18 May 2017
EMA/CHMP/269671/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Insulin lispro Sanofi

insulin lispro

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Insulin lispro Sanofi, intended for the treatment of diabetes mellitus. The applicant for this medicinal product is Sanofi-Aventis groupe.

Insulin lispro Sanofi will be available as a solution for injection (100 units/ml). The active substance of Insulin lispro Sanofi is insulin lispro, a fast-acting insulin analogue (ATC code: A10AB04) which is absorbed more rapidly by the body and can therefore act faster than human insulin. The replacement insulin acts in the same way as naturally produced insulin; it works by facilitating uptake of glucose into skeletal muscle and fat tissue, and by inhibiting glucose output from the liver.

Insulin lispro Sanofi is a biosimilar medicinal product. It is highly similar to the reference product Humalog (insulin lispro), which was authorised in the EU on 30 April 1996. Data show that Insulin lispro Sanofi has comparable quality, safety and efficacy to Humalog. More information on biosimilar medicines can be found here.

The full indication is:

> "For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Insulin lispro Sanofi is also indicated for the initial stabilisation of diabetes mellitus."

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact