

PATIENT GROUP DIRECTION (PGD)

The supply of Ulipristal 30mg Tablets for Emergency Contraception (UPA-EC) by community pharmacists working within the boundaries of East Sussex County Council (ESCC)
Version 4

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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.

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

| CHANGE HISTORY | |
|----------------|---|
| Version/Date | Change details |
| Version 4 | Updated Summary of Product Characteristics (SmPC) Updated Faculty of Sexual and Reproductive Healthcare (FSRH) guidance Updated National Institute for Health and Care Excellence (NICE) Guidance |

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| Date PGD comes into effect | 1 st April 2022 |
| PGD Review date | 1 st April 2023 or earlier in the light of significant changes in best practice |
| PGD Expiry date | 31 st March 2024 |



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

| NAME/ROLE | SIGNATURE | DATE |
|-----------------------------|-----------|-----------|
| Dr Karen Skinner | | 21/4/2022 |
| | | |
| | | |
| Pharmacist Janet Rittman | | 14/3/22 |
| Clinical Governance Lead | | |

Short Life Working Group Membership

| Name | Designation |
|-------------------|---|
| Janet Rittman* | Pharmacist |
| Dr Karen Skinner* | Doctor |
| Tony Proom | Strategic Commissioning Manager - Sexual Health |

* Core working group members and PGD signatories

ORGANISATIONAL APPROVAL

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

| Patient Group Direction Authorised by: | | |
|---|-----------|------------|
| TITLE /ORGANISATION | SIGNATURE | DATE |
| Darrell Gale Director of Public Health East Sussex County Council | | 22/04/2022 |

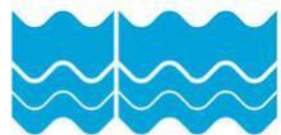
PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council (GPhC) Standards for Pharmacy Professionals and Pharmaceutical Society 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 April 2022

HEALTHCARE PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD

ESCC authorises the use of this document by accredited community pharmacists who are working within the boundaries of **East Sussex County Council**

DECLARATION: I am a registered pharmacist, employed

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

Characteristics of Staff

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

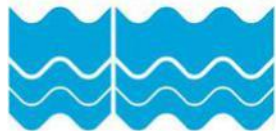
Qualifications

I am registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI)

Specialist qualifications and competencies

I am competent to provide the Community Pharmacy: Emergency Hormonal Contraception to individuals aged 25 and under and Chlamydia Screening Public Health Local Service Agreement (PHSLA) because:

1. I have completed the accreditation and training requirements detailed in the Community Pharmacy: EHC to individuals aged 25 and under and Chlamydia screening PHSLA.
2. 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>.
3. I have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment.
4. I have reviewed my competency to operate under this PGD using the [NICE Competency Framework for health professionals using patient group directions](#)
5. I am aware of local safeguarding policies and contact information.
6. I have reviewed the local policies and documentation for this service and references associated with this PGD.
7. 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

Date

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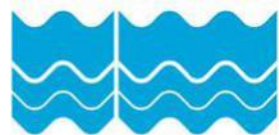
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Name of Authorising Pharmacist or Pharmacy Manager

