November 17, 2023

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically via regulations.gov

Re: Labeling for Biosimilar and Interchangeable Biosimilar Products (FDA-2016-D-0643)

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the U.S. Food and Drug Administration (FDA) for the opportunity to provide comments in response to the draft guidance titled "Labeling for Biosimilar and Interchangeable Biosimilar Products" (Draft Guidance), issued on September 18, 2023.

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 healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 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 health programs.

AMCP believes that providing biosimilar manufacturers as much clarity and flexibility as possible, while maintaining the FDA's high standards for patient safety, is the appropriate guiding principle for agency decisions around specific provisions of the proposal.

Biosimilarity Statement

The Draft Guidance uses the same biosimilarity statement for both biosimilars and interchangeable biosimilars. AMCP's members have expressed confusion around the lack of explanation for this change, given the statement in the 2018 version of the guidance that a separate interchangeability statement would be provided in future guidance. If FDA is moving away from emphasizing interchangeability for products with such a designation, AMCP believes that additional clarity on FDA's plans and thought process would be useful to biosimilar manufacturers and healthcare providers alike.

AMCP and its members have ongoing concerns about use of the interchangeability designation in the United States. The simple existence of the interchangeability designation may cause confusion for healthcare providers when considering whether to prescribe a biosimilar or an

interchangeable biosimilar.[1] Although interchangeable biosimilars must meet additional standards required by the Biologics Price Competition and Innovation Act (BPCIA), there is no meaningful scientific distinction between biosimilars and interchangeable biosimilars. There are no requirements that an interchangeable biosimilar bear any greater degree of similarity to the reference product or have any difference in product quality over a biosimilar that lacks the interchangeable designation.[2]

Interchangeability is viewed differently in other parts of the world. For example, the European Medicines Agency (EMA) views any approved biosimilar as being interchangeable with the reference product or with other biosimilars of the same reference product.[3] "The lack of harmonization between USA and Europe may introduce confusion for stakeholders and biosimilars makers and could be delaying access to life-saving treatments."[4] AMCP acknowledges that the interchangeability designation is statutory rather than regulatory in nature, but requests guidance on the direction that FDA intends to head with respect to this designation.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing to work on these issues with FDA. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Manager of Regulatory Affairs, Vicky Jucelin, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer

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[1] AMCP believes in educating pharmacists, physicians, nurses, and other health care providers on biosimilars to improve understanding and confidence in their safety and effectiveness. In partnership with leading national pharmacy organizations, AMCP launched the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), an unbiased, policy-neutral repository of educational resources and information on biosimilars. The consortium can be accessed at www.bbcic.org.

[2] McKinley, L.; Kelton, J.M; Popovian, R. *Sowing confusion in the field: the interchangeable use of biosimilar terminology* (2019), Current Med. Research and Opinion, 35:4, 619-621, DOI: 10.1080/03007995.2018.1560223. Available at: https://www.tandfonline.com/doi/full/10.1080/03007995.2018.1560223

[3] European Medicines Agency, *Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU* (2023). Available at: https://www.ema.europa.eu/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf

[4] Derbyshire, M. *USA and Europe differ in interchangeability of biosimilars* (2017). Generics Biosimilars Initiative J. 2017;6(4): 183–184, DOI: 10.5639/gabij.2017.0604.039. Available at: https://gabi-journal.net/wp-content/uploads/GJ-2017-4-p183-184-SpecialReport.pdf.