



**Publications Gateway Reference: 2015239**

## **PATIENT GROUP DIRECTION (PGD)**

Administration of Bexsero<sup>®</sup> ▼ suspension for injection (Meningococcal group B vaccine (rDNA, component, adsorbed))

Individuals from 8 weeks of age eligible for the national routine immunisation programme and prevention of secondary cases of MenB disease

For the administration of Bexsero<sup>®</sup> ▼ suspension for injection (Meningococcal group B vaccine (rDNA, component, adsorbed)) by nurses currently registered with the Nursing and Midwifery Council (NMC) to individuals from 8 weeks of age eligible for the national routine immunisation programme and prevention of secondary cases of MenB disease for active immunisation against *Neisseria meningitidis* group B.

Reference no: *MenB PGD*  
Version no: *v01.00*  
Valid from: *1 September 2015*  
Review date: *1 March 2017*  
Expiry date: *31 August 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:


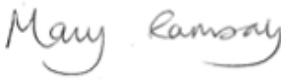

[Immunisation@phe.gov.uk](mailto:Immunisation@phe.gov.uk)

## Change history

| Version number | Change details             | Date         |
|----------------|----------------------------|--------------|
| V01.00         | New Men B PHE PGD Template | 21 July 2015 |
|                |                            |              |
|                |                            |              |

## 1. PGD Template Development

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

| Developed by:                      | Name   | Signature  | Date       |
|------------------------------------|--|--|------------|
| <b>Pharmacist</b><br>(Lead Author) | Elizabeth Graham<br>Lead Pharmacist Immunisation<br>Services, PHE  |  | 21/07/2015 |
| <b>Doctor</b>                      | Mary Ramsay<br>Consultant Epidemiologist and Head<br>Immunisation, Hepatitis & Blood Safety<br>Department, PHE |  | 21/07/2015 |
| <b>Registered Nurse</b>            | David Green<br>Nurse Consultant – Immunisations,<br>PHE  |  | 21/07/2015 |

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   |
|---------------------|---|
| Dr Shamez Ladhani   | Paediatric Infectious Disease Consultant, Public Health England   |
| Dr Vanessa Saliba   | Consultant Epidemiologist, Public Health England  |
| Dr Max Kammerling   | Screening and Immunisations Lead (SIL) – Surrey and Sussex  |
| 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. |


## 2. 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.

**NHS England North (Yorkshire and the Humber)** 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   |
| <p>Authorised for the administration of Bexsero to eligible patients in line with national guidance by nurses currently registered with the Nursing and Midwifery Council (NMC) in primary care organisations commissioned by or on behalf of NHS England. The PGD has been authorised following NHS England's governance processes so that it meets the legal requirements for a PGD. Under clinical governance it is good practice for the Governance Lead in the provider organisation to sign the additional signatory's box. Individual practitioners working under the PGD must be authorized by their employing organization.</p> <p>The PGD has been reviewed by the PGD steering group on behalf of Yorkshire and the Humber prior to authorization.</p> |
| Limitations to authorisation  |
| <p>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.</p>  |

| Organisational Approval (legal requirement) |             |  |         |
|---|-------------|--|---------|
| Role  | Name        | Sign   | Date    |
| Medical Director                            | Paul Twomey |  | 27.8.15 |

| Additional signatories according to locally agreed policy             |               |  |         |
|---|---------------|--|---------|
| Role  | Name          | Sign   | Date    |
| Medicines Management Pharmacist – Rotherham CCG                       | Lisa Murray   |  | 25.8.15 |
| CCDC/Vaccination and Immunisation Lead – PHE Yorkshire and the Humber | Graham Sutton |  | 25.8.15 |

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| <b>Screening and Immunisation Manager – NHS England – North (Yorkshire and the Humber)</b> | <b>Kathy Wakefield</b> |  | <b>25.8.15</b> |
| <b>Organisational Governance Lead</b>  |                        |  |                |

Local enquiries regarding the use of this PGD may be directed to your local Screening and Immunisation Team or the local PHE Health Protection Teams:

Bassetlaw - 0344 2254524

South Yorkshire - 0114 3211177

West Yorkshire – 0113 3860300

North Yorkshire and the Humber – contact Screening and Immunisation Co-ordinator for your CCG

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.

