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Leslie Kux, Associate Director for Policy
Division of Drug Information
Center for Drug Evaluation and Research,
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Building, 4th Floor
Silver Spring, MD 0993

RE: Nonproprietary Naming of Biological Products; Draft Guidance for Industry

Dear Associate Director Kux,

Thank you for the opportunity to provide comments to the guidance entitled, "Nonproprietary Naming of Biological Products" released on August 28, 2015. We support the FDA's efforts to develop effective policies for the approval and uptake of biosimilar products.

BCBSA is a national federation of 36 independent, community-based, and locally-operated Blue Cross and Blue Shield Plans that collectively provide health care coverage for more than 105 million – one in three – Americans. Blue Cross and Blue Shield Plans offer coverage in every market and every ZIP Code in America. Plans also partner with the Government in Medicare, Medicaid, the Children's Health Insurance Program, and the Federal Employees Health Benefits Program.

We appreciate that the FDA has asked for stakeholder feedback regarding the real world implications of its proposed naming convention for biologic products on providers, payers, patients and pharmacies. It is BCBSA's perspective that choices made about the proposed naming convention could have profound impacts on uptake of biosimilars by providers and patients and therefore on the viability of a robust biosimilars markets and the savings to the healthcare system from their use.

Payers may have a uniquely holistic perspective on the implications of a naming convention as they have purview over coverage and payment for biologics as well as a role in ensuring patient safety and optimal prescribing decisions. Therefore, we recommend FDA work closely with the Centers for Medicare and Medicaid Services (CMS) as it navigates development of policy regarding biosimilars as these decisions will have direct impacts on coverage provided to over a hundred million Americans.

For this reason, in our comments regarding this naming convention, we would like to reiterate comments submitted to CMS regarding their proposal to amend Medicare Part B coding rules to account for the availability of biosimilars. In that letter, we recommended that CMS require prescribers to provide additional information on Part B claims, specifically national drug codes (NDCs) and/or code modifiers, that would allow payers to determine the specific biologic product that was administered. NDCs are already used in the retail setting, and are used for billing drugs under the medical benefit when Medicaid is the payer. The NDC includes information that identifies the manufacturer, drug, dosage form, strength, and package size. Also, we are aware that in the future, updates will be made to the NCPDP SCRIPT standard which will allow for product lot number to be shared. Lot number and NDC are the most detailed information for pharmacovigilence efforts. This level of detail is also necessarily for payers to track utilization by product for purposes of contractual relationships with manufacturers.

If CMS were to require prescribers to use NDCs in Medicare when billing for drugs under the medical benefit, then it is our belief that the use of a single non-proprietary proper name without a suffix for related biologics becomes feasible and many of the issues regarding suffixes raised by the FDA in this proposed rule would resolve themselves. For example, the question of whether to develop suffixes that are meaningless or that are derived from the manufacturer's name goes away because the reference product and the biosimilars could share the same non-proprietary name, as the NDC would sufficiently identify each product and manufacturer. Further, the issue regarding how to change suffixes derived from manufacturers' names upon merger or acquisition becomes moot.

Therefore, in response to the FDA proposal, we support utilizing the nonproprietary naming convention for biologics without any prefix or suffix. We believe the FDA should follow the long established approach already in place for prescription drug medications wherein the nonproprietary name is the same among various products including both innovator and generic counterparts. Establishing a new naming process will create confusion for prescribers, pharmacists and patients, impeding on patient access to these cost saving medicines. A complicated prefix or suffix assignment system could lead to delays in dispensing, delays in care, and both prescribing and dispensing errors. We recommend the FDA leverage the already existing nonproprietary naming convention used for small molecule drugs for all biological products (originator biologics, related biologics, biosimilars, and interchangeable biosimilars), coupled with additional information requirements on claims.

If the FDA determines to proceed with the naming convention employing a suffix, the Association prefers using a suffix with meaning, derived from the manufacturer's name. We are concerned that the use of suffix without meaning or logic may lead to arbitrary and/or erroneous usage of biological products, for example, disproportionate usage of a biological product because its suffix appears first alphabetically. However, as stated above, we recognize that using a suffix based on the manufacturer name creates long-term naming issues, for example, in the scenario that the drug manufacturer changes over time (e.g. sells the product, is acquired by a competitor, files for bankruptcy, etc.).

Regarding the question of interchangeable products, BCBSA recommends that biosimilars designated as interchangeable by the FDA should share the non-proprietary name with the reference product, just as generic drug products share the same chemical name with their reference product, with no distinguishing suffix. The FDA should encourage, where possible and appropriate, proprietary submission (and completion) of the interchangeable pathway for all biosimilar products. Demonstration of interchangeability is an important regulatory and public health milestone for wider acceptance and appropriate usage of biosimilar products, and all barriers for this pathway should be minimized.

A recent survey published in the Journal of Managed Care & Specialty Pharmacy noted that 74.6 percent of pharmacists indicated that they would be confident or very confident in substituting an interchangeable biosimilar with the reference product if both shared the same nonproprietary name. In contrast only 37.3 percent of pharmacists were confident in substituting when the biologic and biosimilar product did not share the same nonproprietary name because of a prefix or suffix.[i] While this study included a small population of pharmacists, it is worth noting that there is already clinician acceptance of the clinical safety of interchangeable biosimilars and therefore any differentiation of products due to FDA naming convention would hamper uptake unnecessarily.

Being approved as an interchangeable product could be a multi-step process in many cases, with the biologic first being approved as non-interchangeable and only later receiving interchangeable status. Having a product undergo a complete name change when it gets an interchangeable status is suboptimal. This change would impact product labeling, cause confusion for physicians, pharmacists, and patients, and will add inefficiencies into an already complex system. This change would also raise additional policy questions, such as: how will a pharmacist deal with refills on a prescription if the drug name changes between refills? Will this require a new prescription with the new drug name? How will this change impact database systems and claims data? A preferable option is to have the status of the product change (from biosimilar to interchangeable biosimilar) in FDA and other listing sites, rather than undergo a name change.

Thank you for your consideration of our comments. If you have questions, please contact Alexis Ahlstrom at alexis.ahlstrom@bcbsa.com or 202.626.8612.

Sincerely,

Justine Handelman
Vice President, Legislative and Regulatory Policy
Blue Cross Blue Shield Association

[i] Fernandez-Lopez,Sara et al; Assessment of Pharmacists' Views on Biosimilar Naming Conventions; Available online @ http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=19101