Diabetes Canada's Input to Stakeholder Consultation on Naming of Biologic Drugs

Submitted online to the Institute for Safe Medication Practices Canada (ISMP Canada)
February 9, 2018

Your responses to this questionnaire will help to inform the development of a naming policy to distinguish between biologic drugs that share the same nonproprietary name. Three naming options are proposed. For all 3 options, all biologic drugs, including biosimilars, will continue to have: a unique brand name, a nonproprietary (common) name that corresponds to the active ingredient and may be shared among biosimilars, reference biologic drugs, and innovator drugs, and a unique DIN.

1. OPTION 1: Continue the current Canadian drug identification and naming approach (status quo)

a) Acceptability of this approach?

We do not find this approach acceptable.

b) Please provide reasons to support your view.

The current Canadian drug identification and naming approach is problematic because it does not sufficiently distinguish between medications referred to by non-proprietary name only. This has the potential to create confusion among prescribers, dispensers, and patients. It must be clear to all who come into contact with a medication what exactly is being recommended and administered.

c) Is this approach compatible within your current practice or environment?

No

Why not, and what changes would be required to implement this approach?

Given the fact that biosimilars are not identical to their reference products, it is important that health care providers with prescribing ability and pharmacists are able to readily

1400 - 522 University Avenue, Toronto, ON M5G 2R5
Call us: 1-800-BANTING (226-8464)
Visit us: www.diabetes.ca

Charitable number: 11883 0744 RR0001

distinguish between the original reference biologic and the biosimilars on the basis of their names, which is questionable with this approach. It is equally imperative for patients to always be aware of the exact medications they are taking for health and safety reasons. This nomenclature also presents challenges in Canada's alignment with other drug administrations, like the FDA, whose proposed naming convention is quite different. An amendment to this approach would resemble option 2 or 3, both of which we support.

2. OPTION 2: Use of the brand name with the nonproprietary name to distinguish among biologics

a) Acceptability of this approach?

We find this approach acceptable.

b) Please provide reasons to support your view.

Assigning a unique name to each medication will assist in the accurate prescribing and dispensing of biosimilars and will help with attributing any side effects to a specific product or manufacturer. We strongly recommend a nomenclature that ensures clarity, which we believe can be achieved with the proposed mandated dual use of the brand name and non-proprietary name.

c) Is this approach compatible within your current practice or environment?

Yes

3. OPTION 3: Implement a 4-letter suffix appended to the nonproprietary name

a) Acceptability of this approach?

We find this approach acceptable.

b) Please provide reasons to support your view.

Like option 2, this approach is also acceptable. It proposes the unique identification of medications with a brand name and non-proprietary name and has the added identifying feature of a meaningless suffix. The suffix may prove to be a source of confusion to prescribers (as they get in the habit of using it) and patients (who may be confounded by its lack of meaning), but the approach achieves the desired goals of accurately identifying biologic drugs throughout the medication-use process (including prescribing, dispensing,

administration, and documentation), ensuring patients receive the drug intended by the prescriber (prevention of medication errors), and accurate attribution and reporting of adverse events for safety monitoring purposes. There would also be the added advantage of compatibility between Canadian and U.S. naming systems.

c) Is this approach compatible within your current practice or environment?
Yes

4. If a suffix were to be appended to nonproprietary names, should previously authorized biosimilars, biologics, and innovator biologics be renamed to conform to the new nomenclature?
Yes

Please provide comments on the potential impact of such a change.
All medications approved for use and sale in Canada should be subject to a common nomenclature.

5. Please suggest any other options or factors that should be considered when developing a naming policy to distinguish between biologic drugs that share the same nonproprietary name. Please provide reasons to support your recommendations.
It is paramount that patients receive the intended medications to treat their conditions and that they are fully aware of what is being administered. A communication strategy and education plan should accompany a new medication naming policy to ensure prescribers, dispensers and patients are all fully aware of the conventions.