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 Ulipristal Acetate 30mg Tablets for Emergency Contraception (UPA-EC) by accredited Community Pharmacists working within the boundaries of West Sussex County Council (WSCC)

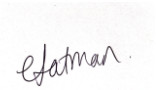
Community pharmacists using this PGD must ensure that it is formally approved and signed by a pharmacist, medical lead and governance lead for the organisation with legal authority, so that this document meets legal requirements for a PGD.

Direction no: WSCC 003 V1

Change History	
Version	Change Details
Version 1	None, new PGD

PGD comes into effect	1st September 2020
PGD review date	1st July 2021
PGD expiry date	31st August 2022

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 Dr E Flatman		04/10/20
Pharmacist Janet Rittman		18/9/20
Clinical Governance Lead Soline Jerram		29/9/20

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**
Stephen Horsley Interim Director of Public Health West Sussex County Council		22 October 2020

This Patient Group Direction (PGD) must only be used by accredited community pharmacists who have been named and authorised by their organisation to practise under it. The most recent and in date final signed version of the PGD must be kept in a designated place within the pharmacy, and be readily accessible to all community pharmacists for reference and audit.

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

Patient group direction effective from 1st September 2020
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

Name of Pharmacy	
Address	
Post Code	

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 Ulipristal Acetate 30mg 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 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

Signature of Authorising Pharmacist or Pharmacy Manager

……

Name of Authorising Pharmacist or Pharmacy Manager

……

Practitioners not listed are not authorised to practice under this PGD.

1. Clinical condition or situation to which this Patient Group Direction applies	
1.1 Definition of clinical situation for use	Ulipristal for emergency contraception (UPA-EC) within 120 hours (5 days) of unprotected sexual intercourse (UPSI) or contraceptive failure.
1.2 Criteria for inclusion	• Any individual aged **13 up to the age of 22 years of age** presenting for emergency contraception (EC) within 120hrs 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 2017) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • Young people 13-17 should be assessed against the Child Sexual Exploitation (CSE) Risk Questionnaire for 'time-limited' contact • Contraception has been used incorrectly or has been compromised. For further information refer to the Summary of Product Characteristics (SmPC) of individual products or Faculty of Sexual and Reproductive Healthcare (FSRH) March 2017 (Updated December 2017) FSRH Guideline Emergency Contraception. http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • The individual has taken UPA-EC but has vomited the tablet within 3 hours of taking. The new dose must still be within 120 hours of the first UPSI of that episode. • 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. • **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. • Individuals 22 years of age or over who cannot easily obtain EC from another NHS source without undue delay (exceptional circumstances only) • All options for emergency contraception discussed and the individual prefers the Oral Hormonal Emergency Contraception method. • The individual has no contraindications to the medication. • Consents to consultation and medication supply by a pharmacist without referral to a doctor.
1.3 Criteria for exclusion	**Personal Characteristics & Reproductive History** • Informed consent not given. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Age <13 years or > 21years of age. • If under 13 years of age follow local safeguarding policy-refer to section 1.5 • Safeguarding or child sexual exploitation (CSE) concerns- refer to section 1.5

	• More than 120 hours since this episode of UPSI. Discuss option of copper intrauterine device (Cu-IUD) and refer to the Integrated Sexual Health Service (ISHS) https://www.sexualhealthwestsussex.nhs.uk **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. If UPSI occurred > 21days 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. **Medical history** • Severe asthma controlled by oral glucocorticoids. **Medication History** • Known hypersensitivity to any constituent of UPA-EC. • **Less than 7 days following ingestion of Levonorgestrel 1.5mg (LNG-EC) tablet.** Consider if another supply of LNG-EC (or Cu-IUD) is appropriate-refer to LNG-EC PGD. • **Less than 7 days following the use of a contraceptive method containing a progestogen.** Consider if LNG-EC is appropriate (or Cu-IUD) refer to LNG-EC PGD. • 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. • 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 LNG-EC (see section 2.11). Refer to an up to date 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/ **Please note:** It may be appropriate to supply individuals taking enzyme inducing drugs with an increased dose of LNG-EC. Refer to the LNG-EC PGD It is imperative to contact the Integrated Sexual Health Service (ISHS) for advice if the pharmacist has any concerns about supplying UPA-EC. Refer to the West Sussex Sexual Health website for contact information https://www.sexualhealthwestsussex.nhs.uk
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. **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.**

