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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): enzalutamide

Procedure No. EMEA/H/C/PSUSA/00010095/202008

Period covered by the PSUR: 30 August 2017 to 30 August 2020

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Scientific conclusions

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

In view of available data on dysgeusia from clinical trial, post-marketing cases and in view of the class effect, the PRAC considers a causal relationship between enzalutamide and dysgeusia is at least a reasonable possibility. The PRAC concluded that the product information of products containing enzalutamide 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 enzalutamide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing enzalutamide 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.