UK Health Security Agency

NHS

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Typhoid Vi Polysaccharide Vaccine Patient Group Direction (PGD)

This PGD is for the administration of typhoid Vi polysaccharide vaccine to overseas travellers at risk of exposure to *Salmonella enterica serovar typhi* (*S. typhi*) in accordance with recommendations from the National Travel Health Network and Centre (NaTHNaC).

This PGD is for the administration of typhoid Vi polysaccharide vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	Typhoid Vi vaccine PGD
Version no:	v4.00
Valid from:	29 February 2024
Review date:	1 September 2026
Expiry date:	28 February 2027

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

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

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 (Characteristics of staff). Sections 2 and 7 can be edited within the designated editable fields provided, **but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in Section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Current versions of UKHSA PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

Any concerns regarding the content of this PGD should be addressed to: immunisation@ukhsa.gov.uk.

[1] This includes any relevant amendments to legislation.

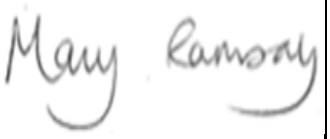
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.nwsit@nhs.net for Lancashire, South Cumbria, Cheshire and Merseyside.

Change history

Version number	Change details	Date
v1.00	New PHE typhoid Vi vaccine PGD	30 January 2018
v2.00	PHE Typhoid Vi vaccine PGD reviewed and amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	28 November 2019
v3.00	Typhoid Vi vaccine PGD reviewed and amended to: • update logo and reference to Public Health England (PHE) to the UKHSA • update cautions section to make reference to facilities for management of anaphylaxis and the vaccination of individuals with bleeding disorders • update references • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs	16 February 2022
v4.00	UKHSA Typhoid Vi vaccine PGD amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs • update the incidence of known adverse reactions following vaccination with typhoid Vi polysaccharide vaccine • include details of NaTHNaC advice line	24 January 2024

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist – Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		22 January 2024
Doctor	Dr Mary Ramsay CBE Director of Public Health Programmes and Consultant Epidemiologist, Head of Immunisation and Vaccine Preventable Diseases Division, UKHSA		22 January 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		22 January 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Management Committee

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Rosie Furner	Specialist Pharmacist-Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Dipti Patel	NaTHNaC Director, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands.
Tushar Shah	Lead Pharmacy Adviser, NHSE London
Laura Smeaton	IDPS Programme Projects Manager and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme, NHSE

2. Organisational authorisations

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

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England- North West authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Immunisations services in Lancashire, South Cumbria, Cheshire and Merseyside commissioned by NHS England – North West.
Limitations to authorisation
Users of this PGD should note that where they are commissioned to immunise certain groups, this PGD does not constitute permission to offer immunisation beyond groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director for Primary Care, NHS England – North West	**Dr Paula Cowan**		**04/02/2024**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Adoption by Independent Contractor/Provider			

Local enquiries regarding the use of this PGD may be directed to england.nwsit@nhs.net for Lancashire, South Cumbria, Cheshire and Merseyside providers.

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

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
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 or 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 undertake immunisation and to discuss issues related to immunisation • 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 UKHSA, NHSE 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 outside of criteria specified in this PGD.

4. 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 *S. typhi* infection in accordance with national recommendations in Chapter 33 of Immunisation Against Infectious Disease: the Green Book and NaTHNaC recommendations for typhoid vaccination for travel.
Criteria for inclusion	Adults and children over 2 years old who: • intend to travel, where typhoid vaccination is currently • recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice on typhoid vaccination) Children aged 12 months up to 2 years (off-label use) who: • intend to travel, where typhoid vaccination is currently recommended for travel by NaTHNaC and if the risk of typhoid fever is considered high (see the Travel Health Pro website for country-specific advice on typhoid vaccination)
Criteria for exclusion[2]	Individuals for whom valid consent or a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • are under 12 months of age • have had a confirmed anaphylactic reaction to a previous dose of typhoid Vi polysaccharide vaccine or to any components of the vaccine, including trace components from the manufacturing process which may include formaldehyde or casein* (see SPC) • are at increased risk of *S. typhi* infection because of their occupation (such as laboratory personnel who may handle *S. typhi* in the course of their work) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) *Note: severe reactions to a previous dose of non-Vi typhoid vaccines do not contraindicate the subsequent use of a Vi-containing vaccine.
Cautions including any relevant action to be taken (continued over page)	Facilities for management of anaphylaxis should be available (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). Individuals who are immunosuppressed or have HIV infection may not make a full antibody response; consider whether postponing vaccination until the end of the disease or treatment is appropriate. Otherwise, vaccination is recommended even if the antibody response may be limited. The importance of scrupulous attention to personal, food and water hygiene must be emphasised. 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. As with all injectable vaccines, TYPHIM Vi® must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since

