26 June 2014
EMA/CHMP/340931/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Abasria

Insulin glargine

On 26 June 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 Abasria, 100 Units/ml, solution for injection intended for the treatment of diabetes mellitus. The applicant for this medicinal product is Eli Lilly Regional Operations GmbH. 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 Abasria is insulin glargine, a long acting insulin analogue (ATC code: A10A E04). Insulin glargine binds specifically to the human insulin receptor and results in the same pharmacological effects as human insulin.

The benefit with Abasria is its ability to lower high blood glucose (BG). The most common side effects are hypoglycaemia, skin and allergic reactions and skin changes at the injection site.

Abasria is a biological medicinal product similar to the reference medicinal product Lantus (insulin glargine), authorised in the EU since 9 June 2000. Studies have shown Abasria to have a comparable quality, safety and efficacy profile to Lantus (insulin glargine).

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

The approved indication is: "Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above."

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.

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