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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): galcanezumab

Procedure No. EMEA/H/C/PSUSA/00010733/201903

Period covered by the PSUR: 26 September 2018 To: 26 March 2019

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Scientific conclusions

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

A signal for hypersensitivity reactions, based on cases reported from post-marketing spontaneous data sources was reviewed by the MAH in the PSUR. 96 cases describing hypersensitivity reactions, anaphylactic reactions or angioedema were identified (29 serious, 0 fatal outcomes); 18 cases (14 serious, 4 non-serious) qualified under the anaphylactic reaction SMQ, 40 cases qualified under the angioedema SMQ (narrow) and 36 cases described as rash.

The cumulative review of the data, taking into account pharmacological plausibility, temporal association to treatment and a general lack of confounding factors, concluded that anaphylaxis, angioedema, and rash should be added as new adverse drug reactions in the SmPC and package leaflet of galcanezumab.

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