22 January 2015
EMA/CHMP/27724/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion [1] (initial authorisation)

Saxenda

liraglutide

On 22 January 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Saxenda, 6 mg/ml, Solution for injection in pre-filled pen intended for weight management. The applicant for this medicinal product is Novo Nordisk A/S. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Saxenda is liraglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist also used for the treatment of type 2 diabetes (A10BX07). The mechanism by which liraglutide treatment results in weight loss is not entirely understood, but liraglutide appears to regulate appetite by increasing feelings of fullness and satiety while lowering feelings of hunger and prospective food consumption. Liraglutide also leads to an enhancement of glucose-dependent insulin secretion and a reduction of glucagon release.

The main benefit with Saxenda is its ability to achieve a clinically relevant weight loss. The most common side effects are gastrointestinal adverse reactions (nausea, vomiting, diarrhoea and constipation).

A pharmacovigilance plan for Saxenda will be implemented as part of the marketing authorisation.

The approved indication is:
"Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of

- ≥ 30 kg/m² (obese), or
- ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Treatment with Saxenda should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5% of their initial body weight."

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

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