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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): thalidomide

Procedure No. EMEA/H/C/PSUSA/00002919/201810

Period covered by the PSUR: 10 October – 09 October

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Scientific conclusions

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

A cumulative search of DRESS cases with thalidomide from spontaneous sources and clinical trials retrieved 8 cases among which 4 cases were assessed as probable or possible drug reaction with eosinophilia and systemic symptoms (DRESS) as per Regiscar criteria. All 4 cases involved other possible contributing factors preventing the establishment of a definite direct causal relationship between thalidomide and DRESS, but a link with thalidomide could also not be excluded. Despite the small number of cases of DRESS, considering that this adverse reaction is a known risk listed in the EU SmPC of the structural analogues lenalidomide and pomalidomide and taking into consideration that other severe cutaneous adverse reactions (SCARs) are already listed in the thalidomide EU SmPC (SJS and TEN), the PRAC concluded that a causal relationship between thalidomide and DRESS cannot be excluded. Therefore, considering the seriousness of this risk, the PRAC considers that the risk should be reflected in the PI of thalidomide. In addition, the addition of interruption or discontinuation recommendations regarding the risk of severe skin reactions in general, in line with the one already approved for the structural analogues lenalidomide and pomalidomide, is supported.

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