South Yorkshire and Bassetlaw Area Team

PATIENT GROUP DIRECTION (PGD)

Hepatitis B Vaccine (Engerix B® and HBvaxPRO®)

For the administration of Hepatitis B Vaccine (Engerix B® and HBvaxPRO®) to eligible patients by nurses currently registered with the Nursing and Midwifery Council (NMC) and/or other registered healthcare professionals e.g. pharmacists, in organisations contracted to or on behalf of NHS England South Yorkshire and Bassetlaw Area Team.

Reference: Hepatitis B Vaccine (Engerix B® and HBvaxPRO®)
Version no: V1
Valid from: 25th June 2014
Review date: March 2016
Expiry date: 24th June 2016

The PGD will be authorised by the NHS England Area Team, following NHS England governance systems, so that it meets the legal requirements for a PGD. Following authorisation each provider organisation using this PGD should formally adopt it via a signature from the provider’s governance lead or lead practitioner.

Practitioners intending to work under the PGD must be individually authorised by their/the designated manager, under the current version of this PGD before working according to it. Each practitioner is professionally accountable for ensuring they have undergone appropriate training and are competent and understand the contents of this PGD and the requirements of the individual vaccine programme, including route of administration, contra-indications etc.
1. Clinical condition or situation to which the direction applies

<table>
<thead>
<tr>
<th>Indication</th>
<th>Immunisation against hepatitis B</th>
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</thead>
<tbody>
<tr>
<td>Objective of programme</td>
<td>The objective of the hepatitis B immunisation programme is to protect individuals at high risk of exposure to the virus or complications of the disease.</td>
</tr>
<tr>
<td>Criteria for inclusion</td>
<td>The PGD covers administration to the following groups of patients who are at high risk of hepatitis B:</td>
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<tr>
<td></td>
<td>• Injecting drug users, their sexual partners, children and household contacts; and those who are likely to progress to injecting.</td>
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<td></td>
<td>• Individuals who change sexual partners frequently.</td>
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<td>• Close family contacts of a case or individual with chronic hepatitis B infection.</td>
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<td></td>
<td>• Families adopting children from countries with a high or intermediate prevalence of hepatitis B.</td>
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<td></td>
<td>• Foster carers and their families who receive emergency placements.</td>
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<td></td>
<td>• Permanent foster carers and their families, who accept a child known to be at high risk of hepatitis B.</td>
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<td></td>
<td>• Individuals receiving regular blood or blood products and carers responsible for administration of such products.</td>
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<td></td>
<td>• Babies born to hepatitis B positive mothers.</td>
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<td></td>
<td>• Individuals in residential accommodation for those with learning difficulties.</td>
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<td></td>
<td>• Individuals in day care, schools and centres for those with severe learning disability, based on a local risk assessment.</td>
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<td></td>
<td>• Individuals from communities with a high prevalence of hepatitis B infection, where locally commissioned.</td>
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<td></td>
<td>• Travellers. Hepatitis B is not included on the list of vaccines that may be given as an NHS service; the GP practice may therefore charge travellers as a private service. This PGD does not authorise private administration. The following groups of travellers to areas of intermediate to high prevalence may be administered under this PGD as an NHS service:</td>
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<tr>
<td></td>
<td>o who are at risk due to sexual activity or injectable drug use</td>
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<td></td>
<td>o who intend to seek employment as healthcare or aid workers</td>
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<td></td>
<td>o who will be travelling/residing in these areas for long periods (3 months or longer)</td>
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<tr>
<td></td>
<td>o who are at high risk of requiring medical or dental procedures in countries using unsafe therapeutic injections (e.g. reuse of contaminated needles and syringes without sterilisation).</td>
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<td></td>
<td>Information on endemicity is available from NaTHNaC country information pages: <a href="http://www.nathnac.org/ds/map_world.aspx">http://www.nathnac.org/ds/map_world.aspx</a></td>
</tr>
</tbody>
</table>

**Criteria for exclusion**

- Patient does not meet inclusion criteria;
- Consent not given/obtained;
- Patients with chronic renal failure, including those on dialysis;
- Individuals who are at increased risk of hepatitis B because of their occupation;
- Post exposure immunisation for persons:
  - who are accidentally contaminated or inoculated with blood (e.g. needle stick injury)
  - who have had unprotected sexual intercourse;
- A confirmed anaphylactic reaction to a previous dose of any component of the vaccine;
- A severe general or local reaction to a previous dose of any component of this vaccine;
- A confirmed anaphylactic reaction to latex;
- Acute severe febrile illness (having a minor illness without a fever, e.g. a cold, is not a reason to delay immunisation);
- Allergy to formaldehyde and potassium thiocyanate - applicable to HBvaxPRO® as these substances are used in the manufacturing process and trace residues may remain.
- Patients with chronic liver disease, HIV infection or hepatitis C carrier status.

