This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

in Public Health Dorset

Version Number 7.1

Change History	
Version and Date	**Change details**
Version 7 June 2021	Latest version in new template based on national version
Version 7.1 June 2024	6-month extension agreed to allow for approval of Dorset ICS PGD policy ahead of review.

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

Valid from: 1st July 2021
Review date: December 2023
Expiry date: 31st December 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1st July 2021
Review date	December 2023
Expiry date:	31st June 2024

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2019.

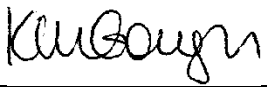
This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michael Nevill	Director of Nursing British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant Marie Stopes UK
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Pan London PGD working group
Dr Sarah Pillai	Pan London PGD working group
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Woking	Specialist Pharmacist PGDs Specialist Pharmacy Service

Group Co-ordinator)	
Samrina Bhatti	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

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

ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

Name	Job title and organisation	Signature	Date
Senior doctor Dr Paul Mason	Prescribing Lead, Dorset CCG		19/07/21
Senior pharmacist Katherine Gough	Head of Medicines Management, Dorset CCG		19/07/21
Senior representative of professional group using the PGD	n/a	n/a	n/a
Person signing on behalf of authorising body Dr Jane Horne	Consultant in Public Health, Dorset County Council		19/07/21

Should you have any questions regarding this PGD please contact Public Health Dorset via email: phcontracts@dorsetcouncil.gov.uk

Commissioner Audit Requirements: As per the Public Health Dorset Emergency Hormonal Contraception service specification, the Provider shall participate in any audit of service provision or assessment of user experience conducted or authorised by the commissioner.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. Before offering the service, all Pharmacists providing treatment under this PGD must complete the CPPE e-learning course and online assessment (including updates) for Safeguarding Children and Emergency Contraception.
Competency assessment	• Complete the CPPE e-learning course and online assessment for Safeguarding Children and Emergency Contraception and any additional local training to address changes to national guidance • Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for emergency contraception. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	Every 3 years • CPPE online assessment on Safeguarding Children and the CPPE Emergency Contraception e-learning course OR • Attend the local CPPE Emergency Hormonal Contraception (EHC) and Safeguarding course • The pharmacy must have a copy of the Current BNF available for reference and be familiar with the information in the BNF about the use of POEC • The pharmacy must have a copy of the CPPE learning pack with updates available for reference.
Lines of accountability	A registered pharmacist is accountable for his or her actions in accordance with the General Pharmaceutical Council. All registered pharmacists are personally accountable for their practice, decision to supply any medicine, and in the exercise of professional accountability there is a requirement to maintain and improve their professional knowledge and competence. The PGD may be used only within the confines of the service specification by pharmacists and pharmacies commissioned by Public Health Dorset

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly.
Criteria for inclusion	• Any individual presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. • No contraindications to the medication. • Informed consent given.
Criteria for exclusion	• 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. • This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours. • Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period). • Less than 21 days after childbirth. • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • Use of levonorgestrel or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications). • Concurrent use of antacids, proton-pump inhibitors or H_2-receptor antagonists. • Severe asthma controlled by oral glucocorticoids. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping. • Acute porphyria
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. • Ulipristal is ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a repeat dose may be given. • Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC

	methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of ulipristal is not 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. • Breast feeding – advise to express and discard breast milk for 7 days after ulipristal dose. • The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section 'Written information and further advice to be given to individual'. • If 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. • If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
Action to be taken if the individual is excluded or declines treatment	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet
Legal category	P
Route of administration	Oral
Off label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off-label use in the following conditions: • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption • Severe hepatic impairment 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. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	• One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI.

Duration of treatment	• A single dose is permitted under this PGD.
	• If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD.
	• Repeated doses can be given within the same cycle. Please note:
	  ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)
	  ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)

Quantity to be supplied	Appropriately labelled pack of one tablet.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	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
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org

	The following side effects are common with ulipristal acetate (but may not reflect all reported side effects): • Nausea or vomiting • Abdominal pain or discomfort • Headache • Dizziness • Muscle pain (myalgia) • Dysmenorrhea • Pelvic pain • Breast tenderness • Mood changes • Fatigue • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers 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 • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report any adverse reactions via organisation incident policy.
Written information and further advice to be given to individual	• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If vomiting occurs within three hours of taking the dose, the individual should return for another dose. • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed. • 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. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • 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. • Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
Advice / follow up	• The individual should be advised to seek medical advice in the

treatment	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). • Individuals advised how to access on-going contraception and STI screening as required.

