Providing NHS Services NHS

Oldham Council

PATIENT GROUP DIRECTION FOR THE SUPPLY OF

Levonorgestrel 1500 microgram Tablet

By registered Pharmacists for Emergency Hormonal Contraception in Community Pharmacy

Version 4.0

Valid from: 28/06/2019

Expires on: 27/06/2021

This Patient Group Direction (PGD) must only be used by registered health 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.

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DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Oldham Council
Address:	Civic Centre, West Street, Oldham, OL1 1UT
Telephone:	0161 770 3000

Revision History

The latest and master version of the unsigned PGD is held by the Greater Manchester Joint Commissioning Team.

Revision Date and Actioned By	Summary of Changes	Version
02/06/2017 S Woods	Finalised ready for signing	3.0
09/04/2019 S Woods	**2. Clinical condition or situation to which the direction applies.** Under 'Criteria for exclusion added the bullet point: ▪ Use of ulipristal acetate emergency contraception within the last 5 days And removed the last paragraph as repeated elsewhere: If the patient is receiving any concomitant medication or treatment, it is the responsibility of the healthcare professional identified in 'Characteristics of Staff' to ensure that treatment with the medicines detailed in this PGD is appropriate. In case of any doubt, further advice must be sought from an appropriate healthcare professional (e.g. patient's GP, sexual health clinic doctor) and this must be recorded as having been sought before the medicine is given. Under 'Cautions (including any relevant action taken)': Added a link to UKMEC 2016 And removed the paragraph: 'If a woman is referred on for a copper intrauterine device (Cu-IUD), levonorgestrel EC should be given at the time of referral in case the Cu-IUD cannot be inserted or the woman changes her mind.' as this is mentioned elsewhere. **3. Details of medicine** Under 'Dose and frequency' changed the second bullet point form: ▪ If the patient is taking enzyme-inducing medication or griseofulvin or has a BMI > 26 kg/m2 or a weight > 70 kg, the dosage should be increased to TWO tablets, i.e. 3000 micrograms. This should be taken as a single dose as soon as possible and no later than 72 hours after UPSI. To: ▪ If the patient is taking (or taken within the last 28 days) enzyme-inducing medication or griseofulvin or has a BMI > 26 kg/m2 or a weight > 70 kg, the dosage should be increased to TWO tablets, i.e. 3000 micrograms. This should be taken as a single dose as soon as possible and no later than 72 hours after UPSI.	3.1

4. Records

Under 'Records' changed content from:

The pharmacist must keep a record of the consultation and outcome on the patient proforma for a period of time in line with Records management: NHS code of practice or use any agreed web based solution. The minimum required information to be collected is:

- Patient's name
- Date of birth
- Dose supplied
- Batch number
- Expiry date
- Significant information e.g. if used off licence reason why
- Record if the treatment is taken away from the pharmacy
- Signature/name of health professional who administered or supplied the medication.

Computerised patients medication records can be used where considered appropriate.

Where there is no web based solution the pharmacist must complete the agreed audit form and submit to the relevant department in line with the service specification.

Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death. (Records Management: NHS Code of Practice - https://www.gov.uk/government/publications/records-management-nhs-code-of-practice)

To:

The pharmacist must keep a record of the consultation and outcome on the patient proforma for a period of time in line with Records management: NHS code of practice or use any agreed web based solution. The minimum required information to be collected is:

- Patient's name
- Date of supply
- Date of birth
- Dose supplied
- Batch number
- Expiry date
- Significant information e.g. if used off licence reason why
- Record if the treatment is taken away from the pharmacy
- Client signature
- Signature/name of health professional who administered or supplied the medication.
- Fraser competence form if required.

Computerised patients medication records can be used where considered appropriate.

Where there is no web based solution the pharmacist must complete the agreed audit form and submit to the relevant department in line with the service specification.

