



May 17, 2017

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Docket No. FDA-2017-D-0154 Comments of the Healthcare Supply Chain Association on “Considerations in Demonstrating Interchangeability with a Reference Product”

On behalf of the Healthcare Supply Chain Association (HSCA), thank you for the opportunity to provide comments on the U.S. Food and Drug Administration’s (FDA) “Considerations in Demonstrating Interchangeability with a Reference Product.”

HSCA represents the nation’s leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America’s 7,700+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. GPOs deliver critical cost savings that allow healthcare providers to focus on their core mission: providing first-class patient care.

The ability to safely substitute FDA-approved biosimilars for reference biologics will be critical to realizing the full cost-savings potential of biosimilars, and will ensure that patients have timely access to safe, less-costly therapies. As such, we applaud the FDA’s release of this guidance, and respectfully offer the following thoughts.

Studies Using Non-U.S. Licensed Originators

The ability to use data comparing a biosimilar to a non-U.S. licensed originator product is a scientifically justified cost-savings mechanism that has been used in most approvals to date. However, the interchangeability guidance specifically precludes the use of foreign originator products in switching studies, due to concerns about subtle differences between the proposed interchangeable biologic and the non-U.S. licensed comparator. Furthermore, the draft guidance did not specifically identify what subtle differences have been recognized as areas of concern. This unwarranted prohibition will increase

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the cost of developing biosimilar products, potentially limiting the number of developers willing to enter the market. This makes interpretation of exclusion guidance difficult, and contributes to the notion that non-interchangeable biosimilars carry a greater risk of use.

Post-Marketing Surveillance

We believe that additional scrutiny over the product’s life cycle – beyond expectations for good manufacturing and quality by design – is not required. These products have already met the standard of biosimilarity, so if such monitoring is required throughout the life cycle of the biosimilar, it should also be required for the originator. Failure to fairly apply this standard to interchangeable products contributes to the baseless perception that biosimilars are less effective, and could potentially harm or limit competition within this market.

Sharing International Nonproprietary Names

HSCA continues to believe that reference biologics and their biosimilars should share the same International Nonproprietary Name (INN) because they are, by definition, highly similar and have no clinically meaningful differences that would require a unique name. Requiring unique names could lead to clinician and patient confusion and hinder the adoption of biosimilars by creating the mistaken impression that a biosimilar product will behave differently than its originator, which could ultimately result in billions of dollars in lost potential cost savings.

Biosimilars have the potential to increase patient access to life-saving medications and to reduce costs for the entire healthcare system. HSCA and its members look forward to continuing to work with FDA to help ensure a pathway to market for biosimilars that prioritizes patient safety and encourages development and uptake of these less-costly therapies. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833 or tebert@supplychainassociation.org.

Sincerely,

Todd Ebert, R.Ph.
President and CEO
Healthcare Supply Chain Association

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