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PATIENT GROUP DIRECTION (PGD)

Administration of low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV) to individuals from 10 years of age, in accordance with the national immunisation programme, for travel, or for the management of cases and contacts of diphtheria, tetanus or poliomyelitis.

This PGD is for the administration of low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV) by currently registered nurses or paramedics.

Reference no: Td/IPV (Revaxis®) PGD
Version no: v02.00
Valid from: 01 November 2017
Review date: 1 May 2019
Expiry date: 31 October 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS 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'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

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 PHE PGD templates for authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation>

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


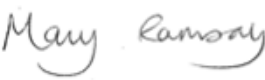

¹ This includes any relevant amendments to legislation (eg [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	16 October 2015
V02.00	Td/IPV (Revaxis) PGD routine review and amended to: <ul style="list-style-type: none">• include vaccination in line with recommendations for the management of diphtheria or polio• remove exclusions regarding timing of previous vaccination (see dose section for schedules)• remove exclusions relating to neurological conditions, encephalopathy and Guillain Barre/brachial neuritis and relevant advice moved to the cautions section• update off-label section in relation to amended indications• update dose section with management of cases and contacts of polio and diphtheria• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	29 September 2017

1. PGD template development

This PGD template has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		06/10/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head Immunisation, Hepatitis & Blood Safety Department, PHE		05/10/2017
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		02/10/2017

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Gayatri Amirthalingam	Consultant Epidemiologist, Public Health England
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Matthew Olley	Immunisation Manager, Public Health England / NHS England London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East


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 South (South Central) authorises this PGD for use by the services or providers listed below:

<p>Authorised for use by the following organisations and/or services</p> <p>Authorised for use by the following organisations and/or services: All NHS England South (South Central) directly commissioned immunisation services.</p> <p>In addition, the PGD may be adopted by provider organisations (providing NHS immunisation and vaccination services) working within the South Central geography. Where this occurs, provider organisations should have this PGD signed off by their governance lead prior to use. Provider organisation staff will be expected to follow local policies and procedures.</p>
<p>Limitations to authorisation</p> <p>None.....</p>

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director	Shahed Ahmad		24/10/17

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to england.southcentral-pgd@nhs.net

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

<p>Qualifications and professional registration</p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • nurses currently registered with the Nursing and Midwifery Council (NMC) • paramedics currently registered with the Health and Care Professions Council (HCPC)
<p>Additional requirements</p>	<p>Additionally practitioners:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction 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 patient group directions) • 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 for Immunisation Training (2005) • 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 Patient Group Direction and associated online resources • should fulfil any additional requirements defined by local policy <p>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</p>
<p>Continued training requirements</p>	<p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>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.</p>

4. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>Indicated for the active immunisation of individuals from 10 years of age for the prevention of diphtheria, tetanus and poliomyelitis, in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: "The Green Book".</p>
<p>Criteria for inclusion</p>	<p>Individuals aged 10 years and over who:</p> <ul style="list-style-type: none"> • require a booster following a primary course of immunisation against diphtheria, tetanus and poliomyelitis (this booster is usually offered at 13 to 18 years of age, unless the course has already been completed) • have no history or an incomplete history of diphtheria, tetanus or poliomyelitis immunisation • are travelling to an area where medical attention may not be accessible should a tetanus prone wound occur, or will be residing in epidemic or endemic areas where tetanus, diphtheria or poliomyelitis protection is required and the final dose of the relevant antigen was received more than 10 years ago, even if the individual has received 5 doses of tetanus containing vaccine previously • have a tetanus prone wound and one or more of the following apply (See Green Book Chapter 30): <ul style="list-style-type: none"> ○ primary tetanus immunisation is incomplete ○ tetanus boosters are not up to date ○ tetanus immunisation status is unknown or uncertain ○ individual has never received tetanus immunisation • require vaccination in line with recommendations for the management of cases and contacts of diphtheria or polio
<p>Criteria for exclusion²</p>	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are aged less than 10 years • have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus or poliomyelitis containing vaccine, including any conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate • have had a confirmed anaphylactic reaction to any component of the vaccine, including neomycin, streptomycin or polymyxin B • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
<p>Cautions including any relevant action to be taken</p> <p>Continued over page</p>	<p>Td/IPV may be given to pregnant women when protection is required without delay eg tetanus prone wound. However, pregnant women from week 16 of pregnancy onwards should instead be protected by the administration of the routinely indicated dTaP/IPV (Boostrix-IPV).</p> <p>The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The</p>

² Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

<p>Cautions including any relevant action to be taken (continued)</p>	<p>risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.</p> <p>If a child has experienced encephalopathy or encephalitis within seven days of immunisation, it is unlikely that these conditions will have been caused by the vaccine and they should be investigated by a specialist. If a cause is identified or the child recovered within seven days, immunisation should proceed as recommended. In children where no underlying cause was found and the child did not recover completely within seven days, immunisation should be deferred until the condition has stabilized or the expected course of the condition becomes clear.</p> <p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Where possible, vaccination should be postponed until immune function has recovered. However, vaccination of subjects with chronic immunodeficiency, such as AIDS, is recommended even if the antibody response might be limited.</p>
<p>Action to be taken if the patient is excluded</p>	<p>If aged under 10 years assess for immunisation with DTaP/IPV/Hib/HepB, DTaP/IPV/Hib, DTaP/IPV or dTaP/IPV as appropriate.</p> <p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as appropriate.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.</p>
<p>Action to be taken if the patient or carer declines treatment</p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>In a GP practice setting, inform or refer to the GP as appropriate.</p>
<p>Arrangements for referral for medical advice</p>	<p>As per local policy</p>

5. Description of treatment

Name, strength & formulation of drug	Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV) eg: <ul style="list-style-type: none"> • Revaxis[®], suspension for injection in a pre-filled syringe.
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>Primary immunisation is off-label administration in accordance with the recommendations given for individuals over 10 years of age in Chapter 15, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: “The Green Book”.</p> <p>Administration to individuals who have received a vaccine containing diphtheria or tetanus toxoids within the previous five years is off-label but indicated for the management of primary immunisation (as above) and for cases and contacts of diphtheria or polio in accordance with PHE disease management guidelines (see Dose and frequency of administration).</p> <p>Administration to individuals who experienced neurological complications following an earlier immunisation against diphtheria and/or tetanus is off-label but may proceed once the cause is identified, the condition has been stabilized or the expected course of the condition becomes clear in accordance with the recommendations in Chapter 15 and Chapter 30 of Immunisation Against Infectious Disease: “The Green Book”.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
Route / method of administration	<p>Administer by intramuscular injection, preferably into deltoid region of the upper arm.</p> <p>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.</p> <p>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.</p> <p>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 Green Book Chapter 4).</p> <p>The vaccine's normal appearance is a cloudy white suspension that may sediment during storage. Shake the pre-filled syringe well to distribute uniformly the suspension before administering the vaccine.</p> <p>The vaccine should not be used if foreign particles are present in the suspension.</p> <p>The SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>

<p>Dose and frequency of administration (continued)</p>	<p>containing vaccine in last 12 months may be given a single reinforcing dose of Td/IPV.</p> <p>Management of cases and contacts of polio</p> <p>Cases and contacts of polio should be managed in accordance with PHE national polio guidelines: Local and regional services and recommendations from the local health protection team.</p> <p>Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes.</p> <p>Management will depend on the level of exposure but may include the administration of a single dose of IPV containing vaccine, regardless of vaccine history.</p> <p>Points to note</p> <p>Where there is no reliable history of previous immunisation, it should be assumed that individuals are unimmunised and the full UK recommendations should be followed.</p> <p>Where children have had a fourth dose of tetanus, diphtheria and polio containing vaccine at around 18 months of age, this dose should be discounted as it may not provide satisfactory protection until the time of the teenage booster. The routine pre-school and subsequent boosters should be given according to the UK schedule.</p> <p>If a person attends for a routine booster dose and has a history of receiving a vaccine following a tetanus-prone wound, attempts should be made to identify which vaccine was given. If the vaccine given at the time of the injury was the same as that due at the current visit and was given after an appropriate interval, then the routine booster dose is not required. Otherwise, the dose given at the time of injury should be discounted as it may not provide long-term protection against all antigens, and the scheduled immunisation should be given. Such additional doses are unlikely to produce an unacceptable rate of reactions.</p>
<p>Duration of treatment</p>	<p>A total of 5 doses (3 primary course doses and 2 booster doses) of diphtheria, tetanus and polio vaccine are indicated for complete immunisation (those doses provided under the age of 10 years will not be provided using this vaccine).</p> <p>A further booster dose may be indicated 10 years after the final dose where risk of exposure is high.</p> <p>A reinforcing dose may be recommended following potential exposure.</p>
<p>Quantity to be supplied / administered</p>	<p>Single 0.5ml dose per administration.</p>
<p>Supplies</p> <p>Continued over page</p>	<p>Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.</p> <p>Vaccine for indications other than the national immunisation programme should be obtained from manufacturers/wholesalers.</p> <p>Protocols for the ordering, storage and handling of vaccines should</p>

Supplies (continued)	be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01 : Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. 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: www.medicines.org.uk
Identification & management of adverse reactions	Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. A small painless nodule may form at the injection site. Common adverse reactions include pyrexia, headache, vertigo, nausea and vomiting. Allergic reactions can occur including generalised skin reactions such as urticaria, anaphylactic reactions, angioedema and shock. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions	Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk 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 patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment	Inform individual/carer/parent of possible side effects and their management. The individual/carer/parent should be advised to seek medical advice in the event of an adverse reaction. When administration is postponed advise the individual/carer/parent when to return for vaccination.
Special considerations / additional information Continued over page	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,

<p>Special considerations / additional information (continued)</p>	<p>immunisation may be postponed until they have fully recovered.</p> <p>Intravenous drug users are at greater risk of tetanus. Every opportunity should be taken to ensure that they are fully protected against tetanus. Booster doses should be given if there is any doubt about their immunisation status.</p> <p>If a person has received vaccination for a tetanus-prone wound with the same vaccine as due for routine immunisation or booster and it was administered at an appropriate interval then the routine booster dose may not be required, refer to advice in Green Book Chapter 30.</p>
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • 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 Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled immunisers record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

6. Key references

<p>Key references</p> <p>Continued over page</p>	<p>Td/IPV vaccine (Revaxis[®])</p> <ul style="list-style-type: none">• Immunisation against infectious disease: The Green Book Chapter 15, Chapter 26 and Chapter 30. Last updated 19 April 2013. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book• Summary of product characteristic for Revaxis[®], Sanofi Pasteur. 23 March 2017. www.medicines.org.uk http://www.medicines.org.uk/emc/medicine/15259• NHS public health functions agreement 2017-18, Service Specification No.12. Td/IPV (teenage booster) immunisation programme. https://www.england.nhs.uk/commissioning/pub-hlth-res/• Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 30 June 2016. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status• Public health control and management of diphtheria (in England and Wales) guidelines. Public Health England. 24 March 2015. https://www.gov.uk/government/publications/diphtheria-public-health-control-and-management-in-england-and-wales• PHE national polio guidelines: Local and regional services. Public Health England. 4 February 2016. https://www.gov.uk/government/publications/polio-national-guidelines <p>General</p> <ul style="list-style-type: none">• PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation• British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.bnf.org https://www.medicinescomplete.com/mc/bnf/current/PHP88119-diphtheria-with-poliomyelitis-and-tetanus-vaccine.htm• National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards• 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. January 2014. https://www.nice.org.uk/guidance/mpg2/resources• Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336• Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013
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Key references (continued)	https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste
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7. Practitioner authorisation sheet

Td/IPV (Revaxis) PGD v02.00 Valid from: 01/11/2017 Expiry: 31/10/2019

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 **NHS England South (South Central)** 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.