

Service	Provision of Emergency Hormonal Contraception from Community Pharmacists to women aged 13 years of age and over via Patient Group Direction (PGD)
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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/static-reports/sexualhealth-reports/2022/E10000032.html?area-name=West%20Sussex>

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.

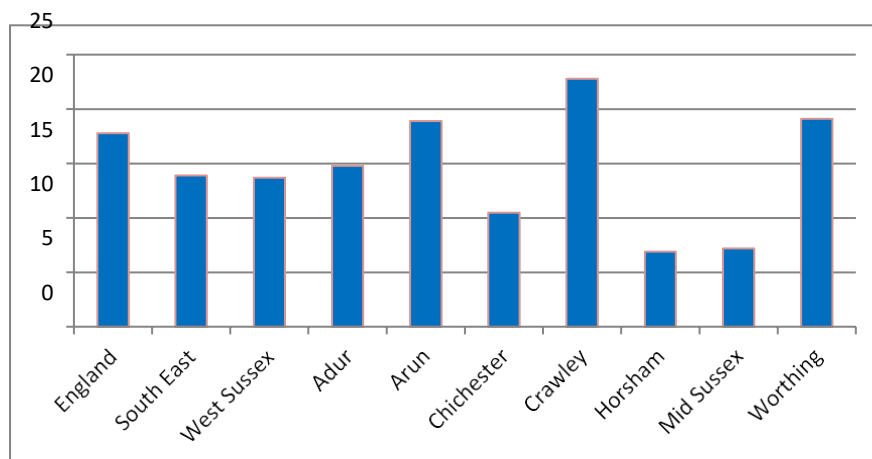
Local Issues

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 individuals aged 13 years of age and over.

- Increase the use of EHC by individuals 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 and technicians 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 and pharmacy technicians working at approved pharmacy premises. Emergency Hormonal Contraception (Levonorgestrel 1.5mg tablets or Ulipristal Acetate 30mg tablets) will only be supplied on completion of the specified consultation and in accordance with the Patient Group Directions (PGD) attached at Appendix 1 and 2. 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 an individual falls outside the inclusion criteria of the Patient Group Direction but requires emergency hormonal contraception, the accredited pharmacist or technician 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/>.

2.3 Service Delivery

The individual 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 or pharmacy technician is not available at the pharmacy (for example due to locum cover) that individual 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 individual with the emergency contraception checklist, pen, clip board and they will be asked to complete as much of the checklist as possible (See Appendix 4). That individual should be directed to the consultation area to await the pharmacist or pharmacy technician.

The consultation must be completed by an accredited pharmacist or pharmacy technician. Prior to delivering any Services under the Contract the Service Provider must ensure that the accredited Pharmacist or pharmacy technician to be administering the Services has signed the current Patient Group Directions for the supply of Emergency Hormonal Contraception and a signed copy has been returned to the Council.

The accredited pharmacist or pharmacy technician may help the individual to complete the checklist before proceeding with the consultation.

Pharmacists or Pharmacy Technician will be guided through the consultation on the web-based reporting system PharmOutcomes, which also allows the pharmacist or pharmacy technician 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 1.5mg 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 or pharmacy technician's professional judgment a supply of emergency contraception is not required and will therefore not be supplied.
- provide a self-testing chlamydia /gonorrhoea kit (condoms, lube and chlamydia kit) and explain how to use OR refer to local Sexual Health Services for STI testing (testing kits will be provided by West Sussex Sexual Health Services and re-ordering process will be advised.)
- Every individual 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.

Exceptional Circumstances

In exceptional circumstances, e.g. if the pharmacy has no stock of Levonorgestrel 1.5mg then Levonelle One Step (Pharmacy (P) Medicine) may be supplied provided all other PGD criteria are met.

Role of the Community Pharmacist

The accredited Community Pharmacist or Pharmacy Technician 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 5) should be available to the individual using the service and is required to be read by that individual or to be read to that individual by the Pharmacist or Pharmacy Technician before the consultation starts – no written consent or acknowledgement is required.

The Services can only be provided in an approved Community Pharmacy premises by an accredited Community Pharmacist or Pharmacy Technician. 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 or pharmacy technician is not available at the pharmacy, individuals 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

Any individual aged 13 years of age and over who have started menstrual periods described in the Patient Group Direction (see Appendix 1 and 2)

2.5 Any acceptance and exclusion criteria

Acceptance and exclusion criteria are described in detail within the relevant sections of the Patient Group Directions (see Appendix 1 and 2).

2.6 Interdependencies with other services

Accredited pharmacists or pharmacy technicians 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

Recording Keeping

The copy of the individual user's EHC Checklist must be kept securely and confidentially in the Service Provider's Pharmacy for a period of 8 years for Service Users over 18 years of age or until that individual's 25th Birthday if under the age of 17 at the time of the consultation, or until that individual's 26th birthday if aged 17.

<https://psnc.org.uk/quality-and-regulations/pharmacy-regulation/retention-of-pharmacy-records/>

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

Incident Monitoring

Pharmacies should follow their own Standard Operating Procedures for incident management and incident monitoring. In the event of an untoward incident occurring, West Sussex County Council requires the EHC Clinical Incident Form (Appendix 6) to be completed and sent to Patrick Stoakes at WSCC (patrick.stoakes@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/>

2.8 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 judgment⁶.

