Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Healthcare professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, *Haemophilus influenzae* type b and hepatitis B (DTaP/IPV/Hib/HepB) vaccine

by registered healthcare professionals

to individuals from 6 weeks (routinely at 8 weeks) to under 10 years of age in accordance with the national immunisation programme or for the management of cases and contacts identified in an outbreak of polio in accordance with the national polio guidelines: local and regional services and recommendations from the local health protection team

in Powys Teaching Health Board

Version number: PGD0141 E

Reference Number: PGD0141 E
Valid from: 01/07/2025
Review Date: 30/01/2028
Expiry Date: 01/07/2028

Change History		
Version number	**Change details**	**Date**
PGD0141	Initial issue	02/11/17
PGD0141-A	Review issue in line with PHE template	01/11/20
PGD0141B	Review issue; PHE template adapted, reviewed and amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs and updated references • addition of Vaxelis® suspension • addition of stability data	01/09/2021
PGD0141-C	Review issue in line with UKHSA template and amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • add management of cases and contacts in an outbreak of polio in accordance with the national guidelines and recommendations from the local health protection teams • add information for vaccinating individuals with family history of seizures as per Green Book Chapter 26 and SPCs in the special consideration and additional information section • Update safeguarding information	03/08/22
PGD 0141 D	Reviewed in line with UKHSA DTaP/IPV/Hib/HepB PGD template v5.00 to: • include updated information from the Infanrix®-hexa SPC, including that excipients include phenylalanine • include updated SPC information on shelf life for Vaxelis® when stored outside of refrigerated conditions; increased from 150 hours to 228 hours • recommend either Vaxelis® or Infanrix®-hexa for individuals with a bleeding disorder who require administration by the deep subcutaneous route (off-label)	24/07/2024

	• remove the recommendation to defer vaccination in individuals with a history of developing either encephalopathy or encephalitis with 7 days of receiving a vaccine containing diphtheria, polio, tetanus or pertussis and where resolution of symptoms took longer than 7 days, in line with Chapter 30 of the Green Book • removal of the recommendation to defer vaccination in individuals with a history of seizures associated with fever, within 72 hours of vaccination. Vaccination should only be deferred where there is evidence of current neurological deterioration in children • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • reflect updated references Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs	
PGD 0141 E	Review issue in line with UKHSA DTaP/IPV/Hib/HepB PGD template v6.0 to: • take account of the forthcoming changes to the childhood immunisation schedule, effective 1 January 2026; a fourth dose of hexavalent vaccine is recommended at 18 months of age for those with a date of birth on or after 1 July 2024 • remove the advice for a dose of monovalent hepatitis B at 12 months for children born on or after 1 July 2024, on the selective neonatal hepatitis B pathway. Dried Blood Spot (DBS) testing may be carried out at any point between 12 and 18 months of age • reflect updated references and guidance • include registered healthcare professionals named in both the Additional Roles Reimbursement Scheme (ARRS) and HMR2012 Reviewed in line with WMAS Advisory document v1.0. Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs	01/07/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA DTaP/IPV/Hib/HepB PGD template v6.0 developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy (also ratified by the UKHSA Medicines Governance Committee).

The template has been adapted for use in PTHB, and advice from the WMAS Advisory document v1.0 has been incorporated.

Developed by the following health professionals on behalf of the UKHSA:

Developed By:	Name
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist – Immunisation Programmes, UKHSA
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Registered Nurse and Midwife (Chair of Expert Panel)	Greta Hayward Consultant Midwife, Immunisation Programmes, UKHSA

Expert panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Jess Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
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Rosie Furner	Advanced Specialist Pharmacist, Medicines Governance (Patient Group Directions and Medicines Mechanisms), NHS Specialist Pharmacy Service
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Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board (ICB)
Elizabeth Luckett	Senior Screening and Immunisation Manager, Screening and Immunisation Team – Kent and Medway, NHSE South East
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	6/25/2025
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423...	6/18/2025
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	6/18/2025
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	6/25/2025

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD. Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation

[1] This includes any relevant amendments to legislation

for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to:
Info.MedicinesManagement.Powys@wales.nhs.uk

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Characteristics of staff

Qualifications and professional registration	**All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below**. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • dieticians, occupational therapists, paramedics, physiotherapists and podiatrists currently registered with the Health and Care Professions Council (HCPC) Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
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 have completed eLfH PGD eLearning Patient Group Directions training (available via learning@wales, PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the

	Green Book), and 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 and online training. Please contact PTHB Immunisation coordinator for further information. • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain. Completion of cold chain training (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the intramuscular injection technique • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date Basic Life Support skills • must have access to the PGD and associated online resources • should fulfil any 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	Updating at least every 2 years on the administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, *Haemophilus influenzae* type b and hepatitis B (DTaP/IPV/Hib/HepB) vaccine. 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). Evidence of ongoing PGD training to be submitted to Line Manager annually. Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly.

