From: Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk>
Sent: Friday, November 19, 2021 6:31:44 PM
To: Ryan Clark
Subject: CSC46623. FAO Alison Banner Simpson

Dear Mr Clark:

Thank you for your e-mail of the 29 September 2021. I am sorry for the length of time it has taken to provide you with a response.

Thank you for the information regarding the report from the Post-Finasteride Syndrome Foundation and the complaint it has raised against the US Food and Drug Administration (FDA) regarding its failure to act on the citizen petition filed by the Foundation in September 2017. I note the concerns you have highlighted from the complaint, particularly with regard to suicide being a side effect. I have found the article from Reuters to which you referred, which deals largely with the labelling of sexual side effects in US product information.

As I am sure you aware, the labelling on the side effects with Propecia are different in the US and in Europe, such that sexual dysfunction (decreased libido, erectile dysfunction and ejaculation disorder) is known to persist after discontinuation of treatment in some patients and this is described in the product information in the UK and EU. The Patient Information leaflet (PIL) supplied with each pack of medicine describes the known side-effects of treatment (including sexual side-effects) and states that some of these are temporary with continued treatment or there can be persistent difficulty having an erection, with ejaculation, or persistent decrease in sex drive after discontinuation of treatment. Additionally, depressed mood, anxiety, depression and, less frequently, suicidal thoughts are known side-effects of treatment with finasteride 1 mg. The product information for healthcare professionals advises that patients should be monitored for psychiatric symptoms and if these occur, treatment with finasteride should be discontinued and the patient advised to seek medical advice. The Patient Information leaflet (PIL) supplied with each pack of medicine advises patients that if they experience mood alterations such as depressed mood, depression (feeling of severe sadness and unworthiness) or suicidal thoughts, they should stop taking the product and contact their doctor as soon as possible.

I note your concerns about the selling and promotion of finasteride online. In the UK, it is legal for medicines to be sold online, provided all other legal requirements in medicines regulations are met – for example, Prescription Only (POM) and Pharmacy medicines may only be legally sold or supplied to the public through registered pharmacy premises, by or under the supervision of a pharmacist and POMs may only be sold or supplied in response to a prescription from an authorised healthcare professional (such as a doctor, dentist, or certain trained nurses and pharmacists). Relevant prescribers include doctors registered in an EEA Member State. A UK registered pharmacy may have a presence on the internet. However, the requirements of medicines legislation apply equally to sales from bricks-and-mortar premises and sales online. Medicines legislation does not prohibit the remote prescribing of POMs by a qualified prescriber. However, prescriptions, including electronic and private prescriptions, must meet the usual requirements set down in medicines legislation.

Regarding the promotion of finasteride, advertising of medicines is acceptable provided it is in line with legislation and agreed standards of good practice. The MHRA's Advertising Standards and Outreach Unit investigates complaints with the advertising of medicines and can be contacted at advertising@mhra.gov.uk if you wish to raise a concern about a specific piece of advertising. Alternatively, you can contact the pharmaceutical self-regulatory body the Prescription Medicines Code of Practice Authority (PMCPA, https://www.pmcpa.org.uk/) for advertisements to health professionals for prescription medicines.

I also note your comments regarding patients' embarrassment and reluctance to report side-effects to doctors and authorities and the fact that doctors may be unaware of 'Post finasteride syndrome' ('PFS'). As mentioned in previous correspondence the MHRA reviews all the Yellow Card reports we receive from healthcare professional and patients and considers these alongside all other sources of evidence to determine if there are new risks with a medicine or if known risks with a particular medicine have changed. As noted previously, 'PFS' is not widely recognised by the scientific community or as a medically recognised syndrome. As such, 'PFS' is not a known side effect of treatment with finasteride. However, many of the individual symptoms which patients consider are associated with 'PFS' are

described in the product information. I have re-investigated our database to see if there has been an increased frequency of reporting of sexual and depression [including suicide] though the Yellow Card scheme. However, the terms which meet our statistical criteria for further investigation and taking Regulatory action are all sexual dysfunction terms which are already listed as known side-effects in the product information. Given the current labelling, there is no new evidence which would warrant any further updates to the product information at present.

I am sorry that you continue to experience distress and I understand that you are deeply affected by your experiences. I hope, however, that you find this information useful.

Your sincerely,

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