**Notice to staff:** If using a paper copy of this document. The PGD page of the internet holds the current and approved version of this guidance. Please ensure you are working to the most current version (https://www.westsussex.gov.uk/social-care-and-health/social-care-and-health-information-for-professionals/adults/public-health-information-for-professionals/#patient-group-directions)

# Patient Group Direction for the supply of Levonorgestrel 1.5mg Tablets for Emergency Contraception (LNG-EC) by accredited Community Pharmacists working within the boundaries of West Sussex County Council (WSCC)

For the supply of LNG-EC by community pharmacists working in WSCC and contracted to provide the Emergency Hormonal Contraception (EHC) service.

Community pharmacists using this PGD must ensure that it is formally approved and signed by a pharmacist, medical lead and governance lead for the organisation with legal authority, so that this document meets legal requirements for a PGD.

Direction no: WSCC 002 V8

| Change History | |
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| Version | Change Details |
| Version 8 | Updated Summary of Product Characteristics (SPC)<br>Updated Faculty of Sexual and Reproductive Healthcare (FSRH) guidance<br>Updated National Institute for Health and Care Excellence (NICE) Guidance |

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| PGD comes into effect | 1st September 2022 |
| PGD review date | 1st September 2023 |
| PGD expiry date | 31st August 2024 |

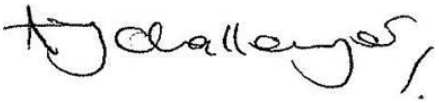
This PGD template has been developed by the following health professionals on behalf of West Sussex County Council (WSCC):

| NAME/ROLE | SIGNATURE | DATE |
|---|---|---|
| Lead Doctor<br>Dr Janet Michaelis |  | 06/07/2022 |
| Pharmacist<br>Janet Rittman |  | 1/7/22 |
| Clinical Governance Lead<br>Matthew Olley |  | 20/07/2022 |

**ORGANISATIONAL APPROVAL**

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

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.

| **Patient Group Direction authorised by:** | | |
|---|---|---|
| **TITLE /ORGANISATION** | **SIGNATURE** | **DATE** |
| Alison Challenger<br>Director of Public Health |  | 22/07/2022 |

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council (GPhC) Standards for Pharmacy Professionals and Pharmaceutical Society of Northern Ireland (PSNI) Code of Ethics for Pharmacists.

No PGD can envisage every clinical situation. Pharmacists are expected to exercise professional judgement and discretion. In any situation where there is a concern a doctor must be consulted.

Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medicines listed only in accordance with the PGD within the specified start and expiry dates. The original copy, signed by all those concerned, should be kept in a designated place within the pharmacy, and be readily accessible for reference and audit purposes.

The pharmacist must work within the service specification agreed between the contracted pharmacy and the commissioning organisation.

| Patient group direction effective from 1st September 2022 |
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| **HEALTHCARE PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD** |
| WSCC authorises the use of this document by accredited community pharmacists who are working within the boundaries of **West Sussex County Council** |
| **DECLARATION:** I am a registered pharmacist, employed at |

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| Name of Pharmacy | |
| Address | |
| | |
| Post Code | |

## Characteristics of Staff

I have read this Patient Group Direction (PGD) and confirm that:

**Qualifications**

- I am registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI).
- I am employed within a community pharmacy commissioned to provide Levonorgestrel 1.5mg (1500mcg) to individuals under the age of 22 years via Patient Group Direction (PGD).

**Specialist qualifications and competencies**

- I have completed the accreditation requirements detailed in the **Provision of Levonorgestrel 1.5mg (1500mcg) from Community Pharmacists to individuals under the age of 22 years via Patient Group Direction (PGD**) service specification.
- I have completed the Emergency Hormonal Contraception Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website https://www.cppe.ac.uk/services/declaration-of-competence
- Pharmacists' personalised statement of declaration should be retained, which may need to be provided to commissioners and/or employers when required via the CPPE Viewer.
- I have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment.
- I am aware of local safeguarding policies and contact information.
- I have reviewed my competency to operate under this PGD using the NICE Competency Framework for health professionals using patient group directions
- I have reviewed the local policies and documentation for this service and references associated with this PGD.
- I am aware that it is my responsibility to keep up-to-date with changes to the recommendations for this medicine and acknowledge any limitations to my knowledge or competence. I will complete continuing professional development as defined by the GPhC or PSNI and take part in an audit as detailed in the service specification.

| Name | GPhC/PSNI registration number | Signature | Date |
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**Signature of Authorising Pharmacist or Pharmacy Manager**

**……**

**Name of Authorising Pharmacist or Pharmacy Manager**

**……**

| 1. Clinical condition or situation to which this Patient Group Direction applies | |
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| **1.1 Definition of clinical situation for use** | The supply of levonorgestrel 1.5 mg for emergency contraception (LNG-EC) to be taken as soon as possible, preferably within 12 hours and no later than 72 hours (may also be used between 72-96 hours after UPSI - off label) of unprotected sexual intercourse (UPSI) or contraceptive failure to reduce the risk of pregnancy. |
| **1.2 Criteria for inclusion** | • Any individual **13 up to the age of 21 years of age** presenting for emergency contraception (EC) within 96 hours (off label use between72-96hrs-see section 2.4) of unprotected sexual intercourse (UPSI). For guidance refer to the **Faculty of Sexual and Reproductive Healthcare (FSRH) Decision-making Algorithms for Emergency Contraception** in the following document Page ix. FSRH Guideline Emergency Contraception March 2017 (Amended December 2020) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf<br>• Young people 13-17 years should be assessed against the Child Sexual Exploitation (CSE) Risk Questionnaire for 'time-limited' contact<br>• Contraception has been used incorrectly or has been compromised. For further information refer to the Summary of Product Characteristics (SPC) of individual products or Faculty of Sexual and Reproductive Healthcare (FSRH) March 2017 (Amended December 2020) FSRH Guideline Emergency Contraception. http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf<br>• All options for emergency contraception discussed and the individual prefers the hormonal method.<br>• The individual has no contraindications to the medication.<br>• The individual has taken LNG-EC but has vomited the tablet within 3 hours of taking. The new dose must still be within 72 hours (96 hours off label) of the first UPSI of that episode.<br>• Must be able to give **informed consent** to treatment. Informed consent is the process by which an individual learns about and understands the purpose, benefits, and potential risks of a treatment and then agrees to receive the treatment.<br>• **If the individual is under 16 years old**, they must be assessed as Fraser Competent (see Appendix 1) or if not assessed as Fraser Competent accompanied by one or both parents, or a legal guardian and consents to the treatment being given.<br>• Individuals 22 years of age or over who cannot easily obtain EC from another NHS source without undue delay (exceptional circumstances only).<br>• Consents to consultation and medication supply by a pharmacist without referral to a doctor. |
| **1.3 Criteria for exclusion** | **Personal Characteristics & Reproductive History**<br>• Age <13 years or > 22 years of age.<br>• Informed consent not given.<br>• Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines.<br>• Individuals 16 years of age and over and assessed as lacking capacity to consent.<br>• If under 13 years of age follow local safeguarding policy- refer to section 1.5. |

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| | • Safeguarding or child sexual exploitation (CSE) concerns- refer to section 1.5<br>• More than 72 hours since this episode of UPSI (96 hours off-label. Consider the supply of ulipristal for emergency contraception (UPA-EC) (refer to ulipristal PGD) if individual meets inclusion criteria and/ or copper intrauterine device (Cu-IUD)<br>• Less than 21 days following childbirth.<br>• Known or suspected pregnancy. If UPSI occurred > 21days ago and no or abnormal period, advise individual to complete a pregnancy test before supplying EC.<br>• Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.<br>• Acute porphyria<br>**Medication History**<br>• Known hypersensitivity to any constituent of LNG-EC. Refer to Summary of product Characteristics (SPC) https://www.medicines.org.uk/emc<br>• **Less than 5 days following ingestion of ulipristal.** Consider if another supply of UPA-EC is appropriate-refer to UPA-EC PGD<br>• Taking a medicine or herbal product that interacts with LNG-EC (see section 2.11). Refer to the British National Formulary (BNF) www.bnf.org or the Faculty for Sexual and Reproductive Healthcare (FSRH) CEU guidance: Drug interactions with hormonal contraception https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/<br><br>**Please note:** It may be appropriate to supply individuals taking enzyme inducing drugs with an increased dose of LNG-EC. Refer to section 2.5.<br><br>It is imperative to contact the Integrated Sexual Health Service (ISHS) for advice if the pharmacist has any concerns about supplying LNG-EC. Refer to the West Sussex Sexual Health website for contact information. https://www.sexualhealthwestsussex.nhs.uk |

