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SKU: 9798214116068-TEST-BANK

Name:_____ Class:_____ Date:_____

Chapter 01: Consumer Safety and Drug Regulations

1. Which of the following requires a prescription but not a DEA number?
   a. Standards
   b. Controlled (schedule) drug
   c. Legend drug
   d. FDA

ANSWER: c

2. Which of these was/were established by the 1906 Pure Food and Drug Act?
   a. Standards
   b. Controlled (schedule) drugs
   c. Legend drugs
   d. National Drug Code Directory

ANSWER: a

3. Which of the following requires both a prescription and a DEA number?
   a. Standards
   b. Controlled (schedule) drug
   c. Legend drug
   d. FDA

ANSWER: b

4. What is the name of the enforcement agency established by the 1970 Controlled Substances Act?
   a. DEA
   b. NDC
   c. USP
   d. FDA

ANSWER: a

5. Which of the following is the approval agency established by the 1938 Federal Food, Drug, and Cosmetic Act?
   a. USP
   b. DEA
   c. NDC
   d. FDA

ANSWER: d

6. Which of the following best describes the uniform strength, purity, and quality of drugs?
   a. Drug laws
   b. Drug standards
   c. NDC
   d. USP/NF

ANSWER: b

7. Drugs that treat diseases affecting a very small number of people are called what?
   a. orphan drugs

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b. OTC drugs
c. legend drugs
d. illicit drugs

ANSWER: a

8. Which of the following is a directory listing drugs by manufacturer and packaging type(s)?
a. DEA
b. Drug standards
c. NDC
d. USP/NF

ANSWER: c

9. Which of the following is a directory listing of officially approved drugs?
a. DEA
b. Drug standards
c. NDC
d. USP/NF

ANSWER: d

10. Which of these describe(s) drugs that can be purchased without a prescription?
a. OTC
b. Drug standards
c. NDC
d. USP/NF

ANSWER: a

11. Which of the following is a drug standard?
a. Color
b. Strength
c. Shape
d. Taste

ANSWER: b

12. Where did the very first documented use of "pharmacology" occur?"
a. Greece
b. Egypt
c. United States
d. Germany

ANSWER: b

13. The 1906 Pure Food and Drug Act includes which of the following provisions?
a. Regulates drugs sold in the United States and Canada
b. Requires labeling to indicate if a medication contains a "dangerous ingredient"
c. Regulates illicit (illegal) drugs

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d. Requires information regarding medications to be handed down from one practitioner to the next

ANSWER: b

14. The Pure Food and Drug Act of 1906 was formulated:
    a. to control the use of drugs being abused by society.
    b. as the first government attempt to establish consumer protection.
    c. in order to make drug manufacturing profitable for drug companies.
    d. as a means to identify addictive or abused drugs.

ANSWER: b

15. Which Act required that drug preparations containing morphine have a label indicating the presence of the morphine?
    a. Federal Food, Drug, and Cosmetic Act of 1938
    b. Federal Food, Drug, and Cosmetic Act Amendment of 1965
    c. Controlled Substances Act of 1970
    d. Pure Food and Drug Act of 1906

ANSWER: d

16. Which of the following is a provision of the Federal Food, Drug, and Cosmetic Act and its amendments?
    a. New products are required to be approved by the Food and Drug Administration.
    b. Defined schedules for substances require specific controls.
    c. To set limitations on the use of prescriptions.
    d. To establish the USP.

ANSWER: a

17. Which drugs are referred to as legend drugs?
    a. Drugs that work so well they become “legendary”
    b. Drugs that have been available for over 100 years
    c. Drugs that must carry the legend “Caution—federal law prohibits dispensing without a prescription”
    d. Drugs that are mentioned in urban legends

ANSWER: c

18. Why was the Food and Drug Administration created?
    a. To oversee testing of only existing drugs
    b. To inspect plants where medical devices are made
    c. To remove unsafe drugs from the market
    d. To suggest alternative ways to use unsafe drugs

