

BIOSIMILARS

INTERCHANGEABILITY AND SUBSTITUTION

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.

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. 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.

WHAT IS PHARMACY SUBSTITUTION?

This is the substitution of the originator biologic with the biosimilar by the pharmacist without the intervention of the prescribing physician.

NON-MEDICAL SWITCHING

Non-Medical Switching (NMS) is the switching of a patient's medicine, often at the behest of a third party, for reasons other than the patient's health and safety. Non-medical reasons for switching a patient's medicine could include:

- To increase the profits of a private insurer.
- To reduce costs for a government agency, or employer.
- An agreement between the payer and a particular manufacturer to favor that manufacturer's product.

ASBM believes that patients and their physician should remain in control of their treatment decisions, rather than an insurer, government, pharmacy, or other third party.

PHARMACY SUBSTITUTION AROUND THE WORLD

Pharmacy-level substitution is not supported by Health Canada, or the European Medicines Agency. Many countries have banned the practice, including the UK, Germany, Ireland, Spain, Sweden, Norway, and Finland. France legally permits it in limited cases but has not implemented this policy.

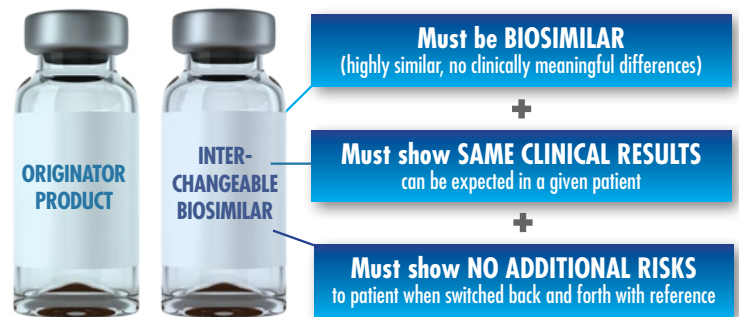
In Latin America, some countries afford physicians prescribing autonomy while others do not. In those instances where physicians do have "DAW" protections, enforcement is not consistent.

In the U.S., substitution is governed by the individual states. As of September 2016, 24 U.S. states and one territory have passed legislation permitting automatic substitution of "interchangeable" biosimilars. All but one have included requirements for clear and timely pharmacist-physician communication and record-keeping in the event of a substitution.

WHAT IS AN “INTERCHANGEABLE” BIOSIMILAR?

An interchangeable biosimilar is a biosimilar that has met a higher standard of evidence required by the U.S. FDA. In the U.S., a pharmacist may only substitute an interchangeable biosimilar in place of the originator biologic without physician involvement.

The specific data requirements to receive regulatory approval for interchangeability are still being determined by the FDA.



WHAT DO PHYSICIANS SAY ABOUT PHARMACY SUBSTITUTION?

Since 2012, ASBM has gathered the perspectives of biologic prescribers in twelve countries, to serve as a resource for policymakers as they craft biosimilar policy.

- 62% of the European physicians, 71% of the Canadian physicians and 85% of Latin American physicians **consider a pharmacy-level determination of which biologic to dispense to their patient to be “unacceptable”**.
- **Notification in the event of a biosimilar substitution was deemed “very important” or “critical”** by 80% of U.S., 77% of European, 85% of Canadian, and 87% of Latin American physicians surveyed.
- The ability to **prevent a substitution by indicating “do not substitute” or “dispense as written” on the prescription was considered “very important” or “critical”** by 82% of U.S., 74% of European, 80% of Canadian, and 85% of Latin American physicians surveyed.

All ASBM surveys may be viewed at www.safebiologics.org/surveys.

WHAT IS ASBM’S POSITION ON PHARMACY SUBSTITUTION?

With patient safety in mind, ASBM supports the following principles related to substitution:

1. Only biosimilars determined to be “interchangeable” by the relevant regulatory authority should ever be substituted.
2. In the event of a substitution, the pharmacist dispensing the medicine should communicate to the physician prescribing the medicine the specific biologic that was dispensed to the patient, who is also notified of the substitution. The result is that everyone involved in patient care knows exactly which medication the patient received. This allows for the appropriate monitoring of a patient’s response to treatment, as well as close tracking of adverse events, and accurate attribution of any problems to the correct product.
3. Physicians should retain the right to prevent a substitution they consider inappropriate by writing ‘dispense as written’ (DAW) or “do not substitute” on the prescription.