Patient Group Direction for the Supply of Levonorgestrel for Emergency Hormonal Contraception by Community Pharmacists

Approved by: Quality and Clinical Governance Committee

On: 20th March 2013

Expiry Date: March 2015

Directorate responsible for Review: Medical Directorate

PGD Number: LLRPGD045
Due Regard

The Trusts commitment to equality means that this PGD has been screened in relation to paying due regard to the general duty of the Equality Act 2010 to eliminate unlawful discrimination, harassment, victimisation; advance equality of opportunity and foster good relations.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

It is judged that it is not proportionate (equality relevant) in respect of this PGD as it specifically enables identified registered pharmacists to supply and administer medicines in accordance with national guidelines. Due regard has been given in respect of accessibility (larger print, Braille etc), including the provision of information or advice in an alternative language and consideration of patient carers and family members for support.
### Staff Characteristics

#### Qualifications
- Registered Pharmacist currently on the practicing section of the pharmaceutical register held by the General Pharmaceutical Council that have completed the required training for accreditation and competency

**ALL HEALTHCARE PROFESSIONALS MUST BE AUTHORISED BY NAME UNDER THIS DIRECTION BEFORE USING IT.**

#### Specialist competencies or qualifications
- The pharmacist must be competent to assess a client’s capacity to understand the nature and purpose of the treatment in order to give or refuse consent.
- Evidence of completion of training (CPPE or PCT online competence assessment) on the administration and supply of medicines under Patient Group Directions.
- Evidence of completion of an approved training package (e.g. CPPE online competence assessment) on EHC.
- Evidence of completion of training (CPPE competence assessment or PCT event) on safeguarding young people and child protection.
- Evidence of completion of locally provided training related to the provision of EHC as part of the pharmacy scheme for under 25’s in Leicester, Leicestershire and Rutland.

#### Continuing training & education
- The practitioner should be aware of any change to the recommendations for levonorgestrel. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.
- Training refresh on Safeguarding young people and child protection every 3 years.

### Referral Arrangements and Audit Trail

#### Additional Facilities and Referral Arrangements
The client must always be advised to talk to her GP or Family Planning Clinic, regardless of whether a supply is made. Where the circumstances are outside the PGD, or where there are medical concerns, or if the client wishes it, the client should be referred to a GP or specialist family planning clinic using the Client Referral Form.

#### Records/audit trail
Records should be made on the Client Record Sheet (Appendix 2) contain the following:
- Patient’s name, address, date of birth and consent given
- Date, time and number of doses administered
- Product name (brand), dose and form administered
- Batch and expiry details
- Advice given to patient or carer (including side effects)
- Signature/name of staff who administered or supplied the medication
- Details of any adverse drug reaction and actions taken including documentation in the patient’s medical record
• Referral arrangements (including self-care)
# Supply of Levonorgestrel for Emergency Hormonal Contraception

## Clinical Condition

<table>
<thead>
<tr>
<th>Indication</th>
<th>Women presenting in the community requesting access to progestogen only emergency contraception (POEC) services who, following appropriate assessment, are at risk of pregnancy because of unprotected sexual intercourse (UPSI)</th>
</tr>
</thead>
</table>
| Inclusion criteria | Emergency hormonal contraception within 72 hours of UPSI for:  
  - Women over 16 years of age and under 25 years of age  
  - Girls under 16 years of age who have been assessed as Fraser competent (see appendix 4)  
  - Client gives their consent to providing the relevant clinical information to the pharmacist after pharmacist has assessed their capacity to consent (see under Staff Characteristics; Client Record Sheet (appendix 2)) |
| Exclusion criteria |  
  - Clients under 16 years who are not considered to be Fraser competent  
  - Client is aged 12 years or under. The Child Protection Team must be contacted for children aged 12 years or under who present having had sexual intercourse  
  - Known hypersensitivity to levonorgestrel or any excipient of the preparation (potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc, lactose monohydrate)  
  - Clients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.  
  - Established pregnancy  
  - Client has had a baby in the last 3 weeks (EHC not required in these circumstances)  
  - Known porphyria  
  - Client taking Ciclosporin  
  - No valid consent obtained from client.  

