PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF PROGESTOGEN ONLY EMERGENCY CONTRACEPTION (POEC) (Levonorgestrel 1.5mg) BY COMMUNITY PHARMACISTS WORKING IN A PHARMACY THAT IS EITHER ON A COMMISSIONED LIST OR IS OPERATING AS AN LPS PHARMACY * ALWAYS REFER TO ACCOMPANYING SLA *

Version 1.1

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

THE PHARMACIST MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

CHANGE HISTORY	
Version/Date	Change details
Version 1.1 March 2013	1. Exclusion Criteria – "Interacting medicines" moved to Cautions section to include individuals taking enzyme inducing medicines or herbal remedies as reflect in dosage recommendations. 2. Updated SPC/BNF references

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CLINICAL CONDITION TO WHICH THIS DIRECTION APPLIES	Postcoital emergency contraception
INCLUSION CRITERIA	Any individual presenting for emergency contraception within 72 hours of unprotected sexual intercourse (UPSI) and who has no contraindications to the medication.
EXCLUSION CRITERIA (I.E. SITUATIONS NOT COVERED BY THE PGD)	**Personal Characteristics & Reproductive History** • Known or suspected pregnancy • Under 16 years of age and assessed as not competent using Fraser guidelines • Known hypersensitivity to any constituent of the POEC • More than 72 hours since this episode of unprotected sexual intercourse
CAUTIONS/NEED FOR FURTHER ADVICE/ACTION TO BE TAKEN	• Emergency post coital intrauterine device (IUD) should always be considered as a more effective alternative when emergency contraception is required and onward referral should be made. • If under 13 years of age follow local safeguarding policy • If individual vomits within two (2) hours from ingestion, a repeat dose may be given. • The dose may be repeated more than once in the same menstrual cycle should the need occur. • Discuss with appropriate health service provider if the pharmacist has any concerns. • Provide written advice on ongoing contraceptive methods **Other conditions** • Interacting medicines –see current BNF on interactions. See dosage/frequency section for individuals taking enzyme inducing medicines/enzyme inducing herbal remedies.
ACTION IF EXCLUDED	• Signpost/ refer to appropriate health service provider as soon as possible with information about further options • Document all actions taken
ACTION IF INDIVIDUAL DECLINES	• Record the refusal in the individual's patient medication record • Signpost/ refer to appropriate health service provider with information about further options

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DRUG DETAILS	
NAME, FORM &STRENGTH OF MEDICINE	Levonorgestrel tablet 1.5mg
ROUTE/METHOD	Oral
LEGAL CATEGORY	Prescription Only Medicine (POM) Levonelle 1500 ® or Pharmacy Only Medicine (P) Levonelle One Step ®
USE OUTSIDE PRODUCT LICENCE	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)
DOSAGE/FREQUENCY	• A single tablet to be taken as soon as possible within 72 hours of unprotected sexual intercourse (UPSI) • Repeated episodes of UPSI may be treated within one menstrual cycle provided each treatment is within 72 hours of the most recent UPSI. **Dose for those individuals taking enzyme inducing medicines or herbal remedies** An individual who requests Levonelle ® while using enzyme-inducing drugs or within 4 weeks of stopping them, should be advised to take a total of 3 mg levonorgestrel (two 1.5 mg tablets) as a single dose and within 72 hours of UPSI.
QUANTITY	Original pack of one tablet (or two original packs if taking enzyme inducing drugs)
DURATION OF TREATMENT	Emergency single dose
MAXIMUM OR MINIMUM TREATMENT PERIOD	Emergency single dose

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SIDE EFFECTS	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for further information. Side effects may include; • Nausea • Low abdominal pain • Fatigue • Dizziness • Headache • Diarrhoea/vomiting • Breast tenderness Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next menstrual period within seven days of the expected time. In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual patient medication record • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk.
ADVICE TO INDIVIDUAL	• Provide Manufacturer's Patient Information Leaflet (PIL) and discuss • Explain mode of action, side effects, benefits and how to take the medication • Advise about the risks of the medication including failure rates and serious side effects and the actions to be taken • Advise on what to do if vomits within two (2) hours of taking the pill **See next page**

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ADVICE TO INDIVIDUAL continued	• Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/media/uploads/helpandadvice/contraception-booklets/emergency-contraception-your-guide.pdf • Offer condoms and advice on safer sex practices. • Signpost/ refer to appropriate health service provider with information about further options
FOLLOW UP	• Individual to seek advice if the period is delayed, abnormal or absent
RECORDS	The pharmacist must ensure the following is documented in the individual's patient medication record • Individual's name, address and date of birth • GP contact details if registered • Attendance date • Reason for attendance • Past and present medical and family history, including drug history • Any known allergy • 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 what action taken • Any referral arrangements • The consent of the individual • If individual is under 16 years of age document competency using Fraser guidelines • If individual is under 13 years of age record action taken. • Record the name of the medication, number of packs supplied e.g. Levonelle 1500® x 1 with batch number and expiry date. • Record any signposting/referral arrangements • Signature of the pharmacist who supplied the medication (follow local procedures for computer records)

