INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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IGBA CONGRATULATES HEALTH CANADA FOR DECISION ON BIOLOGICS NAMING THAT SUPPORTS GROWING GLOBAL CONSENSUS

Geneva, 27 February 2019 - The International Generic and Biosimilar medicines Association (IGBA) welcomes Health Canada's decision[1] to proceed with a biologic naming policy that identifies all biologic medicines, including biosimilars, by their unique brand name and non-proprietary (common) name, without the addition of a product-specific suffix. Health Canada made the decision following a domestic consultation process with stakeholders.

Health Canada's decision highlights a growing global consensus against the use of a product-specific suffix, as seen in long-standing EU experience and the Australian Government's decision to also reject this approach. Additionally, the decision aligns with the World Health Organization's (WHO) approach for nomenclature of biological medicines and WHO's decision to put on hold any further discussions of a biological qualifier.

The decision draws attention to the United States as a notable outlier diverging from this growing global consensus. The recognition that product-specific suffixes pose an unnecessary degree of complexity is highlighted as a core consideration in the Health Canada's decision.

This decision is a strong choice for patient safety, particularly considering a recent European Academic and Regulators study[2] on pharmacovigilance systems that found 96.7% overall product identification was achieved across 10 classes of biologic products, including biosimilar medicines, sharing the same International Non-proprietary Name (INN). There are over 700 million patient days of safe clinical experience with EU-approved biosimilar medicines alone, based on shared INNs with their respective reference products.

"*Health Canada's decision supports quality use of medicines, including safe prescribing and dispensing practice, by avoiding the complexity and potential confusion that would be associated with the introduction of a non-memorable suffix-based system,"* said Jim Keon, Chair of the IGBA.

"*The IGBA urges the U.S. Food and Drug Administration to reconsider its divergent approach to biologic naming and align with its regulatory partners in Europe, Canada, Australia, and other jurisdictions. There is no data available that demonstrates that added non-memorable suffixes in the U.S. have improved, or will improve, the U.S. pharmacovigilance system. IGBA continues to oppose any measures which have the potential to hamper public health and patient access to medicines*," he added.

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[1] Government Canada: Notice to Stakeholder – Policy Statement on the Naming of Biologic Drugs. Available on line at: https://bit.ly/2VjYmKz

[2] Vermeer, et al. "Identifiability of Biologicals in Adverse Event Reaction Reports Received From European Clinical Practice." Clinical Pharmacology. Available on line at https://bit.ly/2NwhBhf

About IGBA

The International Generic and Biosimilar medicines Association (IGBA) was founded to strengthen cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. The IGBA is at the forefront of preserving sustainable competition within our industry, by stimulating competitiveness and innovation in the pharmaceutical sector; thereby, ensuring millions of patients around the world have access to high quality, pro-competitive medicines. For more details, regarding IGBA and its member associations, see the IGBA website at: www.igbamedicines.org.