East Sussex County Council

# 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 5

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Community pharmacy contractors using this PGD must ensure that it is formally approved and signed by a senior pharmacist, a senior doctor and the 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 | |
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| Version/Date | Change details |
| Version 5 | Updated Summary of Product Characteristics (SmPC)<br>Updated Faculty of Sexual and Reproductive Healthcare (FSRH) guidance |

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| Date PGD comes into effect | 1st April 2024 |
| PGD Review date | September 2026 or earlier in the light of significant changes in best practice |
| PGD Expiry date | 31st March 2027 |

| NAME/ROLE | SIGNATURE | DATE |
|---|---|---|
| GP Lead in Public health<br>Dr Lisa Sansom<br>East Sussex County Council |  | 2/2/2024 |
| Public Health Pharmacist<br>Janet Rittman<br>East Sussex County Council |  | 2/2/2024 |
| Darrell Gale<br>Director of Public Health<br>East Sussex County Council |  | 22/02/24 |

Short Life Working Group Membership

| Name | Designation |
|---|---|
| Janet Rittman* | Pharmacist |
| Dr Lisa Sansom* | Doctor |
| Tony Proom | Strategic Commissioning Manager - Sexual Health |
| Paula Sowter | Consultant Nurse in Contraception |
| Dr Isabel Okpaluba | Consultant in Sexual Health |
| Julia Powell | Chief Executive Officer<br>Community Pharmacy Surrey and Sussex |

* Core working group members and PGD signatories

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 community 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.

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| Patient group direction effective from 1st April 2024 |
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| **HEALTHCARE PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD** |
| ESCC authorises the use of this PGD by accredited community pharmacists who are working within the boundaries of **East Sussex County Council** |
| **DECLARATION:** I am a registered pharmacist, working at |

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| Name of Pharmacy | |
| Address | |
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| 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) ) https://www.eastsussex.gov.uk/social-care/providers/health/contracts/public-health-local-service-agreements-phlsas-for-gp-practices-and-pharmacies/community-pharmacies 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 within the last 2 years. 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.
3. I have completed the mandatory Health Education England Safeguarding Children level 2 and Safeguarding Adults level 2 e-learning for healthcare (this can be accessed through the CPPE website https://www.cppe.ac.uk/programmes/l/safegrding_elfh-e-02/ and passed the associated level 2 assessment within the last 2 years.
4. I have reviewed my competency to operate under this PGD using the NICE Competency Framework for health professionals using patient group directions

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5. I am aware of local safeguarding policies and contact information. Information is available via the following links https://www.esscp.org.uk https://www.eastsussexsab.org.uk
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.

The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.

| Name | GPhC/PSNI registration number | Signature | Date |
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**Authorising manager/pharmacist**

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the Community Pharmacy for the above-named health care professionals who have signed the PGD to work under it.

| **Name** | **Designation** | **Signature** | **Date** |
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| **1. Clinical condition or situation to which this PGD applies** | To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly. |
| **1.1 Criteria for inclusion** | • Any individual **13 to 25 years of age** presenting for emergency contraception (EC) within 120 hours (5 days) of UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. 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 July 2023) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf<br>• The individual has no contraindications to the medication.<br>• Individuals 26 years of age or over who cannot easily obtain EC from another NHS source without undue delay (exceptional circumstances only).<br>• All options for emergency contraception discussed and the individual prefers the hormonal method.<br>• 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.<br>• 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.<br>• Consents to consultation and medication supply by a pharmacist without referral to a doctor. |
| **1.2 Criteria for exclusion** | **Personal Characteristics & Reproductive History**<br>• Age <13 years or > 25 years of age. Individuals 26 years of age or over can be included in exceptional circumstances- refer to inclusion criteria.<br>• Informed consent not given.<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 https://www.esscp.org.uk<br>• Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. Refer to section 1.4.<br>• Child Sexual Exploitation (CSE) concerns follow the local safeguarding policy https://www.esscp.org.uk<br>• Safeguarding concerns refer to local policy https://www.eastsussexsab.org.uk<br>• This episode of UPSI occurred more than 120 hours ago. 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. |

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| | • 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.<br>• Less than 21 days following childbirth.<br>• Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease(GTD)<br>• Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics<br>• Use of levonorgestrel (LNG-EC) or any other progestogen in the previous 7 days (i.e. hormonal contraception including combined oral contraception, depot injection, hormone replacement therapy ( or use for other gynaecological indications). Consider if LNG-EC is appropriate (or Cu-IUD) refer to LNG-EC PGD.<br>• Concurrent use of antacids, proton-pump inhibitors or $H_2$-receptor antagonists including any non-prescription (i.e. over the counter) products being taken.<br>• Severe asthma controlled by oral glucocorticoids.<br>• Acute porphyria<br>• Taking a medicine or herbal product ( for example St John's Wort) 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(May 2022) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ **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**.**<br>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 |
| **1.3 Cautions including any relevant action to be taken** | • All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider.<br>• UPA-EC is ineffective if taken after ovulation.<br>• If an individual vomits within 3 hours from ingestion a repeat dose may be given.<br>• Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. |

