abbvie

# COMMITTED TO BIOLOGIC INNOVATION

**AbbVie is a global leader in biopharmaceutical innovation and has extensive experience in discovering, developing, and manufacturing biologic therapies. AbbVie continues to focus its research and development on expanding its expertise in immunology and exploring potential new treatments for kidney disease, liver disease, neuroscience, oncology and women's health. In the past two years, AbbVie has invested more than $6.2 billion in research and development, including a large commitment to biologic innovation. Access to safe and effective medicines, including biologics, is important to patients, to those who care for them, and to AbbVie.**

## OUR POSITION ON BIOSIMILARS

A new class of medicines called "biosimilars" is beginning to reach patients around the world. There are important differences between biosimilars and originator biologics.

Biosimilars are biologics that are similar to - though not the same as - previously approved originator biologics. Unlike traditional chemically synthesized, small-molecule medicines, biologics are large-molecule medicines that are grown in or derived from living organisms.

Biosimilars are not generic versions of originator biologics. In fact, it is not currently possible to create an exact copy of a biologic due to the size and complexity of biologic molecules and the sensitivity of the manufacturing process to small changes. Many health authorities therefore acknowledge that the standards for regulating biosimilar medicines should be different from the standards for regulating generic chemically made, small-molecule medicines. These new standards should be based on sound science and patient-focused.

In particular, given the size and complexity of biologic medicines and how they interact with the human body, it is currently not possible to fully predict how a biosimilar will behave in a patient without robust clinical studies that evaluate their efficacy and safety. Consequently, all biologics, including biosimilars, should bear distinguishable non-proprietary names in order to help improve the accuracy of dispensing and adverse event reporting. Finally, current science does not support the automatic substitution of one biologic for another, including a biosimilar. The decision of which biologic treatment to use should remain with the physician and patient.

These standards - and others related to biosimilars - have significant implications for patients, providers, and others. AbbVie supports the entry of biosimilars that have been shown, with robust evidence, including clinical trials, to be as safe and efficacious as originator biologic medicines. The company is using its extensive biologic expertise to help shape these standards on a global basis. It is one of the many ways we strive to make a remarkable impact on patients' lives.