20 March 2014
EMA/CHMP/164151/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Victoza

liraglutide

On 20 March 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Victoza. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication to include the combination of Victoza with basal insulin. The full indication for Victoza now reads as follows:

“Victoza is indicated for treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with: oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4 and 5.1 for available data on the different combinations).”

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

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