



Academy of
Managed Care
Pharmacy®

19 September 2014

Dr. R. Balocco Mattavelli
Department of Essential Medicines and Health Products
World Health Organization
1211 Geneva 27
Switzerland

RE: INN Working Doc. 14.342. Biological Qualifier: An INN Proposal; Programme on International Proprietary Names

Dear Dr. Mattavelli:

The Academy of Managed Care Pharmacy (AMCP) would like to share its concerns with the World Health Organization (WHO) about the recent proposal to establish a random, voluntary alphabetic code, known as the biologic qualifier (BQ). As described in the WHO proposal, the BQ identifies biological products produced at a specific site to be used in conjunction with International Nonproprietary Naming (INN). AMCP supports comment INNs without prefixes or noted in previous comments to WHO in response to the proposal in the executive summary of the 56th INN Consultation in November 2013. AMCP is concerned that the addition of a voluntary BQ, despite not being directly attached to the INN, would create confusion in identifying two products with the same active biologic components. This random assignment of voluntary BQs for each manufacturer at each production site may also give the impression to some prescribers, pharmacists, and other health care providers that interchangeable biosimilar products are not the same. This could result in lower market adoption of cost effective biosimilars, especially interchangeable biosimilars.

AMCP is also concerned that the use of the BQ could lead to difficulties in programming and selecting appropriate biologics in pharmacy management systems, electronic health records, and other electronic recordkeeping systems. Some pharmacies and health systems would have to enter the BQs manually because they may not appear in the databases. Even with careful data entry, errors could occur when entering the BQs thus leading to additional problems with selection of biologics and tracking problems. Rather than adopting a new, voluntary coding system, AMCP encourages WHO to help facilitate adoption of existing methodologies, including brand name and lot numbers, described below as a means for identifying and tracking specific biologic products.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy benefits.

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AMCP understands the need to gather accurate, reliable postmarketing data on biologics in the marketplace, to examine performance in patient groups, and track adverse drug events, but this may be accomplished through the use of current mechanisms currently in use, including the use of lot number, brand name, and manufacturer. In addition, the United States has adopted National Drug Codes, a widely understood system to specifically identify products and packages. While AMCP understands that a single system to track specific medications and biologics has not been universally adopted worldwide, the addition of a voluntary identification system using random BQs could potentially lead to additional medication related problems as described above. Therefore, AMCP recommends that WHO support the use of existing product-specific identifiers to track biologic agents rather than creating an additional voluntary system that may create additional, unnecessary confusion.

AMCP thanks WHO for considering its concerns related to the adoption of a voluntary BQ. If you have questions regarding AMCP comments or require further information, please contact me at (001)703.683.8416 (extension 645) or erosato@amcp.org.

Sincerely,



Edith Rosato, RPh, IOM
Chief Executive Officer

CC: Commissioner Margaret Hamburg, Food and Drug Administration