Gibraltar Health Authority

PATIENT GROUP DIRECTION

Issued under Part 2 of the Medicines (Prescription Only) Regulations, 1987 by the Director of Public Health with the consent of the Minister

Pneumococcal polysaccharide vaccine (PPV23) Pneumovax ® 23 Patient Group Direction (PGD)

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority (GHA) St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	3rd November 2025		
Date of expiry	3rd November 2025		
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 Natasha Cerisola Ag Director of Nursing		
Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for[2] Health 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 (GNRB) • practitioners currently registered with the Gibraltar Medical Registration Board (GMRB) • 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 national GHA standard operating procedures • 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 handling of the vaccine product, procedure for dilution of the vaccine and use of the correct technique for drawing up the correct dose • must be competent in the injection technique • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions • 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 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 from 65 years of age and individuals from 2 years of age in a clinical risk group, for the prevention of pneumococcal disease in accordance with the GHA immunisation programme and the public health management of clusters of severe pneumococcal disease in closed settings Chapter 25 of Immunisation Against Infectious Disease: the 'Green Book'. Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals

Criteria for inclusion	Individuals who: • are aged 65 years and over. • are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book Chapter 25 Table 25.2. • have asplenia, splenic dysfunction or chronic kidney disease (see https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25) and require a pneumococcal polysaccharide vaccine (PPV23) booster. • are recommended vaccination by the Director of Public Health, Gibraltar for the public health management of pneumococcal disease in accordance with managing clusters of pneumococcal disease in closed settings. 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. **Note:** Individuals at risk of frequent or continuous occupational exposure to metal fumes (such as welders) should be considered for immunisation taking into account exposure control measures in place. This indication is outside the remit of this PGD.

Criteria for exclusion[3]	Individuals for whom no valid consent has been received, or 'best-interests' decision in accordance with the Lasting Powers of the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016, has not been obtained (for further information on consent see Chapter 2 of The Green Book. The Patient information leaflet (PIL) for the vaccine to be used should be available to inform consent. Individuals who: • are less than 2 years of age. • have previously received PPV23 over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see Green Book Chapter 25) and those recommended vaccination for the public health management of clusters of severe pneumococcal disease in closed settings. • have had a confirmed anaphylactic reaction to a previous dose of PPV23 or to any component of the vaccine. • have received pneumococcal conjugate vaccine (PCV) in the preceding 8 weeks. • are suffering from acute severe febrile illness (the presence of a minor infection 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	Antibody response may be impaired in those with immunological impairment and those with an absent or dysfunctional spleen (see Special considerations / additional information section regarding appropriate timing of vaccination).

Action to be taken if the patient is excluded	If aged less than 2 years PPV23 is not indicated, ensure PCV immunisation is up to date. If PPV23 has previously been received over the age of 2 years and the individual does not have asplenia, splenic dysfunction or chronic kidney disease (see Green Book Chapter 25) and the individual is not recommended vaccination for the public health management of clusters of severe pneumococcal disease in closed settings, further PPV23 is not indicated. Individuals who have received PCV in the preceding 8 weeks postpone immunisation until 8 weeks has elapsed. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity.

Action to be taken if the patient is excluded (continued)	Seek appropriate advice from the Director of Public Health Gibraltar 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. Where a person lacks the capacity, in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of 'The Green Book'. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications. 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	Pneumovax® 23 solution for injection in a pre-filled syringe Each 0.5ml dose contains 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.
Legal category	Prescription only medicine (POM)
Black triangle	No
Off-label use	Administration of a further dose of PPV23 to high-risk individuals who have already received a dose of PPV23 more than 12 months previously is off-

