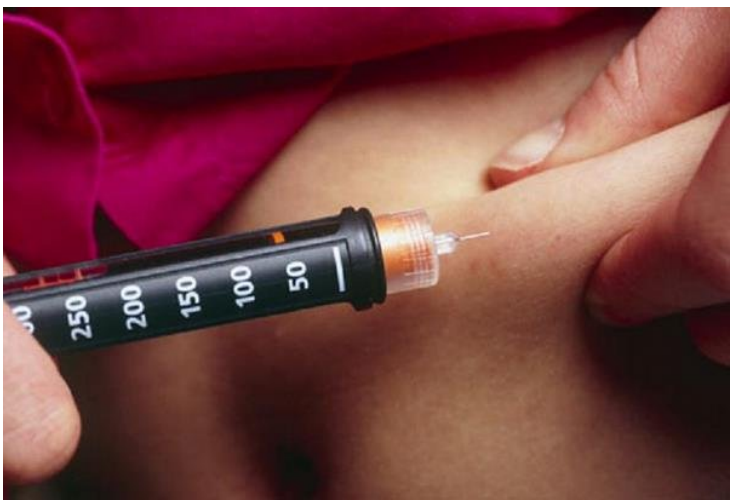


## Biocon and Mylan announce regulatory submission for insulin Glargine accepted for review by European Medicines Agency

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**Biocon and Mylan announce regulatory submission for insulin Glargine accepted for review by European Medicines Agency**



Mylan N.V. and Biocon Ltd. announced that the European Medicines Agency (EMA) has accepted for review Mylan's Marketing Authorization Application (MAA) for insulin glargine, a long-acting insulin analog used to treat adults with type 2 diabetes and adults and pediatric patients (children 6 years and older) with type 1 diabetes for the control of high blood sugar.

Mylan and Biocon, which have co-developed insulin glargine, look forward to offering another insulin treatment option for diabetic patients, who are often facing significant expense to manage their disease. This filing includes analytical, functional and pre-clinical data, as well as results from the pharmacokinetics (PK) and confirmatory efficacy/safety global clinical trial in Type 2 diabetes patients comparing Mylan's and Biocon's Insulin glargine with Lantus. The PK study demonstrated PK and PD bioequivalence of Mylan's and Biocon's insulin glargine relative to that of the reference drug Lantus.

Mylan President Rajiv Malik commented: "The acceptance of our regulatory submission for insulin glargine in Europe is yet another example of the strong progress we continue to make across the exciting portfolio of complex products we have in development, and is another demonstration of the success of our partnership with Biocon. Fifteen percent of the world's pharmaceutical spend will be on diabetes medicines by 2020[1] and there is a significant unmet need around the world for more affordable versions of injectable insulin products. We look forward to helping serve this patient population, building on our existing strength in oral diabetic drugs, by bringing this product to the European market and other markets around the world upon approval."

Dr Arun Chandavarkar, CEO & Joint MD, Biocon, commented: "The acceptance of the insulin glargine application for review by the EMA is another important milestone in Biocon's collaboration with Mylan. This is the third filing from our portfolio comprising biosimilar monoclonal antibodies, insulin analogs and other recombinant proteins to be accepted by EMA in 2016. Importantly, this is the first filing in a developed market that incorporates product validated at our state-of-the-art Malaysia facility and takes us a step closer to our mission of improving access to more affordable insulins globally."