Chapter 01: Information Sources, Regulatory Agencies, Drug Legislation, and Prescription Writing
Haveles: Applied Pharmacology for the Dental Hygienist, 7th Edition

MULTIPLE CHOICE

1. Knowledge of pharmacology aids the dental professional in:
   a. obtaining a patient's health history.
   b. administering drugs in the office.
   c. handling emergency situations.
   d. lifelong learning.
   e. all of the above.

   ANS: E
   Correct: All of the choices are true.
   Incorrect choices: Because many of our patients are being treated with drugs, knowledge of pharmacology helps in understanding and interpreting patients' responses to health history questions. Knowledge of the therapeutic and adverse effects of medications obviously helps in their proper administration in the office. Emergency situations may be caused by drugs or treated by drugs; thus, knowledge of pharmacology is of great help, especially because a rapid response is sometimes required. A clear understanding of the concepts of drug action, drug handling by the body, and drug interactions will allow the dental practitioner to make proper judgments and grasp the concepts relevant to new drug therapies on the market.

   REF: Role of the Dental Hygienist | pp. 3-4 OBJ: 1

2. Which of the following statements is true regarding planning appointments?
   a. Whether or not patients are taking medication for systemic diseases is of little consequence in the dental office.
   b. Asthmatic patients should have dental appointments in the morning.
   c. Diabetic patients usually have fewer problems with a morning appointment compared with afternoon appointments.
   d. Both b and c are true.

   ANS: C
   Correct: Diabetic patients usually have relatively fewer problems with a morning appointment.
   Incorrect choices: Asthmatic patients should have afternoon appointments. Patients taking medication for systemic diseases may require special handling in the dental office.

   REF: Role of the Dental Hygienist (Appointment Scheduling) | p. 3
   OBJ: 1

3. Nutritional or herbal supplements:
   a. carry the U.S. Food and Drug Administration (FDA) approval for disease states.
   b. are not drugs.
   c. can cause adverse effects.
   d. will not interact with other drugs the patient may be taking.

   ANS: C

Correct: Nutritional or herbal supplements are quite capable of causing adverse effects.
Incorrect choices: The majority of nutritional or herbal supplements do not carry FDA approval for treating disease states. These supplements are drugs and can cause adverse effects and interact with different drugs.

REF: Role of the Dental Hygienist (Nutritional or Herbal Supplements) | pp. 3-4
OBJ: 1

4. Which type of drug name usually begins with a lowercase letter?
   a. Brand name
   b. Code name
   c. Generic name
   d. Trade name

   ANS: C
   Correct: Before any drug is marketed, it is given a generic name that becomes the "official" name of the drug. Each drug is assigned only one generic name selected by the U.S. Adopted Name Council, and the name is not capitalized.
   Incorrect choices: The brand name is equivalent to the trade name and is capitalized. Although the brand name is technically the name of the company marketing the product, this term is often used interchangeably with the trade name. The code name is the initial term used within a pharmaceutical company to refer to a drug while it is undergoing investigation and is often a combination of capital letters and numbers, the letters representing an abbreviation of the company name.

   REF: Drug Names | p. 5 OBJ: 3

5. A drug's generic name is selected by the:
   a. pharmaceutical company manufacturing it.
   b. Food and Drug Administration (FDA).
   c. U.S. Adopted Name Council.
   d. Federal Patent Office.

   ANS: C
   Correct: Each drug is assigned only one generic name (e.g., ibuprofen). It is selected by the United States Adopted Name Council.
   Incorrect choices: The generic name is not selected by the FDA or the Federal Patent Office. The pharmaceutical company manufacturing the drug clearly has an influence on the generic name given its drug, but the final decision is not the company's.

   REF: Drug Names | p. 5 OBJ: 4

6. Which of the following is true concerning generic and trade names of drugs?
   a. A drug may only have one generic name and one trade name.
   b. A drug may only have one generic name, but it may have several trade names.
   c. A drug may have several generic names, but it may only have one trade name.
   d. A drug may have several generic names and several trade names.

   ANS: B
   Correct: Each drug has only one generic name but may have several trade names.

Incorrect choices: For each drug, there is only one generic name. It is not capitalized, and it becomes the "official" name of the drug. The pharmaceutical company discovering the drug gives the drug a trade name. The trade name is protected by the Federal Patent Law for 20 years from the earliest claimed filing date, plus patent term extensions. Although the brand name is technically the name of the company marketing the product, it is often used interchangeably with the trade name.

