**PHE publications gateway number: 2015561**

## PATIENT GROUP DIRECTION (PGD)

Administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis and *Haemophilus influenzae* type b conjugate vaccine (DTaP/IPV/Hib)

Individuals from 8 weeks to under 10 years of age in accordance with the national immunisation programme

## For the administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis and *Haemophilus influenzae* type b conjugate vaccine (DTaP/IPV/Hib) by currently registered nurses or paramedics to individuals from 8 weeks to under 10 years of age in accordance with the national immunisation programme for active immunisation against diphtheria, tetanus, pertussis, poliomyelitis and *Haemophilus influenzae* type b.

Reference no: *DTaP/IPV/Hib PGD*

Version no: *v01.00*

Valid from: *15 December 2015*

Review date: *1 June 2017*

Expiry date: *30 November 2017*

**Public Health England has developed this PGD for local authorisation by NHS England to facilitate delivery of the national immunisation programme.**

Those using this PGD must ensure that it is formally authorised and signed by a clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of NHS England for their geographical area, so that this document meets legal requirements for a PGD. **THE PGD IS NOT LEGAL OR VALID WITHOUT THIS LOCAL, FORMAL AUTHORISATION.**

Authorising organisations must not alter or amend the body of this document; such action will invalidate the clinical sign-off with which it is provided.

Operation of this PGD is the responsibility of commissioners and service providers.

**THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

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. Current versions of PHE PGD templates for local authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation>

Any concerns regarding the content of this PGD should be addressed to:

[Immunisation@phe.gov.uk](mailto:Immunisation@phe.gov.uk)

# **Change history**

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| **Version number** | **Change details** | **Date** |
| V01.00 | New PHE PGD template | 15 Dec 2015 |
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1. **PGD template development**

This PGD template has been developed by the following on behalf of Public Health England:

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| **Developed by:** | **Name** | **Signature** | **Date** |
| Pharmacist (Lead Author) | Elizabeth Graham  Lead Pharmacist Immunisation Services, PHE | C:\Users\beth.graham\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Word\Signature 1.jpeg | 15/12/2015 |
| Doctor | Mary Ramsay  Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE |  | 15/12/2015 |
| Registered Nurse | David Green  Nurse Consultant – Immunisations, PHE |  | 15/12/2015 |

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE Policy for PGD Templates. It has been ratified by PHE Medicines Management Group and PHE Clinical Governance Group.

**Acknowledgements**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Gayatri Amirthalingam | Consultant Epidemiologist, Public Health England |
| Jacqueline Lamberty | Medicines Management Adviser – Public Health England |
| Gill Marsh | Senior Health Protection Nurse Practitioner, Cheshire & Merseyside Health Protection Team, Public Health England |
| Lesley McFarlane | Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire and Lincolnshire |
| Sue Mulvenna | Pharmacist Lead - NHS England South West |
| Graham Munslow | Clinical Screening and Immunisation Manager, NHS England Lancashire & Greater Manchester / Public Health England. |

1. **Organisational authorisations**

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.

INSERT AUTHORISING BODY NAME authorise this PGD for use by the services or providers listed below:

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| Authorised for use by the following organisations and/or services |
| eg All NHS England sub-region commissioned immunisation services |
| Limitations to authorisation |
| eg Any local limitations the authorising organisation feels they need to apply in-line with the way services are commissioned locally. This organisation does not authorise the use of this PGD by …. |

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| Organisational approval (legal requirement) | | | |
| Role | Name | Sign | Date |
| Complete eg NHSE Governance Lead, Medical Director |  |  |  |

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| Additional signatories according to locally agreed policy | | | |
| Role | Name | Sign | Date |
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Local enquiries regarding the use of this PGD may be directed to…………….

Organisations must add an individual practitioner authorisation sheet or list of authorised practitioners. This varies according to local policy but this should be a signature list or an individual agreement as included at the end of this PGD.

#### Characteristics of staff

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| **Qualifications and professional registration** | Registered professional with one of the following bodies:   * nurses currently registered with the Nursing and Midwifery Council (NMC) * paramedics currently registered with the Health and Care Professions Council (HCPC) |
| **Additional requirements** | Additionally practitioners:   * must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction 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](https://www.nice.org.uk/guidance/mpg2/resources) for health professionals using patient group directions) * must be familiar with the vaccine products and alert to changes in their Summary of Product Characteristics, Immunisation Against Infectious Disease (“[The Green Book](https://www.gov.uk/government/collections/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 for Immunisation Training (2005)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/362171/National_Immun_Train_Stand1.pdf) * 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” * must be competent in the recognition and management of anaphylaxis * must have access to the Patient Group Direction and associated online resources * should fulfil any additional requirements defined by local policy   **THE 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 England and/or NHS England 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. |

1. **Clinical condition or situation to which this PGD applies**

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| **Clinical condition or situation to which this PGD applies** | Indicated for the active immunisation of individuals from 8 weeks to under 10 years of age for the prevention of diphtheria, tetanus, pertussis, poliomyelitis, and *Haemophilus influenzae* type b in accordance with the national immunisation programme and recommendations given in [Chapter 15](https://www.gov.uk/government/publications/diphtheria-the-green-book-chapter-15), [Chapter 16](https://www.gov.uk/government/publications/haemophilus-influenzae-type-hib-the-green-book-chapter-16), [Chapter 24](https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24), [Chapter 26](https://www.gov.uk/government/publications/polio-the-green-book-chapter-26) and [Chapter 30](https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30) of Immunisation Against Infectious Disease: “The Green Book”. |
| **Criteria for inclusion** | Individuals from 8 weeks to under 10 years of age who:   * require a primary course of immunisation against diphtheria, tetanus, pertussis, poliomyelitis and *Haemophilus influenzae* type 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](https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30)) |
| **Criteria for exclusion[[1]](#footnote-2)** | Individuals for whom no valid consent has been received.  Individuals who:   * are less than 8 weeks of age * are aged 10 years and over * have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis or poliomyelitis containing vaccine, including any conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate * have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture, these may include neomycin, polymyxin, polysorbate 80, streptomycin, glutaraldehyde, formaldehyde and bovine serum albumin (refer to relevant SPC) * have received immunisation with diphtheria, tetanus, pertussis, polio or Hib antigen in the preceding 4 weeks * have experienced neurological complications, eg encephalopathy or encephalitis, occurring within 7 days following previous vaccination with diphtheria, tetanus or pertussis unless they have been assessed by a paediatrician or paediatric neurologist and deemed fit for immunisation (see “The Green Book” [Chapter 15](https://www.gov.uk/government/publications/diphtheria-the-green-book-chapter-15), [Chapter 24](https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24) and [Chapter 30](https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30)) * currently have an unstable neurological condition of unknown cause, including poorly controlled epilepsy (see “The Green Book” [Chapter 15](https://www.gov.uk/government/publications/diphtheria-the-green-book-chapter-15), [Chapter 24](https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24) and [Chapter 30](https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30)) * are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) |

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| **Cautions including any relevant action to be taken** | If a seizure associated with a fever occurred within 72 hours of a previous immunisation with pertussis containing vaccine, immunisation should continue as recommended if a cause 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.  The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate.  Patients who are immunosuppressed may not be adequately protected against tetanus, despite having been fully immunised. If they have a tetanus prone wound they should be managed as if they were incompletely immunised ie provide a reinforcing dose of vaccine.  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 48-72 hrs 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 48-72 hrs. |
| **Action to be taken if the patient is excluded**  (continued over page)  **Action to be taken if the patient is excluded**  (continued) | If aged less than 8 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 under a PSD to infants from 6 weeks of age if required eg if travelling abroad.  If aged 10 years or over assess for immunisation with Td/IPV as appropriate.  If previous primary dose administered within last 4 weeks defer immunisation for an appropriate interval.  Individuals with a current unstable neurological condition of unknown cause, including poorly controlled epilepsy, should defer immunisation and the individual should be referred to a specialist for investigation to see if an underlying cause can be identified. If a cause is not identified, immunisation should be deferred until the condition has stabilised. If a cause is identified immunisation should proceed as recommended.  If a child experiences encephalopathy or encephalitis within seven days of immunisation, the advice in the flow chart in “The Green Book” [Chapter 24](https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24) Figure 24.5 should be followed. It is unlikely that these conditions will have been caused by the vaccine and they should be investigated by a specialist. If a cause is identified or the child recovers within seven days, immunisation should proceed as recommended. In children where no underlying cause was found and the child did not recover completely within seven days, immunisation should be deferred until the condition has stabilised.  Seek appropriate advice from the local Screening and Immunisation Team, a Consultant in Health Protection or the individual’s clinician where appropriate as a PSD may be indicated.  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.  In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.  **Temporary exclusion**  In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. |
| **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.  Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.  Document advice given and the decision reached.  In a GP practice setting, inform or refer to the GP as appropriate. |
| **Arrangements for referral for medical advice** | As per local policy |

1. **Description of treatment**

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| **Name, strength & formulation of drug** | Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed), DTaP/IPV/Hib  Eg:   * Infanrix®-IPV+Hib, powder (Hib) in vial and suspension (DTaP/IPV) for suspension for injection in pre-filled syringe * Pediacel®,suspension for injection in pre-filled syringe |
| **Legal category** | Prescription only medicine (POM) |
| **Black triangle▼** | No |
| **Off-label use** | Administration of Infanrix®-IPV+Hib to individuals over 3 years of age and Pediacel® to individuals aged 4 years and over is off-label but is indicated until 10 years of age under this PGD in accordance with PHE recommendations for the [vaccination of individuals with uncertain or incomplete immunisation status](https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status) and the relevant chapters of “The Green Book”.  Administration by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in [Chapter 4](https://www.gov.uk/government/publications/immunisation-procedures-the-green-book-chapter-4) of “The Green Book”. |
| **Route / method of administration** | Some vaccine products (eg Infanrix®-IPV+Hib) **must be reconstituted** in accordance with the manufacturers’ instructions prior to administration.  Administer by **intramuscular injection**, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid region of the upper arm may be used in individuals over one year of age  When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual’s records.  For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see “The Green Book” [Chapter 4](https://www.gov.uk/government/publications/immunisation-procedures-the-green-book-chapter-4)).  The vaccine's normal appearance is a uniform cloudy, white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension prior to reconstitution (if applicable) and before administering the vaccine.  The vaccine should be inspected prior to and after any required reconstitution and should not be used if discoloured or foreign particles are present.  The vaccine’s Summary of Product Characteristics (SPC) provides further guidance on administration and is available from the electronic Medicines Compendium website:  [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Dose and frequency of administration** | Single 0.5ml dose per administration  **Routine Childhood Immunisation Schedule**  DTaP/IPV+Hib 0.5ml should ideally be given as follows:   * first primary immunisation visit (usually at age 2 months) * second primary immunisation visit (usually at age 3 months) * third primary immunisation visit (usually at age 4 months)   When primary vaccination has been delayed the individual should be immunised at the earliest opportunity with an interval of one month between each dose.  3 doses to be administered at one month intervals usually starting at 2 months of age, although can be given until 10 years of age  If the primary course is interrupted it should be resumed but not repeated, allowing an interval of one month between the remaining doses.  **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](https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30) Table 30.1.  Individuals may also require human tetanus immunoglobulin (see “The Green Book” [Chapter 30](https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30)). |
| **Duration of treatment** | The primary course usually consists of three doses with an interval of one month between each dose.  Other diphtheria, tetanus, pertussis and polio vaccines (DTaP/IPV or dTaP/IPV) 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** | 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. |
| **Storage** | Store in a refrigerator at +2°C to +8°C.  Store in original packaging in order to protect from light.  Do not freeze. |
| **Disposal** | Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a proper, puncture-resistant ‘sharps’ box, according to local authority regulations and guidance in the [technical memorandum 07-01](https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste): Safe management of healthcare waste (Department of Health, 2013). |
| **Drug interactions[[2]](#footnote-3)** | Immunological response may be diminished in those receiving immunosuppressive treatment.  May be given at the same time as other vaccines. |
| **Identification & management of adverse reactions2** | Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. A small painless nodule may form at the injection site.  Common adverse reactions include fever, abnormal crying, irritability, restlessness, diarrhoea, vomiting, appetite loss, somnolence, decreased activity and injection site bruising.  Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare.  A detailed list of adverse reactions is available in the vaccine’s Summary of Product Characteristics, which is available from the electronic Medicines Compendium website:  [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Reporting procedure of adverse reactions** | Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <http://yellowcard.mhra.gov.uk>  Any adverse reaction to a vaccine should be documented in the individual’s record and the individual’s GP should be informed. |
| **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](https://www.gov.uk/government/publications/a-guide-to-immunisations-for-babies-up-to-13-months-of-age) * [A quick guide to childhood immunisation for the parents of premature babies](https://www.gov.uk/government/publications/a-quick-guide-to-childhood-immunisation-for-the-parents-of-premature-babies)   Available from: [www.gov.uk/government/collections/immunisation](http://www.gov.uk/government/collections/immunisation) |
| **Patient advice / follow up treatment** | Inform the individual/carer of possible side effects and their management.  The individual/carer should be advised to seek medical advice in the event of an adverse reaction.  When administration is postponed advise the individual/carer when to return for vaccination. |
| **Special considerations / additional information**  Continued over page  **Special considerations / additional information**  (continued) | 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.  Wherever possible, the same DTaP-containing vaccine product should be used for all three doses of the primary vaccine course. If this is not possible, whichever primary vaccine is available (Pediacel® or Infanrix®-IPV+Hib) should be used. Vaccination should not be delayed because the vaccine used for previous doses is unavailable or not known.  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, see: <http://apps.who.int/immunization_monitoring/globalsummary/>  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  Un- 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 vaccine is given.  If a person 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](https://www.gov.uk/government/publications/tetanus-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 that the individual is protected against future exposure. Individuals may also require human tetanus immunoglobulin (see “The Green Book” [Chapter 30](https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30)). |
| **Records** | Record:   * that valid informed consent was given; * name of individual, address, date of birth and GP with whom the individual is registered * name of immuniser * name and brand of vaccine * date 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 excluded or declines immunisation * details of any adverse drug reactions and actions taken * record supplied via Patient Group Direction (PGD) * records should be signed and dated (or password controlled immunisers record on e-records)   All records should be clear, legible and contemporaneous.  This information should be recorded in the individual’s GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual’s GP informed.  The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age.  A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

