



SafeBiologics

ALLIANCE *for* SAFE BIOLOGIC MEDICINES

September 7, 2017

Biological Science Section
Therapeutic Goods Administration (TGA)
PO Box 100
Woden ACT 2606

Re: Therapeutic Goods Administration, Consultation: Nomenclature of Biological Medicines

Dear Sir or Madam,

The Alliance for Safe Biologic Medicines (ASBM) respectfully submits the following comments in response to the recent consultation on *Nomenclature of Biological Medicines*, Version 1.0, July 2017.

ASBM is an organization focused on promoting the use of biologic medicines, while ensuring that regulations and policies governing the use of these medicines support patient safety. It is the mission of the Alliance to serve as an authoritative resource center of information for the general public and healthcare and health policy communities on issues surrounding biologic medications. We provide information on the development, regulation, safety and quality of biologics, advocate for policies that keep medical decisions between patients and physicians, and seek solutions that ensure affordability and accessibility of biologic medications, while never compromising patient safety.

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. ASBM has been an active participant on the World Health Organization's (WHO) International Nonproprietary Naming Stakeholders Sessions, and the ASBM

[REDACTED] have jointly presented to this forum twice. In the most recent session, in April 2017, the duo provided perspectives from both a physician and pharmacist viewpoint on the WHO's Biological Qualifier (BQ) proposal.

As TGA is well aware, biosimilars are similar but not identical to the biologic drug they are 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. Additionally, biologics are extremely sensitive to changes in their manufacturing process, which has the potential to change how the medicine behaves in the body. A consistent and transparent naming system that clearly and distinctly identifies each individual product by manufacturer can help manage these risks and increase physician comfort with biosimilars.

Importantly, this view is shared by Australian prescribers of biologic medicines. In June 2016, ASBM conducted a survey among 160 Australian prescribers of biologics. Most (94%) had at least 6 years in clinical practice; 42% had 11–20 years of clinical experience. Each physician was board certified in a specialty for which biologics are routinely used (dermatology, rheumatology, oncology, gastroenterology, endocrinology, nephrology, and neurology). Among those surveyed, 76% believed that TGA should insist on distinct nonproprietary names for all biosimilars and reference products. Respondents were split as to whether biosimilars should receive an identifying prefix (38%), suffix (30%), or completely unique name (29%). These opinions mirror those of physicians from the United States, Europe, and Latin America.

These data were shared for the first time in mid-February in a series of meetings with the Australian Department of Health, the TGA, politicians and senior political advisers with Health portfolio responsibilities to highlight challenges, which if properly addressed, can help increase biosimilar utilization in Australia.

ASBM appreciates the science-based methodology that TGA has demonstrated to date in developing biosimilar policy. We share TGA's commitment to pharmacovigilance and patient safety and appreciate the thoughtful approach that TGA has taken in considering nomenclature of biosimilar products, in particular clearly outlining the outcomes sought as a result of any adopted naming convention. ASBM is confident that ***Option 4: Introduction of the use of suffixes to the naming of biological medicines*** will achieve all of the outcomes sought, but most importantly, it will: 1) result in an improved ability to monitor the incidence of adverse reactions that might occur through the use of a biological medicine; and 2) will provide healthcare practitioners with confidence in the use of these medicines, thereby encouraging uptake.

We respectfully submit our opinions on each of the four options outlined in the consultation for your consideration.

1. Status Quo

It is ASBM's opinion that the 'Status Quo' – use of the Approved Biological Name, typically the INN - does not allow for a pharmacovigilance system that fully and comprehensively 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. Distinguishable names for biologics and biosimilars will allow for the rapid identification of the product a patient received, which will enable clinicians to appropriately monitor their patients and establish a system that supports traceability for any emerging issues related to safety or batch. Unlike generic versions of small-molecule drugs, biosimilars are not exact duplicates of their reference products. They may or may not have been approved for or evaluated in the same indications as the originator biologic. For these reasons accurate identification and tracking are essential with biosimilars.

Further support for distinguishable names can be found in ASBM's survey data which suggests that having the same nonproprietary name for two biologic medicines can create confusion among healthcare professionals. Among physicians surveyed by ASBM, 52% thought that giving two distinct biologic medicines the same nonproprietary scientific name suggested that the medicines are identical. Furthermore, 80% believed 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 identity could lead physicians to prescribe medicines inappropriately, which is not in the best interest of patients.

While use of the INN in combination with the proprietary trade name would allow for unique identification of individual products, our survey data indicate that only a minority of physicians (21%) capture both the INN and brand name on their patient's record. Therefore, this does not appear to be a reliable approach that could be employed consistently across health systems.

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

2. Status Quo plus activities to increase public reporting of adverse events

ASBM supports any activity that strengthens pharmacovigilance to protect patient safety. We support the educational activities designed to encourage healthcare professionals and the public to report all adverse events by their trade name, AUST R, and batch number, as outlined in Option 2. However, it is ASBM's view that this approach has two potential flaws when considering pharmacovigilance: the first being that it is dependent on the success of the educational activities to change the behavior of healthcare professionals. Second, even if the educational efforts are successful, the system is heavily reliant on healthcare professionals consistently reporting multiple data sources, adding more complexity and difficulty relative to recording a unique name which identifies product and

manufacturer in a single data point. Our survey data indicate that only 34% of Australian physicians currently capture both brand name and nonproprietary name when reporting adverse events, 53% rarely or never use the batch number, and 20% inconsistently use the batch number.

ASBM does not believe this system is sufficient to ensure adequate traceability of biologic medicines if employed in the absence of distinguishable names.

ASBM does not support this option, unless combined with the use of a distinguishable naming policy.

