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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): avatrombopag

Procedure No. EMEA/H/C/PSUSA/00010779/202005

Period covered by the PSUR: 20/11/2019 To: 20/05/2020

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Scientific conclusions

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

In view of available data on hypersensitivity reactions from clinical trial(s) and spontaneous reports, the PRAC considers a causal relationship between avatrombopag and hypersensitivity is at least a reasonable possibility. The PRAC concluded that the product information of products containing avatrombopag 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 avatrombopag the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing avatrombopag 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.