Guidance for Pharmacists on the Safe Supply of Non-Prescription Levonorgestrel 1500mcg for Emergency Hormonal Contraception

Pharmaceutical Society of Ireland

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Updates made following the European Medicines Agency's review in 2016 are highlighted in grey

Contents

1. Introduction

Certain formulations of Levonorgestrel 1500mcg, when used as Emergency Hormonal Contraception, are licensed for supply by pharmacists to patients without a prescription.

This guidance sets out the issues to be considered by pharmacists in ensuring the safe supply of Levonorgestrel 1500mcg tablets to patients.

Pharmacists practice within a robust regulatory framework which requires that the practice by a pharmacist of his/her profession must be directed toward maintaining and improving the health, wellbeing, care and safety of patients. Pharmacists should use their professional skills, competence, and specialised knowledge, to encourage the rational and safe use of medicines. They are also required to provide a proper standard of care to those to whom they provide professional services.

The supply of non-prescription medicines by a pharmacist must also comply with regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) which states that, in relation to the sale or supply of any non-prescription medicine, a registered pharmacist must be satisfied that the purchaser is aware of the appropriate use of the medicine, that it is being sought for that purpose and that it is not intended for abuse and/or misuse.

Due to the nature of these medicines and associated patient counselling requirements, a private consultation between the pharmacist and the individual patient herself is required to determine the appropriateness of the supply and provide an opportunity to meet the appropriate patient counselling requirements. This consultation should take place in the pharmacy's patient consultation area.

2. Guidance

- The supply of Levonorgestrel 1500mcg tablets should only be made personally by a pharmacist following a structured, documented consultation with the patient. Each time this medicine is supplied the pharmacist must be satisfied that, in the exercise of his or her professional judgment, the supply of such a medicine is safe and appropriate for the individual patient.

- Consultations between the pharmacist and the patient should take place in the pharmacy's patient consultation area and due consideration must be given to the patient's right to privacy and confidentiality. All requests for this medicine should be handled sensitively.

- Levonorgestrel 1500mcg tablets should only be supplied and used in accordance with the terms of the specific product's marketing authorisation. Levonorgestrel 1500mcg tablets have been authorised as a non-prescription medicine for use as emergency contraception within 72 hours after unprotected sexual intercourse or in case of failure of a contraceptive method. For the products authorised in Ireland for this purpose, their individual Summary of Product Characteristics (SmPCs) are available for referral on the Health Products Regulatory Authority's (HPRA) website (www.hpra.ie).

- The current authorisations for Levonorgestrel 1500mcg tablets state that there is no age limit for patients using the product. Pharmacists should be aware that patients aged 16 years and over are entitled by law to give their own consent to medical treatment. Where a patient is under the age of 16 years it is usual that parental consent is sought. Pharmacists should also be aware that the age of sexual consent in Ireland is 17 years. Where appropriate, pharmacists need to assure themselves of the age of the patient. Having regard to the age and

circumstances of the individual patient, and any child protection issues arising, pharmacists should consider whether referral to a medical practitioner, other healthcare professional, or other agency or authority, is appropriate.

2.1 Clinical Considerations

In order to determine the appropriateness of the supply, the pharmacist should be familiar with the relevant information in the specific product's SmPC, including therapeutic indication, contraindications, special warnings, precautions for use and interactions. The pharmacist's consultation with the patient should include the following clinical considerations.

2.1.1 Therapeutic Indication and Efficacy

- The length of time since unprotected sexual intercourse or failure of a contraceptive method took place.
- The pharmacist should bear in mind, and discuss with the patient the fact that the efficacy of Levonorgestrel 1500mcg is higher the sooner after the unprotected intercourse the treatment is initiated. The tablet must be taken as soon as possible, preferably within 12 hours after the unprotected sexual intercourse, and no longer than 72 hours after unprotected sexual intercourse.
- Studies have indicated that blood Levonorgestrel levels are consistently reduced by concomitant use of liver enzyme inducers, mainly inducers of CYP3A4 enzymes. This reduction in plasma Levonorgestrel levels may reduce contraceptive efficacy of Levonorgestrel and lead to contraceptive failure. Examples of liver enzyme inducers are given in Section 2.1.4. Patients who have used liver enzyme inducers during the preceding 4 weeks should be advised to use a non-hormonal emergency contraceptive i.e. a copper intrauterine device which is not affected by liver enzyme inducers. If this is not an option for the patient or she is unable to see her doctor promptly, a doubling of the usual dose of Levonorgestrel from 1500mcg to 3000mcg is recommended to compensate for the reduction in blood Levonorgestrel levels.
- Patients should be informed that there is limited and inconclusive data on the effect of high body weight and high BMI on contraceptive efficacy of Levonorgestrel 1500mcg. Patients should be advised to take emergency contraception as soon as possible after sexual intercourse regardless of their BMI or body weight.
- If appropriate to the patient circumstances, the pharmacist should discuss with the patient that an alternative method of emergency contraception may be available upon referral to a medical practitioner.

