13 December 2018
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/00010186/201805

Period covered by the PSUR: 20 November 2017 to 19 May 2018

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Scientific conclusions

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

Based on plausible mechanism and available number of spontaneous reports of herpes zoster, the PRAC concluded that the product information should be updated with herpes zoster as a new adverse drug reaction with frequency uncommon.

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.