BEST PRACTICE GUIDELINES FOR THE SUPPLY BY PHARMACISTS OF THE EMERGENCY CONTRACEPTIVE PILL (ECP)

Levonorgestrel is classified as a restricted medicine when: *"in medicines for use as emergency post-coital contraception when in packs containing not more than 1.5 milligrams except when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health".* Outside of this use as emergency contraception by pharmacists and appropriately recognised nurses, levonorgestrel remains as a prescription medicine.

The Pharmacy Council has prescribed standards for the supply of the ECP by pharmacists. To comply with ECP Standard 1, pharmacists may not sell the ECP without prescription unless they have successfully completed an education programme accredited by the Pharmacy Council and become accredited providers of emergency hormonal contraception.

The following Pharmaceutical Society best practice guidelines provide explanatory notes on aspects of the standards that pharmacists must meet in order to supply the ECP appropriately. In addition, they outline:

- key points that a pharmacist must consider before supplying the ECP,
- the advice that should be given when a decision to supply has been made, and
- general information about the product.

STANDARDS FOR THE SUPPLY BY PHARMACISTS OF THE EMERGENCY CONTRACEPTIVE PILL

The Charge Pharmacist of a pharmacy which provides a service for the supply of the Emergency Contraceptive Pill must ensure that the following standards are observed when the supply of emergency hormonal contraception as a restricted medicine is made by an accredited pharmacist.

ECP Standard 1

The Emergency Contraceptive Pill (ECP) must be supplied only by pharmacists who have become accredited providers of emergency hormonal contraception after completing successfully an education programme accredited by the Pharmacy Council of New Zealand.

A sign indicating the availability of the ECP from that pharmacy, and the availability of an advisory service from an accredited pharmacist, may be displayed, with an invitation for women wanting to purchase the ECP to ask the accredited pharmacist for assistance. Where the accredited pharmacist is absent from the pharmacy, women seeking the ECP must be referred to a doctor, a family planning, or sexual health, clinic or to another pharmacy in which an accredited pharmacist is present.

ECP Standard 2

Requests for emergency contraception must be received sensitively, with due regard for the woman's right to privacy and confidentiality. In all cases, the woman must be offered the opportunity for the consultation to be conducted in a private area.

Given the nature of emergency contraception and the many issues around why women might require it, pharmacists must ensure the consultation is undertaken in a private and non-judgmental manner. The seeking of information and the provision of advice is best conducted in a private area and this must always be offered. Pharmacy staff must also be trained to handle requests for the ECP in a confidential and sensitive manner, and to immediately refer the woman to an accredited pharmacist.

ECP Standard 3

The pharmacist must attend to the request personally and assess whether to supply the medicine or refer the woman to an appropriate health care professional.

The pharmacist must obtain sufficient information from the woman to assess whether or not it is appropriate to supply the ECP, or refer her to another health care professional. While only pharmacists who have been accredited by the Council can supply the ECP, it is important for all other staff in the pharmacy to be aware of the key issues regarding supply. This ensures they are able to respond to inquiries sensitively and appropriately, and refer the woman to the pharmacist as soon as the nature of the inquiry is recognised.

ECP Standard 4

The pharmacist must ensure that all necessary advice and information is provided in an appropriate manner to enhance the woman's understanding, and to enable her to make an informed choice and give consent to the supply of the medicine.

As part of the assessment undertaken for compliance with standard 3, and relevant to the provision to the woman of advice and information (as required by standard 4, by obligation 2.4 of the Code of Ethics for Pharmacists, and by rights 5 and 6 of the Code of Health and Disability Services Consumers'

Rights), the pharmacist must assess the woman's competence and ensure that the information and advice provided is understood by the woman, so that she can make an informed choice and give consent to the supply of the medicine. In assessing the woman's competence, account must be taken of her age, level of functioning, language and other communication abilities.

ECP Standard 5

The pharmacist must supply the ECP directly to the woman herself, unless exceptional circumstances apply.

