AMCP Academy of Managed Care Pharmacy®

August 2, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Re: Labeling for Biosimilar Products: Guidance for Industry (FDA-2016-D-0643)

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to the draft guidance document titled "*Labeling for Biosimilar Products: Guidance for Industry*" published in the Federal Register on April 4, 2016. AMCP supports several elements of the draft guidance and applauds the FDA for focusing on the scientific evidence necessary for health care providers to safely and effectively use biosimilar products. However, AMCP has concerns with certain elements of the draft guidance that may impact adoption and impede patient access to biosimilars. Specifically, AMCP offers comments on the Biosimilarity Statement and Biosimilar Product Identification & Naming sections of the draft guidance regarding areas that should be removed, improved, or clarified.

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

The Biosimilarity Statement is Unnecessary and Should be Removed

AMCP is concerned about FDA's requirement to include a biosimilarity statement on all biosimilar labels. The FDA has never required a similar statement for generic products found to be therapeutically equivalent, and has not provided sufficient justification for its inclusion in biosimilar labels. This type of statement is unprecedented in medication labeling and may lead health care providers and patients to unnecessary conclusions that biosimilars are not safe and effective in comparison to the reference product.

This differentiation between biosimilars and their reference products risks undermining the important health care provider education that is being undertaken by FDA, AMCP and others. Informing health care providers that biosimilars have "no clinically meaningful differences in terms of safety, purity and potency

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(safety and effectiveness) from the reference product"[1] while requiring a differentiator on the label sends mixed signals to health care providers responsible for driving familiarity and comfort with these products.

Given the potential barriers to biosimilars adoption that may be caused by the inclusion of a biosimilarity statement, AMCP strongly urges the FDA to remove it upon finalization of the guidance document.

The Use of Multiple Biosimilar Product Identifiers Will Cause Confusion and is Premature Absent Final Guidance on Biosimilar Naming

AMCP is concerned that the use of multiple biosimilar product identifiers (reference product name, biosimilar product name, core name, or a combination of these names) throughout the label will cause confusion for health care providers and patients, thereby impacting the ability to safely use these medications. Prior to finalization, AMCP urges FDA to carefully consider the ramifications of using multiple product identifiers on the label, and to provide results from cognition testing on health care providers and patients demonstrating that the proposed labeling framework adds value to the public safety, is easily understood and comprehended by health care providers, and does not result in increased confusion.

AMCP is also concerned that the use of multiple product identifiers is premature because FDA has yet to finalize biosimilar naming guidance. AMCP has been seeking a decision from the FDA regarding biosimilar naming for several years and was disappointed with the draft proposal released in August 2015. The proposed naming convention would establish a framework to assign a random four-letter suffix for use in conjunction with the international nonproprietary name (INN), both prospectively for all biosimilars and retrospectively for all currently marketed biologic reference products. AMCP supports a biosimilar naming convention using the same INN that has proven safe and effective globally for small molecule drugs and for biological products in Europe, and therefore it should be the standard in the United States. Using the same INN for biosimilars would also alleviate the need for multiple product identifiers in biosimilar labeling and therefore eliminate the potential for confusion by health care providers and patients.

In conclusion, while AMCP believes the draft guidance is a step in the right direction to allow for the safe and effective use of biosimilars, AMCP remains concerned that several elements steer away from that mission and may result in increased confusion for health care providers and patients. AMCP urges FDA to carefully re-consider the elements outlined above and work towards a labeling guidance document that allows for consistency and predictability to alleviate the potential for confusion and further enhance the safe use of biosimilars.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on this issue with the FDA. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer