ASHP House of Delegates

POLICY RECOMMENDATION 1:

NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS

To advocate that originator biological products, related biological products, and biosimilar products share the same global nonproprietary name as defined by the United States Adopted Name Council, the World Health Organization Programme on International Nonproprietary Names, and United States Pharmacopeial Convention; further,

To oppose unique nonproprietary naming for originator biological products, related biological products, and biosimilar products.

Rationale

As biosimilar products obtain approval for use in patients in the U.S., discussion continues among stakeholders over what type of naming process should be applied. A number of stakeholder groups have adopted policy regarding biologic and biosimilar naming, including FDA, National Council for Prescription Drug Programs, (NCPDP), United States Pharmacopoeia (USP), United States Adopted Name (USAN) Council, World Health Organization (WHO), American Medical Association (AMA), and other national pharmacy groups.

The recognized authorities for applying standardized principles of drug and biologic naming include the WHO Programme on International Nonproprietary Names (INN), USAN Council, and USP. These authorities have developed a harmonized biosimilar naming approach based on applying a shared nonproprietary name for originator biological products, related biological products, and biosimilar products. Under their authority, these products essentially share the same nonproprietary name (e.g., “filgrastim” for Neupogen, Zarxio, and Granix), but can be individually identified through their unique National Drug Code (NDC), other unique codified identifiers, and trade names. Thus, well-accepted and widely used existing mechanisms for distinguishing individual products obviate the need for deviation from these existing authoritative approaches by adding a prefix or suffix to the nonproprietary name. Other national pharmacy organizations (e.g., American Pharmacists Association [APhA], Academy of Managed Care Pharmacists [AMCP], National Association of Chain Drug Stores [NACDS], and National Community Pharmacists Association [NCPA]) as well as NCPDP support application of the identical nonproprietary name to these products.

FDA has proposed a nonproprietary naming process that deviates from the existing standardized approach that has been applied by international authorities such as INN and

USAN. Under FDA's proposal, a unique, randomly generated suffix composed of four lowercase letters, or a suffix relating to the license holder of the product (which could change over time), would be applied to originator biological products, related biological products, and biosimilar products.

In its proposed rule for the biologics to which this naming method would initially be applied, FDA has recommended changing the official names for biologics with globally adopted INNs and USANs as outlined below.

INN/USAN Name	Proposed FDA Name(s)	Former FDA Placeholder Name
filgrastim	filgrastim-bflm filgrastim-vkzt filgrastim-jcwp	filgrastim-sndz tbo-filgrastim
epoetin alfa	epoetin alfa-cgkn	
pegfilgrastim	pegfilgrastim- ljfd	
infliximab	infliximab-hjmt	

These would be just the first name changes that FDA would implement. The proposed plan would then retrospectively change the names of a broad group of existing products to include unique, randomly generated, four-letter suffixes. Such a naming regime would require extensive education and reprogramming present a risk for medication errors.

Although FDA's proposed naming process differs from the internationally recognized naming processes supported by WHO, USAN, NCPDP, USP, and others, it appears similar to WHO's current proposal for four-consonant biological qualifiers that can be employed by countries not having other effective means of tracking specific drug products (e.g., with NDCs or other codified identifiers). Thus, it would result in the existence of two different four-letter modifications of the INN for the same product—the one assigned independently by FDA and the one assigned by WHO. For example, under this scenario, FDA would assign the nonproprietary name "epoetin alfa-cgkn" to the product INN would maintain under the long-established nonproprietary name "epoetin alfa," but the FDA guidance would allow a qualified name such as "epoetin alfa-xktz."

FDA cites safety concerns and the ability to track these products precisely to the patients receiving them as justifications for the proposed naming standard. However, stakeholders such as NCPDP have recently commented in opposition to FDA's proposed naming standard, arguing that FDA's random, no-vowel suffix could create confusion among clinicians and a potential safety issue if unrecognizable names are used.

Background

This policy recommendation was expedited for Board and House of Delegates consideration because ASHP currently has no policy on naming of biological products, including biosimilar products, and the FDA is seeking comments on a proposed rule and guidance on the topic.

The Council on Public Policy discussed the issue at length and received input from an outside expert on drug nomenclature. Ultimately, the Council decided in favor of proposing policy that supports the same global, nonproprietary name for all biologics, including

biosimilars, and opposes a separate naming standard for biosimilar products that deviates from internationally accepted standards. Consistent with other standard-setting groups, national pharmacy organizations, and WHO, the Council did not believe that there is a need to develop a naming convention that differs from the current standard. In addition, without any well-designed testing, it is unclear whether FDA's proposed naming convention would achieve high-level pharmacovigilance or result in confusion among clinicians who rely on nonproprietary names for self-reporting. To the contrary, principles of human behavior and cognition suggest that such constructs would be unlikely to achieve FDA's goals of product recognition and recall by prescribers, patients, and others, since four-consonant non-meaningful, unpronounceable suffixes are unlikely to be readily recalled or associated accurately with specific products.

Tracking by NDC. The biosimilar naming policy adopted by the Council relies on the ability to track medications by NDC or other standard product identifier and would present a challenge to healthcare organizations that do not track products by NDC or other standard product identifier. Such organizations may apply a surrogate NDC to reflect an array of NDCs for related drug and biologic products. Although tracking by specific NDC remains a challenge for these healthcare organizations, the Council decided that the recommended policy should reflect best practices rather than convenience or ease of implementation. The Council agreed on recommending this policy with the caveat that solutions be developed that would ensure NDC-specific product tracking. Initially, this would involve the six biological products included in the FDA proposed rule. Further, the Council chose to not recommend new policy regarding the NDC issue at this time but instead will revisit the issue during its February 2016 conference call.

The Council discussed two options available to these healthcare organizations that could be implemented until a more permanent solution is developed. The first is to apply the current Vaccine Adverse Event Reporting System (VAERS) model already in effect to the other biological and biosimilar products. This regulatory framework already exists for vaccines in all clinical settings and could be applied by FDA to ensure pharmacovigilance. In addition, consideration could be given to greatly simplifying the vaccine reporting requirements to meet FDA's current intent with the six proposed biologic products.

The second option is to manually enter the NDC into the patient's electronic health record. Given that the current universe of biological and biosimilar products proposed by FDA is small, this could serve as an initial solution while a more permanent one is developed.

The Council also believes that ASHP should create a task force to explore a permanent NDC tracking system that could be implemented in healthcare organizations nationwide. The task force should consist of a cross section of ASHP membership representing supply chain experts, clinicians, and informaticists.

The Council also noted that hospital tracking of products by NDC will eventually be required under the Drug Quality and Security Act (P.L. 113-54). While full implementation of the law is still eight years away, compliance will eventually be required, underscoring the urgent need to begin developing a permanent solution to surrogate NDC application in hospitals.