



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2024
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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/00010745/202402

Period covered by the PSUR:
14/02/2023 To: 13/02/2024



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 lichenoid eruption from spontaneous cases and the literature including in some cases a close temporal relationship and positive de-challenge, the PRAC considers a causal relationship between apalutamide and lichenoid eruption 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.