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Panamanian Ministry of Health
National Center of Pharmacovigilance
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To: Health Professionals

MEDICATION SAFETY NOTE

EVALUATION OF THE POTENTIAL RISK OF SUICIDAL THOUGHTS AND/OR BEHAVIORS (SUICIDAL IDEATION) WITH FINASTERIDE USE

THE NATIONAL CENTER FOR PHARMACOVIGILANCE OF THE MINISTRY OF HEALTH, MONITORING THE ALERTS AND INFORMATIVE NOTES ISSUED BY INTERNATIONAL REGULATORY AUTHORITIES REGARDING MEDICINES, CONSIDERS PERTINENT TO COMMUNICATE THE FOLLOWING INFORMATION:

Medicines regulatory agency Health Canada conducted a safety review for finasteride, due to reported cases of suicidal ideation and self-harm received in Canada and internationally. The cases led to the investigation of a possible relationship between finasteride use and suicidal ideation through a series of evaluations.

The topic of finasteride and suicide/self-harm has been continuously monitored by Health Canada since 2011. A first safety review was completed in 2012, and it was recommended that the topic be reevaluated in 2 years. A second safety review was completed in 2014, where data at the time could not confirm whether there was a link between finasteride use and suicide/self-harm.

It was recommended as a precautionary measure to inform physicians of the potential risk and to evaluate the subject again after another 2 years.

Security Review Results

• At the time of the review, Health Canada had received 26 reports from Canada related to suicide or self-harm with the use of finasteride. Between 2012 and 2016, the reporting rate in Canada for finasteride-related adverse reactions and suicide/self-harm increased 2.5-fold. In evaluating the reports from Canada, a cause-and-effect relationship could not be confirmed or denied, and as a result, a link between finasteride and suicide/self-harm related events was considered possible.

• A search of the World Health Organization Adverse Drug Reactions database found 368 international reports related to suicide/self-harm recorded in patients treated with finasteride, as of September 16, 2018.

• 5 studies that were published between 2015 and 2018 on finasteride and suicide-related events were reviewed. These publications support a link between the use of finasteride and the risk of suicidal ideation.

• In 2018, the European Medicines Agency (EMA) added a warning to the Proscar and Propecia product information about suicidal ideation in patients treated with finasteride (1mg and 5mg), and that patients should be monitored for symptoms psychiatric. Currently, the US Food and Drug Administration (FDA) has not required labeling for this risk for Proscar and Propecia.

• International reports, literature, and regulatory information reviewed could neither confirm nor deny a cause-and-effect relationship between finasteride and suicide/self-harm.

Situation in Panama

Commercial products containing finasteride as an active ingredient are currently registered in the National Directorate of Pharmacy and Drugs. To date, no reports of adverse reactions of suicidal thoughts and/or behavior associated with the use of finasteride have been received by the National Pharmacovigilance Center.

Actions of the National Pharmacovigilance Center

The National Pharmacovigilance Center has published the following informative notes related to the safety of the use of finasteride, which are published on the website of the Ministry of Health in the section "Medication Safety Notes" httos://minsa. gob.pa/informacion-salud/alertas-y-communiqués.

► Note 0859/CNFV/DNFD of July 17, 2014, entitled “Case of adverse reactions associated with the inappropriate use of products containing the active ingredients finasteride, spironolactone and minoxidil in combination with retinoids for the treatment of alopecia in women.”

► Note 0086/CNFV/DFV/DNFD of July 30, 2015, entitled “Finasteride and Dutasteride (5 alpha reductase inhibitors): Risk of High Grade Prostate Cancer.”

► Note 082/CNFV/DFV/DNFD of August 07, 2017, entitled "Safety review of Finasteride and the potential risk of serious side effects related to the muscles.

► Note 172/CNFV/DFV/DNFD of November 20, 2017, entitled “Reports of depression and suicidal thoughts with Finasteride.”

We recommend that health professionals take into consideration the safety information communicated for products that contain the active ingredient finasteride. Patients are advised to consult their healthcare professional with any questions or concerns about their therapy.

Manufacturers must update the monographs and insert including safety information on the potential risk of suicidal thoughts and/or behavior (suicidal ideation) for products containing finasteride in their formulation.

Given the suspicion of adverse reactions, pharmaceutical failures and therapeutic failure, we recommend health professionals to notify the CNFV of the Ministry of Health (MINSA). Phone 512-9404; e-mail: fvigilancia@minsa.gob.pa.

Health professionals are encouraged to take into consideration the information set forth in this safety note.

Bibliographical sources:

• Health Canada Medicines Regulatory Agency [Accessed: 05/06/19] [online] https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lanq=en&linkID=SSR00218

• Sanitary Registry Database of the National Directorate of Pharmacy and Drugs; Ministry of Health, Panama. [Consulted: 05/06/19]