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Debate Continues Around Biosimilar Naming Conventions

Author: Lauren Santye, Assistant Editor
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Major disagreements persist regarding naming conventions for biosimilars, which has hindered their entrance to the US market.

Recently published in the *Journal of Managed Care & Specialty Pharmacy* (*JMCP*), researchers reviewed the advantages and disadvantages of various naming approaches for biologics and biosimilars in the United States. The researchers surveyed members of the Academy of Managed Care Pharmacy (AMCP) and the Hematology Oncology Pharmacists Association regarding preferences for biosimilars.

The findings revealed a preference for a distinct name for biosimilars, more specifically respondents preferred the use of a nonproprietary name with a designated suffix. However, of the respondents who preferred a nonproprietary name plus a suffix, 83.4% preferred a suffix tied to the manufacturer, compared with 16.6% who preferred a suffix devoid of meaning.

Additionally, the survey results showed that pharmacists reported more confidence in substituting interchangeable biosimilars when it shares a nonproprietary name, and that the confidence in substitution decreased when a unique name, such as a nonproprietary name plus a suffix, is used instead.

In the current review, researchers noted that the first approved biosimilar in the United States filgrastim-sndz (Zarxio) had a common United States Adopted Name (USAN) and a suffix (sndz) that reflected the manufacturer (Sandoz). But the second FDA approved biosimilar, infliximab-dyyb (Inflectra), manufactured by Celltrion, was named using a common USAN with an apparently random suffix devoid of meaning.

It was not until August 2015 that the FDA released its draft guidance for the naming of biological products. The draft called for all biologics to be named with a core name – which the FDA intends to be the USAN, if available– plus a designated hyphenated suffix unique and devoid of meaning or reference to the manufacturer, according to the study. This is an approach similar to World Health Organization (WHO) recommendations.

The rationale for the FDA naming convention draft guidance, which is consistent with the views expressed by pharmacists whose priority is the protection of patient safety and public health, is that there is a need for a method that distinguishes between biological products that are not interchangeable for pharmacovigilance purposes, the researchers wrote. In order to adopt the FDA draft guidance's naming convention, it would require already approved reference biological products to be renamed by adding a suffix.

Some argue that requiring suffixes for only biosimilars, and not reference products, could lead to a perception of inferior safety and efficacy for biosimilar or that they differ in clinically meaningful ways, which could result in hindering acceptance by patients and providers. This particular belief was confirmed by a study that discovered surveyed pharmacists had the highest confidence level in substituting interchangeable biosimilars if they shared the same nonproprietary name as the reference product, the researchers wrote.

However, the FDA believes that sharing the same nonproprietary name could lead to inadvertent substitution and medication errors since biosimilars can be approved for fewer indications than the reference product or have fewer approved routes of administration.

The FDA prefers the use of a suffix as opposed to a prefix because it would allow products with the same core name to be grouped together in electronic databases and systems for ordering, administering medications, and dispensing. However, in the draft guidance, the FDA stated that it is still considering whether interchangeable products should share the same suffix as the reference product.

There have been numerous organizations in support of a distinct name for biosimilars for pharmacovigilance purposes, however, there are 2 key areas of concern that have been voiced, the study noted.

One area is that there is a lack of consensus whether interchangeable biosimilars should share the same core name and suffix as the reference product or not. Some believe that sharing a common core name and suffix could be a tool to identify a biosimilar as being interchangeable, with some arguing that it may facilitate the adoption and uptake of approved biosimilars.

But the problem of differentiating interchangeable biological products for pharmacovigilance purposes remains. Additionally, market research in international markets indicate that the distinguishable nonproprietary names for biosimilars do not negatively impact market acceptance, according to the study.

The second area of concern is in regards to FDA recommendations to use a suffix for biologics and biosimilars that it is devoid of meaning. Although some biosimilars may eventually be designated as interchangeable by the FDA, the study authors stated that there is still a need for specificity in naming to help facilitate identification because an adverse event may be specific to the product, but not the entire class of products.

The study authors stated that if the biosimilars shared a common nonproprietary name with the reference biologics, there are other options that could be put into consideration to help differentiate the products from pharmacovigilance purposes. One option includes the use of different brand names, a process used in the European Union, but it seems to fall short of full traceability.

The best approach to help minimize inadvertent substitution and to facilitate pharmacovigilance is to assign interchangeable biosimilars and biosimilars a nonproprietary name with a meaningful suffix, according to the study authors.

With the concern that surrounds the proposed guidance from the FDA and WHO calling for a suffix devoid of meaning, the authors stated that using these suffixes could lead to significant unintended consequences, some of which may end up causing harm overall to pharmacovigilance efforts. Furthermore, although the use of a suffix that indicates the manufacturer of the product would be understood by patients and providers, the use of a suffix devoid of meaning would likely cause confusion and difficulty in the identification and communication of the precise product that an individual would receive, according to the study.

In particular, this type of suffix would cause in issue when making an attempt to accurately identify products in spontaneous adverse event reporting systems. It could also cause a significant issue in transitions of care when a patient moves from one place of care to another.

Researchers concluded that since pharmacists and prescribers play an important role in the safety, use, and promotion of uptake of biosimilars, they urge all stakeholders to clearly consider the important issue of biosimilar naming from a pharmacovigilance and patient safety perspective to help ensure the protection of public health.

Furthermore, authors confirmed that the best option is to require biosimilars to be named with a common USAN with the reference product and a suffix that is memorable. The approach supports the FDA's mission of protecting patient safety and public health, facilitating pharmacovigilance, and minimizing inadvertent switching of products, according to the study.