapter 30, last updated 6 June 2022; Chapter 24, last updated 7 April 2016; and Chapter 18, last updated 7 February 2022 www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Immunisation Collection www.gov.uk/government/collections/immunisation • Infanrix hexa - Patient Information leaflet PIL https://www.medicines.org.uk/emc/product/2586/pil Summary of Product Characteristics for Vaxelis®, Sanofi, last updated 9 April 2024 www.medicines.org.uk/emc/product/12264 • Medicines Compendium www.medicines.org.uk • Summary of Product Characteristic for Infanrix®-hexa, GlaxoSmithKline. Last updated on eMC 01 January 2021 www.medicines.org.uk/emc/product/2586/smpc • The hexavalent DTaP/IPV/Hib/HepB combination vaccine information for healthcare practitioners www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance • Vaccination of individuals with uncertain or incomplete immunisation status

Key references (Continued)	www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • Medicines and Healthcare products Regulatory Agency (MHRA) https://yellowcard.mhra.gov.uk/ • MenB vaccine and paracetamol https://www.gov.uk/government/publications/menb-vaccine-and-paracetamol • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. 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. www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. www.nice.org.uk/guidance/mpg2/resources • Public Health Gibraltar https://healthygibraltar.org/infections-and-immunisation/ • Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • What to expect after vaccinations https://www.gov.uk/government/publications/what-to-expect-after-vaccinations

6. Practitioner authorisation sheet

HEXAVALENT VACCINE DTAP/IPV/HIB/HEPB (INFANRIX®-HEXA) Valid from: 6/08/2025 Expiry: 06/08/2027

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.