



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): ruxolitinib

Procedure No. EMEA/H/C/PSUSA/00010015/201702

Period covered by the PSUR: 23 February 2016 to 22 February 2017



## **Scientific conclusions**

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

The review of post-marketing cases revealed 11 noteworthy cases of pneumonia in myelofibrosis patients (MF). Several of these cases support a causal association between ruxolitinib and pneumonia with an at least reasonable possibility. Infections including pneumonia are described as important identified risks in the current RMP and are being closely monitored and as such discussed in each PSUR. The MAH should include pneumonia as an adverse drug reaction (ADR) in MF patients in section 4.8 of the SmPC.

During the interval one noteworthy case of tuberculosis was reported in a polycythemia vera (PV) patient. Tuberculosis is included as an important identified risk in the RMP and it is listed as an uncommon ADR for MF patients in the SmPC including a relevant warning. The MAH should update the warning to include that tuberculosis has been reported also in PV patients.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC rapporteur considered that changes to the product information of medicinal products containing ruxolitinib were warranted.

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.