Records Management Code of Practice for Health and Social Care 2016 recommends the following storage periods for health records:

	8 years (in adults) or until 25th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death. - https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016 **6. References used to develop this PGD** References updated.	
08/05/2019 S Woods	**Changes made after decision by Oldham Council to use ulipristal 30mg as the first line oral choice.** **2. Clinical condition or situation to which the direction applies.** Under 'Indication (Clinical condition or situation to which this PGD applies)' changed the second bullet point from: ▪ A patient requesting oral emergency contraception who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential contraception failure. To: ▪ A patient requesting emergency contraception who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential contraception failure and refuses or is unable to be treated using a copper intrauterine device (Cu-IUD) and ulipristal acetate 30mg. Under 'Criteria for inclusion' changed the first bullet point from: ▪ Have been given information regarding the other methods available for EC (see Advice to be given to the patient or carer) and provided with information on services that can provide them, but decides not to access them. (If a woman is referred on for a copper intrauterine device (Cu-IUD), levonorgestrel EC should be given at the time of referral in case the Cu-IUD cannot be inserted or the woman changes her mind.) To: ▪ Have been given information regarding the other methods available for EC (ulipristal 30mg and Cu-IUD) and provided with information on services that can provide the Cu-IUD; but decides not to access or are unsuitable for either option. ▪ Women who are referred on for a Cu-IUD can be given levonorgestrel EC at the time of referral, if ulipristal is unsuitable or refused, in case the Cu-IUD cannot be inserted or the woman changes her mind. And added an additional bullet point: ▪ Vomited within three hours of taking an initial dose; another dose can be provided, but this must fall within the 72 hours since UPSI occurred. **3. Details of medicine** Under 'Dose and frequency' changed the third bullet point, in line with SPCs, from: ▪ If vomiting occurs within two hours of taking, another dose should be taken immediately, but this must fall within the 72 hours since UPSI occurred. To: ▪ If vomiting occurs within three hours of taking, another dose should be taken immediately, but this must fall within the 72 hours since UPSI occurred.	3.2

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S Woods 25/06/2019	Minor corrections made and final formatting for signatures.	4.0

Approvals

This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr John Patterson	Chief Clinical Officer, Oldham CCG		4.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, Greater Manchester Joint Commissioning Team		4.0
Alan Higgins	Director of Public Health, Oldham Council		4.0
Dipesh Raghwani	Clinical Lead, GM LPC		4.0

Distribution

This PGD has been distributed, during its development, to:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr John Patterson	Chief Clinical Officer, Oldham CCG	22/05/2019 25/06/2019	3.2 4.0
Dipesh Raghwani	Clinical Lead, GM LPC	22/05/2019 25/06/2019	3.2 4.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, Greater Manchester Joint Commissioning Team	07/06/2019 25/06/2019	3.2 4.0
Lianne Davies	Public Health Business & Strategy Manager	25/06/2019	4.0

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PGD Development

Originally developed / Reviewed by:	Stephen Woods	Senior Medicines Optimisation Pharmacist, Greater Manchester Joint Commissioning Team
	Dr John Patterson	Chief Clinical Officer, Oldham CCG
	Dipesh Raghwani	Clinical Lead, Greater Manchester LPC

Date applicable:	28th June 2019
Review date:	1st January 2021
Expiry date:	27th June 2021

PGD Authorisation

This Patient Group Direction has been approved for use in the Oldham Council area by:

Designation	Name	Signature	Date
Doctor (Chief Clinical Officer, Oldham CCG)	Dr John Patterson		25.6.2019
Senior Pharmacist (Strategic Medicines Optimisation Pharmacist Greater Manchester Joint Commissioning Team)	Andrew Martin	A Martin	24/6/19
Authorising Signatory (Acting Director of Public Health, Oldham Council)	Katrina Stephens	K Stephens	26/6/19
Pharmacist Representative (Clinical Lead, GM LPC)	Dipesh Raghwani		24/6/19.
Pharmacist Author (Senior Medicines Greater Manchester Optimisation Pharmacist Joint Commissioning Team)	Stephen Woods		24/6/19

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1. Characteristics of Staff

Qualifications required	▪ Pharmacist with current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within Oldham Council area
Additional requirements	▪ Has undertaken training in the use of PGDs ▪ Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply the treatment according to this PGD as detailed in the service specification. ▪ Has satisfied the competencies and completed the self-declaration form appropriate to this PGD, as detailed in the CPPE and NHS Health Education England *Declaration of Competence for pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document (https://www.cppe.ac.uk/services/declaration-of-competence#navTop). ▪ Is competent in the assessment of the individuals using Fraser guidelines
Continued training requirements	▪ The pharmacist should be aware of any change to the recommendations for the medicine listed. ▪ Must be able to show regular update in the field of family planning and reproductive health care including emergency contraception ▪ Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document ▪ It is the responsibility of the pharmacist to keep up-to-date with continuing professional development ▪ It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed.
Suggested supporting learning	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education England *Declaration of Competence for pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document.