	Practitioners must make a self-declaration of competency on PADR (if relevant). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. Compliance with all mandatory NHS training (if relevant). Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and/or the UKHSA, NHS England (NHSE) 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. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**

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 in accordance with the national polio guidelines: local and regional services guidelines and recommendations from the local health protection team. **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no**

	reasons for exclusion before proceeding with immunisation. If there is any reason for concern, seek medical advice.
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 and 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) • require vaccination in line with the management of cases and contacts of polio in an outbreak in accordance with the national polio guidelines: local and regional services guidelines and recommendations from the local health protection team • Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy • Medical and drug history taken, no reason for exclusion Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).
Criteria for exclusion 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	Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual, parent or carer section). 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 the manufacturing process, including para-aminobenzoic acid, which may cause bronchospasm (see name, strength and formulation of drug plus the relevant SPC) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) Conditions outside of the clinical situations criteria. Refer to sections action to be taken if the individual is excluded and action to be taken if the individual, parent or carer declines treatment.
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). 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 preventable infection. Vaccination should be promptly given once either the diagnosis or expected course of the condition (or both) becomes clear. 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 additional 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. Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list) Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and

	• Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads
Action to be taken if the individual is excluded	If aged less than 6 weeks, advise the parent or carer to return for routine immunisation when the infant 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 if there is an increased risk of contracting hepatitis B virus and a dose of HepB vaccine is due. If aged 10 years or over, assess for immunisation with Td/IPV as appropriate (see the Td/IPV PGD 0182). 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 local Screening and Immunisation Team, local Health Protection Team or the individual's clinician 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. Explain reason to individual / carer. Inform or refer to the individual's GP or a prescriber as appropriate.
Action to be taken if the individual, parent or carer	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where an individual lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be

declines treatment	made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. The patient information leaflet should be available to inform consent. Advise the individual, parent or 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. Inform the Child Health department if appropriate – if any vaccination is declined for a child under 19 years, Child Health must be informed and appropriate form completed. Where appropriate, inform the GP using the local agreed system.
Arrangements for referral for medical advice	Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary. Document any advice given.

Description of treatment

Name, strength and 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, para-aminobenzoic acid and polymyxin. It contains a source of phenylalanine. • Vaxelis® suspension for injection in a pre-filled syringe. The vaccine may contain traces of glutaraldehyde, formaldehyde, neomycin, streptomycin, polymyxin B and bovine serum albumin.
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 stabilised or the expected course of the condition becomes clear (see cautions), in line with the recommendations in the associated chapters 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 and the national polio guidelines: local and regional services guidelines. Individual Summaries of Product Characteristics (SmPCs) may differ in their licensed indications from official vaccination policy as specified in the Green Book and Welsh Policy. On these occasions, Green Book recommendations should take precedence and provides the rationale for any off-label use. Practitioners using authorised PGDs should also be familiar with the relevant chapters of the Green Book, SmPCs and Welsh Policy, and be constantly alert to any subsequent recommendations from Public Health Wales and/or Welsh Government and other sources of medical information. 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 the All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance. Where vaccines are 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, as part of the consent process, consider informing the individual, parent or carer that the vaccine is being offered in accordance with national guidance but outside of product licence.

Route and method of administration	Infanrix®-hexa is presented in 2 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 one year of age. The deltoid muscle of the upper arm may be used in individuals over one year of age. See Green book chapter 4. 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 into 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. 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	Single 0.5ml dose per administration **Routine Childhood Immunisation Schedule** The national recommendation for infants and young children is for a 4 dose course of DTaP/IPV/Hib/HepB. DTaP/IPV/Hib/HepB 0.5ml should ideally be given at: • 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 (from 1 January 2026, for children born on or after 1 July 2024)

	*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 one dose only) when required, for instance due to impending travel to an endemic country. A 4 week interval is otherwise required. As per WHC2025/19, within Wales the Hib/MenC (Menitorix®) vaccine will no longer be offered after 01 July 2025: Children **born on or before 30 June 2024** who present for their **one-year appointment** on or after 01 July 2025, should be offered a fourth dose of hexavalent (DTaP/IPV/Hib/HepB) vaccine alongside the other vaccines scheduled at one year of age (i.e. MenB, PCV13 and first MMR dose). Children **born on or after 01 July 2024** should be offered a fourth dose of hexavalent (DTaP/IPV/Hib/HepB) vaccine at the new routine **18-month appointment** alongside their second MMR dose. 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. From 1 January 2026, 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 PGD0073. 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 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. 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 born on or after 1 July 2024** Infants born to women living with hepatitis B infection should receive monovalent hepatitis B (HepB) vaccine (see HepB PGD 0041) 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 PGD0041 for more information. **Management of cases and contacts of polio outbreak** Cases and contacts of polio should be managed in accordance with national polio guidelines: Local and regional services guidelines and recommendations from the local health protection team. 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	See dose and frequency of administration
Quantity to be administered	Single 0.5ml dose per administration.
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.
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. Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage. See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion. 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 All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion. Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via PTHB Once for Wales Reporting System.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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 waste disposal arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste)

	and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	The immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended for eligible individuals, even if the antibody response may be limited and is not a reason to withhold vaccination. The individual, parent or carer should be advised of this. May be given at the same time as other vaccines- see identification and management of adverse reactions below. A detailed list of interactions associated with the infant hexavalent vaccine is available from the product's SPC.
Identification and 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 and the NHS Wales vaccination 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, dyspnoea, erythema multiforme, 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 from the product's SPCs. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS, INACTIVATED POLIOMYELITIS, HAEMOPHILUS INFLUENZAE TYPE b AND HEPATITIS B VACCINE (DTaP/IPV/Hib/HepB)-** state the brand of vaccine • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.