REF: Drug Names | p. 4 OBJ: 3

7. Which of the following is the most common reference book in the dental office?
   a. *United States Pharmacopeia-Drug Information* (USP DI)
   b. *Physicians' Desk Reference* (PDR)
   c. *Mosby's Dental Drug Reference*
   d. *Lexi-Comp's Drug Information Handbook for Dentistry*

   ANS: B
   Correct: The PDR is the most common reference book in the dental office because of its historically inexpensive price. Information provided comes directly from the manufacturer's package insert.
   Incorrect choices: The USP DI provides the health professional with necessary information regarding basic pharmacology and pharmacokinetics, dosing, adverse reactions, and drug interactions. Mosby's Dental Drug Reference provides access to information on drugs commonly taken by patients. Lexi-Comp's Drug Information Handbook for Dentistry contains concise lists of drug attributes and sections relevant to dentistry for each drug.

   REF: Box 1-2: Pharmacologic References and Resources Recommended for the Dental Office | p. 4
   OBJ: 2

8. How many years must pass after a drug patent expires before other drug companies can market the same compound as a generic drug?
   a. 20 years
   b. 17 years
   c. 7 years
   d. 0 years

   ANS: D
   Correct: Once a drug patent expires, competing companies may immediately market the same compound in generic form.
   Incorrect choices: After 17 years, the patent of the original drug expires, and other companies can market the same compound under a generic name.

   REF: Drug Names (Drug Substitution) | p. 5 OBJ: 4

9. Two drug formulations that produce similar concentrations in the blood and tissues after drug administration are termed _____ equivalent.
   a. chemically
   b. biologically
   c. therapeutically

   ANS: B

Correct: Biologic equivalence refers to identical pharmacokinetic parameters of two drug formulations (bioequivalence, for short).
Incorrect choices: Chemical equivalence indicates that two formulations of a drug meet the chemical and physical standards established by the regulatory agencies. Therapeutic equivalence means that two formulations produce the same therapeutic effects over the same duration.

REF: Drug Names (Drug Substitution) | p. 5 OBJ: 4

10. The federal body that determines whether a drug is considered a controlled substance and to which schedule it belongs is the:
    a. Food and Drug Administration (FDA).
    b. Federal Trade Commission (FTC).
    c. Drug Enforcement Administration (DEA).
    d. United States Pharmacopeia (USP).

    ANS: C
    Correct: The DEA regulates the manufacture and distribution of substances with abuse potential. Hence prescriber DEA numbers must appear on prescriptions for controlled substances.
    Incorrect choices: The FDA does not have any special powers in regard to drugs of abuse. The FTC regulates commerce and advertising claims of foods, over-the-counter (OTC) products, and cosmetics. The USP regulates the uniformity and purity of drugs.

    REF: Federal Regulations and Regulatory Agencies (Drug Enforcement Administration) | p. 5
    OBJ: 5

11. Which federal regulatory body is part of the U.S. Department of Health and Human Services (DHHS)?
    a. FDA
    b. OTC
    c. FTC
    d. DEA

    ANS: A
    Correct: Of the legitimate agencies listed, only the FDA is part of DHHS.
    Incorrect choices: OTC is a nonsense answer. It is an abbreviation for “over-the-counter” as in medications that may be purchased without a prescription. The FTC is an independent agency that reports to the U.S. Congress on its actions. The DEA is a part of the Department of Justice.

    REF: Federal Regulations and Regulatory Agencies (Food and Drug Administration) | p. 5
    OBJ: 5

12. Which federal regulatory body regulates the trade practices of drug companies and prohibits false advertising of foods, nonprescription drugs, and cosmetics?
    a. FDA
    b. FTC
    c. DEA
    d. OBRA

ANS: B
Correct: Consumers who refer to care labels on their clothes, product warranties, or stickers showing the energy costs of home appliances are using information required by the FTC. Businesses must be familiar with the laws requiring truthful advertising and prohibiting price fixing. These laws are also administered by the FTC. When the FTC was created in 1914, its purpose was to prevent unfair methods of competition in commerce. Over the years, the U.S. Congress has passed additional laws giving the agency greater authority to police anticompetitive practices.
Incorrect choices: The FDA grants approval so that drugs can be marketed in the United States. Before the FDA can approve a drug, the drug must be determined to be both safe and effective. The DEA regulates the manufacture and distribution of substances that have a potential for abuse. OBRA (Omnibus Budget Reconciliation Act) is not a regulatory body; it is an act that mandates that pharmacists must provide patient counseling.

