



**Publications Gateway Reference: GOV-8557**

**Meningococcal group A, C, W and Y (MenACWY) conjugate vaccine PGD**

This PGD is for the administration of meningococcal group A, C, W and Y (MenACWY) conjugate vaccine to individuals eligible for the national routine MenACWY vaccination programme; university freshers (catch-up); outbreak control and contacts of confirmed cases, for active immunisation against *Neisseria meningitidis*.

This PGD is for the administration of MenACWY vaccine by registered healthcare professionals identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

Reference no: MenACWY PGD  
Version no: v04.00  
Valid from: 01 July 2021  
Review date: 01 January 2023  
Expiry date: 31 July 2023

**Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation in line with national recommendations.**

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

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

**Individual practitioners 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 authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd>

Any concerns regarding the content of this PGD should be addressed to:  
[immunisation@phe.gov.uk](mailto:immunisation@phe.gov.uk)

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: *Insert local contact details such as SIT inbox*


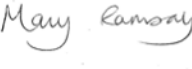

<sup>1</sup> This includes any relevant amendments to legislation (eg [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).

## Change history

Version number	Change details	Date
Version 01.00	New PHE PGD	10 July 2015
Version 02.00	<p>PHE MenACWY PGD amended to:</p> <ul style="list-style-type: none"> <li>remove specific information on individual catch-up cohorts from previous years</li> <li>removal of preferred vaccine choice and related update to off-label section following changes to the Nimenrix<sup>®</sup> license</li> <li>reference the protocol for ordering storage and handling of vaccines</li> <li>update wording regarding authorisation in line with agreed PHE PGD template changes</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	04 May 2017
Version 03.00	<p>PHE MenACWY PGD amended to:</p> <ul style="list-style-type: none"> <li>include additional healthcare practitioners in Section 3</li> <li>refer to vaccine incident guidelines in off-label and storage sections</li> <li>remove the exclusion of individuals who are at increased risk of invasive meningococcal infection and redirect from the inclusion criteria to the MenACWY Risk Groups PGD where applicable</li> <li>extend expiry date through to the end of the school year (end of July)</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li> </ul>	20 February 2019
Version 04.00	<p>PHE MenACWY PGD amended to:</p> <ul style="list-style-type: none"> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs and updated references</li> </ul>	14 June 2021

## 1. PGD Development

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

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead Author)	Jacqueline Lamberty Lead Pharmacist Medicines Management Services, PHE	 J.Y. LAMBERTY	14 June 2021
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		14 June 2021
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation and Countermeasures, PHE		14 June 2021

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Governance Group and the PHE Quality and Clinical Governance Delivery Board.

### Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Gayatri Amirthalingam	Consultant Epidemiologist, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands) /
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)


## 2. Organisational Authorisations


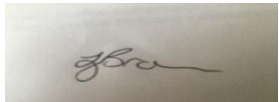
The PGD is not legally valid until it has had the relevant organisational authorisation.

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.

**NHSE&I North East and Yorkshire** authorises this PGD for use by the services or providers listed below:

<b>Authorised for use by the following organisations and/or services</b>
All NHS England & Improvement (NHSE&I) commissioned immunisation services providing immunisation services.
<b>Limitations to authorisation</b>
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE&I North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE&I region of North East and Yorkshire

<b>Organisational Approval (legal requirement)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
Assistant Medical Director and Responsible Officer, NHS England and NHS Improvement –NEY	<b>Dr James Gossow</b>		21.7.21

<b>Additional signatories according to locally agreed policy</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
<b>NHSE&amp;I NEY PGD Governance assurance review</b> (Medicines Optimisation Pharmacist, NHS NECS)	<b>Sue White</b>		20.7.21
<b>NHSE&amp;I NEY PGD Governance assurance review</b> (Screening and immunisation coordinator, PHE Yorkshire and the Humber/NHSE&I NEY)	<b>Laura Brown</b>		12.7.21

