Unit 1

Fundamental Concepts

and Principles of Pharmacology

Chapter 1

Introduction to Pharmacology and Drug Regulations in Canada

**Question 1**

**Type:** MCMA

What key elements are included in the definition of Pharmacology?

***Note: Credit will be given only if all correct choices and no incorrect choices are selected.***

**Standard Text:** Select all that apply.

**1.** Physiological effects of drugs

2. Chemical makeup of drugs

3. Formularies of drugs

4. Approval processes for new drugs

5. Mechanism of action

**Correct Answer:** 1,2.5

**Rationale 1**: The definition of pharmacology includes the actual responses produced by the drug

**Rationale 2**: The study of medicines include how they are made, including their chemical properties.

**Rationale 3**: Formularies are a list of drugs and are not an element that defines pharmacology

**Rationale 4**: Approval processes for new drugs is important understanding but not an element of the definition of pharmacology.

**Rationale 5**: How a drug exerts its effect is an element of the defined term pharmacology.

**Cognitive Level:** Applying

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Implementation

**Learning Outcome:** 1-1: Define pharmacology

**Question 2**

**Type:** MCSA

While many substances can be considered drugs, which of the following drug definitions is the most accurate?

**1.** Any substance that is found in nature or that normally occurs in the body.

**2.** Any substance that is synthesized and tested in the laboratory setting.

**3. S**ubstances that are taken to prevent, cure, or reduce symptoms of a medical condition

**4. S**ubstances that can be isolated from natural substances in nature

**Correct Answer:** 3

**Rationale 1**: A drug is not a substance that is found in nature or that normally occurs in the human body.

**Rationale 2**: A drug is not only a substance that is synthesized and tested.

**Rationale 3**: A drug is considered to be any substance that is taken to prevent, cure, or reduce symptoms of a medical condition.

**Rationale 4**: A drug is not only a substance isolated from natural substances.

**Cognitive Level:** Understanding

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Implementation

**Learning Outcome:** 1-4: Compare and contrast conventional drugs, biologics and natural health products*.*

**Question 3**

**Type:** MCSA

Pharmacotherapy is a critical intervention for many conditions, and a key part of nursing intervention. Which statement best describes pharmacotherapy?

**1.** The study of medicine and drug therapy

**2.** The application of natural substances to cure diseases

**3.** The application of drugs for the prevention and treatment of disease and human suffering

**4. The u**nderstanding of the difference between trade and generic medications

**Correct Answer:** 3

**Rationale 1**: Pharmacotherapy is not just the study of medicine and drug therapy.

**Rationale 2**: Pharmacotherapy is not the application of natural substances to cure diseases.

**Rationale 3**: Pharmacotherapy is the application of drugs for the prevention and treatment of diseases and human suffering.

**Rationale 4**: Pharmacotherapy comprises more than understanding the difference between trade and generic drugs.

**Cognitive Level:** Understanding

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Implementation

**Learning Outcome:** 1-3: Compare and contrast therapeutics and pharmacology

**Question 4**

**Type:** MCMA

***Note: Credit will be given only if all correct choices and no incorrect choices are selected.***

**Standard Text: Select all that apply.**

A student nurse is learning about how drugs are dispensed in her pharmacology class. Which of the following are considered true in dispensing of prescription drugs when compared to over the counter (OTC)?

**1.** May only be obtained by a physician

**2.** Are easily obtainable

**3.** Choice of drug is usually more specific

4. Frequency of the drug can be controlled

**Correct Answer: 3,**4

**Rationale 1**: Prescription drugs are not *only* available by physicians, other health care providers can write prescriptions.

**Rationale 2**: Prescription drugs are *less* easily obtainable than OTC, they require an appointment with a health care provider.

**Rationale 3**: The choice of drug is considered more specific because the health care provider has the opportunity to examine the client and come up with a diagnosis.

**Rationale 4**: The dose and frequency of the drug is controlled through prescription dispensing.

**Cognitive Level:** Applying

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Teaching/Learning

**Learning Outcome:** 1-5: Identify the advantages and disadvantages of prescription and over-the-counter (OTC) drugs

**Question 5**

**Type:** MCMA

Which of the following criteria are assessed in order to market a pharmaceutical drug?