As part of the EHC consultation process, the individual will be asked their age and the accredited pharmacist or technician must complete the Fraser Guidelines section of the

PharmOutcomes form for any service user under the age of 16. The pharmacist or technician 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 the young person receives treatment their 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 or pharmacy technician to become accredited by West Sussex County Council they must first satisfy the following criteria:

- Each pharmacist or pharmacy technician must read and sign the relevant Patient Group Directions that are applicable to the delivery of the Services. The current applicable PGDs are attached at Appendix 1 and 2 of this Specification.
- Each pharmacist or pharmacy technician wishing to be accredited must complete 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> and have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment.
- Every pharmacist or pharmacy technician wishing to be accredited will 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 or pharmacy technician is expected to ensure they are familiar with the latest EHC guidance <http://www.rpharms.com/home/home>

Training

The accredited pharmacist pharmacy technician 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 that individual consents or, unless disclosure would be to protect the Service User from serious harm but the pharmacist should discuss this with the individual. Users' consent is not retained for record purposes.

Child Protection and Safeguarding Issues (including domestic abuse)

The Community Pharmacist or technician will be required to adhere to the West Sussex Safeguarding Children Partnership (WSSCP)

<https://www.westsussexscp.org.uk>

Concerns about a young person's welfare may be raised in a number of ways:

- behavioural 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 or technician has serious concern for the safety of the young person, advice should be sought from Social and Caring Services and the young person informed.

Sussex Child Protection and Safeguarding Procedures, including useful contacts are available at: _West Sussex Safeguarding Children Partnership (WSSCP)

<https://www.westsussexscp.org.uk>

For issues around protection of vulnerable adults: Safeguarding Adults at Risk produced by the Safeguarding Adults Board is available at <https://www.westsussexsab.org.uk>

4. Key Service Outcomes/Objectives

To improve availability and access to Emergency Hormonal Contraception (EHC) for individuals aged 13 years of age and over.

Increase the use of EHC by individuals 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 or technicians 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 1.5mg or Ulipristal Acetate 30mg was issued through the PGD	PharmOutcomes IT System Reported daily

<p>Numbers of consultations where it was not considered necessary or inappropriate to issue hormonal contraception under the PGD</p>	<p>PharmOutcomes IT System Reported daily</p>
<p>Number of self-testing chlamydia /gonorrhoea kits provided</p>	<p>PharmOutcomes IT System Reported daily</p>

Appendix 1



Patient Group Direction (PGD) for the supply of Levonorgestrel 1.5mg Tablets

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 (PGD) for the supply of Levonorgestrel 1.5mg Tablets for Emergency Contraception (LNG-EC) by accredited community pharmacists and pharmacy technicians working within the boundaries of West Sussex County Council (WSSC)

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



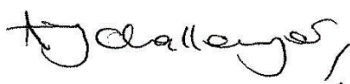
Community pharmacists and pharmacy technicians using this PGD must ensure that it is the formally approved version signed by a senior pharmacist, a senior doctor and the governance lead for the organisation with legal authority, so that this document meets legal requirements for a PGD.

Direction no: WSSC 002 V9

Change History	
Version	Change Details
Version 9	Updated Summary of Product Characteristics (SPC) Updated Faculty of Sexual and Reproductive Healthcare (FSRH) guidance

PGD comes into effect	1 st December 2024
PGD review date	1 st April 2027 or earlier in the light of significant changes in best practice
PGD expiry date	30 th November 2027

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

NAME/ROLE	SIGNATURE	DATE
Dr Janet Michaelis Associate Specialist and Service lead in Sexual and Reproductive Health West Sussex Sexual Health		04/11/2024
Public Health Pharmacist Janet Rittman West Sussex County Council		01/11/2024
Alison Challenger Director of Public Health West Sussex County Council		08.11.2024

Short Life Working Group Membership (*Core working group members and PGD signatories)

Name	Designation
Janet Rittman*	Pharmacist
Dr Janet Michaelis*	Doctor
Kate Bailey (Member of Working Group from start of review till 1 st Oct 2024)	Consultant in Public Health
Claire Currie (Member of the Approval Group from 1 st Oct 2024 onwards)	Consultant in Public Health
Patrick Stoakes	Public Health Lead – Sexual health
Julia Powell	Chief Executive Officer Community Pharmacy Surrey and Sussex

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 and Guidance for Pharmacy Professionals.

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

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

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

Patient group direction effective from 1st December 2024

HEALTHCARE PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD

WSSCC authorises the use of this document by accredited community pharmacists and pharmacy technicians who are working within the boundaries of **West Sussex County Council**

Characteristics of Staff

Declaration. (Sign on next page)

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

Qualifications

I am registered with the General Pharmaceutical Council (GPhC)

