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/00002919/202010

Period covered by the PSUR: 10 October 2019 - 09 October 2020

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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:

In view of available data on hypothyroidism from cumulative review and based on a possible class effect, the PRAC Rapporteur considers that addition of the class wording on monitoring of the thyroid function is warranted, in addition to the information already provided regarding this risk in section 4.8 of the SmPC. The PRAC Rapporteur concluded that the product information of products containing thalidomide 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 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.