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

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圖文傳真

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24th February 2017

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Warnings for Levonorgestrel-containing Hormonal Contraception

On 23rd February 2017, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest overseas recommendations on interactions of levonorgestrel-containing hormonal contraception with liver enzyme inducers, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing levonorgestrel should include the following new information:

For oral emergency contraceptive products:

Interactions
The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers, mainly cytochrome P450 3A4 enzyme inducers. Concomitant administration of efavirenz has been found to reduce plasma levels of levonorgestrel (AUC) by around 50%.

Examples of drugs, which are not exhaustive, suspected of having similar capacity to reduce the plasma levels of levonorgestrel include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, and griseofulvin. If you have further doubts, please consult your doctors or pharmacists.

For women who have used enzyme-inducing drugs in the past 4 weeks and need emergency contraception, the use of non-hormonal emergency contraception (i.e. a copper intrauterine device) should be considered.

For combined oral contraceptive products:

Interactions
Interactions can occur with drugs that induce microsomal enzymes (especially cytochrome P450 3A4) which can result in increased clearance of sex hormones and which may lead to breakthrough bleeding and/or contraceptive failure.

Women on short term treatment with any of these drugs should temporarily use a barrier method in addition to the combined oral contraceptives or choose another method of contraception. The barrier method should be used during the time of concomitant drug administration and for 28 days after their discontinuation.

For women receiving long-term therapy with enzyme inducers, another method of contraception should be used.

You are therefore required to review and revise, if necessary, the sales pack labels and/or package inserts of the concerned products registered by your company to ensure that the products comply with the above requirements. The revised sales pack labels and/or package inserts should be submitted to the Committee 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 by the Committee.

If you have any enquiries on the above issue, please contact Mr Arthur Lee at 2319 8453.

Yours sincerely,

(Clive CHAN)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee

c.c. 7-15/3, Product Files

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