EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Remicade

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

International non-proprietary name: infliximab

Procedure No. EMEA/H/C/000240/PSUV/0180

Period covered by the PSUR: 24 August 2010 – 23 August 2013

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Scientific conclusions

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

The PI contains extensive wording regarding TB, including recommendations that *If inactive ('latent') tuberculosis is diagnosed, treatment for latent tuberculosis must be started with antituberculosis therapy before the initiation of Remicade, and in accordance with local recommendations*. There are also recommendations to consult with a physician with expertise in the treatment of tuberculosis, as well as to consider anti-TB treatment before start of infliximab treatment also in other situations. However, the fact that there have been cases of reactivation of TB despite that the patient has been given prophylactic TB treatment is not included in the SPC. Since this is considered an important piece of information for the prescriber, section 4.4 should be updated.

Regarding HSTCL, the cases reviewed during the reporting period did not identify any new safety concerns that indicate a change in the safety profile of infliximab. However, the current CCDS describes the condition as having been reported only in patients with CD or UC. Given that there are cases also in other patient groups that UC and CD, the current wording in section 4.4 and section 4.8 of the SmPC should be updated.

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 Remicade, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance infliximab is favourable subject to the proposed changes to the product information.

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