



This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

## **PATIENT GROUP DIRECTION (PGD)**

### **Supply of emtricitabine/tenofovir disoproxil and raltegravir tablets for HIV Post Exposure Prophylaxis (HIV PEP) infection in York and North Yorkshire Sexual health services including specialist clinical outreach services**

Version Number 1.1

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 1.0 August 2021	New template
Version 1.1 August 2022	Updated to include advice on interaction between PEP and antacids/multi vitamin and mineral preparations and management of this interaction.

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

**PGD DEVELOPMENT GROUP**

Date PGD template comes into effect:	01/08/2021
Review date	February 2024
Expiry date:	31/07/2024

This PGD template has been peer reviewed by the PEP for SARC PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the British HIV Association (BHIVA), British Association for Sexual Health and HIV (BASHH) in July 2021.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

Name	Designation
Angelique Whitfield	Head of Performance and Assurance Health and Justice NHS England & NHS Improvement
Dr Cath White	Clinical Director, Saint Mary's Sexual Assault Referral Centre, Manchester
Denise Farmer	National Pharmaceutical Adviser Health and Justice Specialised Commissioning, NHS England & NHS Improvement
Dipti Patel	Pharmaceutical adviser, Mountain Healthcare Limited
Esther Silva	SAAS Programme Lead, NHS England & NHS Improvement
Jo Jenkins (SLWG co-ordinator)	Specialist Pharmacist (PGDs) Specialist Pharmacy Service
Paula Wilkinson	Chief Pharmacist G4S Health Services, G4S Care & Justice
Telisha Jenkinson	Forensic Nurse Examiner, West Midlands Children and Young People Service, Horizon SARC
Tracy Rogers	Director Specialist Pharmacy Service

The PGD has also been reviewed by members of the Sexual Health PGDs Short Life Working Group in accordance with their Terms of Reference.

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and

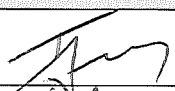
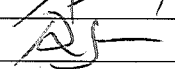



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	Reproductive Health
Chetna Parmar	Pharmacist adviser, Umbrella
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Rachael Jones	Consultant in HIV and Sexual Health, Chelsea and Westminster NHS Foundation Trust
Dr Rita Browne	Consultant in Sexual Health and HIV
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Belinda Loftus	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services

### Glossary

<b>ART</b>	Anti-Retroviral Therapy
<b>BASHH</b>	British Association for Sexual Health and HIV
<b>BHIVA</b>	British HIV Association
<b>eGFR</b>	Estimated Glomerular Filtration Rate
<b>GUM</b>	Genitourinary Medicine
<b>HIV</b>	Human Immunodeficiency Virus
<b>PEP</b>	Post Exposure Prophylaxis
<b>RCN</b>	Royal College of Nursing
<b>STI</b>	Sexually Transmitted Infection

### ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Ian Fairley, Lead Consultant		01/08/22
Senior pharmacist	Paul Jackson		9/9/22
Senior representative of professional group using the PGD	Steve Evans Nelson Chorvater	 pp.	01/09/22
Person signing on behalf of authorising body	Jennie Booth, Lead Nurse Medicines Management		27-09-2022
	Stuart Parkes, Chief Pharmacist		22/09/22

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## 1. Characteristics of staff

<b>Qualifications and professional registration</b>	<p>Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p>
<b>Initial training</b>	<p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals leading to an assessment of risk of infection of the condition listed.</p> <p>The registered healthcare professional authorised to operate under this PGD must have experience in the delivery of emergency or unplanned care in primary/secondary including, as relevant occupational health, sexual health medicine and/or the pre-hospital care setting, including forensic medicine.</p> <p>Recommended requirement for training would be successful completion of a HIV PEP specific relevant module/course accredited or endorsed by BHIVA, BASHH, RCN or a university or advised in the RCN Sexual Health Education directory.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.</p>
<b>Competency assessment</b>	<ul style="list-style-type: none"> <li>• Individuals operating under this PGD must be assessed as competent to operate under this PGD.</li> <li>• Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></li> </ul>
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.</li> <li>• Completion of PGD awareness session via Trust Learning HUB</li> </ul>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

