

FDA allows automatic 'generic' swap for brand-name insulin

July 29 2021, by Linda A. Johnson



This July 2021 image provided by Viartis shows Semglee insulin. On Wednesday, July 28, 2021, U.S. regulators took action that will make it easier to get a cheaper and similar version of a brand-name insulin at the drugstore. The Food and Drug Administration agreed that Viartis Inc.'s Semglee was interchangeable with widely use Lantus, a fast-acting insulin. Credit: Viartis via AP

U.S. regulators took action Wednesday that will make it easier to get a cheaper, near-copy of a brand-name insulin at the drugstore.

Doctors now have to specifically prescribe what's called a biosimilar or OK substituting it for a more expensive brand-name insulin.

Wednesday's move by the Food and Drug Administration will allow pharmacists to automatically substitute the cheaper version, just as they do with generic pills for other kinds of drugs.

It's the FDA's first approval of an "interchangeable" biosimilar, a near-copy of an injected biologic medicine that's manufactured inside living cells. It could save diabetics and health plans millions of dollars annually and encourage other drugmakers to create more biosimilar medicines. Health data firm IQVIA projects U.S. savings from increasing use of biosimilars from 2020 through 2024 will top \$100 billion.

The FDA agreed that Viatrix Inc.'s Semglee was interchangeable with widely used Lantus, a long-acting insulin.

Approval of a second such interchangeable biosimilar of a fast-acting insulin appears imminent from the same developers, Pittsburgh-based generic giant Viatrix and its partner, India's Biocon.

Mylan N.V., one of two companies that merged to create Viatrix last December, launched Semglee in the U.S. last summer.

Red tape, lengthy patents and pushback from brand-name drugmakers have limited U.S. sales of biosimilars to far below levels in Europe.

"These products are highly similar but much more affordable," said Sean McGowan, head of biosimilars at AmerisourceBergen, a top drug wholesaler.

Only 20 of 29 FDA-approved biosimilars—for cancer and immune disorders like rheumatoid arthritis—are sold in the U.S. so far, he said.

Depending on the pharmacy, Semglee injector pens cost about \$150 to \$190 without insurance for a typical month's supply, compared to \$340 to \$520 for the same supply of brand-name Lantus.

© 2021 The Associated Press. All rights reserved. This material may not be published, broadcast, rewritten or redistributed without permission.

Citation: FDA allows automatic 'generic' swap for brand-name insulin (2021, July 29) retrieved 19 April 2024 from

<https://medicalxpress.com/news/2021-07-fda-automatic-swap-brand-name-insulin.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.