EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): semaglutide

Procedure No. EMEA/H/C/PSUSA/00010671/201911

Period covered by the PSUR: 01/06/2019 To: 30/11/2019

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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 the clinical studies, hypersensitivity events (e.g., urticaria, rash) considered causally related by investigator were reported in 0.3% of patients receiving semaglutide.

Further, the MAH has presented 4 post-marketing reports of 'hypersensitivity' supporting a causal relationship with semaglutide. The cases have a causal temporal relationship and a positive re-challenge. No confounding factors have been identified.

Based on the information provided it is agreed that these cases reflect a causal relationship between semaglutide and hypersensitivity reactions and it is therefore agreed to update the product information 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.