PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

Your Ref. :
貴處檔號

Our Ref. : DH DO PRIE/1-55/1
本局檔號

Tel. No. : **3974 4175**
電　話

Fax No. : **2803 4962**
圖文傳真

Drug Office
Department of Health
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong
香港九龍觀塘巧明街100號
Landmark East 友邦九龍大樓
20樓2002-05室
衞生署藥物辦公室

28 June 2024

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

Strengthening the Sales Control of
Oral Contraceptives that are currently not regulated as Poisons

The Pharmacy and Poisons Board (the Board) and its Committees have reviewed the sales control of oral contraceptives that are currently not regulated as poisons (i.e. non-poison OCs).

The Board have carefully considered that oral contraceptives should be sold at licensed premises (i.e. authorized sellers of poisons or listed sellers of poisons), the potential drug interactions and health risks of oral contraceptives, as well as the accessibility issue, and decided to strengthen the sales control of non-poison OCs, i.e. to regulate them as Part 2 poisons by adding under Part 2 of the Poisons List provided under the Schedule 10 to the Pharmacy and Poisons Regulations (Cap. 138A) (the Regulations), and to impose additional labelling requirements to these oral contraceptives for better protection of public health.

In this regard, the gazette amendment to the Regulations for the above is published on 28 June 2024.

According to the gazette, the following substances will be repealed in the Schedule 2 to the Regulations and added under Part 2 of Schedule 10 to the Regulations. Such amendments will come into operation on 28 June 2025, i.e. 12 months from the date of gazette—

(i) Preparations intended to be taken orally for contraceptive purposes only which contain not more than the following per dose—
- 0.15 milligrams Desogestrel;
- 3.00 milligrams Drospirenone;
- 0.05 milligrams Ethinyloestradiol;
- 0.10 milligrams Gestodene;
- 0.25 milligrams Levonorgestrel;
- 2.50 milligrams Lynoestrenol;
- 0.05 milligrams Mestranol;
- 1.00 milligrams Norethisterone;
- 0.25 milligrams Norgestimate; and
- 0.50 milligrams Norgestrel.

Further to the strengthening of the sales control of these oral contraceptives, the Board also decided that the sales packs of these products should include the following bilingual safety information to advise women to seek advice from healthcare professionals before commencement of oral contraceptives:

"You should consult a healthcare professional before commencing this medication. 在首次服用此藥物前，你應先接受醫護人員的評估。"

You are therefore required to review and ensure the sales packs of the concerned products registered by your company contain the above safety information. Please submit application for the change of registered particular(s) to the Drug Office via the online Pharmaceutical Registration System 2.0 (PRS 2.0) at www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not being renewed by the Committee upon certificate expiry. You are also reminded that any illegal sale of Part 2 poisons or unregistered pharmaceutical products is an offence under the Pharmacy and Poisons Ordinance and its Regulations. The maximum penalty for each offence is a fine of $100,000 and two years' imprisonment.

For further enquiries on the registration of pharmaceutical products, please contact the Drug Office at 3974 4175.

Yours faithfully,

(Y. F. YEUNG)
Secretary, Pharmacy and Poisons
(Registration of Pharmaceutical Products & Substances: Certification of Clinical Trial/ Medicinal Test) Committee

c.c. DH DO PRIE/7-15/3