Assessment Test
A Health-System Pharmacist’s Guide to Biosimilars:
Regulatory, Scientific, and Practical Considerations – Discussion Guide

This activity is located at

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1. Which of the following laws established the abbreviated pathway for approval of biosimilars in
the United States?
   b. Public Health Service Act.

2. Which of the following statements about the FDA standard for interchangeability is correct?
   a. The innovator and biosimilar product must be evaluated for the same indications.
   b. The innovator and biosimilar product must have the same chemical structure, purity,
      and stability.
   c. The effectiveness of the biosimilar product must the same as that of the innovator
      product.
   d. The risk for harm must not increase when switching between the innovator and
      biosimilar product.

3. Compared with traditional drugs, biopharmaceuticals are more:
   a. Homogenous.
   b. Stable.
   c. Immunogenic.
   d. Simple in structure.

4. The process for manufacturing biopharmaceuticals is:
   a. Straightforward but costly.
   b. Straightforward and readily reproducible.
   c. Complex but predictable.
   d. Complex and costly.

5. Which of the following will be required by FDA for biosimilars approval?
   a. A comprehensive approach with analytical, preclinical, and clinical evidence that exceed
      a threshold designed to ensure patient safety.
   b. A totality-of-the-evidence approach with no defined threshold for evidence because the
      agency may determine that some requirements are not needed.
   c. A standardized approach with analytical, preclinical, and clinical evidence to ensure
      fairness among market competitors.
   d. A step-wise approach with progressively greater requirements for analytical, preclinical,
      and clinical evidence.
6. Which of the following statements about the adverse effect profiles of biosimilars and innovator biological products is correct?
   a. They will be highly similar.
   b. They will be identical.
   c. They could differ in clinically-important ways.
   d. They could differ but not in clinically-important ways.

7. Which of the following is an aspect of the pathway for biosimilars approval by the European Union that has been or is likely to be adopted by FDA?
   a. Assignment of unique nonproprietary names.
   b. Establishment of criteria for automatic substitution.
   c. Establishment of product- and class-specific data requirements.
   d. Granting 10-11 years of exclusivity before acceptance of biosimilars applications for marketing approval.

8. The projected cost savings from the use of biosimilars instead of the innovator product in the United States are as high as:
   a. 20%.
   b. 40%.
   c. 60%.
   d. 80%.

9. Based on a survey by the National Comprehensive Cancer Network, which of the following statements about the educational needs of physicians, nurses, pharmacists, and patients on biosimilars is correct?
   a. Physicians and nurses are not as aware of biosimilars as pharmacists are, and education of physicians, nurses, and patients is needed.
   b. Physicians and nurses are as aware of biosimilars as pharmacists are, and education is not needed.
   c. Physicians and nurses are as aware of biosimilars as pharmacists are, but education of patients is needed.
   d. Physicians are as aware of biosimilars as pharmacists are, but education of patients is needed.

10. Which of the following postmarketing pharmacovigilance activities is the most cost-effective, prospective strategy used by health-system pharmacists to assess the safety of biosimilar use in the health system?
    a. Standardized REMS.
    b. Customized REMS.
    c. Data mining of billing claims databases.
    d. Patient registries.