*Note: Credit will be given only if all correct choices and no incorrect choices are selected.*

**Standard Text:** Select all that apply.

**1.** Efficacy

**2.** Need

**3.** Cost

**4.** Safety

**5.** Quality

**Correct Answer: 1,4,5**

**Rationale 1**:The Therapeutic Products Directorate (TPD), a branch of Health Canada authorizes marketing of a pharmaceutical drug or medical device once a manufacturer presents sufficient scientific evidence of the product’s safety, efficacy, and quality.

**Rationale 2**: The need for a particular drug does not influence the marketing of drugs in Canada. Despite need, all drugs must go through the same degree of rigour in order to promote safety, efficacy and quality.

**Rationale 3**: Cost is not considered criteria for marketing drugs.

**Rationale 4**: The Therapeutic Products Directorate (TPD), a branch of Health Canada authorizes marketing of a pharmaceutical drug or medical device once a manufacturer presents sufficient scientific evidence of the product’s safety, efficacy, and quality.

**Rationale 5**: The Therapeutic Products Directorate (TPD), a branch of Health Canada authorizes marketing of a pharmaceutical drug or medical device once a manufacturer presents sufficient scientific evidence of the product’s safety, efficacy, and quality.

**Cognitive Level:** Understanding

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Assessment

**Learning Outcomes: 1-7:** Discuss the role of Health Canada and the Health Products and Food Branch (HPFB) of Health Canada and its Therapeutic Products Directorate in the drug approval process.

**Question 6**

**Type:** MCMA  
Mrs. Morton expresses concern to the nurse about a new drug on the market that has been prescribed for her health condition; she worries about the safety of the medication. What can the nurse tell Mrs. Morton about drug regulatory standards in Canada that are intended to protect patients?

*Note: Credit will be given only if all correct choices and no incorrect choices are selected.*

**Standard Text:** Select all that apply.

**1.** All drugs go through a 3 step approval process before marketed for human use.

**2.** The first phase of clinical trials involves testing on 1000-3000 individuals with the target disorder.

**3**. Once a drug is considered safe on animals, the manufacturer applies for clinical trials.

**4.** Health Canada continues to monitor the safety of drugs even after initial marketing

**Correct Answer:** 3,4

**Rationale 1**: Drugs go through a 7 step approval process from pre-clinical trials to the monitoring of drugs after marketing.

**Rationale 2**: The first phase of clinical trials involves a small group of healthy individuals.

**Rationale 3:** After the preclinical trials, an application for Clinical trials is submitted to Health Canada.

**Rationale 4**: Health Canada monitors the efficacy of the drug and any safety concerns after it has been marketed. This is done by regular inspection, notices, newsletters, and feedback from consumers and healthcare professionals.

**Cognitive Level:** Remembering

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Implementation

**Learning Outcome:** 1-6 Identify key Canadian Drug regulations that help to ensure the safety and efficacy of medications.

**Question 7**

**Type:** MCSA

In clinical trials, a new drug is tested on healthy individuals.Which of the following is a reason for this step in the process?

**1.** To determine adverse effects.

2.To identify how a drug is metabolized

3. To determine drug incompatibilities.

4. To maximize a drugs effectiveness at different doses.

**Correct Answer:** 2

**Rationale 1**: Adverse effects would be determined during pre-clinical trials.

**Rationale 2**: Clinical investigators perform tests on 20 to 100 healthy volunteers to determine dosage and to assess how the drug is absorbed, metabolized, and excreted by the body.

**Rationale 3**: This occurs during the last phase of clinical trials.

**Rationale 4**: This occurs during pre-clinical trials.

**Cognitive Level:** Remembering

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Assessment

**Learning Outcome:** 1-8: Describe the stages of approval for therapeutic and biologic drugs in Canada.

**Question 8**

**Type:** MCSA

Which of the following characteristics are true of a a biologic?

**1.** A biologic is an ingredient extracted from plants.

**2.** Insulin is an example of a biologic.

**3.** Biologics have no adverse effects.

**4.** Biologics do not require a prescription.

**Correct Answer: 2**

**Rationale 1**: N**atural health products (nhps)( not biologics)** may include natural plant extracts,

**Rationale 2**:B**iologics** are agents naturally produced in animal cells; Examples of biologics include hormones,( hormone) monoclonal antibodies, natural blood products and components, interferon, and vaccines.

**Rationale 3**: Biologics are therapeutics that can produce adverse effects if not given according to proven treatment regimes.

**Rationale 4**: Biologics are not available over the counter.

**Cognitive Level:** Understanding

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Assessment

**Learning Outcome:** 1-4: Compare and contrast conventional drugs, biologics, and natural health products.

**Question 9**

**Type:** MCSA

Mr Brisbois is in the pre-operative assessment clinic for consults before his knee replacement. . The pharmacist asks him about prescription, OTC and herbals remedies that he is currently taking. Mr Brisbois asks him why information on herbals is important. What is the best response?

**1.** Herbal remedies may be ordered to enhance recovery.

2. Herbals can be substituted for prescribed drugs because of their decreased incidence of adverse effects

3. Some herbals may contain the same ingredients as prescription drugs in different forms.

4. Herbals may be ordered instead of prescription drugs to control costs

**Correct Answer:** 3

**Rationale 1**: While herbals may be used to enhance recovery, they are normally not ordered by a physician. It is most important that the health care providers know about all medications to decrease incidence of receiving multiple forms of the same drug and herbals that may counteract ordered medications necessary for recovery.

**Rationale 2**: Herbal medications can have adverse effects and can interact with prescribed drugs.

**Rationale 3**: To ensure that the client does not receive two different forms of the same drug or drugs that may counter- act the home remedy.

**Rationale 4**: There is no evidence to support that herbals would be substituted for thoroughly studied medications, ordered for a specific effect.

**Cognitive Level: Remembering**

**Client Need:** Physiological IntegrityClient Need Sub: Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process-Implementation

**Learning Outcome:** 1-4: Compare and contrast conventional drugs, biologics, and natural health products.

**Question 10**

**Type:** MCSA

A new drug has been approved by Health Canada for the treatment of psoriasis. What determines when a health care provider will be able to order it for his clients?

**1.** Once approved by Health Canada, medications are available in all provinces and territories.

**2.** Medication will be available after the 4 level provincial testing is completed

**3.** Following direct to consumer advertising to determine market need**.**

**4. F**ollowing.a Common Drug Review to provide a formulary listing recommendation.

**Correct Answer:** 4

**Rationale 1**: Each territory and province decides on whether to include newly approved drugs in their formularies.

**Rationale 2**: There is no specific testing completed at the provincial level.

**Rationale 3**: Direct to consumer marketing of prescription medications is not allowed in Canada.

**Rationale 4**: A common Drug Review is completed after Health Canada’s approval process to expedite jurisdictional review for provinces and territories.

**Cognitive Level:** Understanding

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Implementation

**Learning Outcome:** 1-8 Describe the stages of approval for therapeutic and biologic drugs in Canada.

**Question 11**

**Type:** MCSA

How is information collected for Health Canada regarding adverse drug reactions after administration of a new drug on the market?

**1.** Voluntary reporting to local Health Authority.

**2.** Mandated reporting to the Institute for Safe Medication Practices.

**3.** Direct reporting to Health Canada.

**4.** Voluntary reporting to Canadian Adverse Drug Reaction Monitoring Program.

**Correct Answer: 4**

**Rationale 1**: Reporting to only the Health Authority would be insufficient in identifying adverse reaction trends nation wide.

**Rationale 2**: Reporting adverse reactions is voluntary. While the ISMP mandates safe medication practices, they are more concerned with medication errors.

**Rationale 3**: Reporting is to the CADRMP, not directly to Health Canada.

**Rationale 4**: The CADRMP collects data from health care professionals and consumers regarding adverse drug reactions. These are then listed in the Canadian Adverse Drug Monitoring Information System( CADMIS) a database used to compile data on reported reactions from drugs.

**Cognitive Level:** Applying

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**NLN Competencies:** Knowledge and Science: Relationships between knowledge/science and quality and safe patient care **Nursing/Integrated Concepts**: Nursing Process: Assessment **Learning Outcome**: 1-6: Identify key Canadian drug regulations that help to ensure the safety and efficacy of medications.