## 2. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	<ul style="list-style-type: none"> <li>• HIV Post-Exposure Prophylaxis (HIV PEP)</li> </ul>
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• Individuals 40kg or greater in weight, presenting within 72 hours of potential HIV exposure risk as per <a href="#">BASHH UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021</a></li> <li>• Individual able and willing to attend either a face to face or telephone follow up appointment with relevant GUM/Sexual Health/HIV clinic within 3 days of PEP being started. In exceptional circumstances where access to a clinic follow up may be delayed due to bank holiday etc. this must be within 5 days.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• Consent not given.</li> <li>• Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines.</li> <li>• Individuals 16 years of age and over and assessed as lacking capacity to consent.</li> <li>• Individuals under 40kg in weight.</li> <li>• Individuals presenting following potential HIV exposure more than 72 hours ago</li> <li>• Known hypersensitivity or allergy to emtricitabine, tenofovir disoproxil, raltegravir or to any component of the product - See current product Summary of Product Characteristics (<a href="#">SPC</a>) for active ingredients and excipients</li> <li>• Individuals are excluded if they are:             <ul style="list-style-type: none"> <li>➤ known to be HIV positive</li> <li>➤ already being treated with anti-retroviral medication</li> <li>➤ known renal impairment where eGFR less than 50ml/minute</li> <li>➤ known hepatitis B infection, liver impairment or disease</li> <li>➤ immunocompromised</li> <li>➤ known pregnancy</li> <li>➤ breastfeeding</li> <li>➤ known to have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption</li> <li>➤ already receiving medication which interacts with anti-retroviral medication and defined as a rating of 'Red' when assessed on Interaction charts produced by the Liverpool HIV Pharmacology Group <a href="http://www.hiv-druginteractions.org">http://www.hiv-druginteractions.org</a> See 'Drug Interactions' section</li> <li>➤ currently taking antacids containing aluminium, calcium carbonate and magnesium either regularly or as required – PEP may be supplied if individual advised and willing/able not to take these products for duration of PEP course (28 days)</li> <li>➤ taking multivitamins/other supplements containing iron, aluminium, calcium, magnesium and zinc either regularly or otherwise – PEP may be supplied if individual advised and willing/able not to take these</li> </ul> </li> </ul>

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<p><b>Cautions including any relevant action to be taken</b></p>	<p style="text-align: center;">products for duration of PEP course (28 days)</p> <ul style="list-style-type: none"> <li>• Individuals with significant psychiatric illness: <ul style="list-style-type: none"> <li>○ Consider contact with mental health team/GP if possible</li> <li>○ Advise individual of risks and also get consent to discuss with their GP/mental health team that they have been given PEP and will need to be monitored to ensure mental health does not deteriorate.</li> <li>○ For individuals who are not monitored, recommend that they should see their GP within next few days to discuss mental health</li> <li>○ Highlight to the referral team that the individual has a pre-existing mental health condition</li> </ul> </li> <li>• Individual already receiving medication which interacts with anti-retroviral medication defined as an 'Amber' or 'Red' rating when assessed on Interaction charts produced by the Liverpool HIV Pharmacology Group <a href="http://www.hiv-druginteractions.org">http://www.hiv-druginteractions.org</a> or where an interaction check is not available via this resource. See 'Drug Interactions' section.</li> <li>• Discuss with an Independent Prescriber regarding conditions/medicines/side effects of which the health care professional is unsure.</li> </ul>
<p><b>Action to be taken if the individual is excluded or declines treatment</b></p>	<ul style="list-style-type: none"> <li>• If declined, ensure individual is aware of the reasons this medication has been offered and the potential consequences of not receiving it. Record reason for declining in record.</li> <li>• Weight under 40kg does not preclude the use of HIV PEP but the individual should be referred to a prescriber for consideration of suitability/an alternative regime.</li> <li>• PEP is generally not recommended beyond 72 hours post-exposure. Any decision on initiation of PEP more than 72 hours after the exposure should be left to the discretion of clinicians in discussion with the exposure recipient, in full knowledge of the lack of evidence of efficacy after this time point. In this circumstance PEP would need to be prescribed – it cannot be supplied under this PGD.</li> <li>• If eGFR known to be less than 50ml/minute - refer to a prescriber for further investigation and consideration of PEP.</li> <li>• Known hepatitis B does not preclude the use of HIV PEP but the individual should be referred to a prescriber.</li> <li>• Pregnancy does not preclude the use of HIV PEP but the individual should be referred to a prescriber.</li> <li>• Breast feeding does not preclude the use of HIV PEP but the individual should be referred to a prescriber.</li> <li>• If excluded, explain the reasons for exclusion to the individual and document in the consultation record.</li> <li>• Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.</li> </ul>

