Service	Provision of **Levonorgestrel 1500 and Ulipristal Acetate 30mg from Community Pharmacists to women under the age of 22 years via Patient Group Direction (PGD)**

1. Population Needs

1.1 National/local context and evidence base

The UK has among the highest rates of teenage conceptions within Western Europe; this has on-going health and social implications for parents and their offspring. The Public Health Outcomes Framework monitors improvements in Public Health and includes reducing under 18 conceptions as one of the Improving Outcomes and Supporting Transparency indicators
https://fingertips.phe.org.uk/profile/sexualhealth/data#page/0/gid/8000057/pat/6/par/E12000008/ati/202/are/E10000032

Following the Government's publication of the Teenage Pregnancy Social Exclusion report (1999) a number of schemes were set-up to try and reduce the number of teenage pregnancies in Britain. Preventative methods, such as widening access to Emergency Hormonal Contraception (EHC), including through Community Pharmacies, were identified in the report as methods for addressing the needs of young people.

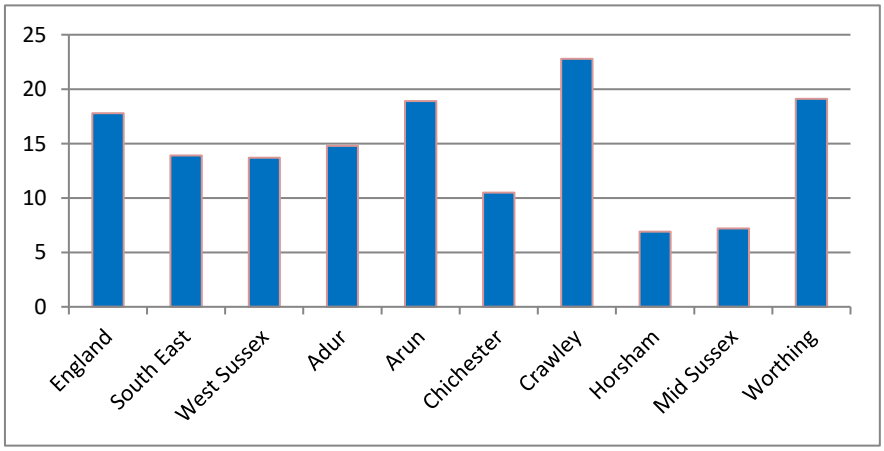
Local Issues

Teenage pregnancy (TP) rates in West Sussex have dropped by over one half since 1998, in line with the national reduction in rates among under 18 year olds.

There is still a variation in TP rates across the county, which indicate that these issues continue to require a focus from West Sussex County Council.

Under 18 year conception rate (2017)

(rate per 1,000 women aged 15-17 years)



2. Scope

2.1 Aims and objectives of Service

Aims

It is envisaged the Services will aid the achievement of the following national and local objectives:

- To improve availability and access to emergency hormonal contraception (EHC) for women under the age of 22 years

- Increase the use of EHC by women who have had unprotected sex and help contribute to a reduction in the number of unplanned pregnancies
- Strengthen the local network of contraceptive and sexual health services to help ensure easy and swift access to advice
- To develop the role of pharmacists by the use of patient group directions.

2.2 Service description/care pathway and referral route

The Services will be available from accredited community pharmacists working at approved pharmacy premises. Emergency Hormonal Contraception (Levonorgestrel 1500 tablets or Ulipristal Acetate 30mg) will only be supplied on completion of the specified consultation and in accordance with the Patient Group Direction (PGD) attached at Appendix 1. The Patient Group Direction has been written in accordance with the Royal Pharmaceutical Society of Great Britain, Professional guidance on the provision of medicines in healthcare settings (2019) (https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/SSHM%20and%20Admin/Admin%20of%20Meds%20prof%20guidance.pdf?ver=2019-01-23-145026-567).

If a Service User falls outside the inclusion criteria of the Patient Group Direction but requires emergency hormonal contraception, the accredited pharmacist will provide referral details to aid the Service User to access an alternative service e.g GP Practice or the Integrated Sexual Health Service http://www.sexualhealthwestsussex.nhs.uk/.

