Sandoz
Biopharmaceuticals

Sandoz Biosimilars

More than a decade of experience

SANDOZ A Novartis Division

A pioneer and global leader in biosimilars

Repeatedly innovating to break new ground

2006

Launched world's first biosimilar in the EU more than a decade ago (biosimilar somatropin)[1]

2009

Launched first biosimilar in Japan (biosimilar somatropin BS S.C.)[2]

Launched first biosimilar in Canada (biosimilar somatropin)[3]

2015

Launched first biosimilar in the US (biosimilar filgrastim)[4]

References:
1. European Medicines Agency. Omnitrope® Summary of Product Characteristics. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000607/WC500043695.pdf [Accessed March 2020].
2. Pharmaceuticals and Medical Devices Agency. PMDA Perspective: Recent Trends in the Regulation of Biopharmaceuticals. Available from: http://www.pmda.go.jp/files/000197722.pdf#page=24 [Accessed March 2020].
3. Generics and Biosimilars Initiative. Biosimilars approved in Canada. Available from: http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Canada. [Accessed March 2020].
4. Food and Drug Administration. Zarxio™ Package Insert. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf [Accessed March 2020].

World-class expertise

In development, manufacturing and delivery of biosimilars to the healthcare community and patients

Technical Development

Ranges from genetic engineering of the cell line, through design and scale-up of the bioprocess and drug substance purification process, until stable formulation and robust manufacturing process for final drug product. The development is supported by 40 different evaluation techniques and over 100 measures of function and structure to ensure biosimilarity to its reference medicine.

Clinical Development

Expertise in major therapeutic areas to deliver medicines that match reference medicines in terms of quality, safety and efficacy

Manufacturing

End-to-end production of several marketed biosimilars using cutting-edge biomanufacturing facilities

Regulatory

Unparalleled experience with eight approved biosimilars[1] available in almost 100 countries[2] around the world

References:
1. European Medicines Agency. European public assessment reports. Available from: https://www.ema.europa.eu/en/medicines [Accessed March 2020].
2. Sandoz data on file.

Unparalleled heritage

Longer than any other company

> 1 decade	**Marketing of biosimilars[1]**
2 decades	**Biosimilar development experience since initiating the first biosimilar development programme[1]**
3 decades	**Developing recombinant proteins[2]**
7 decades	**Biotechnology experience dating back to the 1940s and the development of penicillin[3]**

References:
1. European Medicines Agency. Omnitrope® Summary of Product Characteristics. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000607/WC500043695.pdf [Accessed March 2020].
2. Rios, M. A Decade of Microbial Fermentation. Available from: http://www.bioprocessintl.com/upstream-processing/fermentation/a-decade-of-microbial-fermentation-331179/ [Accessed March 2020].
3. Bud, R. 2007. *Penicillin: Triumph and Tragedy.* Great Britain: Oxford University Press.

Long-term commitment

To the healthcare community

Value-added services to support patient care:

– SensoReady®
– SurePal®
– OmniSource®
– OmniPal®

Key disease areas include:

– Immunology
– Oncology
– Endocrinology
– Complex and underserved

Changing lives

By increasing patient access to high-quality, affordable biologics

Biosimilars liberate healthcare resources:

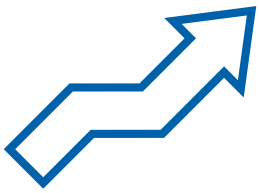
Potential aggregate savings between approx.

EUR 49 billion-EUR 98 billion

between 2016-2020 (EU5 and US)[1]

Increasing access and treatment choice:

Introduction of biosimilars drives competition helping to stimulate R&D into next-generation biologics, resulting in increased patient access to these innovative medicines



More patients have access to biologic treatments[2]

Sandoz helping to improve lives:

8

marketed biosimilars[3]

in almost

100

countries[4]

with more than

530

million patient days of experience[5]

References:
1. IMS Institute for Healthcare Informatics: Delivering on the Potential of Biosimilar Medicines report. IMS Institute Report. March 2016.
2. IQIVA Advancing Biosimilar Sustainability in Europe [Accessed March 2020].
3. European Medicines Agency. European public assessment reports. Available from: https://www.ema.europa.eu/en/medicines/ [Accessed March 2020].
4. Data on file.
5. PSUR data on file.

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