### 3. Characteristics of Staff

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| <b>Qualifications and professional registration</b> | <p>Nurses currently registered with the Nursing and Midwifery Council (NMC).</p>  |
| <b>Additional requirements</b>                      | <ul style="list-style-type: none"> <li>• Must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it.</li> <li>• Must have undertaken appropriate training for working under PGDs for supply/administration of medicines.</li> <li>• Must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using patient group directions).</li> <li>• Must be familiar with the vaccine product and alert to changes in Summary Product Characteristics, Immunisation Against Infectious Disease (“<a href="#">The Green Book</a>”), and national and local immunisation programmes.</li> <li>• Must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards for Immunisation Training (2005)</a>.</li> <li>• Must be competent to undertake immunisation and to discuss issues related to immunisation.</li> <li>• Must be competent in the handling and storage of vaccines, and management of the “cold chain”.</li> <li>• Must be competent in the recognition and management of anaphylaxis.</li> <li>• Have access to the Patient Group Direction and associated online resources.</li> <li>• Should fulfil any additional requirements defined by local policy.</li> </ul> <p><b>THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</b></p> |
| <b>Continued training requirements</b>              | <ul style="list-style-type: none"> <li>• 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).</li> <li>• Practitioners should be constantly alert to any subsequent recommendations from the Public Health England and/or NHS England and other sources of medicines information.<br/>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.</li> </ul>   |

#### 4. Clinical condition or situation to which this PGD applies

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| <p><b>Clinical condition or situation to which this PGD applies</b></p>                              | <p>Bexsero<sup>®</sup>▼ suspension for injection (Meningococcal group B vaccine (rDNA, component, adsorbed)) is indicated for the active immunisation of patients from 8 weeks of age against <i>Neisseria meningitidis</i> group B, in accordance with the recommendations given in the <a href="#">MenB bipartite letter</a> and <a href="#">Chapter 22</a> of Immunisation Against Infectious Disease: The Green Book.</p>  |
| <p><b>Criteria for inclusion</b></p>   | <p><b>Routine immunisation of infants born on or after 01/05/2015</b></p> <ul style="list-style-type: none"> <li>• Aged from 8 weeks up to their second birthday</li> </ul> <p>Vaccination of preterm infants using Bexsero<sup>®</sup>▼ is indicated (without correction for prematurity) if the infant is clinically stable. As the benefit of vaccination is high in premature and very premature infants, vaccination should not be withheld or delayed (see Cautions).</p> <p><b>Prevention of secondary cases of MenB disease</b></p> <ul style="list-style-type: none"> <li>• This PGD also enables vaccination for the <b>prevention of secondary cases of Men B</b>, following specific advice from Public Health England health protection teams.</li> </ul> <p>For further information on preventing secondary cases see: <a href="https://www.gov.uk/government/publications/invasive-meningococcus-capsular-group-b-menb-preventing-secondary-cases">https://www.gov.uk/government/publications/invasive-meningococcus-capsular-group-b-menb-preventing-secondary-cases</a></p>   |
| <p><b>Criteria for exclusion<sup>1</sup></b></p> <p>Criteria for exclusion (continued over page)</p> | <ul style="list-style-type: none"> <li>• Patients for whom no valid consent has been received</li> </ul> <p>Patients who:</p> <ul style="list-style-type: none"> <li>• Are less than 8 weeks old</li> <li>• Are over 2 years of age, unless advised by PHE for the prevention of secondary cases of MenB infection</li> <li>• Have had a confirmed anaphylactic reaction to a previous dose of the vaccine</li> <li>• Have had a confirmed anaphylactic reaction to any constituent or excipient of the vaccine including kanamycin.</li> </ul> <p><b>Exclusions from PGD</b></p> <ul style="list-style-type: none"> <li>• Individuals at increased risk of invasive meningococcal infection. Patients with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment i.e. eculizumab) should be vaccinated in accordance with the recommended schedules in <a href="#">Chapter 7</a> and <a href="#">22</a> of “The Green Book” – A Patient Specific Direction (PSD) will be required</li> <li>• Vaccination for occupational health reasons e.g. laboratory workers working with meningococci – Individual’s occupational health services should provide vaccination</li> <li>• Individuals with a history of severe (i.e. anaphylactic) allergy to latex, Bexsero<sup>®</sup>▼ should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction – A Patient Specific Direction (PSD) will be required</li> </ul> |