REF: Federal Regulations and Regulatory Agencies (Federal Trade Commission) | p. 5
OBJ: 5

13. An investigational new drug application (INDA) is submitted _____ trials.
    a. before preclinical
    b. before phase 1 clinical
    c. after phase 2 clinical
    d. before phase 3 clinical

ANS: B
Correct: Preclinical testing usually lasts about 3 years. After the preclinical trials have been completed, an INDA must be filed with the FDA before a drug company can commence phase 1 clinical trials.
Incorrect choices: Animal testing data must be accumulated from preclinical trials before filing an INDA. Phase 1 is the first trial using patients, and phases 2 and 3 follow phase 1. An INDA must be filed before any testing in humans can commence.

REF: Clinical Evaluation of a New Drug | p. 6 OBJ: 6

14. Phase 1 clinical trials involve all of the following *except* which one?
    a. Safe dose range
    b. Toxic effects of the drug
    c. Metabolism
    d. Effectiveness

ANS: D
Correct: In phase 1 clinical trials, small and then increasing doses are administered to a limited number of healthy human volunteers, primarily to determine safety. This phase determines the biologic effects, metabolism, safe dose range in humans, and toxic effects of the drug. The main purpose of phase 2 is to test effectiveness.
Incorrect choices: Biologic effects, metabolism, safe dose range in humans, and toxic effects of the drug are, in fact, goals of phase 1 clinical trials.

REF: Clinical Evaluation of a New Drug | p. 6 OBJ: 6

15. Which of the following is determined during a phase 3 clinical evaluation of a new drug?
    a. Effectiveness

b. Safety and efficacy
c. Dosage
d. Both a and b
e. Both b and c

ANS: E
Correct: Both safety and efficacy must be demonstrated during phase 3 of the clinical evaluation of a new drug. Dosage is also determined during this phase. During phase 3, clinical evaluation takes place involving a large number of patients who have the condition for which the drug is indicated.
Incorrect choices: The main purpose of phase 2 clinical evaluation is to test a drug's effectiveness.

REF: Clinical Evaluation of a New Drug | p. 6 OBJ: 6

16. Which of the following is a schedule II controlled substance?
a. Heroin
b. Propranolol
c. Amphetamine
d. Dextropropoxyphene (Darvon)

ANS: C
Correct: Amphetamine, oxycodone, morphine, and secobarbital are all schedule II controlled substances.
Incorrect choices: Heroin is a schedule I substance. Propranolol is a nonscheduled prescription drug. Dextropropoxyphene is a schedule IV substance.

REF: Table 1-2: Schedules of Controlled Substances | p. 7 OBJ: 6

17. Controlled substances in schedule _____ require a written prescription with the provider's signature and do not permit refills.
a. II, III, and IV
b. II and III
c. III and IV
d. II only
e. III only

ANS: D
Correct: Controlled substances in schedule II require a written prescription with the provider's signature and do not permit refills. Any prescription for schedule II drugs must be written in pen or indelible ink or typed. A designee of the dentist, such as the dental hygienist, may write the prescription, but the prescriber must personally sign the prescription in ink and is responsible for what any designee has written.
Incorrect choices: Prescriptions for controlled substances in both schedule III and schedule IV may be telephoned, and no more than five prescriptions in 6 months are permitted.

REF: Table 1-2: Schedules of Controlled Substances | p. 7 OBJ: 6

18. Schedule III controlled substances may be telephoned to the pharmacist *and* may be refilled no more than five times in 6 months.
a. Both parts of the statement are true.

b. Both parts of the statement are false.
c. The first part of the statement is true; the second part is false.
d. The first part of the statement is false; the second part is true.

ANS: A
Correct: Both parts of the statement are true. Schedule III controlled substances may be telephoned to the pharmacist *and* may be refilled as many as five times in 6 months.
Incorrect choices: Both parts of the statement are true for schedule III and schedule IV controlled substances. Schedule I controlled substances have no accepted medical use. Schedule II controlled substances require a written prescription with the provider's signature, and no refills are permitted. Schedule V controlled substances can be bought OTC in some states.

