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50-State Network Advocate Brief:
Biosimilars Naming Requirements

How can you help?

In March 2010, a U.S. biosimilar pathway was signed into law as part of the Affordable Care Act (ACA). In February 2012, the Food and Drug Administration (FDA) issued three draft guidance documents on biosimilar product development to assist industry in developing such products in the United States. What, if any, additional guidance FDA may issue, and when, is uncertain. [1]

One of the primary issues that the FDA will address in this future guidance are naming requirements for biosimilar products. Many stakeholders believe that biosimilars should follow the naming conventions that generics have with respect to their small molecule reference medicines, by using the same name. However, a "biosimilar" medicine is not the same as a generic. A biosimilar product is highly similar to, but not the same as it's reference biologic product. From a patient safety perspective, it is not appropriate to allow the same name to be used for biologic products and biosimilars when they are in fact not the same.

Unique, distinguishable names are needed to ensure timely detection, assessment, and prevention of any adverse effects from a product. It is pivotal that each biologic medicine have unique distinguishable names. Innovator biologic manufacturers, biosimilar manufacturers, pharmacists, and physicians are well represented in the discussions. We must make sure the patient voice is not forgotten in this pivotal time! As a 50-State Network Advocate, now is your time to shine.

What are biologics?

A biologic medicine is a large molecule typically made from living cells and used in the treatment, diagnosis or prevention of disease. Biologic medicines include therapeutic proteins, DNA vaccines, monoclonal antibodies and fusion proteins. Biologic medicines are often 200 to 1,000 times the size of widely used small molecule drugs and are far more complex structurally. They are also highly sensitive, making them more difficult to characterize and produce.[2]

What are biosimilars?

Unlike generic medicines where the active ingredients are identical, biosimilars – by definition – are not likely to be identical to the originator biologic. They are similar, but not the same. Biologics made by different manufacturers differ from the original product and from each other.[3]

Why are biosimilars important?

With expanding demand for good-quality healthcare, comes the challenge of controlling healthcare costs. The safe and regulated introduction of biosimilars into the market has been forecasted to increase and improve access to much needed biologic medicines and reduce costs.[4]

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[1] U.S. Food and Drug Administration. Guidance for Industry. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.Draft Guidance. U.S. Food and Drug Administration. [Online] Febuary 2012. [Cited: November 20, 2012.] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf
[2] U.S. Food and Drug Administration. What are biologics: Questions and Answers. U.S. Food and Drug Administration. [Online] April 14, 2009. [Cited November 20, 2013] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.html
[3] European Medicines Agency. Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1). European Medicines Agency - Europa. [Online] May 24, 2012. [Cited: November 20, 2013.] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/05/WC500127960.pdf.
[4] Mellstedt, H., et. al. The challenge of biosimilars. Annals of Oncology 19. March 2008, pp. 411-419.

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50-State Network Advocate Talking Points:
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1. As patients, our core concerns are to safeguard safety and the physician-patient relationship.

2. The physician-patient relationship is all about trust. As patients we want to know that what we're being prescribed is safe and effective.

3. We want to have confidence that our biosimilars and biologic medications are distinguishable, so that we can know what we're putting into our bodies.

4. If I experience an adverse event, side effect, or change in my condition, I want my physician to be able to quickly track which biologic or biosimilar medication I was given.