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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/00011019/202211

Period covered by the PSUR: 31.05.2022 – 13.11.2022

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## Scientific conclusions

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

In view of available data on injection site pain from spontaneous reports, the PRAC considers a causal relationship between tirzepatide and injection site pain is established. The PRAC concluded that the product information of products containing tirzepatide 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 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.