



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/00010015/201602

Period covered by the PSUR: 23 Feb 2015 to 22 Feb 2016





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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:

Based on a review of the marketing authorisation holder's (MAH's) global safety database where an increase in severity of tuberculosis and other opportunistic infections was observed, the PRAC agreed with the MAH's proposal that a warning on opportunistic infections should be added to section 4.4 of the Summary of Product Characteristics (SmPC).

In addition, increases in cholesterol, LDL and HDL were observed in patients treated with ruxolitinib. Furthermore, a few reported adverse events that may have been associated with lipid abnormalities. Whilst hypercholesterolemia and hypertriglyceridemia are listed as adverse drug reactions in section 4.8 of the SmPC, the PRAC agreed with the MAH's proposal to include a warning in section 4.4 of the SmPC to add information about increases in lipid parameters and a recommendation to monitor lipid levels and treat dyslipidaemia according to clinical guidelines.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC 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.