The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of the their self-declaration and sign up to the current PGD.

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2. Clinical condition or situation to which the direction applies.

Indication (Clinical condition or situation to which this PGD applies)	▪ Sexual health services provided by community pharmacies commissioned by Oldham Council ▪ A patient requesting emergency contraception who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential contraception failure and refuses or is unable to be treated using a copper intrauterine device (Cu-IUD) and ulipristal acetate 30mg.
Criteria for inclusion	Women with spontaneous menstrual cycles presenting within 72 hours of UPSI or potential contraception failure (e.g. condom failure, severe vomiting/diarrhoea whilst on oral hormonal contraception), and who: ▪ Have been given information regarding the other methods available for EC (ulipristal 30mg and Cu-IUD) and provided with information on services that can provide the Cu-IUD; but decide not to access or are unsuitable for either option. ▪ Women who are referred on for a Cu-IUD can be given levonorgestrel EC at the time of referral, if ulipristal is unsuitable or refused, in case the Cu-IUD cannot be inserted or the woman changes her mind. ▪ Have no known contraindications to progestogen in their known medical history ▪ Understand the risks, benefits and side effects of treatment with levonorgestrel. ▪ Meet Fraser guidelines, if under 16 years of age. *Note children under 13 years of age must be notified to the local Safeguarding Team; however, this should not prevent treatment if considered necessary under this PGD.* ▪ Are competent to consent to treatment ▪ Has reached the menarche. ▪ Vomited within three hours of taking an initial dose of levonorgestrel; another dose can be provided, but this must fall within the 72 hours since UPSI occurred.
Criteria for exclusion[1]	▪ Patients who decide to access treatment with ulipristal acetate 30mg. ▪ Use of ulipristal acetate emergency contraception within the last 5 days ▪ UPSI more than 72 hours ago ▪ Allergy / known intolerance to progestogen or other product ingredients ▪ Active acute porphyria ▪ Known pregnancy. (Suspected pregnancy should be excluded using a pregnancy test[2].)

[1] Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it may be outside the remit of the PGD and another form of authorisation may be suitable.

[2] Although there is potential for a false negative where fertilisation occurred less than 3 weeks previously, the FSRH CEU recommends that LNG can be used more than once in the same cycle or can be used for a recent episode of UPSI even if there has been an earlier episode of UPSI outside the treatment window (>120 hours) (outside product licence), as

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	▪ Unexplained or unusual vaginal bleeding. ▪ Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.
Cautions (including any relevant action to be taken)	Refer to the current version of the UK Medical Eligibility Criteria for Contraceptive use (UKMEC; http://ukmec.pagelizard.com/2016) and where necessary explain the benefits and risks.
Action if excluded	▪ Refer to a doctor or to the nearest available contraceptive clinic as appropriate. ▪ Document action taken.
Action if patient or carer declines treatment	▪ Inform patient/carer re risks of not receiving treatment compared to the benefits. ▪ Refer to a doctor or to the nearest available contraceptive clinic as appropriate. ▪ Document action taken.

there is no evidence to indicate LNG is not safe in pregnancy. Please note in this PGD use is only allowed within the treatment window of ≤72 hours.

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3. Details of medicine

Name, strength & formulation of drug	Levonorgestrel 1500 microgram tablet
Presentation	Oral tablet
Storage	Store in the original package in order to protect from light.
Legal category	POM
Black Triangle▼	No
Unlicensed / off label use	Check product SPC to identify off label usage as this can vary between manufacturers. *If used outside the licensed indication then this must be documented in the consultation record.*
Route / method	Oral
Dose and frequency	▪ One tablet to be taken as a single dose as soon as possible and no later than 72 hours after UPSI. ▪ If the patient is taking (or taken within the last 28 days) enzyme-inducing medication or griseofulvin or has a BMI > 26 kg/m^2 or a weight > 70 kg, the dosage should be increased to TWO tablets, i.e. 3000 micrograms. This should be taken as a single dose as soon as possible and no later than 72 hours after UPSI. ▪ If vomiting occurs within three hours of taking, another dose should be taken immediately, but this must fall within the 72 hours since UPSI occurred.
Quantity to be administered and/or supplied	Single dose of 1500 micrograms or 3000 micrograms to be supplied. Patients should be observed taking the medication unless they are breast feeding, when they can be allowed to take away for later consumption if necessary, but this must occur within the 72 hour window.
Maximum or minimum treatment periods	Single episode of treatment which may be repeated in the same cycle if appropriate.
Disposal	All waste must be disposed of in accordance with the relevant waste regulations.

