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USP Not Moving Forward with Biologics Nomenclature Proposal based on Stakeholder Feedback

Postpones Implementation of Epoetin Monograph

USP continues focus on 'performance standards' and raw materials for biologics

Rockville, MD – April 27, 2018 - USP announced it will not move forward with the proposal published in the *Pharmacopeial Forum* on biologics naming (General Notices Section 2.20). The announcement comes after a review of comments received from the Food and Drug Administration (FDA) and other stakeholders. USP stated that it will not move forward in addressing nomenclature issues without further collaboration with FDA and other stakeholders.

USP also announced that it is postponing the implementation date of the monograph for Epoetin, a biologic medicine commonly used to treat anemia in patients with certain medical conditions. The monograph, which had been under development long before today's announcement on product naming, was scheduled to become official on May 1, 2018. It had been initiated with support by several industry stakeholders. With this postponement, the monograph will not be made official. It can still be used as an informational resource by biologics manufacturers and others, and USP will continue dialogue with stakeholders about future needs.

Acknowledging the critical role public standards play in ensuring the quality of all drugs, including biologics, and facilitating access to them, USP will continue its focus on developing 'performance standards,' which are applicable to classes of biologics (e.g. monoclonal antibodies or cell therapies), as well as standards for raw materials. Performance standards ensure the effectiveness of testing methods that industry and others use to assess quality of biologics. USP is developing these standards by working closely with industry to identify key challenges in biologics development and establishing common benchmarks for quality.

USP also intends to move forward with a revision aimed to ensure alignment with FDA on the use of the descriptive term "with sensor" in approved product names, for drug therapies with sensor technology that verifies when a patient has taken their medication. The amended language ensures the continued applicability of the *USP-NF* monograph for the underlying drug product. USP has not received comments on this amendment, but noted it has previously received FDA support for this revision.

"USP's biologics performance standards can help manufacturers ensure the quality of their products and are part of the overall safety net that helps protect our medicine supply in the United States," said Jaap Venema, Ph.D., chief science officer.

Additional Information:

USP's letter to FDA ***regarding the biologics nomenclature proposal, and restatement on USP approach to drug-product monographs for biologics products***

General Notices and Requirements, ***Biological Products Nomenclature Proposal will be Deferred***

Stakeholder comments ***received by USP regarding proposed change to USP-NF Section 2.20, Official Articles of the General Notices and Requirements***

Revision Bulletin - ***Postponement of Epoetin Monograph***

About USP

USP is an independent non-profit organization that collaborates with the world's top health and science experts to develop high-quality standards that set the bar for manufacturing and distributing safe and effective medicines, supplements and food around the globe. Two billion people world-wide have access to quality medicines, dietary supplements and food as a result of USP's standards, advocacy and education.