

# Drug Supply Management

**By**  
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# DRUG SUPPLY MANAGEMENT COURSE SYLLABUS

- **Module Code:** PharM3141
- **Module Name:** Social and administrative pharmacy  
Module
- **Course code:** Phar 3144
- **Course title:** Drug Supply Management
- **Course ECTS credits:** 5 ECTS = 135 study hours

# Recommended Readings:

- Management sciences for Health (1997) managing drug supply. Second Edition, revised and expanded, Kumar press, West Hartford, Conn., USA.
- Ministry of Health of Ethiopia (1997). The National Drug Policy of the transitional government of Ethiopia, Addis Ababa, Ethiopia.
- Federal Ministry of Health of Ethiopia (1996). Manual on Drug Supply Management, Prepared by Drug Administration and control Department, Addis Ababa, Ethiopia
- WHO (1988) .Guidelines for Developing National Drug Policies, WHO, Geneva, Switzerland.
- WHO (2001). How to develop and implement a national drug policy. Second edition. Geneva, Switzerland.
- Smith, H.A. (2003). Principles and Methods of Pharmacy Management, 2nd ed. Lea & Febiger, Philadelphia, 1980.
- WHO (1997). The use of Essential Drugs: Seventh Report of the WHO Expert Committee (including the revised Model List of Essential Drugs), TRS 867, WHO, Geneva, Switzerland.
- WHO (1988). Estimating Drug Requirements, a practical Manual, WHO/DAP/88.2
- WHO (1994). Indicators for Monitoring National Drug policies, a Practical Manual, WHO/DAP/94.12, WHO Geneva, Switzerland.
- WHO (1990) Management of Drugs at Health Facilities, WHO/DAP/90.10 WHO, Geneva, Switzerland.
- Troy BD (ed) (2006). Remington: The Science and Practice of Pharmacy, 21st ed, Lippincott Williams and Wilkins, Philadelphia.
- Fess and Warren. Accounting Principles. South-Western Publishing Co., 16th.

# Course Description:

- Drug supply management (DSM) course introduces students with the concept of
  - Essential drugs, drug policy, and rational drug use and tools to investigate use of medicines.
- It also gives an insight on functions of drug supply management cycle, namely,
  - Selection, Quantification, Procurement, Distribution, and Rational use.
- Furthermore, accounting principles, as well as marketing and sales management principles and techniques will be introduced.

# Course Objective:

- After completion of this course, students will be able to describe
  - The concept of essential drugs,
  - The national drug policy including the core objectives and key strategies,
  - Drug management cycle,
  - The tools used to investigate drug use,
  - The principles of accounting,
  - Principles of marketing pharmaceutical products and the sales management techniques, and also
  - The monitoring and evaluation of whole activity.

# Chapter 1 Outline

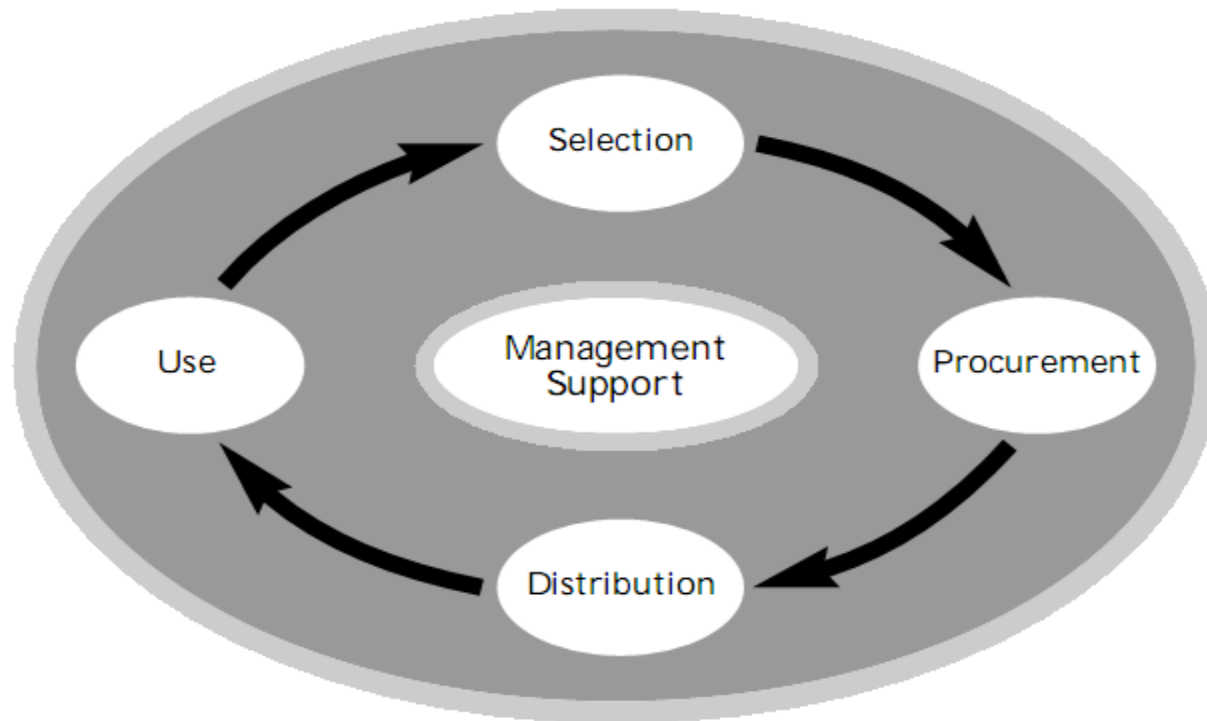
- Overview of the course
- Ethiopian Health Care system
  - History of modern medicine
  - Structure (strategy) of the health care
- Essential drugs
- National Drug Policy

