



**Patient Group Direction For The Administration Of DTaP/IPV/Hib/HepB
 (Hexavalent) Vaccine By Approved Healthcare Professionals Working
 Within NHS Grampian, Highland, Orkney, Shetland, Tayside And
 Western Isles**

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	Consultation Group: See relevant page in the PGD	Approver: NoS PGD Group Authorisation: NHS Grampian
---	---	--

Signature: 		Signature: 
--	--	--

NoS Identifier: NoS/PGD/Hexavalent/MGP G1285	Review Date: August 2024 Expiry Date: August 2025	Date Approved: August 2022
---	--	--------------------------------------

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have
 authorised this Patient Group Direction to help individuals by providing them with
 more convenient access to an efficient and clearly defined service within the NHS
 Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are
 completed.

Uncontrolled when printed

Version 2

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from PHS national PGD and supersedes the previous NoS/PGD/Hexa/MGPG1045.	
Date of change	Summary of Changes	Section heading
February 2022	NoS PGD adapted from PHS national PGD.	
February 2022	Infanrix®-Hexa removed from title of PGD.	Throughout
February 2022	Vaxelis® added to PGD.	Throughout
February 2022	Staff groups authorised to use the PGD expanded to include all healthcare professionals authorised under current PGD legislation to use a PGD.	Characteristics of staff authorised to administer vaccine under PGD
May 2022	Children requiring booster post chemotherapy (NHST only) added.	Inclusion criteria

NoS Identifier:

NoS/PGD/Hexavalent/MGPG1285

Keyword(s):

PGD Patient Group Direction immunisation
 infanrix hexa® Vaxelis® hexavalent hepatitis B
 vaccine

Policy Statement:

It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document: Drafted: February 2022
 Completed: July 2022
 Approved: August 2022 (published – August 2022
 Amended &
 reauthorised:

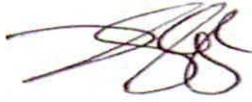
Organisational Authorisations

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


PGD Developed/Reviewed by;

<p>Medical practitioner</p>	<p>Name: Dr Susan Laidlaw Health Board: NHSS Title: Consultant in Public Health Contact email: susan.laidlaw2@nhs.scot Signature  Date: 18/08/2022</p>
<p>Senior representative of the professional group who will provide care under the direction</p>	<p>Name: Fiona Browning Health Board: NHSG Title: Health Protection Nurse Specialist Contact email: fiona.browning@nhs.scot Signature  Date: 09/08/2022</p>
<p>Lead author</p>	<p>Name: Frances Adamson Health Board: NHSG Title : Medicines Management Specialist Nurse Contact email: frances.adamson@nhs.scot Signature  Date: 02/08/2022</p>
<p>Pharmacist</p>	<p>Name: Findlay Hickey Health Board: NESH Title : Medicines Management Pharmacist Contact email: findlay.hickey2@nhs.scot Signature  Date: 18/08/2022</p>

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		02/08/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		19/08/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:

Title:

Frances Adamson

Lead Author: Medicines Management Specialist Nurse
NHSG

Findlay Hickey
Dr Susan Laidlaw
Fiona Browning

Pharmacist: Medicines Management Pharmacist NHSH
Medical Practitioner: Consultant in Public Health NHSS
Senior Representative: Health Protection Nurse Specialist
NHSG

Lynda Davidson
Jacqueline Donachie
Liam Callaghan
Russell Mackay

Health Protection Nurse NHSH
Vaccination Programmes Manager NHST
Chief Pharmacist NHSWI
Clinical Pharmacist NHSO

Patient Group Direction For The Administration Of DTaP/IPV/Hib/HepB (Hexavalent) Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Clinical indication to which this PGD applies

