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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/00010186/201705

Period covered by the PSUR: 20 November 2016 to 19 May 2017

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Scientific conclusions

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

Based on the identification 35 cases of pneumonia in which the temporal and a causal relationship with vedolizumab could not be ruled, it is proposed to add the term pneumonia as adverse reaction (ADR) with a frequency very rare. Upper respiratory tract infection is a listed ADR of vedolizumab, consequently the biologically plausible association between vedolizumab and pneumonia cannot be ruled out.

In addition, at least 23 case reports of blurred vision presented information suggestive of a causal association between Entyvio and blurred vision. With high probability blurred vision is associated with listed ADR infusion related reaction. Nevertheless, the Committee concluded that blurred vision must be mentioned separately as ADR in the product information.

Therefore, an update of section 4.8 of the SmPC and relevant section of the Package Leaflet is recommended.

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.