



**FRESENIUS  
KABI**

caring for life

# Biosimilars by Fresenius Kabi

Living beyond disease



# caring for life

Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. Our products and services are used to help care for critically and chronically ill patients. In the field of biosimilars we focus on autoimmune and oncology therapeutic areas.

## A trusted heritage

We are a specialist in products and services for hospital and outpatient care, with a comprehensive portfolio of products and services to enable efficient clinical outcomes in the daily medical routine.

As a global healthcare company headquartered in Germany, with a decentralized organization, we are well placed to meet the needs of our patients and customers worldwide. Each day, more than 37,000 employees share the passion of "caring for life".

## Our biosimilars

Our heritage of devotion towards providing high-quality and affordable treatments while upholding our tradition of putting patients first constitutes a fundamental part of our reputation, which we are now carrying forward into our emergent biosimilars offering.

# We are well established in the manufacture and supply of essential medicines and medical devices

With our long history in healthcare, Fresenius Kabi is well established in the manufacture and supply of products spanning a variety of therapeutic areas. Benefiting from our extensive experience in injectables and complex formulations, we manufacture a comprehensive range of medical devices for the safe administration of our products.

## We leverage our manufacturing expertise to develop and deliver high-quality biosimilars

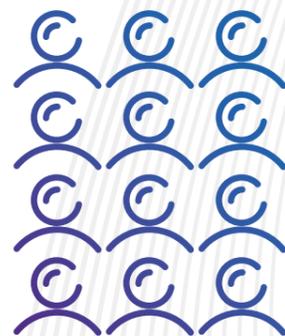
Using our broad and integrated product portfolio, we make an essential contribution to complex therapeutic areas by bringing innovative products, generics and life-changing biosimilars to the market. With around 70 production sites and compounding centers around the globe, Fresenius Kabi can leverage a robust supply chain to increase access to essential medicines and medical devices for patients. This is one of the reasons why we are recognized as a reliable partner by our healthcare customers.

We are equipped with the necessary global expertise in manufacturing and biotechnology with the goal of achieving high similarity to the reference biologic treatment. Driven by excellence in product quality, Fresenius Kabi biosimilars are manufactured in Europe in compliance with the statutory GMP guidelines.

GMP, good manufacturing practice



**Global**  
COMPANY



**37,000+**  
EMPLOYEES

## Our global footprint



# Our expertise in enhanced patient care is unlocking access to life-changing treatments for more patients through biosimilars



## What is a biosimilar?

A biosimilar is a drug that is similar to another approved biopharmaceutical drug despite minor differences in clinically inactive components, and has no clinically meaningful differences in terms of effectiveness, safety or exposure from the reference product.<sup>1</sup>

### Biopharmaceutical drugs<sup>2,3</sup>

- Large complex molecules
- Innovative medicine with targeted mode of action
- Multiple indication fields  
e.g. cancer, diabetes, asthma, rheumatism, autoimmune diseases

### Reference product

Basic research,  
extensive clinical trials



### Biosimilar

- Highly similar "copies" of reference product
- More affordable therapies for a larger number of patients
- Comparable in biological activity and safety
- Clear development guidelines in relation to reference product

## We bring years of pharmaceutical development experience to our biosimilar offering

In line with our corporate philosophy of "caring for life", we are entering into the biosimilars area, as part of our passion and commitment to unlocking access to life-changing medicines for more patients.

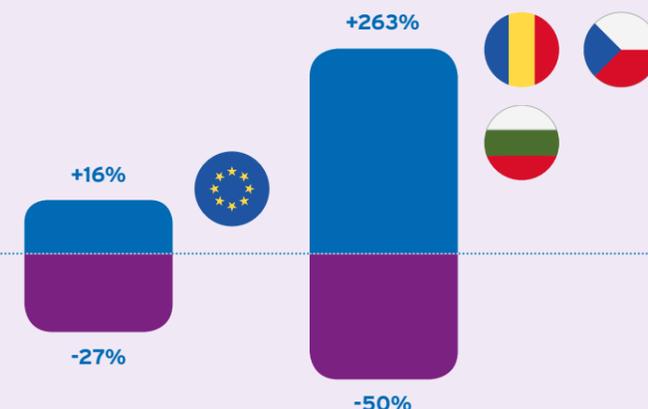
Well positioned to achieve this goal, Fresenius Kabi is equipped with extensive experience in the manufacture and supply of injectables and complex formulations, as well as global expertise in the development of biologics. Fresenius Kabi applies the same high-quality standards in developing and producing biosimilars as is required for the reference product in the areas of oncology and autoimmune diseases.