<sup>1</sup> Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

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| <b>Criteria for exclusion</b><br>(continued)                         | <b>Temporary Exclusion</b> <ul style="list-style-type: none"> <li>Acute febrile illness – postpone administration until completely recovered</li> </ul>  |
| <b>Cautions including any relevant action to be taken</b>            | <p>Tip cap of the syringe may contain natural rubber latex. For latex allergies other than anaphylactic allergies (e.g. a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain latex can be administered.</p> <p>Very premature infants (born <math>\leq 28</math> weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hours.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an IM route should be given by deep subcutaneous injection to reduce the risk of bleeding (see “The Green Book” <a href="#">Chapter 4</a>)</p> <p>Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p> |
| <b>Action to be taken if the patient is excluded</b>                 | <p>Seek appropriate advice from the local Screening and Immunisation Team, a Consultant in Health Protection or the patient’s clinician, as a PSD may be indicated.</p> <p>The risk to the patient of not being immunised must be taken into account.</p> <p>Document reason for exclusion and any action taken in patient’s clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or prescriber.</p> <p><b>Temporary exclusion</b><br/>In case of postponement of routine immunisation due to acute illness, advise the parent/carer when the infant/child can be vaccinated and ensure another appointment is arranged. Individuals assessed for secondary prevention of Men B with symptoms of acute illness should be medically reviewed as appropriate.</p>  |
| <b>Action to be taken if the patient or carer declines treatment</b> | <p>Informed consent, from the patient or a person legally able to act on the patient’s behalf, must be obtained for each administration.</p> <p>Advise patient/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and decision reached.</p> <p>In a GP practice setting, inform or refer to the GP.</p>   |
| <b>Arrangements for referral for medical advice</b>                  | <p>As per local policy</p>   |



## 5. Description of Treatment

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| <b>Name, strength &amp; formulation of drug</b> | Bexsero <sup>®</sup> ▼ suspension for injection, 0.5mL, in a pre-filled syringe<br>Meningococcal group B Vaccine (rDNA, component, adsorbed).   |
| <b>Legal category</b>                           | Prescription Only Medicine (POM).   |
| <b>Black Triangle▼</b>                          | Bexsero <sup>®</sup> ▼ is black triangle, <i>any</i> suspected adverse reactions should be reported via the National Reporting System and Yellow Card Scheme.   |
| <b>Off-label use</b>                            | <ul style="list-style-type: none"> <li>• Vaccine schedule as recommended by the Joint Committee of Vaccination and Immunisation (JCVI) and Public Health England, in line with <a href="#">Chapter 22</a> of “The Green Book”.</li> <li>• Administration by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in <a href="#">Chapter 4</a> and <a href="#">Chapter 22</a> of “The Green Book”.</li> </ul>  |
| <b>Route / method of administration</b>         | <p>Bexsero<sup>®</sup>▼ is given as a 0.5mL dose by <b>intramuscular injection</b>.</p> <p>In infants, it is recommend that all doses of Bexsero<sup>®</sup>▼ be given in the <b>left thigh</b>, ideally on their own, so that any local reactions can be monitored more accurately. Vaccine should be administered in the deltoid muscle region of the upper arm in older subjects. If another vaccine needs to be administered 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.</p> <p>The vaccine must not be injected intravenously or intradermally and must not be mixed with other vaccines in the same syringe.</p> <p>The vaccine must not be given subcutaneously except to individuals with a bleeding disorder when vaccines normally given by an IM route should be given by deep subcutaneous injection to reduce the risk of bleeding (see Green Book <a href="#">Chapter 4</a>)</p> <p><b>Handling of vaccine before administration</b></p> <p>Upon storage a fine off-white deposit may be observed in the pre-filled syringe containing the suspension.</p> <p>Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension.</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>The Summary of Product Characteristics for Bexsero<sup>®</sup>▼ provides further guidance on administration and is available from the electronic Medicines Compendium website:<br/> <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p> |



