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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): tirzepatide

Procedure No. EMEA/H/C/PSUSA/00011019/202311

Period covered by the PSUR: 14/05/2023 To: 13/11/2023

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Scientific conclusions

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

In view of available data on dysgeusia from clinical trials, including cases of positive de-challenge, and from spontaneous reports including in some cases a close temporal relationship and a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between tirzepatide and dysgeusia is at least a reasonable possibility. The PRAC concluded that the product information of products containing tirzepatide should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for tirzepatide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tirzepatide 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.