SUPPLY BY PHARMACISTS OF A NON-PRESCRIPTION MEDICINAL PRODUCT CONTAINING LEVONORGESTREL (NORLEVO® 1.5MG TABLETS) AS EMERGENCY HORMONAL CONTRACEPTION

GUIDANCE FOR PHARMACISTS ON SAFE SUPPLY TO PATIENTS

(This guidance was revised in December 2013, for ease of reference the amended sections are highlighted in grey)

Introduction

The medicinal product Norlevo® 1.5 mg tablets (PA1166/2/1), used as Emergency Hormonal Contraception, can now be supplied by pharmacists to patients without a prescription.

This guidance sets out the issues to be considered by pharmacists in ensuring the safe supply of Norlevo® 1.5 mg tablets to patients.

Pharmacists practice within a robust regulatory framework that 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.

Guidance

1. Supply by a pharmacist of Norlevo® 1.5mg tablets

a) The supply of Norlevo® 1.5mg 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.

b) 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.

c) Norlevo® 1.5mg tablets should only be supplied and used in accordance with the terms of the product's marketing authorisation. Norlevo® 1.5mg 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. The Summary of Product Characteristics (SPC) for the product authorised in Ireland is available on the IMB website (www.imb.ie).

d) In the current authorisation for Norlevo® 1.5mg tablets 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.

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

- **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 is higher the sooner after the unprotected intercourse the treatment is initiated and 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.
  - Patients should be informed that that in clinical trials, contraceptive efficacy was reduced in women weighing 75kg or more (11 st, 11lbs), and that Norlevo® 1.5mg is not effective in women weighing more than 80kg (12 st, 8lbs).

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.

- **Contraindications:**

  - Norlevo® 1.5mg is contraindicated for patients with hypersensitivity to levonorgestrel or any of the excipients.

- **Special warnings:**

  - Norlevo® 1.5mg is not recommended for patients with a history of infection of the fallopian tubes (salpingitis), ectopic pregnancy or severe hepatic dysfunction.

  - The efficacy of Norlevo® 1.5mg 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.

  - Norlevo® 1.5mg should not be supplied to patients with the rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

- **Drug interactions:**

  - The metabolism of Norlevo® 1.5mg is enhanced by the concomitant use of liver enzyme inducers: anticonvulsants (phenobarbital, phenytoin, primidone, carbamazepine); rifabutin; rifampicin; griseofulvin; ritonavir or *Hypericum perforatum* (St. John's wort), thereby, potentially reducing the medicines efficacy.

  - The concomitant use of levonorgestrel and drugs containing ulipristal acetate 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.

f) If the supply of Norlevo® 1.5mg 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.
- Advice on using a barrier method of contraception until next menstrual period.
- Advice on 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.

- Advice that emergency hormonal contraception is an occasional method of contraception and should not replace a regular contraceptive method.
- Advice on taking their current long-term contraception appropriately (the use of Norlevo® 1.5mg does not contraindicate the continuation of regular hormonal contraception).
- Advice on 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.
- Advise 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 SPC for the medicine and consult the SPC for further information on the above points.

2. 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

Principle One of the Code of Conduct for pharmacists states that the practice by a pharmacist of his/her profession must be directed toward maintaining and improving the health, wellbeing, care and safety of the patient. The Code also requires pharmacists to ensure, that in instances where they are unable to provide services to a patient, they take reasonable action to ensure those medicines/services are provided and that the patient's care is not jeopardised. 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 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 pharmacists to personally carry out the supply, the medicine should be stored in an area of the pharmacy under the direct control and supervision of the pharmacists such as the dispensary.

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 those of the Data Protection Acts 1988 and 2003.

6. Pharmacovigilance

As with all medicines any suspected adverse reaction should be reported to the Irish Medicines Board, preferably online, via the IMB website www.imb.ie.

7. Policies, procedures and training within a pharmacy

Superintendent pharmacists must ensure that documented policies and procedures, which address the supply of Norlevo® 1.5mg tablets and the associated patient counseling by pharmacists, are in place in the pharmacies under their control. These documents should address all issues identified in this interim 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 relevant procedures.

Supply of Norlevo® 1.5mg tablets: Checklist for Pharmacists

The important elements of this interim guidance are highlighted in the checklist below which is intended to assist pharmacists in drawing up the relevant policies and procedures. Pharmacists should ask themselves the following questions and ensure the points are adequately addressed:

Ask Yourself	Yes	No	N/A	Required Action
Are there documented policies and procedures relating to the supply of Norlevo® 1.5mg 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 any relevant contact details 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 SPC for Norlevo® 1.5mg tablets (PA 1166/2/1)?				
Is a copy of the SPC readily available to all pharmacists in the pharmacy?				

Is a copy of the PSI interim guidance on the supply of Norlevo® 1.5mg tablets readily available to all pharmacists in the pharmacy?				
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 Norlevo® 1.5mg tablets and related sexual health matters?				
Is the medicine stored appropriately within the pharmacy?				
Are all pharmacists familiar with the procedure for reporting a suspected adverse reaction to the IMB?				