Gibraltar Health Authority

PATIENT GROUP DIRECTION

Issued Under Part 2 of the Medicines (Prescriptions Only) Regulations, 1987 by the

Director of Public Health with the consent of the Minister for

Meningococcal Groups ACWY conjugate vaccine PGD (Menveo®, Menitorix® and MenQuadfi®)

Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar Contact Telephone: + (350) 20079160		
Date effective	11th April 2025		
Date of expiry	11th April 2027		
Staff characteristics	See below (section 1)		
Professional Authorisation		SIGNATURE	DATE
Lead Doctor	Dr Helen Carter Director of Public Health [1]		
In Consultation with		SIGNATURE	DATE
Lead Pharmacist	Ms Melanie Gordon Chief Pharmacist		
Lead Nurse	Ms Sandra Gracia Director of Nursing		
Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for Health [2] Gemma Arias-Vasquez MP		

[1] A Patient Group Direction issued shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.

[2] See footnote 1.

1. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses or midwives currently registered with the Gibraltar Nursing Registration Board (NRB) • Paramedics or other professionals currently registered with the Gibraltar Medical Registration Board (MRB) Or anyone deemed by the Director of Public Health to be competent who meets the additional requirements below.
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016) and to discuss issues related to vaccination • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from the GHA, Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals, detailed in the inclusion criteria, against *Neisseria meningitidis* serogroup A, C, W and Y in accordance with the recommendations given in Chapter 22 of Immunisation Against Infectious Disease: 'The Green Book' and Guidance for Public Health Management of Meningococcal Disease in the UK.
Criteria for inclusion	Individuals who are: • 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 • 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) • aged 10 years to less than 25 years with an incomplete or unknown MenC vaccination history • 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. • a close contact of a confirmed case of Neisseria meningitidis group A, C, W or Y disease and who has not been vaccinated with a MenACWY conjugate vaccine in the last 12 months • in a cohort recommended MenACWY immunisation following a local outbreak of Neisseria meningitidis and specific advice from the Director of Public Health. **Note**: Individuals with an underlying medical condition which puts them at increased risk from Neisseria meningitidis, 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 Chapter 7 of 'The Green Book'. In an outbreak situation, under written instruction from the Director of Public Health, specific additional groups of the population may be offered an inactivated seasonal influenza vaccine as specified in the written instruction.

Criteria for exclusion [3]	Individuals for whom no valid consent has been received. Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of the vaccine or to any constituent or excipient of the vaccine, including diphtheria toxoid, CRM197 carrier protein (Menveo®) and tetanus toxoid (Nimenrix® and MenQuadfi®) • have had a confirmed anaphylactic reaction to any constituent or excipient of the vaccine, including diphtheria toxoid, CRM 197 carrier protein (Menveo®), tetanus toxoid (Nimenrix®) • have previously received MenACWY conjugate vaccine when over 10 years old, with the exception of contacts of confirmed Neisseria meningitidis group A, C, W or Y infection • require vaccination for occupational health reasons, such as laboratory workers working with meningococci • require vaccination for the purpose of travel • are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)

[3] 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.

Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed. However, re-immunisation may need to be considered. 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.
Action to be taken if the patient is excluded	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 Neisseria meningitidis 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. 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. 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. In case of postponement due to acute severe febrile illness advise when the individual may be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document reason for exclusion and any action taken in individual's clinical records. In a GP practice setting, inform or refer to the GP or prescriber as appropriate.

Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained for each administration. Advise individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local GHA policy

3. Description of treatment

Name, strength & formulation of drug	**Menveo®**, 0.5ml reconstituted vaccine solution containing: Originally contained in powder vial: • Meningococcal group A oligosaccharide1 10micrograms Originally contained in the solution vial: • Meningococcal group C oligosaccharide1 5 micrograms • Meningococcal group W135 oligosaccharide1 5 micrograms • Meningococcal group Y oligosaccharide1 5 micrograms 1conjugated to Corynebacterium diphtheriae CRM197 protein Or **Nimenrix®**, 0.5ml reconstituted vaccine solution containing: Originally in powder: • Neisseria meningitidis A polysaccharide2 5 micrograms • Neisseria meningitidis C polysaccharide2 5 micrograms • Neisseria meningitidis W135 polysaccharide2 5 micrograms • Neisseria meningitidis Y polysaccharide2 5 micrograms 2 conjugated to tetanus toxoid carrier protein 44 micrograms Solvent for solution for injection in pre-filled syringe Or • MenQuadfi®, 0.5ml solution for injection containing: • Neisseria meningitidis group A polysaccharide3 10 micrograms • Neisseria meningitidis group C polysaccharide3 10 micrograms • Neisseria meningitidis group W polysaccharide3 10 micrograms

	• Neisseria meningitidis group Y polysaccharide3 10 micrograms • 3 conjugated to tetanus toxoid carrier protein 55 micrograms
Legal category	Prescription Only Medicine (POM).
Black triangle	MenQuadfi®. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme
Off-label use	Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 of 'The Green Book'. Menveo® is off-label for children under 2 years of age. Nimenrix® is licensed from 6 weeks of age for a schedule with a 2 month interval between doses, but a one-month interval is in accordance with the advice in Chapter 22 of 'The Green Book'. Either vaccine is recommended in accordance with the advice in Chapter 22 of 'The Green Book'. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. 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.

