20 July 2023
EMA/422404/2023
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): tezepelumab

Procedure No. EMEA/H/C/PSUSA/00011015/202212

Period covered by the PSUR: 17 June 2022 to 16 December 2022

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Scientific conclusions

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

In view of available data on risk of 'hypersensitivity (including anaphylactic reaction)' from received reports including 30 cases with reported discontinuation of tezepelumab after observed hypersensitivity/anaphylactic reactions, 19 cases (out of 30) with stated improvement or recovery of the reaction, 9 cases (out of 30) with a close temporal relationship (within minutes/hour or in the same day), the PRAC considers a causal relationship between tezepelumab and 'hypersensitivity (including anaphylactic reaction)' is at least a reasonable possibility. The PRAC concluded that the product information of products containing tezepelumab 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 tezepelumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tezepelumab 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.