Local enquiries regarding the use of this PGD may be directed to your local Public Health England (PHE) screening and immunisation teams. See area specific contacts below:

**For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:**

NHS England Screening and Immunisation Team: Tel. 011382 53017 / email [england.cane.screeingimms@nhs.net](mailto:england.cane.screeingimms@nhs.net) or NECS Medicine Optimisation Pharmacists: Hira Singh or Sue White: Tel 01642 746875 or 0191 217 2533 or [high.singh@nhs.net](mailto:high.singh@nhs.net) / [sue.white14@nhs.net](mailto:sue.white14@nhs.net)

Please note - All North East and North Cumbria PGDs can be found at:

<https://medicines.necsu.nhs.uk/resources/patient-group-directions/>

**For Yorkshire and Humber Area use the following:**

West Yorkshire [england.wy-screeningandimms@nhs.net](mailto:england.wy-screeningandimms@nhs.net)

South Yorkshire and Bassetlaw [england.sybsit@nhs.net](mailto:england.sybsit@nhs.net)

North Yorkshire and Humber [ENGLAND.NYAHSIT@nhs.net](mailto:ENGLAND.NYAHSIT@nhs.net)

or the Health Protection Team Acute Response Centre (ARC): Contact Number: **0113 3860 300**.

Please note - All Yorkshire and Humber PGDs can be found at: <https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds/>

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

### 3. Characteristics of Staff

<p><b>Qualifications and professional registration required</b></p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>• paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p><b>Additional requirements</b></p>	<p>Additionally practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD 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 PGDs)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), 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 and Core Curriculum for Immunisation Training</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>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</b></p>
<p><b>Continued training requirements</b></p>	<p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement 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.</p>

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

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<p>Indicated for the active immunisation of individuals, detailed in the inclusion criteria, against <i>Neisseria meningitidis</i> group A, C, W and Y in accordance with the recommendations given in <a href="#">Chapter 22</a> of Immunisation Against Infectious Disease: 'The Green Book' and <a href="#">Guidance for Public Health Management of Meningococcal Disease in the UK</a>.</p>
<p><b>Criteria for inclusion</b></p>	<p>Individuals who are:</p> <ul style="list-style-type: none"> <li>• eligible for routine MenACWY immunisation, that is the whole birth cohort in school year 9 and/or 10 as per national recommendations and local delivery of concurrent adolescent immunisations including Td/IPV</li> <li>• eligible for routine MenACWY conjugate vaccine, born on or after 1 Sep 1996 and until their 25th birthday, who have missed the routine vaccination offer in year 9 or year 10, and have unknown or incomplete MenACWY vaccination history (Note: this includes individuals in catch-up cohorts)</li> <li>• aged 10 years to less than 25 years with an incomplete or unknown MenC vaccination history</li> <li>• prospective students up to 25 years of age who are entering university for the first time and who have not received a dose of MenACWY conjugate vaccine after their tenth birthday Note: Vaccination should be offered before they enrol or as soon as possible thereafter, ideally at least two weeks before attending university to ensure timely protection.</li> <li>• a close contact of a confirmed case of <i>Neisseria meningitidis</i> group A, C, W or Y disease</li> <li>• in a cohort recommended MenACWY immunisation following a local outbreak of <i>Neisseria meningitidis</i> and specific advice from Public Health England and the local Health Protection Team</li> </ul> <p>Note: Individuals with an underlying medical condition which puts them at increased risk from <i>Neisseria meningitidis</i>, such as individuals with asplenia, splenic dysfunction or complement disorders (including those on, or due to receive, complement inhibitor treatment such as eculizumab), may require additional 'routine' vaccination outside the inclusion criteria for this PGD - see MenACWY Risk Groups PGD and <a href="#">Chapter 7</a> of 'The Green Book'.</p>
<p><b>Criteria for exclusion<sup>2</sup></b></p> <p>Continued over page</p>	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <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 diphtheria toxoid, CRM 197 carrier protein (Menveo<sup>®</sup>), tetanus toxoid (Nimenrix<sup>®</sup>)</li> <li>• have previously received MenACWY conjugate vaccine when over 10 years old, with the exception of contacts of confirmed <i>Neisseria meningitidis</i> group A, C, W or Y infection</li> <li>• require vaccination for occupational health reasons, such as</li> </ul>

