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Viatris Wins Landmark First US Interchangeability Designation For Semglee

Allows Pharmacy Substitution For Insulin Glargine Biosimilar Rival To Lantus

by David Wallace

Viatris has revealed its commercial strategy for its Semglee insulin glargine biosimilar in the US after winning a landmark first designation of interchangeability for the product from the FDA that will allow pharmacy-level substitution with a year of exclusivity.

Viatris has broken new ground in the US biosimilars market after winning a landmark first interchangeability designation from the US Food and Drug Administration for the firm's Semglee (insulin glargine-yfgn) biosimilar to Sanofi's Lantus blockbuster.

The interchangeability designation – a US-specific separate standard to biosimilarity – potentially offers a significant commercial advantage. It will allow pharmacy-level substitution for Semglee, while also giving Viatris and partner Biocon Biologics a year of first interchangeable biosimilar exclusivity, dating from commercial launch of the interchangeable version of the product.

Semglee was first approved by the FDA just over a year ago following a series of legal victories over the originator. (Also see "*Mylan And Biocon's Semglee Insulin Glargine Approved In US*" - Generics Bulletin, 12 Jun, 2020.)

At that time, Semglee was approved as a biologic under section 351(a) of the Public Health Service Act, rather than as a 351(k) biosimilar as it has now been classified following the latest FDA decision, making it the 30th approved US biosimilar. It had initially been filed through the agency's 505(b)(2) hybrid new drug application pathway and then converted after the US regulation of insulins changed from drugs to biologics in March 2020.

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Launch of the product followed a couple of months after FDA approval. (Also see "*Mylan And Biocon Launch Semglee Insulin Glargine In US*" - Generics Bulletin, 1 Sep, 2020.)

Ahead of the FDA decision, *Generics Bulletin* took a detailed look at the controversial interchangeability designation in the US, highlighting dramatically different views across the biosimilars industry on the desirability and likely impact of this additional standard to biosimilarity (*see sidebar*).

Setting out its plans for the interchangeable version of Semglee, Viatris said "the interchangeable Semglee product, which will allow substitution of Semglee for the reference product, Lantus, at the pharmacy counter, will be introduced before the end of the year."

Moreover, the firm emphasized that it "is eligible to have exclusivity for 12 months before the FDA can approve another biosimilar interchangeable to Lantus." (Also see "*Biosimilars: US FDA Developing Guidance For First Interchangeable Exclusivity*" - Generics Bulletin, 20 Nov, 2020.)

"Commercial preparations for launch are underway," Viatris confirmed, indicating that "over the next few months, Viatris will transition the current product to the 351(k) interchangeable product."

The diabetes treatment "has an identical amino acid sequence to Lantus and is approved for the same indications," Viatris emphasized.

Earlier this year, management had indicated that the interchangeability designation would offer an opportunity to relaunch Semglee and capture a greater share of the market. (Also see "*Viatris Expects First Interchangeable Biosimilar Designations For Insulins In July*" - Generics Bulletin, 13 May, 2021.)

"Once we have an interchangeable aspart, once we have interchangeability around there, it's an opportunity to basically relook into this, the challenges which we have faced so far in picking up the market share," Viatris president Rajiv Malik said. "We have been slowly and steadily picking up," he added, putting Viatris' share of the insulin glargine market at roughly 2.5%.

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

Viatris and Biocon Biologics' insulin glargine has received regulatory approval in more than 60 countries around the world and was the third biosimilar approved by the FDA through the pair's collaboration, after Ogivri (trastuzumab-dkst) and Fulphila (pegfilgrastim-jmdb).

'Milestone' Approval Will Broaden Insulin Access

Viatris CEO Michael Goettler said the firm was "extremely proud to achieve the industry's first approval of an interchangeable biosimilar product in the US, which will help broaden access to this important diabetes medicine for patients, physicians, payers and providers."

"This is yet another important milestone for our company," Goettler said, "that not only continues to underscore the strength of our internal scientific capabilities, but also supports our belief in the promising future of our company as we continue to work to identify innovative ways to increase access to complex treatments for patients."

