Biosimilars Naming: Why Terminology Matters and Where It Stands

As more biosimilars are approved to treat a broad range of illnesses, a key outstanding issue is how these medicines should be named to ensure patient safety and enable physicians, pharmacists, patients and caregivers to differentiate between biosimilars and original biologic medicines. This distinction is important because the biosimilar, as its name implies, is a biologic that is similar to another biologic drug approved by the U.S. Food and Drug Administration (FDA), but not an exact copy. The FDA naming system is intended to help prevent potential errors in prescribing and administration of these medicines and allow for more accurate tracking of adverse events.

Setting a Precedent and Establishing a Naming System
In March 2015, the FDA approved the first biosimilar product in the United States: Sandoz’s Zarfino™, to which the agency assigned the nonproprietary name filgrastim-sndz. The first part of this name matches that of Zarfino’s reference product, Amgen’s Neupogen® (filgrastim). Once the FDA determined that Zarfino was biosimilar to Neupogen, it approved Zarfino for all five indications of Neupogen, even though Sandoz had conducted clinical studies in only one indication. Although the FDA has authority to approve biosimilars as interchangeable (i.e., substitutable in accordance with state law), the FDA did not approve Zarfino as interchangeable with Neupogen.

The suffix attached to Zarfino’s nonproprietary name is intended to help prescribers and physicians distinguish which indications the medicine has received, and in this case, note that they are not interchangeable with the reference product.

FDA Draft and Final Guidances

In early 2015, the FDA finalized three guidances to implement the Biologics Price Competition and Innovation Act (BPCI), including considerations in regards to demonstrating biosimilarity to a reference product.

In August 2015, the FDA issued draft guidance on nonproprietary naming for biologic medicines, proposing that all original biologic medicines and biosimilars share a core, nonproprietary name that is accompanied by a unique suffix to distinguish them from one another for the purposes of prescribing and administration. In an example offered by the FDA, the nonproprietary name of an original biologic could be “replicamab-cznm” and a biosimilar to that biologic could be “replicamab-hixf.” This draft guidance is currently undergoing a 60-day comment period during which the public can provide feedback.

In addition to this guidance, the FDA also issued a proposed rule to provide nonproprietary names with unique suffixes to six biologics the agency has previously approved. This proposed rule is open to a 75-day public comment period.
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PhRMA's Position on Biosimilars Naming

PhRMA has long maintained that patient safety should be the paramount concern when considering the naming of biosimilars. It is important that there are distinguishable non-proprietary names to facilitate the attribution of potential adverse events to the correct biologics, which will in turn enable detection of any safety differences between and among biologics. These names will also help ensure that provider decisions regarding treatment choices for individual patients are respected, and prevent errors in the prescribing, dispensing and administration of biologics.

To further avoid confusion between and among biologics, a globally consistent biological qualifier (BQ) should be attached to and used in all circumstances where the international nonproprietary names (e.g., “INN-BQ”) are used. An orderly transition to this BQ system will be imperative, so as to not cause confusion among health care professionals and patients.

PhRMA continues to review the draft guidance on nonproprietary naming and will submit comments to the FDA that address a number of key outstanding issues.