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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/00010213/201810

Period covered by the PSUR: 28 April 2018 to 27 October 2018

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Scientific conclusions

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

The PRAC noted the recurrent concomitant use of delamanid with bedaquiline in patients experiencing QTc prolongation. Since both medications are known to prolong the QT interval, the MAH is asked to update the SmPC and PL of delamanid to list bedaquiline as one of the concomitant drugs known to prolong the QTc interval.
There is evidence in the last PSUR to suspect the possibility of a causal relationship of liver disorders with delamanid, but the scientific evidence is insufficient to conclude that the association is causal. Liver disorders is categorised as an important potential risk. The PRAC requests a cumulative review of this risk in next PSUR, using appropriate PT terms, in order to assess whether an update of the risk is needed.

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.