For nearly 60 years, Mylan has been a champion for people’s right to high quality, affordable medicine. As a part of that cause, we are working to make biologics more accessible.

What is a Biologic?

Biologics have become the standard of care for many devastating and debilitating diseases like cancer and autoimmune disorders. Unlike conventional medicines, which are made up of chemical compounds, biologics are complex products composed of proteins, sugars or nucleic acids, or may be living entities such as cells and tissues. Their complex molecules contain hundreds of thousands of atoms.

While reliance on these important treatment options continues to increase, access to these medicines is being restricted due to their high cost.

To help address this challenge, manufacturers are working to develop more affordable versions of these medicines called biosimilars. These products are biologic medicines deemed by a regulatory authority to be highly similar to an already approved biologic product. According to regulatory authorities, there are no clinically meaningful differences between a biosimilar and its reference product in terms of safety, purity and potency, and the products are expected to offer the same therapeutic benefits.

Biosimilar medicines offer an opportunity to provide greater access to more affordable healthcare treatment options.

There is an urgent, unmet need for patients to have greater access to more affordable advanced treatment options.
A biosimilar is a complex-to-manufacture biologic medicine that is developed to be highly similar to an existing biologic medicine, or reference biologic medicine. Manufacturers must demonstrate that their biosimilar has no clinically meaningful differences in safety, purity and potency from the reference biologic.

“Biosimilars are safe, effective, more affordable and offer improved patient access.”

- Association for Accessible Medicines
Today's Biosimilar Landscape

More than a decade ago, Europe pioneered the introduction of biosimilars. Today, biosimilars are approved and available in more than 70 countries, including the U.S. Their use has generated more than 700 million patient days of clinical experience.

Significantly, no differences in health outcomes have been demonstrated between people who used the biosimilar therapy and those who used the reference biologic. In addition, biosimilars clearly drive expanded access to treatment. In the seven years after a biosimilar was launched in Europe, for instance, access jumped 44%.

Successes like these are prompting wider adoption of biosimilars, including in the U.S.

Today, a total of 11 biosimilars developed by several companies are approved in the U.S. According to the FDA, more than 60 biosimilars are in development. As more biologics lose their patent protection, additional biosimilars can be brought to market, and the resulting competition will push prices down. It is projected that biosimilars will generate a savings of $54 billion across all products in direct spending on biologic drugs in the U.S. between 2017 and 2026.

Mylan's Commitment to Biosimilars

Mylan’s belief is that the 7 billion people across the globe deserve access to high-quality, affordable medicine.

Mylan’s first biosimilar was successfully introduced in India and is now available to patients in more than 30 countries around the world. In the U.S., Mylan has approved biosimilars and expects to submit applications for additional products in the coming years. Additional regulatory applications are under review around the world.

Mylan’s deep experience and ability to develop and manufacture complex products and successfully commercialize products on a global basis have positioned us to be a worldwide leader in the biosimilars space.

To learn more visit:
MylanBiosimilars.com
FDA.gov/biosimilars

THE BIOSIMILAR DEVELOPMENT PROCESS IN THE U.S.