Because of the need for informed consent, and given the nature of the information to be sought from a woman before deciding on the appropriateness of supply, and provided at the time of supply, the ECP should be supplied directly to the woman. Supply to a third party should be in exceptional circumstances only. The pharmacist would need to be satisfied that particular circumstances are exceptional. This might include situations where the woman is housebound through illness or disability, or where cultural reasons prevent the woman attending the pharmacy. In such cases, the pharmacist must be satisfied that the other criteria for supply, as provided in these practice guidelines, are met. Contact with the woman, for example by telephone, is important for establishing this, and for confirming consent.

ECP Standard 6

The pharmacist must record the sale of ECP as a dispensed medicine.

Pharmacists are expected to treat the supply of the ECP akin to pharmacist-prescribing and a record of the supply must therefore be kept - for example in the dispensary computer. The record must include the name of the medicine, the quantity and date supplied, and the pharmacist's name. Also, it must include a unique prescription number, and the name and address of the woman (except when she does not wish to have her personal details recorded). Clinical details of note, and confirmation that the pharmacist has followed the standards and best practice guidelines and that the woman has consented to its supply, also should be added to the record as an aid memoir for the pharmacist.

While the name and address of the woman for whom supply is being made should be recorded, where she wishes to withhold those details, this would not be grounds for refusing to supply - in spite of it being a pharmacist-only medicine which requires the name of the purchaser to be recorded. However, pharmacists are expected to explain the importance of recording such information, confirm its confidentiality, and encourage the woman to provide her personal details.

ECP Standard 7

The pharmacist must label the medicine with its name, directions for use, date of supply, the name of the woman for whom the medicine is intended (unless she wishes that information not to be recorded), a prescription number, and the name and address of the pharmacy.

Where the woman does not wish to be identifiable, the label will not include name, however, this must be the exception, rather than the rule.

ECP Standard 8

The pharmacist must make reasonable efforts to inform the woman about the limitations of the ECP as an ongoing method of contraception, and where appropriate provide information about regular methods of contraception, sexual health matters and disease prevention, and advise her where to obtain further information.

Women must be informed that the ECP is not an effective method of contraception on a long-term on- going basis, and that it will not provide protection against pregnancy associated with other episodes of unprotected sexual intercourse; nor against sexually transmissible infections. For further advice on these matters women should be referred to a doctor, family planning service or sexual health clinic.

ECP Standard 9

The pharmacist must advise the woman to seek from a doctor or family planning clinic further advice if her next period is lighter than usual, late or different in any way, or if any other unusual bleeding or lower abdominal pain occurs.

The woman should be advised that the ECP is not 100% effective and that she should seek further advice if her next period is light, late by more than 5 days or unusual in any way. This is to establish whether or not she is pregnant - and if she is, to ensure the pregnancy is not ectopic, and to screen for sexually transmissible infections.

POINTS TO CONSIDER BEFORE SUPPLYING ECP

1. IS THE WOMAN AT RISK OF PREGNANCY BECAUSE OF UNPROTECTED SEXUAL INTERCOURSE IN THE LAST 72 HOURS?

Levonorgestrel is effective when used within 72 hours of unprotected sexual intercourse (including contraceptive failure or missed contraceptive pills). Where contraception is compromised because of missed pills or reduced pill efficacy, the need for ECP depends on the point in the pill-taking cycle at which these events have occurred. See points 3 and 4 in the section on *General ECP Information*.

2. IS THE ECP REQUEST FOR SUPPLY FOR FUTURE USE?

ECP is not a substitute for regular contraception and supply in advance of need should not be made on this basis. However, for some women having the ECP on hand in case of emergency is important and supply for future use is legitimate. In such situations the pharmacist must ensure that accompanying the product is written information to which the woman can refer at the time the medicine is required for use.

Women, who on previous occasions have experienced vomiting from taking the progestogen-only ECP, may request supply of an additional pack and this would not be unreasonable for the pharmacist to consider.

3. IS SUPPLY DIRECT TO THE WOMAN PRESENT IN THE PHARMACY?

The pharmacist must give the medicine directly to the woman, except in exceptional circumstances (such as when the woman is housebound or cultural reasons prevent a woman from attending a pharmacy). In such cases, contact with the woman, for example by telephone, is important to check that treatment is appropriate, to provide advice and obtain consent.

4. ARE YOU SATISFIED THAT THE WOMAN IS COMPETENT TO MAKE AN INFORMED CHOICE AND TO GIVE CONSENT?

The pharmacist must assess the woman's competence and, in a manner that she understands, obtain from her information and provide to her advice and information relevant to the supply of the ECP. Only then can the pharmacist be assured that the woman is making an informed choice in consenting to the supply. Obtaining the woman's signed informed consent is an option for pharmacists to consider, but is not a requirement.

Provision of the ECP to a woman under the age of 16 years is possible providing the pharmacist is satisfied that there is compliance with the requirements for informed consent.

5. IS SUPPLY OF THE ECP NECESSARY?

Having obtained and assessed relevant information, the pharmacist may consider that there is no risk of pregnancy, and that emergency contraception is not necessary. However, if after discussion the woman still is concerned about pregnancy and wishes to purchase the ECP then, in the absence of any contraindications, there is no need to withhold supply on safety grounds.

6. COULD THE WOMAN BE PREGNANT ALREADY?

The ECP will not work if the woman is pregnant already, although it is not considered harmful to the foetus. To assess how likely it is that the woman might be pregnant, the following questions could be asked:

- Is your period late? How late?
- Was your last period lighter or shorter than normal? Was your last period unusual in any other way?
- At any time before this occasion and since your last period, have you had unprotected sexual intercourse?

If the woman answers 'yes' to any of these questions, then a referral, or a pregnancy test, should be recommended. [Refer to point 6 of the *General ECP Information* section] Supply of ECP could however be considered for a woman who, in addition to this current incident of unprotected sexual intercourse, has had within her current cycle previous incidents of unprotected intercourse since pregnancy may not have resulted from these, but could now. A postcoital copper IUD can be inserted to cover both previous unprotected intercourse in the same cycle and the current episode as long as it can be determined that implantation has not commenced yet.

7. IS THE WOMAN TAKING ANY OTHER MEDICATION?

Medicines and herbal remedies that induce liver enzymes can reduce blood levels of levonorgestrel and its efficacy. This interaction involves barbiturates and some other medicines used to treat epilepsy (e.g. topiramate, phenytoin and carbamazepine), rifampicin, rifabutin, ritonavir and St John's Wort. In such cases pharmacists should consider either recommending an increase (i.e. double) in dose of levonorgestrel, or referring the woman to her doctor or family planning clinic for advice, as emergency contraception options other than levonorgestrel may be more appropriate.

Levonorgestrel may increase the risk of ciclosporin toxicity and medical referral is advised for women taking ciclosporin.

8. DOES THE WOMAN HAVE A CONDITION THAT MIGHT AFFECT LEVONORGESTREL ABSORPTION?

Severe malabsorption syndromes, e.g. Crohn's disease, may impair the efficacy of levonorgestrel. While this does not preclude levonorgestrel use, in theory, severe malabsorption may interfere with emergency contraceptive pill efficacy. The hormone is absorbed in the small intestine, so that conditions such as Crohn's disease that affect the large intestine should not interfere with levonorgestrel emergency contraception.

A meta-analysis published in 2011 showed a more than 3-fold increased risk of pregnancy in women taking the levonorgestrel ECP who have a BMI greater than 30, compared to those with a BMI under 25. This suggests that in these women, taking the levonorgestrel ECP confers no advantage and it is considered prudent to offer a copper IUD, with its failure rate of less than 1% instead. A pharmacokinetic study has shown that an increase in time taken to achieve therapeutic concentrations of levonorgestrel in obesity may be a possible mechanism for this effect. At present there is no evidence to support increasing the dose of levonorgestrel in an attempt to compensate for this and this is not recommended.

If there are any concerns about efficacy of the ECP in an individual, the woman should be referred to a doctor or family planning clinic.