Drug interactions[3]

- If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction see Appendix 1 of BNF (https://www.medicinescomplete.com/mc/) or the Summary of Product Characteristics (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF) or refer to *Clinical Guidance: Drug Interactions with Hormonal Contraception* (FSRH, January 2017)
- In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given.
- If the requirements of this Patient Group Direction cannot be complied with the patient must be referred to a suitable independent prescriber.

Identification & management of adverse reactions[2]

Very common and common adverse effects	
Very common (≥ 10%)	**Common (≥ 1/100 to <1/10)**
Headache	Dizziness
Nausea Lower abdominal pain	Diarrhoea Vomiting
Bleeding not related to menses*	Delay of menses more than 7 days ** Irregular menstruation Breast tenderness
Fatigue	

* Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time.

** If the next menstrual period is more than 5 days overdue, pregnancy should be excluded.

If pregnancy occurs after treatment with levonorgestrel 1500microgram, the possibility of an ectopic pregnancy should be considered. Severe abdominal pain may be an indication of ectopic pregnancy.
For a full adverse effects profile, refer to the Summary of Product Characteristics (SPC – www.medicines.org.uk) or the most current edition of the British National Formulary (BNF – https://www.medicinescomplete.com/#/)

In the event of any adverse reaction:

- Record the adverse reaction in the patient consultation note
- Inform the patient's GP if the patient consents to this

If appropriate report the adverse reaction under the Yellow Card scheme (forms can be found at the back of the BNF or completed online at http://yellowcard.mhra.gov.uk)

[3] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

4. Records

Records	The pharmacist must keep a record of the consultation and outcome on the patient proforma for a period of time in line with Records management: NHS code of practice or use any agreed web based solution. The minimum required information to be collected is: ▪ Patient's name ▪ Date of supply ▪ Date of birth ▪ Dose supplied ▪ Batch number ▪ Expiry date ▪ Significant information e.g. if used off licence reason why ▪ Record if the treatment is taken away from the pharmacy ▪ Client signature ▪ Signature/name of health professional who administered or supplied the medication. ▪ Fraser competence form if required. Computerised patients medication records can be used where considered appropriate. Where there is no web based solution the pharmacist must complete the agreed audit form and submit to the relevant department in line with the service specification. *Records Management Code of Practice for Health and Social Care 2016* recommends the following storage periods for health records: ▪ 8 years (in adults) or until 25th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death. - https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016

5. Patient Information

Written information to be given to the patient or carer	The patient/carer should be given the following written information if appropriate: ▪ The product specific patient information sheet supplied with the medicine. ▪ Provide a copy of the Family Planning Association (FPA) leaflet 'Your guide to emergency contraception' (available at https://www.sexwise.fpa.org.uk/resources) to patients.
Advice to be given to the patient or carer (Continued on next page)	The patient/carer should be given the following information verbally if appropriate and requested: ▪ Advise women that the Cu-IUD is the most effective method of EC. ▪ Advise women that UPA-EC has been demonstrated to be more effective than LNG-EC.

