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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/00001892/201512

Period covered by the PSUR: 1 July 2015 – 30 December 2015

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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:

Based on the signal on lipase increased and the events of increase in mean lipase values received from clinical trials and from post-marketing sources, the PRAC considered that the product information should be updated to add the adverse reactions ‘increased lipase’ and ‘increased amylase’ in section 4.8 of the SmPC with a frequency common. The package leaflet should be updated accordingly.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing liraglutide were warranted

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.