Specialist qualifications and competencies

- I am competent to provide the Provision of Emergency Hormonal Contraception from Community Pharmacists and Pharmacy Technicians to individuals in WSSCC service under PGD because:
- I have completed the training and accreditation requirements detailed in the Provision of Levonorgestrel 1.5mg (1500mcg) for EHC from Community Pharmacists and Pharmacy Technicians to individuals under Patient Group Direction (PGD) service specification.
(<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>)
- I have completed the Emergency Hormonal Contraception Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website <https://www.cppe.ac.uk/services/declaration-of-competence> within the last 2 years. Pharmacists/pharmacy technicians personalised statement of declaration should be retained, as it may need to be provided to commissioners and/or employers when required via the [CPPE Viewer](#).
- I am aware of local safeguarding policies and contact information. Information is available via the following link <https://www.westsussexscp.org.uk/#>
- I have completed one of the recommended NHS eLearning for healthcare (elfh) Safeguarding level 3 training materials or have direct access to professional advice from someone who can advise on Safeguarding at Level 3. [Safeguarding Children and Adults Level 3 for Community Pharmacists](#) – video on elfh or [Safeguarding Level 3 Learning for Healthcare Safeguarding Children and Young People \(SGC\) – Safeguarding Children Level 3](#).
- I have reviewed my competency to operate under this PGD using the [NICE Competency Framework for health professionals using patient group directions](#)
- I have reviewed the local policies and documentation for this service and references associated with this PGD.
- I am aware that it is my responsibility to keep up-to-date with changes to the recommendations for this medicine and acknowledge any limitations to my knowledge or competence. I will complete continuing professional development as defined by the GPhC and take part in an audit as detailed in the service specification.
- The decision to supply any medication rests with the individual registered healthcare professional who must abide by the PGD and any associated organisational policies.

DECLARATION: I am a registered pharmacist/pharmacy technician working at

Name of Pharmacy	
Address	
Post Code	

Name	Designation (Pharmacist or Pharmacy Technician)	GPhC registration number	Signature	Date

Authorising manager/pharmacist

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

Name	Designation	Signature	Date

1. Clinical condition or situation to which this Patient Group Direction applies	
1.1 Definition of clinical situation for use	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly.
1.2 Criteria for inclusion	<ul style="list-style-type: none"> Any individual 13 years of age and over presenting for emergency contraception (EC) preferably within 12 hours and no later than after 72 hours (may also be used between 72-96 hours after UPSI but efficacy decreases with time, off label use between 72-96hrs - see section 2.4) or when regular contraception has been compromised or used incorrectly. For guidance refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) Decision-making Algorithms for Emergency Contraception in the following document pages ix, x. FSRH Guideline Emergency Contraception March 2017, amended July 2023) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf Young people 13-17 years should be assessed against questions 1-5 (CERQ5) of the Child Sexual Exploitation Risk Questionnaire (CSERQ15). https://abuhb.nhs.wales/files/sexual-and-reproductive-health/cserq-guidance-15-10-2019-pdf/ All options for emergency contraception discussed and the individual prefers the hormonal method. The individual has no contraindications to the medication. The individual has taken LNG-EC but has vomited the tablet within 3 hours of taking. The new dose must still be within 72 hours (96 hours off label) of the first UPSI of that episode. 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 – refer to Appendix 1. Consents to consultation and medication supply by a pharmacist/pharmacy technician without referral to a doctor.
1.3 Criteria for exclusion	<ul style="list-style-type: none"> Age <13 years. If under 13 years of age follow local safeguarding policy https://www.westsussexscp.org.uk refer to section 1.5. 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.

- Safeguarding or child sexual exploitation (CSE) concerns- refer to section 1.5.
- This episode of UPSI occurred more than 96 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 96 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 (GTD).
- Acute porphyria.
- Known hypersensitivity to any constituent of LNG-EC. Refer to Summary of product Characteristics (SPC) <https://www.medicines.org.uk/emc>
- Use of ulipristal acetate (UPA-EC) emergency contraception in the previous 5 days.
- Taking a medicine or herbal product (for example St John's Wort) that interacts with LNG-EC (see section 2.12). 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 (or within 4 weeks of stopping) with an increased dose of LNG-EC. Refer to section 2.5.

It is imperative to contact the local Sexual Health Service (SHS) for advice if the pharmacist/pharmacy technician 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

- All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider.
- UPA-EC can delay ovulation until closer to the time of ovulation than levonorgestrel (LNG-EC). Consider UPA-EC if the individual presents in the five days leading up to estimated day of ovulation.
- LNG-EC is ineffective if taken after ovulation.
- If individual is taking enzyme-inducing drugs (or herbal products for example St John's Wort) or has taken them in the last 28 days (includes prescribed and purchased medicines) – **see adjusted dosage recommendations in section 2.5.**
- If individual vomits within three hours from ingestion, a repeat dose may be given.
- **Body Mass Index (BMI) greater than or equal to 26kg/m² or weighs 70kg (11 stone) or more**, individuals should be advised that although oral EC methods are safe, a high BMI may reduce effectiveness. A CU-IUD should be recommended as the most effective method of EC. If CU-IUD is not accepted then either advise the individual to take a total dose of 3mg levonorgestrel (two 1.5mg tablets) as a single dose (off label indication) or consider Ulipristal 30mg tablet. **Refer to section 2.5.**
- Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of LNG-EC is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed.
- If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.
- If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. <https://www.westsussexscp.org.uk>
- If the individual has not yet reached menarche consider onward referral for further assessment or investigation.

