EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 December 2020
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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): bortezomib

Procedure No. EMEA/H/C/PSUSA/00000424/202004

Period covered by the PSUR: 26 April 2019 – 25 April 2020

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Scientific conclusions

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

In view of available data from the literature and spontaneous reports including, in some cases, a close temporal relationship, positive de-challenge and in view of a plausible mechanism of action supporting the known neurotoxicity of bortezomib, the PRAC considers a causal relationship between bortezomib and Guillain-Barrè Syndrome and Demyelinating polyneuropathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing bortezomib 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 bortezomib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bortezomib 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.