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FDA Releases Final Biosimilar Naming Guidance

Author: Lauren Santye, Assistant Editor, January 13, 2017

The FDA on Thursday released final guidance for the industry on the nonproprietary naming of biological products, which is expected to smooth the pathway to uptake for biosimilars.

The guidance is designed to describe the FDA's current thoughts on the need for biological products licensed under the Public Health Service Act (PHS Act) to bear nonproprietary names that include an FDA designated suffix, according an FDA report.

The naming convention is intended to be applied to interchangeable products featuring a core name and a suffix included in the proper name. However, the FDA reported it will continue to consider the appropriate format of the suffix for these products. The naming guidance will be applied to both newly licensed and previously-licensed biological products.

The FDA recommends that previously approved originator drugs should also have distinguishable suffixes to help minimize the inadvertent substitution of any products that have not yet been determined to be interchangeable.

Under the naming convention, the FDA will designate a distinguishing suffix devoid of meaning, and comprised of 4 lowercase letters in the nonproprietary names or originator biological products, related biological products, and biosimilar products.

The American College of Rheumatology (ACR) was pleased with the final guidance recommending distinct suffixes for biosimilars and reference biologics, which they said is critical to ensure patient safety and prescribing confidence in the biosimilars landscape.

"The American College of Rheumatology has long advocated for explicit guidance about distinct names and suffixes for biosimilars in order to prevent inadvertent or inappropriate substation, increase prescriber confidence and uptake of biosimilars, and ensure pharmacovigilance," Dr Angus Worthing, MD, FAP, chair of the ACR's government affairs committee, said in a press release.
"This is a welcomed step toward ensuring that biosimilars reach out patients as safely, transparently, and efficiently as possible."

In August 2016, investigators surveyed members of the Academy of Managed Care Pharmacy and the Hematology Oncology Pharmacists Association regarding their preferences for biosimilars.

The findings showed a preference for a distinct name for biosimilars, in particular, respondents preferred the use of a nonproprietary name with a designated suffix.

However, of the respondents who preferred a nonproprietary name plus a suffix, 93% preferred a suffix tied to the manufacturer, compared with 16.6% who preferred a suffix devoid of meaning.

"The Alliance for Patient Access is pleased that FDA has determined that distinguishing names are vital for expanding biosimilars marketplace," Brian Kennedy, executive director of the Alliance for Patient Access, said in a press release. "Biological medications' 4-letter suffixes will differentiate their nonproprietary names, allow physicians to accurately determine which medication a patient takes and to address any problems that might impact patient safety."

Although Kennedy stated his appreciation for the FDA's efforts to engage all stakeholders and integrate their input into the final guidance, he was hoping a more memorable naming convention would be established.

"According to this guidance, however, the 4-letter suffix will be randomly generated and devoid of any meaning," Kennedy said. "As patient advocates, we would have preferred a memorable suffix, which is the surest way for patients and providers to know which medication is being taken."

However, Kennedy thanked the agency for reiterating the rationale and primary focus of the FDA naming convention—consistent with the views expressed by pharmacists—on pharmacovigilance and patient safety in the use of biological medications.