SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

October 13, 2017

Dr. Tedros Adhanom Ghebreyesus
Director General
World Health Organization
Avenue Appia 20
1211
Geneva 27
Switzerland

cc: Ms. Emer Cooke, Regulation of Medicines and other Health Technologies, WHO
Dr. Rafaella Balocco, INN Expert Group, WHO
Dr. Suzanne Hill, Head EMP, WHO
Dr. Ian Michael Smith, Executive Director, HQ/ODG
Dr. Isabelle Nuttall, Director, HQ/ODG
Mrs. Cynthia Meier, Administration Assistant, HQ/ODG
Theodore Allegra, Chargé d'Affaires ad interim, U.S. Mission to the United Nations and Other International Organizations, Geneva, Switzerland

Re: Request to adopt the World Health Organization (WHO) Biological Qualifier (BQ) Suffix

Dear Dr. Ghebreyesus,

We are writing to urge you to support the recommendation of the WHO's INN Expert Group and implement the Biological Qualifier (BQ) –a random, non-memorable 4-letter consonant-only suffix assigned to all biological active substances.

As an introduction, the Alliance for Safe Biologic Medicines (ASBM) is an organization focused on promoting the use of biologic and biosimilar medicines, while ensuring their safety and efficacy. 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.

Biosimilars are playing an important role in increasing treatment options and broadening access to life changing medications for patients with serious grievous illnesses. However, with multiple products with the same active substance on the market, it is important to distinguish between each product to ensure accurate prescribing and dispensing and to ensure adverse events are attributed to the correct product. As National Competent Authorities (NCAs) begin to implement or consider their own naming conventions, the BQ, used in conjunction with the INN, can be viewed as an adjunct to existing Pharmacovigilance systems affords the perfect opportunity for distinguishable naming for all biotherapeutics whilst avoiding a proliferation of other naming conventions, the latter being a primary concern of the WHO's INN Expert Committee.

Over the past several years, ASBM has taken an active role in shaping biosimilar policy, and has been actively engaged with regulatory agencies around the importance of distinguishable naming for biologics. Since 2013, ASBM has been a regular and active participant at the International Nonproprietary Name (INN) Consultations run by the World Health Organization. In the April 2013 Consultation ASBM's first chairman, Richard Dolinar, MD shared our view that distinguishable naming for biologics is essential to ensure patient safety.

In July 2014, the INN Expert Group put forward a recommendation for a distinguishable naming approach for all biotherapeutics, the Biological Qualifier (BQ) suffix—a 4-letter random, non-memorable suffix assigned to a biological active substance. This recommendation has yet to be implemented.

At the most recent session of the INN Expert Group, in April 2017, ASBM's immediate past Chairman Harry Gewanter, MD, FACR and International Advisory Board Chair and pharmacist, Professor Philip J. Schneider, MS, FASHP presented survey data from 12 countries showing broad support for the BQ among clinicians who prescribe and administer biologic medicines. At this meeting, ASBM also demonstrated the feasibility of BQ implementation via a web-based, BQ-generating algorithm, *SuffixDB*.

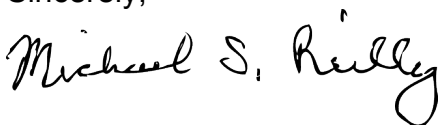
SuffixDB applies BQ naming rules to generate random suffixes, ensuring there are no conflicts with existing suffixes, or similarities with existing words, medical terms, or stock symbols. *SuffixDB* also maintains a registry of current international biosimilar suffixes. During the meeting, ASBM demonstrated that, using *SuffixDB*, the WHO BQ suffix system can be an effective solution for biologic naming.

ASBM believes that implementation of BQ suffixes is a global solution to the global challenge of biologic naming. We urge you to implement the recommendation of the INN Expert Group and adopt the BQ suffix as soon as possible.

The BQ has the potential to become at an important adjunct to global pharmacovigilance systems for all biologic medicines and it should be implemented before further proliferation of national naming schemes occurs. This is especially important for those countries who have less developed pharmacovigilance systems, and who may not have appropriate naming policies in place for biologics and biosimilars.

ASBM will be presenting again at an upcoming INN meeting on October 17th, represented by our third Chair, Madeline Feldman, MD, FACR and Professor Schneider. We welcome the opportunity to discuss the importance of adopting the BQ at that time. Thank you for the opportunity to weigh in on this important issue.

Sincerely,



Michael Reilly,
Executive Director,
Alliance for Safe Biologic Medicines

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