REF: Drug Legislation (Scheduled Drugs) | p. 7 OBJ: 6

19. What is the purpose of a "black box warning" on a package insert?
a. It is used to reconstruct the events leading to a fatality resulting from a medication error.
b. It is issued by the Drug Enforcement Administration (DEA) to indicate medications that may be used to manufacture illicit drugs such as methamphetamine.
c. It is used to draw attention to potentially fatal, life threatening, or disabling adverse effects for different medications.
d. It means that the effects of the drug have not yet been determined.

ANS: C
Correct: A black box warning is about a drug the FDA has required a manufacturer to prominently display in a box in the package insert. The intent of the black box is to draw attention to the specific warning and make sure that both the prescriber and patient understand the serious safety concerns associated with that drug.
Incorrect choices: A black box on an airplane is used to reconstruct events prior to a tragedy; however, the black box warning on a medication package insert is used to warn about safety concerns with the drug. A black box is not used as a warning about illicit use of medications. All drugs must go through preclinical and clinical trials prior to being marketed.

REF: Drug Legislation (Black Box Warning) | p. 7 OBJ: 7

20. An "orphan drug" is:
a. not related to any other medication currently available.
b. developed specifically to treat a rare medical condition.
c. a drug that has been on the market for longer than 20 years and generic substitution is permitted.
d. no longer available for use as newer, more effective medications are available.

ANS: B
Correct: Rare medical conditions with orphan status refer to diseases that occur in fewer than 200,000 people in the United States.
Incorrect choices: Orphan drugs may be related to other medications. Orphan drug status is not related to the time the drug has been available. Many newer drugs have been assigned orphan status.

REF: Drug Legislation (Orphan Drugs) | p. 7 OBJ: 7

21. The word *stat* on a prescription means:
    a. before meals.
    b. at bedtime.
    c. immediately.
    d. every.

    ANS: C
    Correct: The word *stat* on a prescription means immediately (now).
    Incorrect choices: The abbreviation *ac* means before meals, *hs* means at bedtime, and *q* means every.

    REF: Table 1-3: Abbreviations Commonly Used in Prescriptions | p. 9
    OBJ: 7

22. The abbreviation used on prescriptions for *four times a day* is:
    a. bid.
    b. qid.
    c. qd.
    d. ud.

    ANS: B
    Correct: *qid* is the abbreviation for quarter in die, or four times a day.
    Incorrect choices: *bid* stands for twice a day, *qd* stands for every day, and *ud* stands for as directed.

    REF: Table 1-3: Abbreviations Commonly Used in Prescriptions | p. 9
    OBJ: 7

23. The heading of a prescription contains the following information *except* the:
    a. name and address of prescriber.
    b. name and address of the patient.
    c. telephone numbers of the patient and the prescriber.
    d. date of birth of the prescriber.
    e. date of the prescription.

    ANS: D
    Correct: Having the date of birth of the patient on the prescription is important, both to determine the proper dose for age and so the patient is not confused with another family member (i.e., mother or daughter).
    Incorrect choices: The heading of a prescription contains the name, address, and telephone number of the prescriber, as well as the name, address, age, and telephone number of the patient and the date of the prescription.

    REF: Prescription Writing (Format) | p. 8 OBJ: 7

24. Which of the following is located in the body of the prescription?
    a. The date of the prescription
    b. The amount of the drug to be dispensed
    c. Directions to the prescriber
    d. Refill instructions

ANS: B
Correct: The R_x symbol, name and dose size or concentration of the drug, amount to be dispensed, and directions to the patient are all found in the body of the prescription.
Incorrect choices: The date of the prescription is found in the heading. The directions to the patient rather than prescriber are found in the body of the prescription. Refill instructions are found in the closing of the prescription.

REF: Prescription Writing (Format) | p. 8 OBJ: 7

25. Where is the information regarding the prescriber DEA number commonly found on the prescription?
    a. Superscription
    b. Heading
    c. Body
    d. Closing

    ANS: D
    Correct: The signature area of the prescription is found in the closing. It should also include a space for the DEA number.
    Incorrect choices: The superscription is a classical description for where the patient information and the symbol R_x are found. The heading contains prescriber and patient contact information, the patient's date of birth, and the date of prescription. The body contains the R_x symbol, dosage instructions, and directions to the patient.