### 3. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	Emtricitabine 200mg/tenofovir disoproxil 245mg tablet (e.g. Truvada®)	Raltegravir 600mg tablet (e.g. Isentress®)
<b>Legal category</b>	POM	POM
<b>Route of administration</b>	Oral	Oral
<b>Dose and frequency of administration</b>	One tablet once daily	1200mg once daily
<b>Duration of treatment</b>	<p>28 days.</p> <p>Individual should be advised that total course length is 28 days but the original containers contain 30 days of medication - all remaining tablets should be returned to a pharmacy for disposal.</p>	
<b>Quantity to be supplied (NOTE both emtricitabine/tenofovir disoproxil and raltegravir tablets must be supplied)</b>	Appropriately labelled pack of 30 x emtricitabine 200mg/tenofovir disoproxil 245mg tablets	Appropriately labelled pack of 60 x raltegravir 600mg tablets
<b>Identification of adverse reactions</b>	<p>A detailed list of adverse reactions is available in <u>BNF</u> or the product <u>SPC</u>. The following side effects are reported as common with emtricitabine/ tenofovir disoproxil:</p> <ul style="list-style-type: none"> <li>• diarrhoea, vomiting, nausea</li> <li>• dizziness, headache</li> <li>• feeling weak</li> <li>• pain, stomach pain</li> <li>• difficulty sleeping, abnormal dreams</li> <li>• problems with digestion resulting in discomfort after meals, feeling bloated, flatulence</li> <li>• rashes (including red spots/ blotches sometimes with blistering and swelling of the skin) which may be allergic</li> <li>• itching, changes in skin colour including darkening of the skin in patches</li> <li>• other allergic reactions, such as wheezing, swelling</li> </ul>	<p>A detailed list of adverse reactions is available in <u>BNF</u> or the product <u>SPC</u>. The following side effects are reported as common with raltegravir:</p> <ul style="list-style-type: none"> <li>• decreased appetite</li> <li>• abnormal dreams, insomnia, nightmare</li> <li>• abnormal behaviour</li> <li>• depression</li> <li>• dizziness, headache</li> <li>• psychomotor hyperactivity</li> <li>• vertigo</li> <li>• abdominal distention, abdominal pain, diarrhoea, flatulence, nausea, vomiting, dyspepsia</li> <li>• rash</li> <li>• asthenia</li> <li>• fatigue,</li> <li>• pyrexia</li> </ul>