<p>1.5 Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> • Explain the reasons for exclusion to the individual and signpost or refer to SHS or GP as soon as possible with information about further options https://www.sexualhealthwestsussex.nhs.uk. • If pregnancy is suspected, (i.e. If UPSI occurred > 21days ago and no or abnormal period) ask individual to complete a pregnancy test (as soon as possible as the supply of EHC is time critical i.e. straight away) before supplying EC and/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 in patient medication record (PMR) • Document all actions taken. • Useful Safeguarding Links <ul style="list-style-type: none"> • Report a Concern about a Child - West Sussex SCP • Reporting Concerns - BHSCP • Welcome to your Pan Sussex Child Protection and Safeguarding Procedures Manual Sussex Child Protection and Safeguarding Procedures Manual • Home Sussex Safeguarding Adults Policy and Procedures (over 18 years)
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<p>2. Description of Treatment</p>	
<p>2.1 Name, strength & formulation of drug</p>	<p>Levonorgestrel tablet 1.5mg (N.B this is equivalent to 1500 mcg levonorgestrel)</p>
<p>2.2 Legal category</p>	<p>Prescription Only Medicine (POM) Pharmacy Only Medicine (P)</p>
<p>2.3 Route of administration</p>	<p>Oral, with or without food. Taking with or after food may reduce the incidence of nausea and vomiting a known side effect.</p>

<p>2.4 Off label use</p>	<p>Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p>This PGD includes off-label use in the following conditions:</p> <ul style="list-style-type: none"> ○ Use between 72 and 96 hours post UPSI ○ Increased dose for individuals with BMI over 26kg/m² or weight over 70kg and in individuals using liver enzyme inducing agent- refer to section 2.5 ○ Increased dose for individuals using liver enzyme inducing agents ○ Severe hepatic impairment ○ Individuals with previous salpingitis or ectopic pregnancy ○ Lapp-lactase deficiency ○ Hereditary problems of galactose intolerance ○ Glucose-galactose malabsorption <p>Note some products may be licenced only for certain age groups (e.g. 16 years and over) – supply of these products outside the licensed age groups is permitted under this PGD.</p> <p>Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.</p> <p>Where a drug is recommended off-label 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.</p>
<p>2.5 Dose and frequency of administration</p>	<ul style="list-style-type: none"> ● Levonorgestrel 1.5 mg (1 tablets) to be taken as soon as possible up to 96 hours of unprotected sexual intercourse (UPSI). ● Dose for those individuals taking enzyme inducing medicines or herbal products: An individual who requests LNG-EC whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1.5mg tablets) as a single dose and within 96 hours of UPSI. Note the effectiveness of this regimen is unknown. ● Dose for those individuals with a body mass index of more than 26kg/m² or who weigh more than 70kg: An individual who requests levonorgestrel with a body mass index of more than 26kg/m² or who weighs more than 70kg can be offered a total of 3mg levonorgestrel (two 1.5mg tablets) as a single dose and within 72 hours of UPSI (96 hours off label). Note the effectiveness of this regimen is unknown.

2.6 Quantity	<ul style="list-style-type: none"> • Single dose 1.5mg tablet to be administered in the pharmacy or dispensed and appropriately labelled for the individual to take away. • Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m² or who weigh more than 70kg.
2.7 Duration of treatment	<ul style="list-style-type: none"> • A single dose is permitted under this PGD. • If vomiting occurs within 3 hours of LNG-EC being taken a repeat dose can be supplied under this PGD. • Repeated doses, as separate episodes of care, can be given within the same cycle. Please note: <ul style="list-style-type: none"> ○ If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC) ○ If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC)
2.8 Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
2.9 Labelling Requirements	<ul style="list-style-type: none"> • Label as per the legislation for a prescription only medicine (POM) if individual is taking the medicine away from the pharmacy. • The individual should be given the patient information leaflet (PIL)
2.10 Identification and management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org</p> <p>The following side effects are common with LNG-EC (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Nausea/vomiting • Lower abdominal pain • Fatigue • Dizziness • Headache • Diarrhoea • Breast tenderness • Mood change <p>The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time.</p>
2.11 Management of and reporting procedure for adverse reactions	<p>In the event of untoward or unexpected adverse reactions:</p> <ul style="list-style-type: none"> • If necessary seek appropriate emergency advice and assistance. • Document in the individual patient medication record and complete incident procedure. If adverse reaction is severe refer to local organisational policy as per service contractual agreement and report as required. • Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk

<p>2.12 Drug interactions</p>	<p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org</p> <p>Additional Sources of information include:</p> <ul style="list-style-type: none"> • 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 (May 2022) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • For interactions with post-exposure prophylaxis for sexual exposure to HIV (PEPSE) regimes it is recommended to check with the online University of Liverpool HIV Drug Interactions Checker https://www.hiv-druginteractions.org/checker <p>If necessary access the individuals NHS Summary Care Record (SCR) (with consent) if they are uncertain about the medications they are taking.</p>
<p>2.13 Written information and further advice to be given to individual</p>	<ul style="list-style-type: none"> • All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. • Explain mode of action, dosage, side effects, and follow-up advice. Provide manufacturer’s patient information leaflet (PIL) and discuss content (refer to https://www.medicines.org.uk/emc for 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. • Explain menstrual disturbances can occur after the use of emergency hormone contraceptives. • Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Provide advice on ongoing contraceptive methods, including how these can be accessed, via GPs, West Sussex Sexual Health Service or through the NHS Pharmacy Contraception Service (started December 2023 https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-services/nhs-pharmacy-contraception-service/) • Refer individual to https://www.contraceptionchoices.org or NHS Contraception webpage Contraception - NHS (www.nhs.uk) to access further information on contraception choices. • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. • Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.

