

# Clinical and Managed Care Implications of Biosimilars: Evaluating the Science and Challenges to Uptake

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# Sample

## Sample of Online Posttest

Choose the best answer for each of the following:

1. A biosimilar product is:
  - A. A generic version of the reference or innovator biologic product
  - B. Interchangeable with the reference biologic product and other biosimilars in the same category
  - C. Highly similar to its original reference or innovator biologic product
  - D. Relatively simple to manufacture using established chemical and production processes
2. The law that established the first abbreviated regulatory pathway for biosimilars is:
  - A. The Federal Food, Drug, and Cosmetic Act
  - B. The Hatch-Waxman Act
  - C. The Biologics Control Act
  - D. The Biologics Price Competition and Innovation Act
3. Which of the following statements is *not* true?
  - A. The European Union (EU) has had a biosimilar approval pathway in place for much longer than the United States
  - B. Any product deemed biosimilar by EU standards will be considered biosimilar by US standards
  - C. All biosimilars approved to date in the European Union have an established safety track record (none have had to be withdrawn from the market)
  - D. The European Medicines Agency (EMA) has issued specific annexes or class guidances for gaining biosimilar status for several categories of biologics, including granulocyte colony-stimulating factor (G-CSF)

Posttest

4. Which of the following is *not* stated within the FDA's initial guidance to the industry on biosimilars?
- A. The FDA will grant interchangeable status to products it approves as biosimilars
  - B. Manufacturers should use a stepwise approach to demonstrate biosimilarity
  - C. The FDA will use a totality-of-the-evidence approach in reviewing biosimilars for approval
  - D. The FDA will consider the complexity of specific therapeutic protein products, including manufacturing process considerations
5. Which of the following is most often cited as a potential concern with using biosimilars?
- A. Biosimilars are not subject to extensive safety and efficacy reviews by regulatory agencies in the European Union and in the United States
  - B. Biosimilar manufacturing facilities do not have to meet the same quality standards as manufacturing facilities of originator biologic products
  - C. Biosimilars may not offer enough cost savings to be justifiable compared with the innovator biologic
  - D. Small structural changes to a biologic protein, which result from changes in the manufacturing process, can induce a range of immunologic responses in humans, some of which can have significant clinical consequences
6. The manufacturer of a biosimilar product:
- A. Is unlikely to be able to exactly duplicate the manufacturing process of the reference product
  - B. Must exactly duplicate the manufacturing process of the reference product
  - C. Is not required to conduct immunogenicity studies in the development process
  - D. Must produce the biosimilar product in all of the same dosage forms as the reference product
7. Biosimilars have been available in Europe since:
- A. 2003
  - B. 2006
  - C. 2009
  - D. 2013
8. How much less are payers expected to pay for biosimilars compared to reference drugs?
- A. 5% to 10%
  - B. 10% to 35%
  - C. 40% to 50%
  - D. 50% to 75%
9. Which of the following is *not* frequently found in biosimilar substitution state legislation?
- A. The FDA must deem the biosimilar as "interchangeable"
  - B. Prescribers are allowed to stop substitution by indicating "Brand medically necessary" or "Dispense as written"
  - C. Pharmacies may substitute without notifying the prescriber or patient
  - D. Immunity is provided for pharmacists who make a substitution
10. A self-administered biosimilar (biologumab-wxyz) has been admitted to the formulary of a hospital. The reference product (biologumab) has remained on the hospital formulary to continue therapy in patients who are already on this product on admission. However, new patient starts will be with the biosimilar. In evaluating patients during medication reconciliation, which of the following is the least important consideration?
- A. How the 2 agents are identified in the computerized order-entry system to distinguish between the 2 products when prescribing
  - B. How to assure that patients started on biologumab-wxyz will be able to continue this medicine when they are discharged from the hospital by assessing coverage by the patient's prescription drug plan
  - C. How to determine whether third-party payers will cover the drug cost when the patient is in the hospital
  - D. How to ensure that the medication administration record is able to distinguish the actual product that the patient received in the hospital, for pharmacovigilance purposes