26 April 2023
EMA/173624/2023
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): ponesimod

Procedure No. EMEA/H/C/PSUSA/00010940/202209

Period covered by the PSUR: 18 March 2022 To: 17 September 2022

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Scientific conclusions

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

In view of available data on seizures from clinical trial(s), including in cases with a reasonable temporal relationship, the PRAC considers a causal relationship between ponesimod and seizure is at least a reasonable possibility. The PRAC concluded that the product information of products containing ponesimod 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 ponesimod the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ponesimod 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.