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 attempts to copy 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 may not be "interchangeable" with its reference product (meaning the Food and Drug Administration (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 U.S. 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 U.S. pharmacists yielded similar results:

WHAT INFORMATION IS IMPORTANT TO INCLUDE ON BIOSIMILAR LABEL?	Physicians (n= 400)[1]	Pharmacists (n =401)[2]	Included in Zarxio labeling?	Included in FDA draft labeling guidance?
	% Rating as Important or Very Important to Include:			
That the product is a biosimilar	90%	81%	✗	✓
Brand name of biosimilar's reference product	77%	71%	✗	✓
Analytical data used to demonstrate biosimilarity	82%	71%	✗	✗
Clinical data used to demonstrate biosimilarity	83%	71%	✗	✗
Clearly distinguish originator product data from biosimilar data	79%	69%	✗	✗
Indications for which the originator is approved, but the biosimilar is not	79%	76%	✗	✓
Whether or not the indications were studied or extrapolated	80%	76%	✗	✗
Whether the biosimilar is interchangeable with the originator product	79%	88%	✗	✓

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/surveys

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 recently issued FDA draft guidance on biosimilar labeling (March 2016) have considerable gaps in information.

For example, despite the importance of this information to physicians and pharmacists, FDA does not currently require a biosimilar label to include the analytical or clinical biosimilarity data generated by its sponsor, or to state whether approval to treat a disease was granted based on study in that disease or extrapolated. FDA has yet to decide what type of information will be included in the product label for interchangeable biosimilars.

Confidence among healthcare providers is critical to the success of biosimilars. As FDA finalizes its draft labeling guidance, 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**.*

SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES