Definition (WHO)

Essential Medicines are "those that satisfy the priority health-care needs of the population." They are selected based on **public health relevance**, **evidence of efficacy and safety**, and **comparative cost-effectiveness**.

Key Principle

Essential medicines should be:

- **Available** at all times within functioning health systems
- **In adequate quantities** and **appropriate dosage forms**
- Of **assured quality** and **affordable** to individuals and communities
- Supported with adequate **information** for safe and effective use

In short, **availability + affordability + quality + rational selection = essential medicine concept**.

Rationale Behind the Concept

- Out of the thousands of medicines available globally, only a **limited number** are truly needed to treat most common diseases effectively.
- Many **older, well-tested, and inexpensive drugs** are just as effective and safe as newer, more costly ones.
- Developing countries, with limited healthcare budgets, must therefore **prioritize essential drugs** to ensure rational, equitable, and cost-effective use of resources.

Goal:
To ensure that every person has access to the medicines they need, when and where they need them, at a cost they can afford.

Criteria for Selection of Essential Medicines (as per WHO)

1. **Efficacy and Safety:**
   Adequate clinical data must prove therapeutic effectiveness and acceptable safety profile.
2. **Quality Assurance:**
   - Stable under local climatic conditions
   - Consistent bioavailability
   - Complies with Good Manufacturing Practices (GMP)
3. **Pharmacokinetic Properties:**
   Predictable absorption, distribution, metabolism, and excretion suitable for target population.
4. **Public Health Relevance:**
   - Addresses diseases that are **common and significant** in the country.
   - Suited to **local epidemiological patterns** and health priorities.
5. **Cost-effectiveness:**

- Should provide **maximum health benefit per unit cost**.
- Comparative economic analysis between alternatives is essential.

6. **Formulation and Combination Products:**
   - **Fixed-dose combinations** only if advantages (compliance, synergy) are proven.
   - Each component must contribute to therapeutic effect.
7. **Treatment Guidelines:**
   - Inclusion must be consistent with **standard treatment guidelines (STGs)** and **rational drug use principles**.
8. **Demographic / Genetic / Environmental Factors:**
   Consider population-specific characteristics influencing drug response.

WHO Model List of Essential Medicines (EML)

Background

- The **first WHO Model List** was published in **1977**, listing about 200 medicines considered essential for basic healthcare.
- It is **revised every two years** to reflect new evidence and public health needs.

Purpose

- Acts as a **guiding template** for countries to develop their **National Essential Medicines Lists (NEML)**.
- Each country adapts the list according to **local disease prevalence, healthcare infrastructure, and affordability.**

Updates

- The **17th WHO Model List** (2011) included essential medicines for both **adults and children**.
- The list continues to evolve; subsequent revisions (e.g., 22nd list in 2021) add newer but cost-effective therapies.

National List of Essential Medicines (NLEM) — India

- India released its first **National Essential Drugs List** in **1996**.
- The **2011 revision** (NLEM-2011) included **348 medicines** covering all major therapeutic categories needed to meet priority healthcare requirements of the Indian population.
- **Latest update:** The **NLEM-2022** (replacing 2015) now includes **384 essential medicines**, with some new additions (e.g., insulin glargine, teneligliptin, ivermectin) and deletions (e.g., ranitidine).

Objectives of NLEM

1. Promote **rational use of medicines**.
2. Guide procurement, supply, and reimbursement systems in public health facilities.

3. Serve as a basis for **drug price control** under the Drugs (Price Control) Order (DPCO).
4. Improve **availability of quality-assured medicines** across all healthcare levels.

Classification of Drugs: Prescription vs. Non-Prescription

Prescription Drugs

- Medicines that **require a doctor's prescription** for sale to ensure safe and supervised use.
- Include potent drugs, controlled substances, and all **antibiotics**.
- In India, governed under:
  - **Schedule H** of Drugs and Cosmetics Rules, 1945
  - **Schedule X** for narcotics and psychotropics (stricter control)
- Dispensing to patients only by **registered pharmacists** on valid prescription.

Examples:
Antibiotics (amoxicillin), antihypertensives, corticosteroids, oral hypoglycemics, antidepressants, etc.

Non-Prescription / Over-the-Counter (OTC) Drugs

- Medicines considered **safe and effective for self-use** without a physician's supervision.
- Typically used for **symptomatic relief of minor ailments**.
- Can be sold even in **non-pharmacy outlets (grocery stores)** in some cases.

Common examples:
Paracetamol, aspirin, simple antacids, laxatives (senna, lactulose), multivitamins, ferrous salts.

Note:
India has no official regulatory category called "OTC," but **non-prescription drugs are recognized** through exclusion from Schedule H or X.

Importance of Essential Medicines Policy

- Ensures **universal access** to vital medicines.
- Promotes **rational prescribing and dispensing.**
- Helps governments **prioritize health budgets** efficiently.
- Reduces irrational combinations, duplication, and wastage.
- Improves **quality assurance and drug monitoring** at all healthcare levels.

