



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Questions and answers

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### Outcome of extension of indication application for Victoza (liraglutide)

New data to be included in product information but no addition of new indication

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) finalised the assessment of an application to add a new indication for Victoza. Although the CHMP did not consider the study results that were submitted as part of the application sufficient to recommend the addition of a new indication for Victoza, the Committee concluded, that the new data were of importance to healthcare professionals involved in treating type 2 diabetes and recommended that they be included in the product information for Victoza.

#### What is Victoza?

Victoza is a medicine that contains the active substance liraglutide. It is available as a solution for injection in pre-filled pens.

It is used in adults who have type 2 diabetes (non-insulin-dependent diabetes) to control their blood glucose (sugar) levels. Victoza is approved for use together with antidiabetes medicines taken by mouth (metformin, sulphonylureas and thiazolidinediones). Victoza has been authorised since June 2009.

#### What was Victoza expected to be used for?

Victoza was to be used in combination with basal insulin (intermediate or long-acting insulin such as insulin detemir) in patients with type 2 diabetes who are not satisfactorily controlled on Victoza and metformin alone.



## **What did the company present to support its application?**

The company presented data from a study in 323 patients with type 2 diabetes where treatment with Victoza plus insulin detemir (a long-acting insulin) and metformin was compared to treatment with Victoza and metformin alone.

The main measure of effectiveness was the change after six months in levels of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

## **What was shown in the study?**

The study found that patients who received insulin detemir in addition to Victoza and metformin had bigger decreases in Hb1Ac than patients who were using Victoza and metformin alone (a decrease of 0.54 % compared to 0.2%). Patients who were using Victoza with insulin detemir had a higher rate of hypoglycaemic episodes (low blood sugar levels).

## **What was the conclusion of the CHMP?**

The study compared treatment with Victoza, insulin detemir and metformin with using Victoza and metformin alone. The study only tested the effects of adding insulin detemir to Victoza and metformin and not those of Victoza when added to insulin detemir and metformin. The CHMP considered that the study should have included another group of patients taking insulin detemir and metformin only. The CHMP was of the view that the study design was inappropriate and did not support the addition of a new indication to the marketing authorisation of Victoza for "treatment of type 2 diabetes mellitus in combination with insulin".

Although the CHMP did not consider the results sufficient to add a new indication for Victoza, the Committee concluded that the new data were of importance to healthcare professionals involved in treating type 2 diabetes and recommended that they be included in the product information for Victoza.

The full European Public Assessment Report for Victoza can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_Public\\_Assessment\\_Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports).