SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

The Alliance for Safe Biologic Medicines (ASBM) response to Health Canada and Institute for Safe Medication Practices Canada Stakeholder Consultation of Naming of Biologic Drugs

Submitted for consideration on February 9, 2018

OPTION 1: Status Quo
Continue the current Canadian drug identification and naming approach

a) Acceptability of this approach?

- ○ I/We prefer this approach
- ○ I/We find this approach acceptable
- ○ I/We do not find this approach acceptable

The Alliance for Safe Biologic Medicines (ASBM) is an organization composed of diverse healthcare groups — from patients to physicians, medical innovators, and others who are working together to ensure patient safety is at the forefront of the biosimilar policy discussion.

The issue of biosimilar naming has been a priority for ASBM for several years, and we have repeatedly engaged with global regulators on this topic, including Health Canada and FDA. ASBM has been an active participant on the World Health Organization's (WHO) International Nonproprietary Naming Stakeholders Sessions, and ASBM has presented to this forum on a number of occasions. In the most recent session, ASBM provided perspectives from both a physician and pharmacist viewpoint on the WHO's Biological Qualifier (BQ) proposal. ASBM shares Health Canada's commitment to pharmacovigilance and patient safety and appreciates the thoughtful approach that has been taken in considering the naming of biologic products.

It is ASBM's opinion that the 'Status Quo' – *Biosimilars, reference biologics, and innovator biologics that share the same non-proprietary name can be distinguished by their unique brand names or DINs, however, in some settings only the non-proprietary name is used* - **does not allow for a pharmacovigilance system that protects patient safety.**

The ability to monitor a patient's response to a medicine as well as track any side effects or adverse events, is an important part of clinical care. This is particularly important for biologics, due to their inherent complexity and variability. Distinguishable names for biologics and biosimilars will facilitate the rapid identification of the product a patient received, which will allow clinicians to

appropriately monitor their patients, as well as establishing a system to support traceability for emerging issues related to safety or batch.
As Health Canada notes, while currently biosimilars and reference biologic drugs are distinguished by their unique brand names and Drug Identification Numbers, in some settings ***only* the non-proprietary name is used**. This observation is supported by survey data collected by ASBM in October 2017. ASBM conducted a survey among 403 Canadian prescribers of biologics. Most (86%) had at least 6 years in clinical practice; 31% had 11–20 years of clinical experience. Each physician is board certified in a specialty for which biologics are routinely used. The data indicate that while most physicians (79%) use the proprietary trade name to identify the biologic drug prescribed in the patient's medical record, 20% use the non-proprietary name (1% use DIN). When it comes to reporting adverse events, 26% use the non-proprietary name. Since the non-proprietary name is shared by reference biologics and biosimilars, this precludes a determination of which drug a patient received, and hampers pharmacovigilance. As more biosimilars enter the Canadian market, the number of biologics sharing a non-proprietary name is increasing, which creates the potential for further confusion. This does not therefore appear to be a robust approach that could be employed consistently across health systems.

Our survey data also suggest that having the same non-proprietary name for two biologic medicines can create confusion among healthcare professionals. Among those Canadian physicians surveyed by ASBM, 52% thought that if two biologic medicines had the same non-proprietary scientific name it suggested that the medicines are identical, with 63% believing that two biologic medicines with the same name were approved for the same indications. Given that a biosimilar medicine may be licensed for fewer indications than the reference product, creating this impression of identicality could lead physicians to prescribe medicines inappropriately, which is not in the best interest of patients.

To protect patient safety, and ensure robust pharmacovigilance, ASBM does not support maintaining the current system.

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

- ○ Yes
- ◉ No

ASBM does not believe this approach is compatible with current clinical practice, and as such **does not allow for a pharmacovigilance system that protects patient safety**.

While currently biosimilars and reference biologic drugs are distinguished by their unique brand names and Drug Identification Numbers, in some settings only the

non-proprietary name is used. In October 2017, ASBM conducted a survey among 403 Canadian prescribers of biologics. Most (86%) had at least 6 years in clinical practice; 31% had 11–20 years of clinical experience. Each physician is board certified in a specialty for which biologics are routinely used. The data indicate that while most physicians (79%) use the proprietary trade name to identify the biologic drug prescribed in the patient's medical record, 20% use the non-proprietary name (1% use DIN). When it comes to reporting adverse events, 26% use the non-proprietary name. Since the non-proprietary name is shared by reference biologics and biosimilars, this precludes a determination of which drug a patient received, and hampers pharmacovigilance. As more biosimilars enter the Canadian market, the number of biologics sharing a non-proprietary name is increasing, which creates the potential for further confusion. This does not therefore appear to be a robust approach that could be employed consistently across health systems.

For the 'status quo' to be successful, Health Canada would have to employ educational efforts to change healthcare professional behavior, i.e. ensuring that healthcare professionals use the brand name or the DIN to identify the biologic, and not the non-proprietary name.

OPTION 2 - Use of the brand name with the non-proprietary name to distinguish among biologics

a) Acceptability of this approach?

- ○ I/We prefer this approach
- ○ I/We find this approach acceptable
- ◉ I/We do not find this approach acceptable

In ASBM's view, this approach will not allow for robust pharmacovigilance, as it is unlikely that physicians will use both the brand name and the non-proprietary name to identify the biologic or use both names in the patient's record or in reporting adverse events. Our survey data indicate that physicians pick the brand name, or the non-proprietary name, or the DIN to identify the drug.
Further, the electronic systems that are used to capture the drug administered do not generally have a character count limit that will allow for capture of both the brand name and the non-proprietary name.

While this approach has recently been adopted by the Australian Therapeutic Goods Administration, it is ASBM's view that it has two potential flaws when it comes to considering pharmacovigilance: the first being that it is dependent on the success of the educational activities in changing healthcare professional behavior, i.e. ensuring that healthcare professionals use both the brand name and non-proprietary name to identify the biologic. Second, even if the educational

efforts are successful, the system is heavily reliant on healthcare professionals consistently reporting multiple data sources. Our survey data indicate that currently, only a minority of physicians capture both brand name and non-proprietary name when reporting adverse events.

ASBM does not believe this a viable approach to consistently distinguish among biologics for prescribing, dispensing, and adverse event reporting purposes, and has the potential to put patient safety at risk.

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

- ○ Yes
- ◉ No

ASBM does not believe this approach is compatible with current clinical practice, and as such **does not allow for a pharmacovigilance system that protects patient safety**. Our survey data indicate that it is unlikely that physicians will use both the brand name and the non-proprietary name to identify the biologic or use both names in the patient's record or in reporting adverse events. Our survey data indicate that physicians pick the brand name, or the non-proprietary name, or the DIN to identify the drug. Further, the electronic systems that are used to capture the drug administered do not generally have a character count limit that will allow for capture of both the brand name and the non-proprietary name.

For this approach to be successful, Health Canada would have to invest in educational efforts to change healthcare professional behavior, i.e. ensuring that healthcare professionals use both the brand name and non-proprietary name to identify the biologic. Even if the educational efforts are successful, the system is heavily reliant on healthcare professionals consistently reporting multiple data sources. Our survey data indicate that currently, only a minority of physicians capture both brand name and non-proprietary name when reporting adverse events.

In addition to these educational efforts, some investment would need to be made to update the electronic systems that are used to capture the drug administered, to allow for a character count limit that can facilitate the capture of both the brand name and the non-proprietary name.

OPTION 3 - Implement a 4-letter suffix appended to the non-proprietary name

a) Acceptability of this approach?

- (●) I/We prefer this approach
- ( ) I/We find this approach acceptable
- ( ) I/We do not find this approach acceptable

ASBM strongly supports the use of a distinguishable suffix added to the end of a shared non-proprietary name. This will enable different biologic products to be distinguished from each other; allow for tracking which biologic a patient received; and prevent inadvertent substitution.