2.1.2 Contraindications

- Levonorgestrel 1500mcg tablets are contraindicated for patients with hypersensitivity to Levonorgestrel or any of the excipients.

2.1.3 Special Warnings

- Levonorgestrel 1500mcg is not recommended for patients with a history of infection of the fallopian tubes (salpingitis), ectopic pregnancy or severe hepatic dysfunction.
- The efficacy of Levonorgestrel 1500mcg may be impaired by severe malabsorption syndromes, such as Crohn's disease.
- The possibility of a thromboembolic event should be considered in patients with pre-existing thromboembolic risk factor(s).
- Repeated administration within a menstrual cycle is not advisable.
- Many formulations of Levonorgestrel 1500mcg tablets contain lactose. Levonorgestrel 1500mcg should not be supplied to patients with the rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

2.1.4 Drug Interactions

- The metabolism of Levonorgestrel 1500mcg is enhanced by the concomitant use of liver enzyme inducers: anticonvulsants (phenobarbital, phenytoin, primidone, carbamazepine); rifabutin; rifampicin; griseofulvin; ritonavir, efavirenz or Hypericum perforatum (St. John's Wort), thereby, potentially reducing the medicine's efficacy.
- Concomitant use of ulipristal acetate and emergency contraception containing Levonorgestrel is not recommended.
- Other potential drug interactions with Levonorgestrel should be considered, e.g. anticoagulants and ciclosporin.

If after discussion of the above points the pharmacist is not satisfied that the supply of the product to the patient is appropriate, the pharmacist should refer the patient to another healthcare professional or service more appropriate to meet the patient's needs.

2.2 Patient Counselling

If the supply of Levonorgestrel 1500mcg to the patient is deemed appropriate by the pharmacist, patient counselling should include information and advice on the following:

- The correct dosage and use of the medicine, including the importance of taking it as soon as possible after unprotected sex.
- The actions to be taken if vomiting occurs within three hours of taking the medicine.
- The potential side effects, including the possibility of disruption to the menstrual cycle.
- No increased risk of side effects is expected for women taking liver enzyme inducers who take a double dose of Levonorgestrel. However, patients should be advised to report any side effects occurring with Levonorgestrel, including any thought to be associated with use of a double dose, to the pharmacist or directly to the HPRA preferably online via their website, www.hpra.ie.
- Using a barrier method of contraception until the next menstrual period.
- Appropriate steps to be taken if the next menstrual period is delayed by more than five days, if abnormal bleeding occurs at the expected date or the patient has symptoms of pregnancy.

- Patients taking liver enzyme inducers who have been advised to take a double dose of Levonorgestrel, should be advised to do a pregnancy test to exclude pregnancy, if their period does not come at the right time or they suspect they could be pregnant. If they are pregnant they should be advised to see a doctor as soon as possible as exposure during pregnancy of some enzyme inducing medicines has been associated with birth defects.
- That emergency hormonal contraception is an occasional method of contraception and should not replace a regular contraceptive method.
- How to take their current long-term contraception appropriately (the use of Levonorgestrel 1500mcg does not contraindicate the continuation of regular hormonal contraception).
- The contraceptive methods available if not currently using long-term contraception.
- Information on sexually transmitted infections.
- If a patient is currently breastfeeding, advice to stop nursing for at least 8 hours following administration.
- Remind the patient to read the product's patient information leaflet and contact the pharmacist if they require further advice, information or assistance.

The pharmacist should be familiar with the SmPC for the specific product supplied to the patient and consult the specific SmPCs for further information on the above points.

