EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2015
EMA/700722/2015
Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: pomalidomide

Procedure No.: EMEA/H/C/PSUSA/00010127/201502

Period covered by the PSUR: 8 August 2014 to 7 February 2015

RMP version number: 8

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

The MAH retrieved 56 arterial thrombotic events from their safety database, including 11 reports with a fatal outcome. The most common clinical presentation of arterial thrombotic events was myocardial infarction (n=32). Of these cases, 26 occurred within 12 months (including 15 that occurred within 3 months of starting pomalidomide). In addition, pomalidomide inhibits angiogenesis, a pharmacodynamic effect which is known to increase the risk of arterial thrombotic events. Based on the available data it has been concluded that a causal association between myocardial infarction and pomalidomide cannot be excluded and therefore the risk of myocardial infarction should be included in the product information.

A cumulative review of cerebrovascular accidents identified 113 events, of which 81 could be classified as ischaemic (n=31) or haemorrhagic (n=50). Where a causality assessment was provided, half of the ischaemic cerebrovascular accident events were judged as related to pomalidomide. Furthermore 14 cerebrovascular accident events included cases of cerebral haemorrhage and 25 included cases with subdural haemorrhage, subdural haematoma or subarachnoid haemorrhage. Therefore the risk of cerebrovascular accident and intracranial haemorrhage should be included in the product information.

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 POMALIDOMIDE the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing 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.