Route / method of administration	The MenACWY vaccines must be reconstituted in accordance with the manufacturers' instructions prior to administration. 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. The MenACWY conjugate vaccines must not be given intravascularly or intradermally and must not be mixed with other vaccines in the same syringe. 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' Chapter 4). 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. 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. 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 storage section). The SPCs for Menveo® , Nimenrix® and MenQuadfi® provide further guidance on reconstitution and administration and are available from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency of administration	**Aged 12 months and over** Single 0.5ml dose of either Menveo® or Nimenrix® vaccine. **Note:** Unless the individual is 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. **Aged 12 months and over** Single 0.5ml dose. **Contacts aged under 12 months** Two 0.5ml doses administered at least 4 weeks apart (see Off-label section)
Duration of treatment	Single dose of 0.5ml (Repeated at least 4 weeks later in children under 12 months of age).
Quantity to be supplied / administered	Single dose of 0.5ml per administration.
Supplies **Storage**	Vaccine for the GHA 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. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3). Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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 PHE Vaccine Incident Guidance.

	After reconstitution of Menveo® and Nimenrix®, 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. MenQuadfi® stability data indicates the vaccine may be used up to 72 hours following exposure to temperatures up to 25°C
Disposal	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 technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited. MenACWY conjugate vaccine may be given at the same time as other vaccines. An interval of at least 8 weeks should be observed between Hib/MenC and MenACWY vaccination, to further boost immune response to the MenC component. A detailed list of interactions associated with Menveo® or Nimenrix® or MenQuadfi® is available in the SPC for the vaccine, which is available from the electronic Medicines Compendium website: http://www.medicines.org.uk/

Identification & management of adverse reactions	**Menveo®** 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. **Nimenrix®** 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 and loss of appetite. Gastro-intestinal symptoms (including nausea, vomiting and diarrhoea) and injection site haematoma are also listed as common side effects. **MenQuadfi®** The most common adverse reactions observed after administration of MenQuadfi® vaccine are malaise, headache, myalgia and injection-site pain. Fever and injection-site induration and erythema are also listed as common side effects. A detailed list of adverse reactions associated with Menveo® or Nimenrix® or MenQuadfi® is available in the SPC for the vaccine, which is available from the electronic Medicines Compendium website: http://www.medicines.org.uk/
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store and send a copy of the Yellow card to the Director of Public Health Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed. **INFORM GIBRALTAR DIRECTOR OF PUBLIC HEALTH IMMEDIATELY IF SEVERE ADVERSE REACTION IS SUSPECTED**

Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. GHA website for further information: • https://www.gha.gi/public-health/ Immunisation promotional material may be provided as appropriate. • Protect yourself against meningitis septicaemia For parents of 'contact' children under 12 months: • Why is my child being offered an 'off-label' vaccine. Available from: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment	**Menveo®**, **Nimenrix®** or **MenQuadfi®** will only confer protection against Neisseria meningitidis group A, C, W and Y. The vaccine will not protect against any other Neisseria meningitidis groups. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis infection. Inform individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of a severe adverse reaction. When applicable, advise the individual/parent/carer when the subsequent dose is due. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. 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. Meningococcal vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating

Records	pregnant women or those who are breast-feeding with inactivated virus or bacterial vaccines or toxoids. **IMMEDIATE ACCESS TO OXYGEN IS NOT A NECESSITY UNDER THIS PGD.** **BASIC LIFE SUPPORT & CALLING EMERGENCY SERVICES IS SUFFICIENT FOR IMMEDIATE RESUSCITATION.** Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password controlled immunisers record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references	**MenACWY Conjugate Vaccine** • Nimenrix® Summary of Product Characteristics. Pfizer Ltd. Updated 30th May 2022 http://www.medicines.org.uk/emc/medicine/26514 • Menveo® Summary of Product Characteristics. GlaxoSmithKline UK. Updated 30th December 2022 http://www.medicines.org.uk/emc/medicine/27347 • Immunisation Against Infectious Disease: The Green Book, Chapter 22 last updated 17 May 2022. https://www.gov.uk/government/publications/meningococcal-the-greenbook-chapter-22 • Guidance for Public Health Management of Meningococcal Disease in the UK, Public Health England, updated February 2018. Published 06 August 2019. https://www.gov.uk/government/publications/meningococcal-diseaseguidance-on-public-health-management • Meningococcal ACWY (MenACWY) vaccination programme. Last updated 26 October 2023. https://www.gov.uk/government/collections/meningococcal-acwymenacwy-vaccination-programme • Meningococcal Disease: Guidance, Data and Analysis. Last updated 29 March 2023 https://www.gov.uk/government/collections/meningococcal-diseaseguidance-data-and-analysis • Enhanced Service Specification: Meningococcal Freshers Vaccination Programme 2018/19. Published 26 June 2018. https://www.england.nhs.uk/publication/gp-contract-2017-18-enhanced-service-specifications/ **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safemanagement-of-healthcare-waste • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018.

	https://www.gov.uk/government/publications/national-minimumstandards-and-core-curriculum-for-immunisation-training-forregistered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incidentguidance-responding-to-vaccine-errors • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-orderingstoring-and-handling-vaccines

5. Practitioner authorisation sheet

Menveo®, 0.5ml reconstituted vaccine. Nimenrix®, 0.5ml reconstituted vaccine PGD.

MedQuadfi® 0.5ml solution for injection

Valid from 11th April 2025 to 11th April 2027.

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 the **GHA** 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.