

WHAT DO I NEED TO KNOW ABOUT BIOSIMILARS?

PRODUCT LABELING

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 replicas 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 it is based on. 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.

WHY INFORMATIVE, TRANSPARENT LABELING IS CRITICAL

A medicine's product label contains approval and safety information that helps physicians choose between two or more similar medicines to select the best option for a particular patient. This also helps pharmacists give their patients informed advice.

With biologics this is especially important because, unlike generics, the biosimilar is a different medicine than its reference product, meaning:

- It may or may not be approved to treat all of the same diseases as its reference product.
- While having been determined to be safe, it may not have been tested in treating a particular disease.
- It may or not be “interchangeable” with its reference product (meaning the FDA has determined that the same result can be expected as with the reference product without additional risks, thus it can be substituted.)



PRESCRIBERS AND PHARMACISTS WANT INFORMATIVE, TRANSPARENT LABELING

In February 2015, one month prior to the approval of the first US biosimilar, Zarxio (filgrastim-sndz), ASBM conducted a survey among 400 physicians who regularly prescribe biologic medicines about their biosimilar labeling preferences. **An overwhelming majority indicated that transparency in labeling was important in building their confidence in the safety and effectiveness of biosimilars.** A survey later that year of 401 US pharmacists yielded similar results:



IMPORTANT TO INCLUDE ON A BIOSIMILAR LABEL?	Prescriber Survey Feb. 2015	Pharmacist Survey Sept. 2015	Required by FDA?
Identify product as a biosimilar	90%	81%	X
Clearly distinguish reference product data from biosimilar data	79%	69%	X
Were approved indications studied or extrapolated?	80%	76%	X
Interchangeable (substitutable) with reference or not?	79%	88%	X

1 Feb. 2015 Survey of 400 U.S. biologic prescribers and Sept. 2015 survey of 401 U.S. pharmacists, conducted by Industry Standard Research. Full results are available at www.safebiologics.org.

TRANSPARENT LABELING BUILDS CONFIDENCE IN BIOSIMILARS

Regulatory authorities globally have taken diverse approaches to biosimilar product labeling, with Health Canada leading the way in its requirements for a fully transparent label, containing all of the information desired by physicians.

In contrast, product labels for biosimilars approved by the European Medicines Authority and the FDA have considerable gaps in information.

For example, despite the importance of this information to physicians and pharmacists, FDA currently does not require a biosimilar to identify itself as such, to include safety data generated by its sponsor, to state whether approval to treat a disease was granted based on study in that disease or another, or to state whether or not it is interchangeable with its reference product.

Confidence among healthcare providers is critical to the success of biosimilars. As FDA develops its comprehensive labeling policy, ASBM encourages regulators to incorporate a high degree of transparency that will build this confidence among patients, physicians, and pharmacists.

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