Assessment Test

Preparing for Biosimilars:
Scientific, Regulatory, and Practice Management Issues for Pharmacists

This activity is located at **http://ashpmedia.org/symposia/lmsvideo/content/biosimcentral/**

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1. Which of the following is a key characteristic of biosimilars regardless of the definition used?
    a. They are used for diagnostic purposes.
    b. They are monoclonal antibodies.
    c. They are identical to human proteins.
    d. They may be approved by FDA through an abbreviated process.

2. Compared with chemical drugs, biopharmaceuticals:
    a. Have a smaller molecular weight.
    b. Are made by a more complex process.
    c. Are obtained from human sources instead of chemicals.
    d. Are made by a more predictable process.

3. Which of the following statements about the results of a 2011 survey by the National Comprehensive Cancer Network (NCCN) of the familiarity of conference attendees with biosimilars legislation is correct?
    a. Many respondents were not at all familiar with biosimilars legislation, with physicians and nurses having less familiarity than pharmacists.
    b. Many respondents were familiar with biosimilars legislation, with physicians and nurses having less familiarity than pharmacists.
    c. Many respondents were familiar with biosimilars legislation, with similar familiarity among physicians, nurses, and pharmacists.
    d. Many respondents were not at all familiar with biosimilars legislation, with similar lack of familiarity among physicians, nurses, and pharmacists.

4. Which of the following types of information about biosimilars was considered very important by the largest percentage of respondents to the 2011 survey by the NCCN of the familiarity of conference attendees with biosimilars legislation?
    a. Payor decisions and requirements.
    b. Studies demonstrating chemical and physical similarities between innovators and biosimilars.
    c. Studies demonstrating pharmacokinetic similarities between innovators and biosimilars.
    d. Studies directly comparing clinical endpoints (i.e., efficacy and safety) between innovators and biosimilars.

5. Bioequivalence requires demonstration of:
    a. an identical molecular weight and structure.
    b. an identical manufacturing process.
    c. the absence of a clinically meaningful difference in the rate and extent to which the drug becomes available at the site of action.
    d. the absence of a significant difference in the rate and extent to which the drug becomes available at the site of action.

6. Which of the following pieces of legislation established an abbreviated pathway for FDA approval of biologics?
    a. Biologics Price Competition and Innovation Act.
    b. Hatch-Waxman Act.
    c. Food, Drug, and Cosmetic Act.
    d. Public Health Service Articles.

7. The duration of patent exclusivity for innovator biological products provided under the Biologics Price Competition and Innovation Act is:
    a. 17 years.
    b. 12 years.
    c. 1 year.
    d. 6 months.

8. Which of the following is required to meet the interchangeability standard of the Biologics Price Competition and Innovation Act?
    a. The same biological source as the reference product.
    b. The same clinical result as the reference product in any given patient.
    c. The same toxicity in animal studies.
    d. The same clinically active and inactive components.

9. Which of the following types of products has the greatest data requirements for FDA approval?
    a. Biosimilar.
    b. Interchangeable biosimilar.
    c. Non-innovator biologic approved under full biologic license application.
    d. The data requirements are the same for biosimilars, interchangeable biosimilars, and non-innovator biologic approved under full biologic license application.

10. Immunogenicity is a concern with biological products largely because:
    a. Products often are not fully characterized.
    b. Desensitization is not feasible.
    c. Products are manufactured in living cells that are considered foreign by the human body.
    d. The manufacturing process often is inconsistent.

11. Which of the following types of possible consequences of the immunogenicity of biosimilars is pure red cell aplasia in patients receiving epoetin biosimilars?
    a. No effect.
    b. Loss of effect.
    c. Antibody-mediated disease.
    d. Excessive effect.

12. Which of the following is the primary advantage of using unique nonproprietary names for biosimilars?
    a. Ability to accurately bill for costly products.
    b. Ability to trace specific products for pharmacovigilance purposes.
    c. Ease of therapeutic interchange.
    d. Avoidance of confusion and error.

13. Which of the following statements about regulations governing the use of biosimilars is correct?
    a. Regulations have been established or are in development throughout the world, including China, India, and South America.
    b. Regulations have been established only in the United States.
    c. Regulations have been established or are in development in the United States, European Union, and other key markets, but limited or no regulations have been established in China, or India.
    d. Regulations have not been established or are in development throughout the world.

14. Which of the following is the most important consideration in evaluating biosimilars for use in health systems?
    a. Therapeutic equivalence (efficacy and safety).
    b. Patient out-of-pocket cost.
    c. Health system financial impact.
    d. Potential additional monitoring costs for substitution.

15. In which of the following situations is the need for an institutional policy on selection of biosimilars most important to minimize switching between innovator and biosimilar products?
    a. Inpatient setting.
    b. Outpatient setting.
    c. Transitions of care.
    d. Long-term-care setting.

16. Which of the following pricing scenarios is most likely for biosimilars in health systems?
    a. A consistently lower price compared with the innovator product because of avoidance of costs for extensive clinical testing.
    b. A lower price compared with the innovator product, unless contract prices favor the innovator.
    c. A higher price compared with the innovator product once the costs for pharmacovigilance activities are taken into consideration.
    d. A higher price compared with the innovator product once the costs for objective evaluation of efficacy and safety to establish therapeutic equivalence are taken into consideration.