EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): ibrutinib

Procedure No. EMEA/H/C/PSUSA/00010301/201811

Period covered by the PSUR: 11 November 2017 To: 11 November 2018

Scientific conclusions

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

Based on a cumulative review of cases reported in clinical trials, in the post-marketing setting and taking into account a published report including 41 relevant cases as well as at least 6 more cases published in the scientific literature since then, the PRAC considers that a causal relationship between ibrutinib and invasive fungal infections (IFI) cannot be excluded and therefore recommends the update sections 4.4 and 4.8 of the Summary of Product Characteristics and section 2 and 4 of Package Leaflet with this adverse reaction.

In addition, the frequency category of the adverse reaction hepatic failure should be updated from “not known” to “uncommon”.

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