Academy of Managed Care Pharmacy®

Submitted via email to JCS@usp.org

March 30, 2018

Jessica Simpson
Manager, Compendial Operations
United States Pharmacopeia

Re: Revision to Section 2.20 Official Articles of the General Notices and Requirements

Dear Ms. Simpson,

The Academy of Managed Care Pharmacy (AMCP) thanks the United States Pharmacopeia (USP) for the opportunity to submit comments in response to Revision to Section 2.20 of the Official Articles of the General Notices and Requirements related to monographic naming for Food and Drug Administration (FDA) approved biologics, including biosimilars. In the notice, USP indicates that the monograph shall include the "title specified in the relevant monograph plus any suffix designed by FDA unless otherwise specified in the applicable monograph."[1] AMCP understands the need for monographs for biologic products to reflect the name associated with the product, including any suffixes, but remains opposed to the addition of a suffix to the nonproprietary name of biosimilars and biologics. AMCP recommends that USP, as a scientific standards development organization, work with stakeholders to obtain from FDA compelling scientific evidence for the new naming convention, including the rationale for its use in pharmacovigilance in lieu of the existing national drug code (NDC) system.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

In a March 8, 2018 presentation before a Policy Conference of America's Health Insurance Plans, FDA Commissioner Scott Gottlieb supported the need for a robust biosimilars marketplace in the United States. AMCP also supports the need for a robust biosimilars marketplace that includes the need for clear and harmonious guidance and regulations that promotes adoption by patients, providers and payers. AMCP opposes regulatory barriers to marketplace adoption of biosimilars, including the use of random four-letter suffixes attached to the international nonproprietary name (INN).[2] In FDA's final guidance on biologics naming, the Agency acknowledges the possibility of inequity with biologic naming conventions if random suffixes are

[1] USP-NF General Notices and Requirements: Notice of Intent to Revise Section 2.20 of the General Notices. Posted September 29, 2107; Updated October 5, 2017.
[2] AMCP Comments to FDA: Nonproprietary Naming of Biological Products (Docket – FDA-2013-D-1543) Designation of Official Names and Proper Names for Certain Biological Products (Docket – FDA-2015- N-0648). Submitted October 2015. https://bit.ly/2GDMrnk. Accessed March 30, 2018.

applied only for biosimilar approvals under the 351(k) pathways of the Public Health Services Act and not for reference products approved under the 351(a) pathway. FDA indicates that such a difference in naming conventions "could be misinterpreted as indicating that the biosimilar products differ from their reference products in a clinically meaningfully way or are inferior to their reference products for their approved conditions of use."[3] This logic follows AMCP's perspective that the adoption of random four-letter suffixes could imply that biosimilar products differ in a clinically meaningful way or are inferior to the reference biologic and therefore, does not promote a robust biosimilar marketplace.

AMCP also notes that the naming convention for biologics currently recognized by FDA is different from the World Health Organization's proposed biologics qualifier that rejects the use of a suffix as a component of the official INN convention.[4] USP indicates in its proposal the need for global harmonization in biologics naming and therefore, should use its responsibility as a standard setting organization to urge FDA to adopt naming conventions that comport with global standards to promote biosimilar acceptance across the world and thus increase the potential for acceptance as alternatives to reference biologics.

AMCP would like to work with USP and other stakeholders to urge FDA to provide the scientific and clinical evidence to support that the randomized four-letter suffix would, in fact, promote safer use of biologics and biosimilar products. If FDA cannot product this evidence, then the currently recognized naming convention must be overturned.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on adoption of biosimilars with USP. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer

[3]Guidance for Industry: Nonproprietary Naming of Biologic Products. FDA; January 2017. https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf. Accessed March 30, 2018.
[4] Biological Qualifier, An INN Proposal. INN Working Doc. 14.342, Rev. Final October 2015.