EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2021
EMA/114770/2021
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/00010671/202005

Period covered by the PSUR: From: 01/12/2019 To: 31/05/2020

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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 available data on angioedema from clinical trials and spontaneous reports including in some cases a close temporal relationship and a positive de-challenge, the PRAC considers a causal relationship between s.c. semaglutide and angioedema is at least a reasonable possibility. The PRAC concluded that the product information of products containing s.c. semaglutide (Ozempic) 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.