14 April 2011
EMA/CHMP/103509/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Bydureon

exenatide

On 14 April 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Bydureon, 2 mg, powder and solvent for prolonged-release suspension for injection, intended for 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 Bydureon is exenatide, drugs used in diabetes, other blood glucose lowering drugs, excl. insulins (ATC code: A10BX04).

Exenatide is an incretin mimetic. Endogenous incretins, such as glucagon-like peptide 1 (GLP-1), facilitate insulin secretion following their release from the gut into the circulation in response to food intake. Exenatide is thought to act by mimicking these and other effects of GLP-1.

Bydureon is a 2 mg suspension formulation which allows once weekly administration of exenatide. Bydureon is the first long acting GLP-1 analogue receiving an opinion for marketing authorisation.

The main benefits of Bydureon is its ability to improve glucose metabolism when added to an existing oral antidiabetic therapy as advised in the summary of product characteristics (SmPC). An additional benefit is the associated loss in body weight, which is in contrast to many other therapeutic options available in this setting. The most common side effects are nausea, injection site reactions, hypoglycaemia (when given with sulphonylureas), and headache.

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

[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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The approved indication is:

“BYDUREON is indicated for treatment of type 2 diabetes mellitus in combination with

- Metformin
- Sulphonylurea
- Thiazolidinedione
- Metformin and sulphonylurea
- Metformin and thiazolidinedione

in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.”

Detailed recommendations for the use of this product will be described in the SmPC, 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.

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