EMA/CHMP/13698/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Semglee

insulin glargine

On 25 January 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Semglee, intended for treatment of diabetes. The applicant for this medicinal product is Mylan S.A.S.

Semglee will be available as a solution for injection (100 units/ml). The active substance of Semglee 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.

Semglee is a biosimilar medicinal product. It is highly similar to the reference product Lantus (insulin glargine), which was authorised in the EU on 9 June 2000. Data show that Semglee has comparable quality, safety and efficacy to Lantus (insulin glargine). More information on biosimilar medicines can be found here.

The full 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

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