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

AJV, Mycobacterium bovis BCG (Bacillus Calmette-Guérin) 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 [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) • 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) • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must have undertaken training appropriate to this PGD as required by local policy and national NHS 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 correct 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 • should fulfil any other 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 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	Under DPH review guided by the recommendations given in chapter 32 of immunisation Against Infectious Disease: the 'Green Book'. Taking into account the Gibraltar context.
Criteria for inclusion	BCG vaccine is licensed for administration from birth; however BCG vaccination should be postponed in those screened for severe combined immunodeficiency (SCID) until the screening result is available and reports that 'SCID not suspected'. Users of this PGD are required to check and the record for a negative SCID result should Gibraltar commence screening all babies for this at birth or confirming that the child was not offered SCID screening before administering the BCG vaccine • All new born infants born in Gibraltar • All previously unvaccinated children aged less than 16 years and resident in Gibraltar • Previously unvaccinated individuals identified as being at risk during an outbreak of TB or who are contacts of cases of open TB (in

	conjunction with Public Health advice as instructed by the Director of Public Health. • Unvaccinated individuals who are potentially at risk in relation to the profession/role or health related studies, advice should be sought from the Occupational Health service providing they have a negative Mantoux/tuberculin or IGRA test In an outbreak situation, under written instruction from the Director of Public Health, specific additional groups of the population may be offered an BCG vaccine as specified in the written instruction
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Criteria for exclusion [3]	**Note:** Vaccination with BCG for travel is not covered by this PGD and individuals should be directed to an appropriate travel health service.
	
	Individuals for whom no valid consent has been received.
	Individuals who:
	• have had a confirmed anaphylactic reaction to a component of the vaccine
	• are 16 years of age or over, unless high risk due to occupational exposure or identified as at risk and they must be reviewed by Occupational Health
	• are awaiting a SCID screening result or where a repeat is needed, until the result is available and reports that 'SCID not suspected'
	• have a SCID screening result reported as 'SCID SUSPECTED'
	• are suffering from malignant conditions (such as lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system)
	• have primary or secondary immune-deficiencies or who are HIV positive
	• **Note:** Infants born to HIV positive mothers should only be given BCG vaccination when the exclusively formula-fed infant is confirmed HIV uninfected at 12–14 weeks. However, infants considered at low risk of HIV transmission (maternal VL <50 HIV RNA copies/mL at or after 36 weeks' gestation) but with a high risk of tuberculosis exposure may be given BCG earlier.
	• are receiving or have received in the past 6 months:
	  ○ immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders
	  ○ immunosuppressive therapy for a solid organ transplant
	• are receiving or have received in the past 12 months:

[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

	○ immunosuppressive biological therapy (for example anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) • are receiving or have received in the past 3 months immunosuppressive therapy including: - high-dose corticosteroids (>40mg prednisolone per day or >2mg/kg/day in children under 20kg) for more than 1 week - lower dose corticosteroids (>20mg prednisolone per day or >1mg/kg/day in children under 20kg) for more than 14 days - non-biological oral immune modulating drugs, such as methotrexate, azathioprine or 6-mercaptopurine, except those on low doses, see Chapter 6 of the 'Green Book', specialist advice should be sought prior to vaccination • are infants born to a mother who received immunosuppressive biological therapy during her pregnancy or breastfeeding, for as long as a postnatal influence on the immune status of the infant remains possible • have already had a BCG vaccination • have a past history of active or latent TB • are tuberculin positive (such that they have an induration of 5mm or more following Mantoux tuberculin skin testing) • have a positive Interferon Gamma Release Assay (IGRA) • are receiving anti-tuberculosis drugs • are less than 2 years of age and in a household where an active TB case is suspected or confirmed, until potential latent TB in the infant/child is excluded from 6 weeks post exposure (see Additional information) • are pregnant • have a generalised septic skin condition • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
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. In persons whose immune status is in question, BCG vaccination should be postponed until their immune status has been evaluated. If eczema exists, an immunisation site should be chosen that is free from skin lesions. Breastfeeding is not a contraindication to BCG, however if there is any doubt as to whether an infant due to receive BCG vaccine may be immunosuppressed due to the mother's therapy, including exposure through breastfeeding, specialist advice should be sought. It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be

	considered when administering to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed. Administering the vaccine too deep increases the risk of discharging ulcer, lymphadenitis and abscess formation. 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 16 years of age and over, BCG vaccination is not usually recommended unless the risk of exposure is great (such as those at occupational risk through direct clinical contact with a patient diagnosed with TB or contact with infectious TB materials). Such individuals should be appropriately referred, for example to their occupational health service provider. Individuals screened for SCID for whom a 'SCID not suspected' result is unavailable should not be vaccinated under this PGD. Individuals who have been screened for SCID but do not yet have a result, or are awaiting a repeat, should be booked in for immunisation once a 'SCID not suspected' result becomes available. Individuals with a 'SCID SUSPECTED' screening result should not be vaccinated under this PGD. These children will be referred for a specialist immunology review and urgent investigations undertaken. The GP and Health Visitor will be alerted to the outcome. They should only be offered BCG vaccine once there is an explicit instruction to do so, and in accordance with a PSD. Note: Individuals for whom SCID screening has been declined or for whom SCID screening is not offered may be clinically assessed for BCG vaccination under this PGD. Individuals who may be immunosuppressed through disease or treatment, including those suffering from malignant conditions, primary or secondary immune-deficiencies or who are HIV positive should not receive BCG vaccination unless their immune status resolves and they fulfil the criteria for inclusion. Immunisation with BCG, should be delayed for 6 months in children born of mothers who were on immunosuppressive biological therapy during pregnancy. If there is any doubt as to whether an infant may be immunosuppressed due to the mother's therapy, including exposure through breastfeeding, specialist advice should be sought. Individuals with a past history of active or latent TB, prior BCG vaccination, a positive Mantoux tuberculin skin test (induration of 5mm or more) or a positive IGRA result should be advised that they do not require BCG vaccination as there is an increased risk of adverse reactions and there is no evidence that repeat BCG offers additional protection. Individuals receiving anti-tuberculosis drugs (such as for chemoprophylaxis) should have vaccination postponed until latent TB infection is excluded. Note: BCG vaccination is contraindicated in individuals with TB or a past history of TB.
Action to be taken if the patient is excluded Continued	Individuals less than 2 years of age in a household where an active TB case is suspected or confirmed should receive chemoprophylaxis and be tuberculin and/or IGRA tested after 6 weeks to exclude latent TB prior to BCG vaccination.

	BCG vaccination is not recommended during pregnancy and vaccination should be postponed until after the pregnancy. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advice when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the Primary Care Centre and Immunisation Team, Public Health Gibraltar or GP 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 individuals 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	BCG vaccine AJV, Mycobacterium bovis BCG (Bacillus Calmette-Guérin), to be diluted with one 1ml of diluted Sauton AJV. This is a multidose container. One vial of reconstituted vaccine contains 1 ml, corresponding to 10 declared doses (of 0.1 ml) for individuals aged 12 months and over or 20 declared doses (of 0.05 ml) for infants under 12 months of age. These are declared number of doses and not the actual number of doses that can be removed in practice. The extractable number of doses that can be removed from the vial of reconstituted BCG Vaccine AJV depends on the specific type of syringe and needle used as well as on the surplus of vaccine removed by the individual vaccine administrator during vaccination. After reconstitution, 1 dose (0.1 ml) for individuals aged 12 months and over contains: • *Mycobacterium bovis* BCG (Bacillus Calmette- Guérin), Danish strain 1331, live attenuated, 2-8 x 105 cfu. After reconstitution, 1 dose (0.05 ml) for infants under 12 months of age contains: • *Mycobacterium bovis* BCG (Bacillus Calmette- Guérin), Danish strain 1331, live attenuated, 1-4 x 105 cfu.
Legal category	Prescription only medicine (POM)
Black triangle	No