ANSWER: c

19. What was the USP/NF established to do?
    a. Provide a reference for all officially approved medications
    b. Legalize the manufacture of medications
    c. Give the public the information needed to safely make their own drugs
    d. Help providers make clinical judgement

ANSWER: a

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20. What does the official abbreviation USP stand for?
    a. U.S. Post Office
    b. U.S. Patrol
    c. U.S. Products
    d. U.S. Pharmacopoeia

ANSWER: d

21. How was drug information relayed to providers prior to the 1906 establishment of the U.S. Pharmacopeia?
    a. The Internet
    b. Encyclopedias
    c. By passing it to the next generation
    d. Schools of medicine and pharmacology

ANSWER: c

22. The Controlled Substances Act of 1970 set much tighter controls on a specific group of drugs that are at risk of being abused by society. Which of the following are included in this group?
    a. Codeine
    b. Drugs listed in the USP/NF
    c. Drugs with herbal components
    d. OTC drugs

ANSWER: a

23. What does the Controlled Substances Act limit?
    a. May be refilled up to five times in six months under Schedule V
    b. Use of prescriptions
    c. The level of pain control to be maintained
    d. How the patient may maintain or store the medication

ANSWER: b

24. The Controlled Substances Act sets tighter controls on which of the following?
    a. Aspirin
    b. Tylenol
    c. Stimulants
    d. Antibiotics

ANSWER: c

25. Who among the following other than drug manufacturers must also be registered and identified with their own DEA numbers?
    a. The healthcare provider writing the prescription
    b. The lab worker working on the prescription
    c. All providers working in the physician's office or clinic
    d. All providers working in the pharmacy

ANSWER: a

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Chapter 01: Consumer Safety and Drug Regulations

26. DEA numbers appear on which of the following?
    a. prescriber's professional license
    b. prescription for a controlled substance
    c. medication bottle containing controlled substance
    d. receipt for the medication

ANSWER: b

27. Who is responsible for maintaining records of all controlled substances received, dispensed, and destroyed?
    a. Non-pharmacy staff
    b. Physiotherapists
    c. All healthcare workers involved
    d. Patients undergoing treatment

ANSWER: c

28. For how long must controlled substance records be kept and available for inspection?
    a. 2 years
    b. 3 years
    c. 5 years
    d. 10 years

ANSWER: a

29. What information does the National Drug Code (NDC) contain for all commercially available products?
    a. The expiration date of the product
    b. The retail price of the drug
    c. Manufacturer, product, and package information
    d. The recommended dosage for adults

ANSWER: c

30. A pharmaceutical manufacturer wants to enhance an already approved medication by adding a new active ingredient to improve its efficacy. What should the manufacturer do before making this change?
    a. Proceed with the addition without any further approvals.
    b. Conduct internal tests and then market the new formulation.
    c. Submit an application to FDA for approval of the new active ingredient.
    d. Add the ingredient and update the product label accordingly.

ANSWER: c

31. How does the DEA regulate the need for a DEA number?
    a. By requiring pharmacies, drug manufacturers, and medical prescribers to obtain a DEA number
    b. By mandating that nursing homes and acute care hospitals register with a DEA number
    c. By regulating grocery stores, convenience stores, and schools of radiology to have DEA numbers
    d. By ensuring medical and nursing schools must possess a DEA number

ANSWER: a

32. Which of the following schedules include drugs with high abuse potential that may lead to severe dependence?

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a. Schedule C-2
b. Schedule C-3
c. Schedule C-4
d. Schedule C-5

ANSWER: a

33. A patient asks their healthcare provider for a prescription for a drug listed under Schedule 1 of controlled substances. How should the healthcare provider respond, considering the regulations for Schedule 1 drugs?
a. Inform the patient that Schedule 1 drugs are not approved for medical use in the United States.
b. Prescribe the drug and allow refills up to five times in six months.
c. Phone in the prescription to the pharmacy for quick access.
d. Explain that the drug has a lower abuse potential compared to other schedules.

