

Biocon, Mylan launch Semglee in Australia

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First Insulin Glargine Biosimilar



Biocon Ltd and [Mylan N.V.](#) have announced the launch of Semglee® (insulin glargine solution for injection 100 IU/mL in a 3mL pre-filled pen), the first insulin glargine biosimilar in Australia available on the Pharmaceutical Benefits Scheme (PBS).

Insulin glargine is a long-acting basal insulin analogue, given once daily to help control the blood sugar levels of those with diabetes. It is indicated for the treatment of type 1 diabetes mellitus in adults, adolescents and children aged six years and above and type 2 diabetes mellitus in adults. Diabetes is recognised as the world's fastest growing chronic condition and is the biggest challenge confronting Australia's health system. Almost two million Australians have diabetes, with 280 Australian developing diabetes every day – one person every five minutes. The total annual cost impact of diabetes in Australia is estimated at \$14.6 billion.

More affordable treatment options for healthcare providers and their patients, such as biosimilars, generate savings that help manage the growing costs of Australia's health care system, particularly the PBS.

The Government recognises the importance of driving biosimilar uptake to create a competitive and sustainable biosimilars market. In 2015, the Government committed to the Biosimilar Awareness Initiative and in 2018 increased its commitment by supporting the Generic and Biosimilar Medicines Association through a \$5 million grant to undertake activities that further promote the appropriate prescribing, dispensing and use of biosimilar medicines.

Dr Christiane Hamacher, CEO, Biocon Biologics said, *"We are extremely excited to enable affordable access to Semglee, a high quality biosimilar Insulin Glargine, co-developed and manufactured by Biocon Biologics, to people with diabetes in Australia. We are committed to use our science, scale and expertise to shift the access paradigm for patients in need of insulins across the globe. As a leading global insulins player, Biocon has been addressing the needs of patients with diabetes for over 15 years and we are confident that availability of Semglee through the Pharmaceutical Benefits Scheme will expand patient access to this therapy in Australia and will reduce the cost burden for PBS. Today, patients in Europe, India and key emerging markets are already benefiting from our biosimilar Insulin Glargine."*

Mylan Australia Country Manager, Sylvain Vigneault commented, *"The launch of Semglee further demonstrates Mylan's ongoing commitment to increase access to biosimilars for patients. Biosimilars mark a new era in treatment. They enable more patients to be treated, deliver significant savings to the PBS and help provide sustainability to the healthcare system overall."*

"We are delighted that Semglee enables Mylan to strengthen and support its global diabetes and metabolism portfolio of approximately 400 products."

Biosimilars have been used safely and effectively in Europe, USA, Australia and many other countries. Since 2006, in the EU alone, over 700 million patient days of clinical experience to more than 20 biosimilar medicines have been recorded.

TGA approval of Semglee, co-developed by Biocon and Mylan, was based on robust data that demonstrated that Semglee is highly similar to the reference insulin glargine, with no clinically meaningful differences in efficacy, safety, purity and potency.

Mylan and Biocon's insulin glargine biosimilar is currently approved in more than 40 countries around the world.