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| <b>Dose and frequency of administration</b><br>(continued) | <b>Prevention of secondary cases of Men B disease</b><br>Vaccination in accordance with recommendations from the local Public Health England health protection team and informed by the Public Health England paper <a href="#">Preventing secondary cases of invasive meningococcal capsular group B (MenB) disease</a>  |   |
|  | <b>Age</b>  | <b>Schedule for Secondary Prevention of MenB disease</b>      |
|  | Unvaccinated infants aged 2 months to less than 2 years   | Follow routine schedule                                       |
|  | Unvaccinated children aged 2-10 years   | 2-dose primary schedule with a 2-month interval between doses |
|  | Adolescents from 11 years of age and adults   | 2-dose primary schedule administered one month apart          |
| <b>Duration of treatment</b>                               | See dose section above  |   |
| <b>Quantity to be supplied / administered</b>              | Single dose of 0.5mL per an administration  |   |
| <b>Supplies</b>  | <p>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. Vaccines for private prescriptions, occupational health use or travel, are NOT provided free of charge and should be ordered from the manufacturers.</p> <p>Vaccine for the national immunisation programme should not be used for the prevention of secondary cases of MenB infection. Vaccine should be ordered from the manufacturer.</p> <p>Vaccine for at risk individuals is outside the PGD and should be purchased from the manufacturer and administered under PSD.</p> |   |
| <b>Storage</b>   | Store in a refrigerator at +2°C to +8°C.<br>Store in original packaging in order to protect from light.<br>Do not freeze.   |   |
| <b>Disposal</b>  | Equipment used for immunisation, including used vials, ampoules, or syringes, 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 <a href="#">technical memorandum 07-01: Safe management of healthcare waste</a> (Department of Health, 2013).   |   |
| <b>Drug Interactions<sup>2</sup></b>                       | <p>Immunological response may be diminished in patients receiving immunosuppressant treatment.</p> <p>Bexsero<sup>®</sup> ▼ can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme.</p>   |   |

<sup>2</sup> Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

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| <p><b>Identification &amp; Management of Adverse Reactions<sup>3</sup></b></p> | <p>The most common local and systemic adverse reactions observed in clinical trials after administration of Bexsero<sup>®</sup>▼ to infants and children (less than 2 years of age) were tenderness and erythema at the injection site, fever and irritability. Diarrhoea and vomiting, eating disorders, sleepiness, unusual crying and the development of a rash were commonly or very commonly seen in this age group.</p> <p>Due to the high incidence of fever when primary doses of Bexsero<sup>®</sup>▼ are administered with other routine immunisations, prophylactic use of paracetamol is recommended by the JCVI. Paracetamol should be administered at the time or shortly after vaccination to reduce the incidence and severity of fever after vaccination. 2.5mL (60mg) of infant paracetamol 120mg/5mL suspension should be given prophylactically every 4-6 hours for three doses. Recent studies have confirmed that prophylactic paracetamol does not affect the immunogenicity of either Bexsero<sup>®</sup>▼ or other routine vaccines in the infant immunisation schedule.</p> <p>Paracetamol prophylaxis is not required if the immunisation visit does not include Bexsero<sup>®</sup>▼ (e.g. the 3-month <i>routine</i> vaccinations) or with the 12-13 month Bexsero<sup>®</sup>▼ booster (because Bexsero<sup>®</sup>▼ does not increase the rates of fever at this age). See Patient Advice/Follow-up.</p> <p>In adolescents and adults the most common local and systemic adverse reactions observed were pain at the injection site, malaise and headache.</p> <p>A detailed list of adverse reactions associated with Bexsero<sup>®</sup>▼ is available in the Summary of Product Characteristics for the vaccine, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p> |
| <p><b>Reporting procedure of Adverse Reactions</b></p>                         | <p>As with all vaccines, healthcare professionals and patients/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>Bexsero<sup>®</sup>▼ is black triangle. Therefore, <i>any</i> suspected adverse reactions should be reported via the National Reporting System and Yellow Card Scheme, documented in the patient's record and the patient's GP should be informed.</p>  |
| <p><b>Written information to be given to patient or carer</b></p>              | <p>Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> <li>• <a href="#">Documents relating to the Meningococcal B (MenB) vaccination programme.</a></li> <li>• <a href="#">A guide to immunisations for babies up to 13 months of age</a></li> <li>• <a href="#">A quick guide to childhood immunisation for the parents of premature babies</a></li> </ul> <p>Available from: <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></p>  |

