Editor's note: This English translation was done by a third party. The original document can be accessed here.

Panamanian Ministry of Health
National Center of Pharmacovigilance
November 20, 2017
172/CNFV/DFV/DNFD

From: Magistra Lisbeth Tristan de Brea
National Director of Pharmacy and Drugs

To: Health Professionals

MEDICATION SAFETY NOTE

REPORTS OF DEPRESSION AND SUICIDAL IDEATION WITH FINASTERIDE

THE NATIONAL PHARMACOVIGILANCE CENTER OF THE NATIONAL DIRECTORATE OF PHARMACY AND DRUGS 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:

The UK Medicines Regulatory Agency (MHRA) issued a safety communication about reports received of depression and, in rare cases, suicidal ideation in men taking finasteride 1mg for male pattern hair loss.

Finasteride is an inhibitor of the enzyme 5-a-reductase type II. This enzyme is responsible for the conversion of testosterone to dihydrotestosterone, a hormone involved in androgenetic alopecia. Finasteride at a dose of 5 mg is indicated for the treatment and control of benign prostatic hyperplasia.

In the UK, some men have reported episodes of depressive illness in association with the use of finasteride for male pattern hair loss. Some men also reported having suicidal thoughts.

Depression and suicidal thoughts have been reported in men with and without a history of depression. Depressed mood has been previously recognized with finasteride. A recent review of the evidence has suggested that depression cases may be a more significant.

Situation in Panama

To date, the National Directorate of Pharmacy and Drugs has registered commercial products that contain finasteride as an active ingredient. Currently, the National Pharmacovigilance Center has not received notifications of suspected adverse reactions of depression and suicidal thoughts after the use of products containing finasteride as the active ingredient.

We recommend health professionals to take into consideration the following:

- Adverse reactions to finasteride have been reported in other countries, suggesting a possible relationship with depression, and in rare cases suicidal thoughts.

- Advise patients undergoing treatment with finasteride that if they develop depression, they should inform a health professional.

- It is also recalled that adverse reactions related to sexual function have been reported in other countries in association with finasteride. These include decreased libido, erectile dysfunction, and ejaculation disorders.

Patients are advised to consult their healthcare professional with any questions or concerns about their therapy.

Actions of the National Pharmacovigilance Center

The National Center for Pharmacovigilance published on the website of the Ministry of Health in the section "Notes on Drug Safety." (http://www.minsa.gob.pa./informacion-salud/alertas-y-comunicados) drug safety notes related to the active ingredient finasteride, which we detail below:

✓ 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/DNFD dated July 30, 2015, entitled “Finasteride and Dutasteride (5 Alpha Reductase Inhibitors): Risk of High-Grade Prostate Cancer.”

✓ Note 082/CNFV/DNFD of August 7, 2017, entitled “Finasteride Safety Review and the Potential Risk of Serious Side Effects Related to Muscles.”

We ask you to extend this information to health professionals. 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.

PO: The objective of this safety note is to disseminate information on the safety of medicines based on communications from the International Medicines Regulatory Agencies. This is a translation of the original text for informational purposes. For any inconsistency in the text, the text in its original language will prevail.

Bibliographical sources:

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3. Sanitary Registration Database of the National Directorate of Pharmacy and Drugs; Ministry of Health, Panama. [Consulted: 11/20/17)