26 January 2023
EMA/193347/2023
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): semaglutide

Procedure No. EMEA/H/C/PSUSA/00010671/202205

Period covered by the PSUR: 01/06/2021 To: 31/05/2022

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Annex IV

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Scientific conclusions

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

In view of the available data on dysgeusia from clinical trials and spontaneous reports, the PRAC considers a causal relationship between semaglutide p.o. (Rybelsus) and dysgeusia is at least a reasonable possibility. The PRAC concluded that the product information of products containing oral semaglutide (Rybelsus) should be amended accordingly.

In view of the available data on delayed gastric emptying from clinical trials, the PRAC considers a causal relationship between semaglutide (Ozempic, Rybelsus and Wegovy) and delayed gastric emptying is at least a reasonable possibility. The PRAC concluded that the product information of products containing semaglutide 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 semaglutide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing semaglutide 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.