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

HAMOPHILUS INFLUENZA TYPE B and MENINGOCOCCAL C CONJUGATE VACCINE (HIB/MENC) MENITORIX® PGD

This PGD is will remain valid until the discontinuation of Hib/MenC (Menitorix®) vaccine production and resultant introduction of changes to the childhood vaccination programme that will be under instruction from the Director of Public Health and withdrawal of this PGD.

LEGAL STATEMENT			
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 Gemma[2] 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) • practitioners currently registered with the Gibraltar Medical Registration Board (MRB) • 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. **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 Public Health Gibraltar and/or the GHA 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, against Haemophilus influenzae type b and meningococcal group C disease: • from their first birthday to under 10 years of age • to individuals of any age for the prevention of secondary cases of meningococcal group C disease Vaccination is to be given in accordance with the national immunisation programme; recommendations given in Chapter 7and 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 aged from their first birthday to under 10 years of age and require a booster or primary dose of MenC and a Hib booster (this immunisation is usually offered on or after their first birthday) • are aged from their first birthday to under 10 years of age and are unimmunised or incompletely immunised against Haemophilus influenzae type b or MenC • require vaccination for the prevention of secondary cases of MenC disease, following specific advice from UKHSA Health Protection Teams **NOTE:** Individuals with an underlying medical condition which puts them at increased risk from *Haemophilus influenza* type B and/or *Neisseria meningitidis* capsular group C, i.e., individuals with asplenia, splenic dysfunction or complement disorders (including those on, or to receive, complement inhibitor treatment ie eculizumab), may require additional 'routine' vaccination outside the inclusion criteria for this PGD – see Hib/MencC Risk groups PGD, 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: • are less than 1 year of age, unless indicated for the prevention of secondary cases of MenC disease • are aged 10 years and over, unless indicated for the prevention of secondary cases of MenC disease • have had a confirmed anaphylactic reaction to a previous dose of Hib or MenC containing vaccine or to any components of the vaccine, including any conjugate vaccines where tetanus toxoid is used in the conjugate. • are suffering from acute severe febrile illness (the presence of a minor infection or minor illnesses without fever or systemic upset are not a contraindication for immunisation)
Cautions including any relevant action to be taken	If a seizure associated with a fever occurred within 72 hours of a previous immunisation, immunisation should continue as recommended if a cause is identified or the child recovers within 24 hours. However, if no underlying cause has been found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable (as assessed by an appropriate clinician such as their GP or paediatrician). The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate. 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	If aged less than 1 year, Hib/MenC is not routinely indicated. If aged 10 years and over or has received a dose of Hib and MenC conjugate containing vaccine from 1 year of age, Hib/MenC immunisation is not indicated unless the individual requires immunisation for the prevention of secondary cases of MenC disease. Individuals suffering acute sever

[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

Action to be taken if the patient is excluded (continued)	e febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity. 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 the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a 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 person's behalf, must be obtained for each administration and recorded appropriately. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per GHA policy

3. Description of treatment

Name, strength & formulation of drug	*Haemophilus influenzae* type b and meningococcal group C conjugate vaccine (conjugated to tetanus toxoid as carrier protein): Menitorix®, powder in vial and solvent for solution for injection in a prefilled syringe; after reconstitution, each 0.5ml dose contains: *Haemophilus* type b polysaccharide (polyribosylribitol phosphate) 5micrograms conjugated to tetanus toxoid as carrier protein 12.5micrograms *Neisseria meningitidis* group C (strain C11) polysaccharide 5 micrograms conjugated to tetanus toxoid as carrier protein 5 micrograms
Legal category	Prescription only medicine (POM)
Black triangle	No

Off-label use	Administration of Menitorix® to individuals aged 2 years and over is off-label but is indicated until 10 years of age under this PGD in accordance with national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and Chapter 16 and Chapter 22 of the 'Green Book'. The Menitorix® SPC states "Menitorix® should be used in accordance with official recommendations". The use of Menitorix® to provide a single priming dose of MenC to individuals from their first birthday is not covered by the SPC but is in accordance with national recommendations following advice from JCVI (see MenC vaccination schedule: planned changes from July 2016). The Menitorix® SPC also states "The timing of the booster dose should be from the age of 12 months onwards and at least 6 months after the last priming dose." However, when primary vaccination has been delayed, the Hib booster dose may be given at the scheduled visit provided it is at least 1 month since the last primary dose was administered in accordance with national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status. Administration of Hib/MenC for the prevention of secondary cases of MenC disease is not covered by the Menitorix® SPC, but Hib/MenC vaccine may be given as an alternative to MenACWY in accordance with national Guidance for Public Health Management of Meningococcal Disease in the UK. Administration of Menitorix® by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 and 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 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 t he 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 vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration. Administer by intramuscular injection. The deltoid region of the upper arm may be used in individuals over one year of age. The anterolateral aspect of the thigh should be used for infants under one year vaccinated for the prevention of secondary cases of MenC disease. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see the 'Green Book' Chapter 4).