<sup>2</sup> Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

<b>Criteria for exclusion</b> (continued)	laboratory workers working with meningococci <ul style="list-style-type: none"> <li>• require vaccination for the purpose of travel</li> <li>• are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)</li> </ul>
<b>Cautions including any relevant action to be taken</b>	<p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed. However, re-immunisation may need to be considered.</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>Individuals who have received MenACWY conjugate vaccine over the age of 10 years do not routinely require further MenACWY immunisation with the exception of contacts of confirmed <i>Neisseria meningitidis</i> group A, C, W or Y infection. Contacts should be offered an appropriate meningococcal sero-group containing vaccine if not received in the preceding 12 months.</p> <p>Individuals requiring vaccination for occupational health reasons, such as laboratory workers working with meningococci, should be referred to their occupational health service provider for vaccination.</p> <p>Individuals requiring vaccination solely for the purpose of travel are not covered by this PGD and should be referred to, or immunised as part of, a travel immunisation service. MenACWY vaccine is not available on the NHS for the purpose of travel.</p> <p>In case of postponement due to acute severe febrile illness advise when the individual may be vaccinated and ensure another appointment is arranged.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document reason for exclusion and any action taken in individual's clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or prescriber as appropriate.</p>
<b>Action to be taken if the patient or carer declines treatment</b>	<p>Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained for each administration.</p> <p>Advise individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.</p> <p>Document advice given and the decision reached.</p> <p>In a GP practice setting, inform or refer to the GP as appropriate.</p>
<b>Arrangements for referral for medical advice</b>	As per local policy



## 5. Description of Treatment

<p><b>Name, strength &amp; formulation of drug</b></p>	<p><b>Menveo®</b>, 0.5ml reconstituted vaccine solution containing:</p> <p>Originally contained in powder vial:  Meningococcal group A oligosaccharide<sup>1</sup> 10micrograms</p> <p>Originally contained in the solution vial:  Meningococcal group C oligosaccharide<sup>1</sup> 5 micrograms  Meningococcal group W135 oligosaccharide<sup>1</sup> 5 micrograms  Meningococcal group Y oligosaccharide<sup>1</sup> 5 micrograms  <sup>1</sup>conjugated to <i>Corynebacterium diphtheriae</i> CRM<sub>197</sub> protein</p> <p>Or</p> <p><b>Nimenrix®</b>, 0.5ml reconstituted vaccine solution containing:</p> <p>Originally in powder:  <i>Neisseria meningitidis</i> A polysaccharide<sup>2</sup> 5 micrograms  <i>Neisseria meningitidis</i> C polysaccharide<sup>2</sup> 5 micrograms  <i>Neisseria meningitidis</i> W135 polysaccharide<sup>2</sup> 5 micrograms  <i>Neisseria meningitidis</i> Y polysaccharide<sup>2</sup> 5 micrograms  <sup>2</sup> conjugated to tetanus toxoid carrier protein 44 micrograms  Solvent for solution for injection in pre-filled syringe</p>
<p><b>Legal category</b></p>	<p>Prescription Only Medicine (POM).</p>
<p><b>Black Triangle▼</b></p>	<p>No</p>
<p><b>Off-label use</b></p>	<p>Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in <a href="#">Chapter 4</a> of 'The Green Book'.</p> <p>Menveo® is off-label for children under 2 years of age. Nimenrix® is licensed from 6 weeks of age for a schedule with a two month interval between doses, but a one-month interval is in accordance with the advice in <a href="#">Chapter 22</a> of 'The Green Book'. Either vaccine is recommended in accordance with the advice in <a href="#">Chapter 22</a> of 'The Green Book'.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">PHE Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<p><b>Route / method of administration</b></p> <p>Continued over page</p>	<p>The MenACWY vaccines must be reconstituted in accordance with the manufacturers' instructions prior to administration.</p> <p>Following reconstitution, MenACWY conjugate vaccine should be given as a single 0.5ml dose by intramuscular injection, preferably in the deltoid region of the upper arm. The anterolateral aspect of the thigh is the preferred site for infants under one year old.</p>

