15 October 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): ruxolitinib

Procedure No. EMEA/H/C/PSUSA/00010015/202002

Period covered by the PSUR: 23 February 2019 to 22 February 2020

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Scientific conclusions

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

In view of available data on risk(s) from clinical trial(s) and post marketing sources including some cases with positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between ruxolitinib and pancytopenia is at least a reasonable possibility.

In view of available data on risk(s) from post marketing and or literature cases where causal association is possible and biologically plausible, the PRAC considers the frequency on the causal relationship between ruxolitinib and HBV reactivation is at least a reasonable possibility.

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