3. Move towards a barcoding system

As TGA notes, the proposed barcoding system relies on healthcare facilities, prescribers, and dispensers recording information by scanning the barcode. To ensure adequate pharmacovigilance using this system, two implementation steps would be required: 1) the widespread adoption of the barcode reading technology across all healthcare facilities in Australia; and 2) education among healthcare providers to ensure that the barcode system was consistently used. These steps would require significant time and money to implement.

Additionally, patients would likely find it challenging to easily identify a specific product that may have caused an adverse event using a 2-D barcoding system. First, it is unlikely that a patient would keep the carton or packaging in which a biologic medicine was originally dispensed; and second, they may have trouble interpreting the barcode and accurately identifying the medicine.

For both of these reasons, ASBM does not support this option.

4. Introduce the use of suffixes to the naming of biological medicines

ASBM supports the use of a distinguishable suffix added to the end of a shared root name. This will enable different biologic products to be distinguished from each other and prevent inadvertent substitution, while ensuring a clear link to the reference product. This view is shared by Australian prescribers of biologic medicines. Of those surveyed by ASBM, 76% believed that TGA should insist on distinct nonproprietary names for all biosimilars and reference products.

We note that the use of a distinguishable suffix is aligned with the approach taken by the United States Food and Drug Administration (FDA), who 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. TGA indicates in the Consultation that use of suffixes could lead to a situation whereby two identical biological medicines have different suffixes in the US and Australia, hampering global pharmacovigilance.

ASBM agrees that this is not in the best interest of patient safety and urges TGA to avoid adoption of TGA-specific suffixes.

Biosimilars began entering the global market 10 years ago, yet global harmonization of biologic naming has not been achieved. The increase in molecular size and complexity- from relatively simpler biologics approved a decade ago to the monoclonal antibodies being approved today- necessitates accurate product identification, tracking, and attribution of adverse events. 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 with this important class of medicines. We strongly believe this approach would benefit patients and minimize the burden on healthcare professionals and healthcare systems. It is ASBM's view that this could be achieved via the use of a globally-unified suffix related to the name of the drug manufacturer. This will minimize confusion but still enable a connection to the biologic manufacturer, thus facilitating traceability and accountability.

The WHO INN Committee has been discussing approaches for global naming harmonization for several years, and ASBM has been engaged with this group since 2013. ASBM believes the WHO proposal to assign Biological Qualifier (BQ) suffixes —an alphabetic suffix assigned at random to a biological active substance manufactured at a specified site— is an easy-to-use model that can become a global standard, allowing for clear product identification, facilitating manufacturer accountability, and protecting patient safety. We were surprised that TGA did not list the adoption of the BQ for consideration as a potential naming option for biologic medicines. We encourage TGA to consider this as a naming option that will meet each of the outcomes sought, with the added benefit of enabling global naming harmonization.

Another way to achieve the same goal, would be to employ the use of a meaningful suffix related to the manufacturer of the biologic, for example, filgrastim-sndz, the name given to biosimilar filgrastim manufactured by Sandoz. This approach could become a global standard that allows clear product identification while facilitating manufacturer accountability.

It is ASBM's position however, that on balance any system of unique names are better than none. If the TGA is not inclined to either the WHO's Biological Qualifier, or a suffix derived from manufacturer name, then harmonizing with the current US FDA approach, for example, would be better than either a TGA-specific approach or no unique names at all.

TGA also notes that use of suffixes would make biosimilar and reference products appear as different drugs for prescribing purposes. In ASBM's view, this is appropriate. Biosimilars are similar but not identical to the biological medicine they are based on, and physicians should retain the right to choose which

medicine is appropriate for their patient. For example, there is a possibility that a biosimilar may not share all of the indications of the reference product. In this instance, it would be essential for a physician to be able to distinguish the biosimilar from the reference biologic and be able to select which medicine is most suitable for their patient. In other instances, a physician may not want to switch a stable patient from one biological medicine to another and should retain the ability to make clinical treatment decisions. Additionally, in many countries, prescription by brand name is not the norm. ASBM's survey revealed Australian prescribers identify biologics in patient records just as often by nonproprietary name (38%) as by brand name (39%). In Latin America, prescribers identify biologics in patient records by nonproprietary name 57% of the time.

Further, ASBM believes that the government's efforts to ensure robust uptake of biosimilars will not be hampered by the use of distinguishable names. Rather, the creation of systems that more fully allow physicians to track which medicine a patient received will increase physicians' comfort in the use of biosimilars, and this will drive uptake.

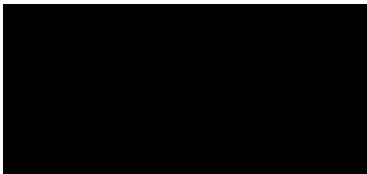
In summary, ASBM supports the introduction of the use of suffixes to the naming of biological medicines, as it will:

- Avoid confusion that could put patient safety at risk
- Facilitate safety surveillance and adverse event reporting
- Allow for traceability and manufacturer accountability
- Prevent inadvertent or medically inappropriate substitution of products
- Increase physician comfort with the use of these medicines which will help to drive uptake.

The availability of biosimilars in Australia represents an opportunity for competition which reduces prices to Government. ASBM is hopeful that reduced prices will ultimately mean the Government will make a decision to give many more patients access to these lifesaving medicines.. Physician confidence in biosimilars is critical to their success. As a naming policy is developed, ASBM encourages TGA to consider the perspectives of those who prescribe these medicines and introduce the use of a suffix to the naming of biological medicines.


ASBM thanks you for the opportunity to weigh in on this important issue.

Sincerely,





The Alliance for Safe Biologic Medicines


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