<p><b>Route / method of administration</b> (continued)</p>	<p>The MenACWY conjugate vaccines must not be given intravascularly or intradermally and must not be mixed with other vaccines in the same syringe .</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>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.</p> <p>The vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect before reconstitution and following reconstitution prior to administration. In the event of either being observed, discard the vaccine.</p> <p>It is recommended that the vaccine be administered immediately after reconstitution, to minimize loss of potency. Discard reconstituted vaccine if it is not used within 8 hours (see <a href="#">storage</a> section).</p> <p>The SPCs for Menveo® and Nimenrix® provide further guidance on reconstitution and administration and are available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<p><b>Dose and frequency of administration</b></p>	<p><b>Aged 12 months and over</b> Single 0.5ml dose of either Menveo® or Nimenrix® vaccine.</p> <p>Note: Unless they are confirmed to have been immunised against the relevant meningococcal sero-group within the preceding 12 months, vaccination should be offered to close contacts of any age.</p> <p><b>Contacts aged under 12 months</b> Two 0.5ml doses administered at least 4 weeks apart (see <a href="#">Off-label</a> section)</p>
<p><b>Duration of treatment</b></p>	<p>Single dose of 0.5ml (repeated at least 4 weeks later in children under 12 months of age).</p>
<p><b>Quantity to be supplied / administered</b></p>	<p>Single dose of 0.5ml.</p>
<p><b>Supplies</b></p>	<p>Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for the national immunisation programme are provided free of charge.</p> <p>Vaccine for the national immunisation programme should not be used for the vaccination of contacts of confirmed cases and in outbreaks of MenACWY infection. Vaccine should be ordered from the manufacturers/wholesalers.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see <a href="#">protocol for ordering storage and handling of vaccines</a> and Green Book <a href="#">Chapter 3</a>).</p>
<p><b>Storage</b> Continued over page</p>	<p>Store between +2°C to +8°C. Store in original packaging in order to protect from light.</p>

<b>Storage</b> (continued)	<p>Do not freeze.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to <a href="#">PHE Vaccine Incident Guidance</a>.</p> <p>After reconstitution, the vaccine should be used immediately. However, stability after reconstitution has been demonstrated for 8 hours below 25°C (below 30°C for Nimenrix®). Discard any reconstituted vaccine not used within 8 hours.</p>
<b>Disposal</b>	<p>Equipment used for immunisation, including used vials, ampoules, or syringes, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the <a href="#">technical memorandum 07-01</a>: Safe management of healthcare waste (Department of Health, 2013).</p>
<b>Drug Interactions</b>	<p>Immunological response may be diminished in individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>May be given at the same time as other vaccines.</p> <p>A detailed list of interactions associated with Menveo® or Nimenrix® is available in the SPC 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>
<b>Identification &amp; Management of Adverse Reactions</b>	<p><b>Menveo®</b> The most common adverse reactions observed after administration of Menveo® vaccine are drowsiness, malaise, headache, nausea, irritability and injection site pain, erythema and induration. Fever, chills, nausea, vomiting, diarrhoea, eating disorders, myalgia, arthralgia and rash are also listed as common side effects.</p> <p><b>Nimenrix®</b> The most common adverse reactions observed after administration of Nimenrix® vaccine are drowsiness, fatigue, headache, loss of appetite, irritability, fever and injection site pain, erythema and induration.</p> <p>Gastro-intestinal symptoms (including nausea, vomiting and diarrhoea) and injection site haematoma are also listed as common side effects.</p> <p>A detailed list of adverse reactions associated with Menveo® or Nimenrix® is available in the SPC 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>
<b>Reporting procedure of Adverse Reactions</b>	<p>Healthcare professionals and individuals/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> or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.</p>

