Canadian Dermatology Association | Association canadienne de dermatologie

CDA·ACD

CANADIAN DERMATOLOGY ASSOCIATION POSITION STATEMENT
BIOSIMILARS

The existence of generic drugs is not a new concept in pharmacology or in medicine. Traditionally a chemical medication could be made by a generic manufacturer to be chemically or, at least, therapeutically equivalent to the medication intended to be dispensed by the physician. The advantage for patients and, more broadly, to the health care system was in potential cost savings while ostensibly retaining medical efficacy and safety. With the advent of so-called 'biologic' medications, the issue of generic alternatives becomes more complicated. Health Canada designates these "generic biologics" as Subsequent Entry Biologics or SEBs.

Biologic medications are large complex molecules derived via manipulation of DNA expression via living systems. Rather than being simple chemical medications, biologics have multiple layers of complexity size and three-dimensional conformation. Because of this, it may be very difficult if not impossible to replicate them exactly. As such, the therapeutic efficacy and safety of biosimilar medications cannot be assumed by the mere fact of their similarity to the original drug.

It is the position of the CDA via the Pharmacy and Therapeutics committee that, while there may be benefit to the entry of SEBs into the medication marketplace:

1. The interchangeability of SEBs with the original medication should be determined via presentation to Health Canada of new, specific and rigorous safety and efficacy data of these new molecules.

2. These data must not be extrapolated from data used to bring the reference biological medications to market as these may not be applicable to the biosimilar medication.

3. These data should be disease state specific as innovator molecules have shown differential benefit from one disease entity to another.

4. SEBs should have distinct names from the original molecules they are intended to simulate.

5. Physicians must be required to give explicit instruction to the dispensing pharmacist when biosimilar medications may be dispensed in place of the original medication.

6. Patients must be made aware that the substitution is taking place.

7. Long term safety monitoring should be undertaken via post-marketing registries to help detect emerging safety signals not gleaned from initial studies.

8. While there may be a cost advantage to biosimilar medications, the physician's choice of medication should be made in the best interest of the patient.