Biotechnology Industry Organization

September 19, 2014

World Health Organization
Department of Essential Medicines and Health Products (EMP)
1211 Geneva 27
Switzerland

Re: INN Working Doc. 14.342 - Biological Qualifier: An INN Proposal

Evaluation of the document: ***3 – I partially agree***

Dear Dr. Balocco:

The Biotechnology Industry Organization (BIO) thanks the World Health Organization (WHO) for the opportunity to submit comments on "INN Working Doc. 14.342 - Biological Qualifier: An INN Proposal." BIO commends WHO on the release of this proposed policy, which aims to create a consistent, global system for ensuring that all biological products are identified by a unique Biologic Qualifier (BQ).

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

GENERAL COMMENTS:

For nearly a decade, BIO has advocated actively for a nonproprietary naming convention that ensures all biological products are distinguishable. BIO believes that a distinguishable nonproprietary naming convention would best facilitate pharmacovigilance, ensure accurate attribution of adverse events to the correct product, prevent inappropriate substitution and unintended switching, and support tracing of products in the event of a recall. In short, BIO strongly believes that distinguishable nonproprietary names enhance patient safety. Thus, BIO supports the development of a system under which nonproprietary names of biological products that are similar to each other in structure and function are distinguishable, but morphologically related, and easy to recognize, remember, and report accurately.

BIO is very encouraged, therefore, that the proposed policy is applicable to all biological products (*i.e.*, innovators and biosimilars); uses a simple, easy to apply/accommodate code; empowers national health authorities; and includes rationale on why distinguishability is important to all stakeholders, most importantly patients. BIO believes that WHO has proposed a policy that effectively addresses the need to further

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identify biological products for traceability purposes while still respecting the scientific rationale that informs the International Nonproprietary Naming (INN) system and, therefore, supports WHO in keeping the Biological Qualifier (BQ) and the INN separate from a technical perspective. However, from a functional perspective, BIO strongly encourages WHO to clarify in the final policy that the BQ scheme will work only if the BQ is used in all circumstances where the INN is used, including labeling, prescribing, advertising and promotion, adverse event reporting, record keeping, *etc*. BIO believes this should be facilitated by strongly encouraging national/regional regulatory authorities to include the BQ as part of the local non-proprietary name (*i.e.*, for the United States, the United States Adopted Name or USAN). In addition, BIO strongly encourages WHO to conduct extensive outreach and education efforts in support of uniform, global implementation of the BQ policy by individual national/regional regulatory authorities.

MAJOR CONSIDERATIONS/CONCERNS:

While BIO is supportive of the proposed policy, there are some concerns that we believe should be addressed by WHO. Chiefly, BIO believes that linking the BQ to drug substance manufacturing sites will add unnecessary complexity to the system and even potentially undermine the goals of the policy. This is of particular concern if multiple BQs are issued for a single product. BIO believes that the same BQ should be shared by all products containing an active substance with the same INN ***and*** having the same world-wide safety responsible employee, who ensures safety surveillance in one global safety database. BIO requests that WHO clarify how these situations will be addressed and confirm that the BQ will be linked with a product that is subject to a single global safety database (*e.g.*, through the product global safety database owner) to prevent the proliferation of multiple BQs.

Similarly, BIO questions the need to include manufacturing site information in the proposed database of Biological Qualifiers and believes the inclusion and maintenance of this information will require resources disproportionate with potential benefits. BIO recommends that WHO omit manufacturing site information from the information to be maintained in the database of Biological Qualifiers. Further regarding the database, BIO requests that all information be treated as confidential other than INN, BQ, intended trade name, and Marketing Authorization Holder (MAH).

BIO requests that WHO provide additional details, including timelines and mechanism of application, about the retrospective implementation of the policy by publishing prospective guidance and allowing for public comment by stakeholders. While BIO supports retrospective implementation of the policy, we believe it is essential to take a "least burdensome" approach, which will include timelines that account for the resources and planning necessary to implement a change to labeling and inserts for currently marketed products. Specifically, because of the complexity of this retrospective implementation, BIO requests that WHO emphasize to regulatory authorities that importation of products being used by patients should not be restricted without a reasonable time for making adjustments to product labeling requirements.

Finally, while BIO appreciates that measures will be taken to ensure that the four-letter BQ is meaningless, because the code will be assigned at random, BIO believes there is the possibility that the BQ could inadvertently infringe on the rights of another entity (*i.e.*, KPMG, HSBC, *etc.*). To mitigate these potential circumstances, BIO requests that WHO clarify that there will be a process to raise concerns if an assigned BQ creates trademark infringement or other concerns.

CONCLUSION:

BIO appreciates this opportunity to comment on "INN Working Doc. 14.342 - Biological Qualifier: An INN Proposal." We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew W. Womack, Ph.D.
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Biotechnology Industry Organization (BIO)