1. European Medicines Agency. 2017. Biosimilars in the EU: Information guide for healthcare professionals. Page 11. Available at: [www.ema.europa.eu/docs/en\\_GB/document\\_library/Leaflet/2017/05/WC500226648.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf) (Accessed December 2018).  
 2. IMS Health 2016. The impact of biosimilar competition. Pages 5, 11, 13, 18. Available at: <https://www.medicinesforeurope.com/wp-content/uploads/2016/08/IMS-Impact-of-Biosimilar-Competition-2016.pdf> (Accessed December 2018).  
 3. IMS Institute 2016. Delivering on the potential of biosimilar medicines. Pages 7, 11, 13, 17. Available at: <https://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS-Institute-Biosimilar-Report-March-2016-FINAL.pdf> (Accessed December 2018).

# Biosimilars facilitate patient access to more affordable treatment options and encourage innovation<sup>1,2</sup>

## Biosimilars can reduce costs as well as increase access to biological treatments<sup>2</sup>

Epoetin use in EU after launch of biosimilars  
Average increase in volume of treatment days



Change of price per treatment day  
in total market between launch and 2014

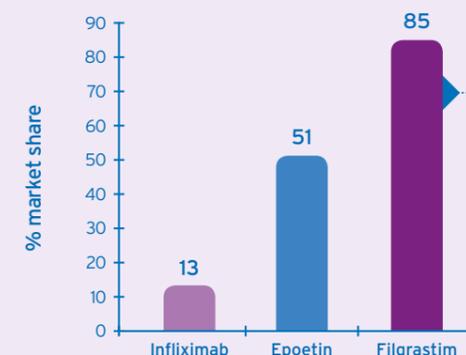


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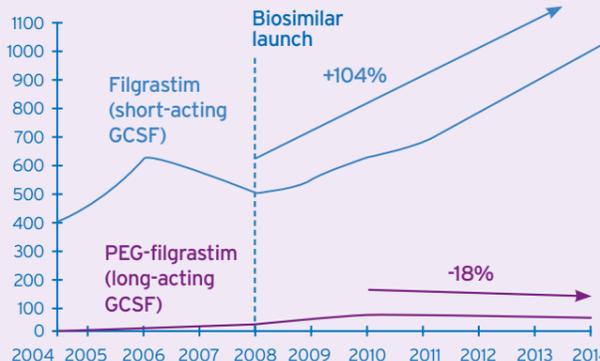
increase in average uptake of epoetin after introduction of biosimilars in countries where access was previously restricted

## Uptake of biosimilars can be rapid and may increase access to medicines<sup>1,2</sup>

Biosimilar market share (treatment days) in the EU in 2015 vs. reference product



Biosimilar filgrastim offered payers opportunity to treat more patients and to treat earlier



GCSF, granulocyte-colony stimulating factor; PEG, polyethylene glycol

1. IMS Health 2016. The impact of biosimilar competition. Pages 5, 11, 13, 18. Available at: <https://www.medicinesforeurope.com/wp-content/uploads/2016/08/IMS-Impact-of-Biosimilar-Competition-2016.pdf> (Accessed December 2018).  
 2. IMS Institute 2016. Delivering on the potential of biosimilar medicines. Pages 7, 11, 13, 17. Available at: <https://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS-Institute-Biosimilar-Report-March-2016-FINAL.pdf> (Accessed December 2018).

# We are committed to putting essential medicines and technologies in the hands of people who help patients

Driven by our philosophy of caring for life, we are committed to putting essential medicines and technologies in the hands of people who help patients, and to finding the best answers to the challenges they face. Fresenius Kabi is engaged to remain responsive to patient needs and continues to be a highly trustworthy partner for healthcare professionals.

## Our dedication and integrity underpin everything we do

The dedication and integrity of our workforce underpins everything we do and we are bringing this to our emergent biosimilars portfolio. Our highly skilled and experienced teams are established throughout the world to support our customers and help make a difference to the quality of life of millions of patients every day. In Germany alone, we support 129,000<sup>1</sup> patient treatments per year with our homecare organization, which was established in 1984. This organization helps bridge hospital care with the patients' home, where our products contribute toward patients' health and wellbeing.



**129,000**  
PATIENT HOME TREATMENTS  
PER YEAR IN GERMANY<sup>1</sup>

## Medicines for Europe



Fresenius Kabi is also an active member of Medicines for Europe, the European association for generics, biosimilars and value-added medicines. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes.

1. Fresenius Kabi. DoF. Micro Strategy SAP.

# Our biosimilars are built on Fresenius Kabi key values

**Customer focus**  
We put customers first

**Collaboration**  
We work well together

**Creativity**  
We deliver solutions



**Quality**  
We demand excellence

**Integrity**  
We are trustworthy

**Passion and commitment**  
We care

# We couple high-quality biologics with highly sought-after patient-centric support services

Fresenius Kabi is committed to providing valued biologic treatments. Our mission includes working closely with healthcare professionals, payers and patients to develop value-added services based on genuine insights to improve patient care.

## Living beyond disease

In fact, we strive to help patients go beyond the disease by seamlessly connecting biologic products with supportive patient programs to leverage the value of comprehensive treatment packages that provide enhanced patient care.



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