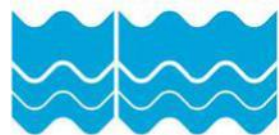
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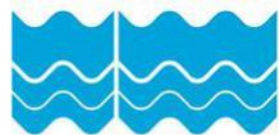
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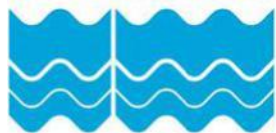
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| <p>1. Clinical condition or situation to which this PGD applies</p> | <p>Ulipristal for emergency contraception (UPA-EC) within 120 hours (5 days) of unprotected sexual intercourse (UPSI) or contraceptive failure.</p> |
| <p>1.1 Criteria for inclusion</p> | <ul style="list-style-type: none"> • Any individual 13 to 25 years of age presenting for emergency contraception (EC) within 120 hours (5 days) of UPSI. For guidance refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) Decision-making Algorithms for Emergency Contraception in the following document pages ix, x. FSRH Guideline Emergency Contraception March 2017 (Amended December 2020) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • The individual has no contraindications to the medication. • Individuals 26 years of age or over who cannot easily obtain EC from another NHS source without undue delay (exceptional circumstances only). • Contraception has been used incorrectly or has been compromised. For further information refer to the Summary of Product Characteristics (SmPC) of individual products or FSRH Guideline Emergency Contraception March 2017 (Amended December 2020) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • All options for emergency contraception discussed and the individual prefers the hormonal method. • The individual has taken UPA-EC but has vomited the tablet within 3 hours of taking. The repeat dose must still be within 120 hours of that UPSI episode. • Must be able to give informed consent to treatment. Informed consent is the process by which a patient learns about and understands the purpose, benefits, and potential risks of a treatment and then agrees to receive the treatment. • 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. • Consents to consultation and medication supply by a pharmacist without referral to a doctor. |
| <p>1.2 Criteria for exclusion</p> | <p>Personal Characteristics & Reproductive History</p> <ul style="list-style-type: none"> • Age <13 years or > 25 years of age. • Informed consent not given. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • If under 13 years of age follow local safeguarding policy. • Child Sexual Exploitation (CSE) concerns- refer to section 1.4 • Safeguarding concerns - refer to section 1.4 |



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| | <ul style="list-style-type: none"> • More than 120 hours since this episode of UPSI. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours. • Less than 21 days following childbirth. • Known or suspected pregnancy. N.B. a previous episode of UPSI in this cycle is not an exclusion. If UPSI occurred > 21 days ago and no or abnormal period advise individual to complete a pregnancy test before supplying EC. • Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease. <p>Medical history</p> <ul style="list-style-type: none"> • Severe asthma controlled by oral glucocorticoids. • Acute porphyria <p>Medication History</p> <ul style="list-style-type: none"> • Known hypersensitivity to any constituent of UPA-EC. Refer to Summary of product Characteristics (SmPC) https://www.medicines.org.uk/emc • Use of levonorgestrel or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications). Consider if LNG-EC is appropriate (or Cu-IUD) refer to LNG-EC PGD. • Concomitant use with a medicine affecting gastric pH (e.g. antacids, histamine H2 antagonists and proton pump inhibitors) • Taking a medicine or herbal product that interacts with UPA-EC (see section 2.9). Refer to the British National Formulary (BNF) 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/ <p>Please note: It may be appropriate to supply individuals taking enzyme inducing drugs (or within 4 weeks of stopping) with an increased dose of LNG-EC. Refer to the LNG-EC PGD</p> <p>It is imperative to contact the Sexual Health Service (SHS) for advice if the pharmacist has any concerns about supplying UPA-EC. Refer to the East Sussex Sexual Health website for contact information https://www.eastsussexsexualhealth.co.uk</p> |
| <p>1.3 Cautions including any relevant action to be taken</p> | <ul style="list-style-type: none"> • A Copper intrauterine device (Cu-IUD) should always be discussed as the most effective option when emergency contraception is required. Cu-IUD can be inserted up to 5 days after first UPSI or up to 5 days after the earliest estimated date of ovulation (whichever is later). Onward referral should be made as appropriate. UPA-EC should be provided even if a Cu-IUD is planned, unless it is to be fitted that day or there is an exclusion to it. • UPA-EC is ineffective if taken after ovulation. |