# 1. Overview of the course

- Most leading causes of death and disability in developing countries can be prevented, treated, or at least alleviated with cost effective essential drugs
- But hundreds of millions of people do not have regular access to essential drugs
- Many of those who do have access are given wrong treatment, receive too little medicine for their illness or do not use drug correctly
- DSM helps to ensure that high quality drugs are available, affordable, and used rationally.

# Overview...

- Drug supply management is organized around the four basic functions of drug management cycles:
  - Selection, procurement, distribution and use

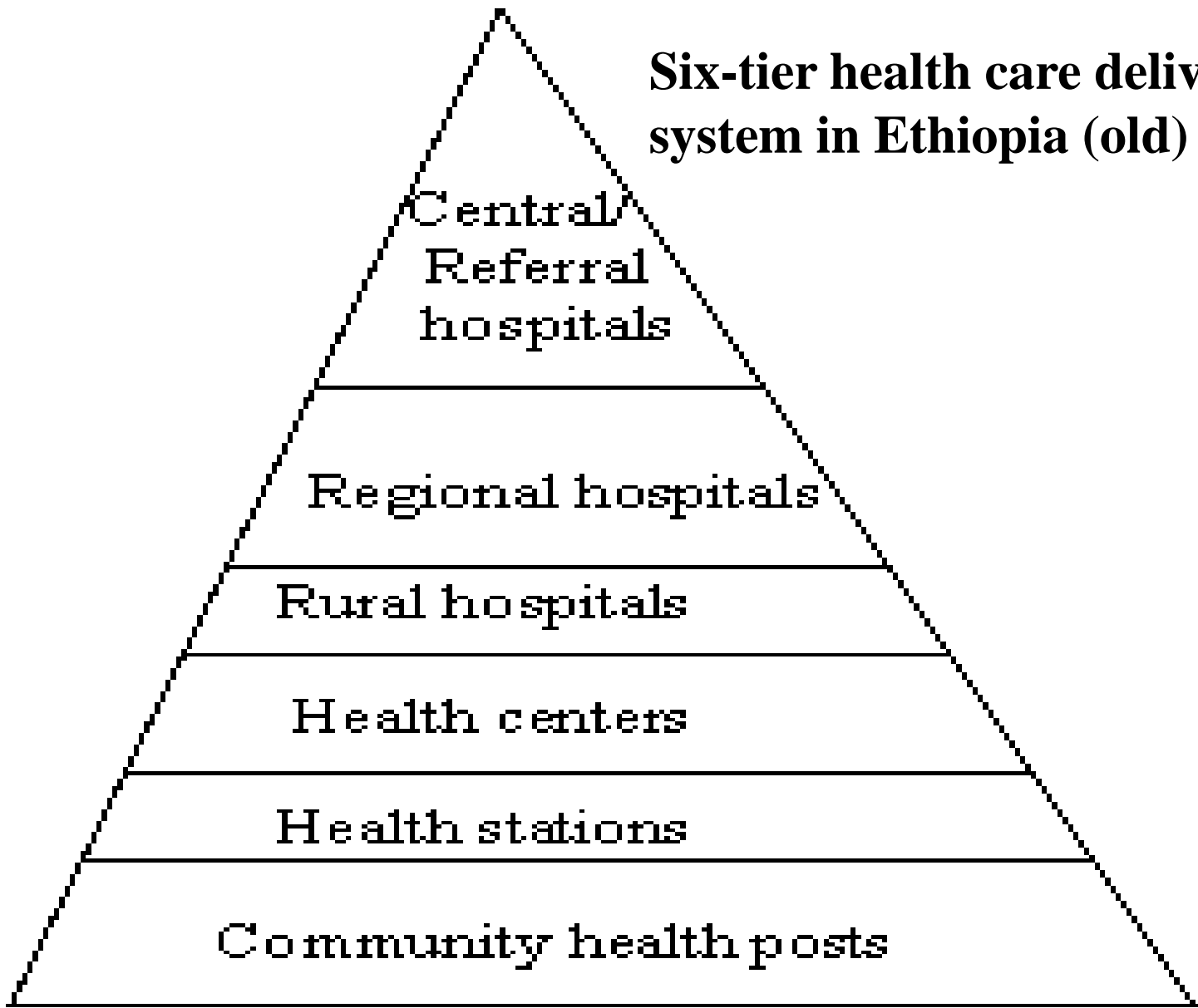




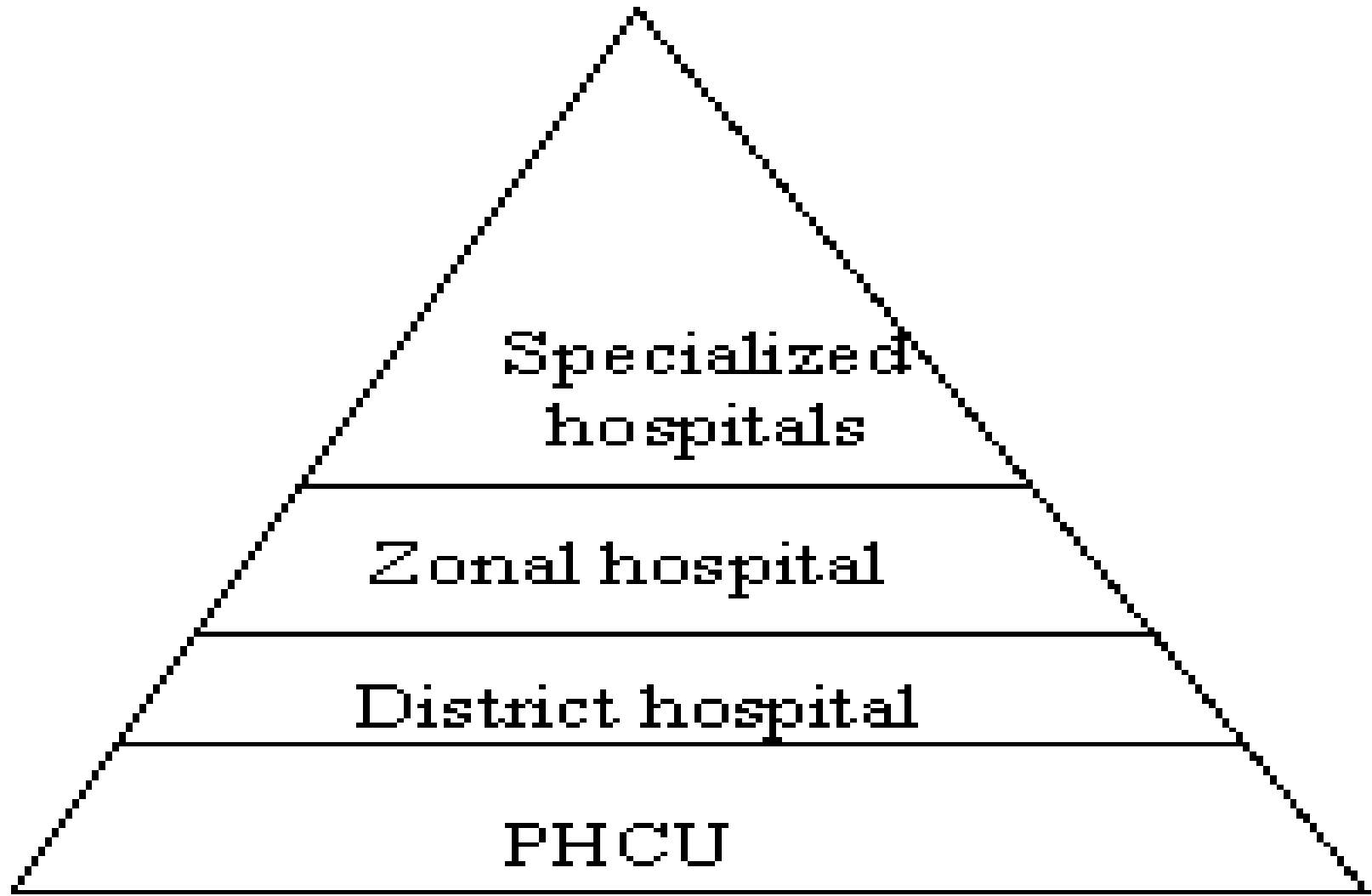
# Ethiopian Health Care system

- A **health care system** is the organization of people, institutions, and resources to deliver health care services to meet the health needs of target populations
- Currently, Ethiopian health care delivery system
  - **Four-tiered model**
    - Primary health care unit, (a network of a health center and five health posts),
    - District hospital
    - Regional hospital and
    - Specialized referral hospital.
- *There is ongoing evaluation and research to change this model of health care delivery system.*

