

Mylan, Biocon receive EC approval for Semglee

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The EC approval of Semglee™ applies to all 28 European Union (EU) member states and the European Economic Area (EEA) member states of Norway, Iceland and Liechtenstein.



Mylan N.V., one of the world's leading pharmaceutical companies, and Biocon Ltd., Asia's premier biopharmaceutical company, have announced that their co-developed biosimilar insulin glargine Semglee™ has received marketing authorization approval from the European Commission following the positive recommendation by the Committee for Medicinal Products for Human Use (CHMP) of European Medicines Agency. Semglee™ 100 units/mL 3 mL prefilled disposable pen for people with diabetes, is the first biosimilar from Biocon and Mylan's joint portfolio to be approved in Europe.

Additionally, the Therapeutic Goods Administration (TGA), Australia has also approved biosimilar insulin glargine Semglee™ 100 IU/mL 3 mL prefilled pen for the people with diabetes in Australia.

Mylan President Rajiv Malik said, "We are excited to be able to bring Mylan and Biocon's biosimilar insulin glargine to Europe and Australia where millions of people are currently living with diabetes, and we are committed to continuing to bring high quality, more affordable biosimilar products to markets around the world. The investments that we have made to develop and manufacture a leading portfolio of complex products, including Semglee™, is one way that we are delivering on our commitment to expand access to high quality medicine."

Dr. Arun Chandavarkar, CEO and Joint Managing Director, Biocon, said, "The approval of Mylan and Biocon's biosimilar insulin glargine by the European Commission and TGA Australia are important milestones in our collaboration. It furthers our mission to provide a high quality, affordable insulin analog for people with diabetes globally. As a credible, global insulins player, we are committed to address the growing healthcare challenges associated with diabetes and have made significant investments in R&D and manufacturing to build scale and make our affordable insulins portfolio available in many markets."

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In addition to these approvals marketing applications for Semglee™ have also been submitted in Canada and the U.S. Several submissions are planned for key Emerging Markets.

Diabetes is the fastest growing chronic condition in the world and the prevalence of this disease is increasing among all ages. In Europe the number of diabetics are expected to grow to 38 million by 2030, while in Australia it currently affects nearly two million* people.

Mylan plans to launch Semglee™ in Australia later this year and expects to begin launching the product across various markets in Europe in the second half of 2018.