Clients are excluded if they have had episodes of UPSI outside the current 72 hours.

## Cautions/Need for further advice

- Clients taking enzyme-inducing drugs (see Table 1 below), or within 28 days of stopping them, should be advised to consider intrauterine device (IUD) as preferred option, but may be offered a 3000 microgram dose of levonorgestrel (explain that this is not based on evidence but on expert clinical judgement of balance of risks and benefits; and that this is outside of product licence).
• Breastfeeding – Faculty of Sexual and Reproductive Healthcare Clinical Guidance recommends that women who are breastfeeding can use Progestogen Only Emergency Contraception without restriction. Unprotected sexual intercourse or contraceptive failure before day 21 postpartum is not an indication for emergency contraception (regardless of method of feeding).

• Repeated use within cycle (appendix 3 for further advice) – advise client that she may already be pregnant (may refer for pregnancy test as appropriate), and that repeated use disturbs menstrual cycle. Advise client to consider IUD as a preferred alternative. Levonorgestrel 1500 microgram will not interrupt a pregnancy. In the case of continued pregnancy, limited epidemiological data indicate no adverse effects on the foetus.

• If the request is due to an episode of vomiting which has occurred within 2 hours of taking the dose, a replacement supply may be issued, providing the dose remains within 72 hours of the episode of UPSI

Interactions

Reduced efficacy of Levonorgestrel (Levonelle 1500)

The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers, and these medications can reduce the efficacy of levonorgestrel. The following table highlights liver-enzyme inducing drugs and classes.

If unsure, consult Appendix 1 of the relevant section of the current British National Formulary, or the SPC for the product being used.

**Table 1. Drugs that induce liver enzymes.**

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-epileptics</td>
<td>Carbamazepine</td>
</tr>
<tr>
<td></td>
<td>Eslicarbazepine</td>
</tr>
<tr>
<td></td>
<td>Oxcarbazepine</td>
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<tr>
<td></td>
<td>Phenytoin</td>
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<tr>
<td></td>
<td>Phenobarbital</td>
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<tr>
<td></td>
<td>Primadone</td>
</tr>
<tr>
<td></td>
<td>Rufinamide</td>
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<td></td>
<td>Topiramate</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Rifampicin</td>
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<td></td>
<td>Rifabutin</td>
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<tr>
<td>Antiretrovirals</td>
<td>Protease inhibitors</td>
</tr>
<tr>
<td></td>
<td>Ritonavir</td>
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<tr>
<td></td>
<td>Amprenavir</td>
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<td></td>
<td>Atazanavir</td>
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<td></td>
<td>Nelfinavir</td>
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<td></td>
<td>Pinavir</td>
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<td></td>
<td>Saquinavir</td>
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<td></td>
<td>Tipranavir</td>
</tr>
<tr>
<td></td>
<td>Darunavir</td>
</tr>
<tr>
<td></td>
<td>Fosamprenavir</td>
</tr>
</tbody>
</table>
Lopinavir

Non-nucleoside reverse transcriptase inhibitors

Efavirenz

Nevirapine

Respiratory drugs

Bosentan

Central nervous system drugs

Modafinil

Aprepitant

Herbal preparations

St John’s wort

Data from: [FSHRH.CEU: Drug Interactions with Hormonal Contraception 2011 (Updated 2012)]

**Action if patient declines or is excluded**

- Clients excluded under this PGD are to be referred for further assessment to a registered medical practitioner (e.g., their own GP), the nearest accessible alternative sexual health service offering contraceptive services or to a family planning doctor/clinic. The advice given should be documented in the client’s record sheet (and Patient Medication Record if appropriate).

- If unprotected sex was within the last 5 days (120 hours) the client may be suitable for IUD (intrauterine device) insertion and referral should be made in a suitable timeframe to allow this to happen.

- Where care is declined by the client, document refusal in client’s clinical records.

- Ensure the client is signposted to different services in the area e.g. Family Planning Clinic/Community Sexual Health Clinic, general practitioner.