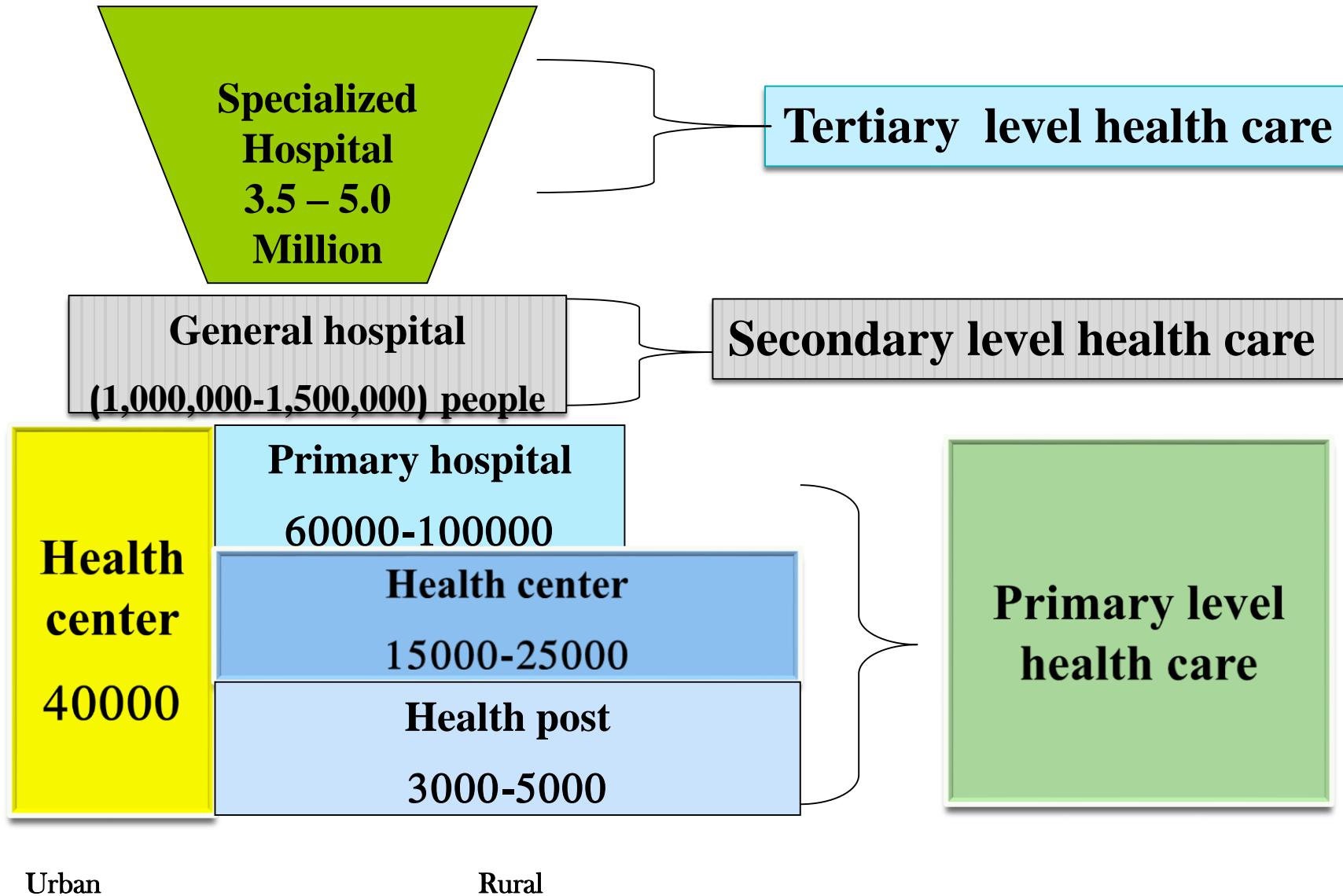
## Six-tier health care delivery system in Ethiopia (old)



# Four -tier health care delivery system



# Ethiopian health tier system (new)



# Ethiopian Health Care system

## **History of modern medicine**

- The historical development of modern medicine in Ethiopia is predominantly public or state-based.
- To date public provision of health care account for 80% whilst the remaining 20% is shared between the private-for-profit and NGO sectors.

# Ethiopian Health Care system History...

- Reading assignment

# Structure (strategy) of the health care

- Major components of the health care strategy:
- **Strengthening**
  - Preventive and promotive health service
  - Curative and rehabilitative care
  - Drugs and medical supplies
  - Health information, documentation and processing
  - Organization and management of the health delivery system
  - Human resource development and management
  - Research and development
  - Financing the healthcare delivery system.

## **2. Essential Drugs**



# Essential Drugs

- Essential drugs as those that satisfy the needs of the majority of the population and be available at all times (WHO).
- Primary health care [PHC] was adopted as a strategy to achieve the goal “Health for All” by the year 2000.
  - Essential Drugs Program have been implemented as one component of PHC

# Essential Drugs...

- Essential medicines are those that satisfy the **priority health care needs** of the population.
- They are selected with due regards to public health relevance, evidence on safety, efficacy, quality and comparative cost-effectiveness.
- They are intended to be available within the context of functioning health systems **at all times**, in adequate amount, appropriate dosage forms **with assured quality**.