Meanwhile, Malik labeled the FDA decision as a "very historic approval" and credited development partner Biocon Biologics "for their collaboration in achieving this milestone."

"Our continued ability to break down barriers to access, bring forth first-to-market products and blaze new trails is a testament to the strength of our scientific, regulatory, operations and legal expertise as well as our focus on patients," Malik insisted.

Biocon Biologics executive chairperson Kiran Mazumdar-Shaw said the company was "extremely proud to be the first to obtain approval of an interchangeable biosimilar product in the US." The "milestone achievement for both Biocon Biologics and our partner Viatris" would, she highlighted, "allow pharmacy level substitution and thereby provide convenient and affordable access to Semglee, a quality biosimilar insulin glargine."

And Biocon Biologics managing director Arun Chandavarkar said the interchangeability approval was "another first to our credit [and] is a testament to our scientific excellence and robust quality comparability data. This allows substitution at the pharmacy counter, thus expanding patient access and sets the stage for future approvals for our other insulin products."

FDA Hails 'Momentous Day' For Diabetes Patients

Announcing the approval, the FDA confirmed that the decision meant that Semglee was "both biosimilar to and interchangeable with Lantus."

"As an interchangeable biosimilar product, Semglee may be substituted for Lantus at the pharmacy-level without the intervention of the prescribing health care provider, subject to state pharmacy laws," the agency indicated.

It emphasized that the decision meant that Semglee had met the following criteria for

interchangeability:

- the interchangeable biosimilar product is biosimilar to the reference product;
- the interchangeable biosimilar product can be expected to produce the same clinical result as the reference product in any given patient; and
- the risk in terms of safety or diminished efficacy of alternating or switching between the interchangeable biosimilar biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

At the same time as it announced its decision, the FDA also released a *fact sheet* about interchangeable products, as well as *updated guidance* for patients and caregivers about interchangeable biologics.

Pointing to the additional data required to support an interchangeability designation, the FDA noted that "while this additional information helps FDA to determine the safety of pharmacy-level substitution, this does not mean that an interchangeable biosimilar is safer or more effective than other biosimilars."

Some industry stakeholders have cautioned that the existence of the separate interchangeability standard in the US could cause confusion by inaccurately implying a higher quality standard than biosimilarity.

> ***"This is a momentous day for people who rely daily on insulin for treatment of diabetes, as biosimilar and interchangeable biosimilar products have the potential to greatly reduce health care costs"***

"This approval furthers FDA's longstanding commitment to support a competitive marketplace for insulin products," the agency stated. "The availability of interchangeable biosimilar insulin products can provide more treatment options to patients, potentially lowering treatment costs and enabling greater access for more patients."

Acting FDA commissioner Janet Woodcock hailed "a momentous day for people who rely daily on insulin for treatment of diabetes, as biosimilar and interchangeable biosimilar products have the potential to greatly reduce health care costs."

Woodcock said that as well as helping the FDA to “support a competitive marketplace for biological products,” the decision “ultimately empowers patients by helping to increase access to safe, effective and high-quality medications at potentially lower cost.”

“Biosimilar and interchangeable biosimilar products have the potential to reduce health care costs, similar to how generic drugs have reduced costs,” the FDA pointed out, noting that “biosimilars marketed in the US typically have launched with initial list prices 15% to 35% lower than comparative list prices of the reference products.”

In recent years, originators such as Novo Nordisk and Eli Lilly have sought to steal a march on insulin biosimilars by launching cheaper versions of their own insulin brands in the US. (Also see "*Lilly Launches More Lower-Priced Insulins In US*" - Generics Bulletin, 27 Apr, 2020.) (Also see "*Novo Nordisk Follows Lilly To Lower-Priced Insulin*" - Generics Bulletin, 12 Sep, 2019.)

“Access to affordable insulin is critical,” said Peter Stein, director of the Office of New Drugs in the FDA’s Center for Drug Evaluation and Research, “and long-acting insulin products, like insulin glargine, play an important role in the treatment of Types 1 and 2 diabetes mellitus.”

“The FDA’s high standards for approval mean health care professionals and patients can be confident in the safety and effectiveness of an interchangeable biosimilar product, just as they would for the reference product.”