[2] 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 (continued)	bleeding may occur following intramuscular administration to these individuals (see Chapter 4 of the Green Book).
Action to be taken if the individual is excluded	Individuals under one year of age are not recommended typhoid vaccine. Where vaccine is not recommended (and even when it is), the importance of stringent personal, food and water hygiene measures should be reinforced. Individuals who have had a confirmed anaphylactic reaction to a previous dose of typhoid Vi polysaccharide vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management. Individuals who are solely at occupational risk of *S. typhi* infection should be referred to their employer's occupational health provider for vaccination. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged. Specialist advice on typhoid management is available from NaTHNaC's advice line. Otherwise, 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. The importance of scrupulous attention to personal, food and water hygiene must be emphasised. 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 individual 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. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and the potential complications. Document advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Typhoid Vi polysaccharide vaccine, 0.5ml dose containing 25 micrograms Vi polysaccharide of *S. typhi* (Ty2 strain): • TYPHIM Vi® vaccine, solution for injection in a pre-filled syringe Note: This PGD does not cover the supply or administration of the live oral (Ty21a) typhoid vaccine, Vivotif®.[3]
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	TYPHIM Vi® vaccine may be administered off-label to children between the age of 12 months and 2 years if the risk of typhoid fever is considered to be high, in accordance with the recommendations in Chapter 33 of the Green Book and NaTHNaC. 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 or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.
Route and method of administration (continued over page)	Administer by intramuscular injection, preferably into the deltoid muscle of the upper arm. 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 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 was given should be noted in the individual's records. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual or carer should be informed about the risk of haematoma from the injection. Typhoid Vi polysaccharide vaccine is a clear colourless solution. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and

[3] The UKHSA do not currently plan to produce a PGD for live oral (Ty21a) typhoid vaccine (Vivotif®) because, as a 3 dose oral course, an appropriately labelled supply would be required. Since the availability of such supplies cannot be assured when writing a national PGD, oral vaccines may be better suited to provision by normal prescription and dispensing services.

Route and method of administration (continued)	administration. Should either occur, do not administer the vaccine and discard the syringe in accordance with local procedures. Shake well immediately before administration. Further guidance on administration is available from the product SPC.
Dose and frequency of administration	A single 0.5ml dose. Vaccination should occur at least 2 weeks prior to potential exposure to infection with *S. typhi*. Based on individual risk assessment, vaccination may be considered up until departure, but protection may be limited. **Revaccination** Individuals who plan to travel to an area where typhoid vaccination is currently recommended for travel by NaTHNaC, and who have not received typhoid vaccine in the preceding 3 years should be revaccinated against *S. typhi*. Individuals who remain at risk of exposure to *S. typhi* should be reassessed and if appropriate, revaccinated at intervals of not less than 3 years (see special considerations and additional information section). Note: Typhoid Vi polysaccharide vaccine may be used for revaccination when individuals have received non-Vi typhoid vaccine for the preceding dose.
Duration of treatment	Single dose. Revaccination may be indicated for individuals who remain at risk of typhoid fever (see Dose and frequency of administration).
Quantity to be supplied and administered	Single 0.5ml dose.
Supplies	Typhoid vaccine is not centrally supplied and should be obtained directly from manufacturers or their wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 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 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 NHSE guidance (HTM 07-01): Management and disposal of healthcare waste.
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 product's SPC.

Identification and management of adverse reactions	Local reactions following vaccination are very common, such as pain, swelling, erythema and induration at the injection site. Adverse reactions to typhoid Vi polysaccharide vaccines are usually mild and transient, disappearing a few days after immunisation. Other commonly reported reactions to typhoid Vi polysaccharide vaccination include fatigue, fever, headache, malaise and myalgia. Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents or carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to individual or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home - Health Publications. Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed in the product's SPC.
Advice and follow up treatment	Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme. The individual, parent or carer should be advised that Typhoid Vi polysaccharide vaccine offers protection against typhoid fever caused by *S. typhi*. It does not prevent paratyphoid fever or infection with any other serotypes of *S. enterica*. The individual, parent or carer should be advised that protection against *S. typhi* by vaccination may be reduced if a large number of infective organisms are ingested. The importance of scrupulous attention to personal, food and water hygiene must be emphasised for all those travelling to endemic areas. When applicable, advise the individual, parent or carer when the subsequent dose is due. When administration is postponed advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information (continued over page)	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. Protective antibody titres to Vi antigen fall over time. Revaccination is necessary when continuing protection is required. Additional doses of Vi vaccine do not boost serum antibody levels; revaccination returns antibody levels to those achieved after the primary immunisation. Non-conjugated polysaccharide vaccines are poorly immunogenic in infants and young children. There is little definitive data on the efficacy of Vi vaccine in children aged less than 18 months.

Special considerations and additional information (continued)	There is no evidence of risk from vaccinating individuals who are pregnant or breastfeeding with inactivated vaccines. Since typhoid polysaccharide vaccine is an inactivated (subunit) vaccine, the vaccine should be given in pregnancy or breastfeeding where there is an identified risk of infection.
Records	The practitioner must ensure the following is recorded: • 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 immunisation declined • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password controlled 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. Where applicable, the local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation or pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Typhoid Vi vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 4, last updated March 2013, Chapter 6, last updated August 2017 and Chapter 33, last updated 4 February 2022 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for TYPHIM Vi®, GlaxoSmithKline UK, last updated 23 February 2023 http://www.medicines.org.uk/emc/medicine/6186 • Factsheet: Typhoid and paratyphoid. NaTHNaC, last updated 1 September 2022. Accessed 27 October 2023 https://travelhealthpro.org.uk/factsheet/49/typhoid-and-paratyphoid https://travelhealthpro.org.uk/countries **General** • NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 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 • UKHSA 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

7. Practitioner authorisation sheet

Typhoid Vi vaccine PGD v4.00
Valid from: 29 February 2024 Expiry: 28 February 2027

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs 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 PGD 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 **insert name of organisation** for the above-named healthcare 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.