- Advise that they may register with any GP practice for contraceptive services.

- It is important to warn the client that a delay in starting treatment will compromise its efficacy.
## Supply of Levonorgestrel for Emergency Hormonal Contraception

### Drug Details

<table>
<thead>
<tr>
<th>Name, form &amp; strength of medicine</th>
<th>Levonorgestrel 1500 micrograms tablet (Levonelle® 1500)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route/Method</td>
<td>Oral</td>
</tr>
</tbody>
</table>
| Dosage                          | One 1500 microgram tablet should be taken as soon as possible, preferably within 12 hours, and no later than 72 hours after UPSI.

If the client is using liver enzyme-inducing medication (see interacting medicines), or within 28 days of stopping them, then TWO tablets of levonorgestrel 1500 micrograms should be taken as the single dose (total dose 3000 micrograms levonorgestrel). Client must be advised that this is an unlicensed indication for levonorgestrel not included in the Summary of Product Characteristics (SPC) and is not evidence-based, but is based on expert family planning specialist recommendation on balance of risks and benefits. Client must give consent to use outside of product licence.

*The client should be encouraged to take the dose whilst in the pharmacy.*

<table>
<thead>
<tr>
<th>Frequency</th>
<th>May be given within the 72 hour timeframe on each occasion, for more than one episode of UPSI within a cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td>A replacement dose of 1500 micrograms can be provided under this PGD as soon as possible (within the 72 hour post UPSI timeframe) if the client has vomited the first dose within 2 hours (NB this is different to the recommendations in the SPC)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of treatment</th>
<th>Single dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum or minimum treatment period</td>
<td>Single dose per episode</td>
</tr>
<tr>
<td>Quantity to supply/administer</td>
<td>1 x 1500 microgram tablet – as a single dose</td>
</tr>
</tbody>
</table>

*If taking liver-enzyme inducing drugs*

2 x 1500 microgram tablet (3000 microgram) – as a single dose if patient is also taking a liver-enzyme inducing drug or within 28 days of stopping a liver enzyme inducing drug
### Side effects

Nausea; vomiting; breast tenderness; headache; dizziness; fatigue.

Temporary disturbance of menstrual bleeding pattern. If the next menstrual bleed is more than 5 days overdue, pregnancy should be excluded (by taking a pregnancy test).

Use the Yellow Card System to report serious adverse drug reactions (ADRs) directly to the Commission on Human Medicines. Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF. Report all significant ADRs to patient’s own GP.

Report all ADRs that occur in young people under 18 years.

### Advice to patient/carer

- Refer to BNF and SPC information
- Advise client to read Manufacturer’s Patient Information Leaflet
- If vomiting occurs within 2 hours of taking the tablet, client should return to pharmacy for replacement supply or seek medical assistance.
- Advise client to read Patient Information Sheet (appendix 1)
- Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have already occurred. Treatment with Levonorgestrel 1500 microgram following the second act of intercourse may therefore be ineffective in preventing pregnancy.
- Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time.
- To seek further medical advice if the subsequent menstrual cycle bleed is abnormal or later than 5 days after the expected date, to exclude pregnancy
- To seek urgent medical advice if experience abdominal pain or irregular bleeding in next few weeks
- After using emergency contraception it is recommended to use a barrier method (e.g. condom, diaphragm or cap) until the next menstrual period starts. Continue to use regular hormonal contraception.
- Advise client taking liver enzyme inducing drug that Intrauterine device (IUD) is the recommended option for emergency contraception
- Repeated administration within a menstrual cycle may lead to disturbance of the cycle, and associated increased risk of failure
as emergency contraception

- Levonorgestrel 1500 microgram is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure. Clients who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception.

- Use of emergency contraception does not replace taking precautions against sexually transmitted diseases.

- Clients under 16 years must be offered the opportunity to seek parental consent, although not giving will not exclude them from supply.

