

衛生署藥物辦公室
藥物註冊及進出口管制部



DEPARTMENT OF HEALTH
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Dr. Donald LI

President

Hong Kong Academy of Medicine

(Fax Number: 2505 5577)

Dear Dr. LI,

European Medicines Agency update on Diane 35 and generics used in the treatment of acne

Your attention is drawn to that the European Medicines Agency (EMA) announced the French medicines agency (ANSM) planned to suspend the marketing authorisation for Diane 35 (cyproterone acetate 2 mg, ethinylestradiol 35 micrograms) and its generics for acne treatment in France. In France, these medicines are only authorised for the treatment of acne. However, they are also authorised for the treatment of acne in women who wish to receive oral contraception, as well as for the treatment of other skin conditions, in other Member States.

The announcement in France follows a review by the ANSM of known data. ANSM considered that Diane 35 and its generics carry a risk of thromboembolism which has been well known for many years, while their effectiveness in treating acne was only moderate and alternative treatments for acne are available. In addition, it noted that they are widely used off-label as a contraceptive.

Although Member States can take unilateral action to suspend the marketing authorisation of a medicine, European legislation requires that there is a coordinated European approach in these instances. As requested by ANSM, EMA will carry out a European-wide review of Diane 35 and its generics. EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will evaluate all evidence on the benefits and risks of these medicines and give a recommendation on whether their marketing authorisations should be varied, suspended or revoked. Pending the outcome of the PRAC review, women who are currently taking Diane 35 or one of its generics are advised not to stop the medicine. If a woman has concerns, she can discuss this with her doctor. For details, please refer to EMA's website:

http://www.emea.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/01/news_detail_001703.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, Diane-35 Tab (HK-43330) is registered by Bayer Healthcare Ltd, and there are nine registered generics. All are prescription-only medicines and are indicated for the treatment of acne. Other registered indications include androgenetic alopecia, mild forms of hirsutism and contraception. The Department of Health will keep vigilance on any safety updates on the above issue from EMA and other overseas regulatory authorities.

We are committed to providing quality client-oriented service

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "Reporting an Adverse Drug Reaction": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,



(Ms Pamela LI)
for Assistant Director (Drug)