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First Interchangeable Biosimilar Launched In US

Viatis And Biocon Introduce Semglee And Unbranded Insulin Glargine Biosimilars

by David Wallace

Viatis and Biocon have introduced their interchangeable Semglee insulin glargine biosimilar in the US, along with an unbranded interchangeable version, marking the first ever launch of an interchangeable biosimilar. The non-interchangeable version is expected to be phased out rapidly.

Biosimilars industry stakeholders will finally be able to see the effect of a US interchangeability designation on a product in the marketplace, after [Viatis](#) and [Biocon](#) launched their Semglee (insulin glargine-yfgn) and unbranded Insulin Glargine biosimilars in the US.

“Both biosimilar products are available in vial and pre-filled pen presentations and are interchangeable for the reference brand, Lantus, allowing for substitution at the pharmacy counter,” the companies highlighted.

The interchangeability designation – which was granted for Viatis and Biocon’s insulin glargine biosimilar earlier this year, with Semglee representing the first ever biosimilar to be designated as interchangeable by the US Food and Drug Administration (Also see “[Viatis Wins Landmark First US Interchangeability Designation For Semglee](#)” - Generics Bulletin, 29 Jul, 2021.) – also confers a year of first interchangeable biosimilar exclusivity, dating from commercial launch of the interchangeable version of the product.

Viatis emphasized that the branded and unbranded versions of the interchangeable product “provide more affordable options for the millions of Americans living with diabetes.”

Following the launch, the company confirmed, “the currently marketed non-interchangeable

Semglee is anticipated to be phased out by the end of the 2021 calendar year.”

Earlier this year, Viatris president Rajiv Malik had indicated that the interchangeability designation would offer the firm an opportunity to relaunch Semglee and capture a greater share of the market, with interchangeability helping the company to overcome “the challenges which we have faced so far in picking up the market share,” which have so far led the firm to capture only a low, single-digit percentage of the market.

And in recent weeks, two leading pharmacy benefit managers in the US have endorsed Viatris and Biocon’s interchangeable insulin glargine.

Express Scripts said the product would move to preferred status on its largest national formulary from 1 January 2022 (Also see "[Viatris’ Interchangeable Semglee Lands On Express Scripts Formulary](#)" - Generics Bulletin, 22 Oct, 2021.); and Prime Therapeutics followed suit shortly afterwards. (Also see "[Viatris Scoops Another Preferred Formulary Listing For Interchangeable Semglee](#)" - Generics Bulletin, 9 Nov, 2021.)

Biosimilar Interchangeability: A Blessing Or A Curse?

By **David Wallace**

09 Jul 2021

Biosimilar interchangeability is a hot topic in the US, with the first FDA decision on a formal interchangeability designation expected this month. But across the industry, views differ dramatically on the desirability and likely impact of this additional standard to biosimilarity.

[Read the full article here](#)

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Commenting on the launch of the interchangeable biosimilars, Viatris head of North America Jose Cotarelo underlined the firm’s “long-standing commitment to improving patient access to sustainable, quality and more affordable healthcare,” adding that the company was “extremely proud to stay true to that promise by bringing to millions of people with diabetes these interchangeable insulin biosimilar treatment options.”

Moreover, Cotarelo said, “we are pleased to also offer a broad range of options to help patients, which are intended to maximize access to these important medicines, regardless of financial circumstances, insurance or channel.”

These include a patient assistance program “which may provide free medicine to eligible patients with demonstrated financial need”; a copay program for eligible commercially-insured patients “which may help reduce out-of-pocket expenses on prescriptions to as little as \$0 per 30-day supply”; a voucher for new patients to receive five free 3ml pens or two free 10ml vials; and cash-pay programs to reduce out-of-pocket costs when paying at the pharmacy counter.

They also include a Medicare Part D senior savings model insulin Medicare savings program, which will “limit patient out-of-pocket costs during all phases of coverage – deductible, initial coverage and coverage gap – to no more than \$35 for a month’s supply.” Membership for this program will begin in 2022.

Meanwhile, Biocon Biologics deputy CEO Shreehas Tambe said that the launch of interchangeable biosimilar insulin glargine by Viatris was “in line with our aspiration to provide our biosimilar insulins to ‘one in five’ insulin dependent people with diabetes, globally.”

“This is indeed a landmark event,” Tambe insisted, “and along with the recent formulary listings, we believe it will allow us to improve accessibility, availability and adoption of biosimilars in the US for the benefit of patients and the overall healthcare system.”