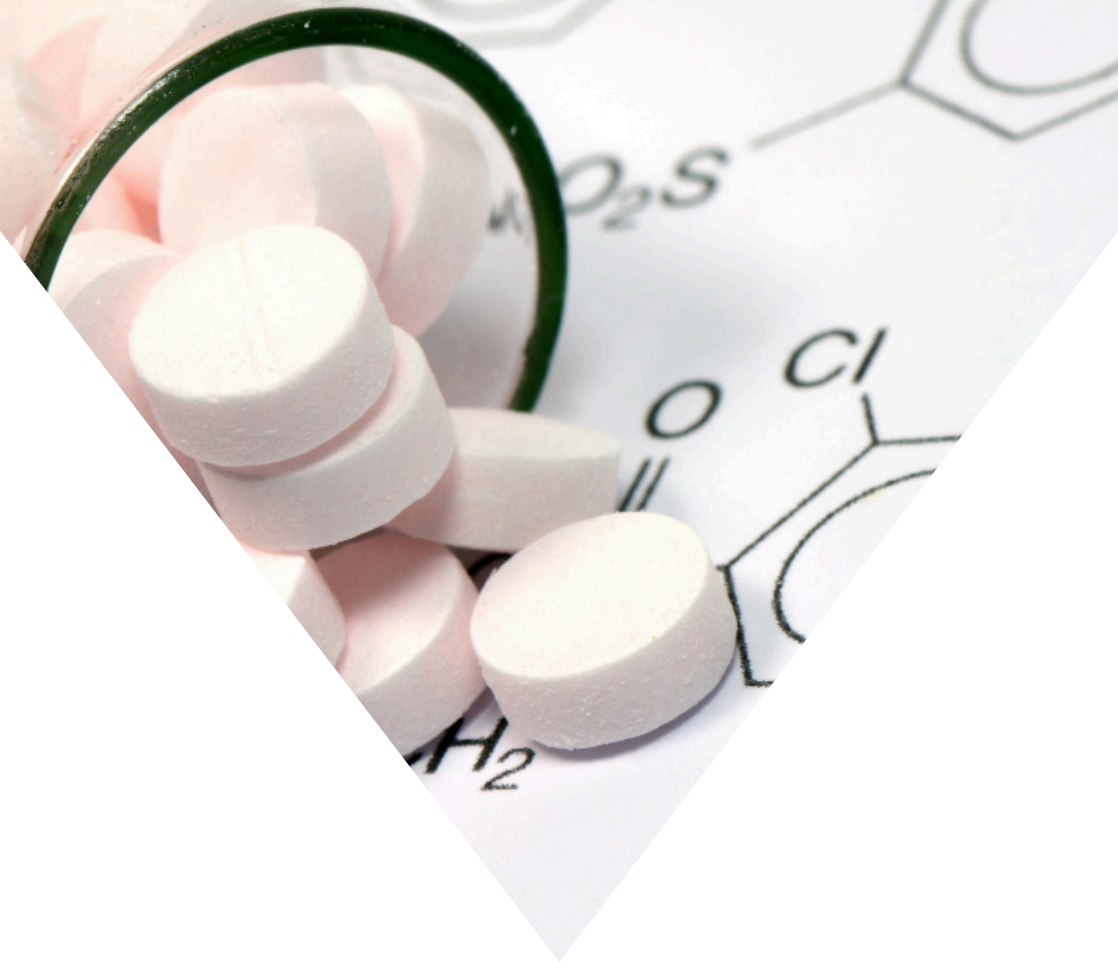

2024

Ethiopian Health Professionals Licensing Examination(EHPLE)

INFORMATION BOOKLET

PHARMACY

ጤና ሚኒስቴር - ኢትዮጵያ
MINISTRY OF HEALTH-ETHIOPIA
የዜጎች ጤና ለሃገር ብልጽግና!

Institute of
Educational Research

Message From the State Minister, Ministry of Health -Ethiopia

Mrs. Frehiwot Abebe

Improving healthcare quality is a global priority for sustainable development, with high quality healthcare being a key component of universal health coverage. One strategy to maintain health care standards is through provision of health professional competency assessment. Consequently, in 2019, the Ministry of Health Ethiopia, initiated the Ethiopian Health Professionals Licensing Examination (EHPLE) for undergraduates in seven health disciplines, which has since expanded to include 13 health disciplines.

The main goal of this competency assessment is to identify health professionals with minimal competencies necessary to perform their duties safely and competently, thus enhancing the quality of health care services. This initiative is overseen by a dedicated Health and Health Related Institutions and Professionals' Regulatory Lead Executive Office (LEO), comprising four desks, which plays a pivotal role in strengthening the system and enabling the LEO to conduct the competency exam more extensively and with improved organization and quality.

It is important to note that this competency assessment differs significantly from traditional academic or employment examinations. Hence, this information booklet has been created to address the informational needs of both examinees and teaching faculty regarding the Ethiopian Health Professionals' Licensure Examination. Additionally, it aims to facilitate the assessment process, while promoting transparency and ensuring the sustainability of the program.

The preparation of this guideline involved the collaboration of esteemed experts from various higher education institutions, the Ministry of Health, JHPIEGO-Ethiopia, Amref/HWIP, Health Professionals' Associations, and the Ministry of Education. Their invaluable contributions are acknowledged with sincere gratitude, alongside appreciation for the Ministry of Health staff for their unwavering commitment and hard work throughout the project.

Acknowledgements

This Information Booklet for Ethiopian Health Professional's Licensure Examinations is a contribution from several educators, researchers, students and concerned individuals with a genuine interest to propel Ethiopia's medical and health sciences education forward.

The Ministry of Health is grateful for the contribution of many individuals and institutions in realizing this endeavor. Among these are Professional Associations, Student Association, Higher Education Institutions (both public and private), JHPIEGO-Ethiopia, AMREF/HWIP, MOE (Ethernet), UNFPA, AAU-IER and all HHRIPR LEOs staff.

Acronyms and Abbreviations

EHPLE	Ethiopian Health Professionals Licensing Examination
ETA	Educational and Training Authority
HEIs	Higher Education Institutions
HHrIPR-LEO	Health and Health-related Institutions and Professionals Regulatory Lead Executive Office
HSTP-II	Health Sector Transformational Plan-II
MCQ	Multiple Choice Question
MoH	Ministry of Health
WHO	World Health Organization

Purpose of the information booklet

The Ethiopian Health Professionals' Licensure Examination (EHPLE) Information Booklet serves as a comprehensive guide for those individuals seeking information about the exam. It typically outlines basic information for candidate registration, exam development and administration processes and procedures, result notification, and the licensing process. It also includes information on the exam framework, i.e., the exam domain, sub-domain, content, process, and task, with sample exam items specific to each profession.