ANSWER: a

34. Which of the following statements about schedules of controlled substances is correct?
a. Schedule 1 drugs can be prescribed or phoned in.
b. Schedule 2 drugs may only be called in during emergencies by a physician, followed by a written prescription.
c. Schedule 3 drugs cannot be phoned in by a physician under any circumstances.
d. Schedule 1, 2, and 3 drugs can all be phoned in without restrictions.

ANSWER: b

35. Why is it important to know which schedules of controlled substances may be called into the pharmacy by the prescriber?
a. Only Schedules 1 and 2 can be called in, which limits their accessibility.
b. Schedules 2 through 4 allow for phone-in prescriptions under specific conditions.
c. Only Schedules 4 and 5 can be called in, simplifying the prescription process.
d. Schedules 1 through 3 can be called in, providing flexibility for prescribers.

ANSWER: c

36. A pharmacist receives a prescription for a controlled substance from a physician that is listed in Schedule 3. The prescription states that it can be refilled. How many times can this prescription be refilled within six months?
a. Up to five times
b. Up to three times
c. Only once
d. Up to ten times

ANSWER: a

37. Which of the following statements about the reliability of information sources regarding drugs is correct?
a. A current drug reference is updated and considered a reliable source of accurate information.
b. A pharmacist is not a trusted professional and provides reliable information about drugs.
c. A coworker may lack the necessary expertise or up-to-date knowledge, making them the least desirable source.
d. A pharmaceutical company representative provides information that may be biased towards their products.

ANSWER: c

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Chapter 01: Consumer Safety and Drug Regulations

38. A physician is researching treatment options for a rare genetic disorder that affects only a small population. Which type of medication would be appropriate for this condition?

a. A drug used only in children
b. An orphan drug
c. An OTC medication
d. An unapproved drug

ANSWER: b

39. Which legislation provides for financial incentives to be provided to pharmaceutical companies for the development of medications that would otherwise be unprofitable because they are designed to treat diseases that affect only a small number of people?

a. 1965 Pure Food and Drug Act
b. 1938 Orphan Drug and Cosmetic Act
c. 1983 Orphan Drug Act
d. OBRA of 1990

ANSWER: c

40. A pharmacist is reviewing a patient's medical record and notes that there are no entries for over-the-counter (OTC) medications. What requirement mandated by legislation should the pharmacist ensure is being followed in this case?

a. All prescriptions are to be included as part of the permanent medical record.
b. Documentation of over-the-counter medications must be entered into the permanent medical record.
c. Pharmacists are not required to provide drug use review and patient counseling prior to dispensing prescriptions.
d. Pharmaceutical companies should be given financial incentives to develop medications for rare diseases.

ANSWER: b

41. Once a drug or device has been approved for use in the United States, the:

a. DEA may withdraw approval if a safety concern exists.
b. only action that can be taken is requiring additional warnings be added to the labeling and recommending voluntary withdrawal by the manufacturer.
c. FDA may reconsider its approval and withdraw it from the market to protect public safety.
d. DEA may demand its withdrawal from the market.

ANSWER: b

42. When was chemotherapy first used to treat cancer?

a. 1906
b. 1922
c. 1928
d. 1936

ANSWER: d

43. Under what circumstances can the FDA request a company to withdraw a medication from the market?

a. When more effective alternatives are available
b. When it is no longer profitable for the company.
c. When the approval is pending with the DEA.

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d. When the risks of a drug outweigh its benefits

ANSWER: d

44. How has the lack of enforcement of drug standards in the illegal drug market impacted consumers?
a. It has made drugs more affordable.
b. It has increased the safety of drug use.
c. It has led to higher-quality drugs being available.
d. It has resulted in a rise in overdose deaths.

ANSWER: d

45. A physician wants to prescribe a benzodiazepine for a patient experiencing severe anxiety. Given the regulations, which of the following actions must the physician take for a Schedule IV drug?
a. Prescribe it electronically without verification.
b. Write a prescription that must be signed and submitted to the pharmacy.
c. Phone in the prescription to the patient.
d. Issue the prescription without any further steps.

ANSWER: b

46. Why is it crucial to monitor prescriptions of Schedule V drugs, such as promethazine with codeine?
a. They have a high potential for abuse.
b. They are always prescribed for severe conditions.
c. They may lead to dependency despite their lower abuse potential.
d. They are not subject to prescription regulations.

ANSWER: c

47. Why is it important to keep prescription pads locked securely in a healthcare facility?
a. To prevent accidental loss of the pads.
b. To ensure that only authorized individuals can write prescriptions.
c. To avoid patient tampering and prevent forged prescriptions.
d. To make them accessible to patients when needed.

ANSWER: c

48. Why are controlled substances double-locked in most situations?
a. To prevent the substances from expiring.
b. To ensure they are accessible only to authorized personnel.
c. To comply with insurance regulations.
d. To keep patients from seeing the medications.

ANSWER: b

49. Why is it essential for healthcare professionals to keep accurate records of controlled substances?
a. To keep track of expiration dates.
b. To ensure accountability and comply with regulations.
c. To prevent healthcare professionals from making errors.
d. To track patient usage of medications.

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ANSWER: b

50. At what stage are healthcare professionals required to double-count controlled substances?
    a. At the end of each month.
    b. When administering medication to a patient.
    c. At the beginning and end of each shift.
    d. After the physician prescribes the medication.

ANSWER: c

51. When can a physician phone in a prescription for a Schedule II controlled substance?
    a. At any time as long as it is an emergency.
    b. Only in an emergency, with a written prescription to follow within seven days.
    c. Only during office hours.
    d. Only if the prescription is for a low-dose medication.

ANSWER: b

52. When should controlled substances records from the last two years be available?
    a. Only during a DEA audit.
    b. Only when requested by a patient.
    c. At all times for inspection by authorities.
    d. When a prescription is renewed.

ANSWER: c

53. How should a healthcare professional properly dispose of expired controlled substances?
    a. By flushing them down the drain.
    b. By following the facility's approved method.
    c. By storing them until the physician decides what to do.
    d. By returning them to the manufacturer.

ANSWER: b

54. How can healthcare professionals ensure they are aware of current drug scheduling changes?
    a. By regularly consulting with pharmaceutical representatives.
    b. By monitoring the activities of the DEA and FDA.
    c. By waiting for changes to be posted at their facility.
    d. By attending monthly seminars.

ANSWER: b

55. A healthcare professional is working in a clinic. A pharmaceutical representative offers their physician an expensive gift in exchange for prescribing a new medication. What should they do?
    a. Ignore the situation since it does not concern them.
    b. Politely remind the physician about the ethical standards and the Sunshine Act.
    c. Accept the gift on behalf of the physician and report it later.
    d. Record the gift in the clinic's log and submit it to the DEA.

ANSWER: b

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56. A patient had a serious adverse reaction to an over-the-counter medication and it was found that a number of other individuals had similar adverse reactions. Which agency is most likely to investigate this situation and take action if a problem is found?

a. Food and Drug Administration
b. U.S. Pharmacopeia
c. National Formulary Enforcement
d. Drug Enforcement Agency

ANSWER: a

57. Which of the following statements about the FDA is true?

a. The FDA has the legal authority to withdraw a marketed drug product itself.
b. The FDA monitors need for changing the schedules of abused drugs.
c. The FDA is concerned with general safety standards in the production of drugs, foods, and cosmetics.
d. The FDA is concerned only with controlled substances.

ANSWER: c

58. What factors does the FDA consider when concluding that a drug should no longer be marketed?

a. Nature and frequency of adverse events
b. Marketing strategies and consumer preferences
c. Advertising budget and sales numbers
d. Clinical trial duration and study design

ANSWER: a

59. When was the first respiratory syncytial virus (RSV) vaccine approved?

a. 1969–1970
b. 1991–1992
c. 2020–2021
d. 2023–2024

ANSWER: d

60. What event led to the establishment of stricter regulations for drug approval by the FDA in 1962?

a. The discovery of penicillin as an antibiotic
b. The Thalidomide crisis causing baby deformities
c. The introduction of the first contraceptive pill
d. The rise in aspirin usage for pain relief

ANSWER: b

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