**Follow up**

<p>| Follow up | None required |</p>
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nick Hunter</td>
<td>Independent Community Pharmacist Consultant</td>
<td>February 2013</td>
</tr>
<tr>
<td>Margaret Warrington</td>
<td>Specialist Nurse ‘Choices’ Young People’s Contraceptive &amp; Sexual Health Services</td>
<td>February 2013</td>
</tr>
</tbody>
</table>
This patient group direction must be agreed to and signed by all health care professionals involved in its use. NHSLLR will hold the original signed copy. The PGD must be easily accessible in the clinical setting.

## Authorisation

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Position</th>
<th>Signature</th>
<th>Date</th>
</tr>
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<tbody>
<tr>
<td><strong>Lead Doctor</strong></td>
<td>Professor Aly Rashid</td>
<td>Medical Director</td>
<td>[Signature]</td>
<td>2/3/13</td>
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<tr>
<td><strong>Lead Pharmacist</strong></td>
<td>Susanna Taylor</td>
<td>Associate Director Medicines Management</td>
<td>[Signature]</td>
<td>3/3/13</td>
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<tr>
<td><strong>Lead Nurse</strong></td>
<td>Maggie Boyd</td>
<td>Director of Nursing</td>
<td>[Signature]</td>
<td>14/3/13</td>
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<tr>
<td><strong>Quality Lead</strong></td>
<td>Liz Rowbotham</td>
<td>Chair of Quality and Clinical Governance Committee</td>
<td>[Signature]</td>
<td>15/3/13</td>
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<tr>
<td><strong>Approved by Quality and Clinical Governance Committee</strong></td>
<td>David Mell</td>
<td>Chair of Quality and Clinical Governance Committee</td>
<td>[Signature]</td>
<td>15/3/13</td>
</tr>
<tr>
<td><strong>Organisational Approval by</strong></td>
<td>Liz Rowbotham</td>
<td>Director of Transition</td>
<td>[Signature]</td>
<td>15/3/13</td>
</tr>
</tbody>
</table>

This PGD is approved for use within the area covered by NHS Leicester City PCT and Leicestershire County and Rutland PCT.

## References

*PGD based on PP004.*

1. Faculty of Sexual Health and Reproductive Healthcare Clinical Guidance from CEU: Drug Interactions with Hormonal Contraception January 2011 (Updated January 2012).

2. Faculty of Sexual Health and Reproductive Healthcare Clinical Guidance from CEU: Emergency Contraception August 2011 (Updated January 2012)

3. Faculty of Sexual Health and Reproductive Healthcare Clinical Guidance from CEU: Postnatal Sexual and Reproductive Health September 2009


Individual Authorisation

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 their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. Pharmacists should initial appropriate PGDs individually and then sign beneath the list of PGDs on the signature sheet below. Each pharmacist should have their own copy of this document.
I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

<table>
<thead>
<tr>
<th>Name of Professional</th>
<th>Signature</th>
<th>Authorising Manager</th>
<th>Date</th>
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</table>
Appendix 1

Patient Information Leaflet

Patient Leaflet – Progestogen – Only Emergency Contraception – Levonelle® 1500

Please read this information, and the information provided with your medication, carefully and don’t hesitate to speak to the pharmacist if you have any questions. If you have any serious medical problems please discuss them with the pharmacist, to ensure emergency contraception is safe for you.

1. How to take the pills

You have been given one tablet (Levonelle 1500®). Please take this now.

2. What to do if you feel sick

If you are sick (vomit) within two hours of taking the tablet, please contact the pharmacy you initially visited as soon as possible for a further supply (within the original 72 hours timeframe). If the pharmacy you originally visited is not open, you may go to another pharmacy offering the scheme and explain the circumstances for a replacement supply.

If this is not possible you should seek alternative medical advice (GP practice, family planning clinic, walk-in centre) urgently.

3. What happens next?

Your next period may arrive earlier, on time or later than usual. It can also be lighter or heavier than normal. If your period is shorter or later than normal request a pregnancy test from one of the pharmacists in the scheme, GP or Family Planning Centre.

If you experience abdominal pain or irregular bleeding in the next few weeks, please seek urgent medical advice.