<p><b>Written information to be given to patient or carer</b></p>	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate.</p> <p>For parents of 'contact' children under 12 months:</p> <ul style="list-style-type: none"> <li>• <a href="#">Why is my child being offered an 'off-label' vaccine.</a></li> </ul> <p>Available from: <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></p>
<p><b>Patient advice /Follow up treatment</b></p>	<p>Menveo® or Nimenrix® will only confer protection against <i>Neisseria meningitidis</i> group A, C, W and Y. The vaccine will not protect against any other <i>Neisseria meningitidis</i> groups. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis infection.</p> <p>Inform individual/parent/carer of possible side effects and their management.</p> <p>Give advice regarding normal reaction to the injection, for example redness and pain at the injection site.</p> <p>The individual/parent/carer should be advised to seek medical advice in the event of a severe adverse reaction.</p> <p>When applicable, advise the individual/parent/carer when the subsequent dose is due.</p> <p>When administration is postponed advise the individual/parent/carer when to return for vaccination.</p>
<p><b>Special Considerations / Additional Information</b></p>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone.</p> <p>Each brand of vaccine uses a different carrier protein and the healthcare professional should refer to the SPC supplied with the vaccine if there has been a previous hypersensitivity reaction to vaccination.</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 with inactivated virus or bacterial vaccines or toxoids.</p>
<p><b>Records</b></p> <p>Continued over page</p>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP with whom the individual 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>• supplied via PGD</li> </ul>

<b>Records</b> (continued)	<p>Records should be signed and dated (or a password controlled immunisers record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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## 6. Key References

<b>Key references</b>	<p><b>MenACWY Conjugate Vaccine</b></p> <ul style="list-style-type: none"><li>• Nimenrix<sup>®</sup> Summary of Product Characteristics. Pfizer Ltd. Updated 23 November 2020. <a href="http://www.medicines.org.uk/emc/medicine/26514">http://www.medicines.org.uk/emc/medicine/26514</a></li><li>• Menveo<sup>®</sup> Summary of Product Characteristics. GlaxoSmithKline UK. Updated February 2021 <a href="http://www.medicines.org.uk/emc/medicine/27347">http://www.medicines.org.uk/emc/medicine/27347</a></li><li>• Immunisation Against Infectious Disease: The Green Book, <a href="#">Chapter 22</a> last updated 20 September 2016. <a href="https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22">https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22</a></li><li>• Guidance for Public Health Management of Meningococcal Disease in the UK, Public Health England, published 13 March 2018, updated 06 August 2019 . <a href="https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management">https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management</a></li><li>• Meningococcal ACWY (MenACWY) vaccination programme 2020/2021 <a href="https://digital.nhs.uk/services/general-practice-gp-collections/service-information/meningococcal-acwy-menacwy-vaccination-programme">https://digital.nhs.uk/services/general-practice-gp-collections/service-information/meningococcal-acwy-menacwy-vaccination-programme</a></li><li>• Meningococcal Disease: Guidance, Data and Analysis. Last updated 20 December 2019 <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></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. <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><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <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. Updated March 2017. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• PHE Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• PHE Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li><li>• Protocol for ordering storage and handling of vaccines. April 2014. <a href="https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines">https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines</a></li></ul>
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## 7. Practitioner authorisation sheet

**MenACWY PGD v04.00 Valid from: 01/07/2021 Expiry: 31/07/2023**

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

### 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 of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

### Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of <b>INSERT NAME OF ORGANISATION</b> for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

### Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.