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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): ixekizumab

Procedure No. EMEA/H/C/PSUSA/00010493/201709

Period covered by the PSUR: 23 September 2016 to 22 March 2017

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Scientific conclusions

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

Based on the identification of 4 post-marketing spontaneous reports of immediate hypersensitivity reactions consistent with anaphylaxis and the mechanistic plausibility the term anaphylaxis was added reference safety information (CDS) and is proposed to have it reflected in the Product Information. The term anaphylaxis should be added with frequency rare to section 4.8 of the Summary of Product characteristics based on the fact that no case of anaphylaxis was reported from Clinical Trials. The warning on hypersensitivity in section 4.4 and relevant sections of the Package Leaflet should be adjusted accordingly.

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 ixekizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ixekizumab 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.