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| **1.4 Cautions including any relevant action to be taken** | • A Copper intrauterine device (Cu-IUD) should always be discussed as a more effective alternative when emergency contraception is required. Available evidence suggests oral EHC is ineffective if taken after ovulation. Cu-IUD can be inserted up to 5 days after first UPSI or up to 5 days after the earliest likely date of ovulation (whichever is later). Onward referral should be made as appropriate. **LNG-EC should be provided even if a Cu-IUD is planned, unless there is an exclusion to it.**<br>• LNG-EC is ineffective if taken after ovulation.<br>• Ulipristal acetate EC (UPA-EC) has been demonstrated to be effective for up to 120 hours after UPSI and should always be considered as first line for EHC.<br>• If UPA-EC (first line) is not appropriate then Levonorgestrel (LNG-EC) is licensed for EC up to 72 hours (up to 96 hours off label) after UPSI. The evidence suggests that LNG-EC is ineffective if taken more than 96 hours after UPSI.<br>• LNG-EC can be supplied if USPI earlier in the same cycle as well as within the last 72 hours (96 hours off label), as evidence suggests it does not disrupt an existing pregnancy and is not associated with fetal abnormality.<br>• If individual is taking enzyme-inducing drugs (or herbal products) or has taken them in the last 28 days (includes prescribed and purchased medicines) – **see adjusted dosage recommendations in section 2.5.**<br>• Individuals receiving post-exposure prophylaxis for sexual exposure to HIV (PEPSE). Refer to section 2.11.<br>• Medicines containing levonorgestrel may increase the risk of cyclosporine toxicity due to possible inhibition of cyclosporin metabolism. Refer for Cu-IUD.<br>• If individual vomits within three hours from ingestion, a repeat dose may be given.<br>• A repeat dose of LNG-EC can be supplied in the same menstrual cycle should the need occur. Consider CU-IUD and signpost for sexual health and contraception advice.<br>• **Body Mass Index (BMI) greater than or equal to 26kg/m$^2$ or weighs 70kg (11 stone) or more**, individuals should be advised that although oral EC methods are safe, a high BMI may reduce effectiveness. A CU-IUD should be recommended as the most effective method of contraception. If CU-IUD is not accepted then either advise the individual to take a total dose of 3mg levonorgestrel (two 1.5mg tablets) as a single dose (off label indication) or consider Ulipristal 30mg tablet.<br>• Severe malabsorption syndromes, such as Crohn's disease, or small bowel resection are likely to impair the efficacy of levonorgestrel. A CU-IUD should be recommended as the most effective method of contraception. Supply EC as appropriate and refer for CU-IUD accordingly if agreed.<br>• If the individual has not yet reached menarche consider onward referral for further assessment or investigation.<br>• Breast feeding mothers are to be informed that limited evidence indicates that LNG-EC has no adverse effects on breastfeeding or on their infants. If concerned advise expressing milk before taking the tablet and no breast feeding for 8 hours. |