Under exceptional circumstances a client who is over 22 years of age can be supplied with the appropriate Hormonal contraceptive Levonorgestrel 1500 or Ulipristal Acetate 30mg via the PGD if the pharmacist is satisfied that NOT supplying hormonal contraceptive free of charge will be detrimental to the client and they will be unable to obtain a supply from another source before the 72 hours has expired. This will be subject to the discretion of the pharmacist involved.

2.3 Service Delivery

The Service User will present and ask for emergency contraception directly to a member of the Community Pharmacy Team (Counter Assistant, Dispenser/ Technician or Pharmacist). If an accredited pharmacist is not available at the pharmacy (for example due to locum cover) the Service User should be directed to the nearest community pharmacy which is able to provide the service. Details of all community pharmacies which deliver the Services can be found at: https://www.sexualhealthwestsussex.nhs.uk/contraception/emergency-contraception/

A member of the Community Pharmacy Team will provide the Service User with the emergency contraception checklist, pen, clip board and they will be asked to complete as much of the checklist as possible (See Appendix 2). The Service User should be directed to the consultation area to await the pharmacist.

The consultation must be completed by an accredited pharmacist. Prior to delivering any Services under the Contract the Service Provider must ensure that the Pharmacist to be administering the Services has signed the Patient Group Direction for the supply of Levonorgestrel 1500 micrograms or ulipristal Acetate 30mg tablet by accredited Community Pharmacists for Emergency Hormonal Contraception in West Sussex, which is current at the time, and a signed copy has been returned to the Council.

The pharmacist may help the Service User to compete the checklist before proceeding with the consultation.

Pharmacists will be guided through the consultation on the web-based reporting system PharmOutcomes, which also allows the pharmacist to assess and record Fraser Competence of the young person http://www.nspcc.org.uk/preventing-abuse/child-

protection-system/legal-definition-child-rights-law/gillick-competency-fraser-guidelines/ .

On completion of the checklist and the consultation the following may occur:

- Levonorgestrel 1500 or Ulipristal Acetate 30mg supply made in accordance with PGD and signed completion of the consultation form.
- Referral to Integrated Sexual Health Service or GP with a completed referral form
- In the pharmacist's professional judgment a supply of emergency contraception is not required and will therefore not be supplied.
- In exceptional circumstances, e.g. if the pharmacist has no stock of Levonorgestrel 1500 then Levonelle One Step (Pharmacy (P) Medicine) may be supplied provided all other PGD criteria are met and WSCC is informed after the supply, as per the PGD. P Medicine are available from a pharmacy without prescription but can only be provided under the supervision of a pharmacist, the pricing structure for Levonelle One Step will be the current price described in the British National Formulary (BNF).

Every Service User accessing the service whether it results in supply or advice only should be provided with the sexual health promotion advice and signposting to appropriate agencies.

Role of the Community Pharmacist
The accredited Community Pharmacist is responsible for explaining the scheme to members of their staff and ensuring the Services are delivered in accordance with this Contract and the PGD

The confidentiality statement (Appendix 3) should be available to the Service Users and is required to be read by the Service User or to the Services User by the Pharmacist before the consultation starts – no written consent or acknowledgement is required by the Service User.

The Services can only be provided in an approved Community Pharmacy premises by an accredited Community Pharmacist. The premises require a suitable confidential area for consultation with Service Users. This may be a quiet area within the Service Provider's pharmacy rather than a separate room.

If an accredited pharmacist is not available at the pharmacy, Service Users wishing to access the Services must be redirected to another approved pharmacy or other services: https://www.sexualhealthwestsussex.nhs.uk/contraception/emergency-contraception/

2.4 Population covered and Geographic Coverage
Females aged between 13 up to the age of 22 years who have started menstrual periods, and older women in exceptional circumstances described in the Patient Group Direction (see Appendix 1)

2.5 Any acceptance and exclusion criteria
Acceptance and exclusion criteria are described in detail within the relevant sections of the Patient Group Direction (see Appendix 1).