**Action to be taken if excluded**

- Consider informing or referring to medical practitioner;
- Patients with chronic renal failure should receive hepatitis B vaccination, as advised by the renal unit, under a patient specific direction;
- Individuals with chronic liver disease, HIV infection or hepatitis C carriage should be vaccinated following assessment on an individual basis, under a patient specific direction;
- Individuals requiring immunisation for occupational reasons should be referred to their employer;
- Post exposure immunisation following accidental exposure or unprotected sexual intercourse should be administered under a patient specific direction after assessment by a medical practitioner;
- For acute severe febrile illnesses advise when the vaccine may be given and arrange a further appointment if needed;
- For severe general or local reactions refer to GP who may wish to discuss further with the Consultant in Communicable Disease Control (CCDC) – contact details below;
- For a confirmed anaphylactic reaction to latex, undertake a risk assessment and refer to GP, who may wish to discuss further with the CCDC (contact details below). Further information is also available in Chapter 6 of ‘Immunisation against infectious disease - the green book’:
- Document exclusions or deferrals in clinical record.

The CCDC may be contacted at the local Public Health England Health Protection Team:

- Bassellaw - 0844 2254524
- South Yorkshire - 0114 3211177

**Action if patient or carer declines**

- Advise about the protective effects of the vaccine and the risk of infection and disease complications.
| treatment/vaccination | Inform or refer to medical practitioner if patient declines treatment. (For non GP practice personnel – ask patient/carer permission first)  
| | Document refusal and reason if possible in clinical records.  
| | If child under the age of 19 years inform Child Health Records Department  
| | If refusal by parent for an infant born to a hepatitis B positive mother, consider other potential safeguarding issues.  

| Reference to National / Local policies or Guidelines | Hepatitis B chapter 18; ‘Immunisation against infectious disease - the green book’. PHE updated Dec 2013. >> accessed 28/02/14<<  
| | SPC for Engerix B® and HBvaxPRO®  
| | [http://www.medicines.org.uk/emc/medicine/9283/SPC/Engerix+B+20+micrograms+1+ml+Suspension+for+injection+in+pre-filled+syringe/](http://www.medicines.org.uk/emc/medicine/9283/SPC/Engerix+B+20+micrograms+1+ml+Suspension+for+injection+in+pre-filled+syringe/)  
| | >>accessed 28/02/14<<  
| | GPC Guidance for GPs: Focus on Hepatitis B Immunisation. BMA August 2012 >>accessed 28/02/14<<  
| | GPC Guidance for GPs: Focus on Vaccines and Immunisation. BMA November 2013 >>accessed 28/02/14<<  
| | NaTHNaC Health Information Sheets ‘Hepatitis B’ >>accessed 28/02/14<<  

| Precautions | As with any vaccine, vaccination with hepatitis B may not result in complete protection in all recipients. A number of factors have been observed to reduce the immune response including older age, male gender, obesity, smoking, route of administration and some chronic underlying diseases, including HIV infection.  
| | Pregnancy and breastfeeding:  
| | There is no evidence of risk from vaccinating pregnant women or those who are breastfeeding with inactivated viral or bacterial vaccines or toxoids. Immunisation with hepatitis B vaccine should not be withheld where there is a clinical need and the benefit is considered to outweigh the risk.  

### 2. Description of Treatment

| Name & formulation of drug | Hepatitis B injectable vaccine  
| | (Engerix B® 20mcg/ml or HBvaxPRO® 10mcg/ml).  
| | Note: this PGD does not cover administration of Fendrix® or HBvaxPRO® 40mcg/ml. These should be administered under a patient specific direction when required for patients with chronic renal failure.  

