30 April 2020
EMA/492111/2020
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/00002919/201910

Period covered by the PSUR: 10 October 2018 – 9 October 2019

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

Considering that thalidomide has been on the market for more than 10 years and that therefore substantial experience in the use of thalidomide has been gained and bearing in mind that there has not been any recent changes to the implementation of the Pregnancy Prevention Programme (PPP), the 6-monthly reporting to EMA by each Member State of the status of implementation of the PPP and the estimate of usage in their Member State could be replaced by a reporting by the Marketing Authorisation Holders in the frame of the yearly PSURs.

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 Annex 127a.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.