2.6 Interdependencies with other services
Accredited pharmacists should signpost Service Users into appropriate services (GP and Integrated Sexual Health Services) to best meet their needs. They must also have clear pathways for reporting Child Protection issues and concerns.

2.7 Any external reporting requirements
Record Keeping

The copy of the Service user EHC Checklist must be kept securely and confidentially in the Service Provider's Pharmacy for a period of 8 years for Service Users over 16 years of age and until a service user's 26th Birthday if under the age of 16 at the time of the consultation.

All information collected through the WSCC approved electronic reporting system, including evidence of Fraser competence which must be completed if a Service User is believed to be under the age of 16 at the time of consultation, will be stored electronically on the system.

Incident Monitoring
Pharmacies are required to record patient safety incidents in an incident log and report these to the National Reporting and Learning Service (NRLS) on a monthly basis, which will be sent to the Commissioner as and when reported (http://psnc.org.uk/contract-it/essential-service-clinical-governance/patient-safety-incident-reporting/). In the event of an untoward incident occurring, West Sussex County Council requires the EHC Clinical Incident Form (Appendix 4) to be completed and sent to Paul Woodcock at WSCC (paul.woodcock@westsussex.gov.uk) for future discussion and shared problem solving. The contents of the Clinical Incident forms are strictly private and confidential and the individuals completing the form may remain anonymous.

Adverse Drugs Reactions (ADRs)
All serious ADRs should be reported, even if the effect is well recognised (See British National Formulary (BNF) for details). ADRs should be reported to the Medicines & Healthcare products
Regulatory Agency (MHRA)using the Yellow Card Scheme
https://yellowcard.mhra.gov.uk/ . Service Users reporting suspected ADRs should be referred to a doctor for further investigation.

Complaints
Pharmacies should follow their own in-house complaints procedures and if required, Service Users may be directed to the Council Complaints Manager for further advice: https://www.westsussex.gov.uk/about-the-council/get-in-touch/comments-and-complaints/

2.9 Monitoring Information, Activity Reports and any other data to be submitted to the Council
Monitoring information will be gathered through the PharmOutcomes reporting system which is an open source Platform used to manage and source code quality. All activity must be managed through this system. PharmOutcomes provides IT solution support for pharmacists which can be viewed and analysed by commissioners.

3.Applicable Service Standards

3.1 Applicable national standards eg NICE, Royal College
Fraser Guidelines
A health professional can give contraceptive advice or treatment to young people under 16 years of age, provided they are satisfied that the young person is competent. Guidelines on providing advice and treatment to under 16s were issued in 1985, as part of Lord Fraser's judgment[6].

As part of the EHC consultation process, every Service User will be asked their age and the accredited pharmacist must complete the Fraser Guidelines section of the

PharmOutcomes form for any Service User under the age of 16. The pharmacist must be satisfied the young person is competent before proceeding with supply.

- The young person understands the advice being given
- The young person cannot be convinced to involve their parents/carers or allow the health professional to do so on their behalf
- Unless she receives treatment her physical or mental health (or both) is likely to suffer
- It is on the best interest of the young person for the treatment to be given without parental consent

3.2 Applicable local standards

Accreditation

In order for a community pharmacist to become accredited by West Sussex County Council they must first satisfy the following criteria:

- Each pharmacist must read and sign the relevant Patient Group Direction that is applicable to the delivery of the Services. The current applicable PGD is attached at Appendix 1 of this Specification.
- Each pharmacist wishing to be accredited must complete the CPPE Emergency Contraception, Contraception and Safeguarding Children and Vulnerable Adults distance learning packs and provide WSCC with evidence they have successfully completed the multiple choice questions which can be monitored by the commissioner who has access to the CPPE Continuing Professional Development section of the website https://www.cppe.ac.uk/ .
- Every pharmacist wishing to be accredited will be be responsible for their own continuing professional development, use the Declaration of Competence to evidence their ability to continue to and to ensure they keep informed about any changes to the scheme or the medication
- Each pharmacist is expected to ensure they are familiar with the latest EHC guidance http://www.rpharms.com/home/home ..

