HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

October 27, 2015

Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA's Draft Guidance "Nonproprietary Naming of Biological Products: Guidance for Industry" RIN 0910-AH25

The Healthcare Supply Chain Association (HSCA) appreciates this opportunity to provide comment on the U.S. Food and Drug Administration's (FDA) draft guidance, "Nonproprietary Naming of Biological Products: Guidance for Industry."

HSCA's member group purchasing organizations (GPO) are crucial cost-savings engines for America's hospitals, clinics, nursing homes, and surgery centers. HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace. Biosimilar drugs have tremendous potential for reducing costs and increasing competition in the market. As such, we support health policy that will enable and encourage widespread adoption of biosimilars.

We firmly believe that requiring reference biologics and their biosimilars to share the same International Nonproprietary Name (INN), without a suffix, is the best way to protect patient safety and ensure widespread adoption of biosimilars.

Proposed Suffix System Would Cause Confusion and Raise Healthcare Costs

Deploying unique suffixes for biosimilars runs counter to their "highly similar" relationship to biologics – one in which "no clinically meaningful differences" exist.[1] A healthcare provider can expect that a biosimilar approved through the rigorous, though abbreviated, 351(k) application process will behave just like its reference biologic. We are concerned that requiring a differentiated suffix of any kind might hinder adoption of biosimilars by creating the mistaken impression that a biosimilar product will behave

[1] 42.U.S.C. 462

"avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway."[2]

In addition to limiting the cost-savings potential of biosimilars by hindering adoption, suffixes will also create an additional financial burden to the system, as existing software across the healthcare supply chain will require changes to account for the addition of new suffixes to INNs.

Proven Efficacy of the INN System

Biologics in the U.S. market have been safely regulated under the INN system without suffixes for over 60 years. When manufacturing changes have occurred in a biologic, introducing biosimilarity into a specific drug, the FDA has overseen the process of verifying "comparability." Before and after manufacturing changes, the biologic has kept the same INN. In short, the supply chain has functioned safely and effectively with highly similar biologics sharing the same INN.

The European Union has successfully implemented a biosimilar approval process that does not require the use of distinctive nonproprietary names for biologics. Since 2006, biosimilar products have been introduced safely and effectively, with appropriate pharmacovigilance, without a differentiated nonproprietary name.

Safeguarding Patient Safety

Medication nomenclature is a critical component in ensuring healthcare providers can clearly identify drugs, the strength of their ingredients, and product differences. Drug name suffix confusion is a common source of errors. According to the 2008 MEDMARX® Data Report, drug name prefix/suffix misinterpretation accounts for approximately 10 percent of medication errors. These errors are due to the failure of healthcare practitioners to identify, recognize, or correctly interpret the prefix or suffix of the drug's name.

Adverse events and product recalls continue to be successfully facilitated using a drug's national drug code (NDC) and lot number. There is no compelling evidence that biosimilars should be handled differently (i.e., using a suffix to facilitate pharmacovigilance and recalls). Further, treating biosimilars differently for this purpose could undermine patient and prescriber confidence in them.

HSCA shares the FDA's deep commitment to safety. That is why we think it is critical for biologics and biosimilars to share the same International Nonproprietary Name, without a suffix. In the event you do require a suffix, we strongly urge for a meaningful suffix to help alleviate prescriber confusion and ultimately support patient safety.

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[2] U.S. Food and Drug Administration, *Nonproprietary Naming of Biological Products: Guidance for Industry* August 2015, Section 5 "Process for Proposing a Suffix for the Proper Name of a Biological Product."

We look forward to continuing to work with FDA as you finalize naming guidance. Please do not hesitate to contact me directly should you have any questions. I can be reached at 202.367.1162 or tebert@supplychainassociation.org.

Sincerely,

Todd Ebert

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President and CEO
Healthcare Supply Chain Association