9. CONTRAINDICATIONS TO THE USE OF THE ECP

In considering the safety of ECP, a WHO review panel has determined that there are no evidence- based contraindications to the use of the ECP.

9.1. MEDICAL CONDITIONS THAT MIGHT PRECLUDE USE OF LEVONORGESTREL?

Medical conditions such as severe liver disease, severe hypertension, diabetes, stroke, heart disease and a past history of breast cancer are regarded as relative contraindications to the use of the ECP. However, the risks of pregnancy in all women, including those with pre-existing medical conditions, are likely to be greater than those associated with use so that the advantages of treatment generally outweigh theoretical or proven risks. Pharmacists still should discuss these issues with women requesting the ECP but its use is likely to be the best option where pregnancy from unprotected sexual intercourse is a possibility. Pharmacists who remain concerned about potential risks for women with these medical conditions should refer them to a doctor or family planning clinic. Women who have acute porphyria are better to consider a postcoital IUD, as they may experience severe abdominal pain after taking a levonorgestrel ECP.

9.2. HYPERSENSITIVITY AND ALLERGIC REACTION TO LEVONORGESTREL?

Hypersensitivity and allergic reaction to levonorgestrel, which is rare, is a contraindication to use of the ECP.

ADVICE THAT SHOULD BE GIVEN

1. HOW TO TAKE

There are two treatment regimens:
(i) For the "Postinor-1" pack that contains one tablet of levonorgestrel 1.5mg – the tablet must be taken as soon as possible (and no later than 72 hours) after unprotected sexual intercourse.
(ii) For the "Next Choice" pack that contains two tablets of levonorgestrel 750mcg, take both tablets at once, as soon as possible (and no later than 72 hours) after unprotected sexual intercourse.

2. SIDE EFFECTS

Around 25% of women taking levonorgestrel-containing ECP may feel nauseous and 5% may vomit. Taking the medicine with food may help to alleviate these side effects. Irregular bleeding and spotting may occur until the next period.

3. VOMITING

If vomiting occurs within three hours of taking an ECP dose, another tablet needs to be obtained as soon as possible and the same dose needs to be repeated.

If on a previous occasion after taking progestogen-only ECP the woman has vomited, prophylactic use of a non-prescription antiemetic could be considered. Prochlorperazine for nausea associated with emergency contraceptive use can be sold by pharmacists (and nurses) who are accredited to sell levonorgestrel for emergency contraception. Up to ten tablets of Buccastem® or Antinaus® may be supplied, with appropriate labelling and recording.

4. CONTINUED CONTRACEPTION
Women should be told that ECP will not provide continued protection against pregnancy for the remainder of the menstrual cycle, and be advised about other contraceptive measures – including recommending referral where appropriate.

A woman seeking ECP because she has missed one or more oral contraceptive pills should be advised to continue taking her pills as normal. Additionally, she should use a barrier method of contraception for the next seven days.

5. BREASTFEEDING
Small amounts of levonorgestrel can appear in breast milk. This is not considered to be harmful.

6. NEXT PERIOD
ECP will not bring on a period straight away but it can alter the timing of the next period. This may start a little early or a little late but if it is more than five days late then pregnancy is a possibility and further follow-up is necessary.

7. FOLLOW UP
The woman should be advised to see her doctor or family planning clinic for a pregnancy test if her next period is more than five days late or is unusual in any way, or for those taking an oral contraceptive, if there is no bleed in the pill-free interval.

8. SEXUALLY TRANSMISSIBLE INFECTIONS
The woman should be warned that ECP does not protect against sexually transmissible infections and medical referral may be necessary to screen for infections. For this purpose, a follow-up appointment with the doctor or family planning or sexual health clinic should be undertaken 2 to 3 weeks after taking the ECP.

GENERAL ECP INFORMATION

1. WHO MIGHT REQUEST ECP?
Women at risk of pregnancy because of unprotected sexual intercourse, contraceptive failure (e.g. split condom or dislodged IUD), or missed oral contraceptive pills, or women in whom conception is a serious risk because of treatment with potentially teratogenic agents. Some women will be seeking the ECP as a result of a non-consensual sexual incident (i.e. rape), or for incest.

