



GLOBAL HEALTHCARE GATEWAY®

POWERED BY VIATRIS

Biosimilars at Viatris

VIATRIS™ is committed to increasing patient access to quality, affordable medicines. One of the ways we're working to achieve this goal is through our focus on biosimilar medicines.

To help meet the urgent need for increased access to biologics in many underserved regions, countries and emerging markets around the world, we offer one of the industry's largest and most diverse global biosimilars franchises focused on the areas of oncology, immunology, endocrinology, ophthalmology and dermatology.

Viatris has been at the leading edge of scientific innovation, including bringing to market the first FDA-approved interchangeable biosimilar in U.S., Semglee® (insulin glargine-yfgn), injection and HULIO® (adalimumab-fkjp) injection, the first biosimilar approved by PMDA in Japan, among other achievements.

Our biosimilars team is an integral member of our GLOBAL HEALTHCARE GATEWAY® partnerships and helps make Viatris a true PARTNER OF CHOICE® by extending our best-in-class in-house biosimilar expertise to your teams.

R&D:

- Project and clinical development excellence
- Clinical study design and execution
- Advanced analytics and CMC oversight
- Device design, development, verification and quality management
- Preclinical and toxicology

Regulatory:

- Strong global regulatory strategy capabilities
- Experience with Global Health Authority interactions (e.g., FDA, EMA, PMDA, ANVISA, Health Canada, TGA, DCGI, etc.)

Commercial:

- Presence in 75+ markets
- Retail, hospital and tender markets capabilities
- Pipeline strategy development
- Insights and analytics bench strength
- In-house Marketing Center of Excellence

Medical:

- Focus on HCP and patient education, access, adherence, outcomes and gaps in healthcare delivery
- Work with international organizations and scientific societies on policy issues
- Drug safety

Operations and Quality:

- Tech services, scale up and tech transfers
- Supply planning and launch management
- Strong quality mindset and expertise

Legal:

- Leadership in IP strategies in close partnership with R&D

Policy:

- Policy expertise across the markets and regions, focusing on biosimilars access

Viatris Biosimilar Fast Facts

1st Interchangeable biosimilar approved by FDA in U.S., Semglee® (insulin glargine-yfgn)*

1st FDA-approved Pegfilgrastim biosimilar in U.S.*

1st Adalimumab biosimilar approved by PMDA in Japan

7 biosimilar molecules launched across various regions globally

10 biosimilar molecules approved or in development

13 biosimilar targets identified for development

300+ secured marketing authorizations across the globe

75+ unique markets where Viatris biosimilars have launched

Data as of December 2020, unless otherwise noted, and does not include impact of previously announced global restructuring program.
*Source of information from U.S. FDA Press Release.





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Leader in Global Biosimilar Markets

U.S.	<ul style="list-style-type: none"> • 1st interchangeable biosimilar approved by FDA in U.S., Semglee® (insulin glargine-yfgn)* • 1st FDA-approved Pegfilgrastim biosimilar in U.S.* • 1st FDA-approved Trastuzumab*
EU	<ul style="list-style-type: none"> • #2 Adalimumab biosimilar both in Germany and France* • 20+ countries launches by 2021 • 69+ product launches
Emerging Markets	<ul style="list-style-type: none"> • 50+ countries launched by 2021 • 100+ MA approvals to date
Japan, Australia, and New Zealand	<ul style="list-style-type: none"> • 1st Adalimumab biosimilar approved by PMDA in Japan • 1st Trastuzumab in Australia • #1 Trastuzumab in Australia* • #1 Adalimumab in Japan*

Data as of December 2020, unless otherwise noted, and does not include impact of previously announced global restructuring program.
 *Source of U.S. information is externally available press releases and for EU and JANZ, the information is from IQVIA Global Sales Data July 2021.

Thought Leadership

Mobilized global stakeholders to address ways to streamline biosimilar approval processes to facilitate greater access to these medicines, including participating as co-author in first peer-reviewed paper of the International Generic and Biosimilar Medicines Association (IGBA) on tailoring clinical trial requirements for biosimilar development.

Advancing Biosimilar Options

Molecule	Countries with Secured Marketing Authorizations (MAs)
Trastuzumab	99
Insulin Glargine	65
Bevacizumab	48
Pegfilgrastim	62
Etanercept	36
Adalimumab	50
Insulin Aspart	28
Total	388 <small>*As of Oct. 2021</small>

We launched our first biosimilar in 2014 and have since secured almost 400 marketing authorizations for biosimilars in countries around the world, demonstrating our commitment to bringing more affordable treatment options to patients living with life-threatening and chronic illnesses, such as cancer, rheumatoid arthritis and diabetes.

Strong Track Record of Partnerships and Collaboration



- Viatris and Biocon's 10+ year partnership led to the industry's first approval of an interchangeable biosimilar product in the U.S., Semglee (insulin glargine-yfgn) injection in July 2021.
- This interchangeable designation allows for substitution of Semglee for the reference product, Lantus®, at the pharmacy counter.
- In addition to Semglee, Viatris and Biocon have partnered on other biosimilars, including Ogivri (Trastuzumab), Fulphila (Pegfilgrastim), Abevmy (Bevacizumab), as well as others in development.

- Since 2018, Viatris and Fujifilm Kyowa Kirin Biologics (FKB) have partnered on Hulio® (adalimumab-fkjp), a high-quality, citrate-free bAdalimumab with a differentiated 2-step auto-injector device.
- Starting in 2018, Hulio has been launched in more than 20 markets across Europe, Canada, and Japan. In the U.S., Hulio was approved by the FDA in July 2020 and is anticipated to launch in 2023.

- Viatris and Momenta (now Janssen) entered into a partnership in 2016 that includes the development and commercialization of a biosimilar version of EYLEA® (afibercept).
- Viatris is primarily responsible for: Clinicals, Operations and Supply Chain, Clinical, Regulatory/CMC, Legal, and Commercialization of this biosimilar.



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