	<ul style="list-style-type: none"> • Advise that after oral EC there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle. Recommend use of appropriate contraceptive methods and how these can be accessed. Supply condoms as needed. • Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. Individuals must be advised to go to ISHS or GP if the pregnancy test is positive. • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. • 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 or refer to local sexual health services for STI testing. • Individuals presenting for repeat supplies of EHC should be referred to the ISHS for additional support. • Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased. • Give individual the opportunity to ask questions and address any concerns or queries.. • Provide contact information for SHS or refer to website_ https://www.sexualhealthwestsussex.nhs.uk
<p>2.13 Advice/follow up treatment</p>	<ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Refer to ISHS or GP for further advice about on-going contraception and screening for sexually transmitted infections (STI).
<p>3. Records</p>	<p>Individuals should be made aware of the confidentiality policies for the service they are attending, including the circumstances in which confidentiality may need to be breached.</p> <p>The PharmOutcomes template will record the following information:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ If individual is under 13 years of age record action taken ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record action taken. • Safeguarding referral if relevant. • Individual's name, date of birth and first 3-4 characters of postcode i.e. BN15. This is a confidential service that can be accessed without a full address and GP notification. • Relevant past and present medical history, including medication history. Examination findings where relevant e.g. weight • Any known medication allergies

	<ul style="list-style-type: none"> • Date of supply • Name and designation of registered health professional operating under the PGD • Record the name and dose of the medication and the 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 • Advice given, including advice given if excluded or declines treatment. • Any referral arrangements • Any follow up arrangements • Recorded that supplied via Patient Group Direction(PGD) • For adults all PGD documentation in a patient's clinical record must be kept for 8 years after the last entry. • For children all PGD documentation in a patient's clinical record must be kept until the child is 25 years old or for 8 years after a child's death. <p>Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
<p>REFERENCES (Accessed August 2024)</p>	<ul style="list-style-type: none"> • Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: Emergency Contraception (March 2017, amended July 2023) https://www.fsrh.org/Public/Documents/ceu-clinical-guidance-emergency-contraception-march-2017.aspx • 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 (May 2022) https://www.fsrh.org/Public/Documents/ceu-clinical-guidance-drug-interactions-with-hormonal.aspx • Faculty of Sexual and Reproductive Healthcare Clinical Guideline (April 2017): Quick starting contraception https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/ • Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit guidance: Recommended Actions after Incorrect Use of Combined Hormonal Contraception (e.g. late or missed pills, ring and patch) (March 2020, Amended July 2021) https://www.fsrh.org/Public/Public/Documents/fsrh-ceu-guidance-recommended-actions-after-incorrect-use.aspx • Specialist Pharmacy Service: Patient Group Directions, Reproductive Health. Supply and/or administration of levonorgestrel 1500mcg tablet(s) for emergency contraception: PGD template.

	<p>https://www.sps.nhs.uk/articles/levonorgestrel-1500-microgram-tablets-for-emergency-contraception/</p> <ul style="list-style-type: none"> • National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017) https://www.nice.org.uk/Guidance/MPG2 • Electronic British National Formulary (BNF) www.bnf.org • Electronic Medicines Compendium https://www.medicines.org.uk/emc • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines • General Pharmaceutical Council Standards and Guidance for Pharmacy Professionals. https://www.pharmacyregulation.org/pharmacists/standards-and-guidance-pharmacy-professionals • Centre for Postgraduate Pharmacist Education (CPPE). Declaration of Competence. https://www.cppe.ac.uk/services/declaration-of-competence
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Appendix 1

Under 16s - Fraser Guidelines

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

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

Competence is demonstrated if the young person is able to:

Understand the treatment, its purpose and nature, and why it is being proposed

Understand its benefits, risks and alternatives

Understand in broader terms what the consequences of the treatment will be

Retain the information for long enough to use it and weigh it up in order to arrive at a decision.

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

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

Reference

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

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

Patient Group Direction (PGD) for the supply of Ulipristal Acetate 30mg Tablets

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 (PGD) for the supply of Ulipristal Acetate 30mg Tablets for Emergency Contraception (UPA-EC) by accredited community pharmacists and pharmacy technicians working within the boundaries of West Sussex County Council (WSCC)

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

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



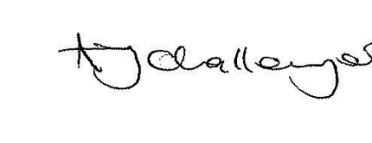
Direction no: WSCC 003 V3

Change History

Version	Change Details
Version 3	Updated Summary of Product Characteristics (SPC) Updated Faculty of Sexual and Reproductive Healthcare (FSRH) guidance

PGD comes into effect	1 st December 2024
PGD review date	1 st April 2027 or earlier in the light of significant changes in best practice
PGD expiry date	30 th November 2027

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

NAME/ROLE	SIGNATURE	DATE
Dr Janet Michaelis Associate Specialist and Service lead in Sexual and Reproductive Health West Sussex Sexual Health		04/11/2024
Public Health Pharmacist Janet Rittman West Sussex County Council		01/11/2024
Alison Challenger Director of Public Health West Sussex County Council		08.11.2024

Short Life Working Group Membership (*Core working group members and PGD signatories)

Name	Designation
Janet Rittman*	Pharmacist
Dr Janet Michaelis*	Doctor
Kate Bailey (Member of Working Group from start of review till 1 st Oct 2024)	Consultant in Public Health
Claire Currie (Member of the Approval Group from 1 st Oct 2024 onwards)	Consultant in Public Health
Patrick Stoakes	Public Health Lead – Sexual health
Julia Powell	Chief Executive Officer Community Pharmacy Surrey and Sussex

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 and Guidance for Pharmacy Professionals.