Emergency hormonal contraception is very successful. Having an IUD (coil) fitted by GP or family planning clinic within 5 days of unprotected sex has an even higher success rate. If you do become pregnant despite taking Levonelle 1500®, there is no evidence that it will harm the pregnancy.

4. Future Contraception

The next time you have sexual intercourse you should use condoms in addition to your usual method.

If you are taking the pill, continue to take it, but also use condoms for the next 7 days.

If you are planning to start the pill you may start it on the first day of your next period / withdrawal bleed subsequent to Levonelle® 1500

WARNING

Emergency contraception does not protect against sexually transmitted infections, however condoms reduce the risk.
Appendix 2

Leicestershire County and Rutland

COMMUNITY PHARMACY EMERGENCY CONTRACEPTION SCHEME

Client Record Sheet for supply of Levonelle®-1500 – To be used in conjunction with the approved PGD.

This form has to be completed to ascertain whether you can be supplied with Emergency Hormonal Contraception (EHC).

Client Background Details:

Client name ........................................... Address: .................................................................

Date of Birth......................... ................. ................. Postcode: ..................

Reason for Request of EHC: (circle that which applies)

No Contraception/ Split Condom/ Missed Pills/ Vomited Levonelle®1500 – dose/ Other (specify)..............................

Ethnic Category: Please request client complete on a voluntary basis (circle that which applies)

White / Mixed/ Asian or Asian British/ Black or Black British/ Other ethnic group/ Not Stated

Client History:

What day of your cycle are you? ....................

What is the Client's current regular method of contraception? (Circle that which applies)

Condom/ Pill / IUD/ None/ Other (specify)..........................

If not on the pill, length of normal menstrual cycle (days)?_______ Usual  Irregular?

If missed pills, give details..........................................................

Has the client had Levonelle®1500 since the LMP?  Yes/ No

CRITERIA FOR INCLUSION – (all answers must be ‘YES’)

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has unprotected sexual intercourse (UPSI) occurred within the previous 72 hours</td>
<td></td>
</tr>
<tr>
<td>Where a client has vomited the dose of Levonelle®-1500, then it must also be confirmed that this occurred within 2 hours of ingestion.</td>
<td></td>
</tr>
<tr>
<td>Have all options for Emergency Contraception been explained and the client prefers hormonal method.</td>
<td></td>
</tr>
</tbody>
</table>
### CRITERIA FOR EXCLUSION

*for supply all answers should be ‘NO’*

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did UPSI occur more than 72 hours ago?</td>
<td>If yes, refer, IUD may be appropriate</td>
</tr>
<tr>
<td>Has the client previously used any other form of Emergency Contraception in this cycle? (Appendix 3 for further advice)</td>
<td>If yes, consider referral for IUD. OR EHC may be given within the 72 hour time limit (appendix 3)</td>
</tr>
<tr>
<td>Is it possible from the menstrual / sexual history that the client may be pregnant?</td>
<td>Is the period late? Was the LMP lighter or shorter than normal or unusual in any way? Since the LMP has the client had UPSI at any other time? Refer to FP Clinic or GP for advice.</td>
</tr>
<tr>
<td>Is the client allergic to any of the ingredients of Levonelle®-1500?</td>
<td>If yes, refer, IUD may be appropriate</td>
</tr>
<tr>
<td>Does the client have hereditary galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption?</td>
<td>If yes, refer, IUD may be appropriate</td>
</tr>
<tr>
<td>Is the client taking an enzyme inducing drug now, or has done so in the last 28 days?</td>
<td>If yes, consider refer for IUD If EHC given, then TWO tablets are required</td>
</tr>
<tr>
<td>Is the client taking ciclosporin?</td>
<td>If yes, refer, to GP or other medical advice dependent upon setting</td>
</tr>
<tr>
<td>Does the client have porphyria?</td>
<td>If yes, refer, to GP or other medical advice</td>
</tr>
<tr>
<td>Has the client had a baby in the past 3 weeks</td>
<td>EHC is not required in these circumstances</td>
</tr>
<tr>
<td>Does the client wish to consult a doctor?</td>
<td>If yes, refer to GP or other medical advice</td>
</tr>
</tbody>
</table>
If under 16 years old, assessment of “compliance to Fraser Guidelines”

An under 16 year old may give a valid consent to treatment if they have sufficient understanding to enable them to comprehend fully the proposed treatment, i.e. she has made a free choice from all the available options, she has gone through a rational decision process and she can understand and tell you about the side effects, failure rates and what to do if treatment fails.

<table>
<thead>
<tr>
<th>Criteria for competence (for supply all answers must be ‘yes’)</th>
<th>YES</th>
<th>NO*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the client understand the advice that she has been given?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you advised and encouraged her to discuss the situation with her parent/guardian?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is her physical and/or mental health likely to suffer unless she receives emergency contraceptive treatment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the treatment in the client’s best interests without parental consent?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* If the answer to any of the above questions is No, the client must be referred to her GP or Family Planning Clinic as a matter of priority so that treatment may still take place within the necessary timeframe.

Detail here any additional information relevant to your decision to supply EHC to this young person.

Counselling  

Tick to indicate you have covered the following

<table>
<thead>
<tr>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness including failure rate discussed.</td>
</tr>
<tr>
<td>Side effects discussed.</td>
</tr>
<tr>
<td>Possible effects on the foetus discussed.</td>
</tr>
<tr>
<td>Medication taken on the premises?</td>
</tr>
<tr>
<td>Follow up discussed.</td>
</tr>
<tr>
<td>Future contraception discussed, including where services located.</td>
</tr>
<tr>
<td>Patient instruction leaflet issued?</td>
</tr>
</tbody>
</table>
**Action Taken:**

Supply of Levonelle® - 1500: YES /NO

**If not supplied:** onward referral made to (please state).…………………………………………………………………………………

Record batch number of Levonelle® - 1500 supply: …………………………………Expiry date:…………………………

Details of referral………………………………………………………………………………………………………………………………………

Any adverse drug reactions? YES /NO

Action taken as a result of reaction:……………………………………………………………………………………………………

Any additional advice given: ………………………………………………………………………………………………………

Copy of this document given to the GP for information YES/ NO

The information is correct to the best of my knowledge. I have been counselled on the use of emergency contraception and understand the advice given to me

I consent to a copy of this document being given to my GP for information. Yes/No

Client’s Signature: …………………………………….. Date: ………………………………………

The stated action was based on the information given to me by the client, which is correct to the best of my knowledge.

Issued By: Name: ________________________________

PHARMACY STAMP Signature:______________________________

Date:______________________________
Appendix 3 - Additional Guidance for Pharmacists

1. Repeat Supply within the Same Cycle:

   - **Vomited Tablets**
     If the dose of Levonelle®-1500 has been vomited within 2 hours of ingestion, the dose may be repeated if it can still be taken within 72 hours of the unprotected intercourse. A further supply should be provided and the client advised to take the replacement. Anti-emetics may be advised and the tablet should be taken with food.

     If the replacement dose would be later than 72 hours after the unprotected intercourse, referral to a GP or Family Planning Doctor is indicated.

   - **Exceptional Circumstances**
     Clients who have already received a supply of Levonelle®-1500 for a previous episode of UPSI in the current cycle should normally be referred to a doctor for any subsequent supply unless access within the 72 hour limit is considered to be impracticable.

2. Recommendations for missed pills and the use of EHC with potential failures of combined oral contraceptives (COC)

   *Reference: Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit: Missed Pill Recommendations (May 2011).*

   **NB. This advice may differ from that printed in patient information leaflets included with oral contraceptives, however is the updated guidance from the reference above.**

   Whenever a woman realises that she has missed pills the essential advice is to take the next pill as soon as she remembers and then try to resume her usual pill-taking schedule (this may mean taking 2 pills in one day). The essential advice is “just keep going”.

   If you have missed **one pill**, anywhere in the pack:
   - Take the last pill you missed now even if it means taking two pills in one day
   - Continue taking the rest of the pack as usual
   - No additional contraception needed
   - Take your 7-day break as normal.

