



## Sandoz

Our Sandoz Division is a global leader in generic pharmaceuticals and biosimilars and sells products in more than 150 countries. In the first half of 2018, Sandoz achieved consolidated net sales of USD 5.0 billion. Sandoz develops, manufactures and markets finished dosage form medicines as well as intermediary products including active pharmaceutical ingredients.

Sandoz products were estimated to reach more than 500 million patients worldwide in 2017 and its divisional strategy is to further increase patient access by driving sustainable and profitable growth. Sandoz executes on its strategy by focusing on several key priorities, including investing in selected markets and therapeutic areas where it is best positioned to make a real difference, increasing the performance of its small-molecule Development and Regulatory organization and maximizing opportunities in biosimilars. Sandoz focuses on products that add more value for patients, payors and healthcare professionals than standard generics, including branded generics and value added medicines. Value added medicines are known molecules that offer relevant improvements, address unmet needs and add value by improving efficacy, safety or tolerability, improving administration / ease of use, or offering new therapeutic uses (indication, population)

Top marketed products in the Sandoz generics medicines portfolio include broad-spectrum antibiotic amoxicillin-clavulanic acid, oncology therapies cyclophosphamide and leuprorelin, pain medication fentanyl, which is delivered using a transdermal patch, multiple sclerosis treatment *Glatopa* (glatiramer acetate injection), hypokalemia treatment potassium, and osteoporosis treatment zoledronic acid.

Sandoz also has a strong and continued strategic focus on biosimilars, which it began developing in 1996 and today sells in more than 80 countries. Sandoz is the market leader in biosimilars and now markets a total of five biosimilars. These are: *Omnitrope*, a human growth hormone; *Binocrit*, an erythropoiesis-stimulating agent used to treat anemia; filgrastim for neutropenia under the brand names *Zarzio* outside the US and *Zarxio* in the US; *Rixathon* (biosimilar rituximab), approved in Europe in 2017 to treat blood cancers and immunological diseases (also approved in the EU as *Riximyo* under a duplicate marketing authorization); and *Erelzi* (biosimilar etanercept), approved in Europe in 2017 to treat multiple inflammatory diseases. Availability of these biosimilars varies by country.

The FDA also approved biosimilar *Erelzi* (etanercept-szszs) in 2016 to treat multiple inflammatory diseases. A confirmatory clinical safety and efficacy study demonstrated that *Erelzi* is equivalent to reference medicine Enbrel<sup>®</sup>. The biosimilar launch in the US is pending litigation with Amgen, which markets Enbrel<sup>®</sup>. In May 2018, we received EU approval for our biosimilar infliximab (*Zessly*) and a CHMP positive opinion for our biosimilar adalimumab, as well as FDA file acceptance for our biosimilar adalimumab. We also received a Complete Response Letter for our biosimilar rituximab submission in the US. We plan to submit additional data for pegfilgrastim to the FDA in 2019 to address a Complete Response Letter received from the FDA in 2016.

According to IMS Health, as of April 2018, Sandoz holds the global number one position in sales of biosimilars and of generic anti-infectives and oncology medicines. In addition, Sandoz holds leading global positions in key therapeutic areas including generic cardiovascular, central nervous system, gastrointestinal, metabolism, pain and respiratory medicines.

Following an internal reorganization announced on January 27, 2016, nineteen mature products were transferred from our Innovative Medicines Division to the Retail Generics franchise of Sandoz.

Sandoz also holds operational responsibility for the Novartis Social Business unit, which comprises the Novartis Access program, the Novartis Malaria Initiative (our largest access-to-

medicine program), the Novartis Healthy Family programs, Sandoz NGO Supply and SMS for Life. . Novartis Access offers a portfolio of medicines to treat chronic diseases in low- and lower-middle income countries. The portfolio addresses cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer, and is offered to governments, non-governmental organizations (NGOs) and other public sector health providers for one US dollar per treatment per month.

## Key Sandoz product launches in 2018

In 2018, product launches in the US included *Glatopa* 40mg/mL (generic Copaxone<sup>®</sup> 40mg/mL), Aloxi<sup>®</sup> (generic palonosetron hydrochloride injection), and generic bupropion XL.

In 2018 product launches in various European countries included generic versions of rosuvastatin film coated tablets, ezetimide and simvastatin film coated tablets, and ezetimide film coated tablets, as well as buprenorphine and Naloxone sublingual tablets.

## Businesses

Sandoz is organized globally in three franchises: Retail Generics, Anti-Infectives, and Biopharmaceuticals.

### Retail Generics

In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals to third parties. Retail Generics includes the areas of cardiovascular, central nervous system, dermatology, gastrointestinal and hormonal therapies, metabolism, oncology, ophthalmics, pain, and respiratory, as well as finished dosage form anti-infectives sold to third parties.

### Anti-Infectives

In Anti-Infectives, Sandoz manufactures and supplies active pharmaceutical ingredients and intermediates – mainly antibiotics – for internal use by Retail Generics and for sale to third-party customers.

### Biopharmaceuticals

In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies.

#### Disclaimer

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