European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 April 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
VICTOZA

International Nonproprietary Name (INN): ***liraglutide***

On 23 April 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Victoza 6 mg/ml solution for injection in a pre-filled pen intended for treatment of type 2 diabetes mellitus. The applicant for this medicinal product is Novo Nordisk A/S.

The active substance of Victoza is liraglutide, a GLP-1 analogue medicinal product (A10BX07). Like native GLP-1, the mechanism of action of liraglutide is mediated via a specific action on GLP-1 receptors, which leads to a stimulation of insulin secretion and decrease glucagon secretion in a glucose-dependent manner, a delay in gastric emptying, and a minor reduction in appetite.

The benefits with Victoza are its demonstrated clinically relevant effect on glycaemic control in type 2 diabetic patients if used in combination with sulphonylurea, with metformin, with metformin and thiazolidinedione or with metformin and sulphonylurea. Another benefit of Victoza is the associated loss in body weight.
The most common side effects are gastrointestinal disorders, in particular nausea and diarrhoea. Additionally, when taking Victoza with metformin headache is also very common. When taking Victoza with metformin and glimepiride hypoglycaemia is also a very common side effect. And when taking Victoza with metformin and rosiglitazone vomiting is also a very common side effect.
Specific safety issues regarding thyroid c-cell cancers, the risk of pancreatitis and neoplasms and the need for a long-term cardiovascular outcome study have been evaluated and addressed in the Summary of Product Characteristics (SPC), in the Risk Management Plan and as post-authorisation follow-up measures.

A pharmacovigilance plan for Victoza, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:

"Treatment of adults with type 2 diabetes mellitus to achieve glycaemic control:
In combination with:
– Metformin or a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulphonylurea
In combination with:
– Metformin and a sulphonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy".

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Victoza and therefore recommends the granting of the marketing authorisation.