Importantly, this view is shared by Canadian prescribers of biologic medicines. Of those surveyed by ASBM, 68% believed that Health Canada should insist on distinct non-proprietary names for all biosimilars and reference products (18% answered no, and 15% had no opinion).

The perspectives of Canadian physicians are aligned with the opinions of other physicians surveyed around the world:

- In Australia, 76% of prescribers believed that the Therapeutic Goods Administration should insist on distinct non-proprietary names for all biosimilars and reference products (18% answered no, and 7% had no opinion).
- In the US, 66% believed that FDA should insist on distinct non-proprietary names for all biosimilars and reference products (11% answered no, and 23% had no opinion).

ASBM applauds Health Canada's desire to support a global approach to distinguishing among biologics sharing the same non-proprietary name. Biosimilars began entering the global market 10 years ago, yet global harmonization of biologic naming has not been achieved. At present, a specific biologic medicine can have different identifiers in different parts of the world, which makes global safety monitoring challenging. Many healthcare professionals and patient and professional groups, including ASBM, support a unification of naming conventions across regions to facilitate patient safety. It is ASBM's view that this could be achieved via the use of a globally-unified suffix that could become a global standard allowing for clear product identification, facilitating manufacturer accountability and protecting patient safety.

The United States Food and Drug Administration (FDA) have taken the lead on the implementation of distinct names for biologics, including biosimilars, releasing *"Nonproprietary Naming of Biological Products: Guidance for Industry"* in January 2017: FDA will assign all biologic drugs receive a unique, meaningless 4-letter

suffix that is appended to the non-proprietary name. In ASBM's view, if Health Canada were to collaborate with FDA and implement a harmonized naming policy, i.e. use the same 4-letter suffix for the same biologic in both Canada and the US, it would encourage other regions to align with this naming paradigm, and drive regulators towards harmonized global naming.

The World Health Organization (WHO) has indicated it intends to review its earlier proposal to assign Biological Qualifier (BQ) suffixes—an alphabetic suffix assigned at random to a biological active substance manufactured at a specified site—to the names of similar biologic products. ASBM has been worked closely with the WHO INN committee since 2013 and believes that if Health Canada and FDA were to align on a naming approach, WHO would adapt the BQ proposal to allow for harmonization.

To allow for easy implementation of suffixes, ASBM recently developed a suffix validation tool, *SuffixAudit*. This tool allows a manufacturer or regulator to quickly test a potential suffix against the FDA established naming rules for biologics, the WHO's proposed BQ standard, or both. ASBM looks forward to meeting with regulators in coming months to offer *SuffixAudit* as an aid to both the implementation of distinguishable naming, and to international harmonization.

Physician confidence in biosimilars is critical to their success. The creation of systems that allow physicians to be able to track which medicine a patient received will create an increased level of comfort in the use of biosimilars, which will drive uptake. As a naming policy is developed, ASBM encourages Health Canada to consider the perspectives of those who prescribe these medicines and **introduce the use of a suffix to the naming of biologics.**

Optional Questions

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

- (●) Yes
- ( ) No

Please provide comments on the potential impact of such a change....

ASBM supports a retrospective naming policy, aligned with that of FDA, as it is only when all biologics have a distinguishable suffix that robust pharmacovigilance is possible. While we acknowledge that there are cost implications associated with this approach, we believe that Health Canada can work with biologic manufacturers and health systems to implement a transition period for the conversion to a distinguishable suffix that will keep costs manageable.

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 non-proprietary name. Please provide reasons to support your recommendations.

Many healthcare professionals and patient and professional groups, including ASBM, support a unification of naming conventions across regions to facilitate patient safety. In ASBM's view, if Health Canada were to collaborate with FDA and implement a harmonized naming policy, i.e. use the same 4-letter suffix for the same biologic in both Canada and the US, it would encourage other regions to align with this naming paradigm, and drive regulators towards harmonized global naming.

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