

Mylan

a champion for access to biologics



There is an urgent, unmet need for patients to have greater access to more affordable advanced treatment options.

>20%

OF CANCER PATIENTS HAVE SKIPPED RECOMMENDED TREATMENTS DUE TO HIGH OUT-OF-POCKET COSTS

INSULIN COSTS HAVE

TRIPLED

OVER THE PAST 10 YEARS

RHEUMATOID ARTHRITIS DRUG COSTS CAN EXCEED

\$1M

OVER THE COURSE OF A LIFETIME

For more than 55 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?

Biologic and insulin medicines have become the standard of care for many devastating and debilitating diseases like cancer, autoimmune disorders and diabetes. 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 thousands, if not millions, 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 biologic 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.

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Bringing Biosimilars to Market

Before any medicine can be sold in the U.S., the U.S. Food and Drug Administration (FDA) evaluates data to determine the safety and efficacy of a drug for its intended purpose. The agency requires generic and biosimilar drugs to be as safe and effective as their corresponding brand, or reference, products. In the case of biosimilars, this requirement is called biosimilarity.

To establish biosimilarity, data are collected over many years, and regulations state that biosimilars must demonstrate high similarity to the reference product in both the lab and clinical settings.

For instance, biosimilar researchers first must characterize, or figure out, the precise makeup and shape of the biologic therapy they wish to reproduce. Characterization is the most important element of demonstrating biosimilarity. State-of-the-art analytical and biotechnology methods are used to characterize a biosimilar medicine, including some methods that may not have been available at the time the reference product was first approved, typically 10-20 years earlier. Once biosimilarity is established,

engineers develop consistent manufacturing processes to ensure the same quality across all quantities of the medicine. Then, clinical trials are conducted in animals and humans to confirm biosimilarity.

These data are assembled into a Biologics License Application (BLA) and reviewed by the FDA. If the agency approves the application, the manufacturer may offer its biosimilar. Approval is based, in part, on demonstrating within the BLA that the biosimilar has the same efficacy and safety as the reference product.

If approved, by the time the biosimilar product begins reaching patients, the company will likely have invested up to \$300 million. That investment is due to the use of state-of-the-art technology of advanced analytical techniques and study of the biosimilar in many patients.

As is the case for all medicines, regulations and guidelines are in place to evaluate the quality, efficacy and safety of biosimilar therapies. Biosimilar manufacturers must be able to demonstrate consistent comparability to the reference product.



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



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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 400 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, five biosimilars 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

the introduction of just 11 biosimilars in the U.S. could save the nation's healthcare system \$250 billion over 10 years.

Mylan's Commitment to Biosimilars

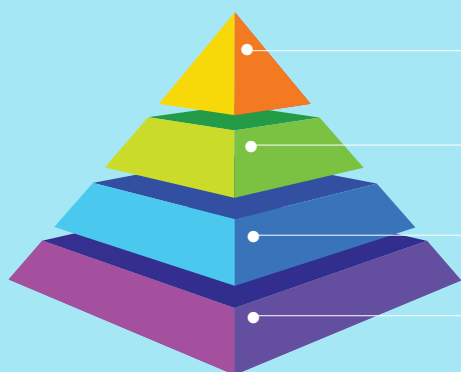
Mylan's belief is that the 7 billion people across the globe deserve access to high-quality, affordable medicine. Whether it is in the more developed parts of the world or in those regions where domestic challenges are barriers to proper treatment, care and access, Mylan is committed to helping patients get the treatment they need. Our first biosimilar was successfully introduced in India and is now available to patients in 13 additional developing markets. In the U.S., we have submitted two Biologics License Applications (BLAs)* and expect 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.



Mylan has 16 biosimilar and insulin analog products on the market or in our product pipeline. They include eight of the world's top 10 biologics focused on the areas of oncology, immunology, endocrinology and ophthalmology.

THE BIOSIMILAR DEVELOPMENT PROCESS IN THE U.S.



ADDITIONAL CLINICAL STUDIES

CLINICAL PHARMACOLOGY STUDIES

NONCLINICAL STUDIES

ANALYTICAL STUDIES

*As of April 2017

Government Relations

+1.202.507.5325

GovernmentRelations@mylan.com

Investor Relations

+1.724.514.1813

InvestorRelations@mylan.com

Media Relations

+1.724.514.1968

Communications@mylan.com

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Better Health
for a Better World™