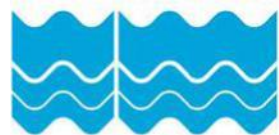


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| | <ul style="list-style-type: none"> • If an individual vomits within 3 hours from ingestion a repeat dose may be given. • UPA-EC can be supplied if USPI earlier in the same cycle as well as within the last 5 days, as evidence suggests it does not disrupt an existing pregnancy and is not associated with fetal abnormality. • A repeat dose of UPA-EC can be supplied in the same menstrual cycle should the need occur. Consider Cu-IUD and signpost for sexual health and contraception advice. • If individual is taking enzyme-inducing drugs (or herbal products) or has taken them in the last 28 days (includes prescribed and purchased medicines) – refer for Cu-IUD or consider supply of a 3mg dose of LNG-EC. A double-dose of UPA-EC is not recommended. • Individuals receiving post-exposure prophylaxis for sexual exposure to HIV (PEPSE). Refer to section 2.9 • The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section 'Written information and further advice to be given to individual' • If stopping oral hormonal contraception or inability to quick start oral contraception for 5 days is likely to cause harm or increase risk of unplanned pregnancy, consider using LNG-EC or offer Cu-IUD as alternative. • if individual has a Body Mass Index (BMI) greater than or equal to 26kg/m² or weighs 70kg (11 stone) or more. Although the use of ulipristal is not contraindicated it may be less effective and so these individuals should be advised that insertion of CU-IUD would be the most effective emergency contraceptive for them. Supply EC as appropriate and refer accordingly if agreed for CU-IUD. If oral hormone contraception is preferred either supply UPA-EC (normal dose) or refer to the LNG-EC PGD for consideration of a 3mg dose of LNG-EC • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of ulipristal is not contraindicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. • If the individual has not yet reached menarche consider onward referral for further assessment or investigation • Breastfeeding: UPA-EC is excreted in breast milk. Advise individual to avoid breastfeeding for 1 week after the UPA-EC dose and to express and discard milk during that time. |
| <p>1.4. Action to be taken if the individual is</p> | <ul style="list-style-type: none"> • Signpost or refer to SHS or GP as soon as possible with information about further options, including referral to SHS for consideration of copper intrauterine device (Cu-IUD) |

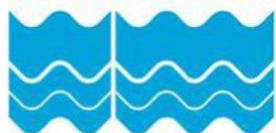


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| excluded or declines treatment | <ul style="list-style-type: none"> • Individuals 26 years of age or older should be given the option to purchase EC over the counter (if appropriate) or be referred to the SHS or GP. • If pregnancy is suspected (i.e. If UPSI occurred > 21days ago and no or abnormal period) supply free pregnancy test and ask individual to complete the test (as soon as possible as the supply of EC is time critical) before supplying EC or refer to SHS. • If exclusion is due to a drug interaction consider if LNG-EC could be supplied as an alternative to UPA-EC or refer for Cu-IUD. • Safeguarding (including child sexual exploitation) concerns identified at presentation should be referred to the East Sussex Safeguarding Children Partnership (ESSCP) https://www.esscp.org.uk • Follow local safeguarding arrangements for vulnerable adults when appropriate https://www.eastsussexsab.org.uk/# • Individuals who lack capacity to consent should be referred to SHS or GP for a Best Interest Assessment undertaken by an authorised prescribing practitioner http://www.legislation.gov.uk/ukpga/2005/9/contents • Record the reason for the declination in the individual's patient medication record (PMR). • Document all actions taken. |
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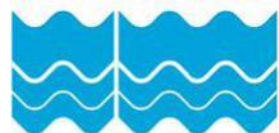
| 2. Description of treatment | |
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| 2.1 Name, strength & formulation of drug | Ulipristal acetate 30mg tablet |



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| 2.2 Legal category | Pharmacy Only Medicine (P) |
| 2.3 Route of administration | Oral, with or without food. Taking with or after food may reduce the incidence of nausea and vomiting a known side effect. |
| 2.4 Off label use | <p>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 (SmPC) https://www.medicines.org.uk/emc</p> <p>This PGD includes off-label use in the following conditions:</p> <ul style="list-style-type: none"> • Severe hepatic impairment • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption <p>For further information regarding use outside product licence refer to the FSRH Guideline Emergency Contraception March 2017 (Amended December 2020) http://www.fsrh.org/pdfs/CEUGuidanceEmergencyContraception11.pdf</p> <p>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.</p> <p>Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.</p> |
| 2.5 Dose and frequency of administration | A single tablet to be taken as soon as possible within 120 hours of unprotected sexual intercourse (UPSI) |
| 2.6 Duration of treatment | <ul style="list-style-type: none"> • A single dose is permitted under this PGD. • If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD. • Repeated doses can be given within the same cycle. Please note: <ul style="list-style-type: none"> ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal) |



