21 March 2024
EMA/105093/2024
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): darolutamide

Procedure No. EMEA/H/C/PSUSA/00010843/202307

Period covered by the PSUR: 30/01/2023 To: 30/07/2023

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Scientific conclusions

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

In view of available data on hepatotoxicity and liver function tests from clinical trials and spontaneous reports, the PRAC considers that the current warning on Hepatotoxicity and description of liver function tests needs to be strengthened. The PRAC concluded that the product information of products containing darolutamide 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 darolutamide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing darolutamide 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.