AMGEN BIOSIMILARS

SCIENCE-BASED EDUCATION HELPS SUPPORT BIOSIMILAR ACCEPTANCE AND USE

As more treatment options become available, scientifically accurate education about biosimilars for healthcare providers (HCPs), patients, payers, employers, and the organizations that represent them, is key to supporting the way in which this important class of medicines is understood and utilized going forward.

TAKE A CLOSER LOOK:

Science-based education for HCPs on the regulatory approval process and data requirements will help **support informed prescribing decisions.**

Encouraging HCPs to use a **unique product identifier** that aids in **pharmacovigilance** will help build confidence in the use of all biologic products.

Demonstrating **interchangeability** to U.S. Food and Drug Administration (FDA), such that the interchangeable product may be substituted for the reference product without the involvement of the prescriber, **requires additional analyses.** Pharmacy substitution should occur only if **appropriate communication and recordkeeping requirements are in effect.**

The growing body of **real-world evidence** will work in tandem with FDA's sound regulatory system to help examine the use of biosimilars in different patient populations and settings.

Science-based education, particularly around defining biosimilars and how biosimilars may help contribute to a sustainable healthcare system, will help build stakeholder confidence. **This is key to driving biosimilar acceptance and empowering patients in determining the right treatment choice for them, as more biosimilars are manufactured, approved and come to market.**

Please find additional information on AmgenBiosimilars.com and the FDA website.

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DEFINITIONS

- **INTERCHANGEABILITY,** or an interchangeable product, refers to a biosimilar that meets additional requirements outlined by the law.[1] An interchangeable product may be substituted for the reference product without the involvement of the prescriber, consistent with state pharmacy laws.
- **PHARMACOVIGILANCE** refers to the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.[2]

REFERENCES

1. U.S. Food and Drug Administration. Biosimilar and Interchangeable Products. URL: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicapplications/Biosimilars/ucm580419.htm. Accessed July 2021.
2. U.S. Food and Drug Administration. FDA Drug Topics: An Overview of Pharmacovigilance in the Center for Drug Evaluation and Research (CDER). March 26, 2019. URL: https://www.fda.gov/media/122835/download. Accessed July 2021.

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