

## **Sandoz Biosimilars " >**

Sandoz, a Novartis division, is a pioneer and a global leader in biosimilars. We invest in research and development to improve the lives of patients and liberate healthcare resources through increased access to high-quality, affordable biologics.

With eight marketed biosimilars across immunology, oncology and endocrinology, we also have a leading biosimilars pipeline with more than 15 molecules in various stages of development.

After initiating the world's first biosimilar development program 25 years ago, we went on to receive the world's first approval of a biosimilar in Europe in 2006<sup>1</sup>. Then, in 2009, we received the first marketing authorization of biosimilars in Japan and Canada<sup>2,3</sup> and opened the US market with the first biosimilars approval in 2015<sup>4</sup>.

Our biosimilars have been used in clinical practice for over 15 years, are available in approx. 100<sup>5</sup> countries with over 970 million patient-days of experience<sup>6</sup>.

Find out more in our "More than a decade of experience" brochure (PDF, 0.4 MB)

## **Unparalleled heritage**

We have a unique heritage in pharmaceutical biotechnology and advancing biologic care, that dates back to the 1940s with the development of penicillin. In 1980, Sandoz produced one of the first recombinant proteins, an interferon alfa<sup>7</sup>. Sandoz also has over 25 years of experience in biosimilar development<sup>1</sup> – longer than any other company.

This has equipped us with extensive knowledge and world-class expertise in the development, manufacture and delivery of biosimilar medicines to the healthcare community and patients.

<b>&gt;1 decade</b>	Marketing of biosimilars <sup>1</sup>
<b>2 decades</b>	Biosimilar development experience since initiating the first biosimilar development programme <sup>1</sup>
<b>3 decades</b>	Developing recombinant proteins <sup>7</sup>
<b>7 decades</b>	Biotechnology experience dating back to the 1940s and the development of penicillin

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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 November 2021]
3. Generics and Biosimilars Initiative. Biosimilars approved in Canada. Available from: <http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Canada>. [Accessed November 2021].
4. Food and Drug Administration. Zarxio™ Package Insert. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/125553lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf) [Accessed November 2021]
5. Sandoz Data on File

6. Periodic Safety Update Reports. Data on file.
7. Rios, M. A Decade of Microbial Fermentation. Available from: <http://www.bioprocessintl.com/upstream-processing/fermentation/a-decade-of-microbial-fermentation-331179/> [Accessed November 2021]
8. Bud, R 2007. Penicillin: Triumph and Tragedy: Great Britain: Oxford University Press [Accessed November 2021]

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**List of links present in page**

- <https://www.sandoz.com/our-work/biopharmaceuticals/sandoz-biosimilars>
- <https://www.sandoz.com/our-work/biopharmaceuticals/sandoz-biosimilar-portfolio-and-pipeline>
- [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/000607/WC500043695.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000607/WC500043695.pdf)
- <http://www.pmda.go.jp/files/000197722.pdf#page=24>
- <http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Canada>
- [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/125553lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf)
- <http://www.bioprocessintl.com/upstream-processing/fermentation/a-decade-of-microbial-fermentation-331179/>