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

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

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

Patient group direction effective from 1st December 2024

HEALTHCARE PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD

WSSCC authorises the use of this document by accredited community pharmacists and pharmacy technicians who are working within the boundaries of **West Sussex County Council**

Characteristics of Staff

Declaration. (Sign on next page)

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

Qualifications

I am registered with the General Pharmaceutical Council (GPhC)

Specialist qualifications and competencies

I am competent to provide the Provision of Emergency Hormonal Contraception from Community Pharmacists and Pharmacy Technicians to individuals in WSSCC service under PGD because:

- I have completed the training and accreditation requirements detailed in the Provision of Ulipristal 30mg for EHC from Community Pharmacists and Pharmacy Technicians to individuals under Patient Group Direction (PGD) service specification.
(<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>)
- I have completed the Emergency Hormonal Contraception Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website <https://www.cppe.ac.uk/services/declaration-of-competence> within the last 2 years. Pharmacists/pharmacy technicians personalised statement of declaration should be retained, as it may need to be provided to commissioners and/or employers when required via the [CPPE Viewer](#).
- I am aware of local safeguarding policies and contact information. Information is available via the following link <https://www.westsussexscp.org.uk/#>
- I have completed one of the recommended NHS eLearning for healthcare (elfh) Safeguarding level 3 training materials or have direct access to professional advice from someone who can advise on Safeguarding at Level 3. [Safeguarding Children and Adults Level 3 for Community Pharmacists](#) – video on elfh or [Safeguarding Level 3 Learning for Healthcare Safeguarding Children and Young People \(SGC\) – Safeguarding Children Level 3](#).
- I have reviewed my competency to operate under this PGD using the [NICE Competency Framework for health professionals using patient group directions](#)
- I have reviewed the local policies and documentation for this service and references associated with this PGD.
- I am aware that it is my responsibility to keep up-to-date with changes to the recommendations for this medicine and acknowledge any limitations to my knowledge or competence. I will complete continuing professional development as defined by the GPhC and take part in an audit as detailed in the service specification.
- The decision to supply any medication rests with the individual registered healthcare professional who must abide by the PGD and any associated organisational policies.

DECLARATION: I am a registered pharmacist/pharmacy technician working at

Name of Pharmacy

Address

Post Code

Name	Designation (Pharmacist or Pharmacy Technician)	GPhC registration number	Signature	Date

Authorising manager/pharmacist

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

Name	Designation	Signature	Date

1. Clinical condition or situation to which this Patient Group Direction applies	
1.1 Definition of clinical situation for use	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly.
1.2 Criteria for inclusion	<ul style="list-style-type: none"> • Any individual aged 13 years of age and over presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. For guidance refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) Decision-making Algorithms for Emergency Contraception in the following document pages ix, x. FSRH Guideline Emergency Contraception March 2017, amended July 2023) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • Young people 13-17 years should be assessed against questions 1-5 (CERQ5) of the Child Sexual Exploitation Risk Questionnaire (CSERQ15). https://abuhb.nhs.wales/files/sexual-and-reproductive-health/cserq-guidance-15-10-2019-pdf/ • All options for emergency contraception discussed and the individual prefers the hormonal method. • The individual has no contraindications to the medication. • 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 – refer to Appendix 1. • Consents to consultation and medication supply by a pharmacist/pharmacy technician without referral to a doctor.
1.3 Criteria for exclusion	<ul style="list-style-type: none"> • Age <13 years. If under 13 years of age follow local safeguarding policy https://www.westsussexscp.org.uk refer to section 1.5. • 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.

- 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 local Sexual Health Service (SHS) <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 (GTD).
- Severe asthma controlled by oral glucocorticoids.
- Acute porphyria.
- Known hypersensitivity to any constituent of UPA-EC. Refer to Summary of product Characteristics (SPC) <https://www.medicines.org.uk/emc>
- Use of levonorgestrel (LNG-EC) or any other progestogen in the previous 7 days (i.e. hormonal contraception including combined oral contraception, depot injection, hormone replacement therapy (or use for other gynaecological indications). Consider if LNG-EC is appropriate (or Cu-IUD) refer to LNG-EC PGD.
- Concurrent use of antacids, proton-pump inhibitors or H₂-receptor antagonists including any non-prescription (i.e. over the counter) products being taken.
- Taking a medicine or herbal product (for example St John's Wort) that interacts with UPA-EC (see section 2.12). 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 (or within 4 weeks of stopping) with an increased dose of LNG-EC. Refer to the LNG-EC PGD.