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| **1.5 Action to be taken if the individual is excluded or declines treatment** | • Signpost or refer to ISHS or GP as soon as possible with information about further options https://www.sexualhealthwestsussex.nhs.uk.<br>• Individuals 22 years of age or older should be given the option to purchase EC over the counter (in exceptional circumstances it can be supplied under this PGD- see inclusion criteria) or refer to the ISHS or GP.<br>• If pregnancy is suspected, (i.e. If UPSI occurred > 21days ago and no or abnormal period) ask individual to complete a pregnancy test before supplying EC or refer to the ISHS.<br>• If exclusion is due to a drug interaction consider if UPA-EC could be supplied as an alternative to LNG-EC or refer for Cu-IUD.<br>• **Safeguarding** (including child sexual exploitation) concerns identified at presentation should be referred to the West Sussex Safeguarding Children Partnership (WSSCP) https://www.westsussexscp.org.uk<br>• Follow local safeguarding arrangements for vulnerable adults when appropriate https://www.westsussexsab.org.uk<br>• Individuals who lack capacity to consent should be referred to ISHS or GP for a Best Interest Assessment undertaken by an authorised prescribing practitioner. http://www.legislation.gov.uk/ukpga/2005/9/contents<br>• If the individual declines treatment discuss implications and record the declination.<br>• Document all actions taken. |

| 2. Description of Treatment | |
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| **2.1 Name, strength & formulation of drug** | Levonorgestrel tablet 1.5mg (N.B this is equivalent to 1500 mcg levonorgestrel) |
| **2.2 Legal category** | Prescription Only Medicine (POM)<br>Pharmacy Only Medicine (P) |
| **2.3 Route of administration** | Oral. Take with or after food to reduce incidence of nausea and vomiting. |
| **2.4 Off label use** | Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).<br><br>This PGD includes off-label use in the following conditions:<br><br>• Use between 72 and 96 hours post UPSI<br>• Increased dose for individuals with BMI over 26kg/$m^2$ or weight over 70kg and in individuals using liver enzyme inducing agent- refer section 2.5<br>• Severe hepatic impairment<br>• Individuals with previous salpingitis or ectopic pregnancy<br>• Lapp-lactase deficiency<br>• Hereditary problems of galactose intolerance<br>• Glucose-galactose malabsorption<br><br>For further information regarding use outside product licence refer to the FSRH Guideline Emergency Contraception March 2017 (Amended December 2020).<br>http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf<br><br>Where a drug is recommended off-label ensure as part of the consent process, the individual/parent/carer is informed that the drug is being offered in accordance with national guidance but that this is outside the product licence.<br><br>Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs 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. |

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| **2.5 Dose and frequency of administration** | • A single dose (1.5 mg or 3 mg) to be taken as soon as possible preferably within 12 hours and no later than 72 hours (96 hours off label) of unprotected sexual intercourse (UPSI).<br>• **Dose for those individuals taking enzyme inducing medicines or herbal products:** An individual who requests levonorgestrel whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1.5mg tablets) as a single dose and within 72 hours of UPSI (96 hours off label).<br>• **Dose for those individuals with a body mass index of more than 26kg/m$^2$ or who weigh more than 70kg:** An individual who requests levonorgestrel with a body mass index of more than 26kg/m$^2$ or who weighs more than 70kg can be offered a total of 3mg levonorgestrel (two 1.5mg tablets) as a single dose and within 72 hours of UPSI (96 hours off label). |
| **2.6 Quantity** | • Single dose 1.5mg tablet to be administered in the pharmacy or dispensed and appropriately labelled for the individual to take away.<br>• Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m$^2$ or who weigh more than 70kg.<br>. |
| **2.7 Duration of treatment** | • A single dose is permitted under this PGD.<br>• If vomiting occurs within 3 hours of levonorgestrel being taken a repeat dose can be supplied under this PGD.<br>• Repeated doses can be given within the same cycle. Please note:<br>  ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)<br>  ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel) |
| **2.8 Storage** | Medicines must be stored securely according to national guidelines and in accordance with the product SPC. |
| **2.9 Labelling Requirements** | • Label as per the legislation for a prescription only medicine (POM) if individual is taking the medicine away from the pharmacy.<br>• The individual should be given the patient information leaflet (PIL) |
| **2.10 Identification & management of adverse reactions** | Refer to current Summary of Product Characteristics (SPC) of individual brands https://www.medicines.org.uk/emc/ and current British National Formulary (BNF) www.bnf.org for further information.<br><br>Side effects may include:<br><br>• Nausea<br>• Lower abdominal pain<br>• Fatigue<br>• Dizziness<br>• Headache<br>• Diarrhoea/vomiting<br>• Breast tenderness<br>• Mood change<br><br>Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next menstrual period within seven days of the expected time. |