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	<ul style="list-style-type: none"> <li>or feeling light-headed</li> <li>• swelling of the face, lips, tongue or throat</li> </ul>	
<p><b>Drug interactions</b></p>	<p>All concurrent medications should be reviewed for interactions.</p> <p>Interactions which mean the named medicines <b>must not be supplied under this PGD</b> are defined as 'Red' rating when assessed on the interaction charts produced by the Liverpool HIV Pharmacology Group <a href="http://www.hiv-druginteractions.org">http://www.hiv-druginteractions.org</a> Refer individual to a prescriber.</p> <p>Where an interaction is defined as 'Amber' rating when assessed on the interaction charts produced by the Liverpool HIV Pharmacology Group <a href="http://www.hiv-druginteractions.org">http://www.hiv-druginteractions.org</a> discuss with a relevant prescriber or pharmacist to confirm suitability of supply. Refer individual to a prescriber where supply not suitable within parameters of this PGD.</p> <ul style="list-style-type: none"> <li>• N.B. The following are exclusions to supply under this PGD due to risk of compromise of raltegravir absorption: <ul style="list-style-type: none"> <li>○ Antacids containing aluminium, calcium carbonate and magnesium</li> <li>○ Multivitamins/other supplements containing iron, aluminium, calcium, magnesium and zinc</li> </ul> </li> </ul> <p>Discuss with a relevant prescriber or pharmacist to confirm suitability of supply in all cases where an interaction is not available on the interaction charts produced by the Liverpool HIV Pharmacology Group <a href="http://www.hiv-druginteractions.org">http://www.hiv-druginteractions.org</a>.</p> <p>Refer individual to a prescriber where supply not suitable within parameters of this PGD.</p>	
<p><b>Off label use</b></p>	<p>Best practice advice is given by <a href="#">BHIVA/BASHH</a> and the Faculty of Forensic and Legal Medicine (FFLM) is used as the reference guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p><b><u>Off label use included within this PGD:</u></b></p> <ul style="list-style-type: none"> <li>• The named medicines within the PGD do not include PEP within their licenced indications – guidance supports its use.</li> </ul> <p>Medicines 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 the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.</p> <p>Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/carer that the</p>	



	drug is being offered in accordance with national guidance but that this is outside the product licence.
<b>Storage</b>	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a></li> <li>Record all adverse drug reactions (ADRs) in the patient's medical record.</li> <li>Report via organisation incident policy.</li> </ul>
<b>Written information and further advice to be given to individual</b>	<ul style="list-style-type: none"> <li>Individual should be advised that total course length is 28 days but the original containers contain 30 days of medication - all remaining tablets should be returned to a pharmacy for disposal</li> <li>Advise that a patient information leaflet (PIL) is provided with the original pack. Note that the regime being taken may not reflect that detailed in the PIL – it is therefore advisable that the HIVPA information leaflet is also offered or the link provided (<a href="https://hivpa.org/wp-content/uploads/2021/04/HIVPA-PEP-PIL-April-2021-generic-TDF-FTC-RAL-OD-Final.pdf">https://hivpa.org/wp-content/uploads/2021/04/HIVPA-PEP-PIL-April-2021-generic-TDF-FTC-RAL-OD-Final.pdf</a>)</li> <li>Explain mode of action, side effects, and benefits of the medicine.</li> <li>PEP should be commenced as soon as possible after exposure, allowing for careful risk assessment, ideally within an hour.</li> <li>Ensure individual is counselled as to dosage regimen.</li> <li>Advise if individual is concerned about any side effects they experience they should contact their clinic as soon as possible.</li> <li>Advise individuals that PEP medicines may interact with other medicines, including medicines purchased over-the-counter and some supplements and herbal remedies. These include: <ul style="list-style-type: none"> <li>Calcium, iron, magnesium, aluminium and zinc which can be found in indigestion remedies, vitamins and mineral tablets. These can prevent raltegravir from being absorbed so should not be taken.</li> <li><b>Advise individual that these must not be taken for the duration of the PEP course (28 days)</b></li> </ul> </li> <li>Advise individuals to seek advice on any new medicines commenced whilst taking PEP (including over the counter medicines) from a prescriber/pharmacist to check for interactions.</li> <li>Advise that PEP is not a contraceptive.</li> <li>Advise on use of condoms until result of final HIV test known (minimum of 73 days/10.5 weeks after exposure assuming full 28 PEP course is completed).</li> </ul> <p><b><u>Emtricitabine/tenofovir disoproxil tablets only</u></b></p> <ul style="list-style-type: none"> <li>If needed, the tablets can be dispersed in approximately 100ml of water, orange juice or grape</li> </ul>