**Question 12**

**Type:** MCSA

The nurse is teaching a class about over-the-counter (OTC) medications at a senior citizen centre. Which statement by a participant indicates the teaching was effective?

**1.** "Over-the-counter medications are safe, as long as we don't take them at the same time as our prescription medications."

**2.** "Over-the-counter medications are safe; otherwise, they would require a prescription."

**3.** "We should inform our primary health care provider of any OTC drugs used because of the potential of interacting with our prescription medications."

**4.** "We must read all the label directions before taking any over-the-counter medications."

**Correct Answer:** 3

**Rationale 1**: Some OTC medications can be taken with prescription medications; others cannot.

**Rationale 2**: Although they have a high margin of safety, OTC medications are not without risks.

**Rationale 3**: Elderly clients often take multiple medications and should consult with their health care provider before taking any over-the-counter medication or supplement to ensure there are no risks for drug interactions.

**Rationale 4**: It is important for clients to read all directions on the label, but this will not protect them if there is a contraindication with another medication they are taking; therefore, they must consult their primary health care provider before taking any OTC medications.

**Cognitive Level:** Applying

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Evaluation

**Learning Outcome: 1-5:** Identify the advantages and disadvantages of prescription and over the counter drugs.

**Question 13**

Type: MCSA

Nursing students are studying how foods and health products are regulated and approved for sale in Canada. Which of the following products is regulated through the Therapeutic Products Directorate?

1. Biologics

2. Food supplements

3. Medications

4. Herbal Supplements

Correct Answer: 3

**Rationale** 1: Biologics are approved through Biologics & Genetic Therapies Directorate **Rationale** 2:.Approval for food supplements is not covered by the Therapeutic Products Directorate

**Rationale 3**: The Therapeutic Products Directorate (TPD) authorizes marketing of a pharma- ceutical drug or medical device once a manufacturer presents sufficient scientific evidence of the product’s safety, efficacy, and quality as required by the Food and Drugs Act and Regulations.

**Rationale** 4: Herbal supplements are approved through the Natural & Non- prescription Health Products Directorate.

**Cognitive Level**: Applying

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Implementation

**Learning Outcome:** 1–7: Discuss the role of Health Canada and the Health Products and Food Branch (HPFB) of Health Canada and its Therapeutic Products Directorate in the drug approval process.

Question 14

**Type:** MCMA

Which statements regarding the 4 phases of clinical research of drug development are true?

*Note: Credit will be given only if all correct choices and no incorrect choices are selected.*

**Standard Text:** Select all that apply.

**1.** 90 % of drugs do not proceed past the 2nd phase because they are found to be ineffective.

**2.** In the second phase, clients with the disease or condition that the drug will treat are given the drug to determine doses and side effects

**3.** The clinical stage of research involves extensive testing on animals in the laboratory to determine if the drug will cause harm to humans.

**4.** Absorption, metabolism and excretion of a drug is determined in the first phase of clinical trials

**5.** A clinical trial will not be suspended until 2000-3000 people with the affected disease or condition have trialled the drug .

**Correct Answer:** 1,2,4

**Rationale 1**: Most drugs do not reach the third phase of clinical trials if there is concern that the drug is ineffective, worsens the condition it is intended to treat, or affects one type of client more than others.

**Rationale 2**: The second phase of clinical trials involves testing the drug on individuals who have the disease or condition that the drug will treat. At this phase, dosage is determined and side effects monitored.

**Rationale 3**: Preclinical, *not* clinical involves extensive testing on human, microbial cells, and animals to determine drug action and to predict whether the drug will cause harm to humans.

**Rationale 4**:.A small population of healthy individuals ( 20-100) is given the drug to determine the drug’s absorption, metabolism and excretion.

**Rationale 5**: This is incorrect. A clinical trial can be abandoned at any time that there is sufficient evidence that a drug is causing harm.

**Cognitive Level:** Applying

**Client Need:** Physiological Integrity

**Client Need Sub:** Pharmacological and Parenteral Therapies

**Nursing/Integrated Concepts:** Nursing Process: Implementation

**Learning Outcome:** 1–6: Identify key Canadian drug regulations that help to ensure the safety and efficacy of medications.