12 October 2023
EMA/CHMP/10331/2024
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): apalutamide

Procedure No. EMEA/H/C/PSUSA/00010745/202302

Period covered by the PSUR:
14/02/2022 To: 13/02/2023

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Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for apalutamide, the scientific conclusions of PRAC are as follows:

In view of available data on restless legs syndrome (RLS) from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between apalutamide and RLS is at least a reasonable possibility. The PRAC concluded that the product information of products containing apalutamide should be amended accordingly.

In view of available data on interstitial lung disease (ILD) from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between apalutamide and ILD is at least a reasonable possibility. The PRAC concluded that the product information of products containing apalutamide should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for apalutamide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing apalutamide is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.