Training

The accredited pharmacist or pharmacy manager will be responsible for ensuring every member of the Service Providers Staff is familiar with the Services and the process for accessing the free and confidential service.

The Lead Pharmacist must ensure that all staff have training which will include all of the following:

- Guidance for working with teenagers
- Child protection issues
- Confidentiality
- Case studies, to consider possible scenarios

Confidentiality

The Council requires each member of the Service Providers Staff at an approved pharmacy to provide a strictly confidential, non-judgmental Service.
Details of the consultation may only be passed to the Service User's General Practitioner or the Integrated Sexual Health Service if the Service User consents or, unless disclosure would be to protect the Service User from serious harm but the pharmacist should discuss this with the Service User first. Service Users consent is not retained for record purposes.

Child Protection Issues

The Community Pharmacist will be required to adhere to the **Pan Sussex Child Protection and Safeguarding Procedures Manual**
http://sussexchildprotection.procedures.org.uk/
Concerns about a young person's welfare may be raised in a number of ways:

- behavioral signs such as being overly anxious or withdrawn

- physical signs of injury such as bruising
- disclosure of abuse
- obvious mis-match in the ages of the 'couple'

Where there are concerns about a service user under the age of 19 years it is preferable to gain the consent of the young person to discuss the situation with the Social and Caring Services Department, WSCC. If the concerns are such that the pharmacist has serious concern for the safety of the young person, advice should be sought from Social and Caring Services and the young person informed.

For issues around protection of vulnerable adults:
https://www.westsussex.gov.uk/social-care-and-health/social-care-support/adults/contact-us-for-social-care-support-or-advice/

Useful telephone numbers:
Children's Social Care: **01403 229900**, Monday to Friday 9am-5pm
Children's Social Care: **033 022 26664**, out of office hours
Named Nurse for Child Protection – **07770 800247**
Adult Social Care: **01243 642121**
Sussex Police - **0845 6070999**

4. Key Service Outcomes/Objectives

To improve availability and access to Emergency Hormonal Contraception (EHC) for women under the age of 22 years

Increase the use of EHC by women who have had unprotected sex and help contribute to a reduction in the number of unplanned pregnancies

Strengthen the local network of contraceptive and sexual health services to help ensure easy and swift access to advice

To develop the role of pharmacists by the use of patient group directions.

5. Key Performance Indicators (KPI's)/Service Levels

Monitoring Service Delivery

The Commissioner and the Service Provider will work collaboratively to monitor and evaluate the service.

The Service Provider will comply with reasonable requests for information as may be required by WSCC relating to service users.

The monitoring information will be used to inform the commissioning decisions of WSCC and will be a component of the annual review process with the Service Provider.

Performance Indicator	Method of measurement
Numbers of consultations where Levonorgestrel 1500 or Ulipristal Acetate 30mg was issued through the PGD	PharmOutcomes IT System Reported daily
Numbers of consultations where it was not considered necessary or inappropriate to issue hormonal contraception under the PGD	PharmOutcomes IT System Reported daily

Number of consultations where Levonorgestrel 1500 or Ulipristal Acetate 30mg was issued to women over 22 years of age via the PGD where the pharmacist is satisfied that **NOT** supplying Levonorgestrel 1500 tablet free of charge will be detrimental to the client	PharmOutcomes IT System Reported daily

Appendix 1

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

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

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

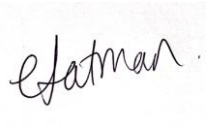
Direction no: WSCC 002 V7

Change History

Version	Change Details
Version 7	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

PGD comes into effect	1st September 2020
PGD review date	1st September 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 Elinor Flatman		26/08/2020
Pharmacist Janet Rittman		26/08/20
Clinical Governance Lead Soline Jerram		27/08/2020