The publication of this Booklet is crucial for the following reasons:

- Clarity and guidance: It provides clear information about the exam by ensuring candidates understand the necessary information to prepare them.
- Accessibility: It serves as a readily accessible resource for individuals pursuing to take the exam, consolidating essential information in one document and facilitating easy access to necessary details. It also helps other stakeholders who might be interested in such resources.
- Transparency: It promotes transparency in the examination process and fosters trust among stakeholders about the exam.

In summary, the publication of this Booklet is essential for creating a transparent, standardized, and accessible framework that guides candidates through the EHPLE process.

Contents

Message From the State Minister, Ministry of Health -Ethiopia i
Acknowledgements ii
Acronyms and Abbreviations iii
Definition of terms vi
1. Introduction 1
1.1. Background 1
1.2. The Rationale of EHPLE 1
2. Key processes of EHPLE 2
2.1. Registration of candidates 2
2.2. Task Analysis 3
2.3. Exam Blueprint 3
2.4. Item Development 3
2.5. Item Review 4
2.6. Standard setting method 4
2.7. Exam Administration 4
2.8. Scoring and post exam analysis 5
2.9. Result notification and appeal management 5
2.10. Licensing 5
3: Examination Framework 6
Sample questions 13
Sample References 22
List of contributors 23
Contact Us 24

Definition of terms

- **Domain:** a broad category or area of knowledge or skills of a profession
- **Sub-domain:** a subset of a broader domain that focuses on knowledge or skills related to the overarching domain
- **Content:** a more specific subcategory, which is a breakdown of the sub-domain
- **Task:** the responsibility, knowledge, skill, and attitude of a junior undergraduate professional in an actual work environment
- **Process:** a systematic sequence of steps or actions designed to achieve a specific outcome
- **Learning outcome**: a clear and measurable statement that describes what the examinee is expected to know or be able to do
- **Relative emphasis:** the proportional importance or weight assigned to different content areas or categories within the assessment
- **Item:** a particular multiple-choice question
- **Item developer:** a subject matter expert responsible for writing test items or questions that make up the examination
- **Item reviewer:** a subject matter expert responsible for reviewing and refining the test items or questions that make up the examination
- **Standard setting:** a process of determining a cut-off point or passing score for an exam
- **Item difficulty index:** a statistical measure that indicates the proportion of examinees who answered a particular test item correctly
- **Discrimination index:** a statistical measure that evaluates how well a particular test item differentiates between high-performing and low-performing examinees
- **Admission paper:** a printout paper generated by the system after completing registration that contains the examinee's photo, QR code, and necessary information

1. Introduction

1.1. Background

Competency assessment is one of the strategies for controlling the standard of healthcare services provided in healthcare facilities. The World Health Organization (WHO) recommends all healthcare professionals to have necessary competencies. In Ethiopia, the Health Sector Transformational Plan-II (HSTP-II) states competency assessment of all graduates before joining the health workforce as one of the strategic initiatives.

The Ministry of Health (MoH) launched the Ethiopian Health Professionals Licensing Examination (EHPLE) for undergraduates in 2019. The Health and Health-related Institutions and Professionals Regulatory Lead Executive Office (HHrIPR-LEO) of the Ministry of Health was given a mission to implement the ministry's objective to achieve competency-related goals. It has the responsibility to ensure that the EHPLE meets technical, professional, and legal standards, and to protect the health, safety, and welfare of the public by assessing candidates' abilities to practice competently.

Currently, the exam is given for 13 health professions (Medicine, Nursing, Public Health, Pharmacy, Medical Laboratory Science, Anesthesia, Midwifery, Dental Medicine, Medical Radiology Technology, Environmental Health, Psychiatric Nursing, Pediatric and Child Health Nursing, and Emergency and Critical Care Nursing). Since its introduction until February 2024, a total of 166293 examinees took the exam in 14 rounds.

1.2. The Rationale of EHPLE

One of the critical functions of the MoH is to guarantee the efficiency, quality, and equity of healthcare delivery and to protect the public from any undesirable consequences in healthcare delivery practices. As professionals' competence is a significant determinant of the quality of health, evaluation of health professionals' competence has now been given due attention. The licensing examination for health professionals serves as a crucial step to ensure that individuals entering the field meet specific competency standards. The sole aim of the competency assessment is to safeguard public health by verifying that health professionals have the minimal basic knowledge, attitude, and skill required to provide safe and effective care.

Licensing exams act as a preventive measure, ensuring that only competent professionals join the health workforce, which, in turn, contributes to reducing the occurrence of medical errors and enhancing overall patient safety. By setting standards through examinations, regulatory bodies strive to minimize the risk of medical errors caused by incompetence.

2. Key processes of EHPLE

EHPLE involves several key processes to ensure the quality and reliability of the examination.

2.1. Registration of candidates

EHPLE has a mandatory online registration system for both new and repeat candidates, which can be found at www.hple.moh.gov.et

Please note these important notes during registration.

New Test Takers:

- The list of eligible candidates from governmental and private Higher Education Institutions (HEIs) will be sent from Ministry of Education (MoE) to MoH and uploaded to the online registration system by MoH.
- Once the name of the candidate is uploaded to the system and registration has opened for the current exam round, the candidate must register at **www.hple.moh.gov.et**by uploading the necessary documents listed below.
  - ✓ a scanned original or temporary degree
  - ✓ a scanned government-issued ID, passport, driving license, or any other legal ID
  - ✓ a passport-size photo of the candidate
  - ✓ For international candidates:
    - Equivalence document from ETA
    - Completing an externship attachment according to assignment by the regulatory body
    - Externship attachment completion letter

Repeat Test Takers:

- Since the information about re-exam candidates already exists in the system, the candidate should register by directly going to **www.hple.moh.gov.et**. There is no need for re-exam candidates to upload their documents.

Both new and repeat candidates:

- After completing the registration, the candidate must download and print the admission paper by logging into his/her account using his/her email address and password
- The candidate can change the exam center by logging into his/her account only during the registration period
- Once an examinee has selected his/her exam center during the registration period, an application for center change will not be allowed

2.2. Task Analysis

The first step of exam development involves conducting a comprehensive task analysis study, which identifies the tasks, knowledge, skills, and abilities required from a junior undergraduate professional in the specific profession. The analysis is typically done through surveys, interviews, or observations of practitioners in the actual work environment, as well as through the Delphi method with subject matter experts.