## 2.1 Objective of EDL

- The main objectives of Essential Drugs Program are:
  1. To make essential drugs **available** and **accessible** to the **majority** of the population;
  2. To **promote** their **rational use**.

# Essential Drugs...

- Provision of effective preventive and curative health services depends on
  - Continuous availability of essential drugs of proven
    - Quality, safety, efficacy and
    - Rational use

# Essential Drugs...

- Continuous availability of essential drugs and their rational use helps to;
  - Increase the credibility of the health service by community
  - Increase utilization of health service and community involvement in their own health affairs

## Essential Drugs...

- However, the health service of our country is severely affected by
  - **Shortage of basic and life saving essential drugs** and medical supplies
    - Majority of the population have **no access** even to those most drugs, which are listed as EDL.

## 2.2 The Principles of Essential Drugs

- The *vast majority of health problems* for most members of the population can *be treated with a small, carefully selected* number of drugs.
- Most prescribers routinely use fewer than 200 drugs.
  - Training and clinical experience should focus on the proper use of these few drugs.
- Procurement, distribution, and other supply activities can be carried out most economically and most efficiently for a limited number of pharmaceutical products
- Patients can be better informed about the effective use of drugs with limited number of drugs
  - **NB.** *These principles will be implemented through the adoption of national drug policies.*

# Implications of EDL

- EDL is meant to guide the *selection, procurement, production, distribution* and *storage* of medicines.
- It can also serve as an informational and educational tool for health care professionals involved in diagnosis and treatment of diseases as well as dispensing of medicines.
- Furthermore, it can improve availability and promote rational use of medicines.



# Implications of EDL...

- The essential drugs concept is central to a national drug policy
  - B/C it **promotes equity** and **helps to set priorities** for the health care system
- Give better quality of care and better value for money
  - B/c they are carefully selected drugs based on agreed clinical guidelines leads to a *better supply of drugs, to more rational prescribing* and *to lower costs*.

# Implications of EDL...

- More price competition and economies of scale due to
  - the procurement of fewer items in larger quantities
- Quality assurance, procurement, storage, distribution and dispensing are all easier with a reduced number of drugs
- Training of health workers and drug information in general can be more focused
  - More recognition of drug interactions and adverse reactions with fewer drugs

# Implications of EDL...

- The Government of Ethiopia, through its drug policy, has reaffirmed its commitment to provide the supply of medicines that adequately meet the common contemporary health needs of the general population of the country.
- Thus is necessary to select medicines which are required for promotion, prevention, diagnosis, treatment/mitigation and rehabilitation of diseases affecting majority of the population

## **2.3 National Drug Policy**

# National Drug Policy (NDP)

- A policy is a guide to action and a commitment to a goal
  - NDP expresses and prioritizes medium- to long-term goals set by the gov't for the phar'cal sector, &
  - Identifies the main **strategies** for attaining them
- Absence of strong and current drug policy, legislation, and regulations
  - Leads to **failure to use** available funds efficiently and consequently shortage of essential drugs occur

# Why NDP is needed?

- A national drug policy is needed for many reasons.
  1. To present a **formal record** of aims, decisions and medium- to long-term government commitments
  2. To define the national **goals and objectives** for the pharmaceutical sector, and set priorities
  3. To identify the **strategies** needed to meet those objectives, and identify the various actors responsible for implementing the main components of the policy
  4. To create a **forum** for **national discussions** on these issues

# Why NDP...

5. It provides a framework to coordinate activities of
- Pharmaceutical sector participants
  - Public and the private sectors
  - Non-governmental organizations
  - Donors, and other interested parties

# Why countries need a national drug policy?

- **NDP is required:**

- As the population has grown the health institution have expanded in size and number
- Appreciation of the effectiveness of modern medicines has grown
  - Increased demand for public health services and for pharmaceutical has also grown
- New diseases have appeared, creating demand for additional and more specialized medicine
- Finally the element of drug abuse and misuse has come on the scene



# NDP...

- **The reasons for lack of adequate supplies of drugs include:**
  - Financial and budgetary constraints
  - Lack of infrastructure and resources
  - Poor attitudes and behaviors of the government, prescriber, dispensers, consumers and the pharmaceutical industry.
- NDP provides the *frame work* and tools for an *adequate supply* of safe and effective drugs of established quality, an affordable price, which should be properly prescribed and used

# General use of NDP

1. Determine the types of drugs to be used in the health services on the basis of the country's health problems and capability.
2. Provide essential drugs in line with the responsibilities of the government for public health care.
3. Facilitate the gradual integration of traditional drugs with modern medicine by giving due attention to traditional practices and identifying the beneficial and harmful aspects through investigation and research.
4. Offer incentives to public and private industries involved in the production of raw and packing materials directly related to the manufacture of drugs.