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| | <ul style="list-style-type: none"> ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel) |
| 2.7 Quantity to be supplied | Single dose – to be administered in the pharmacy or dispensed and appropriately labelled for the individual to take away. |
| 2.8 Storage of products | Medicines must be stored securely according to national guidelines and in accordance with the product SmPC. |
| 2.9 Drug interactions | A detailed list of drug interactions is available in the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org |
| | Additional Sources of information include: |
| | <ul style="list-style-type: none"> • Stockley’s Drug Interactions https://about.medicinescomplete.com/publication/stockleys-drug-interactions/ |
| | <ul style="list-style-type: none"> • 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/ |
| | <ul style="list-style-type: none"> • 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 |
| | If necessary access the individuals NHS Summary Care Record (SCR) (with consent) if they are uncertain about the medications they are taking. |
| 2.10 Identification & management of adverse reactions | A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org |
| | <p>The following side effects are common with ulipristal acetate (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Nausea or vomiting • Abdominal pain or discomfort • Headache • Dizziness • Muscle pain (myalgia) • Dysmenorrhea • Pelvic pain • Breast tenderness • Mood changes • Fatigue • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception <p>Effects on ability to drive and use machines. Mild to moderate dizziness is common after taking ulipristal,</p> |

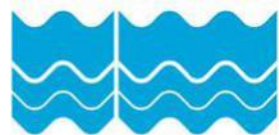


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| | <p>somnolence and blurred vision are uncommon. Advise individual not to drive or use machinery if they experience such symptoms.</p> |
| <p>2.11 Management of and reporting procedure for adverse reactions</p> | <p>In the event of untoward or unexpected adverse reactions:</p> <ul style="list-style-type: none"> • If necessary seek appropriate emergency advice and assistance. • Document in the individual patient medication record and complete incident procedure if adverse reaction is severe (refer to local organisational policy) • 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/ The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so. <ul style="list-style-type: none"> • Report any adverse reactions via organisation incident policy. |
| <p>2.12 Written information and further advice to be given to individual</p> | <ul style="list-style-type: none"> • 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. • Explain mode of action, dosage, side effects, and follow-up advice. Provide manufacturer’s patient information leaflet (PIL) and discuss content • 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 SHS • Explain that menstrual disturbances can occur after emergency hormonal contraceptives. • Advise that after oral EC there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle. Recommend use of appropriate contraceptive methods and how these can be accessed. Supply condoms as needed. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • A pregnancy test is recommended 21 days after treatment especially if the next menstrual period is delayed by more than 7 days, is lighter or shorter than usual or is associated with abdominal pain that is not typical of the individuals usual dysmenorrhea |



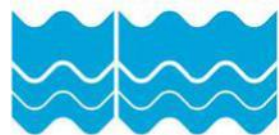
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| | <ul style="list-style-type: none"> • Individuals who start hormonal contraception after use of UPA-EC should be advised to have a pregnancy test at 3 weeks even if they have bleeding; bleeding associated with the contraceptive method may not represent menstruation. • A free pregnancy test can be issued to individuals under 26 years of age or under. Individuals must be advised to go to SHS or GP if the pregnancy test is positive. • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. • Discuss long term contraception options and refer individual to the Sexwise website https://www.sexwise.fpa.org.uk to access further information. |
| <p>2.13 Advice/follow up treatment</p> | <ul style="list-style-type: none"> • Concurrent use of a barrier method should be encouraged and the risks of sexually transmitted infections (STIs) discussed. If appropriate provide a self-testing chlamydia /gonorrhoea test and explain how to use. • Individuals presenting for repeat supplies of EC should be referred to the SHS for additional support. • Give individual the opportunity to ask questions and address any concerns or queries. • Provide contact information for SHS or refer to website https://www.eastsussexsexualhealth.co.uk |
| | <ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Advise individual to contact the SHS or GP 3 weeks after taking UPA-EC if the pregnancy test is positive or if the expected period is more than 7 days late. • Refer to SHS or GP for further advice about long term contraception and screening for sexually transmitted infections (STI). |

