SAFETY ALERT

DRAP SAFTEY ALERT NO. 35

Safety alert of potential risk of suicidal ideation/thoughts & self-injury with Finasteride.

Date: 11th of April, 2023.

Target Audience:

- Manufacturers and importers of Finasteride;
- Healthcare Professionals; and
- Patients, consumers or caregivers.

Background:

The Health Sciences Authority (HSA) of Singapore in August 2022 reminded healthcare professionals of the potential risk of suicidal ideation with the use of finasteride following results of a recent pharmacovigilance study that suggests younger patients with alopecia may be more vulnerable to the risk of suicide ideation. In the study, disproportionality analysis was used to assess whether suicidality or psychological adverse events (AEs) were more frequently reported for finasteride than would be expected by chance alone by comparing them against similar reports for all other drugs in VigiBase (WHO global database of ICSRs). The study identified 356 reports of suicidality and 2,926 reports of psychological AEs in users of finasteride, reported from 1993 to 2019. Among the reports with data available, the majority (99%) occurred in males, and 71% occurred in individuals aged between 18 and 44 years. Significant disproportionality signals for suicidality (reporting odds ratio [ROR], 1.63; 95% CI, 1.47-1.81) and psychological AEs (ROR, 4.33; 95% CI, 4.17-4.49) were identified in finasteride users.

On 19th of January, 2023, Health Canada through its summary safety review informed that it is

working with the manufacturers to update the product safety information in the Canadian product monographs (CPM) 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. The 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. 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 for the risk of suicide. However, strengthening of warning statements was warranted.

It was informed that Health Canada was monitoring the risk of suicidal ideation with the use of finasteride since 2012 and has 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, the agency completed a third safety review that found a possible link between finasteride and the risk of suicidal ideation. The CPMs of finasteride were accordingly updated to include the risk of suicidal ideation.

Most recently in 2022, due publication of a media article that discussed the potential risk of suicide in patients using Propecia (finasteride) for male pattern hair loss, Health Canada completed a review of the risk of suicidal ideation and potential risks of suicide and self-injury with the use of finasteride. The purpose of the current review was to consider recent information and determine if additional measures were warranted. A 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. Therefore, strengthening of warning statements on the risks of suicidal ideation and self-injury was warranted and Health Canada is working on it.

Furthermore, the most recent Vigilyze statistics related to the finasteride and Standard MedDRA Query(SMQ) selected Depression and suicide/self-injury study identified 2,995 reports and 471 reports specifically with suicidal ideation. The larger portion of the reactions in known gender occurred in males (31.9%, and 45.6% in individuals aged between 18 and 44 years respectively, with the broader SMQ and specifically suicidal ideation. Significant disproportionality signals for suicidal ideation (reporting odds ratio [ROR], 10.6) and SMQ (ROR, 4.5) were identified.

Action in Pakistan:

Accordingly, the case of the potential risk of suicidal ideation/thoughts & self-injury with finasteride was discussed in the 2nd meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the National Pharmacovigilance Centre (NPC), Division of Pharmacy Services, Drug Regulatory Authority of Pakistan (DRAP), which decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that registration holders should update prescribing information/safety specification of finasteride containing drugs by strengthening the warning statements on the risks of suicidal ideation and self-injury, and to include information about patient screening for psychiatric risk factors before starting treatment.

Therapeutic Goods Affected.

Name: **Finasteride.**

Finasteride is indicated for the treatment of benign prostatic hyperplasia and androgenic alopecia.

Advice for patients.

Patients are advised to immediately consult their doctors if they experience mood alterations including depression and less frequently, suicidal ideation or self-injury etc.

Advice for healthcare professionals.

Healthcare professionals are informed that mood alterations including depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride and are hereby advised to consider the potential risk of psychological adverse events when assessing the benefit-risk of finasteride for their patients. Healthcare professionals should also advise their patients to consult their doctors at the earliest when such thoughts are developed.

Guidelines for reporting Adverse Drug Reactions (ADRs):

Both healthcare professionals and patients are requested to report any suspected adverse drug reaction (ADRs) with finasteride to the National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan through the Med Vigilance E-Reporting System available on the DRAP website. Similarly, ADRs can also be reported through Med Safety App which is available for download from the App store (for iOS devices) and Google Play (for Android devices).

References:

1. Minutes of 2nd meeting of Pharmacovigilance Risk Assessment Expert Committee.

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