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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): axitinib

Procedure No. EMEA/H/C/PSUSA/00010022/201901

Period covered by the PSUR: 27 January 2018 To: 26 January 2019

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Scientific conclusions

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

Based on the review of the data submitted in the PSUR procedure, including case reports and one literature article, and considering that a plausible biological mechanism exists, there is at least a reasonable possibility that axitinib may cause cholecystitis. Therefore, the product information should be updated to include cholecystitis as an ADR in section 4.8 of the SmPC and section 4 of the PL, with frequency 'common'.

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