12 December 2024
EMA/101887/2025
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/00011019/202405

Period covered by the PSUR:
14 September 2023 To: 13 May 2024

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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 dysaesthesia from clinical trials, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action for dysaesthesia, the PRAC considers a causal relationship between tirzepatide and dysaesthesia is at least a reasonable possibility.

In view of available data on delayed gastric emptying from clinical trials, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action for delayed gastric emptying, the PRAC considers a causal relationship between tirzepatide and delayed gastric emptying 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.