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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

9 May 2025

Dear Healthcare Professionals,

Measures to minimise risk of suicidal thoughts with finasteride and dutasteride medicines

Your attention is drawn to the European Medicines Agency's (EMA) announcement that following an EU-wide review of available data on finasteride and dutasteride medicines, EMA's safety committee, PRAC, has confirmed suicidal ideation (suicidal thoughts) as a side effect of finasteride 1 and 5 mg tablets. The frequency of the side effect is unknown, meaning that it is not possible to estimate it from available data.

Most cases of suicidal ideation were reported in people using 1 mg finasteride tablets, which are used to treat androgenetic alopecia (hair loss due to male hormones). A warning about mood changes, including depression, depressed mood and suicidal ideation, is already included in the product information for finasteride medicines. Patients who experience mood changes should seek medical advice and, if taking finasteride 1 mg, should also stop treatment.

The product information for finasteride 1 mg tablets will now also alert patients about the need to seek medical advice if they experience problems with sexual function (such as decreased sex drive or erectile dysfunction), which are known side effects of the medicine and may contribute to mood changes. A patient card will be included in the packages of 1 mg finasteride tablets to remind patients of these risks and to advise them about the appropriate course of action.

The recommendations follow a review of the risks of suicidal thoughts and behaviours with finasteride and dutasteride medicines. The PRAC agreed that suicidal ideation should be included as a side effect of finasteride tablets but concluded that the benefits of finasteride and dutasteride medicines continue to outweigh their risks for all approved uses.

Finasteride 1 mg tablets and finasteride skin spray are used to treat early androgenetic alopecia (hair loss due to male hormones), while finasteride 5 mg tablets and dutasteride 0.5 mg capsules are used to treat benign prostatic hyperplasia (enlarged prostate that can cause problems with urine flow).

Although it was not possible to establish a link between suicidal ideation and dutasteride based on the reviewed data, dutasteride works in the same way as finasteride and therefore information about the mood changes seen with finasteride will also be added to dutasteride's product information as a precaution.

The review found no evidence linking suicidal ideation to finasteride skin sprays and no new information is being included in the product information for these sprays.

In reaching its conclusion, the PRAC assessed available information on the effectiveness and safety of finasteride and dutasteride medicines, including data from clinical trials, EudraVigilance (the European database of reported suspected side effects), literature case reports and studies in the scientific literature. The review identified 325 relevant cases of suicidal ideation in EudraVigilance, 313 reported for finasteride and 13 for dutasteride (with 1 case reported for both). These cases were considered either probably or possibly related to treatment, and most cases concerned patients treated for alopecia. These numbers were considered in the context of an estimated exposure of around 270 million patient years for finasteride and around 82 million patient years for dutasteride (1 patient year is the equivalent of one patient taking the medicine for one year).

The Committee also considered information received during the review from patients or their relatives, healthcare professionals, academics, and patient and consumer organisations, who shared their experiences with finasteride treatment and/or provided additional data on finasteride use.

Information for healthcare professionals:

- Advise patients using 1 mg oral finasteride for androgenetic alopecia to stop treatment and seek medical advice if they experience depressed mood, depression or suicidal ideation.
- Some patients using 1 mg oral finasteride have reported sexual dysfunction, which may contribute to mood alterations, including suicidal ideation. Inform patients to seek medical advice if they experience signs of sexual dysfunction and consider discontinuing treatment.
- A patient card will be included in the packages of 1 mg finasteride tablets to inform patients being treated for androgenetic alopecia about these possible side effects and the appropriate course of action.
- The Agency's recommendations are based on an EU-wide review of available data on medicines containing finasteride (1 and 5 mg tablets and cutaneous spray solutions) and dutasteride (0.5 mg capsules). The review concluded that the level of evidence of the risks differed according to the indications, active substances and formulations.

- The review found insufficient evidence to establish a causal association between dutasteride and the risk of suicidal ideation. As a precautionary measure, based on a possible class effect of 5-alpha reductase inhibitors (5-ARIs), the product information for dutasteride will be updated to include information about the potential risk of suicidal ideation.
- A direct healthcare professional communication (DHPC) will be sent to relevant healthcare professionals in due course and published on a dedicated page on the EMA website.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/measures-minimise-risk-suicidal-thoughts-finasteride-dutasteride-medicines

In Hong Kong, there are 31 and 10 registered pharmaceutical products containing finasteride and dutasteride respectively. All products are prescription-only medicines. So far, the Department of Health (DH) has received 5 cases of adverse drug reaction with regard to finasteride, of which 2 cases were reported as decreased libido, erectile dysfunction and depression. With regard to dutasteride, the DH has received 4 cases of adverse drug reaction, but these cases were not related to mood changes or problems with sexual function.

Related news on the risk of mood changes and problems with sexual function associated with the use of finasteride was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 25 May 2017, with the latest update posted on 5 Oct 2024. Letters to inform local healthcare professionals were issued by the DH on 25 May 2017 and 20 Jan 2023. In Feb 2015, Sep 2017 and Apr 2024, the Registration Committee of the Pharmacy and Poisons Board discussed the matter. In Feb 2015 and Sep 2017, the Committee decided that the sales pack label and/or package insert of finasteride-containing products should include safety information on mood changes (including depressed mood, depression and suicidal ideation) and problems with sexual function (including decreased libido and erectile dysfunction).

In light of the above EMA's announcement associated with both finasteride and dutasteride, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": 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 digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Vincent CHIANG)
for Assistant Director (Drug)