Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure No: EMEA/H/A-31/1539

Finasteride- and dutasteride-containing medicinal products

Divergent statement

The following CMDh members consider that the benefit-risk balance of medicinal products containing finasteride 1 mg is not favourable based on the following grounds:

Finasteride is a 4-azasteroid, which inhibits human type II 5- alpha reductase (5-ARI). Finasteride 1 mg is indicated in men 18 – 41 years of age for the early stages of androgenetic alopecia. As per the approved indication, finasteride stabilises the process of androgenetic alopecia. Efficacy in bitemporal recession and end-stage hair loss has not been established.

Finasteride 1 mg is available in oral form and has been authorised for more than 25 years in Europe. It has never been approved in Belgium.

In September 2024, France triggered a referral procedure under Article 31 of Directive 2001/83/CE in view of new serious adverse reactions added to SmPC Section 4.8 of medicines containing finasteride 1 mg (Propecia) and 5 mg (Proscar), i.e. "suicidal ideation". The PRAC was specifically asked to assess all available data on suicidal ideation and suicide related to finasteride- and dutasteride-containing products, as well as the impact of these possible risks on the benefit-risk balance of those products.

Based on the reported cases and available relevant literature, the PRAC and CMDh concluded that a causal relationship between oral finasteride 1 mg and suicidal ideation is confirmed and that a positive benefit-risk balance in the androgenetic alopecia indication remains positive subject to the implementation of adequate risk minimisation measures.

However, the analysis of the referral data has clearly established new aspects of the risks associated with psychiatric disorders and sexual dysfunction. These risks considerably affect the safety profile of oral finasteride 1 mg in light of the approved indication for androgenetic alopecia, which is a benign, aesthetic, and lifelong condition. The expected benefits, i.e. stabilisation of hair loss, in this benign condition do not outweigh the seriousness of these risks, including potential fatal outcomes, in the target population of young healthy patients. The recommended risk minimisation measures including product information updates, patient card and DHPC, will not sufficiently prevent the new important identified risk of suicidal ideation. Indeed, in France, despite the implementation over the years of various risk minimisation measures (including communications via the ANSM's website, patient information sheet, DHPC, boxed warning, and QR code on the outer packaging), serious cases of psychiatric disorders and sexual dysfunction continue to be reported. Moreover, in some patients, these adverse effects may persist for years even after treatment discontinuation and could lead to suicidal ideation. In this context, no effective measures can mitigate these risks.

Therefore, taking into account the above, we consider that the benefit-risk balance of finasteride 1 mg for androgenetic alopecia is negative.

CMDh members expressing a divergent opinion:

- Roselien Poppe (Belgium)
- Mathilde Geynet-Kovacs (France)