2.3. Exam Blueprint

Based on the task analysis findings, a test blueprint is created that outlines the content areas to be covered in the examination and the weight or emphasis given to each area. This ensures that the exam reflects the key competencies and knowledge needed for competent practice in that specific profession. Blueprint or test specification is the matrix or chart that shows the number and type of test questions represented across the topics in the content area, consistent with the learning outcome and relative weight of the test given to each content area. The blueprint also identifies the percentage weighting of cognitive dimensions as the level of competence tested in each knowledge domain.

Key components of a blueprint are:

- Domain
- Sub-domain
- Content
- Task
- Process
- Learning outcome
- Assessment methods
- Assessment tools/instrument (test format)
- Relative emphasis (in percentage)

2.4. Item Development

The items are developed following specific guidelines to ensure clarity, relevance, and fairness. Subject matter experts with experience in the field are selected from HEIs to develop test questions (items) that align with the test blueprint. The exam questions will focus mainly on “knows how” according to the competency level of the Miller's pyramid. The items are produced in a secure location on designated computers that are free from internet connectivity. The items are scenario-based and constructed with stem, lead-in, and four options/alternatives. All items will have a single-best-answer type of Multiple Choice Question (MCQ) that addresses the learning outcome defined in each content area. Standard text books, updated guidelines, and standards are used as reference materials.

2.5. Item Review

Once developed, the items undergo a rigorous review process by item reviewers. The main purpose of the exam review process is to evaluate content relevance, technical accuracy, clarity, and sensitivity related to culture and religion. More experienced subject matter experts as well as psychometric experts will do the review to ensure the items meet psychometric standards. Subject matter experts shall review the items to confirm that they are accurate, clearly stated, and correctly keyed using the checklist. Psychometric experts shall reviews the items to ensure that they are not technically flawed. They also work on editorial review to check grammar, punctuation, and spelling errors. This helps ensure the reliability and validity of the items.

2.6. Standard setting method

The standard setting or cut-off point of the EHPLE is determined using the Modified-Angoff method, which is one of the most widely used and legally defensible standard setting approaches to set a cut-off point for high-stake competency examinations.

The method involves a panel of subject matter experts who evaluate each test question and then estimate the probability that a minimally competent examinee would answer each test item correctly. The average of the experts' predictions for a test question becomes its predicted difficulty. The average of the predicted difficulty values across all items on a test is the recommended cut-off point. This point indicates the minimum level of knowledge and skill required to pass.

2.7. Exam Administration

The EHPLE is administered following established protocols and guidelines. Proper test administration procedures, appropriate security measures, and appropriate consideration for test-takers who need special support will be applied during exam administration at exam centers. The exam is administered in selected HEIsnationally, where candidates can choose based on their convenience at the time of registration. The exam schedule will be posted ahead of time on the MOH website and official Facebook page. Examinees who have a valid admission paper are eligible to sit for the exam. The mode of exam administration is computer-based testing.

CAUTIONS

- Candidates are allowed

- Attend the orientation session in order to sit for the exam
- Arrive at the exam center on time
- Bring a legal ID and admission paper
- Complete the exam within the allotted time frame

- Candidates are **NOT** allowed

- To bring reference materials, blank paper, or notes into the exam center
- To smoke, eat, or drink in the exam room
- To bring mobile phones, tablets, smart watches, camera devices, eyeglasses, calculators or any type of electronic device into the exam center
- To bring their personal belongings to the exam center
- To bring weapons and sharp materials into the exam center
- To give or receive assistance to or from other candidates during the examination

2.8. Scoring and post exam analysis

Once the exam is completed, the scoring process begins. The exam scoring process involves computerized scoring using software.

Post-exam analysis is the process of analyzing examinees' responses to individual test items in order to assess the quality of the items and the exam as a whole. This phase helps to identify any poorly performing items that may need revision or removal from the exam. The item difficulty index, discrimination index, and reliability coefficient are elements of exam analysis.

2.9. Result notification and appeal management

After scoring and analysis, individual score reports are generated and provided to examinees through the website *www.hple.moh.gov.et*.After result notification, examinees can submit their appeal through phone or email within 10 working days after result notification.

2.10. Licensing

The list of examinees who passed the exam will be sent to regional and city administration regulatory bodies. A license is obtained from the regional/zonal health bodies where he/she permanently lives.

Requirements for professional licensing are:

- Passing the EHPLE
- Original or temporary degree
- Educational documents (10th and 12th certificates)
- Medical certificate
- Government issued ID
- Additional prerequisites based on the requirements of regional regulatory bodies

3: Exam Framework

The key broader professional roles, also known as domains or main knowledge areas serve as a building framework for the licensing examination content for pharmacists. The domains are further divided into discrete professional attributes that constitute sub-units (also referred to as sub-domains) defining the professional identity of pharmacists. Tasks specifying the performance level of each sub-domain serve as the final characteristic of the professional duties on which the licensing exam focuses.

The contents of the licensing examination are presented below, structured into key roles (domains), sub-units (sub-domains), and tasks. The examination emphasis for each domain and sub-domain, out of the total 100% questions, is indicated in brackets.

Key professional roles/ domains

- *Patient Care (53.0%)*
- Pharmaceutical technology (12.0%)
- Pharmacy law and regulatory affairs (10.0%)
- Scholar *(3.0%)*
- Professionalism *(5.0%)*
- Leadership and management *(14.0%)*
- Health promotion and disease prevention *(3%)*

Key role/ domain *1*: Patient care *(53.0%)*

Description: This domain encompasses the professional roles of pharmacists in the provision of high-quality, safe, and patient-centered pharmaceutical care services within their scope of practice. The provision of up-to-date, ethical, and resource-efficient pharmaceutical services requires the application of integrated knowledge of biomedical, clinical, behavioral, and social sciences. As patient care providers, pharmacists shall establish therapeutic relationships with their clients; carry out pharmaceutical client assessments that identify actual or potential drug therapy problems (DTPs); develop individualized care plans to resolve or prevent DTPs; implement the plan; monitor and evaluate the effectiveness of the plan in meeting the desired goals of therapy; and modify plans as needed. To demonstrate competence in this domain, candidates shall apply such integrated knowledge in the following sub-areas:

- Pharmaceutical care (25.0%)
- Dispensing (21.0%)
- Drug information system (7.0%)

Key role/ domain *2*: Pharmaceutical technology *(12.0%)*

Description: This domain encompasses the professional roles of pharmacists in pharmaceutical technology services within their scope of practice and adhering to GMP standards. The provision of up-to-date, ethical, and resource-efficient pharmaceutical technology services requires the application of integrated knowledge of biomedical, clinical, behavioral, social, and GMP sciences. As pharmaceutical technology service providers, pharmacists shall formulate the design, perform preclinical and clinical testing, conduct quality control and assurance procedures, label and package products, and document procedures. To demonstrate competence in this domain, candidates shall apply such integrated knowledge in the following sub-areas:

- ❑ Drug Discovery (1.0%)
- ❑ Pharmaceutical development and manufacturing (11.0%)

Key role/ domain *3*: Pharmacy law and regulatory affairs *(10.0%)*

Description: This domain encompasses the professional roles of pharmacists in pharmacy law and regulatory affairs to promote public health and to ensure that healthcare practice is safe, effective, good quality, and as per good practices. The provision of up-to-date, ethical, and resource-efficient pharmaceutical technology services requires the application of integrated knowledge of GMP, biomedical, clinical, behavioral, and social sciences. As pharmaceutical technology service providers, pharmacists shall support product regulatory activities such as new dossier submission, renewal of submission, handling variation applications, and granting market authorization for pharmaceuticals and medical devices. Pharmacists shall also possess essential applied knowledge to regulate healthcare providers and facilities ensuring public safety. To demonstrate competence in this domain, candidates shall apply such integrated knowledge in the following sub-areas:

- ❑ Institution regulation (4.0%)
- ❑ Product regulation (4.0%)
- ❑ Professional regulation (1.0%)
- ❑ Pharmacy law (1.0%)

Key role/ domain *4*: Scholar *(3.0%)*

Description: This domain encompasses the professional roles of pharmacists in generating and utilizing scientific data to improve the health and well-being of the community and broaden their scientific knowledge within the *healthcare system and community setting*. Providing this service requires the application of integrated knowledge in research methods, measurements of health and disease, biostatistics, epidemiology, clinical audit, evidence-based practice, and research ethics. To demonstrate competence in this domain, candidates must possess applied knowledge in

planning, problem identification, data collection, analysis, interpretation, report write-up, and dissemination of research outputs.

Key role/ domain *5*: Professionalism *(5.0%)*

Description: This domain encompasses the professional commitment of pharmacists to promoting the health and well-being of individuals and society through adhering to ethical standards, maintaining personal integrity, and upholding high standards of competence in all areas of *practice*. To exhibit competence in this domain, candidates must possess applied knowledge of ethical principles, medico-legal practices, effective communication, accountability to the profession and society, maintenance of professional excellence and personal health, and professional values such as compassion, respect, integrity, honesty, altruism, and humility. To demonstrate competence in this domain candidate shall possess essential applied knowledge of the following sub-areas.

- ❑ Ethical principles (2.0%)
- ❑ Communication and Collaboration (2.0%)
- ❑ Standards of professional conduct and practice (1.0%)

Key role/ domain *6*: Leadership and management *(14.0%)*

Description: This domain encompasses the professional roles pharmacists in envisioning a high-quality healthcare system through self-awareness, active participation in healthcare teams, leading teams, and managing health systems. Providing this service requires the application of integrated knowledge in continuous quality improvement, effective health system leadership, management, and healthcare ethics. To demonstrate competence in this domain candidate shall possess applied knowledge to plan, organize, staff, lead, execute, monitor, and control healthcare resources and activities.

- ❑ Management/Leadership (2.0%)
- ❑ Health commodities supply chain management (12.0%)

Key role/ domain *7*: Health promotion and disease prevention *(3.0%)*

Description: This domain encompasses the professional roles of pharmacists in enhancing the health and well-being of patients, communities, and the larger populations they serve through health advocacy, disease prevention, health promotion, health protection, and the promotion of health equity. Providing this service takes an integrated understanding of determinants of health, health informatics, epidemiology, communicable disease control, and health education.

Table 1 Exam content for Pharmacy profession

Domain 1: Patient care	
Sub-domain 1.1: Pharmaceutical care	
Pharmacotherapy (Contents)	**Processes**
Infectious (HIV & OIs, TB, Pneumonia, Meningitis, UTI, Parasitic infections(Malaria, giardia, ameobea, helments, shistomiasis, leshmaniasisetc), Infective endocarditis, Fungal infections (Topical, systemic fungal infections), URTI (Tonsillitis,Sinusitis, pharygitis, bronchitis etc), GI Infections (Cholera, shigellosis, typhoid, typhus etc), Intraabdominal infections, Bone and joint infection (osteomyelitis, Septic arthritis etc), Ear infection (like otitis media), STI, Surgical antibiotic prophylaxis, Ophthalmic infections)	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Psychiatry disorders (Depression, mania Anxiety, Bipolar disorder, Schizophrenia etc)	Assessment
	Drug therapy problem identification
	Monitoring and evaluation
Neurologic disorders (Sleep disorders, Epilepsy, Headache, Pain, Parkinsonism etc)	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Cardiovascular and renal disorders (Hypertension, Pulmonary Hypertension, Heart failure, Ischemic heart disease, Angina, Arrhythmia, Shock (Cardiogenic, hypovolemic), Dyslipidemia, Stroke, Venous thromboembolism, Acute kidney injury, Chronic kidney diseases etc)	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Respiratory disorders (Asthma, COPD, Allergic rhinitis etc)	Assessment
	Drug therapy problem Identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Endocrine disorders (Diabetic mellitus, Thyroid disorders, Adrenal gland disorders etc)	Assessment
	Drug therapy problem Identification
	Care plan preparation and recommendation
	Monitoring and evaluation
GIT disorders Gastro Esophageal Reflex Disease (GERD,) Peptic ulcer disease, Chronic liver disease and its complications, Diarrhea (non-infectious), Nausea and Vomiting, Constipation, Hemorrhoids)	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Hematologic disorders (Anemia, Coagulation and Bleeding disorders (including drug induced))	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Musculoskeletal disorders (Gout/hyperuricemia, Osteoporosis, Rheumatoid arthritis, Osteoarthritis etc.)	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Dermatologic disorders (Acne, Psoriasis, Drug induced skin disorders, Eczema, Scabies etc.)	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Oncologic diseases (Breast cancer, Lung Cancer, Colorectal Cancer, Leukemia, Lymphoma, Ovarian Cancer, Prostate	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation

cancer, Neutropenic fever, Chemotherapy induced nausea and vomiting, Tumor lysis syndrome etc.)	Monitoring and evaluation
Miscellaneous (Labor, Abortion, Contraception, Infertility, Sexual dysfunctions, Menstrual related disorders, Glaucoma, BPH, Pregnancy and lactation, First aid)	Assessment
	Drug therapy problem identification
	Care plan preparation and recommendation
	Monitoring and evaluation
Sub-domain 1.2: Dispensing	
Pharmaceuticals (Contents)	**Processes**
Medications (Types of prescription, Components of Prescription, Interpretation of prescription, Dosage forms Identification, Route of administration identification, Reconstitution of powders, Dose calculation, Packaging, Drug Interactions (drug -drug, drug -herbal, drug-food) including incompatibility, Drug category, Adverse drug reaction, Contraindication), Storage condition, etc	Prescription receiving, evaluation and interpretation or receiving clients request for Over-the-Counter medication
	Selection and manipulation
	Labeling and dispensing
	Counseling
	Documentation
Medical Supplies, devices, and Reagents	Prescription receiving, evaluation and interpretation or receiving clients request for OTC
	Selection and manipulation
	Labeling and dispensing
	Counseling
	Documentation
Sub-domain 1.3: Drug information system	
Content	**Drug information procedures**
Educational and standard materials on medicines information (alerts, newsletters, brochures, posters, bulletins, monographs, Formulary, STG, drug list etc.)	Determining the area of information (topic of interest)
	Strategic searching (literature, database or other references including local evidence), evaluation and synthesis
	Dissemination
	Documentation
Responding to queries (patients, health professionals and institutions)	Receiving the query and obtaining background information
	Determining and categorizing the request type
	Searching (literature, database, or other references), evaluation and synthesis
	Responding
	Documentation

Domain 2: Pharmaceutical technology	
Sub-domain 2.1. Drug Discovery	
Content	**Process**
	Drug discovery and Development
Sub-domain 2.2. Pharmaceutical development and manufacturing (Dosage forms)	
Content	**Process**
Solid dosage forms (Tablets, Capsules, Powders, Granules, Suppository, Pellet)	Design and Development of Formulations
	Quality control
	Production, Packaging & labeling
	Storage, handling, and distribution D
	Documentation
Semisolid dosage forms (Ointment & paste, Cream, Gel)	Design and development of formulations
	Quality control

	Production, Packaging & labeling
	Storage, Handling, and distribution
	Documentation
Liquids dosage forms (Solutions, Suspensions, Emulsions)	Design and Development of Formulations
	Quality control
	Production, Packaging & labeling
	Storage, Handling, and distribution
	Documentation
Gaseous dosage forms (Aerosols)	Design and development of formulations
	Quality Control
	Production, Packaging & Labeling
	Storage, Handling and Distribution
	Documentation

Domain 3: Pharmacy Law and Regulatory Affairs
Sub-domain 3.1: Institution regulation (Manufacturing industry, Drug retail outlets, Importers, and wholesales)
Content
Pre-licensing Inspection and licensing
Periodic Inspection
Re-licensing inspection
Sub-domain 3.2: Product regulation
Content
Product registration/market authorization
Pharmaceutical Promotion & Advertising
Pharmacovigilance
Sub-domain 3.3: Professional regulation
Content
Pharmacy Professional registration, licensing, relicensing, Suspending
Sub-domain 3.4: Pharmacy law
Content
Law governing the practice of pharmacy

Domain 4: Leadership and management	
Subdomain 4.1: Management/Leadership	
Contents	**Process**
Management function, Concepts, and principles of management (organizing, staffing, leading and decision making), Primary healthcare and Ethiopian health policy, Monitoring and evaluation	Planning
	Implementation
	Monitoring and evaluation
Sub-domain 4.2: Health commodities supply chain management	
Contents (Health commodities)	**Process**
Medicines (including drugs, biological products, and herbal remedies), Medicated cosmetics (Medical supplies, Reagents, Medical devices/ equipment)	Selection
	Quantification
	Procurement
	Ware-house and inventory management
	Distribution and use

Domain 5: Scholar (Research and evidence based practice)
Contents
Problem identification

Critical appraisal of the literature
Setting objective
Study design
Sample size determination and sampling technique
Data collection tool preparation and pre-test
Data collection method
Data quality assurance [see inclusion of methods for reducing bias]
Data summarization and presentation
Estimation
Hypothesis testing
Data analysis (Descriptive and inferential statistics)

Domain 6: Professionalism
Sub-domain 6.1: Ethical principles and theories (covers issues of ethical practice in all settings of pharmacy practice)
Sub-domain 6.2: Communication and Collaboration
Sub-domain 6.3: Standards of professional conduct and practice

Domain 7: Health Promotion	
Contents	**Processes**
Antimicrobial resistance	Assessment
Substance abuse including smoking cessation	Assessment
Sexual health (including emergency hormonal contraception)	Intervention development
Nutrition and physical activity	Intervention development and quality assurance

Sample questions

1. A 35-year-old man, with history of heart failure, has been admitted to a medical ward with a complaint of shortness of breath, dyspnea particularly on exertion, and cough of two days duration. Physical examination revealed S3gallop along with mitral valve regurgitation murmur. Chest x-ray showed acute cardiogenic pulmonary edema and pleural effusion confirming congestive heart failure.

   What is the most appropriate initial therapy for this patient?
   (A) Furosemide 40 mg IV bolus dose repeated every 30min
   (B) Metoprolol succinate 12.5 mg IV given every 1 to 2 hours
   (C) Furosamide 80mg PO repeated every one hour
   (D) Digoxin 0.5mg IV given every 30 minutes

Answer key: The answer is **A**
Explanation: Diuretics are indicated in HF patients with congestion (pulmonary and/or peripheral edema). They produce rapid symptomatic relief. Loop diuretics, including furosemide, bumetanide, and torsemide, are the diuretics of choice in the management of AHF. Diuretics decrease preload by functional venodilation within 5 to 15 minutes of administration and subsequently by an increase in sodium and water excretion. To produce the fastest response (Option B), IV diuretics such as furosemide of 20-40mg as bolus dose given intermittently till the patient responds to therapy, monitoring renal function, urine output and serum electrolytes. Digoxin having slow onset of action (Option A) cannot be used for immediate effect. This is the case of decompensated heart failure with volume overload and beta-blockers (option C) are contraindicated till the patient becomes euvolumic. As the patient is in an acute condition, oral route of administration (option D) cannot be the answer.

