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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): fremanezumab

Procedure No. EMEA/H/C/PSUSA/00010758/202103

Period covered by the PSUR: 13 September 2020 to 13 March 2021

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Scientific conclusions

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

In view of available data on spontaneous reports including in several cases with a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between fremanezumab and anaphylactic reaction is at least a reasonable possibility. The PRAC concludes that the product information of products containing fremanezumab should be amended accordingly.

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