Route / method of administration (continued)	The vaccine's normal appearance is a white powder and a clear colourless solvent. Following reconstitution the vaccine is a clear colourless solution. 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. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.

Dose and frequency of administration	Single 0.5ml dose **Routine Childhood Immunisation Schedule** A single dose to be administered, usually on or after their first birthday, although it may be administered until 10 years of age. When primary vaccination with Hib has been delayed, the Hib booster dose (Hib/MenC) may be given at the scheduled visit, on or after their first birthday, provided it is at least 4 weeks since the last primary Hib dose was administered. **Incomplete immunisation history** Children from their first birthday to under 10 years of age who have completed a primary course of diphtheria, tetanus, pertussis and polio but have not received Hib containing vaccines should receive a single dose of Hib/MenC vaccine. All unimmunised or incompletely immunised children under 10 years of age require one dose of Hib and MenC over the age of 1 year in accordance with the vaccination of individuals with uncertain or incomplete immunisation status guidance. **Secondary prevention of MenC disease** Vaccination for the prevention of secondary cases of MenC disease should be in accordance with recommendations from the local UKHSA Health Protection Team and informed by national guidance (see Guidance for Public Health Management of Meningococcal Disease in the UK). Unless they have been vaccinated against MenC in the preceding 12 months, contacts from one year of age should receive one dose of MenC containing vaccine. Individuals less than one year of age should receive two doses of MenC containing vaccine one month apart.
Duration of treatment	A single dose from 1 year of age or a two dose course for contacts under 1 year of age. Other meningococcal vaccines (such as MenACWY) are used for subsequent routine boosters in adolescence.
Quantity to be supplied / administered	Single 0.5ml dose per administration.

Supplies	Vaccine for the management of contacts of MenC disease should ideally be ordered from the manufacturer/wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. After reconstitution, the vaccine should ideally be administered promptly or kept between +2°C to +8°C and used within 24 hours. Experimental data show that the reconstituted vaccine could also be kept up to 24 hours at ambient temperature (25°C). If it is not used within 24 hours, do not administer the vaccine. 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 Vaccine Incident Guidance.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements 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 those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.

Identification & management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site. Mild side effects such as irritability, loss of appetite, drowsiness and slightly raised temperature commonly occur. Less commonly crying, insomnia, abdominal pain, diarrhoea, vomiting, atopic dermatitis, rash, malaise and fever over 39.5˚C have been reported. Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium. website
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 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 a vaccine should also 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. Immunisation promotional material may be provided as appropriate: • A guide to immunisation for babies born on or after February 2022 Available from: whttps://www.gov.uk/government/collections/immunisation#childhood-immunisation-schedules

Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. 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 1,000 injection and access to a telephone at the time of vaccination. Two Hib containing vaccines may be given at the same time (such as Hib/MenC and DTaP/IPV/Hib/HepB) when required to catch-up immunisations in individuals who are un- or incompletely immunised (see vaccination of individuals with uncertain or incomplete immunisation status). Meningococcal and Hib-containing 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 bacterial vaccines. The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely. For guidance see Chapter 7 of the Green Book. **IMMEDIATE ACCESS TO OXYGEN IS NOT A NECESSITY UNDER THIS PGD. BASIC LIFE SUPPORT & CALLINEMERGENCY SERVICES IS SUFFICIENT.**

Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser's 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

Hib/MenC vaccine

• Immunisation Against Infectious Disease: The Green Book Chapter 16, last updated 19 April 2013, and Chapter 22, last updated 20 September 2016. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

• Summary of Product Characteristic for Menitorix®, GlaxoSmithKline. https://www.medicines.org.uk/emc/product/167 6 May 2020.

• Vaccination of individuals with uncertain or incomplete immunisation status. 17 March 2022. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status

• Guidance for Public Health Management of Meningococcal Disease in the Updated August 2019. https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management

General

• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/

• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-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

• Immunisation Collection
https://www.gov.uk/government/collections/immunisation

• Vaccine Incident Guidance
https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

5. Practitioner authorisation sheet

Menitorix®, powder in vial and solvent for solution for injection in a prefilled syringe.
Date of issue: 11th April 2025. Date for review: 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.

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