



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 October 2022
EMA/129416/2023
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/00010745/202202

Period covered by the PSUR: 14 August 2021 to 13 February 2022



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 the risk of DRESS (drug reaction with eosinophilia and systemic symptoms) from the literature and spontaneous reports including review of epidemiology and biological plausibility, the PRAC considers a causal relationship between apalutamide and DRESS is at least a reasonable possibility. The PRAC concluded that the product information of products containing apalutamide 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.