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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): omalizumab

Procedure No. EMEA/H/C/PSUSA/00002214/201512

Period covered by the PSUR: 01 January 2015-31 December 2015

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**Scientific conclusions**

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

Cases of systemic lupus erythematosus (SLE) in relation to Xolair treatment, including two cases with positive dechallenge and one case with positive dechallenge /rechallenged, were reported. Although in the majority of cases the information was too limited to allow a causality assessment, confounding factors such as pre-existing lupus, including potential incipient SLE, were present in many of the remaining cases and the pathogenesis of SLE/drug-induced lupus is still poorly understood and probably multifactorial, it does not appear unreasonable that Xolair, a drug that forms immune complexes with IgE with the potential to induce immune complex injury and for which events such as serum sickness have been rarely reported, could play a role in the pathogenesis of SLE/drug-induced lupus. After a thorough assessment of the available data, there appears to be reasonable support for the possibility of a causal relationship between Xolair and systemic lupus erythematosus.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing omalizumab 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 omalizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing omalizumab 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.