EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: pemetrexed

Procedure No. EMEA/H/C/PSUSA/00002330/201502

Period covered by the PSUR: 5 February 2012 – 4 February 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for pemetrexed, the scientific conclusions of CHMP are as follows:

The MAH identified a signal of “immune haemolytic anaemia” during the reporting period. The analysis retrieved 8 cases with a probable or possible causal relationship with Pemetrexed. Half of the cases were clearly evidenced by the positive direct antiglobulin test and for 2 of those by a reaction between the patient’s serum or plasma with red blood cells in presence of pemetrexed or the presence of spherocytes, reticulocytes and/or nucleated red blood cells. The other 4 cases were evidenced by a positive rechallenge. This risk is already listed with the frequency ‘rare’ in the product information, the type of haemolytic anaemia however is not specified.
Therefore, in view of available data regarding immune haemolytic anaemia, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for pemetrexed the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing pemetrexed is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.