22 July 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): lenalidomide

Procedure No. EMEA/H/C/PSUSA/00001838/202012

Period covered by the PSUR: 17 July 2020 to 26 December 2020

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Scientific conclusions

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

In view of available data on tumour lysis syndrome from spontaneous reports in myelodysplastic syndrome indication, the PRAC concluded that the product information of products containing lenalidomide should be amended accordingly.

Update of section 4.4 of the SmPC to update a warning on tumour lysis syndrome.

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 lenalidomide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lenalidomide 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.