Orphan Drugs

Definition

Orphan drugs are **pharmaceutical agents or biological products** used for **diagnosis, prevention, or treatment of rare diseases**—conditions that affect a **very small portion of the population**.

Because of limited market potential, **pharmaceutical companies lack financial incentive** to develop and market these drugs.

Characteristics

- Used for **rare or neglected diseases** (e.g., Gaucher's disease, cystic fibrosis, leishmaniasis).
- High cost of R&D but small patient pool → **"orphan" market** (commercially unviable).
- Often **life-saving or life-prolonging**, but not easily accessible.

Regulatory Support & Incentives

To encourage research and production, many countries have special regulations:

- **USA:** *Orphan Drug Act (1983)* — provides tax credits, market exclusivity (7 years), fee waivers, and grants.
- **European Union:** Similar legislation offering 10-year exclusivity.
- **India:** *National Policy for Rare Diseases (2021)* includes provision for financial support and incentives to import or manufacture orphan drugs.

Examples of Orphan Drugs

Drug	Indication
Sodium Nitrite	Cyanide poisoning
Fomepizole	Ethylene glycol or methanol poisoning
Liposomal Amphotericin B	Fungal infections; visceral leishmaniasis
Miltefosine	Visceral leishmaniasis (kala-azar)
Rifabutin	Mycobacterium avium infections in HIV patients
Succimer (DMSA)	Lead poisoning (chelating agent)
Somatropin	Growth hormone deficiency
Digoxin Immune Fab	Digoxin toxicity
Liothyronine (T3)	Hypothyroidism (in specific situations)

Challenges in Essential Medicine Implementation

1. **Poor procurement systems** → inconsistent supply, stock-outs.
2. **Inadequate funding** for essential drug programs.
3. **Irrational prescribing** and over-promotion of non-essential brands.
4. **Public awareness gaps** about rational use and generic names.
5. **Counterfeit/substandard drugs** in unregulated markets.
6. **Unequal distribution** between urban and rural health facilities.

Role of Pharmacists

Pharmacists are critical in ensuring the **rational selection, storage, distribution, and use** of essential medicines.

Key responsibilities:

- Maintain **updated knowledge** of NLEM & WHO-EML.
- Ensure **availability and quality** of essential medicines in hospital/community pharmacy.
- Promote **generic prescribing and dispensing.**
- Participate in **Pharmacy & Therapeutics Committee (PTC)** decisions on formulary management.
- Educate patients on **safe, rational, and economical use** of medicines.
- Report **adverse drug reactions** and maintain pharmacovigilance.

Summary Table

Concept	Definition / Purpose	Key Points
Essential Medicines	Medicines that satisfy priority healthcare needs	Safe, effective, affordable, available always
Prescription Drugs	Sold only on doctor's order	Schedule H/X, potent drugs needing supervision
Non-Prescription / OTC	Safe for self-use	Minor ailments; simple analgesics, antacids, vitamins
Orphan Drugs	For rare diseases with small patient pool	Supported by incentives (e.g., Orphan Drug Act 1983)
NLEM (India)	National adaptation of WHO list	Promotes rational use & guides price control

Conclusion

The **Essential Medicines concept** remains a cornerstone of rational and equitable healthcare delivery.
By focusing on drugs that are **clinically proven, safe, and cost-effective**, nations can:

- Ensure **universal access to vital therapies**,
- Reduce **healthcare expenditure**, and
- Promote **rational drug use**.

Pharmacists, as drug experts, play a pivotal role in maintaining availability, counselling on use, and ensuring that every patient receives the **right medicine, in the right dose, at the right time, and at the right cost.**

Rational Use of Medicines (RUM)

(Expanded Notes – Based on WHO Concepts and Indian Context)

"Rational use of medicines means prescribing the **right drug**, in the **right dose**, for the **right duration**, and at the **lowest cost** to the patient and community."
— *WHO, 1985*

In other words, a medicine is used rationally when:

- The **drug is appropriate** for the patient's clinical condition,
- **Dosage and duration** meet individual requirements, and
- The **cost is affordable** and justified by therapeutic benefit.

Core Requirements for Rational Use

According to the WHO:

- Patients receive **medications appropriate** to their clinical needs.
- In **doses that meet individual requirements.**
- For an **adequate period of time.**
- At the **lowest possible cost** to them and their community.

Thus, **rational use balances efficacy, safety, suitability, and cost**.

Learning Objectives

To understand:

1. The **concept** of rational use of medicines.
2. **Factors influencing irrational use**.
3. **Consequences** of irrational use.
4. **Concept of fixed-dose combinations (FDCs)**.
5. **Role of pharmacist** in promoting rational use.
6. **Importance of patient education.**

Background and Need

- **Drug Explosion:** Tremendous increase in number of available drugs complicates the prescriber's choice.
- **Antimicrobial Resistance:** Overuse and misuse of antibiotics accelerate bacterial resistance.
- **Rising Costs:** Irrational therapy adds to patient and government expenditure.
- **Consumer Protection Act (CPA):** Legal liability for irrational or harmful prescribing.
- **Informed Society:** Patients are more aware of therapy options and demand rational treatment.

