25 September 2014
EMA/CHMP/524609/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trulicity

dulaglutide

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trulicity, 0.75 mg and 1.5 mg, solution for injection for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is Eli Lilly Nederland B.V.. 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 Trulicity is dulaglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist generated by fusion of a GLP-1 analogue to a modified human immunoglobulin fragment, resulting in a much prolonged half life. Like native GLP-1, dulaglutide leads to an enhancement of glucose-dependent insulin secretion and a reduction of glucagon release.

The benefits with Trulicity are its clinically relevant effect on glycaemic control in patients with type 2 diabetes when used in combination with other glucose-lowering medicinal products including insulin or on its own when metformin cannot be used. Trulicity has a beneficial effect on body weight. The most common side effects are hypoglycaemia when used in certain combinations and gastrointestinal side effects such as nausea and diarrhoea.

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

The approved indication is:

" Trulicity is indicated in adults with type 2 diabetes mellitus to improve glycaemic control as:

Monotherapy

When diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications.

[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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Add-on therapy

In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see section 5.1 for data with respect to different combinations). "

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 Trulicity and therefore recommends the granting of the marketing authorisation.