2. WHEN IN THE CYCLE CAN ECP BE USED?
Levonorgestrel can be used at any time during the menstrual cycle, unless menstrual bleeding is overdue - indicating possible pregnancy in which case referral is recommended.

3. WHEN DOES MISSING PILLS LEAD TO RISK OF PREGNANCY?
For combined pills, the data-sheets state that a missed pill includes taking a pill more than 12 hours after the normal time. However, international research has shown that this advice is very conservative, and that contraceptive efficacy is only compromised when missing 2 pills in a row. The loss of efficacy also depends on which week of hormone pills is involved:

- Efficacy is compromised if two or more pills are missed from the first seven active tablets in a packet.
- If two or more pills are missed from the last seven active tablets in a packet, emergency contraception is not needed provided that the pill-free break is omitted.
- As long as the hormone pills in the first and last week have been taken correctly, there is no concern about missed pills in the middle week of the combined pill packet.

For progestogen-only pills, contraceptive efficacy is compromised for traditional pills such as Noriday® and Microlut® if one pill is taken more than 3 hours later than the normal time. For Cerazette®, contraceptive efficacy is compromised if one pill is taken more than 12 hours later than the normal time.

For both types of contraceptive pills, when pills have been missed, additional means of contraception, e.g. barrier methods, are required until effectiveness is re-established. For combined pills, this means for seven days following the missed pills, for progestogen-only pills, for two days, although for ovulation suppression with Cerazette®, seven days may be recommended.

4. HOW EFFECTIVE IS ECP?
Clinical trial data suggest that levonorgestrel ECP prevents 85% of expected pregnancies, resulting in pregnancy rates between 0.7% and 1.6% when the ECP is taken up to 72 hours from the episode of unprotected intercourse.
There is evidence that heavier women experience higher failure rates after taking levonorgestrel ECP, such that for women with a BMI of 30 or more, failure rates are similar to those for women who have not taken an ECP. If there is significant risk of conception, these women should be advised to obtain a post-coital IUD.

5. HOW DOES IT WORK?
Depending on when it is taken in the menstrual cycle, ECP is thought to work by delaying ovulation, interfering with sperm migration and therefore preventing fertilisation. There is no evidence of effect after fertilisation.

6. WHAT IF THE WOMAN IS PREGNANT ALREADY OR TREATMENT FAILS?
The questions asked before supply (see point 6 in the *Points to Consider Before Supplying ECP* section) are intended to establish if the woman is likely to be pregnant. ECP will not work if the woman is pregnant already and should not be given. However, if a woman does take ECP without knowing she is pregnant, or if the treatment fails and pregnancy occurs, she can be reassured that ECP does not appear to pose any risk to the pregnancy, or to have any adverse effects on the developing foetus.

7. CAN ECP BE USED MORE THAN ONCE IN A CYCLE?
If the ECP is used more than once in a menstrual cycle it can disturb the cycle. ECP is not as effective as conventional methods of contraception and is not recommended for regular use.

8. WHAT IF IT IS MORE THAN 72 HOURS SINCE UNPROTECTED SEXUAL INTERCOURSE?
A copper IUD, for use as emergency contraception, can be fitted by a doctor up to 5 days after ovulation.

ADDITIONAL INFORMATION

Only pharmacists who are accredited by the Pharmacy Council can supply the ECP without a prescription. It is pharmacists who are accredited, not pharmacies.

If an accredited pharmacist is not on site to undertake the consultation then the ECP cannot be supplied unless pursuant to a prescription.

Rather than a sale, supply of the ECP is akin to pharmacist prescribing with all the consultation and information requirements that apply. A record of the supply must be kept and the medicine labelled as if dispensed.

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These guidelines have been developed by the Pharmacy Council of New Zealand and the Pharmaceutical Society of New Zealand Inc., in consultation with Family Planning New Zealand.