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		28 August 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 Levonorgestrel 1.5mg (1500mcg) from Community Pharmacists to individuals under the age of 22 years via Patient Group Direction (PGD**) service specification.
  I have completed the Emergency Hormonal Contraception Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website https://www.cppe.ac.uk/services/declaration-of-competence Pharmacists' personalised statement of declaration should be retained, which may need to be provided to commissioners and/or employers when required via the CPPE Viewer.
- I have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment.
- I am aware of local safeguarding policies and contact information.
- I have reviewed 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	The supply of levonorgestrel 1.5 mg for emergency contraception (LNG-EC) to be taken as soon as possible, preferably within 12 hours and no later than 96 hours of unprotected sexual intercourse (UPSI) or contraceptive failure.
1.2 Criteria for inclusion	• Any individual **13 to 21 years of age** presenting for emergency contraception (EC) within 96 hours (off label use between72-96hrs-see section 2.4) of unprotected sexual intercourse (UPSI). For guidance refer to the **Faculty of Sexual and Reproductive Healthcare (FSRH) Decision-making Algorithms for Emergency Contraception** in the following document Page ix. FSRH Guideline Emergency Contraception March 2017 (Amended December 2017) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • Young people 13-17 years 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 LNG-EC but has vomited the tablet within 3 hours of taking. The new dose must still be within 96 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 hormonal method. • The individual has no contraindications to the medication. • Consents to consultation and medication supply by a pharmacist without referral to a doctor.
.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 96 hours since this episode of UPSI. Consider the supply of ulipristal for emergency contraception (UPA-EC) (refer to Ulipristal PGD) and/ or copper intrauterine device (Cu-IUD) • 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. **Medication History** • Known hypersensitivity to any constituent of LNG-EC. • **Less than 5 days following ingestion of ulipristal.** Consider if another supply of UPA is appropriate-refer to UPA-EC PGD • Taking a medicine or herbal product that interacts with LNG-EC (see section 2.11). Refer to the British National Formulary (BNF) www.bnf.org or the Faculty for Sexual and Reproductive Healthcare (FSRH) CEU guidance: Drug interactions with hormonal contraception https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ **Please note:** It may be appropriate to supply individuals taking enzyme inducing drugs with an increased dose of LNG-EC. Refer to section 1.4 and 2.5. It is imperative to contact the Integrated Sexual Health Service (ISHS) for advice if the pharmacist has any concerns about supplying LNG-EC. Refer to the West Sussex Sexual Health website for contact information https://www.sexualhealthwestsussex.nhs.uk
1.4 Cautions including any relevant action to be taken	• A Copper intrauterine device (Cu-IUD) should always be discussed as a more effective alternative when emergency contraception is required. Available evidence suggests oral EHC is ineffective if taken after ovulation. Cu-IUD can be inserted up to 5 days after first UPSI or up to 5 days after the earliest likely date of ovulation (whichever is later). Onward referral should be made as appropriate. **LNG-EC should be provided even if a Cu-IUD is planned, unless 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. B 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. B 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. B EC providers should advise women that UPA-EC has been demonstrated to be more effective than LNG-EC. B 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) – **see adjusted dosage recommendations in section 2.5** • Individuals receiving post-exposure prophylaxis for sexual exposure to HIV (PEPSE). Refer to section 2.11. • Medicines containing levonorgestrel may increase the risk of cyclosporine toxicity due to possible inhibition of cyclosporin metabolism. Refer for Cu-IUD. • A repeat dose of LNG-EC can be supplied in the same menstrual cycle should the need occur. Please discuss with the patient the theoretical reduction in efficiency if given again within 7 days. Consider CU-IUD and signpost for sexual health and contraception advice. • Consider ulipristal 30mg tablet for emergency contraception (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 advise individual to take a total dose of 3mg levonorgestrel (two 1.5mg tablets) as a single dose (off licence indication). Refer to section 2.5. • Consider UPA-EC (refer to PGD) if the individual presents in the 5 days leading up to expected day of ovulation. • Severe malabsorption syndromes, such as Crohn's disease, or small bowel resection are likely to impair the efficacy of levonorgestrel. Supply EC as appropriate and refer for CU-IUD. • 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. • Breast feeding mothers are to be informed that limited evidence indicates that LNG-EC has no adverse effects on breastfeeding or on their infants. If concerned advise expressing milk before taking the tablet and no breast feeding for 8 hours. ○ 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, individuals with previous salpingitis or ectopic pregnancy. Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg and use between 72-96 hours are also off-label. 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 the ISHS. • If exclusion is due to a drug interaction consider if UPA-EC could be supplied as an alternative to LNG-EC or refer for Cu-IUD. • **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	Levonorgestrel tablet 1.5mg (N.B this is equivalent to 1500 mcg levonorgestrel)
2.2 Legal category	Prescription Only Medicine (POM) 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 • Use between 72 and 96 hours post UPSI • Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg and in individuals using liver enzyme inducing agent- refer section 2.5 • Severe hepatic impairment • Individuals with previous salpingitis or ectopic pregnancy • 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 LNG-EC has shown efficacy up to 96 hours post UPSI. It is possible that a higher weight or BMI could reduce the effectiveness of LNG-EC therefore a 3mg dose is recommended by the FSRH. LNG-EC contains lactose however guidance from the FSRH does not exclude it's use in individuals 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 LNG 1.5mg is therefore acceptable. The absolute risk of ectopic pregnancy is likely to be low, as levonorgestrel prevents ovulation and fertilisation. FSRH guidance states that absolute numbers of ectopic pregnancies remain very small and LNG-EC reduces absolute risk of ectopic pregnancy by reducing pregnancy risk overall. 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 dose (1.5 mg or 3 mg) to be taken as soon as possible preferably within 12 hours and no later than 96 hours of unprotected sexual intercourse (UPSI)
	• Repeat episodes of UPSI may be treated within one menstrual cycle provided each treatment is within 96 hours of the most recent UPSI. 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 levonorgestrel being taken a repeat dose can be supplied under this PGD.
	
