BIOSIMILARS NAMING: WHY TERMINOLOGY MATTERS FOR PATIENTS AND PROVIDERS

Naming for biologics and biosimilars remains an outstanding issue on which the U.S. Food and Drug Administration (FDA) must finalize regulations. The FDA has issued a draft guidance on nonproprietary naming for biologic medicines, proposing that all original biologic medicines and biosimilars share a core, nonproprietary name that is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 prescribing and administration. PhRMA supports the proposal for distinguishable nonproprietary names for biologics, but recommends that suffixes be unique to the license holder, generally derived from the company's name and generally shared across all of the license holder's biological products.

Distinguishable nonproprietary names are important for pharmacovigilance

The practice of monitoring the effects of medicines after they have been approved for use by the FDA, especially to identify and evaluate serious adverse drug reactions, is called pharmacovigilance. Tools such as product names, accurate record-keeping, and physician and patient knowledge about potential adverse drug reactions are all essential for effective pharmacovigilance. For biologics, the potential for immunogenicity makes the accurate reporting and attribution of serious side effects to the correct biologic(s) critically important to detecting any safety signals between and among products. Distinguishable nonproprietary names will help facilitate the accurate attribution of adverse events to the correct biologic(s), which will in turn enhance pharmacovigilance for all biological products.

Distinguishable nonproprietary names are important for facilitating physician and patient choice

Distinguishable nonproprietary names will help ensure that physician decisions regarding treatment choices for individual patients are respected and will help prevent errors in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices for biological products.

PhRMA's support of the Biologics Price Competition and Innovation Act (BPCIA)

In 2010, Congress approved the Biologics Price Competition and Innovation Act (BPCIA), which created an abbreviated approval pathway for biosimilars and provided 12 years of data protection for biologics. The legislative intent was to balance increased competition from biosimilar products with the need to provide biopharmaceutical researchers with certainty to make long-term research and development decisions and support future medical innovation.

PhRMA supported the enactment of the BPCIA and has actively participated in FDA's ongoing efforts to implement the statute. PhRMA's consideration of biosimilar policies is guided by our support for:

- **Science-based implementation** of the Biologics Price Competition and Innovation Act (BPCIA) and regulatory decision-making;
- **Patient safety** through effective identification of biologics and robust pharmacovigilance;
- **Health care provider and patient choice** in prescribing;
- **Regulatory transparency** that enables stakeholders to understand the basis for FDA's decisions; and;
- **Long-term stability of the biosimilar user fee program** through financial transparency, efficiency and accountability.

Since the enactment of the BPCIA, FDA has been working to issue guidance to resolve key scientific policy issues to implement the legislations. In August 2015, the FDA issued draft guidance on nonproprietary naming for biologic medicines.

PhRMA supports the FDA's draft guidance calling for the prospective assignment of distinguishable nonproprietary names

Guided by our principles, PhRMA supports the FDA's proposal for the prospective assignment of distinguishable nonproprietary names – comprising a common "core name" (the United States Adopted Name (USAN) for the drug substance) and a suffix identifier connected by a hyphen – for all biological products. PhRMA recommends the suffix be unique to the license holder (the company manufacturing the biologic or biosimilar) and generally shared across all of the license holder's newly approved products.

PhRMA believes that patient safety should be the paramount concern when considering the naming of biological products, and agrees with FDA that the use of distinguishable nonproprietary names as described will:

- Facilitate the attribution of adverse events to the correct biologic(s);
- Minimize inadvertent substitution;
- Enhance pharmacovigilance for all biological products;
- Help ensure that physician decisions regarding treatment choices for individual patients are respected; and,

- Help prevent errors in ordering, prescribing, dispensing, recordkeeping and pharmacovigilance practices for biological products.

In order to enhance the memorability of suffixes and thus improve pharmacovigilance, PhRMA requests that the FDA require biopharmaceutical companies to propose suffixes that are, in general, derived from the name of the license holder.

PhRMA believes that adopting meaningful suffixes that are generally derived from that name of the sponsor or application holder will enhance prescriber recognition, use, and memory of suffixes and thus, the utility of suffixes for their pharmacovigilance and safety objectives. Meaningful suffixes will minimize confusion and burdens associated with implementation of suffixes.

PhRMA also supports, in principle, the retrospective application of the described suffix convention to existing biologic nonproprietary names through an orderly process.

It will be vital to have careful implementation and phase-in of the suffix convention to existing nonproprietary names in a manner that:

- Minimizes confusion and regulatory burdens on the agency;
- Avoids disruption in the healthcare delivery system; and,
- Affords license holders sufficient flexibility to make labeling changes to meet the needs of patients as well as license holders' operational requirements.