	label but may be recommended in accordance with the Managing clusters of pneumococcal disease in closed settings. 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 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	Administer by intramuscular or subcutaneous injection. The preferred site is the deltoid region of the upper arm. The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by subcutaneous injection to reduce the risk of bleeding in accordance in 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's normal appearance 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 per administration Individuals with asplenia, splenic dysfunction or chronic kidney disease (see Chapter 25) should be revaccinated at 5 year intervals. PPV23 should be offered to high-risk individuals recommended vaccination by the Director of Public Health, Gibraltar for the public health management of pneumococcal disease in accordance with Managing clusters of pneumococcal disease in closed settings , unless they have received PPV23 in the previous 12 months. Revaccination is not routinely indicated for other individuals
Duration of treatment	Single 0.5ml dose (see Dose and frequency of administration regarding indications for revaccination).
Quantity to be supplied / administered	Single 0.5ml dose.
Supplies	GHA clinics should order/receive PNEUMOCOCCAL POLYSACCHARIDE VACCINE from the St Bernard's Hospital Pharmacy department. The Pharmacy department will source the vaccine via the national appointed supply route for the GHA. NHS/GHA standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of PNEUMOCOCCAL POLYSACCHARIDE VACCINE , which ensure use is in accordance with the product's SPC and official national/GHA recommendations.
Storage	**Store at 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 Vaccine Incident Guidance
Disposal	Follow local clinical waste policy and GHA/NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local GHA 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, but it is important to still immunise this group. PPV23 may be given at the same time as other vaccines. PPV23 can also be given at the same time as shingles vaccine, Zostavax®, as recommended in the 'Green Book' following assessment of the evidence, concluding that there is no reduction in the effectiveness of Zostavax®.
Identification & management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling, warmth, soreness, induration and/or redness at the injection site. A small painless nodule may form at the injection site. A low-grade fever may occur. The most common systemic adverse events reported are asthenia/fatigue, myalgia and headache. Hypersensitivity reactions and anaphylaxis can occur but are very rare. Rarely, injection site cellulitis has been reported. Other adverse events have been reported in clinical trials and post-marketing surveillance but the frequency of these is not known. 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: •Splenectomy leaflet Available from: Public Health Gibraltar website Immunisation - GOV.UK
Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. Vaccination may not result in complete protection in all recipients. Individuals at especially increased risk of serious pneumococcal infection (such as individuals with asplenia, splenic dysfunction and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due.

Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. 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. Individuals who are a contact of pneumococcal disease do not usually require PPV23. Immunisation may be indicated where there is a confirmed cluster of severe pneumococcal disease in a closed setting and should be on the advice of your GHA Health Protection Team. Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids.
Special considerations / additional information (Continued)	**Timing of vaccination** Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given pneumococcal vaccines according to the recommendations. Wherever possible, immunisation or boosting of immunosuppressed or HIV-positive individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen. The optimal timing for any vaccination should be based upon a judgement about the relative need for rapid protection and the likely response. For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least two weeks before commencement. In some cases, this will not be possible and therefore vaccination may be carried out at any time and re-immunisation considered after treatment is finished and recovery has occurred. Ideally, PPV23 should be given four to six weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to two weeks before treatment (see Green Book Chapter 25). If it is not practicable to vaccinate two weeks or more before splenectomy, immunisation should be delayed until at least two weeks after the operation. If it is not practicable to vaccinate two weeks or more before initiation of chemotherapy and/or radiotherapy, immunisation should be delayed until at least three months after completion of therapy in order to maximise the response to the vaccine.

	Immunisation of these individuals should not be delayed if this is likely to result in failure to vaccinate. Splenectomy, chemotherapy or radiotherapy should never be delayed to allow time for vaccination.
Records	**Record:** • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016. • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP). •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 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. The simplest way to do this is recording on the EMIS record; templates will be made available to help facilitate this. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with GHAl policy.

Key references	**Pneumococcal conjugate vaccine** Immunisation Against Infectious Disease: The Green Book Chapter 25 last updated 13 January 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Summary of Product Characteristic for Pneumovax® 23vaccine, Merck Sharp & Dohme Limited. Last updated 29 January 2021. https://www.medicines.org.uk/emc/product/9692/smpc Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. Updated 21 February 2020. https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings Pneumococcal polysaccharide vaccine: change to the supply route from June 2021 letter https://www.gov.uk/government/publications/pneumococcal-polysaccharide-vaccine-change-to-the-supply-route-from-june-2021-letter **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/ Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act, 2016. https://www.gibraltarlaws.gov.gi/ 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. 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

Pneumococcal polysaccharide vaccine (PPV23) Pneumovax ® 23. Valid from 03/11/25 to 03/11/27

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.