



COMMITTED TO BIOLOGIC INNOVATION

AbbVie is a global leader in biopharmaceutical innovation and has extensive experience in discovering, developing, and manufacturing biologic therapies. AbbVie focuses on discovering and developing transformative therapies that deliver compelling patient benefits, strong clinical performance and clear economic value to payers, while purposefully advancing the standard of care for patients. We continue to expand our expertise in immunology and explore potential new treatments in oncology, neuroscience and virology.

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

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. Patients and physicians around the world are facing an increasingly complex treatment landscape with multiple biosimilars entering the markets. But there are important differences between biosimilars and more common generic medicines.

Biosimilars are biologics that are similar to - though not exactly the same as - originator biologics, while generic medicines are identical copies of traditional chemically made small-molecule medicines.^{1, 2, 3} Unlike small-molecule medicines, biologics are generally more complex, 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. Currently, given the size and complexity of biologic medicines and how they interact with the human body, it is not possible to fully predict how a biosimilar will behave in a patient without robust clinical studies that evaluate their efficacy and safety.^{1, 2, 3}

To help improve the accuracy of dispensing and adverse event reporting, AbbVie considers that all biologics, including biosimilars, should bear distinguishable non-proprietary names.

Finally, AbbVie believes that decisions to switch a patient to a different treatment should remain between a physician and his or her patient based on medical considerations.

References:

1. ABPI position on biologic medicines, including biosimilar medicines
2. FDA's Overview of the Regulatory Guidance for the Development and Approval of Biosimilar Products in the US, 2016
3. EMA Guideline on similar biological medicinal products, 2014

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