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20 Jan 2023

Dear Healthcare Professionals,

Finasteride: Assessing the potential risks of suicide, suicidal thoughts (suicidal ideation) and self-injury

Your attention is drawn to the Health Canada's announcement that it has been monitoring the risk of suicidal ideation with the use of finasteride since 2012. Health Canada completed 2 safety reviews in 2012 and 2015, and the information available at the time was considered too limited to determine whether there was a link between the use of finasteride and suicidal thoughts and behaviours (suicidality).

In 2019, following reports of Canadian and international cases of suicide, suicidal ideation and self-injury with the use of finasteride, Health Canada completed a third safety review that found a possible link between finasteride and the risk of suicidal ideation. The Canadian product monographs (CPMs) of finasteride were updated to include the risk of suicidal ideation.

In 2022, Health Canada completed a review of the risk of suicidal ideation and potential risks of suicide and self-injury with the use of finasteride. This latest safety review was triggered by the publication of a media article that discussed the potential risk of suicide in patients using Propecia (finasteride) for male pattern hair loss. The purpose of the current review was to consider recent information and determine if additional measures were warranted.

Health Canada reviewed the available information from searches of the Canada Vigilance database, the World Health Organization's Adverse Drug Reaction database, and the scientific literature. Health Canada reviewed 401 cases (29 Canadian and 372 international) of suicide, suicidal ideation and/or self-injury in patients using finasteride from the Canada Vigilance database. Of the 401 cases, 25 (10 Canadian) met the criteria for further assessment to determine if there was a link between the use of finasteride and suicide, suicidal ideation and self-injury. Of the 25 cases, 23 (9 Canadian) were found to be possibly linked to the use of finasteride. Two cases (1 Canadian) could not be assessed. Eight of the 14 international cases were fatal (resulted in a completed suicide). In 17 of the 25 cases assessed by Health Canada, patients

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were 40 years of age or younger and taking finasteride for male pattern hair loss. The number of cases of suicide, suicidal ideation and self-injury reported to Health Canada is considered to be low in individuals treated with finasteride (approximately 1 Canadian case for every 10.1 million tablets dispensed in Canada). Health Canada also reviewed 16 publications in the scientific literature. There is a growing body of scientific evidence regarding the association between the use of finasteride and the risks of suicide, suicidal ideation and self-injury. Although there were limitations, the publications reviewed supported a possible link between the use of finasteride and suicidal ideation during treatment and following discontinuation of finasteride, especially in patients treated for male pattern hair loss.

Health Canada's review of the available information found a possible link between the use of finasteride and the risks of suicidal ideation and self-injury. At this time, there is not enough information to establish a link between the use of finasteride and the risk of suicide.

Health Canada is working with the manufacturers to update the CPMs for finasteride-containing products to strengthen the warning statements on the risks of suicidal ideation and self-injury, and to include information about patient screening for psychiatric risk factors prior to starting treatment, as well as continuous patient monitoring during and after stopping treatment.

Please refer to the following website in Health Canada for details:

<https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00290>

In Hong Kong, there are 32 registered pharmaceutical products containing finasteride. All products are prescription-only medicines. So far, the Department of Health (DH) has received 4 cases of adverse drug reaction related to finasteride, but these cases were not related to suicidal ideation, self-injury or suicide. Related news on the risk of suicidal ideation 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 31 Aug 2022. Letters to inform local healthcare professionals were issued by the DH on 25 May 2017. In Sep 2017, the Registration Committee of the Pharmacy and Poisons Board discussed the matter and decided that the sales pack label and/or package insert of finasteride-containing products should include safety information on suicidal ideation. In light of the above Health Canada's announcement, the matter will be further 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 Adverse Drug Reaction 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,



(Terence MAN)

for Assistant Director (Drug)