## General use of NDP...

5. Give special incentives to manufacturers who manufacture essential drugs and market them in their generic names.
6. Create favorable conditions to encourage private investors to participate in the manufacture, import and distribution of drugs.
7. Establish an effective system of drug administration and control at all levels, especially by developing the capacity to ensure drug safety, efficacy and quality.
8. Make the necessary efforts to establish rational use of drugs among the health professionals and the public at large.

# General use of NDP...

9. Devise a program for the training of professionals able to contribute to solving the health problems of the country as required and create conditions for the application and development of their skills.
10. Conduct a coordinated research on modern and traditional drugs attuned to the country's problems and capacity and strive for the application of their results.
11. Create favorable conditions for the transfer and further development of appropriate technology and modern know-how that could assist in meeting the drug needs of the country.
12. Create favorable conditions for the export of local products.

## General use of NDP...

13. Make the necessary efforts to deter the illegal manufacturing, distribution and consumption of narcotics and psychotropic drugs.
14. Strengthen National and International relations to help develop and expand the pharmaceutical sector and give due attention to the implementation of international obligations.

## 2.4 General Objectives of NDP

- The general objectives of a national drug policy are to ensure:
  1. **Access:** equitable availability and affordability of essential drugs
  2. **Quality:** the quality, safety and efficacy of all medicines
  3. **Rational use:** the promotion of therapeutically sound and cost-effective use of drugs by health professionals and consumers.

# Core Objectives of NDP

1. To meet the country's demand for essential drugs and to systematize its supply, distribution and use.
2. To create conducive situations to make the prices of drugs compatible with the people's purchasing power
3. To ensure the safety, efficacy and quality of drugs
4. To develop a domestic drug manufacturing capacity and gradual supply to the export market

## Core Objectives...

5. To *expand the training of manpower* and drugs research and development.
6. To devise ways and means for the utilization of traditional drugs in the regular health services after ensuring their safety and efficacy.



## 2.5 Key component Strategies

### 1. Selection of drugs

- National drug list is formulated with full consideration of
  - A. Country's health problems
  - B. Trained manpower
  - C. Financial resources and infrastructure; and
  - D. Safety, efficacy, quality & cost of drugs.
  
- A national drug advisory committee composed of highly skilled professionals **in medicine & pharmacy**

# Key strategies...

## 2. Drug supply

- Establish drug manufacturing plants by government or jointly with private investors
- Giving support to manufacturers involved in
  - Production of raw and packing materials for drugs
  - Production of essential drugs
  - Compounding of drugs in hospitals and pharmacies

## Key strategies...

- Government shall **establish an enterprise** which is independent of producers and suppliers to procure and distribute drugs at national & regional levels (**PFSA**).
- Government shall **give incentives** to private importers and distributors of essential drugs at reasonable prices.
- Foreign procurement shall be carried in such a way that it does not weaken local drug manufacturing.

# Key strategies...

## 3. Stock management & distribution

- Issue specification for the establishment of storage facilities and pertinent to the climatic conditions of the locality.
- Give priority & efficient transport for the movement of drugs from ports and distribution points
- Every distribution net work shall be subject to strict drug inventory control and supervision

## Key strategies...

- Distribution of drugs shall be carried out in accordance to a standard list of drugs appropriate for the level of the health institution and retail enterprise.
- Public health institutions and pharmacies within them shall be given priority by the government owned drug distribution system.

# Key strategies...

## 4. Drug administration and control

- The national drugs advisory committee shall evaluate the safety, efficacy, quality, price and other vital information about drugs & register them before they are marketed.
- Registration certificates shall be issued for drugs that meet the required standards
- Drug quality standards shall be set.
  - Government operated quality control laboratories will be established both centrally and regionally.

## Key strategies...

- Drug samples for quality control shall be collected from manufacturing plants, distribution outlets, retailers, etc. and
- Substandard products shall be withdrawn from the market.
- An appropriate system shall be devised for the collection of new information about the harmful and beneficial effects of drugs from health professionals compiled and analyzed, the findings shall be publicized at national and international level.

## Key strategies...

- Laws and regulations shall be instituted and enforced governing the supply, stock management, distribution, use and disposal of narcotic and psychotropic drugs.
- Qualified inspectors shall be assigned to enforce laws and regulations issued to implement the policy
- Registration, classification and licensing of professionals in the sector shall be carried out by the appropriate body
- Any pharmaceutical org. can only be established under license from the policy enforcing body.



## Key strategies...

### 5. **Human resource development Training and utilization**

- Formal pharmaceutical trainings shall be based on the requirements and health needs of the country.
- Strategies shall be devised to upgrade professionals who are in service
- Professionals in the sector shall receive on the job training and continuing education.
- Conducive situations shall be created so as to engage trained manpower in the best possible service of the public.
- Various incentives and conducive career structures for professionals shall be instituted

## Key strategies...

### 6. Drug information and promotion

- The content and distribution of drug information to health professionals and the public shall be subject to monitoring & control.
- Current and accurate information and reference materials on drugs shall be produced and distributed to practitioners in the field.
- Drug promotion shall be carried out by trained professionals who have appropriate registration.