    REF: Prescription Writing (Format) | p. 9 OBJ: 7

26. On a prescription, the directions to the patient are preceded by:
    a. R_x.
    b. Sig.
    c. #.
    d. Disp.

    ANS: B
    Correct: *Sig*. is the abbreviation for the Latin word *signa,* or write. This word precedes the instructions to the patient.
    Incorrect choices: R_x means *take thou* and precedes the prescription instructions, # denotes the number of tablets, capsules, and so forth to be dispensed. *disp*. is short for *dispense* and precedes the amount to be dispensed, analogous to #.

    REF: Prescription Writing (Format) | pp. 8-9 OBJ: 7

MULTIPLE RESPONSE

1. How are computer and online resources enhancing printed books as a source of information about drugs? *(Select all that apply.)*
    a. Web-based physicians can diagnose patient conditions and prescribe medication over the Internet.
    b. Tablet computers and smart phones may be used for medication information databases.
    c. Some publishers have apps that can be downloaded to smart phones.

d. Websites such as WebMD have decision trees whereby patients can identify their own health condition and determine appropriate treatment and medication.
e. Older editions of textbooks have been placed in the public domain and are useful for information about medications and drug interactions.

ANS: B, C
Correct: Tablet computers and smart phones are being used more and more for recording, storing patient information, calculating drug doses, and using medication information databases. Some online websites have apps that can be downloaded to smart phones as well as computer-based online sites.
Incorrect choices: There are many legal issues with health care professionals dispensing advice over the Internet. For example, a health care provider may not be licensed to practice in the state where the person asking for information resides. Websites do not provide the means for patients to determine their own health condition. There are many sites with useful information, but most have a disclaimer recommending that the person seek help from a qualified practitioner. Medications change rapidly, and it is important to use current sources of information.

REF: Sources of Information (Computers and Online Resources) | p. 4
OBJ: 2

2. Which of the following are true of an off-label use of a drug? *(Select all that apply.)*
   a. Prescribers are allowed to use drugs for off-label use under certain circumstances.
   b. The FDA approves the use of drugs for specific indications, which are listed or labeled on the package insert of the drug.
   c. Drug manufacturers have much useful information regarding off-label uses of their drugs on their websites.
   d. Off-label use of drugs is not permitted in the United States.
   e. Off-label drugs are repackaged for sale by clandestine organizations outside the United States and are illegal to transport or distribute.

   ANS: A, B
   Correct: Practitioners are allowed to use off-label drugs if good medical practice justifies their use, the use is well documented in the medical literature, and the drug meets the current standard of medical care. The FDA approves the use of drugs for specific indications, and they are listed or labeled on the package insert of the drug.
   Incorrect choices: Drug manufacturers are not allowed to bring up off-label uses when speaking with the prescribing practitioner, nor can they distribute written material regarding off-label uses. The off-label use of drugs is permitted in the United States provided that several rules are followed.

   REF: Drug Legislation (Labeled and Off-Label Uses) | p. 7 OBJ: 7

3. Which of the following are associated with increased patient nonadherence to medication therapy? *(Select all that apply.)*
   a. Some patients may fear of the side effects of the medication.
   b. A longer duration of drug therapy is associated with the risk for nonadherence with medication therapy.
   c. Increased dosing frequency is associated with nonadherence with medication therapy.
   d. The issue of nonadherence to medication therapy is not important, as patients

reliably take their medication as prescribed.

ANS: A, B, C
Correct: Many factors are associated with nonadherence to medication therapy. These include poor understanding of the disease and a need for medication to treat it, fear of side effects of the medication, distrust of health care professionals, economic factors, or forgetfulness. Longer duration of drug therapy and the number of times a day the patient must take a prescription increase the chances that a patient will not adhere to the regimen. For example, patients are more compliant with twice-a-day dosing than they are with four-times-a-day dosing.
Incorrect choices: Statistics reveal that only a minority of patients will take their medication as prescribed.

REF: Prescription Writing (Role of the Dental Hygienist and Patient Adherence to Medication Therapy) | p. 10 OBJ: 7

TRUE/FALSE

1. The body of a prescription includes directions to the patient.

   ANS: T
   Correct: The body of the prescription contains the R_x symbol, name and dose size or concentration of the drug, amount to be dispensed, and directions to the patient.

   REF: Prescription Writing (Format) | p. 8 OBJ: 7

2. Refill instructions are found in the body of a prescription.

   ANS: F
   Correct: Refill instructions are found in the closing, rather than body, of the prescription.

   REF: Prescription Writing (Format) | pp. 8-9 OBJ: 7