

Healthcare Supply Chain Association (HSCA) Position:

Biosimilars have the potential to increase patient access to life-saving medications and to reduce costs for the entire healthcare system, with one recent study projecting savings of \$250 billion over ten years. HSCA and its members are working with FDA to help ensure a pathway to market for biosimilars that prioritizes patient safety and encourages development and uptake of these less-costly therapies. To protect patient safety, ensure robust market competition and facilitate swift uptake of FDA-approved biosimilars, these medicines should share the same International Nonproprietary Name (INN) as their reference biologic.

Biosimilars Will Increase Patient Access to Life-Saving Therapies and Reduce Costs for the Entire Healthcare System

- ✓ Biologic medicines have revolutionized treatment for many living with serious chronic or life-threatening conditions, but the high price tag for some biologics has put them beyond reach for many patients.
- ✓ Biosimilars – or biologic therapies that have no clinically meaningful differences from their reference biologics and can be produced and sold for a lower price – will increase market competition for biologics, reduce costs, and increase patient access to vital medications.
- ✓ A 2013 Express Scripts study found that the United States could save up to \$250 billion from 2014-2024 should only the 11 likeliest biosimilars enter the market.

Biosimilars Should Share the Same International Nonproprietary Name (INN) as Their Reference Biologic

- ✓ FDA-approved biosimilars should share the same international nonproprietary name (INN) as their reference biologics because they are, by definition, highly similar and have no clinically meaningful differences that would require a unique name.
- ✓ If biosimilars are not allowed to share the INN of their reference biologic, it could jeopardize patient safety, inhibit market competition, and slow the uptake of biosimilars, which could result in billions of dollars in lost potential cost savings.
- ✓ Multiple nonproprietary names may increase confusion among patients and providers and hamper the clinical decision-making of physicians.
- ✓ Requiring unique names would run counter to existing international naming standards for generic pharmaceuticals. Shared INNs are already being safely and effectively used in highly regulated countries in the EU, Canada, Australia and Japan. Since 2006, in Europe there have been no issues with traceability of biosimilars that use the same INN in their products. The manufacturer name, National Drug Code (NDC), and lot number guarantee full traceability.

FDA Should Issue Clear, Robust Guidance on Interchangeability; States Must Act to Ensure Biosimilar Implementation

- ✓ The ability to safely substitute FDA-approved biosimilars for innovator biologics will be critical to realizing the full cost-savings and access potential of biosimilars. FDA should issue clear and robust guidance on the requirements to obtain an “interchangeable” designation.
- ✓ Manufacturers should be allowed to use data collected from Europe to gain FDA approval for interchangeability in the U.S.
- ✓ HSCA urges states to support a pathway for the expedient and safe implementation of biosimilars as these drugs are approved.