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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): pomalidomide

Procedure No. EMEA/H/C/PSUSA/00010127/202102

Period covered by the PSUR:07/02/2019 To: 07/02/2021

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Scientific conclusions

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

In view of available data on solid organ transplant rejection from the literature and spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between pomalidomide and solid organ transplant rejection can be established. The PRAC Rapporteur concluded that the product information of products containing pomalidomide 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 pomalidomide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pomalidomide 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.