Off-label use	In accordance with the advice in Chapter 32 of the 'Green Book', BCG Vaccine AJV may be administered off-label to an infant born to an HIV positive mother only once the exclusively formula-fed infant is confirmed HIV uninfected at 12–14 weeks. Infants considered at low risk of HIV transmission (maternal VL <50 HIV RNA copies/mL at or after 36 weeks' gestation) but with a high risk of tuberculosis exposure may be given BCG Vaccine AJV earlier off-label. Administration of a live vaccine within 4 weeks of BCG Vaccine AJV is off-label but in accordance with the recommended intervals between vaccines in Chapter 11 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	BCG Vaccine AJV is administered strictly by the intradermal route, only by those suitably trained and competent to do so (see Section 3 Characteristics of staff). See the 'Green Book' Chapter 32 and the manufacturer's SPC for further details on the intradermal administration technique. The multidose vial of BCG Vaccine AJV must be reconstituted prior to administration with 1ml Diluted Sauton AJV in accordance with the manufacturer's instructions. Carefully invert the vial a few times to suspend the lyophilised BCG completely. DO NOT SHAKE. Gently swirl the vial of resuspended vaccine before drawing up each subsequent dose. If the skin is visibly dirty it should be washed with soap and water. The vaccine is administered through either a specific tuberculin syringe or, alternatively, a 1ml graduated syringe fitted with a 26G 10mm (0.45mm x 10mm) short bevelled needle6 for each individual. The correct dose of BCG vaccine should be drawn into the tuberculin syringe and the 26G short bevelled needle attached to give the injection. The needle must be attached firmly and the intradermal injection administered with the bevel facing up. BCG vaccine must be administered strictly by intradermal injection, normally into the lateral aspect of the left upper arm at the level of the insertion of the deltoid muscle (just above the middle of the left upper arm – the left arm is recommended by WHO). Sites higher on the arm, and particularly the tip of the shoulder, are more likely to lead to keloid formation and should be avoided. The vaccine's normal appearance is a white powder in a vial (which might be difficult to see due to the small amount of powder in the vial) and a clear colourless solvent in a vial without any visible particles. Following reconstitution the vaccine is a colourless, slightly opaque, homogenous suspension. 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: www.medicines.org.uk

Dose and frequency of administration	A single intradermal dose of: 0.05ml for infants under 12 months of age 0.1ml for individuals aged 12 months and over
Duration of treatment	A single dose.
Quantity to be supplied / administered	A single dose.
Supplies	GHA clinics should order/receive BCG vaccines from SBH Pharmacy dept. The Pharmacy dept will source the vaccine via the national appointed supply route for the GHA. NHS/GHA standard operating procedures should be followed for the appropriate ordering, storage, handling, preparation, administration and waste minimisation of BCG Vaccine, which ensure use is in accordance with the products SPC and official national/GHA recommendations (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. 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. BCG Vaccine AJV should be reconstituted with the diluent supplied by the manufacturer (Diluted Sauton AJV) and used immediately. Reconstituted vaccine may be used for up to four hours at room temperature, after which any unused reconstituted vaccine should be discarded.
Disposal	Follow local clinical waste policy and GHA/NHS standard operational procedures and ensure safe and secure waste disposal. Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe, 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	May be given at the same time as other vaccines, including other live vaccines which can also be administered at any time before or after BCG vaccination (see Chapter 11 of the 'Green Book'). Other vaccines to be given at the same time as BCG Vaccine AJV should not be given into the same arm. It is advisable not to give further vaccination in the arm used for BCG vaccination for 3 months because of the risk of regional lymphadenitis. A detailed list of drug interactions is available in the SPC, which is available from: www.medicines.org.uk
Identification & management of adverse reactions	The expected reaction to successful vaccination with BCG Vaccine AJV includes induration at the injection site followed by a local lesion that may ulcerate some weeks later and heal over some months leaving a small, flat scar. A local site reaction may include erythema and tenderness. It also may include enlargement of a regional lymph node to less than 1 cm. Other side-effects are uncommon but may include headache and fever. Individuals with severe local reactions (ulceration greater than 1cm, caseous lesions, abscesses or drainage at the injection site) or with regional suppurative lymphadenitis with draining sinuses following BCG vaccination should be referred to a TB physician or paediatrician for investigation and management. An excessive response to the BCG Vaccine AJV may result in a discharging ulcer. This may be attributable to inadvertent subcutaneous injection or to excessive dosage. The ulcer should be encouraged to dry and abrasion (by tight clothes, for example) should be avoided. Expert advice should be sought regarding the appropriate treatment regimen for the management of systemic infections or persistent local infections following vaccination with BCG Vaccine AJV. Hypersensitivity reactions (including anaphylactic reactions), more severe local reactions such as abscess formation, and disseminated BCG complications (such as osteitis or osteomyelitis) are rare and should be managed by a specialist. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from: 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 http://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 All serious or unusual adverse reactions possibly associated with BCG vaccination (including abscess and keloid scarring) should be recorded and reported through the Yellow Card scheme, and vaccination techniques should be reviewed. Every effort should be made to recover and identify the causative organism from any lesion constituting a serious complication. 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: • Immunisations up to 13 months of age • TB, BCG and your baby leaflet Available from: www.gov.uk/government/collections/immunisation

Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. Advise the individual/parent/carer of the expected site reaction to successful BCG vaccination which includes: • a slight swelling, redness and tenderness at the injection site followed by a local lesion • some weeks later this lesion evolves into a small ulcer • after some months this ulcer will heal leaving a small, flat scar • a slight swelling of the lymph nodes in the armpit may be experienced Advise the individual/parent/carer that it is not necessary to protect the site from becoming wet during washing and bathing. The injection site is best left uncovered to facilitate healing. The ulcer should be encouraged to dry, and abrasion (by tight clothes, for example) should be avoided. Should any oozing occur, a temporary dry dressing may be used until a scab forms. It is essential that air is not excluded. If absolutely essential (e.g. to permit swimming), an impervious dressing may be used but it should be applied only for a short period as it may delay healing and cause a larger scar. Inform the individual/parent/carer that other immunisations are not recommended to be given in the same arm for 3 months following BCG vaccination. The individual/parent/carer should be advised to seek medical advice if the lesion looks like it may have become infected. 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. The vaccine stopper must not be wiped with any antiseptic or detergent. If alcohol is used to swab the rubber stopper of the vial, it must be allowed to evaporate before the stopper is penetrated with the syringe needle. Likewise the injection site should be clean and dry. If the skin is visibly dirty it should be washed with soap and water. If antiseptics (such as alcohol) are applied to swab the skin, they should be allowed to evaporate completely before the injection is made. Household contact or contacts with exposure equivalent to that of household contacts or equivalent contacts of cases of sputum smear-positive pulmonary or laryngeal TB should be managed in line with public health advice as instructed by the Director of Public Health. There are few data on the protection afforded by BCG vaccine when it is given to adults (aged 16 years or over), and virtually no data for persons aged 35 years or over. BCG is not usually recommended for people aged over 16 years, unless the risk of exposure is great (such as healthcare or laboratory workers at occupational risk through direct clinical contact with a patient diagnosed with TB or contact with infectious TB materials). Newborn babies who are contacts of a non-infectious TB case should be immunised with BCG at the earliest opportunity and, if screened for SCID, as soon as a SCID screening result is available and reports that 'SCID not suspected'.

Records	Record: • that valid informed consent was given • 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 and that appropriate advice has been given) • name of immuniser • name and brand of vaccine • date of administration • date and time the vial left frozen storage • date and time the vial was thawed or put in refrigeration • date and time the vial was diluted to its full volume • time of administration, and duration from when the vial was diluted • 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 Patient Group Direction (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 GHA policy.

5. Practitioner authorisation sheet

BCG vaccine AJV, Mycobacterium bovis BCG (Bacillus Calmette-Guérin), to be diluted with one 1ml of diluted Sauton AJV
DATE OF ISSUE 11th April 2025 DATE OF EXPIRY: 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.