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| | **In the event of untoward or unexpected adverse reactions:**<br><br>• If necessary seek appropriate emergency advice and assistance.<br>• Document in the individual patient medication record and complete incident procedure if adverse reaction is severe (refer to local organisational policy)<br>• Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA).Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at https://yellowcard.mhra.gov.uk/<br><br>The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so. |

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| **2.11 Drug interactions** | A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org<br><br>Additional Sources of information include:<br><br>• Stockley's Drug Interactions https://about.medicinescomplete.com/publication/stockleys-drug-interactions/<br>• Faculty for Sexual and Reproductive Healthcare (FSRH) CEU guidance: Drug interactions with hormonal contraception (May 2022) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/<br>• For interactions with post-exposure prophylaxis for sexual exposure to HIV (PEPSE) regimes it is recommended to check with the online University of Liverpool HIV Drug Interactions Checker https://www.hiv-druginteractions.org/checker<br><br>If necessary access the individuals NHS Summary Care Record (SCR) (with consent) if they are uncertain about the medications they are taking. |

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| **2.12 Written information and further advice to be provided** | • All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception.<br>• Explain mode of action, dosage, side effects, and follow-up advice. **Provide manufacturer's patient information leaflet (PIL) and discuss content** Levonorgestrel 1.5mg Tablets - Patient Information Leaflet (PIL) - (emc) (medicines.org.uk).<br>• Advise individual to take the tablet with or after food. If vomiting occurs within 3 hours, a second dose should be taken immediately. Advise individual to return to the pharmacy for a second dose or to contact the ISHS.<br>• Explain menstrual disturbances can occur after the use of emergency hormone contraceptives.<br>• Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.<br>• A pregnancy test is recommended 21 days after last UPSI or if next menstrual period is delayed by more than 7 days, is lighter than usual or is associated with abdominal pain that is not typical of the individuals usual dysmenorrhea. **Individuals must be advised to go to ISHS or GP if the pregnancy test is positive.**<br>• Individuals who start hormonal contraception after use of LNG-EC should be advised to have a pregnancy test even if they have bleeding; bleeding associated with the contraceptive method may not represent menstruation.<br>• Advise patients that LNG-EC will not protect against further UPSI later in the cycle. Recommend use of local barrier method or abstaining until the next menstrual period starts or long term contraceptive method effective.<br>• Concurrent use of a barrier method should be encouraged and the risks of sexually transmitted infections (STIs) discussed. If appropriate provide or refer for a self-testing chlamydia /gonorrhoea test and explain how to use.<br>• If the need for emergency contraception is because of incorrect use of hormonal contraceptive methods refer to the product SPC/PIL and explain how to restart the contraceptive method. |

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| | • Individuals presenting for repeat supplies of EHC should be referred to the ISHS for additional support.<br>• Give individual the opportunity to ask questions and address any concerns or queries.<br>• There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency contraception.<br>• Provide contact information for ISHS or refer to website https://www.sexualhealthwestsussex.nhs.uk |
| **2.13 Advice/ follow-up treatment** | • The individual should be advised to seek medical advice in the event of an adverse reaction.<br>• The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned.<br>• Advise individual to contact the ISHS or GP 3 weeks after taking LNG-EC if the pregnancy test is positive or if the expected period is more than 7 days late.<br>• Refer to ISHS or GP for further advice about long term contraception and screening for sexually transmitted infections (STI). |
| **2.14 Records** | Record the consultation and clinical assessment as prompted on the Pharmoutcomes (PO) emergency contraception template, include additional notes on the patient medication record (PMR) when necessary.<br><br>Individuals should be made aware of the confidentiality policies for the service they are attending, including the circumstances in which confidentiality may need to be breached.<br><br>The Pharmoutcomes template will record the following information:<br><br>• Informed consent of the individual.<br>• Safeguarding referral if relevant.<br>• If individual is under 16 years of age document competency using Fraser guidelines<br>• If individual is under 13 years of age record safeguarding action taken.<br>• Individual's name, date of birth and first 3-4 characters of postcode i.e. TN34. This is a confidential service that can be accessed without a full address and GP notification.<br>• Name of registered health professional operating under the PGD<br>• Medical and medication history as prompted by PO.<br>• Any known allergy.<br>• Date of supply.<br>• Record the name of the medication, number of packs supplied with batch numbers and expiry dates.<br>• Any advice given about the medication including side effects, benefits, how to take it and when, and what to do if any concerns.<br>• Details of any adverse drug reactions and any action taken.<br>• Any supply outside the terms of the product marketing authorisation<br>• Any referral arrangements.<br>• Any follow up arrangements. |