	Dose for those individuals taking enzyme inducing medicines or herbal products- refer to section 2.11
	An individual who requests progestogen only 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. However women should be informed the effectiveness of this regime is unknown. UPA-EC is not recommended in this situation.
	
	Dose for those individuals with BMI over or equal to 26Kg/m^2 or weight of 70Kg(11stone) or over (Off Label)
	An individual who requests LNG-EC who falls into this category may be advised to take a total of 3mg levonorgestrel (two 1.5mg tablets) as a single dose or consider UPA-EC (refer to PGD) if appropriate.

2.6 Duration of treatment	Single dose (1.5 mg or 3 mg) to be administered in the pharmacy or dispensed and labelled according to prescription only medicine (POM) legislation for the individual to take away.
2.7 Quantity to be supplied	Original pack of one tablet (or two original packs if taking enzyme inducing drugs or weight greater than 70Kg)
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 • Lower abdominal pain • Fatigue • Dizziness • Headache • Diarrhoea/vomiting • Breast tenderness • Mood change 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 levonorgestrel is enhanced by concomitant use of liver enzyme inducers. The following drugs have capacity to reduce plasma levels of levonorgestrel: barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St.John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin and efavirenz. **See section 2.5 for dosage advice**. Medicines containing levonorgestrel may increase the risk of cyclosporine toxicity due to possible inhibition of cyclosporin metabolism. 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/8626 • 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.** • "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 LNG-EC should be advised to have a pregnancy test even if they have bleeding; bleeding associated with the contraceptive method may not represent menstruation. • Advise patients that LNG-EC will not protect against further UPSI later in the cycle. Recommend use of local barrier method or abstaining until the next menstrual period starts (or long term contraceptive method effective) • Concurrent use of a barrier method should be encouraged and the risks of sexually transmitted infections (STIs) discussed. If appropriate provide or refer for a self-testing chlamydia /gonorrhoea test and explain how to use. • 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 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 need for emergency contraception is because of incorrect use of other hormonal contraceptive methods refer to the individual product

