16 December 2021
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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): delamanid

Procedure No. EMEA/H/C/PSUSA/00010213/202104

Period covered by the PSUR: 27 April 2020 to 27 April 2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on risk from clinical trial(s) and spontaneous reports, including four paediatric cases with a close temporal relationship and a positive de-challenge, the PRAC considers a causal relationship between delamanid and hallucination is at least a reasonable possibility.

In view of available data from the literature on in vitro studies that have shown cross-resistance with pretomanid, the PRAC considers that the information on resistance should be updated.

The PRAC concluded that the product information of products containing delamanid 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 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.