February 20, 2020

Lubna Merchant
Deputy Director
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Lubna.merchant@fda.hhs.gov

RE: Interpretation of multi-component biologics

Dear Ms. Merchant:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, ANSI-Accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

For over 40 years NCPDP has been 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 and health-related products within NCPDP's stated mission, NCPDP's Work Group 2 Product Identification deals with product identification systems and any type of descriptive data, including naming, that serves to uniquely identify a product with the intent of establishing standards for product identification to avoid ambiguity in distinguishing one product from another.

The product information exchange procedures developed and maintained by NCPDP are used by all originator biologics and biosimilars licensed in the US to date, and it is anticipated that they will also be used for all originator biologics, biosimilars, and interchangeable biologics in the future. As such, NCPDP is central to developing standards by which these products are distributed and recorded, including identification of products for the purpose of pharmacovigilance.

It is NCPDP's position that biosimilars and interchangeable biologics should carry the same nonproprietary names as their respective reference products. We incorporate by reference our submission of August 20, 2012 to US FDA Commissioner Hamburg in which we state that the International Nonproprietary Name (INN) "should not be redesigned to respond to concerns about pharmacovigilance and drug tracking."

NCPDP's position on the FDA's suffix-based naming policy has not changed despite ongoing efforts by the Agency to continue to implement this new US naming approach. In fact, NCPDP's opposition to the Agency's approach has only strengthened because of the resultant confusion about policy interpretation and implementation that has ensued in the electronic drug information and standards industries as well as in many other sectors (e.g., prescribers, dispensers, prescription processors, drug knowledge bases).

NCPDP has maintained long-standing and ongoing communication with the FDA on this issue. Most recently NCPDP invited the FDA to attend our August 2019 Work Group meeting in Philadelphia to address the latest confusion resulting from the implementation of a new suffix-based naming strategy the Agency applied to fixed-combination biologic products with the introduction to the US market of Herceptin Hylecta®. Without input from the affected downstream healthcare, drug information, and prescription processing sectors, the FDA chose to implement a highly ambiguous proper name—trastuzumab and hyaluronidase-oysk—that caused significant confusion in application of the naming convention by the National Library of Medicine (NLM), drug compendia, and others.

NCPDP is grateful for the FDA's participation in the August 2019 Work Group meeting and the ongoing dialog. The principal purpose of this letter is to seek clarification on the FDA's proposed solutions for addressing the confusion that resulted from implementation of this naming approach. NCPDP will then obtain the advice and recommendations of its members to provide needed feedback to the Agency on its proposal.

It is notable that additional confusion was created with the recent FDA introduction of the proper name for Enhertu®, where the Agency chose to apply both a prefix and a suffix—fam-trastuzumab deruxtecan-nxkl—in the proper US name chosen for this product. Acknowledging this is a conjugated drug, NCPDP requests clear articulation of how the FDA intends to apply its naming approach to this and other biologics product variations and why it is continuing to use prefixes when the Agency has acknowledged the unique set of problems that prefixes cause downstream.

NCPDP requests the FDA fully articulate its proposed naming policies aimed at addressing the current confusion with biologic combinations so our members can provide much needed feedback on downstream ramifications. As we stated in the August 2019 Work Group meeting, the FDA should fully articulate the clarifying policy it plans to apply to the above identified products, as well as, to future products such as insulin combinations and the already highly complex vaccine names. While we remain hopeful the FDA will continue to exclude vaccines from suffix-based naming, we nonetheless would like to understand what approach the Agency has discussed if it were to override this exclusion.

Again, we thank you for your openness in continuing to value NCPDP's input on this issue. NCPDP looks forward to our continued close work in addressing this issue as the resulting confusion in the industry will continue to grow without agreement on a clear and unambiguous path forward.

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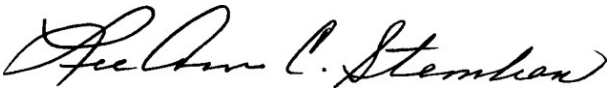
Sincerely,



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Enclosure

cc: NCPDP Board of Trustees