21 July 2016
EMA/551825/2016
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/00001838/201512

Period covered by the PSUR: 27 December 2014 – 26 December 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

## Scientific conclusions

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

During the assessment of the previous PSUR, 1 of the 4 cumulative cases of acquired haemophilia was of concern, and close monitoring remained requested. During the period of this PSUR, 1 further new case of acquired haemophilia, well documented, was reported, with a total of 5 cases cumulatively.

Considering cases with events chronology highly suggestive for causal relationship between lenalidomide and acquired haemophilia, and positive dechallenge and rechallenge, a causal relationship between acquired haemophilia and lenalidomide is strongly suggested and consequent update of the product information is required.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing lenalidomide were warranted.

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.