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Committee for Medicinal Products for Human Use (CHMP)

Victoza

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: LIRAGLUTIDE

Procedure No. EMEA/H/C/001026/PSUV/0029

Period covered by the PSUR: 1 July 2013 – 30 June 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Victoza, the scientific conclusions of PRAC are as follows:

An evaluation and cumulative review for overdose identified a total of 84 cases (92 events) associated with the use of liraglutide. The majority of overdose-related events were non-serious including severe nausea, vomiting and diarrhoea. None of the patients reported severe hypoglycaemia and all patients recovered without complications. Based on this data the PRAC concluded that section 4.9 of the Summary of Product Characteristic (SmPC) and the corresponding section in the Package Leaflet (PL) should be updated regarding the risk of overdose.

Therefore, in view of available data regarding liraglutide, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Victoza, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance LIRAGLUTIDE is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.