Records	Record:
	• The consent of the individual and
	  ○ 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
	• Name of individual, address, date of birth
	• GP contact details where appropriate
	• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight
	• Any known medication allergies
	• Name of registered health professional operating under the PGD
	• Name of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied
	• Advice given, including advice given if excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns
	• Any referral arrangements made
	• Any supply outside the terms of the product marketing authorisation
	• Recorded that administered/supplied via Patient Group Direction (PGD)
	
	Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.
	
	All records should be clear, legible and contemporaneous.
	
	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references (accessed December 2019)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ • 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

Appendix A - Registered health professional authorisation sheet

PGD Name/Version **Valid from:** **Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

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 Public Health Dorset for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

Appendix B - FRASER COMPETENCE – form to use for EHC consultations

If a client is believed to be under 16 years of age, the pharmacist must assess the client's competence using Fraser Guidelines, and complete this separate section of the protocol. Discussion with the young person should explore the following issues at each consultation. This should be documented below:

Assessment of Fraser competence	**YES**	**NO**
Does the client appear to understand the advice given?		
Have you discussed with her about informing her parents about the treatment?		
Has consideration been given to the effect on the physical or mental health of the young person if advice or treatment is withheld?		

IF YOU HAVE ANSWERED NO TO ANY OF THE ABOVE QUESTIONS, THE CLIENT CANNOT BE DEEMED TO BE 'FRASER COMPETENT'. IN THIS CASE, YOU WILL NEED TO ENSURE THEY ATTEND A SEXUAL HEALTH CLINIC OR SEE A GP AS SOON AS POSSIBLE.

The Sexual Offences Act 2003 states that no child under 13 years is able to consent to any sexual activity. If the client is believed to be under 13 years of age, providing they have been assessed as 'Fraser competent', you should not withhold treatment, as the duty to safeguard the child from most harm, would include protecting them from an unintended pregnancy.

You should record all the details of the consultation and discuss at the earliest opportunity with the Child Care Duty Team at the Local Authority (Social Services) or a member of the CCG Safeguarding Children Team (See contact details below) In an emergency, you can contact the police.

SAFEGUARDING CHILDREN GUIDANCE

If a client appears to be under 18 years of age, the pharmacist must assess the welfare of the young person using the following protocol:

SAFEGUARDING CHILDREN ASSESSMENT	**YES**	**NO**
Is the client under 13 years of age?		
Is there any concern about Fraser competency?		
Is there any evidence of a coercive relationship (such as older partner, reluctance to allow young person to be seen alone)		
Is the client under 18 years of age and is the partner in a position of trust e.g. teacher/sports coach/youth worker?		
Is there any evidence that the young person may be engaged in prostitution?		
Is there any evidence of domestic violence?		
Is there any evidence of drug or alcohol misuse, relating to the sexual activity?		
Is there any evidence of threats, or attempts to gain secrecy?		
Is there any evidence of self-harm/psychiatric illness?		

Are there any other issues, which lead you to be concerned about the young person's safety or welfare? If yes, please give details:		

IF YOU HAVE ANSWERED YES TO ANY OF THE ABOVE QUESTIONS, OR YOU HAVE ANY OTHER CONCERNS REGARDING THE WELFARE OF THE YOUNG PERSON, PLEASE CONTACT THE CHILD CARE DUTY TEAM AT THE LOCAL AUTHORITY (SOCIAL SERVICES) OR ONE OF THE PCT SAFEGUARDING CHILDREN TEAM AS FOLLOWS:

Contact	Contact Details
Safeguarding Children Team helpline	01305 213644 Open 9am to 5pm Monday to Friday Your call will be transferred to the on-call safeguarding children advisor.
Local Authority children's social work department, including out of hours	Bridport 01308 422234 Christchurch 01202 474106 Ferndown 01202 877445 North Dorset 01258 472652 Weymouth/Portland 01305 760139 Purbeck 01929 553456 Dorchester/Sherborne 01305 224150 Poole 01202 735046 Bournemouth 01202 458102 Out of Hours 01202 657279

PLEASE REMEMBER THAT IF YOU SUSPECT THAT A CHILD IS BEING ABUSED:

- **Discuss with the Child Care Duty Team at the Local Authority (Social Services)**

  OR

- **Discuss with a member of the Safeguarding Children Team**

  OR

- **Inform the police, if you suspect a crime has been committed**
- **Don't think someone else is doing something**
- **Doing nothing is NOT an option**