2.3 Patient Referral

The pharmacist should refer the patient to another healthcare professional, service or organisation if the pharmacist is not satisfied that the supply of the product to the patient is appropriate, or if the patient requires additional diagnosis, treatment, support or advice. This referral may be to a medical practitioner, family planning clinic, the HSE Crisis Pregnancy Programme, the Irish Family Planning Association, the Rape Crisis Centre or other counselling or support services. Contact details and information material for these services should be available within the pharmacy.

3. Code of Conduct for Pharmacists

The Code of Conduct for pharmacists requires that a pharmacist must always put the patient first and make their health, wellbeing and safety their primary focus. The Code also requires pharmacists to refer patients to an alternative provider if they cannot provide a professional service or medicinal product, ensuring that patient care is not jeopardised or compromised. If supply to a patient is likely to be affected by the personal moral standards of a pharmacist, he or she must inform their superintendent and supervising pharmacist, who must ensure that suitable policies and procedures are in place to ensure patient care is not jeopardised or compromised and the patient is facilitated in accessing the information or service required to meet their needs.

Pharmacists must provide honest, relevant, accurate, current and appropriate information to patients regarding the nature and benefit of medicines, health-related products and services provided by them.

Pharmacists should never abuse the position of trust which they hold in relation to a patient and in particular, they must respect a patient's rights, including their dignity, autonomy, and entitlements to confidentiality and information.

Pharmacists should be aware of important issues such as non-consensual intercourse, child protection and vulnerable adults.

4. Storage

Due to the nature of this medicine and the requirement for the pharmacist to personally carry out the supply, non-prescription medicines containing Levonorgestrel should not be accessible to the public for self-selection and should be stored in the dispensary under the direct control and supervision of the pharmacist.

5. Recording Supply

It is recommended that the supply of this medicine be appropriately recorded, for example in a patient consultation record or a Patient Medication Record (PMR), in line with good pharmacy practice. This recording should be made with the patient's full knowledge and consent, and patients must be assured of the confidentiality of such records. The management of any data or information recorded, collected or retained should be in accordance with relevant legislative provisions, including Data Protection legislation.

6. Pharmacovigilance

As with all medicines any suspected adverse reaction should be reported to the HPRA, preferably online, via their website www.hpra.ie.

7. Policies, Procedures and Training within a Pharmacy

Superintendent pharmacists must ensure that documented policies and procedures, which address the supply of Levonorgestrel 1500mcg tablets and the associated patient counselling by pharmacists, are in place in the pharmacies under their control. These documents should address all issues identified in this guidance and be reviewed and updated in line with further guidance or any further relevant information on this issue.

Superintendent and supervising pharmacists must ensure that there is adequate staff training in place to ensure compliance with all of these policies. All pharmacists providing the service should be trained in these policies and procedures. All other staff in the pharmacy should be familiar with the policies of the pharmacy and should be appropriately trained in the procedures relevant to their role.

Version Number	Date
1	February 2011
2	December 2013
3	January 2015
4	December 2016
5	April 2019
6	October 2019

8. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Are there documented policies and procedures relating to the supply of Levonorgestrel 1500mcg tablets available in the pharmacy?				
Are all relevant staff aware of, and trained in, the pharmacy's policies and procedures?				
Does the pharmacy policy include information around the circumstances under which the patient should be referred to another healthcare professional, service or organisation and are relevant contact details for these services readily available?				
Does the pharmacy policy address the relevant Code of Conduct issues?				
Does the pharmacy's policy around recording supply include statements on patient consent and data protection requirements?				
Are all pharmacists familiar with the SmPCs for specific formulations of Levonorgestrel 1500mcg tablets?				
Are copies of the relevant SmPCs readily available to all pharmacists in the pharmacy?				
Is a copy of the PSI's Guidance on the supply of Levonorgestrel 1500mcg tablets readily available to all pharmacists?				
Are all pharmacists aware that the patient consultation should take place in the pharmacy's patient consultation area to ensure patient privacy?				
Are all pharmacists aware of the patient counselling requirements for the supply of Levonorgestrel 1500mcg tablets and related sexual health matters?				
Are all non-prescription products containing Levonorgestrel stored in the dispensary under the direct control and supervision of the pharmacist?				
Are all pharmacists familiar with the procedure for reporting a suspected adverse reaction to the HPRA?				