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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): avacopan

Procedure No. EMEA/H/C/PSUSA/00010967/202309

Period covered by the PSUR: 26/03/2023 To: 26/09/2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for avacopan, the scientific conclusions of PRAC are as follows:

In view of available data on drug-induced liver injury (DILI) and vanishing bile duct syndrome (VBDS) from spontaneous reports and the literature, including 8 cases of DILI with a compatible time to onset (TTO)(<90days) and a positive dechallenge, at least 12 serious cases of liver enzyme elevations suggestive of DILI grade 3 or 4 with a compatible TTO and 3 cases of VBDS, confirmed by biopsy with a compatible TTO (<60 days), the PRAC considers a causal relationship between avacopan and DILI and between avacopan and VBDS is at least a reasonable possibility. The PRAC concluded that the product information of products containing avacopan as per EURD list 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 authorisations

On the basis of the scientific conclusions for avacopan the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing avacopan is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisations should be varied.