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REFERENCES	• Faculty of Sexual and Reproductive Healthcare (2012) Emergency Contraception. Clinical Effectiveness Unit http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • Faculty of Sexual and Reproductive Healthcare (2009) UK Medical Eligibility Criteria for Contraceptive Use; http://www.fsrh.org/pdfs/UKMEC2009.pdf • Faculty of Sexual and Reproductive Healthcare(2011) Drug interactions with hormonal contraception (updated January 2012) http://www.fsrh.org/pdfs/CEUGuidanceDrugInteractionsHormonal.pdf • Faculty of Sexual and Reproductive Healthcare (2010) Antiepileptic drugs and contraception: CEU statement January 2010 http://www.fsrh.org/pdfs/CEUStatementADC0110.pdf • Faculty of Sexual and Reproductive Healthcare (2010) CEU: Quick starting contraception http://www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf • Manufacturer's Summary of Product Characteristics (SPC) Levonelle 1500 microgram tablet. Last updated 27/11/2012 http://www.medicines.org.uk/EMC/medicine/16887/SPC/Levonelle+1500+microgram+tablet/- • Manufacturer's Summary of Product Characteristics (SPC) Levonelle one-step Last updated 11.11.2010 http://www.medicines.org.uk/EMC/medicine/15227/SPC/Levonelle+One+Step/ • British National Formulary Number 64 British Medical Association and Royal Pharmaceutical Society of Great Britain; London: Year 2012 http://www.bnf.org/bnf/index.htm • General Pharmaceutical Council Standards of Ethics Conduct and Performance http://www.pharmacyregulation.org/standards/conduct-ethics-and-performance • The Pharmaceutical Society of Northern Ireland (PSNI) http://www.psni.org.uk/consumers/code-of-ethics/code-of-ethics.php • National Prescribing Centre; Patient Group Directions 2009 http://www.npc.co.uk/non_medical/resources/patient_group_directions.pdf • Competency and Training Framework defined by North West Pharmacy Workforce Harmonisation and Accreditation Group (HAG) for the provision of emergency hormonal

	contraception http://www.pharmacyworkforcenw.nhs.uk/?page=143

STAFF CHARACTERISTICS	
The pharmacist authorised to supply and/or administer medications under the PGD must meet the following criteria:	**BEFORE WORKING TO THIS PGD, THE PHARMACIST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION.** **Qualifications** • Pharmacists must be registered with the General Pharmaceutical Council or Pharmaceutical Society of Northern Ireland **Specialist qualifications and competencies** • Meets the requirements set out in the Competency and Training Framework for the provision of Emergency Hormonal Contraception defined by the Harmonisation of Accreditation Group in NHS North West. (CTF EHC) • http://www.pharmacyworkforcenw.nhs.uk/?page=143 **Maintenance of competencies** • The pharmacist should ensure she/he is aware of any changes to the recommendations for this medication. It is the responsibility of the pharmacist to keep up-to-date with continuing professional development and take part in audit on a regular basis

An up to date list and signatures of registered practitioners who are authorised to practice under this PGD is kept in London Boroughs of Camden and Islington by the Sexual Health Commissioner.

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

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NHS LONDON SEXUAL HEALTH PROGRAMME

Date PGD comes into effect:	20.2.2013
Review date	30.11.2014 or earlier in the light of significant changes in best practice
Expiry date:	28.2.2015

Peer reviewed and ratified by NHS London Sexual Health Programme PGD Project Leads:

NAME/ROLE	POSITION	DATE
Kathy French Project Manager	Nurse Advisor –London Sexual Health Programme (LSHP)	19.2.2013
Angela Bussey Project Advisor	Principal Pharmacist Medicines Information Projects. Guy's and St Thomas' NHS Foundation Trust.	19.2.2013
Lead Doctor Dr Sarah Pillai	Lead Associate Specialist, Contraceptive Health Service Barnet Central London Community Health NHS Trust	19.2.2013
Lead Pharmacist Sandra Wolper	Head of Pharmacy and Prescribing Hounslow and Richmond Community Healthcare NHS Trust	19.2.2013
Lead Nurse Sandra Bennett	Lead Nurse: Sexual and Reproductive Health Your Healthcare CIC Kingston	19.2.2013

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

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ORGANISATIONAL APPROVALS AND OTHER LEGAL REQUIREMENTS

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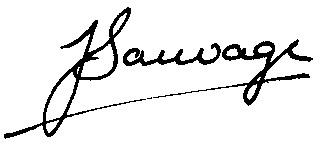
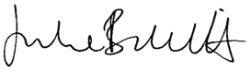
It is the responsibility of the NHS organisation and/or authorised Provider in which the PGD is to be used to ensure that all legal and governance requirements are met.

To ensure compliance with the law, organisations must add local authorisation details i.e. signatories on behalf of the clinical speciality and the organisation. Complete details below or use format agreed according to local policy.

Organisation Approvals	Signature	Date
Lead Pharmacist: Mr Amalin Dutt Head of Medicines Management, Islington CCG		1 April 2014
Medical Lead: Dr Josephine Sauvage GP and Vice-chair, Islington CCG		1 April 2014
Clinical Governance approval: Dr Julie Billett Director of Public Health, London Borough of Camden and London Borough of Islington.		1 April 2014

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 Standards of Ethics Conduct and Performance. 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.

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

ADDITIONAL INFORMATION

- Local training and competency assessment documentation.
- Service Level Agreement – please ensure you refer to this in conjunction with the PGD.

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This Patient Group Direction must be agreed to and the individual authorisation register signed by all pharmacists involved in its use. The CCG Head of Medicines Management should hold the original signed copy. The PGD must be easily accessible in the clinical setting.	
Organisations	London Borough of Camden London Borough of Islington Camden Clinical Commissioning Group Islington Clinical Commissioning Group

Authorisation. To be completed by the approved pharmacist:	
I have received, read and fully understand the following: • **The relevant Patient Group Direction** • **I have undertaken training which approved practitioners must undertake before being authorised to supply levonorgestrel 1.5mg under the relevant Patient Group Direction** • **I agree to act as an approved practitioner within the terms of the Patient Group Direction and to supply accordingly** • **I understand that by agreeing to act as an approved practitioner under Patient Group Directions I am adjusting my scope of professional practice**	
Name: **GPhC number:**	**Name of Pharmacy:** **Address of Pharmacy:**
Signature:	**Date:**