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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/00010745/202502

Period covered by the PSUR: 1 year to 13 February 2025

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on apalutamide and neutropenia as well as agranulocytosis from spontaneous cases with positive dechallenge and/or rechallenge and compatible time to onset, data from clinical trials and in the literature, and in view of a potential mechanism of action, a causal relationship between apalutamide and neutropenia as well as apalutamide and agranulocytosis is at least a reasonable possibility and the product information of apalutamide containing products should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

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.