25 September 2014

EMA/CHMP/772707/2014
Committee for Medicinal Products for Human Use (CHMP)

Imnovid

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: pomalidomide

Procedure No.: EMEA/H/C/002682/PSUV/0006

Period covered by the PSUR: 08 February 2013 – 07 February 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Imnovid, the scientific conclusions of PRAC are as follows:

From review of completed studies with pomalidomide, epistaxis has been observed with a frequency of 9.7% and grade 3/4 epistaxis has been observed with a frequency of 0.7%. The PRAC therefore concluded that epistaxis (all reactions) should be listed in section 4.8 of the SmPC with a frequency of common and epistaxis (grade 3/4) with a frequency of uncommon. In addition nosebleeds should be listed in section 4 the package leaflet with a frequency of common.

Therefore, in view of available data regarding pomalidomide, the PRAC considered that changes to the product information were warranted. The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Imnovid, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance pomalidomide is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.

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