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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): vedolizumab

Procedure No. EMEA/H/C/PSUSA/00010186/201711

Period covered by the PSUR: 20 May 2017 to 19 November 2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

The cumulative review of all cases related to anaphylaxis identified 30 cases of anaphylactic reaction and 8 cases of anaphylactic shock. There is reasonable evidence that the vedolizumab exposure is causative factor for anaphylaxis. Therefore section 4.8 Undesirable effects of the SmPC the table of adverse drug reactions should be updated in the Immune system disorders SOC with anaphylactic reaction and anaphylactic shock with frequency 'very rare'.

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