EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/00002919/201710

Period covered by the PSUR: 10 October 2016 to 09 October 2017

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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:

Based on the evidence from 11 case reports of leukocytoclastic vasculitis following thalidomide administration with 2 of them having positive re-challenge, and bearing in mind that this adverse drug reaction (ADR) is already present in the product information of another product of the class, the PRAC considers that leukocytoclastic vasculitis should be included as an ADR in section 4.8 of the summary of product characteristics (SmPC) of thalidomide with the frequency 'not known'.

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.