# WHAT DO I NEED TO KNOW ABOUT BIOSIMILARS?

## BIOLOGIC NAMING

### BIOLOGIC AND BIOSIMILAR MEDICINES

Biologic medicines are large, complex molecules that are made in living cells, grown in a laboratory. Some examples include vaccines and therapeutic proteins that help your body to fight illnesses such as cancer and arthritis.

Biosimilars are copies of biologic medicines. However, exact copies of biologic medicines are not possible. Biologics are made in living cells, and because of this, there will always be small differences between a biosimilar and the biologic medicine upon which it is based. Testing biosimilars in patients as part of a clinical trial is very important in evaluating whether these small differences have any effect on the way the medicine works in the body.

### WHY SHOULD I CARE ABOUT WHAT A BIOSIMILAR IS CALLED?

The ability to monitor a patient's response to a medicine as well as track any side effects, is an important part of clinical care. Similarly, the ability to look at how a medicine behaves in a population over time, and as more and more patients receive it, is an important part of monitoring real-world drug effectiveness.

One easy way to achieve both of these public health priorities is to track the use of medicines using their name. For an individual patient, this means capturing the medicine name in their medical record. For evaluating the effect of the drug among patient populations as a whole, this means being able to identify data associated with a given drug name. In both instances, clear product identification is essential.

This is especially important for biologics and biosimilars. The extreme complexity and large molecular size of biologic medicines mean that even minor differences between two similar biologics can cause unexpected reactions in patients, including unwanted immune reactions. Additionally, biologics are extremely sensitive to any changes in the manufacturing process which has the potential to change how the medicine behaves in the body.

For both of these reasons, it is important that biosimilars have unique non-proprietary names, distinguishable from the name given to the biologic on which they are based, to ensure patient safety.

### BENEFITS OF DISTINGUISHABLE NAMING

ASBM has conducted a number of surveys among healthcare providers using and prescribing biologics and biosimilars. Across a number of regions around the world, using the same name for both the original biologic and the biosimilar implied to physicians that the medicines were both structurally identical and interchangeable with each other. Neither are true, and assuming otherwise has the potential to impact patient safety.

**In summary, unique, distinguishable names:**

- Avoid confusion that could put patient safety at risk
- Prevent inadvertent or medically inappropriate substitution of products that have not been deemed interchangeable with each other
- Facilitate safety surveillance and adverse event reporting allow for traceability and manufacturer accountability

## WHERE DO REGULATORY AUTHORITIES STAND ON BIOSIMILAR NAMING?

The World Health Organization (WHO) has developed a random four-letter suffix called a "Biologic Qualifier" to append to a root name shared by a biologic and its biosimilars.

In Europe, biosimilars are generally referred to by their trade names, which are different from those of the brand-name reference drug, but the non-proprietary names of European biosimilars are identical to those of their reference drug. For example, Nivestim™ is Hospira's biosimilar to Amgen's Neupogen®, but both molecules share the non-proprietary name filgrastim.

In its first biosimilar approval (March 2015), the U.S. FDA assigned a meaningful suffix to Zarxio (filgrastim-sndz), in which "-sndz" referred to its manufacturer, Sandoz. Subsequent biosimilars approved by the FDA were named using a random four-letter suffix approach. For example: infliximab-dyyb (approved April 2016) and etanercept-szzs (approved August 2016).

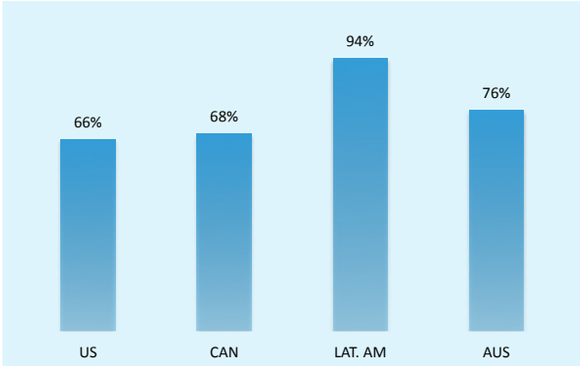
Health Canada has expressed support for distinct naming and is in the process of developing a policy.

## PHYSICIANS AND PHARMACISTS SUPPORT DISTINCT NAMES, MEMORABLE SUFFIXES

In 2015, ASBM conducted a survey of 400 U.S. prescribers of biologics, and found that **66% supported FDA issuing distinct names** for all biologics, including biosimilars. **60% of respondents preferred suffixes based on the manufacturer's name.** Among 401 U.S. pharmacists surveyed, **68% supported the FDA issuing distinct names**, with 77% supporting manufacturer-based suffixes.

Similarly, 68% of Canadian and 76% of Australian physicians supported distinct naming. 94% of Latin American physicians surveyed were supportive of the WHO's distinct naming plan as a tool to ensure their patients receive the correct medicine.

All surveys are available at www.safebiologics.org.




*ASBM's surveys of prescribers in 12 countries show strong support for the distinct naming for all biologics, including biosimilars. View surveys at www.SafeBiologics.org/surveys.*

## WHERE DOES ASBM STAND ON BIOSIMILAR NAMING?

ASBM supports the FDA's continuing its policy of using a distinguishable meaningful, user friendly, suffix related to the company manufacturing the biologic, added to the end of a shared root name.

This will enable different biologic products to be distinguished from each other while ensuring a clear link to the reference product. We believe that a memorable suffix is preferable to a random series of characters, as it will minimize confusion, while enabling a connection to the biologic manufacturer, facilitating traceability and promoting accountability.

Many healthcare professionals and patient and professional groups, including ASBM, support a harmonization of naming conventions across regions to facilitate patient safety with this important class of medicines.

*The Alliance for Safe Biologic Medicines is a diverse group of stakeholders including physicians, pharmacists, patients, researchers, and manufacturers of both biologics and biosimilars. ASBM is an organization focused on promoting the use of biologic medicines, while ensuring their safety and efficacy. Learn more at* ***www.safebiologics.org****.*

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ALLIANCE *for* SAFE BIOLOGIC MEDICINES