# Key strategies...

## 7. Drug use

- A list shall be prepared to show prescription and nonprescription drugs
- A standard prescription form to be used all over the country
- Health practitioners shall be advised & encouraged to prescribe drugs in their generic names.
- Drug dispensing shall be under taken and closely monitored by licensed professionals.
- Appropriate education, promotion, counseling etc. shall be offered in every possible way to raise public awareness about drug use.

## Key strategies...

- Licensed professionals and enterprises shall be monitored and controlled to ensure that they comply with the rules of drug dispensing.
- A pharmacist shall have the right to dispense *generic drugs as substitutes* for prescribed brand names

## Key strategies...

### 8. Traditional drugs

- Attention shall be given to strengthening the sector through research and development.
  - Research priorities shall be given to those traditional drugs which are in **wide use**.
- Create favorable conditions for the application of traditional drugs ascertained to be safe & effective for treatment.

# Key strategies...

## 9. Research and development

- Favorable conditions shall be created for the introduction of appropriate technology and know how to vitalized the drug sector.
- Appropriate means shall be instituted to strengthen the drug sector through research and development.
- Research and development activities shall be conducted at manufacturing plants, compounding laboratories, training & research institutions etc.

## Key strategies...

- An independent research center shall be established to carry out drug research and development
- Researches shall be undertaken on procurement methods, stock management, distribution, use of drugs, etc. in order to strengthen the pharmaceutical service's quality and competence at all levels.

## Key strategies...

### **10. National, regional and International relations.**

- National, regional and international relations shall be established with the aim of strengthening and expanding the sector
- Attention shall be given to the implementation of conventions on narcotics, psychotropic drugs, radioactive pharmaceutical & poisons



## Key strategies...

### **11. Drug pricing**

- The government shall make all efforts to make sure that the public gets drugs at reasonable price.

### **12. Policy enforcement**

- Relevant laws, regulations, and rules shall be instituted to enforce the policy.

## **2.6 The National Drug Policy Process**

# Overview of The national drug policy process

- A national drug policy involves a complex process of policy development, implementation and monitoring.

1<sup>st</sup>. Formulation of the national drug policy

2<sup>nd</sup>. Implementing strategies and activities by the various parties aimed at achieving policy objectives

3<sup>rd</sup>. Monitoring and evaluation the effect of these activities and adjust the policy if necessary

# Planning

- Careful planning of the implementation steps and activities necessary to arrive at the expected outcome is important
  - There are two types of plans
    - 1. The strategic plan to develop the policy itself**
      - Specify the various steps in the development process, and
      - Plan for the involvement of as many stakeholders as possible
    - 2. Implementation (master) plan**
      - Details the various activities for each component of the policy

# Involving all parties

- There should be consultation, dialogue and negotiations with all interested groups and stakeholders throughout the policy process (and not only in the development phase)
- These include
  - Other ministries (higher education, trade, industry)
  - Physicians, pharmacists and nurses
  - Local and international pharmaceutical industries, drug sellers
  - Academia, NGOs, professional associations & consumer groups

# Political dynamics

- Formulating and implementing a national drug policy are highly political processes
- B/c such a policy usually seeks to achieve
  - Equity of access to basic health care
    - Primarily by making the pharmaceutical sector
      - More efficient
      - Cost-effective and
      - Responsive to health needs

# Formulating a national drug policy

## Steps in formulating a national drug policy

### Step 1: Organize the policy process

- MOH- take the lead role in formulating a national drug policy
- 1<sup>st</sup> step is to decide how to organize the development process
  - Identify the structure of the policy
  - Identify major objectives and
  - Identify its priority components
- Identify all the interested parties that need to be involved,
- Identify the necessary resources, and how these can be obtained

# Formulating a national drug policy...

## Step 2: Identify the main problems

- In order to set realistic objectives
  - Thorough analysis and understanding of the main problems in the pharmaceutical sector are needed
- Select experts from d/t disciplines
  - Examine the situation systematically
  - Identify the main problems
  - Make recommendations about
    - What needs to be done
    - What can be done, and
    - Identify possible approaches



# Formulating a national drug policy...

## Step 3: Make a detailed situation analysis

- A more detailed situation analysis of the pharmaceutical sector and its components may be needed
  - Further analyze the source of the problems
  - Identify potential solutions
  - Choose the most appropriate strategies
  - Set priorities and
  - Serve as a baseline for future systems of monitoring and evaluation

# Formulating a national drug policy...

## **Step 4: Set goals and objectives for a national drug policy**

- Goals and priority objectives identified after the problem is defined
- The selection of appropriate strategy is more complex
  - A workshop involving a small number of key policy-makers may be helpful
- Outlined main objectives and strategies be discussed with all interested parties

