



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

Amsterdam, 30 January 2025  
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/PSR/S/0049



## **Scientific conclusions**

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final study report for the medicinal product(s) mentioned above, the scientific conclusions of CHMP are as follows:

The study CC-5013-MDS-012 was a condition of the marketing authorisation and Annex II should therefore be updated, as the study has been completed.

Therefore, in view of available data regarding the PASS final study report, the PRAC considered that changes to the conditions of the marketing authorisation were warranted.

The PRAC considered the updated RMP acceptable.

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 the results of the study for the medicinal product(s) mentioned above, the CHMP is of the opinion that the benefit-risk balance of these medicinal product(s) is unchanged, subject to the proposed changes to the product information.

The CHMP is of the opinion that the terms of the marketing authorisation(s) of the medicinal product(s) mentioned above should be varied.