Defense Health Agency (DHA) Clinical Communities Speaker Series

2025 JUNE CCSS: Evidence-Based Approaches for Advancing Excellence in Primary Care

2025 JUNE CCSS S03: Biosimilar and Interchangeable Biological Products: An Overview of Scientific Concepts and Practical Resources

Resource List

The Academy of Managed Care Pharmacy (AMCP) supports the abbreviated licensure pathway for the approval of Biosimilar Drug Therapies (2025) by the U.S. Food and Drug Administration (FDA). Biological products play an important role in the treatment of disease and increased drug costs. A streamlined approval process for biosimilar and interchangeable products provides a needed incentive for the development of new therapeutic products. This ensures greater access to additional therapies at costs expected to be below those of an FDA-approved biological product. AMCP understands the importance of educating pharmacists, physicians, nurses, and other health care providers on biosimilars in order to improve understanding and confidence in their safety and effectiveness.

The American Cancer Society reports Biosimilar Medicines (2024) are used to treat many types of cancer. They can be used for the same indications as their reference biologics, including managing side effects, supporting the immune system, or directly targeting cancer cells. While they are not exact copies, biosimilars follow strict FDA guidelines to ensure they work the same and are just as safe as brand name biologic medicines. They are developed to match the reference product in terms of safety, purity, and potency, with no clinically meaningful differences. The FDA rigorously evaluates biosimilars to ensure they meet stringent standards for approval. Once approved, healthcare providers can prescribe biosimilars with confidence in their efficacy and safety.

The Centers for Disease Control and Prevention (CDC) Drug Service (2024) is responsible for distributing special biologic agents and drugs that are not commercially available in the United States. These products are managed by the Division of Core Laboratory Services and Response and the Division of Global Migration Health. Many of the biologic agents and drugs distributed by the CDC address critical medical needs and support public health surveillance. However, due to the limited demand within the U.S., commercial production and licensure are often not practical or profitable for pharmaceutical companies. As a result, these products are not readily available through standard commercial channels. To facilitate the availability of these unlicensed drugs, the CDC maintains them under an Investigational New Drug (IND) application. This allows for their use in treating serious or life-threatening conditions when no satisfactory alternative therapies are available.

Biosimilars are additional treatment options that are approved based on robust analytical and clinical comparisons with their reference biologic. At the time of initial approval, the full safety profile of a biosimilar is inferred from the reference biologic. Nonetheless, there are still lingering concerns related to the long-term safety of biosimilars. Long-Term Real-World Post-Approval Safety Data of Multiple Biosimilars from One Marketing-Authorization Holder After More than 18 Years Since Their First Biosimilar Launch (2023) reviews the post-approval pharmacovigilance data for eight marketed biosimilars from one Marketing Authorization Holder (MAH) to summarize their safety experience in a real-world setting for up to 18 years since their first biosimilar launch. This is one of the largest reviews of post-approval biosimilar pharmacovigilance data to date by one MAH. It was concluded that the overall benefit-risk profile of each remains favorable and is consistent with the respective reference biologics.

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References

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