2. A 40-year-old woman, from rural area, is presented with epigastric pain, described as burning sensation and haematemesis of two weeks duration. She described the pain gets relived upon having food; and denied taking any non-steroidal anti-inflammatory drugs (NSAIDs). On physical examination, she is tachycardic and hypotensive. Her CBC test shows that her hemoglobin level is 10 g/dL. Upon endoscopic examination and Urea breath tests, she is found to have duodenal peptic ulcer caused by H.pylori. After fluid therapy for hypotension, the internist prescribed her pantoprazol, amoxicillin and clarithromycin for two weeks. After taking the medications for a week, she has complaints of nausea, abdominal pain, diarrhea and headache, fatigue and dizziness after taking this new anti-peptic ulcer drug regimen.

   What is the most likely cause of this manifestation?
   (A) Pantoprazole
   (B) Amoxicillin
   (C) Clarithromycin
   (D) Sucralfate

Answer key: The answer is **A**
Explanation: The Proton Pump Inhibitors (PPIs) are all benzimidazole derivatives that control gastric acid secretion by inhibition of gastric H+, K+-ATPase, the enzyme responsible for the initial step in gastric acid secretion from the parietal cells. Clinical experience suggests that PPIs are a remarkably safe group of drugs. The most commonly reported side effects are diarrhea, headaches, abdominal pain, nausea, fatigue and dizziness which resolve on drug discontinuation. Possible mechanisms for diarrhea include bacterial overgrowth, changes in intestinal pH and bile salt abnormalities (Option A). Although, amoxicillin (Option B) and Clarithromycin (option C) are associated with some of these side effects like diarrhea, the remaining effects are not usually associated with these antibiotics. On the other hand, sucralfate (option D) is not associated with those side effects.

3. A 41-year- old known Type 2 diabetic and chronic kidney disease (CKD) male patient comes to ambulatory clinic for his regular follow up. He has been taking Glibenclamide 5 mg P.O BID, Amilodipine 10 mg P.O daily, and Enalapril 10 mg P.O BID and Epoetin alpha 30mg/kg IV three times per week. Currently, he ~~is~~ presents ~~presented~~ with persistent hacking dry cough with tickling sensation around throat. Complete blood count results were within the normal range and chest-X ray also suggests no respiratory infection.

   What is the most likely responsible drug for the development of the patient's condition?
   (A) Glibenclamide
   (B) Amilodipine
   (C) Epoetin alpha
   (D) Enalapril

Answer key: The answer is **D**

Explanation: Cough is commonly seen with Angiotesnin Converting Enzyme (ACE) inhibitor drugs, such as enalapril (5%–15%) (Option D) and may be related to accumulation of tissue bradykinins. It can be challenging to distinguish a cough of ACE inhibition from pulmonary congestion. A productive or wet cough usually signifies congestion, whereas a dry, hacking cough is more indicative of a drug-related etiology. If a cough is determined to be ACE inhibitor induced, its severity should be evaluated before deciding on a course of action. If the cough is truly bothersome, switching to an Angiotesnin ii Receptor Blocker (ARB) such as losartan, valsartan, or candesartan is warranted. The antidiabetic medication, glibenclamide (Option A), the antihypertensive drug (dihydropyrideine calcium channel blocker), amilodipine (Option C), erythropoietin used to treat anemia of chronic diseases, Epoetin alpha (option C) are not associated with dry cough that the patient in this scenario suffers from.

4. A 45-year-old male patient presents to hospital with complaints of right flank pain and decreased urine output of two days duration. In addition, he had metatarsophalangeal joint pain and swelling. On investigations, the erythrocyte sedimentation rate, the serum creatinine, C-reactive protein and serum uric acid levels were raised from the normal limit. The patient was diagnosed with gouty arthritis.

   Which of the laboratory investigation is typical to diagnose gouty arthritis in this patient?
   (A) Raised serum uric acid
   (B) Raised serum creatinine
   (C) Raised C-reactive protein
   (D) Raised erythrocyte sedimentation rate

Answer key: The answer is **A**
Explanation: Laboratory investigation of gouty arthritis typically involves analyzing blood and synovial fluid samples. Key tests include serum uric acid levels (Option A), which are often elevated in gouty arthritis and synovial fluid analysis to detect monosodium urate crystals, confirming the diagnosis. Additional tests for kidney function (Option B), inflammation markers like C - reactive protein (CRP) (option C) and erythrocytes sedimentation rate (ESR) (option D) can assess the diseases severity, but cannot be typically used for the diagnosis of gouty arthritis.

5. A man gets headache while drinking alcohol. When the headache becomes severe, he takes 2000mg of paracetamol.

   What could be the possible adverse effect from this combination?
   (A) Increased palpitation and confusion
   (B) Increased drowsiness and sedation
   (C) Increased craving for alcohol
   (D) Increased hepatotoxicity

Answer key: The answer is **D**

Explanation: Both paracetamol and alcohol are metabolized by the liver cytochrome p450 enzymes. Paracetamol (acetaminophen) primarily metabolized by cytochrome p450 specifically CYP2E1 AND CYP3A4) in to a non-toxic metabolite called paracetamol sulfate and glucuronide. However, when alcohol is present, it competes with paracetamol for metabolism by these liver enzymes. This competition can lead to increased levels of a toxic metabolite of paracetamol called N-acetyl-p-benzoquinone imine (NAPQI), a reactive oxygen species damaging DNA, protein, and membrane of liver depleting glutathione stores (a natural antioxidant molecule) in the liver leading to liver damage (option D). Others such as skin reaction, decrease in platelet counts and on long-term use, kidney damage are some of other adverse effects associated with paracetamol use. Therefore, option (A) and option (B) are some of the toxicities related to aspirin, but not to paracetamol and option D is neither.

6. A pharmacist working in drug information center wants to prepare newsletter on new drug for health care professionals working in a hospital.

   What are the most appropriate steps for the compilation of this newsletter?
   (A) Summary → Body → Conclusion
   (B) Introduction → body→ Conclusion
   (C) Introduction → Methods → Result→ Discussion
   (D) Summary→ Result →Result→ Conclusion

Answer key: The answer is **B**
Explanation: In preparing a newsletter on new drugs for healthcare professionals the following basic steps are considered sequentially:

1. **Introduction**: This part includes the greeting and introduction of the purpose of the communication
2. **Body**: The body of new letters includes drug name, indications, mechanism of action, clinical efficacy, safety profile, dosing and administration, drug interaction, guidance on special population, and post-marketing surveillance stressing on the importance of on-going monitoring.
3. **Conclusion**: Summarizes the key points and offers further assistance. Hence, options (A, C, D) are the appropriate steps to prepare new letter on new drugs as drug information for health professionals

7. A pharmacist receives a call requesting an advice for a seven-year-old child, who swallowed 24 tablets of 500-mg Acetaminophen tablets, 5 hours before. These tablets were prescribed for the mother of the child. The child started to have nausea, vomiting, malaise, and diaphoresis.

   What is the most appropriate advice for the request?
   (A) Give plenty of water and take a rest for one day
   (B) Buy sodium bicarbonate from nearby pharmacy
   (C) Visit the emergency department of a hospital
   (D) Observe the child for new symptoms at home

Answer key: The answer is **C**
Explanation: Management of poisoned or overdosed patients is primarily based on symptomatic and supportive care. The most prior action in poisoned first aspect of patient management should always be basic support of airway, breathing, and circulation (the "ABCs") which can only be done in a health care facility (Visit the emergency department of a hospital-option C). Besides, early treatment of Acetaminophen toxicity with its antidote, N-acetylcysteine (NAC), is essential to prevent hepatotoxicity. Sodium bicarbonate (Option B) is used to treat the cardiotoxicity arising from tricyclic antidepressant overdoses. Giving plenty of water and taking rest for one day (option A) and observing the child for new symptoms at home (option D) donot support the poisoned patient looking an immediate management; instead these actions will further endanger the patient.

8. A 40-year-old client repeatedly visits a community pharmacy asking for cough medication. The pharmacist suspects that the client smokes cigarettes and wants to counsel on cigarette smoking cessation.

   What is the most likely recommended initial step for smoking cessation counseling?
   (A) Advising the client to quit smoking altogether
   (B) Assess the client's readiness to quit smoking
   (C) Assist the client to quit smoking
   (D) Asking whether the patient is smoking or not

Answer key: The answer is **D**
Explanation: Due to the repetitive request of the client for cough medication, the suspicion of the pharmacist that the client might be a smoker is right. However, the pharmacist he/she could not come to conclusion without further assessment of the client's status. Therefore, the most likely first step should be confirming whether the client is a smoker or not. Advising (option A), assessing readiness (option B), and assisting (option C) all follow after ensuring that the client is a smoker. Therefore, any of the three options cannot be considered as an answer. If the pharmacist does these before identifying the smoking status, the client might be disappointed. Besides, it is obvious that smoking is not the only factor that leads to coughing.

9. A pharmacist, who is the secretary of a hospital drug and therapeutics committee, was asked to suggest criteria to be considered during development of the hospital's medicines list.

   What is the most likely criteria that should be considered first?
   (A) The availability of treatment facilities
   (B) The affordability of the medicine
   (C) The prevalence of disease in the area
   (D) Experience of the health professionals

Answer key: The answer is **C**
Explanation: In case of preparing a hospital's medicine list, the first step is to prepare a list of common health problems in the catchment area. If the disease is not prevalent in the catchment area, we do not need to select and list a medicine for it. After identifying the common diseases in the catchment area, we will identify the first choice of treatment for each health problem. The available treatment facilities (option A), the affordability of the medicine (option B) and the experience of the health professional (option D) are important preconditions for deciding medicines to be included in the list, however, these can be known only after identifying the health problem.

10. A pharmacist, who is working in a branch office of the food and drug administration, was recently promoted to a new position with the responsibility of planning, organizing, staffing and controlling in the organization.

    What capacity best describes the role of the pharmacist in the current position?
    (A) Leader
    (B) Manager
    (C) Supervisor
    (D) Coordinator

Answer key: The answer is **B**
Explanation: The term management refers to the activities of often the group of people involved in five general functions: planning, organizing, staffing, leading, and controlling. Managers perform and integrate these five functions throughout their organizations. Leader (option A) is an individual who, by his/her action establishes direction and influence others to follow that direction. Supervisor (option C) and coordinator (option D) are people who develop an operational plan as the means to achieve operational objectives in support of tactical plans.

11. A pharmacist, who is working in a pharmaceutical industry manufactured diazepam 5 mg per 1 ml emulsion for injection. After testing the formulation, it was found non sterile which resulted in degradation of the emulsifying agent.

    What type of instability has most likely happened in this case?

    (A) Physical
    (B) Thermal
    (C) Chemical
    (D) Microbial

Answer key: The answer is **D**

Explanation: A drug product intended for injection is expected to be sterile. However, microbes were detected within the formulation which makes the product non sterile and microbially unstable. So, the type of instability is microbial (option D). Physical instability (option A), microbial contamination causes a phase separation which is among the physical instability of an emulsion. The presence of phase separation was not addressed. Thermal instability (option B) happens at high or low storage temperature which affects the stability of the formulation components. Chemical instability (option C) is related with potency and impurity levels in the formulation which were not performed during the test.

12. A man who comes from a town 500km away to collect medications for his severely sick child, presents a prescription to the pharmacist. But, the pharmacist asked him to wait. After a while, one of his colleagues, who is working at the hospital. came to fill her friend's prescription and the pharmacist dispenses the medication to his colleague while the man was still waiting.

    What is the most likely ethical principle violated by the pharmacist in this case?

    (A) Justice
    (B) Autonomy
    (C) Beneficence
    (D) Non-maleficence

Answer key: The answer is **A**

Explanation: Health care personnel are expected to treat every client equally and ethically. In this scenario, a man with sick child is in higher need of the medication, and has long way to go back to home. The man with his patient child has already been waiting for medication before the pharmacist's collegue, requests drugs for her friend. This means, the man with sick child should get priority based on principle of justice as he came first and from far place. Justice is an act of treating all patients equally, irrespective of their sex, education, income or other personal background. Thus, the principle of justice is violated in this scenario while trying to give priority for his colleague's prescription. Beneficence (option C) and non-malefincense (option D) are also violated indirectly. The issue of autonomy (option B) was less entertained in this scenario.

13. A pharmacist collects ordinal data on the utilization of medication in a community. The pharmacist is interested to present the data obtained in order from low to high.

    Which graphical presentation is appropriate for this data?

    (A) Bar graph
    (B) Ogive curve
    (C) Box and Whisker plot
    (D) Stem and leaf display

Answer key: The answer is **A**

Explanation: Bar graph is one of the data presentation methods used for the categorical variables. Categorical variable could be ordinal or nominal type. The scenario tells us that the utilization of medication is ordinal data. So, the appropriate method of data presentation for the utilization of medication is bar graph (choice A). Choice (B) is method of presenting cumulative frequencies of a distribution of the numerical data; choice (C) graphical representation of a data set that gives a visual impression of location, spread, and the degree and direction of skewness. It also allows for the identification of outliers; choice (D) is also important to visual impression of location, spread, and the degree and direction of skewness data.

14. A quality assurance officer, who is working in a drug manufacturing company, strives to produce quality drug products as per the product specifications required by the regulatory authority.

    What is the most appropriate practice the officer has to apply in this case?

    (A) Good Manufacturing Practice
    (B) Good Clinical Practice
    (C) Good Laboratory Practice
    (D) Good Dispensing Practice

Answer key: The answer is **A**

Explanation: The manufacturer must produce medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the Marketing Authorization and do not place patients at risk due to inadequate safety, quality or efficacy. In order to achieve the quality objectives comprehensively designed and correctly implemented system of Quality Assurance incorporating GMP and thus QC is mandatory. GCP (option B) is required to ensure safety of the study subject and reliability of the results during clinical trials. GLP (option C) is important during non-clinical tests. Good dispensing practice (option D) is implemented while the drug product is dispensed to a client.

15. A man presents has been brought to a clinic after a car accident. The emergency physician requested for brain imaging.

    What is the best imaging technique for detection of bleeding in the brain?

    (A) Magnetic Resonance Imaging (MRI)
    (B) X-ray
    (C) Computed Tomography (CT) scan
    (D) Ultrasound

Answer key: The answer is **C**

Explanation: CT scan of the head is an important diagnostic tool for detecting the presence of bleeding, fracture, mass lesions and structural signs of edema (e.g, midline shift, compressed ventricles). It reveals an area of hyper intensity (white) identifying that a hemorrhage has occurred and best to indicate fresh bleeding. MRI (option A) is recommended to identify detail brain injury that may not be detected by CT scan when the patient condition is worsening. X-ray (option C) is considered when CT scan is not available as it does not indicate the whole brain damage. Ultrasound (option D) is used for pediatric patients to avoid radiation exposure.

Sample References

- Federal Ministry of Health of Ethiopia. (2014). Standard Treatment Guidelines for General Hospitals (3rd ed). FMHACA.
- Dipiro, J. T., et al. (2014). Pharmacotherapy: A Pathophysiologic Approach (9th ed.) McGraw-Hill Education.
- Dipiro, J. T., et al. (2014). Pharmacotherapy: A Pathophysiologic Approach (12th ed) McGraw-Hill Education
- Zeind, C. S., et al. (2021). Applied Therapeutics: The Clinical Use of Drugs (12th ed) Wolters Kluwer.
- Benowitz, E. A. (2001). Principles of Management. Hungry Minds, Inc.
- Mahato, R. I., & Narang, A. S. (2016). Pharmaceutical Dosage Forms and Drug Delivery (2nd ed.,). CRC Press
- Ghosh, T. K., & Jasti, B. R. (Eds.). (2005). Theory and Practice of Contemporary Pharmaceutics. CRC Press.
- Ministry of Health. (2017). Compassionate, Respectful and Caring Health Workforce Training Participants Manual.
- Sharp, J. (2005). Good Pharmaceutical Manufacturing Practice: Rationale and Compliance CRC Press.
- Ethiopian Food, Medicine and Healthcare Administration and Control Authority (EFMHACA). (2014). Good Manufacturing Practice Guideline for Pharmaceutical Products (First Edition,).
- Getu, D., & Fasil, T. (2005). Biostatistics Lecture Note for Health Sciences Students (University of Gondar).

List of contributors

Mr. Endalkachew Tsedal	MoH/ HHRIPR LEO
Dr. Meron Yakob	MoH/ HHRIPR Exam Development and Administration Desk Lead
Ermias G/Yohannes	MoH/ HHRIPR
Bethelhem Buzuayehu	MoH/ HHRIPR
Dr. Wudasie Teshome	MoH/ HHRIPR
Dr. Melese Achamo	MoH/ HHRIPR
Tsedale Tafesse	MoH/ HHRIPR
Mekonnen Desie	MoH/ HHRIPR
Abera Bezabih	MoH/ HHRIPR
Fikadie Dagnaw	MoH/ HHRIPR
Lemeneh Wondimu	MoH/ HHRIPR
Melkamu Gereme	MoH/ HHRIPR
Tadele Asefa	MoH/ HHRIPR
Nibretie Chalachew	MoH/ HHRIPR
Demeke Getu	MoH/ HHRIPR
Mebrat Tadesse	MoH/ HHRIPR
Neway H/Michael	MoH/ HHRIPR
Mebrahtu Tarekegn	MoH/ HHRIPR
Milkoman Ayele	MoH/ HHRIPR
Bethelhem Shikabew	MoH/ HHRIPR
Amanuel Tesfay	MoH/ HHRIPR
Dr. Alemseged Agmassie	Jhpiego/HWIP
Dr. Yohannes Molla	Jhpiego/HWIP
Bekalu Assamnew	AMREF HWIP project
Dr. Equlinet Misganaw	AMREF HWIP project

Dr Belay Hagos	AAU- IER
Dr Birhanu Abera	AAU- IER
Dr Girma Lema	AAU- IER
Dr Daneal Desta	AAU- IER
Dr Firdisa jebessa	AAU- IER
Dr Wessenu Yimam	AAU- IER
Dr. Abdnasir Ahmed	AAU- IER
Tamirat Tekilu	Ethiopian Health Students Association
Dr. Wondmagegn Tamiru	Ethiopian Pharmacy Association
Nanati Legesse	Haromaya University
Dr. Legesse Chelkeba	Addis Ababa University
Dr. Admassu Hassen	Wollo University
Wassie Negash	Debre Birhan University
Sisay Shunie	Debre Birhan University
Agezegn Asegeid	Wachemo University

Contact Us

Ministry of Health – Ethiopia
Street Address: - **1234 Sudan Street, Addis Ababa – Ethiopia**
Telephone: **+251-118275936**
Hotline service: - **952**
Website: **https://www.moh.gov.et**

EHPLE Information Booklet 2024