EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/517770/2020
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): lenalidomide

Procedure No. EMEA/H/C/PSUSA/00001838/201912

Period covered by the PSUR: 26 December 2018 – 26 December 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 lenalidomide, the scientific conclusions of CHMP are as follows:

In view of the large number of cases of pulmonary hypertension collected in the cumulative review, including cases with a suggestive chronology and positive dechallenge, and considering that there is a plausible mechanism of action and a possible class effect, the PRAC considers that a causal relationship between lenalidomide and pulmonary hypertension is plausible. The PRAC concluded that the product information of products containing lenalidomide 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 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.