May 6, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852
Submitted VIA ELECTRONIC SUBMISSION at www.regulations.gov

RE: **Docket No. FDA-2013-D-1543 Nonproprietary Naming of Biological Products: Update**

Dear Sir or Madam,

The National Council for Prescription Drug Programs (NCPDP) submits this letter to the Agency in response to a request for comments on ways to balance development of biosimilars and interchangeable biologics with innovation of new therapeutic proteins.

NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,500 members. The organization provides a multi-stakeholder forum of high-level expertise and diverse perspectives for developing and promoting industry standards and business solutions that improve patient safety and health outcomes, while also decreasing costs.

NCPDP is committed to furthering the interoperable electronic exchange of information among a wide array of healthcare stakeholders. To assist in consistent and accurate identification of drugs, NCPDP's Work Group 2 Product Identification deals with product identification systems and data, including naming, that serve to uniquely identify a product with the intent of establishing standards for product identification to avoid ambiguity in distinguishing one product from another. NCPDP is central to developing standards by which biologic and biosimilar products are distributed and recorded, including identification of products for the purpose of pharmacovigilance.

NCPDP has already commented that, in our opinion, biosimilars and interchangeable biologics should carry the same nonproprietary names as their respective reference products, without modification. We incorporate by reference our submission of August 20, 2012 to Commissioner Hamburg in which we stated the INN "should not be redesigned to respond to concerns about pharmacovigilance and drug tracking."[1]

NCPDP continues to disagree with FDA's recently adopted approach to naming biologics whereby nonproprietary names ("proper names") include unique meaningless 4-letter suffixes which are

[1] https://ncpdp.org/NCPDP/media/pdf/20120820-NCPDP-Ltr-to-FDA-Biosimilars.pdf

unlikely to be recalled reproducibly by prescribers, pharmacists, patients, and others. NCPDP remains hopeful the agency will eventually recognize the application of such suffixes is an approach that is unnecessary, unproven, burdensome, and ineffective at substantially improving the accurate identification of unique products that share the same unmodified nonproprietary name ("core name").

NCPDP applauds Health Canada's recent decision to implement a biologics naming policy that is brand name-centric rather than adopt the aforementioned suffix application to the nonproprietary name. In Canada, a biologics naming convention that applies both nonproprietary (with no suffix) and brand names will be used throughout the medication use process, including prescribing, dispensing, and pharmacovigilance settings. In this manner, biosimilars, reference biologics, and innovator biologics that share the same nonproprietary name would be distinguished by their unique brand names.

In commenting about their decision, Health Canada indicated this approach achieved the pharmacovigilance objective of clearly distinguishing unique products with the same nonproprietary name without imposing an unnecessary regulatory burden, and avoided the complexity associated with implementing a suffix-based naming convention.

Evidence from adverse drug event reporting in both Canada and the US has shown reporting by brand name is largely successful in achieving accurate product-level attribution of spontaneously reported adverse effects for suspected biologics. Analysis of data from the FDA Adverse Event Reporting System (FAERS) through December 2018 shows over 99% of safety reports for all marketed US biosimilar products was by brand name. NCPDP believes the application of suffixes is far less likely to result in substantially improved reporting accuracy than can be achieved with brand names and therefore questions the unnecessary regulatory burden that FDA's suffix-based naming policy places on a wide array of downstream users and systems.

NCPDP's Principal Concerns with FDA's March 2019 Draft Update to the Guidance for Industry on Biologics Naming

Consistent with NCPDP's continued position regarding the overall approach to biologics naming, we are strongly opposed to the following proposals included in the March 2019 Draft Update to the Guidance for Industry referenced above:

- Exemption from suffix modification of the shared nonproprietary name ("core name") for existing reference products
- Possible application of the suffix-based naming scheme to vaccines

Exempting existing reference products from FDA's newly adopted suffix-based naming scheme would add further confusion in drug naming standards that are now being applied to biologics. As a result, two separate naming standards for related products sharing identical nonproprietary

("core") names would have to be accommodated at the data systems level, adding to the burden of an already arduous downstream implementation. Dissimilar naming standards for related products must be avoided as it amplifies confusion and error potential. In addition, such naming distinctions would add to the complexity of maintaining clinically relevant drug relationships in data systems and applications.

Such an exemption also risks favoring the innovator product by creating a false sense of superiority by the absence of any modifying suffix relative to competitive products. For products with identical core names, it also will favor alphabetical listing and probable product selection of the reference (innovator) product in listings organized by nonproprietary names.

FDA's proposal that the nonproprietary name of existing reference products remain unmodified also would lead to a situation whereby pharmacovigilance reports received by nonproprietary name without a suffix, will automatically be ascribed to the reference product. Furthermore, prescriptions issued by nonproprietary name but lacking a suffix would automatically be dispensed as reference product only. This slows acceptance of biosimilars, contrary to the stated desires articulated in the FDA Biosimilars Action Plan.

One rationale given for FDA's decision not to apply the same suffix-based naming standard to the reference (innovator) product was because the process would be too burdensome to the innovator manufacturer (March 20, 2019 Pink Sheets). Yet downstream implementation of FDA's suffix-based naming policy at the broad health system level is likely to result in billions of dollars in unnecessary implementation costs.

For all the aforementioned reasons, NCPDP strongly opposes application of two distinct naming policies for reference products versus competitive products sharing identical core names.

NCPDP's second principal objection is the application of suffix-based naming policy to vaccines, many of which already have extremely long and complex nonproprietary names. Additionally, vaccines already are assigned CVX codes that uniquely identify each product as well as MVX codes for the distributing pharmaceutical company. This coding is included in the patient profile at the time of vaccination. Adding suffixes could greatly exaggerate existing challenges in accurately identifying combination vaccine products and could exceed the character limits of existing information systems. Vaccines also are subject to existing stringent pharmacovigilance procedures such as the Vaccine Adverse Event Reporting System (VAERS), making suffixes unnecessary.

Finally, NCPDP wishes to highlight recent confusion that resulted from the introduction of the combination Herceptin Hylecta, to which the following ambiguous proper name—trastuzumab and hyaluronidase-oysk- was applied. The National Library of Medicine and several drug database publishers mistakenly interpreted this ambiguous naming structure to mean "trastuzumab" combined with "hyaluronidase-oysk", when the suffix was intended to apply to both ingredients.

A non-ambiguous representation of FDA's intent would be: "(trastuzumab and hyaluronidase)-oysk". NCPDP has noted the confusion this has already caused and will continue to pursue an unambiguous naming solution for this and other complex products that may come to market in the future. For example, how would a competitive combination product with an existing suffix-modified trastuzumab component be named?

NCPDP continues to recommend that biosimilars and interchangeable biologics should carry the same nonproprietary names as their respective reference products, without modification. NCPDP members look forward to working with the FDA to establish practical ways to ensure the safety and proper identification of biologics by use of standardized, unambiguous electronic medication information transfer.

For direct inquiries or questions related to this letter, please contact
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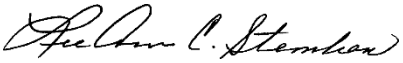
Sincerely,



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