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| <p>3. Records</p> | <p>Record the consultation and clinical assessment as prompted on the Pharmoutcomes (PO) emergency contraception template, include additional notes on the PMR when necessary.</p> <p>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.</p> <p>The Pharmoutcomes template will record the following information:</p> |
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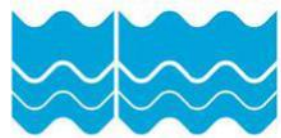


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| | <ul style="list-style-type: none"> • Informed consent of the individual including if Fraser Guidelines used and actions taken if not competent to consent. • Safeguarding referral if relevant. • Individual's name, date of birth and first 3-4 characters of postcode i.e. TN34. This is a confidential service that can be accessed without a full address and GP notification. • Medical and medication history as prompted by PO. • Any known allergy. • Date of supply. • Record the name of the medication, number of packs supplied with batch numbers and expiry dates. • Any advice given about the medication including side effects, benefits, how to take it and when, and what to do if any concerns. • Details of any adverse drug reactions and any action taken. • Any referral arrangements. • Any follow up arrangements. • The consultation should be submitted on the PharmOutcomes system. • For adults all PGD documentation in a patient's clinical record must be kept for 8 years after the last entry. • 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. <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 <u>policy</u>.</p> |
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| REFERENCES | <ul style="list-style-type: none"> • Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: Emergency Contraception (March 2017, amended December 2020) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • 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/ • Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit (CEU) guidance: Drug interactions with hormonal contraception (Jan 2017, last reviewed 2019) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ |
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- 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/>
- 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) <https://www.fsrh.org/documents/fsrh-ceu-guidance-recommended-actions-after-incorrect-use-of/>
- Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit Statement: Response to Recent Publication Regarding Banh, et al. 17 November 2020 <https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-response-to-recent-publication-regarding/?action=accept-all-cookies&module=privacy>
- Specialist Pharmacy Service: Patient Group Directions, Reproductive Health. Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception: PGD template. <https://www.sps.nhs.uk/articles/supply-and-or-administration-of-ulipristal-acetate-30mg-tablet-for-emergency-contraception-pgd-template/#:~:text=pGD%20contraception>
- National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017) <https://www.nice.org.uk/Guidance/MPG2>
- British National Formulary (BNF) www.bnf.org
- Electronic Medicines Compendium <https://www.medicines.org.uk/emc>
- General Pharmaceutical Council Standards for Pharmacy Professionals May 2017 https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf
- The Pharmaceutical Society of Northern Ireland (PSNI), The code of ethics for pharmacists in Northern Ireland. March 2016 <http://www.psni.org.uk/about/code-of-ethics-and-standards/>
- Centre for Postgraduate Pharmacist Education (CPPE). Declaration of Competence. <https://www.cppe.ac.uk/services/declaration-of-competence>



Appendix 1

Under 16s- 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.

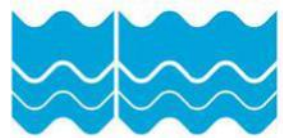
While the Fraser Guidelines below relate specifically to contraceptive advice or treatment, the principles are applicable to other sexual health services for young people under 16. A young person's age should not be a barrier to them accessing condoms.

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 Clinical Effectiveness Unit March 2010 (Amended May 2019)

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