# Formulating a national drug policy...

## **Step 5: Draft the text of the policy**

- A draft text of the national drug policy be prepared
- Set out the general & specific objectives , followed in each case by the strategy to be adopted
- In most countries this is used to ensure that essential drugs are accessible to the entire population
- Drafting of the policy can be done by a small group of experts who have been involved in the earlier stages of the process

## Formulating a national drug policy...

### **Step 6: Circulate and revise the draft policy**

- The draft document should be widely circulated for comments (with in and outside the org.)
- The draft document should be revised in the light of the comments received, and finalized

## Formulating a national drug policy...

### **Step 7: Secure formal endorsement of the policy**

- The parliament endorse the proposed document

### **Step 8: Launch the national drug policy**

- Extent of the policy's *success* depends on
  - The level of understanding of different sectors of society, and
  - Their support for its objectives
- Information should be disseminated through a variety of channels to reach different target groups

## Implementing a national drug policy

- Every drug policy needs an overall implementation plan or “master plan”
- Each component of the policy needs a detailed strategy and specific action plans

### **Priorities for implementation**

- Severity of the problems
- Available resources

# Implementing a national drug policy...

## **Implementation (master) plan**

- Covers 3–5-year period
- This implementation plan spells out for each component of the policy
  - What needs to be done
  - Who is responsible
  - Estimates the budget requirement and
  - Proposes a rough time frame
  - Set a priority activities (insufficient resources)

# Implementing a national drug policy...

## **Master plan ...**

- Facilitates monitoring and follow-up
- Communicated to all parties involved
- Broken down into annual work plans with various agencies involved in the implementation

## **Work plan**

- Should outline the approaches and activities for each component, specifying in detail
  - Who is responsible
  - Listing the major tasks
  - Describing the target output,
  - The detailed time frame and the exact budget



## Responsibilities in implementation

- MOH oversees and coordinate all activities, and monitor the extent of implementation and the achievement of targets
- Key players in drug policy implementation
  - Drug regulatory agency,
  - Pharmacy department in the ministry of health
  - Central medical stores, and
  - District or provincial health offices
  - Other agencies dealing with finance, trade, economic planning and education.

# Financial resources

- Match the strategies and action plans with available financial resources
- Allocations from government funds and revenue from drug registrations and fees are the usual funding sources
- Contributions from international and local donors are also possible sources
- However, there should be no conflict of interest in accepting donor contributions
  - E.g. NGOs might be interested in funding activities that are of low priority in the national drug policy

# Reading assignment

- List all the possible strategies that a drug policy can successfully be implemented  
(How to develop NDP, WHO)

# Monitoring and evaluation

- **Monitoring**
  - A form of continuous review which gives a picture of the implementation of planned activities
  - Indicates whether targets are being met
  - Carried out using a combination of various methods
    - E.g. Supervisory visits

# Monitoring and evaluation...

## Evaluation

- Way of analyzing progress towards meeting agreed objectives and goals
  - **Done in three phases**
- *Start of a program*- used to provide a clear needs assessment
- *A mid-term evaluation*- provide valuable information about whether the program is working, and if not, why not.
- *Final evaluation* - allows a complete review of program achievements from which lessons can be drawn for the future

# Monitoring and evaluation...

- A system for monitoring and evaluation is a constructive management tool
  - It enables a continuous assessment of progress
  - Helps to make the necessary management decisions
  - Provides transparency and accountability and
  - Creates a standard by which comparisons can be made between countries

# Indicators for monitoring national drug policies

- Standardized indicators determine whether adequate progress is being achieved or not
- Indicators can be selected and used
  - To measure changes
  - Make comparisons and
  - Assess whether the targets are being met
- Indicators should be
  - Clear
  - Useful
  - Measurable
  - Reliable and valid

## Indicators ...

- Currently there are four categories of drug policy indicators:
  - Background information
  - Structural indicators
  - Process indicators and
  - Outcome indicators.



# Indicators for monitoring...

- Core indicators cover the following aspects

**A. Access to essential drugs**, and other indicators on drug financing schemes, and public supply management;

- Provide information on access to essential drugs

**B. Functions and efficiency**

➤ Drug regulatory authority

➤ Quality control laboratory and

➤ Drug handling to maintain good quality

- Provide information about drug quality

**C. Drug prescribing and dispensing,**

➤ use of the list of essential drugs and clinical guidelines

- Provide information about drug use patterns

# Who can use the results?

- Policy-makers
- Implementers and
- Managers can get a clear picture of the problems in the country so that they can reassess their strategies and priorities.
- Results can be used as a guide
  - To set priorities and
  - To strengthening those strategies that can have the best impact

# Periodic evaluations of the national drug policy

- The national drug policy should be periodically evaluated
  - E.g. Every four years