Written information to be given to individual, parent or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Babies and pre-school - Public Health Wales • phw.nhs.wales/topics/immunisation-and-vaccines/leaflets/babies-and-pre-school/what-to-expect-after-vaccinations-bilingual-leaflet/ • https://phw.nhs.wales/topics/immunisation-and-vaccines/leaflets/babies-and-pre-school/6-in-1-vaccine-for-babies-and-children/ Further information for printing and website links suitable for the public can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources. For resources in accessible formats and alternative languages, please visit Home- Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.
Advice and follow up treatment	Inform the individual, parent or 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 or carer about administering prophylactic paracetamol with routine immunisations scheduled at 8 weeks and 12 weeks of age when DTaP/IPV/Hib/HepB is co-administered with MenB vaccine (see identification and management of adverse reactions). Also refer to the MenB PGD0092. **NB. For premature babies, check with a doctor or NNU outreach to confirm the correct dose of paracetamol to be given, according to the infant's weight at the time of vaccination** The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card scheme.

	Give appropriate advice if medication is used off-label. When administration is postponed, advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working 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 6 months of life and most common in the second year of life. After this age, the frequency falls and they are rare after 5 years of age (see the Green Book Chapter 26). Children coming to the UK 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 UK. 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 UK recommendations should be followed. Unimmunised or incompletely immunised children require one dose of Hib over the age of one 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; please send unscheduled form to child health to document

	in child's notes; 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 consultation details as required by local procedures. The practitioner must ensure the following is recorded: • 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 2005. Record name of representative who gave consent if appropriate. • name of individual, address, date of birth and GP with whom the individual is registered • medical and drug history taken, including any allergies and previous adverse events • printed name and signature of immuniser • name and brand of vaccine • date and time of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if the individual is excluded or declines immunisation • details of any adverse drug reactions and actions taken • **administered via PGD, record PGD title and version number** Records should be signed and dated (or password-controlled 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.

	The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation or pathway as required by any local or contractual arrangement. If a vaccine is administered to a child up to 19 years of age, forward a notification of vaccination given to Child Health Department using the appropriate documentation/pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age). A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Key references

Key references	DTaP/IPV/Hib/HepB vaccine

- Immunisation Against Infectious Disease: The Green Book Chapter 15, Chapter 16, Chapter 18, Chapter 24, Chapter 26 and Chapter 30 www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Summary of Product Characteristics for Infanrix®-hexa, GlaxoSmithKline, last updated 7 April 2025 https://www.medicines.org.uk/emc/product/2586/smpc
- Summary of Product Characteristics for Vaxelis®, Sanofi, last updated 9 April 2024 https://www.medicines.org.uk/emc/product/12264
- Personal communication. Sanofi UK and Ireland Medical Information, received 16 April 2024
- The hexavalent DTaP/IPV/Hib/HepB combination vaccine information for healthcare practitioners, updated 13 May 2024 https://www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance
- Vaccination of individuals with uncertain or incomplete immunisation status, www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status
- The National Society for Phenylketonuria (NSPKU) Medical Advisory Panel: Vaccines and PKU, issued 2 October 2024 https://nspku.org/download/vaccines-and-pku/
- National polio guidelines: Local and regional services, updated 26 September 2019 assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/833211/National_polio_guidelines_2019.pdf
- Changes to the routine childhood schedule letter, published 30 April 2025 https://www.gov.uk/government/publications/changes-to-the-routine-childhood-schedule-letter

General

- NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/

- National Minimum Standards and Core Curriculum for Immunisation Training, published 7 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 27 March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018. https://www.nice.org.uk/guidance/mpg2/resources
- Immunisation Collection https://www.gov.uk/government/collections/immunisation
- Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

Additional References

- Advisory Document: Handling & Storage of Vaccines, 7th revision. September 2017. Available from: https://www.wmic.wales.nhs.uk/vaccine-ordering-storing-handling [accessed 04 June 2025]
- NHS Wales. Welsh Health Technical Memorandum 07-01 – Safe Management of Healthcare Waste. 2013. Available from: https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/ [accessed 04 June 2025]
- Public Health Wales. Leaflets and accessible vaccination information. Available from: https://phw.nhs.wales/topics/immunisation-and-vaccines/vaccination-information-in-accessible-formats/ [accessed 04 June 2025]
- Welsh Government. Health circulars. Available from https://www.gov.wales/health-circulars [accessed 04 June 2025]
- Welsh Government. Records management code of practice for health and social care 2022. Published 02 March 2022. Available from https://www.gov.wales/managing-health-and-social-care-records-code-practice-2022 [accessed 04 June 2025

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comments "	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.