1. **Key references**

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| **Key references** | **DTaP/IPV/Hib vaccine**   * Immunisation Against Infectious Disease: The Green Book [Chapter 15](https://www.gov.uk/government/publications/diphtheria-the-green-book-chapter-15), [Chapter 16](https://www.gov.uk/government/publications/haemophilus-influenzae-type-hib-the-green-book-chapter-16), [Chapter 26](https://www.gov.uk/government/publications/polio-the-green-book-chapter-26) and [Chapter 30](https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30). Last updated 19 April 2013. [Chapter 24](https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24). Last updated 28 April 2015   <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>   * Summary of Product Characteristic for Infanrix®-IPV+Hib, GlaxoSmithKline. 12 March 2015. <http://www.medicines.org.uk/emc/medicine/28678> * Summary of Product Characteristic for Pediacel®, Sanofi Pasteur MSD Ltd. 6 March 2014. <http://www.medicines.org.uk/emc/medicine/26217> * NHS public health functions agreement 2015-16. Service specification No.4. Immunisation against diphtheria, tetanus, poliomyelitis, pertussis and Hib programme. December 2014. <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/386234/No04_DtapIPVHib_Immunisation.pdf> * Use of Infanrix-IPV+Hib in the infant schedule: information for healthcare professionals. 25 March 2015.   <https://www.gov.uk/government/publications/use-of-infanrix-ipvhib-in-the-infant-immunisation-schedule>   * Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 22 September 2015.   <https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status>  **General**   * PHE Immunisation Collection <https://www.gov.uk/government/collections/immunisation> * British National Formulary (BNF) and British National Formulary for Children (BNF-C). October 2015. [www.BNF.org](http://www.BNF.org) [http://www.evidence.nhs.uk/formulary/bnf/current](http://www.evidence.nhs.uk/formulary/bnf/current/14-immunological-products-and-vaccines/144-vaccines-and-antisera/diphtheria-vaccines/diphtheria-containing-vaccines/diphtheria-containing-vaccines-for-children-under-10-years) * National Minimum Standards for Immunisation Training (2005) <https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards> * NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013. <https://www.nice.org.uk/guidance/mpg2> * NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. <https://www.nice.org.uk/guidance/mpg2/resources> * Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. <http://www.rcn.org.uk/__data/assets/pdf_file/0011/641918/RCN_PHE_immunisation_TOOL_2015_WEB.pdf> * Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste> |

1. **Individual practitioner authorisation sheet**

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.

**Practitioner**

**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.**

Signed……………………………….………………………….…..Date……….….………….....

Name (Print)…………….…………..………….………………………………………….…….............

Designation……………………………………………………………….…..……………….......

**Authorising manager**

Manager to give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the named health care professional who has signed the PGD.

Signed…………………………………….………………………. Date………………………..........

Name (Print)………………………..…………………………………….……………..………..........

Designation………………………………………………………………..…………….…….............

**Note to authorising manager**

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD.

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 [↑](#footnote-ref-2)
2. Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list [↑](#footnote-ref-3)