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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): abiraterone

Procedure No. EMEA/H/C/PSUSA/00000015/201804

Period covered by the PSUR: 28 April 2017 to 27 April 2018

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Scientific conclusions

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

Based on a cumulative review of the data in relation to latency of rhabdomyolysis/myopathy cases, almost half of these cases occurred between 1 to 6 months after initiation of therapy with abiraterone acetate (AA). Based on this observed trend, the product information (SmPC Section 4.4) should be updated to reflect that rhabdomyolysis/myopathy may occur between 1 to 6 months after initiation of therapy with AA.

Moreover, sections 4.3 and 4.4 of the SmPC should be amended to reflect the contraindication of the use of Xofigo (Radium-223) in combination with abiraterone acetate and prednisone/prednisolone and the increased risk for fractures and mortality in patients treated with Radium-223 in combination with abiraterone.

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 abiraterone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing abiraterone 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.