	• EC providers should advise women that the Cu-IUD is the most effective method of EC. EC providers should advise women that ulipristal acetate EC (UPA-EC) has been demonstrated to be effective for EC up to 120 hours after UPSI. EC providers should advise women that levonorgestrel EC (LNG-EC) is licensed for EC up to 72 hours after UPSI. The evidence suggests that LNG-EC is ineffective if taken more than 96 hours after UPSI. • EC providers should advise women that UPA-EC has been demonstrated to be more effective than LNG-EC. EC providers should advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. • 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 to section 2.11 or consider supply of LNG-EC (refer to LNG-EC PGD) • Individuals receiving post-exposure prophylaxis for sexual exposure to HIV (PEPSE). Refer to section 2.11. • It is recommended that hormonal contraception (HC) should not be used for 5 days after taking UPA-EC. As this may make the UPA-EC less effective. A barrier contraceptive (or abstain) should be used during the 5 days. This should continue for a further 7 days (9 for Qlaira) when using a combined oral contraceptive (COC) pill or 2 days if using a progestogen only pill (POP) to enable the ongoing contraception to become effective. • Consider UPA-EC if individual has a **Body Mass Index (BMI) greater than or equal to 26kg/m^2 or weighs 70kg (11 stone) or more**. If UPA-EC is not appropriate refer to the LNG-EC PGD for consideration of a 3mg dose of LNG-EC. Individuals should be informed that a higher weight or BMI could reduce the effectiveness of oral EC and that the effectiveness of the Cu-IUD is not known to be affected by weight or BMI. • Consider UPA-EC if the individual presents in the 5 days leading up to the expected day of ovulation. • Some porphyria patients have an increased risk of an acute attack if supplied the EHC therefore a risk versus benefits discussion needs to be had and documented before supplying. • Breastfeeding: UPA-EC is excreted in breast milk. Advise individual to avoid breastfeeding for 1 week and to express and discard milk during that time. • Severe malabsorption syndromes, such as Crohn's disease or small bowel resection might impair the efficacy of UPA-EC. Supply EC as appropriate and refer for CU-IUD. ○ This PGD includes unlicensed use (refer to section 2.4) in the following conditions: severe hepatic impairment, lapp-lactase deficiency, hereditary problems of galactose intolerance, glucose-galactose malabsorption. Discuss FSRH guidance regarding these conditions and document consultation.
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 • Individuals 22 years of age or older should be given the option to purchase EC over the counter (if appropriate) or be referred to the ISHS or GP.

	• If pregnancy is suspected, ask individual to complete a pregnancy test before supplying EC or refer to ISHS. • If exclusion is due to a drug interaction consider if LNG-EC (refer to LNG PGD) 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 West Sussex Safeguarding Children Partnership (WSSCP) https://www.westsussexscp.org.uk • Follow local safeguarding arrangements for vulnerable adults when appropriate https://www.westsussexsab.org.uk • 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 • If the individual declines treatment discuss implications and record the declination on PharmOutcomes. • Document all actions taken.

2. Description of Treatment	
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. Take with or after food to reduce incidence of nausea and vomiting.
2.4 Off label use	This PGD includes off-label use in the following conditions: • Severe hepatic impairment • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption For further information regarding use outside product licence refer to the FSRH Guideline Emergency Contraception March 2017 (Amended December 2017) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf 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 UPA-EC contains lactose however guidance from the FSRH does not exclude it's use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. FSRH guidance also states that pregnancy poses a significant risk in individuals with severe hepatic impairment and expert opinion suggests the use of a single dose of UPA 30mg is therefore acceptable. 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.
2.5 Dose and frequency of administration	• A single tablet (30mg) to be taken as soon as possible up to 120 hours of unprotected sexual intercourse (UPSI) • UPA-EC should be taken after food to reduce the incidence of nausea and vomiting. • Repeated doses can be given within the same cycle. Please note: ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)

	○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel) ○ If vomiting occurs within 3 hours of UPA-EC being taken a repeat dose can be supplied under this PGD. **Dose for those individuals taking enzyme inducing medicines or herbal products** An individual who requests emergency contraception while using enzyme-inducing drugs or within 4 weeks of stopping them, should be offered a Cu-IUD (unaffected by liver enzyme-inducing drugs) or advised to take a total of 3 mg levonorgestrel (two 1.5 mg tablets) as a single dose –refer to LNG PGD. **UPA-EC is not recommended in this situation**.
2.6 Duration of treatment	• UPA should be taken orally as a single dose • UPA should be taken after food to reduce the incidence of nausea and vomiting. • Repeated doses can be given within the same cycle. Please note: ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal) ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)
2.7 Quantity to be supplied	Original pack of one tablet
2.8 Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SmPC.
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. • The individual should also be given the patient information leaflet (PIL)
2.10 Side Effects	Refer to current Summary of Product Characteristics (SmPC) of individual brands https://www.medicines.org.uk/emc/ and current British National Formulary (BNF) www.bnf.org for further information. Side effects may include: • Nausea/vomiting • Lower abdominal pain • Fatigue • Dizziness/ Headache • Breast tenderness, pelvic pain, dysmenorrhea • Mood change • Myalgia/ back pain **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. 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.