<p>Definition of situation/Condition</p>	<p>This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer DTaP/IPV/Hib/HepB (hexavalent) vaccine (Infanrix®-hexa and Vaxelis®) to individuals for active immunisation against diphtheria, tetanus, pertussis, poliomyelitis, <i>haemophilus influenzae</i> type b and hepatitis B in line with Scottish Government immunisation programme.</p> <p>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book and the individual Summary of Product Characteristics (SmPC).</p>
<p>Inclusion criteria</p>	<p>Infants from 6 weeks of age to under 10 years of age requiring primary vaccination as part of the routine immunisation schedule.</p> <p>The following inclusion is relevant to NHS Tayside only and does not apply in any other NoS Board: Children requiring booster doses 6 months after completing chemotherapy.</p> <p>Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.</p>
<p>Exclusion criteria</p>	<p>Individuals who:</p> <ul style="list-style-type: none"> • Are infants less than 6 weeks of age • Are aged 10 years and over • Have a confirmed anaphylactic reaction to a previous dose of Infanrix®-hexa or Vaxelis® vaccine • Have 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 • Who have a confirmed anaphylactic reaction to any component of the vaccine, including glutaraldehyde, formaldehyde, neomycin and polymixin, streptomycin and

	<p>bovine serum albumin. Practitioners must check the marketing authorisation holder’s summary of product characteristics (SmPC) for details of vaccine components</p> <ul style="list-style-type: none"> • Have received immunisation with combined diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenza type b and hepatitis B containing vaccine in the preceding 3 weeks (there is no minimum gap required between DTaP/IPV/Hib/HepB vaccine and a previous dose of monovalent hepatitis B vaccine) • Are suffering from acute severe febrile illness – postpone immunisation until patient has fully recovered • With a history of severe reaction (i.e. anaphylactic reaction) to latex where vaccine is not latex free.’ As circumstances change you should check each time latex sensitive individual presents. <p>Individuals for whom no valid consent has been received.</p>
<p>Precautions and special warnings</p>	<p>Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.</p> <p>The Green Book advises that there are very few individuals who cannot receive DTaP/IPV/Hib/HepB vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.</p> <p>The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.</p> <p>If a child has experienced encephalopathy or encephalitis within 7 days of a previous immunisation with a pertussis-containing vaccine, it is unlikely these conditions will have been caused by the vaccine and they should have been investigated by a specialist.</p> <p>If a cause was identified or the child recovered within 7 days, immunisation should proceed as recommended. In children where no underlying cause was found and the child did not recover completely within 7 days, immunisation should be</p>

	<p>deferred until the condition has stabilized or the expected course of the condition becomes clear.</p> <p>If the child has not been investigated by a specialist, then immunisation should be deferred until a specialist opinion is obtained.</p> <p>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 if a cause is identified or the child recovers within 24 hours. However, if no underlying cause has been found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable.</p>
<p>Action if excluded from treatment</p>	<p>Medical advice must be sought – refer to relevant medical practitioner for advice on the vaccine and circumstances under which it could be given using a patient specific direction.</p> <p>The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records.</p> <p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged.</p> <p>If aged less than 6 weeks advise to return for routine immunisation when the child is eight weeks old or over and give an appropriate appointment. Immunisation can be administered from six weeks of age if required e.g. if travelling to an endemic country or at increased risk of hepatitis B virus and dose of Hep B vaccine is due. If aged 10 years and over assess for immunisation with Td/IPV as appropriate.</p> <p>Document the reason for exclusion under the PGD and any action taken in the individual’s appropriate clinical records.</p>
<p>Action if treatment is declined</p>	<p>Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached.</p> <p>Inform/refer to the relevant medical practitioner if parent/carer declines treatment.</p>

	Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.
--	--

Description of vaccine available under the PGD

Name form and strength of vaccine	<p>DTaP/IPV/Hib/HepB Infanrix[®]-hexa vaccine, powder and suspension for injection.</p> <p>DTaP/IPV/Hib/HepB Vaxelis[®] vaccine, suspension for injection in a pre-filled syringe.</p> <p>See SmPC for further details.</p>
Legal status	Infanrix [®] -hexa and Vaxelis [®] are Prescription-only Medicines (POM).
Is the use out with the SmPC?	<p>Administration of Infanrix[®]-hexa to individuals born before 24 weeks of gestational age and to individuals over 3 years of age is off label but is indicated until 10 years of age under this PGD in accordance with The Green Book recommendations.</p> <p>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 The Green Book recommendations.</p> <p>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 The Green Book</p> <p>Administration 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.</p> <p>The parent/carer should be informed prior to the administration that the use is off-label, however the vaccine is being offered in accordance with national guidance.</p> <p>Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines guidance. Where vaccine is</p>

	assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Dosage/Maximum total dose	0.5mL
Frequency of dose/Duration of treatment	<p>The course consists of three doses with a recommended interval of at least 4 weeks between the doses although one of these doses may be given up to a week early when required e.g. due to impending travel to an endemic country. No more than one dose should be given early in the three dose schedule.</p> <p>The routine childhood immunisation schedule recommends doses as follows:</p> <ul style="list-style-type: none"> • First primary immunisation at 8 weeks* • Second primary immunisation at 12 weeks • Third primary immunisation at 16 weeks <p>*The first dose of primary immunisations can be given at 6 weeks of age if required in certain circumstances e.g. travel to an endemic country.</p> <p>If the primary course is interrupted it should be resumed but not repeated, allowing an interval of at least four weeks between the remaining doses.</p> <p>Vaxelis® and Infanrix®- hexa vaccines are considered interchangeable, but where possible and if local stock allows, it is preferable that the same DTaP/IPV/Hib/HepB vaccine be used for all 3 doses of the primary course. However, vaccination should never be delayed because the vaccine used for previous doses is not known or unavailable.</p> <p>Those individuals with uncertain or incomplete immunisation status should be vaccinated in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart.</p>
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of administration	<p>Intramuscular injection.</p> <p>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.</p> <p>Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of</p>

	<p>bleeding. However, the SmPC for Vaxelis[®] specifically states to not administer by intravascular, intradermal or subcutaneous injection. Therefore, where a deep subcutaneous injection is required, use Infanrix[®]-hexa.</p> <p>If the only available vaccine is Vaxelis[®], individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route.</p> <p>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/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/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/carer should be informed about the risk of haematoma from the injection.</p> <p>DTaP/IPV/Hib/HepB vaccine can be given at the same time as the other vaccines administered as part of the childhood immunisation programme including BCG. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Infanrix[®]-hexa or Vaxelis[®]. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.</p> <p>The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.</p>
<p>Quantity to be administered</p>	<p>0.5mL dose per administration.</p>
<p>Storage requirements</p>	<p>Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Do not freeze.</p> <p>Store in original packaging in order to protect from light.</p>

	<p>Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.</p>
<p>Additional Information</p>	<p>Very premature infants (born less than or equal to 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hrs when given their first routine immunisations, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first routine immunisations, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hrs.</p> <p>The immunogenicity of the vaccine could be reduced in immunosuppressed individuals. However, vaccination should proceed in accordance with national recommendations.</p> <p>Infants born to a hepatitis B surface antigen positive mother will require additional doses of paediatric hepatitis B vaccine at 0 and 4 weeks of age and at 12 months.</p>
<p>Follow-up (if applicable)</p>	<p>Following immunisation individuals should remain under observation in line with individual NHS Board policy.</p> <p>The parent/carer should not leave if they have any concerns that the vaccine recipient is unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.</p>
<p>Advice (Verbal)</p>	<ul style="list-style-type: none"> • Advise parent/carer what to expect and of the possible side effects and their management • The parent/carer should be advised to seek medical advice in the event of a severe adverse reaction • Parents/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. <p>When administration is postponed advise the parent/carer when to return for vaccination.</p>

	<p>If appropriate, advise when subsequent doses are due and if any follow up is required.</p>
<p>Advice (Written)</p>	<p>The PIL contained in the medicine(s) should be made available to the parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</p> <p>More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation</p>
<p>Identifying and managing possible adverse reactions</p>	<p>Fever, and pain, swelling or redness at the injection site commonly occurs and are seen more frequently following subsequent doses. A small, painless nodule may form at the injection site; this usually disappears and is of no consequence. Other common adverse reactions include fever, abnormal crying, irritability, restlessness, appetite loss, fatigue, diarrhoea, vomiting and nervousness.</p> <p>Studies have shown that when hepatitis B vaccine is added to DTaP/IPV/Hib vaccine, the frequency and type of adverse reactions experienced are similar to those seen when the DTaP/IPV/Hib vaccine is given alone or with monovalent hepatitis B vaccine.</p> <p>Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare and facilities for its management must be available.</p> <p>As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.</p> <p>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</p> <p>BNF/BNFC: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE</p> <p>SmPC/PIL/Risk Minimisation Material: Home - electronic medicines compendium (emc) MHRA Products Home RMM Directory - (emc)</p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p>