It is imperative to contact the local Sexual Health Service (SHS) for advice if the pharmacist/pharmacy technician 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

- All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider.
- UPA-EC is ineffective if taken after ovulation.
- If an individual vomits within 3 hours from ingestion a repeat dose may be given.
- UPA-EC can be supplied if USPI earlier in the same cycle as well as within the last 5 days, as evidence suggests it does not disrupt an existing pregnancy and is not associated with fetal abnormality.
- If individual is taking enzyme-inducing drugs (or herbal products) or has taken them in the last 28 days (includes prescribed and purchased medicines) refer for Cu-IUD or consider supply of a 3mg dose of LNG-EC. Refer to LNG-EC PGD.
- The effectiveness of ulipristal can be reduced by progestogen (i.e. hormonal contraception including combined oral contraception, depot injection, hormone replacement therapy) taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. UPA- EC is generally not recommended in a missed pill situation. See section 'Written information and further advice to be given to individual'.
- **Body Mass Index (BMI) greater than or equal to 26kg/m² or weighs 70kg (11 stone) or more**, individuals should be advised that although oral EC methods are safe, a high BMI may reduce effectiveness. A CU-IUD should be recommended as the most effective method of EC. If CU-IUD is not appropriate refer to the LNG-EC PGD for consideration of a 3mg dose of LNG-EC.
- Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of UPA-EC is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed.
- If pregnancy is suspected (i.e. If UPSI occurred > 21days ago and no or abnormal period) advise a pregnancy test and ask individual to complete the test (as soon as possible as the supply of EHC is time critical i.e. straight away) before supplying EHC. If individual is unable to return to the pharmacy refer to the ISHS.
- Breast feeding - advise to express and discard breast milk for 7 days after UPA-EC dose.
- If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.
- If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. <https://www.westsussexscp.org.uk>
- If the individual has not yet reached menarche consider onward referral for further assessment or investigation.

<p>1.5 Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> • Explain the reasons for exclusion to the individual and signpost or refer to SHS or GP as soon as possible with information about further options https://www.sexualhealthwestsussex.nhs.uk. • If pregnancy is suspected, (i.e. If UPSI occurred > 21days ago and no or abnormal period) ask individual to complete a pregnancy test (as soon as possible as the supply of EHC is time critical i.e. straight away) before supplying EC and/or refer to the ISHS. • If exclusion is due to a drug interaction consider if UPA-EC could be supplied as an alternative to UPA-EC or refer for Cu-IUD. • Safeguarding (including child sexual exploitation) concerns identified at presentation should be referred to the 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 in patient medication record (PMR) • Document all actions taken. • Useful Safeguarding Links <ul style="list-style-type: none"> • Report a Concern about a Child - West Sussex SCP • Reporting Concerns - BHSCP • Welcome to your Pan Sussex Child Protection and Safeguarding Procedures Manual Sussex Child Protection and Safeguarding Procedures Manual • Home Sussex Safeguarding Adults Policy and Procedures (over 18 years)
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<p>2. Description of Treatment</p>	
<p>2.1 Name, strength & formulation of drug</p>	<p>Ulipristal tablet 30mg (N.B this is equivalent to 30000 mcg Ulipristal)</p>
<p>2.2 Legal category</p>	<p>Pharmacy Only Medicine (P)</p>
<p>2.3 Route of administration</p>	<p>Oral, with or without food. Taking with or after food may reduce the incidence of nausea and vomiting a known side effect.</p>

<p>2.4 Off label use</p>	<p>Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p>This PGD includes off-label use in the following conditions:</p> <ul style="list-style-type: none"> • Severe hepatic impairment • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption <p>Note some products may be licenced only for certain age groups (e.g. 16 years and over) – supply of these products outside the licensed age groups is permitted under this PGD.</p> <p>Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.</p> <p>Where a drug is recommended off-label 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.</p>
<p>2.5 Dose and frequency of administration</p>	<ul style="list-style-type: none"> • A single tablet (30mg) to be taken as soon as possible up to 120 hours of unprotected sexual intercourse (UPSI).
<p>2.6 Duration of treatment</p>	<ul style="list-style-type: none"> • UPA should be taken orally as a single dose • If vomiting occurs within 3 hours of UPA-EC being taken a repeat dose can be supplied under this PGD • Repeated doses, as separate episodes of care can be given within the same cycle. Please note: <ul style="list-style-type: none"> ○ If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC) ○ If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC)
<p>2.7 Quantity to be supplied</p>	<p>Single dose -to be administered in the pharmacy or dispensed and appropriately labelled for the individual to take away.</p>
<p>2.8 Storage</p>	<p>Medicines must be stored securely according to national guidelines and in accordance with the product SPC.</p>
<p>2.9 Labelling Requirements</p>	<ul style="list-style-type: none"> • Label as per the legislation for a prescription only medicine (POM) if individual is taking the medicine away from the pharmacy. • The individual should be given the patient information leaflet (PIL)

<p>2.10 Identification and management of adverse reactions</p>	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org</p> <p>The following side effects are common with UPA-EC (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Nausea/vomiting • Lower abdominal pain • Fatigue • Dizziness • Headache • Diarrhoea • Breast tenderness • Mood change • Fatigue • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception <p>Effects on ability to drive and use machines. Mild to moderate dizziness is common after taking ulipristal, somnolence and blurred vision are uncommon. Advise individual not to drive or use machinery if they experience such symptoms.</p>
<p>2.11 Management of and reporting procedure for adverse reactions</p>	<p>In the event of untoward or unexpected adverse reactions:</p> <ul style="list-style-type: none"> • If necessary seek appropriate emergency advice and assistance. • Document in the individual patient medication record and complete incident procedure. If adverse reaction is severe refer to local organisational policy as per service contractual agreement and report as required. • Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk
<p>2.12 Drug interactions</p>	<p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org</p> <p>Additional Sources of information include:</p> <ul style="list-style-type: none"> • 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 (May 2022) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • For interactions with post-exposure prophylaxis for sexual exposure to HIV (PEPSE) regimes it is recommended to check with the online