	In the event of untoward or unexpected adverse reactions: 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.
2.11 Drug interactions	The metabolism of ulipristal is enhanced by concomitant use of liver enzyme inducers thereby reducing its efficiency. The following drugs have capacity to reduce plasma levels of ulipristal: barbiturates (including primidone), phenytoin, fosphenytoin, oxcarbazepine, carbamazepine, herbal medicines containing hypericum perforatum (St.John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin nevirapine and efavirenz. Current recommendations from the British Association for Sexual Health and HIV (BASHH) https://www.bashh.org for post-exposure prophylaxis for sexual exposure to HIV (PEPSE) regimes (Truvada and raltegravir) contain no enzyme inducing drugs that would reduce the effectiveness of oral EC. For other PEPSE regimes it is recommended to check with the online University of Liverpool HIV Drug Interactions Checker https://www.hiv-druginteractions.org/checker **Refer to these sources of information for the full list of drug interactions and for further information:** • Summary of Product Characteristics (SmPC) https://www.medicines.org.uk/emc • British National Formulary (BNF) - current edition Appendix 1 or https://www.bnf.org • Stockley's Drug Interactions https://about.medicinescomplete.com/publication/stockleys-drug-interactions/ • 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/ If necessary access the individuals NHS Summary Care Record (SCR) (with consent) if they are uncertain about the medications they are taking.

2.12 Written information and further advice to be provided	• Explain mode of action, dosage, side effects, and follow-up advice. **Provide manufacturer's patient information leaflet (PIL) and discuss content** https://www.medicines.org.uk/emc/product/9437/pil • 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.** • Advise individuals that LNG-EC does not provide long term contraception Discuss long term contraception options and refer individual to the Sexwise website https://www.sexwise.fpa.org.uk to access further information. • 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.** • Individuals who start hormonal contraception after use of UPA-EC should be advised to have a pregnancy test even if they have bleeding; bleeding associated with the contraceptive method may not represent menstruation. • It is recommended that **hormonal contraception (HC) should not be used for 5 days after taking UPA-EC (because it reduces the effectiveness of UPA-EC)**. Advise individual to use a barrier method of contraception (or abstain). If starting or restarting hormonal contraception refer to the individual product SmPC/PIL and FSRH guidance. • If the need for emergency contraception is because of missed oral contraceptive pills (refer to missed pill guidance in SmPC and PIL). Advise individual they will need to stop the Oral Contraceptive method and use a barrier method of contraception for 5 days and for the duration of time it takes for the oral contraceptive to become effective. It is a requirement to take **7 combined oral contraceptive pills (COC), 9 pills for Qlaira and 2 progestogen-only pills (POP) consecutively** before full contraceptive cover is resumed. • **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.** • Advise patients that UPA-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) • 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 EHC should be referred to the ISHS or GP for additional support. • Give individual the opportunity to ask questions and address any concerns or queries. • 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.

	• 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 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. The Pharmoutcomes template will record the following information: • Informed consent of the individual. • Safeguarding referral if relevant. • If individual is under 16 years of age document competency using Fraser guidelines • If individual is under 13 years of age record safeguarding action taken. • 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. • Name of registered health professional operating under the PGD • 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 supply outside the terms of the product marketing authorisation • Any referral arrangements. • Any follow up arrangements. • The consultation should be submitted on the PharmOutcomes system; claims for payment will be generate at the end of each month. **All records will be kept for 10 years after last attendance, or up to the individuals 26th birthday if longer than 10 years away.** Records are subject to audit within each pharmacy.

3. Staff Group	
3.1 Authorised staff	**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 Ulipristal Acetate 30mg 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 Ulipristal Acetate 30mg 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 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.

REFERENCES (accessed June 2020)	• Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: Emergency Contraception (March 2017, amended December

	2017) 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/ • 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/ • National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017) https://www.nice.org.uk/Guidance/MPG2 • British National Formulary https://bnf.nice.org.uk • 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 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 • Specialist Pharmacy Service. Patient Group Directions: Sexual Health Patient Group Direction (PGD) Template. https://www.sps.nhs.uk/category/services/guidance-and-governance/patient-group-directions/

Appendix 1

Under 16s- Fraser Guidelines

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.

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

- The young person understands the professionals' 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 2019)

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