	SmPC/ PIL and FSRH guidance explain how to restart the contraceptive method. • Individuals presenting for repeat supplies of EHC should be referred to the ISHS 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 ISHS or GP 3 weeks after taking LNG-EC if the pregnancy test is positive or if the expected period is more than 7 days late. • 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 Levonorgestrel 1.5mg (1500mcg) to individuals under the age of 22 years via Patient Group Direction (PGD). **Specialist qualifications and competencies**: • I have completed the accreditation requirements detailed in the **Provision of Levonorgestrel 1.5mg (1500mcg) from Community Pharmacists to individuals under the age of 22 years via Patient Group Direction (PGD**) service specification. • I have completed the Emergency Hormonal Contraception Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website https://www.cppe.ac.uk/services/declaration-of-competence. Pharmacists' personalised statement of declaration should be retained, which may need to be provided to commissioners and/or employers when required via the CPPE Viewer. • I have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment. • I am aware of local safeguarding policies and contact information. • I have reviewed 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 2

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)

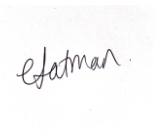
Community pharmacists using this PGD must ensure that it is formally approved and signed by a pharmacist, medical lead and governance lead for the organisation with legal authority, so that this document meets legal requirements for a PGD.

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.

4. 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.

5. 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.

6. 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 3

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/

EMERGENCY HORMONAL CONTRACEPTION CHECKLIST

The pharmacist will come and speak with you as soon as possible but in the meantime, please help the pharmacist by answering as many of the questions below as possible. Your answers will allow the pharmacist to help decide if it is safe for you to take emergency contraception tablets.

Any information you give on this form and during your consultation with the pharmacist is strictly **confidential**. The only reason why we might need to consider passing on confidential information, would be to protect you or someone else from serious harm but we would always try to discuss this with you first.

Is the emergency contraception for you to take?	
How many hours is it since you had unprotected sex?	hours
Is this the only time you have had unprotected sex since your last period?	☐ Yes ☐ No
Have you used emergency contraception since your last period or within the last 4 weeks?	☐ Yes ☐ No
Do you usually have regular periods every 4 weeks?	☐ Yes ☐ No
What was the date of the first day of your last period?	
Was your last period unusually light or unusually heavy?	
What type of contraception do you usually use e.g. the contraceptive pill, none, condoms etc?	

Have you experienced side effects with emergency contraception or oral contraceptive pills in the past? If yes, please give details:

Do you suffer from any liver problems (like jaundice), inflammatory bowel problems (like Crohn's)? If yes, please give details:

Are you feeling unwell at the moment (like an upset stomach)? If yes, please give details:

Are you currently taking any medicines either prescribed or bought over the counter, including herbal medicines like St Johns Wort?
If yes, please give details:

THANK YOU

Appendix 4

Confidentiality Statement

You can be sure that anything you discuss with any member of staff will stay confidential.

Even if you are under 16 nothing will be said to anyone - including parents, other family members, care workers or teachers - without your permission.

The only reason we might consider passing on confidential information without your permission would be to protect you or someone else from serious harm.

We will always try to discuss this with you first.

Appendix 5

Levonelle Patient Group Direction Scheme
INCIDENT MONITORING FORM

Please note, this is a generic form designed for a variety of incidents and it may not always exactly fit the incident you wish to describe. If this is the case, please complete the sections where you can and include a separate sheet detailing the incident.

FORM completed by*:

Name of Pharmacy*: …….. Date: ……..

NATURE OF THE INCIDENT:

Continue on extra sheet if required…

WHO WAS INVOLVED e.g. client and pharmacist (can be anonymous)

DETAILS OF INCIDENT:
(Please continue on an extra sheet if required and attach to this form)

……

……

……

* This is optional, but would be useful in order to follow-up for more details / feedback

Please send to: **Paul Woodcock**, **Commissioner: Sexual Health, Public Health & Wellbeing Directorate, West Sussex County Council, 1st Floor, The Grange, Tower Street, Chichester, West Sussex PO19 1QT**

PRIVATE AND CONFIDENTIAL
Fax transmission of form is not considered confidential