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| | • 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 foetal abnormality. If UPSI occurred > 21 days ago and no or abnormal period, advise individual to complete a pregnancy test before supplying EC.<br><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) – refer for Cu-IUD or consider supply of a 3mg dose of LNG-EC. Refer to LNG PGD.<br>• The effectiveness of UPA-EC can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs, including combined oral contraception, for 5 days after UPA-EC.UPA EC is generally not recommended in a missed pill situation. See section 'Written information and further advice to be given to individual'.<br>• 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 UPA-EC is not contra-indicated 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.<br>• Breast feeding – advise to express and discard breast milk for 7 days after UPA-EC dose.<br>• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.<br>• If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy.<br>• If the individual has not yet reached menarche consider onward referral for further assessment or investigation |
| **1.4. Action to be taken if the individual is excluded or declines treatment** | • Explain the reasons for exclusion to the individual and 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).<br>• 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.<br>• 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 EHC is time critical i.e. straight away) before supplying EHC. If individual is unable to return to the pharmacy refer to SHS.<br>• 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. |

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| | • **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<br>• Follow local safeguarding arrangements for vulnerable adults when appropriate https://www.eastsussexsab.org.uk/#<br>• 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<br>• Record the reason for the declination in the individual's patient medication record (PMR).<br>• Document all actions taken. |

| **2. Description of treatment** | |
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| **2.1 Name, strength & formulation of drug** | Ulipristal acetate 30mg tablet |
| **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** | 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>• Severe hepatic impairment<br>• Lapp-lactase deficiency<br>• Hereditary problems of galactose intolerance Glucose-galactose malabsorption<br><br>Medicines 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.<br><br>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. |
| **2.5 Dose and frequency of administration** | One tablet (30mg) to be taken as soon as possible up to 120 hours of unprotected sexual intercourse (UPSI) |

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| **2.6 Duration of treatment** | • A single dose is permitted under this PGD.<br>• If vomiting occurs within 3 hours of UPA-EC being taken a repeat dose can be supplied under this PGD.<br>• Repeated doses, as separate episodes of care, can be given within the same cycle. Please note:<br>  ○ If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC)<br>  ○ If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC) |
| **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<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 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/<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. |
| **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<br><br>The following side effects are common with ulipristal acetate (but may not reflect all reported side effects):<br>• Nausea or vomiting<br>• Abdominal pain or discomfort<br>• Headache<br>• Dizziness<br>• Muscle pain (myalgia)<br>• Dysmenorrhea<br>• Pelvic pain<br>• Breast tenderness<br>• Mood changes<br>• Fatigue |

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| | • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.<br><br>**Effects on ability to drive and use machines**. Mild to moderate dizziness is common after taking ulipristal, somnolence and blurred vision are uncommon. Advise individual not to drive or use machinery if they experience such symptoms. |
| **2.11 Management of and reporting procedure for adverse reactions** | In the event of untoward or unexpected adverse reactions:<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/ The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.<br>• Report any adverse reactions via the organisation incident policy. |
| **2.12 Written information and further advice to be given to individual.** | • 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.**<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 SHS.**<br>• Explain that menstrual disturbances can occur after emergency hormonal contraceptives.<br>• Provide advice on ongoing contraceptive methods, including how these can be accessed.<br>• 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.<br>• Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur.<br>• In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following UPA-EC use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.<br>• Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), |

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| | or if using hormonal contraception which may affect bleeding pattern.<br>• 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.<br>• A free pregnancy test should 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.**<br>• There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.<br>• Discuss long term contraception options and refer individual to the Sexwise website https://www.sexwise.fpa.org.uk to access further information.<br>• Concurrent use of a barrier method should be encouraged and provided. The risks of sexually transmitted infections (STIs) should be discussed. and a self-testing chlamydia /gonorrhoea swab provided and explained how to use.<br>• Individuals presenting for repeat supplies of EC should be referred to the SHS for additional support.<br>• Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased.<br>• Give individual the opportunity to ask questions and address any concerns or queries.<br>• Provide contact information for SHS or refer to website https://www.eastsussexsexualhealth.co.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 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.<br>• Refer to SHS or GP for further advice about ongoing contraception and screening for sexually transmitted infections (STI). |

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| **3. Records** | Record the consultation and clinical assessment as prompted on the Pharmoutcomes (PO) emergency contraception template, include additional notes on the 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>• The consent of the individual and<br>○ If individual is under 13 years of age record action taken |

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| | ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.<br>○ If individual over 16 years of age and not competent, record action taken.<br>• Safeguarding referral if relevant<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>• Relevant past and present medical history, including medication history. Examination findings where relevant e.g. weight<br>• Any known medication allergies<br>• Name of registered health professional operating under the PGD<br>• Date of supply<br>• Record the name and dose of the medication and the 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>• Advice given if excluded or declines treatment.<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<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>Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.<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 July 2023) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf |

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| | • 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) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/<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 July 2021) https://www.fsrh.org/documents/fsrh-ceu-guidance-recommended-actions-after-incorrect-use-of/<br>• 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<br>• National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017) https://www.nice.org.uk/Guidance/MPG2<br>• Electronic British National Formulary (BNF) www.bnf.org<br>• Electronic Medicines Compendium https://www.medicines.org.uk/emc<br>• Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines<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. March 2016 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 |

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**Appendix 1**

| Under 16s- Fraser Guidelines |
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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/

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