	<p>Document in accordance with locally agreed procedures in the individual's record.</p> <p>Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA.</p>
<p>Facilities and supplies required</p>	<p>The following are to be available at sites where the vaccine is to be administered:</p> <ul style="list-style-type: none"> • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

<p>Professional qualifications</p>	<p>The following classes of registered healthcare professionals are permitted to administer vaccines as identified and included in individual Board immunisation delivery plans:</p> <ul style="list-style-type: none"> • Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • Pharmacists currently registered with the General Pharmaceutical Council (GPhC) • Chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • Dental hygienists and dental therapists registered with the General Dental Council • Optometrists registered with the General Optical Council.
---	--

<p>Specialist competencies</p>	<p>Approved by the organisation as:</p> <ul style="list-style-type: none"> • Competent to assess the parent’s/carer’s capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Familiar with the vaccine product and alert to changes in the product information. • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the “cold chain” • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
<p>Ongoing training and competency</p>	<p>All professionals working under this PGD must:</p> <ul style="list-style-type: none"> • Have undertaken NoS PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with individual Board requirements • Have undertaken immunisation training • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. Note: All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD. • Have knowledge and familiarity of the following; <ul style="list-style-type: none"> ○ Current edition of the Green Book ○ SmPC for the vaccine to be administered in accordance with this PGD ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
<p>Responsibilities of professional manager(s)</p>	<p>Professional manager(s) will be responsible for;</p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p>

	<p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.</p>
--	--

Documentation

Authorisation of administration	<p>Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following:</p> <p>Nurses, midwives and health visitors can be authorised by their line manager.</p> <p>Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration.</p> <p>The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiroprodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.</p>
Record of administration	<p>An electronic or paper record must be completed to allow audit of practice.</p> <p>An electronic/Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes.</p>

	<p>If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum:</p> <ul style="list-style-type: none"> • Date and time of vaccine administration • Individuals name, address and CHI • GP with whom the individual is registered • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered • Advice given, including advice given if excluded or declined vaccination under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine, and who undertook the assessment of the individual’s clinical suitability for the vaccine • Where childhood immunisations are given information of the administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS). • Record of any adverse effects and the actions taken (advise individuals’ GP/relevant medical practitioner). <p>Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate.</p> <ul style="list-style-type: none"> • Child Health Information Services if appropriate • Hand-held records such as red book if appropriate • Individual’s GP records if appropriate • HEPMA • Individual service specific systems. <p>Local policy should be followed with respect to sharing information with the individual’s General Practitioner.</p> <p>All records should be clear, legible and contemporaneous and in an easily retrievable format.</p>
<p>Audit</p>	<p>All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</p>

References	<p>Electronic Medicines Compendium http://www.medicines.org.uk</p> <p>Infanrix®-hexa – Date of revision of text 01/01/2021, accessed 08/02/22.</p> <p>Vaxelis® – Date of revision of text 01/01/2021, accessed 08/02/22.</p> <p>British National Formulary for Children accessed 08/02/22.</p> <p>Department of Health (2006): Immunisation against Infectious Disease [Green Book]</p> <ul style="list-style-type: none">• chapter 15• chapter 16• chapter 18• chapter 24• chapter 26• chapter 30 <p>All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s). CMO letters can be viewed at the following website SHOW - SGHSC - Scottish Government Health and Social Care Directorates</p> <p>American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.</p>
-------------------	--



Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of DTaP/IPV/Hib/HepB Hexavalent Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

Appendix 2

**Healthcare Professionals Authorisation to Administer Vaccine
 Under Patient Group Direction**

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.

**Patient Group Direction For The Administration Of DTaP/IPV/Hib/HepB
 Hexavalent Vaccine By Approved Healthcare Professionals Working
 Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western
 Isles**

Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

