23 October 2014
EMA/CHMP/33893/2015
Committee for Medicinal Products for Human Use (CHMP)

Cimzia

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

International non-proprietary name: certolizumab pegol

Procedure No.: EMEA/H/C/001037/PSUV/0041

Period covered by the PSUR: 7 March 2013 – 06 March 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
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Scientific conclusions

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

Cases of tuberculosis (TB) have been reported despite the patients receiving tuberculosis treatment before or concomitantly with certolizumab pegol treatment. The PRAC therefore recommended updating section 4.4 of the SmPC to reflect this fact. In addition, as cases of extrapulmonary TB have been reported (which is already reflected in section 4.4 of the SmPC), the PRAC recommended updating SmPC section 4.8 as well for further clarity.

In the table of Section 4.8, for the system organ class (SOC) Infections and Infestations, viral infections (including herpes, papillomavirus, influenza) are listed. Given that several cases of herpes zoster have been reported, it is recommended that the SmPC should be clarified by adding 'zoster' to the example of herpes.

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

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

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