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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): liraglutide

Procedure No. EMEA/H/C/PSUSA/00001892/201912

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

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Scientific conclusions

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

In view of available data on hypoglycaemia with liraglutide overdose, from clinical trial(s), literature and spontaneous reports, the PRAC considers a causal relationship between liraglutide overdose and hypoglycaemia a reasonable possibility. The existing wording in section 4.9 of the SmPC and corresponding sections in the Package Leaflet of liraglutide in T2DM and WM should be amended to inform HCP's that hypoglycaemia has occurred in cases of liraglutide overdose.

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 liraglutide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing liraglutide 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.