<sup>3</sup> Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

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| <p><b>Patient advice /Follow up treatment</b></p>             | <p>Bexsero<sup>®</sup>▼ is not expected to provide protection against all circulating meningococcal group B strains. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis infection.</p> <p>Inform patient/parent/carer of possible side effects and their management.</p> <p>Advise the patient/parent/carer about the use and timing of paracetamol doses to reduce the risk, intensity and duration of fever as per information in the written information materials for the patient.</p> <p>The patient/parent/carer should be advised to seek medical advice in the event of an adverse reaction or if they are concerned that their infant is unwell at any time.</p> <p>When applicable, advise patient/parent/carer when the subsequent vaccine dose is due.</p> <p>When administration is postponed advise the patient/parent/carer when to return for vaccination.</p> |
| <p><b>Special Considerations / Additional Information</b></p> | <p>Immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone.</p> <p>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. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing signs or symptoms to adverse effects of the vaccine.</p> <p>Meningococcal vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding.</p>  |

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| <p><b>Records</b></p> | <p>Record:</p> <ul style="list-style-type: none"> <li>• That valid informed consent was given</li> <li>• Name of patient, address, date of birth and GP with whom the patient is registered</li> <li>• Name of immuniser</li> <li>• Name and brand of vaccine</li> <li>• Date of administration</li> <li>• Dose, form and route of administration of vaccine</li> <li>• Quantity administered</li> <li>• Batch number and expiry date</li> <li>• Anatomical site of vaccination</li> <li>• Advice given, including advice given if excluded or declines immunisation</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Record supplied via Patient Group Direction (PGD)</li> <li>• Records should be signed and dated (or password controlled immunisers record on e-records)</li> </ul> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the patient's GP record AND infant's Personal Child Health Record ("Red Book") completed.</p> <p>The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway.</p> <p>A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.</p> |
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## Key References

|                       |   |
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| <b>Key references</b> | <b>Meningococcal B Vaccination</b> <ul style="list-style-type: none"><li>• Bexsero® ▼ Summary of Product Characteristics. Novartis Vaccines Updated 6 February 2015<br/><a href="http://www.medicines.org.uk/emc/medicine/28407">http://www.medicines.org.uk/emc/medicine/28407</a></li><li>• Immunisation Against Infectious Disease: The Green Book, <u>Chapter 22</u>.</li><li>• Meningococcal B (MenB) vaccination programme. Published 30 June 15.<br/><a href="https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme">https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme</a></li><li>• Bipartite Letter: Introduction of MenB vaccination for infants. Published 22 June 2015.<br/><a href="https://www.gov.uk/government/publications/menb-vaccination-introduction-from-1-september-2015">https://www.gov.uk/government/publications/menb-vaccination-introduction-from-1-september-2015</a></li><li>• Meningococcal Disease: Guidance, Data and Analysis<br/><a href="https://www.gov.uk/government/collections/meningococcal-disease-guidance-data-and-analysis">https://www.gov.uk/government/collections/meningococcal-disease-guidance-data-and-analysis</a></li><li>• Invasive meningococcus capsular group B (MenB): preventing secondary cases, Public Health England. Published 12 April 2014<br/><a href="https://www.gov.uk/government/publications/invasive-meningococcus-capsular-group-b-menb-preventing-secondary-cases">https://www.gov.uk/government/publications/invasive-meningococcus-capsular-group-b-menb-preventing-secondary-cases</a></li></ul> <b>General</b> <ul style="list-style-type: none"><li>• PHE Immunisation Collection<br/><a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• British National Formulary (BNF) and British National Formulary for Children (BNF-C) <a href="http://www.BNF.org">www.BNF.org</a></li><li>• National Minimum Standards for Immunisation Training (2005)<br/><a href="https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards">https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions<br/><a href="https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-60468733">https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-60468733</a></li><li>• Competency Framework – assessment tool (Appendix). Supporting the delivery of immunisation education. Royal College of Nursing (RCN) 2013.<br/><a href="http://www.rcn.org.uk/data/assets/pdf_file/0005/553748/004479.pdf">http://www.rcn.org.uk/data/assets/pdf_file/0005/553748/004479.pdf</a></li><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20<sup>th</sup> March 2013<br/><a href="https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste">https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</a></li></ul> |
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## 6. 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