| Presentation | Engerix B® 20mcg/ml  
Suspension of hepatitis B surface antigen adsorbed onto aluminium hydroxide available as 0.5ml and 1ml prefilled syringe and 1ml vial with rubber butyl stopper.  
HBVaxPRO® 10mcg/ml  
Suspension of hepatitis B surface antigen adsorbed onto aluminium hydroxide available as 0.5ml and 1ml prefilled syringe with a chlorobutyl plunger stopper. |
|-------------|---------------------------------------------------------------|
| Storage     | Store in a refrigerator (2 °C – 8 °C).  
Do not freeze.  
| Legal Status| POM |
| Black Triangle▼ | No |
| Unlicensed / Off label use | The only unlicensed use authorised under the PGD is administration of the very rapid schedule of Engerix B® to those aged 16 to 18 years (see under ‘Frequency of administration’). |
| Route / method of administration | Intramuscular injection into the deltoid region in adults and children or in the anterolateral thigh in infants and young children.  
For patients with bleeding disorders, give deep subcutaneous injection to reduce the risk of bleeding. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes after the injection.  
Do not inject into the buttocks or by intradermal injection as this may result in a lower immune response  
Under no circumstances should it be given intravenously.  
The vaccine should be inspected visually in order to detect any appearance of precipitate or discolouring of the content prior to administration. If these conditions exist, the product should not be administered.  
Before use, the syringe should be well shaken.  
Where more than one vaccine is administered at the same time, the vaccines should be given at a separate site, preferably in a different limb. If more than one vaccine is given in the same limb, they should be given at least 2.5cm apart. The sites at which each vaccine was given should be noted in the individual’s health records. |
| Dose        | Engerix B®  
• Child (0 to 15 years): 0.5 ml (10mcg)*  
• Adult (16 years and over): 1 ml (20mcg)  
*In children aged 11 to 15 years the adult dose of 20mcg in 1ml may be
| Frequency of administration | Primary course:  
Accelerated schedule: 3 doses at 0, 1, 2 months with fourth dose at 12 months if at continued risk. This confers protection quickly and should be used in most adult and childhood risk groups. 
Alternative schedule: 3 doses at 0, 1, 6 months should only be used where rapid protection is not required and there is a high likelihood of compliance.  

For children born to hepatitis B positive women the accelerated immunisation schedule is recommended.  

Engerix B® only:  
Alternative regimen for children 11 to 16 years: 2 doses of 20mcg at 0 and 6 months. This schedule should be used only where there is a low risk of hepatitis B infection during the vaccination course and when completion of the two-dose vaccination course can be assured.  

Very rapid schedule for those who are at immediate risk and where a more rapid induction of protection is required:  
Adult over 16 years: 3 doses at 0, 7, 21 days and fourth dose at 12 months. Although unlicensed for those aged 16 to 18 years, this schedule is recommended by the JCVI for this age group where it is important to provide rapid protection and maximise compliance.  

Reinforcing immunisation  
- A single booster dose 5 years after primary immunisation is recommended for those at continuing risk of infection.  
- For children born to hepatitis B positive mothers a booster dose is recommended, given with the pre-school booster for other childhood immunisations. These children thus receive 5 doses in total.  
- For travellers who have completed a primary course of vaccination, a single booster dose of vaccine at five years is not required, unless they are considered to be at continuing risk of infection. |

| Total doses | Up to 5 doses in total, as detailed under ‘Frequency of administration’ |


| Drug Interactions | Hepatitis B vaccine must not be mixed with any other vaccine in the same syringe.  
Hepatitis B vaccine can be given at the same time as other vaccines, including travel vaccines. See ‘Route/method of administration’ for further information.  
Hepatitis B vaccine may be given concurrently with specific hepatitis B |
### Immunoglobulin

When this is indicated according to recommendations in chapter 18 'Immunisation against infectious disease – the green book'.

### Potential Adverse Reactions

Some reactions to vaccination are predictable (although it is not possible to predict who will be affected and to what extent), most are mild and resolve quickly, however some people will have a more severe reaction to the vaccine administered.

**Commonly reported symptoms**

- Pain, discomfort, redness or swelling at the injection site
- Low grade fever, headache, malaise, irritability, drowsiness, gastrointestinal symptoms

The above symptoms usually disappear within one to two days without treatment.

**Other adverse events may include** (but are not limited to):

- Influenza-like illness, myalgia, arthralgia, rash
- Apnoea in very premature infants (≤ 28 weeks of gestation)

The manufacturer’s patient information leaflet and Summary of Product Characteristic sheet should be referred to for full details.

Advice is available from either your screening and immunisation coordinator within the South Yorkshire and Bassetlaw Screening and Immunisation Team or from the Consultant in Communicable Disease Control (CCDC) at your local Public Health England Health Protection Team:

- 0844 2254524 for Bassetlaw
- 0114 3211177 for South Yorkshire.

### Reporting procedure of adverse reactions

All vaccine related incidents (including adverse events, administration errors, vaccine quality, device defects etc.) must be reported to the Screening and Immunisation Team at NHS England Area Team via england.sybsl@nhs.net

Suspected adverse events following vaccination must be reported in line with guidance as issued by the Medicines and Healthcare Products Regulatory Agency (MHRA), see: [http://www.mhra.gov.uk/SafetyInformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/Whattoreport/index.htm](http://www.mhra.gov.uk/SafetyInformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/Whattoreport/index.htm)


or via the MHRA: [https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)

Defective Vaccines e.g. errors in packaging, labelling, contamination etc. must be reported to the Defective Medicines Report Centre (DMRC) at the MHRA – Information available from [http://www.mhra.gov.uk/SafetyInformation/Howwemonitorthesafetyofproducts/Medicines/DefectiveMedicinesReportCentre/index.htm](http://www.mhra.gov.uk/SafetyInformation/Howwemonitorthesafetyofproducts/Medicines/DefectiveMedicinesReportCentre/index.htm)

Defective Medical Devices e.g. syringes, needles, vials, ampoules etc. must be reported to the Medical Devices Adverse Incident Centre (AIC) at MHRA – Information available from [http://www.mhra.gov.uk/Safetyinformation/Reportingproblems/Device](http://www.mhra.gov.uk/Safetyinformation/Reportingproblems/Device)
### Advice to patient / carer including written information and follow up treatment

- The purpose and benefits of immunisation
- Give advice regarding normal reaction to the injection, e.g. sore arm.
- Possible side effects and their management
- Issue vaccine manufacturer’s Patient Information Leaflet (PIL).
- If treatment is deferred, explain why and arrange a new appointment
- Whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. It is recommended that these drugs are not routinely used to prevent fever following vaccination as there is some evidence that prophylactic administration of antipyretic drugs around the time of vaccination may lower antibody responses to some vaccines.
- Give advice: discomfort, swelling, fever, aching muscles and joint pains - usually disappear within one to two days, but can treat with self-administration of paracetamol or ibuprofen if required. NB Ibuprofen should be avoided in pregnancy. Patients/carers may be referred to the local community pharmacist for further advice.
- Dosage and frequency of follow-up treatment should be as per manufacturer’s instructions.
- Advise to seek urgent medical attention if the patient develops swelling (other than localised), rash or breathlessness

Health professionals can refer to the British National Formulary or British National Formulary for children: [http://www.bnf.org/bnf/index.htm](http://www.bnf.org/bnf/index.htm)

### Special considerations and additional information

- 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. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing signs or symptoms to adverse effects of the vaccine.
- As with most vaccines, anaphylactic reactions are extremely rare. An anaphylaxis pack which enables immediate access to epinephrine (adrenaline) 1 in 1000 injection and access to a telephone must always be readily available in case of an anaphylactic event following the administration of the vaccine. A PGD for adrenaline 1 in 1000 injection is not required as it is exempt from the prescription-only medicine requirement when administered for the purpose of saving a life in an emergency.
- Engerix B® or HBvaxPro® vaccine can be used, under the terms of this PGD, to complete a primary course or as a booster in individuals who have previously received another hepatitis B containing vaccine.
- For information on when it is necessary to measure antibody titres, refer to chapter 18 ‘Immunisation against infectious disease – the green book’

### Records

In all cases, regardless of the setting where the vaccine is administered, vaccinators must ensure that records are kept in line with NMC Record Keeping Guidance (2009) and other professional codes of practice as applicable. Documentation includes the Personal Held Child Record (PHCR)
- Red book), other hand held records (e.g. maternity), GP records, computerised records and data collection for Child Health Information Services (CHIS), where applicable. The patient’s clinical record must be updated as soon after vaccination as reasonably practicable (ideally within one working day) as delays may result in clinical error. For providers outside of general practice and who therefore do not hold the patients clinical record, notification of vaccination should ideally be reported to the practice within one working day but must be in accordance with any local service specifications.

The record should include:
- Assessment of the patient's need in relation to the intervention
- Patient’s name, address, date of birth and GP with whom the patient is registered.
- Dose and form of vaccine administered
- Site and route of administration
- Brand, batch number and expiry date of vaccine
- Date given
- Name of the practitioner administering the vaccine
- Consent – following local guidelines
- Advice given to the patient/carer
- Advice given if excluded or declines treatment
- For any contraindications/exclusions the course of action taken and the outcome.
- Record how the patient’s central record or GP surgery record will be updated, where applicable
- Details of any adverse drug reactions and actions taken
- Record that the supply was made via PGD

Medications given under a PGD must be appropriately READ coded in the patients clinical record. The READ codes to be used are:
- SystmOne - Xa QA7
- Emis – 8BMN

Entries made in any record should ensure the practitioner delivering the care is clearly identifiable. Clinical records must be kept for at least 8 years following completion of treatment. In patients aged under 17 years, clinical records must be kept until the patient’s 25th birthday, or for 8 years following a child’s death.

