



Academy of
Managed Care
Pharmacy®

May 19, 2017

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

***Re: Considerations in Demonstrating Interchangeability With a Reference Product: Guidance for Industry
[Docket No. FDA-2017-D-0154]***

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 “*Considerations in Demonstrating Interchangeability With a Reference Product: Guidance for Industry [Docket No. FDA-2017-D-0154]*” as published in the *Federal Register* on January 18, 2017. AMCP fully supports the implementation of a robust biosimilars pathway to ensure that Americans receive access to safe, effective, and affordable biologics and biosimilars, including interchangeable biologic products. In general, AMCP is pleased to see that in the draft guidance the FDA outlines a flexible, step-wise, and totality of the evidence approach to demonstrating interchangeability and avoid being too prescriptive recognizing that a one-size-fits-all approach is not feasible given the complexity of biological and biosimilar products. However, AMCP provides recommendations to provide additional clarity to implement the biosimilar pathway prior to finalizing the guidance document.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

Postmarketing Surveillance and Pharmacovigilance

AMCP is pleased to see the FDA describe ways that postmarketing surveillance and studies may provide valuable evidence for reviewing biosimilar products for interchangeability consideration. AMCP believes this type of information can provide important insight into the effects of patient switching, comparative

effectiveness, and eventually considerations for interchangeability among biosimilars that share the same reference product. AMCP has taken a proactive approach to pharmacovigilance and recently launched the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), a significant, independent, research-focused nationwide initiative to proactively monitor both biologics and biosimilars using data from distributed research networks for millions of de-identified patients. BBCIC research protocols are currently in progress and initial research findings are anticipated to be presented in the Fall of 2017. BBCIC will serve as a valuable resource to address important questions about the use, impact, safety, and clinical effectiveness of biologics and biosimilars on human health.

Use of Foreign Reference Product

AMCP is concerned with the FDA's guidance to require an applicant seeking an interchangeable designation to rely on switching studies exclusively using U.S.-licensed reference product. There is no scientifically justifiable distinction between reference products acquired in the U. S. and those licensed in other comparable markets. This requirement will create a significant burden on biosimilar sponsors pursuing switching studies, who can often acquire equivalent samples of reference products from other highly regulated markets at much lower costs. Requiring switching studies to rely on more expensive, U.S.-licensed reference product samples over less costly samples from other markets, without any real clinical difference between the two will simply create additional, unnecessary barriers to entry for biosimilar developers. Therefore, AMCP urges the FDA to align its policy in this guidance with its policy for the 351(k) pathway, where it is acceptable to use a non US-licensed reference product when there is a bridging study to the US-licensed product.

Outstanding Issues Not Considered in Draft Guidance

Prior to finalizing this guidance document, AMCP recommends that FDA consider the following issues not considered in the draft guidance:

- AMCP would like more clarity on the requirements for a biosimilar sponsor to demonstrate interchangeability for a new or expanded indication of a reference product.
- Labeling information for new indications of a reference product vs. approved indications of an interchangeable biosimilar product must be harmonized and aligned. Prescribers and pharmacists require updated and accurate information to know products that may be interchanged. Currently, the draft guidance is unclear regarding how this process will occur in a timely manner. For this reason, AMCP would like more clarity on the process that this alignment will occur.
- As noted above, multiple biosimilar products to a reference product may potentially be interchangeable to each other. Ensuring competition and access to a wide range of biosimilars and biologics will not only allow patients to receive these medications at more affordable prices but also allow for cost savings that encourages the use and adoption of other innovative treatments and medications.
- FDA has not yet defined how interchangeable biologic products will be named. Clarity on this issue is critical prior to publishing the final guidance document.
- Certain protein products, such as insulin and human growth hormone, will be deemed to be licensed under Section 351 of the pathway beginning in 2020 when the FDA will no longer approve applications

for these biologics under the 505 pathway. AMCP would like more guidance on whether products would be considered new biologic products or biosimilars and the requirements for interchangeability.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with 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,

A handwritten signature in black ink, appearing to read "SCantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer