

Self-Assessment Test

The FDA Amendments Act of 2007: Impact of Risk Evaluation and Mitigation Strategies on Health System Pharmacy

This program is located at www.ashpadvantage.com/fdaaa



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There are a total of 23 questions associated with this self-assessment test.

1. Elements to assure safe use (ETASU) include all of the following EXCEPT
 - a. Requirements for provider and/or pharmacy training and certification.
 - b. Laboratory test requirements for patients on the medication.
 - c. Requirement that participating pharmacists be board certified.
 - d. Requirement that patients using the drug be enrolled in a registry.

2. Which one of the following statements regarding Risk Minimization Action Plans (RiskMAPs) is TRUE?
 - a. RiskMAPs followed REMS as a strategy to improve drug safety.
 - b. RiskMAPs are developed after the drug approval process has been completed.
 - c. RiskMAPs were created for products that required additional risk management strategies beyond standard product labeling.
 - d. Restricted drug distribution systems (RDDS) are never a requirement of RiskMAPs.

3. All of the following statements regarding Medication Guides are true EXCEPT
 - a. Medication Guides existed before REMS.
 - b. Medication Guides are now a part of most REMS.
 - c. Medication Guides are prepared by manufacturers.
 - d. Medication Guides do not require approval by FDA.

4. Periodic assessment of RiskMAPs is required under the law to ensure that they are meeting the goals of providing safe access to a particular medication by the patient.
 - a. True.
 - b. False.



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5. As a result of Title IX of the FDA Amendments Act of 2007, FDA can
 - a. Require manufacturers to make safety-related labeling changes.
 - b. Impose pricing freezes on new products.
 - c. Require that a drug in short supply be made available to certain patient populations.
 - d. Halt manufacturing of products that are deemed prohibitively expensive.

6. Which one of the following is NOT a component of REMS?
 - a. Payment plan.
 - b. Medication Guide.
 - c. Communication plan from the manufacturer to healthcare providers.
 - d. ETASU.

7. If a manufacturer does not comply with a REMS requirement, FDA has the authority to do all of the following EXCEPT
 - a. Consider the drug misbranded.
 - b. Impose civil monetary penalties.
 - c. Impose criminal penalties.
 - d. Prevent the sale of the drug.

8. Pharmacist input on how REMS may be standardized so as to not be unduly burdensome on patient access to medications is a requirement of FDAAA.
 - a. True.
 - b. False.

9. REMS assessments may be required
 - a. 18 days, 3 months, and 7 months after initial approval.
 - b. 3 months, 7 months, and 18 months after initial approval.
 - c. 18 months, 3 years, and 7 years after initial approval.
 - d. 3 years, 7 years, and 18 years after initial approval.

10. A Medication Guide would likely be required if FDA determines that
 - a. A drug is important to health and patient adherence to directions for use is not essential to its effectiveness.
 - b. A drug has serious risks that patients should be aware of, even though such knowledge would not influence the patient's use of the drug.
 - c. A drug has so few adverse effects that the Guide could replace the need for pharmacist counseling on its use.
 - d. The Guide could help prevent serious adverse events.



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11. A Medication Guide only is required to inform patients of the serious risks associated with use of each of the following EXCEPT
 - a. Ciprofloxacin for risk of tendinitis and tendon rupture.
 - b. Ritonavir for risk of cardiovascular arrhythmias.
 - c. Lopinavir for risk of cardiovascular arrhythmias.
 - d. Tetracycline for risk of dental staining.

12. The REMS for certolizumab pegal includes all of the following EXCEPT
 - a. ETASU.
 - b. Medication Guide.
 - c. Communication plan that includes a Dear Healthcare Provider letter.
 - d. Communication plan that includes a dedicated website.

13. Which one of the following is NOT included in the ETASU for alvimopan?
 - a. Hospitals dispensing the drug must have obtained special certification.
 - b. Required drop shipment program.
 - c. The drug may be dispensed only to hospitals and retail pharmacies
 - d. The drug may be dispensed only to patients who demonstrate evidence of safe use conditions.

14. Requiring certification of distributors to ensure that certain REMS requirements are followed is an example of
 - a. A communication plan.
 - b. An implementation system.
 - c. ETASU.
 - d. Medication Guide.

15. All restricted drug distribution systems are imposed by FDA.
 - a. True.
 - b. False.

16. All of the following are reliable sources for obtaining information on the growing number of REMS EXCEPT
 - a. Wikipedia.
 - b. The FDA's website (www.fda.gov).
 - c. The medication's web site.
 - d. Using drug's name and REMS as search terms on Google.



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17. All of the following are elements to address when developing policies and procedures for REMS implementation EXCEPT
 - a. Communications and reporting.
 - b. Cost.
 - c. Provider certification.
 - d. Distribution of Medication Guides.

18. As medication experts, health-system pharmacists are positioned to be the sole stakeholders in the REMS movement.
 - a. True.
 - b. False.

19. All of the following are considered strengths of health-system pharmacists in the management of REMS EXCEPT
 - a. Strong relationships with providers and patients.
 - b. Involvement in continuity of care and transitions in care.
 - c. Access to electronic medical records, including laboratory results.
 - d. Infrastructure to manage REMS (personnel, time, expertise).

20. Which one of the following is an example of a drug for which a REMS and restricted drug distribution system is required?
 - a. Mycophenolate.
 - b. Botulinum toxin.
 - c. Ciprofloxacin.
 - d. Alvimopan.

21. All of the following represent opportunities for health-system pharmacists in the management of REMS EXCEPT
 - a. Improved patient safety and medication outcomes.
 - b. Assurance that specialty drugs are dispensed by the health system.
 - c. Reliance of physicians on outside companies for REMS management and drug distribution.
 - d. Ability to dispense REMS drugs directly to patients when possible.



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