EMA/540391/2023
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): delamanid

Procedure No. EMEA/H/C/PSUSA/00010213/202304

Period covered by the PSUR: 26/10/2022 To: 26/04/2023

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Scientific conclusions

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

In view of available data on paradoxical reactions from the literature and spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between delamanid and 'Paradoxical drug reaction' is at least a reasonable possibility. In addition, in view of available data on nightmares from clinical trial PHOENIx (study 242-201-00004) including in some cases a close temporal relationship and a positive de-challenge, the PRAC considers that a causal relationship between delamanid and 'Nightmare' is at least a reasonable possibility. The PRAC concluded that the product information of products containing delamanid 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 Authorisation(s)

On the basis of the scientific conclusions for delamanid the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing delamanid 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.