   If you have missed **two or more pills (i.e. more than 48 hours late)**, anywhere in the pack:
   - Take the last pill you missed now even if it means taking two pills in one day
   - Leave any earlier missed pills
   - Continue taking the rest of the pack as usual and use an extra method of contraception for the next 7 days
   - You may need emergency contraception
   - You may need to start the next pack of pills without a break.
Assessing when to give EHC:

<table>
<thead>
<tr>
<th>If ONE pill has been missed (&gt;24 hours and &lt; 48 hours late)</th>
<th>If TWO or more pills have been missed (&gt; 48 hours late)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHC not usually required, but may be considered if pills have been missed earlier in the packet or the in last week of the previous packet.</td>
<td>Pills missed in first week (Pills 1-7) Pills missed in second week (Pills 8-14) Pills missed in third week (Pills 15-21)</td>
</tr>
<tr>
<td>EHC Should be considered if unprotected sex occurred</td>
<td>No indication for EHC if pills in preceding 7 days have been taken consistently and correctly</td>
</tr>
<tr>
<td></td>
<td>OMIT pill-free interval and start new pack next day</td>
</tr>
</tbody>
</table>

Starting the next pack after missing two or more pills (more than 48 hours late)

If Seven or more pills are left in the pack after the last missed pill
- Finish the pack
- Have usual 7-day break.

If less than Seven pills in the pack after the last missed pill
- Finish the pack and start new one the next day (i.e. no break between packs)

3. **Use of Contraception after taking Levonelle® 1500**

Use of a barrier method should be recommended (e.g. condom) until the next menstrual period starts.

If using the Pill the woman should continue taking tablets as normal, using additional protection (barrier) for 7 days. If there are less than seven pills remaining in the packet, the woman should continue with the next pack omitting the seven-day break or placebo tablets, if taking ED pills.
Appendix 4 - Fraser Competence – Clients Under 16 Years

The Gillick ruling in 1985 established the current legal position in England and Wales, which states that people under the age of sixteen are legally able to consent on their own behalf to medical or dental procedures or treatment.

In considering the provision of advice or treatment on contraception, doctors and other professional staff need to take special care not to undermine parental responsibility and family stability. The doctor or health professional should therefore, always seek to persuade the young person to tell their parents or guardian (or other person in loco parentis) or to let the doctor inform them, that contraceptive advice is being sought and the nature of any advice or treatment that is given.

Exceptionally there will be cases where it is not possible to persuade the young person either to inform the parents or to allow the health professional to do so. In such cases, a doctor or other health professional would be justified in giving advice and treatment without parental knowledge or consent provided that the doctor or other health professional was satisfied that the Fraser Guidelines (often referred to as Gillick Competence) were met:

The Fraser Guidelines
1. The young person can understand the advice and has sufficient maturity to understand what is involved in terms of moral, social and emotional implications.
2. The young person cannot be persuaded to involve the parents, nor will they allow notification to the parent that contraceptive advice was being sought.
3. The young person will be very likely to begin or continue to have sexual intercourse with or without contraceptive treatment.
4. Without contraceptive advice or treatment the young person’s physical and/or emotional health will be likely to suffer.
5. The young person’s best interests require the health professional to give contraceptive advice and/or treatment without parental consent

Source: The Fraser Ruling: Gillick v West Norfolk and Wisbech Area Health Authority (1985)

The Fraser guidelines in practice
If a client is believed to be under the age of sixteen, the pharmacist should:
1. Assess the maturity of the client in terms of understanding any advice given.
2. Encourage the client to involve her parents.
3. Consider the effect on the physical or mental health of the client if advice or treatment is withheld.
4. Make a decision as to whether the client's best interests require the provision of contraceptive advice or supplies or both without parental consent

Where the pharmacist does not consider a young person meets the Fraser guidelines a supply of Levonelle®-1500 may not be provided. The pharmacist should recommend (and assist where necessary) the client to attend their GP or a Family Planning Clinic.