28 January 2021
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/00010186/202005

Period covered by the PSUR: 18/05/2019 To: 18/05/2020

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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:

During the previous PSUSA the MAH performed cumulative review of interstitial lung disease (ILD) cases on the PRAC Rapporteur request. Eighty-seven reports were retrieved from the company safety database describing 87 events. According to MAH assessment ten cases were out of scope, 34 cases were labelled as confounded, 36 cases were regarded as limited information cases, so finally there were no cases of interest. In PRAC opinion for 10 cases, potentially confounded there were no sufficient grounds to exclude vedolizumab as a causative agent. Based on the available evidence the PRAC recommended cumulative review of ILD cases in the current PSUR. In the reporting period (1 year) additional 47 cases have been reported, thus altogether 134 cases of ILD have been recorded for vedolizumab including 15 cases with positive de-challenge. There is a significant increase in the ILD cases (87 cases / 11 years vs 47 cases during the last reporting period). Interstitial lung diseases are known adverse drug reactions of biological drugs with different mechanism of action (anti-TNF agents, rituximab, tocilizumab, abatacept).

Based on the available evidence: fifteen vedolizumab induced ILD cases with positive de-challenge including two published in the literature by Lissner, 31 cases tagged as confounded but in which vedolizumab contribution cannot be excluded and at least three cases regarded as possible, the PRAC is of the opinion that the product information update is 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 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.