3. Characteristics of Staff

<table>
<thead>
<tr>
<th>Qualifications required</th>
<th>Registered Nurse, currently registered with the NMC, or other registered healthcare professional in organisations contracted to or on behalf of the NHS England SYB Area Team and who has completed a relevant immunisation training programme recognised by their employing organisation. This should ideally be in accordance with the HPA national standards for immunisation training.</th>
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<tr>
<td>Additional requirements</td>
<td>All health professionals responsible for immunisation must have appropriate training for resuscitation of a patient with anaphylaxis to prevent disability and loss of life. They must be familiar with their employing organisations’</td>
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</table>
policy on the management of anaphylaxis for adults and children. If the employing organisation does not have such a policy/protocol then vaccination under this PGD is not permitted.

Knowledge of and access to:

- Patient information leaflet (PI) for Engerix B® and HBvaxPro® available from: [http://www.medicines.org.uk/emc/](http://www.medicines.org.uk/emc/)
- NMC (2009) Record Keeping Guidance (Nurses and Midwives)
- NMC (2010) Standards for Medicines Management (Nurses and Midwives)
- Relevant professional code of practice
- CCG or individual organisations' Consent Policy

<table>
<thead>
<tr>
<th>Continued training requirements</th>
<th>Maintenance of own level of updating with evidence of continued professional development as appropriate and in line with PREP (Post Registration Education and Practice) or other professional registration requirements.</th>
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<tbody>
<tr>
<td></td>
<td>Annual vaccination and immunisation updates are recommended for all staff involved in immunisation.</td>
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<td>Annual updates on resuscitation skills for adults and children (including defibrillation training where defibrillator is available) and the management of anaphylaxis within the community.</td>
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</table>
### 4. PGD Development Team

<table>
<thead>
<tr>
<th>Developed &amp; Produced by:</th>
<th>Name of Developer, Employing Organisation and Job Title</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td>Senior Pharmacist</td>
<td>Hilde Storke, NHS Sheffield CCG; Medicines Governance Pharmacist</td>
<td>[Signature]</td>
<td>29/05/14</td>
</tr>
<tr>
<td>Doctor (Lead Author)</td>
<td>Dr Nachi Arunachalrm – PHE Health Protection Team South Yorkshire; Consultant in Communicable Disease Control</td>
<td>[Signature]</td>
<td>29/05/14</td>
</tr>
<tr>
<td>Senior Registered Nurse</td>
<td>Kathy Wakefield – PHE South Yorkshire and Bassetlaw Area Team (on behalf of NHS England Area Team); Screening and Immunisation Manager</td>
<td>[Signature]</td>
<td>29/05/14</td>
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</table>
Acknowledgements (this may include representatives from CCG Medicine Management Teams who have contributed via consultation)

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<thead>
<tr>
<th>Name</th>
<th>Designation</th>
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5. 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.

<table>
<thead>
<tr>
<th>Approved by:</th>
<th>Name and Job Title</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td>NHS England SYB</td>
<td>David Black</td>
<td></td>
<td>19/6/14</td>
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<tr>
<td>Area Team</td>
<td>Medical Director</td>
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<tr>
<td>NHS England SYB</td>
<td>Margaret Kitching</td>
<td></td>
<td>23/6/14</td>
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<tr>
<td>Area Team</td>
<td>Nurse Director</td>
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Approved by NHS England South Yorkshire and Bassetlaw Area Team Senior Management Team  
Date: 1/7/14

Adoption for use by the provider organisation (to be determined locally if relevant i.e may not be applicable if independent single pharmacy)

<table>
<thead>
<tr>
<th>Name of Provider Organisation</th>
<th>Name of Person accepting on behalf of provider organisation (please print)</th>
<th>Designation of Person accepting on behalf of provider organisation (please print)</th>
<th>Signature of Person accepting on behalf of provider organisation</th>
<th>Date</th>
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PATIENT GROUP DIRECTION: Hepatitis B Vaccine (Engerix B® and HBvaxPRO®)

Individual Practitioner Authorisation

Organisations must complete an Individual Practitioner Authorisation sheet for each person planning to practice under this PGD. You do not need to return signed sheets to the Area Team but you should retain copies as part of your organisation’s internal governance arrangements. You may wish to retain a copy in the individual’s personal file.

Practitioner

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PATIENT GROUP DIRECTIONS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE AND PROFESSIONAL CODE.

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

Designated Manager to give authorisation * for the Health Care Professional named above and who has signed the PGD

Signed......................................................... Date..................................

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

Designation.................................................................................................

On behalf of: Name of organisation ................................................................

*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.