	<p>University of Liverpool HIV Drug Interactions Checker https://www.hiv-druginteractions.org/checker</p> <p>If necessary access the individuals NHS Summary Care Record (SCR) (with consent) if they are uncertain about the medications they are taking.</p>
<p>2.13 Written information and further advice to be given to individual</p>	<ul style="list-style-type: none"> • All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. • Explain mode of action, dosage, side effects, and follow-up advice. Provide manufacturer’s patient information leaflet (PIL) and discuss content (refer to https://www.medicines.org.uk/emc for 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. • Explain menstrual disturbances can occur after the use of emergency hormone contraceptives. • Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Provide advice on ongoing contraceptive methods, including how these can be accessed, via GPs, West Sussex Sexual Health Service or through the NHS Pharmacy Contraception Service (started December 2023 https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-services/nhs-pharmacy-contraception-service/) • Refer individual to https://www.contraceptionchoices.org or NHS Contraception webpage Contraception - NHS (www.nhs.uk) to access further information on contraception choices. • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. • Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Advise that after oral EC there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle. Recommend use of appropriate contraceptive methods and how these can be accessed. Supply condoms as needed. • Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. Individuals must be advised to go to ISHS or GP if the pregnancy test is positive. • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. • 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 or refer to local sexual health services for STI testing.

	<ul style="list-style-type: none"> • Individuals presenting for repeat supplies of EHC should be referred to the ISHS for additional support. • Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased. • Give individual the opportunity to ask questions and address any concerns or queries.. • Provide contact information for SHS or refer to website_ https://www.sexualhealthwestsussex.nhs.uk
2.13 Advice/follow up treatment	<ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Refer to ISHS or GP for further advice about on-going contraception and screening for sexually transmitted infections (STI).
3. Records	<p>Individuals should be made aware of the confidentiality policies for the service they are attending, including the circumstances in which confidentiality may need to be breached.</p> <p>The PharmOutcomes template will record the following information:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ If individual is under 13 years of age record action taken ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record action taken. • Safeguarding referral if relevant. • Individual's name, date of birth and first 3-4 characters of postcode i.e. BN15. This is a confidential service that can be accessed without a full address and GP notification. • Relevant past and present medical history, including medication history. Examination findings where relevant e.g. weight • Any known medication allergies • Date of supply • Name and designation of registered health professional operating under the PGD • Record the name and dose of the medication and the 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 • Advice given, including advice given if excluded or declines treatment. • Any referral arrangements • Any follow up arrangements • Recorded that supplied via Patient Group Direction (PGD) • For adults all PGD documentation in a patient's clinical record must be kept for 8 years after the last entry.

	<ul style="list-style-type: none"> For children all PGD documentation in a patient's clinical record must be kept until the child is 25 years old or for 8 years after a child's death. <p>Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
REFERENCES (Accessed August 2024)	<ul style="list-style-type: none"> Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: Emergency Contraception (March 2017, amended July 2023) https://www.fsrh.org/Public/Documents/ceu-clinical-guidance-emergency-contraception-march-2017.aspx 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 (May 2022) https://www.fsrh.org/Public/Documents/ceu-clinical-guidance-drug-interactions-with-hormonal.aspx Faculty of Sexual and Reproductive Healthcare Clinical Guideline (April 2017): Quick starting contraception https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/ Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit guidance: Recommended Actions after Incorrect Use of Combined Hormonal Contraception (e.g. late or missed pills, ring and patch) (March 2020, Amended July 2021) https://www.fsrh.org/Public/Public/Documents/fsrh-ceu-guidance-recommended-actions-after-incorrect-use.aspx Specialist Pharmacy Service: Patient Group Directions, Reproductive Health. Supply and/or administration of Ulipristal 1500mcg tablet(s) for emergency contraception: PGD template. https://www.sps.nhs.uk/articles/Ulipristal-1500-microgram-tablets-for-emergency-contraception/ National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017) https://www.nice.org.uk/Guidance/MPG2 Electronic British National Formulary (BNF) www.bnf.org Electronic Medicines Compendium https://www.medicines.org.uk/emc Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines General Pharmaceutical Council Standards and Guidance for Pharmacy Professionals. https://www.pharmacyregulation.org/pharmacists/standards-and-guidance-pharmacy-professionals Centre for Postgraduate Pharmacist Education (CPPE). Declaration of Competence.

	https://www.cppe.ac.uk/services/declaration-of-competence
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Appendix 1

Under 16s - Fraser Guidelines

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

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

Competence is demonstrated if the young person is able to:

Understand the treatment, its purpose and nature, and why it is being proposed

Understand its benefits, risks and alternatives

Understand in broader terms what the consequences of the treatment will be

Retain the information for long enough to use it and weigh it up in order to arrive at a decision.

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

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

Reference

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

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

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

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.

Emergency Hormonal Contraception Patient Group Direction Scheme

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)

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

Please send to: **Patrick Stoakes, Public Health Lead: Sexual Health, Public Health & Wellbeing Directorate, West Sussex County Council, Northleigh Building , Ground Floor, West Street, Chichester, West Sussex PO19 1QT or e-mail to patrick.stoakes@westsussex.gov.uk**

PRIVATE AND CONFIDENTIAL

Fax transmission of form is not considered confidential