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| | • The consultation should be submitted on the PharmOutcomes system.<br>• For adults all PGD documentation in a patient's clinical record must be kept for 8 years after the last entry.<br>• For children all PGD documentation in a patient's clinical record must be kept until the child is 25 years old or for 8 years after a child's death.<br><br>All records should be clear, legible and contemporaneous.<br><br>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

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| **REFERENCES** | • Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: Emergency Contraception (March 2017, amended December 2020) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf<br>• Faculty of Sexual and Reproductive Healthcare. UK Medical Eligibility Criteria (UKMEC) for Contraceptive Use; April 2016 (Amended September 2019) https://www.fsrh.org/standards-and-guidance/uk-medical-eligibility-criteria-for-contraceptive-use-ukmec/<br>• Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit (CEU) guidance: Drug interactions with hormonal contraception (May 2022)<br>• FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) - Faculty of Sexual and Reproductive Healthcare<br>• Faculty of Sexual and Reproductive Healthcare Clinical Guideline (April 2017): Quick starting contraception https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/<br>• Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit guidance: Recommended Actions after Incorrect Use of Combined Hormonal Contraception (e.g. late or missed pills, ring and patch) ( March 2020, Amended 6 July 2021)<br>• https://www.fsrh.org/documents/fsrh-ceu-guidance-recommended-actions-after-incorrect-use-of/<br>• National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017) https://www.nice.org.uk/Guidance/MPG2<br>• British National Formulary https://bnf.nice.org.uk<br>• Electronic Medicines Compendium https://www.medicines.org.uk/emc<br>• General Pharmaceutical Council Standards for Pharmacy Professionals May 2017 https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf<br>• The Pharmaceutical Society of Northern Ireland (PSNI),The code of ethics for pharmacists in Northern Ireland http://www.psni.org.uk/about/code-of-ethics-and-standards/<br>• Centre for Postgraduate Pharmacist Education (CPPE). Declaration of Competence. https://www.cppe.ac.uk/services/declaration-of-competence<br>• Specialist Pharmacy Service. Patient Group Directions: Sexual Health Patient Group Direction (PGD) Template. https://www.sps.nhs.uk/home/guidance/patient-group-directions/templates/ |

## Appendix 1

## Fraser Guidelines

In England, Wales and Northern Ireland, in order to provide contraception to young people under 16 years of age without parental consent, it is considered good practice to follow the Fraser Guidelines/criteria.

While the Fraser Guidelines below relate specifically to contraceptive advice or treatment, the principles are applicable to other sexual health services for young people under 16. A young person's age should not be a barrier to them accessing condoms.

Competence is demonstrated if the young person is able to:

Understand the treatment, its purpose and nature, and why it is being proposed
Understand its benefits, risks and alternatives
Understand in broader terms what the consequences of the treatment will be
Retain the information for long enough to use it and weigh it up in order to arrive at a decision.

A young person is competent to consent to contraceptive advice or treatment if:

- The young person understands the professional's advice
- The professional cannot persuade the young person to inform their parents or allow the professional to inform the parents that they are seeking contraceptive advice.
- The young person is very likely to begin or continue having intercourse with or without the contraceptive treatment.
- Unless they receive contraceptive advice or treatment, the young person's physical or mental health or both are likely to suffer.
- The young person's best interests require the professional to give contraceptive advice, treatment or both without parental consent.

Reference

- Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Contraceptive Choices for Young People (March 2010, Amended May 2019)

https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/