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Advice to be given to the patient or carer (Continued)	▪ EC providers should advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. ▪ Effectiveness of method is dependent on length of time from UPSI / potential contraceptive failure to treatment. ▪ Beneficial effects, side effect and risks should be discussed. ▪ Advise women that after oral EC there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle. ▪ How to take the pill correctly, preferably as an immediate dose in the pharmacy. Breast feeding mothers may be allowed to take away with them to allow them to feed their child before taking. This should only occur if it fits within the allowed time limits. They can also avoid feeding for a further 8 hours after taking, however, there is no evidence that levonorgestrel causes harm to the baby. ▪ If vomiting occurs within two hours of taking, a repeat dose is required, but must be given within the 72 hours since UPSI. ▪ When to seek further medical advice e.g. INR check if on warfarin. ▪ To refer to Sexual Health Clinic or GP if no / light period up to three weeks after treatment. ▪ Advise women that oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or abstain from sex to avoid further risk of pregnancy. ▪ Discuss on going contraception including Quick Starting Contraception guidance (recommending starting contraception immediately after oral emergency hormonal contraception with additional protection as appropriate for the method used). ▪ Discuss long-acting reversible contraception and give written information that is in line with NICE guidance, CG 30, updated September 2014. ▪ Encourage use of condoms and reinforce the safer sex message. ▪ Recommend sexually transmitted infections screening. ▪ Supply or recommend condoms as detailed in the service specification. ▪ Use of the product outside the terms of its licence should be discussed with the patient, including the reasons why this may be necessary. ▪ Advise where the patient will continue to use a hormonal method of contraception that they should use an additional contraceptive method for 7 days (2 days for Progestogen Only Pill; 9 days for *Qlaira®*) ***To patients taking (or taken within the last 28 days) enzyme-inducing medication or griseofulvin or has a BMI > 26 kg/m2 or a weight > 70 kg:*** ▪ Advise on the need for an increased dose of levonorgestrel to 3000microgram (two tablets).

6. References used to develop this PGD

References

1. Faculty of Sexual and Reproductive Healthcare, Clinical Effectiveness Unit all accessed at https://www.fsrh.org/standards-and-guidance/:
   - FSRH Guideline - Emergency Contraception, March 2017 (updated December 2017). Accessed on 10th April 2019
   - Contraceptive Choices for Young People. Clinical Guidance, March 2010 (updated May 2019). Accessed on 22nd May 2019
   - Clinical Guidance: Drug Interactions with Hormonal Contraception. January 2018. Accessed on 10th April 2019
   - UK Medical Eligibility Criteria for Contraceptive Use (UKMEC 2016) Digital version. Accessed on 9th April 2019
2. Manufacturer's Summaries of Product Characteristics (SPC)
   - Levonelle® 1500microgram tablet, Bayer plc. Date of last revision of the text 21/06/2018 https://www.medicines.org.uk/emc/product/133/smpc. Accessed on 10th April 2019
   - Levonorgestrel 1.5mg Tablets, Lupin (UK) Ltd. Date of last revision 01/04/2019 https://www.medicines.org.uk/emc/product/7308/smpc. Accessed on 10th April 2019
   - Upostelle 1500 microgram tablet, Consilient Health Ltd. Date of last revision 24.07/2018 https://www.medicines.org.uk/emc/product/5142/smpc. Accessed on 10th April 2019
3. General Pharmaceutical Council.
   - Standards for pharmacy professionals, May 2017. https://www.pharmacyregulation.org/spp. Accessed on 10th April 2019.
   - Guidance on maintaining clear sexual boundaries, May 2017. https://www.pharmacyregulation.org/guidance-support-spp. Accessed on 10th April 2019.
   - Guidance on patient confidentiality, June 2018. https://www.pharmacyregulation.org/guidance-support-spp. Accessed on 10th April 2019.
   - In practice: Guidance on consent, Revised June 2018. https://www.pharmacyregulation.org/guidance-support-spp. Accessed on 10th April 2019.
4. Centre for Pharmacy Postgraduate Education
   - Declaration of competence for pharmacy services; Emergency Contraception Service with the use of a Patient Group Direction. Version 19 (August 2018) https://www.cppe.ac.uk/services/commissioners#navTop. 10th April 2019.

References (Continued)	5. NHS Digital ▪ Records Management Code of Practice for Health and Social Care 2016. https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016. Accessed 18th December 2017.

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The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer. The healthcare professional retains a copy of the PGD. The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them.

Individual Authorisation

By signing this PGD you are agreeing that:

- You have read and understood the content;
- To the best of your knowledge, the content of the PGD is correct and supports best practice;
- You will act within the parameters of the PGD;
- You take responsibility for maintaining your competence and on-going training requirements to continue to use the PGD safely

Named Healthcare Professional: _____

Designation: _____

The above named healthcare professional is authorised to work within the confines of this Patient Group Direction

Name of Employer: _____
/ Contractor

Address of Employer: _____
/ Contractor

_____

_____

_____

Signature of Employer: _____
/ Contractor

I, the undersigned, have read and understood this PGD and agree to work within its confines

Signature of Named

Healthcare Professional: _____

Date: _____

One copy to be retained by the named healthcare professional
One copy to be retained by the employer / contractor
The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.