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	<p>juice and taken immediately.</p> <ul style="list-style-type: none"> <li>• It is preferable that these tablets are taken with food.</li> <li>• If a dose is missed within 12 hours of the time it is usually taken, the dose should be taken as soon as possible and the normal dosing schedule should be resumed. If a dose is missed by more than 12 hours and it is almost time for the next dose, the missed dose should not be taken and the usual dosing schedule should be resumed.</li> <li>• If vomiting occurs within 1 hour of taking the tablet, another tablet should be taken. If vomiting occurs more than 1 hour after taking the tablet a second dose should not be taken</li> </ul> <p><b><u>Raltegravir tablets only</u></b></p> <ul style="list-style-type: none"> <li>• Tablets can be administered with or without food. The tablets <b>should not</b> be chewed, crushed or split due to anticipated changes in the pharmacokinetic profile.</li> </ul>
<p><b>Follow up treatment</b></p>	<ul style="list-style-type: none"> <li>• Individuals must be referred to a relevant HIV, GUM, Sexual Health or infectious disease departments for regular clinical follow-up during the period of PEP, to monitor possible toxicity and adherence to the antiretroviral regimen.</li> <li>• Individuals exposed to HIV should have follow-up counselling, post-exposure testing and medical evaluation whether or not they have received PEP under this PGD.</li> <li>• Final HIV testing is recommended at a minimum of 45 days after the PEP course is completed. If the 28 day course is completed, this is a minimum of 73 days (10.5 weeks) after exposure. For sexual exposures this can be performed at 12 weeks to align with syphilis testing – advise individual on appropriate appointment schedule/s.</li> <li>• Advise that it may take 14 days for a chlamydia test to show a positive result after infection and 3 months for hepatitis B, C, or syphilis tests to show positive results – advise individual on appropriate testing appointment schedule/s.</li> <li>• Individuals should be advised of signs of infection with any STI and if symptoms of infection develop they should seek medical advice.</li> </ul>
<p><b>Records</b></p>	<p><b>Record:</b></p> <ul style="list-style-type: none"> <li>• The consent of the individual and/or <ul style="list-style-type: none"> <li>○ If individual is under 16 years of age document capacity using Fraser guidelines.</li> <li>○ If individual is under 13 years of age and not competent, record action taken</li> <li>○ If individual is under 16 years and not competent, record action taken</li> <li>○ If individual over 16 years of age and not competent, record action taken</li> </ul> </li> <li>• Name of individual, address, date of birth</li> <li>• GP contact details where available/appropriate</li> <li>• Relevant past and present medical history</li> <li>• Relevant medication history (to include over the counter, herbal medications, supplements and recreational drug</li> </ul>

	<p>use).</p> <ul style="list-style-type: none"> <li>• Examination or microbiology finding/s where relevant.</li> <li>• Any known allergies</li> <li>• Name of registered health professional</li> <li>• Name of medication supplied</li> <li>• Date of supply</li> <li>• Dose supplied</li> <li>• Quantity supplied</li> <li>• Advice given, including advice given if excluded or declines treatment</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Advice given about the medication including, dosing regimen, side effects, benefits, and when and what to do if any concerns</li> <li>• Any referral arrangements made</li> <li>• Any supply outside the terms of the product marketing authorisation</li> <li>• Recorded that supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</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>
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#### 4. Key references

<p><b>Key references (accessed July 2021)</b></p>	<ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• NICE Medicines practice guideline “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 <a href="https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines">https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines</a></li> <li>• BASHH UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021 <a href="https://www.bashhguidelines.org/current-guidelines/hiv/post-exposure-prophylaxis/">https://www.bashhguidelines.org/current-guidelines/hiv/post-exposure-prophylaxis/</a></li> </ul>
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**Note to authorising manager**

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

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

**This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.**

**When the expiry date is exceeded, this PGD ceases to be a legal document. Staff authorisation records must be maintained for 8 years if the PGD relates to adults only, 10 years for implants and 25 years after the expiry date if the PGD relates to children**