Hence, rational use is both a **clinical and ethical obligation**.

Factors Promoting Irrational Drug Use

1. **Lack of information** among healthcare providers.
2. **Inadequate medical education** or training in clinical pharmacology.
3. **Poor communication** between doctors, pharmacists, and patients.
4. **Lack of diagnostic facilities**, leading to empirical or wrong therapy.
5. **Patient pressure/demand** for quick relief or specific brands.
6. **Ineffective drug regulation** and weak supply systems.
7. **Aggressive pharmaceutical marketing** and incentives to prescribers.
8. **Cultural beliefs** ("every illness needs a pill").

Examples of Irrational Use

Type	Example
Unnecessary use	Antibiotics for viral flu or sore throat
Wrong drug selection	Tetracycline for diarrhea instead of Oral Rehydration Salts (ORS)
Unproven efficacy	Antimotility agents in acute infectious diarrhea
Failure to use proven drugs	Not prescribing vaccines or ORS in diarrheal illness
Incorrect dose / route / duration	Giving IV antibiotics when oral form is adequate
Expensive drugs when cheaper alternatives exist	Using 3rd generation cephalosporin instead of amoxicillin
Dangerous drug combinations	Combining antipyretic (causes sweating) with anticholinergic (blocks sweating) → risk of hyperthermia

Consequences of Irrational Drug Use

1. **Therapeutic failure or worsening illness.**
2. **Increased morbidity and mortality.**
3. **Adverse drug reactions (ADRs)** and drug toxicity.
4. **Antimicrobial resistance.**
5. **Increased treatment cost** and economic burden.
6. **Loss of patient confidence** in health system.
7. **Drug shortages** and wastage of resources.

Underlying Causes of Irrational Use

- Lack of **continuing medical education** and updated therapeutic knowledge.
- Absence of a **strong regulatory system** to monitor drug quality and use.
- Existence of **too many brands and irrational formulations** in the market.
- Aggressive **promotion and incentives** from pharmaceutical companies.
- **Public misconceptions** (belief that injections or new drugs are more effective).

Examples of Irrational / Banned Drugs (India)

Drug	Indication	Reason for Ban

Analgin	Analgesic	Bone marrow depression
Cisapride	GERD, constipation	Cardiac arrhythmias
Furazolidone	Antidiarrheal	Carcinogenic potential
Nimesulide	Pain, fever	Hepatotoxicity
Piperazine	Anthelmintic	Neurotoxicity
Phenylpropanolamine	Cold remedies	Stroke risk
Nitrofurazone	Topical antibacterial	Carcinogenicity

These examples highlight how **post-marketing surveillance** and **pharmacovigilance** are critical to maintaining rational use.

Essential Drugs (ED) & Rational Use

- Essential drugs are those that **satisfy the healthcare needs** of the majority population and must be available at **all times, in appropriate dosage forms, and at affordable prices.**

WHO List (Example)

- Around **312 items and 518 formulations**, including **36 FDCs**.

India's National List of Essential Medicines (NLEM)

- **279 items and 489 formulations**, including **11 FDCs**.

But: The Indian pharmaceutical market has **>1 lakh formulations**, and about **70% are FDCs**, many irrational.

Fixed-Dose Combinations (FDCs)

Definition

A **Fixed Dose Combination** is a formulation containing **two or more active ingredients** combined in fixed ratios of doses.

Rational FDCs (Examples)

Category	Example	Purpose
Anti-TB	Rifampicin + Isoniazid	Improves compliance, prevents resistance
Anti-Parkinsonism	Levodopa + Carbidopa	Reduces peripheral metabolism of levodopa
Antiviral (HIV)	Stavudine + Lamivudine + Nevirapine	Combination antiretroviral therapy
Antimalarial	Artesunate + Amodiaquine	Dual mechanism, reduces resistance

Irrational FDCs

- Combine drugs with **opposing actions**, **unrelated indications**, or **duplicated mechanisms**.
  Example: Paracetamol + antihistamine + antispasmodic + caffeine – no rational therapeutic basis.

Steps in Rational Prescribing Process

Step	Description
I	**Make a specific diagnosis** — accurate identification of disease.
II	**Consider pathophysiology** — understand mechanism to guide drug choice.
III	**Set therapeutic objectives** — define treatment goals (cure, control, relief).
IV	**Select the drug of choice** — based on efficacy, safety, suitability, cost.
V	**Determine dose regimen** — route, dose, frequency, and duration.
VI	**Check interactions and contraindications.**
VII	**Monitor therapy** — observe for efficacy and adverse effects.
VIII	**Educate the patient** — on correct use, adherence, and warning signs.

Role of Pharmacists in Promoting Rational Use

Pharmacists are **key players** in ensuring rational drug therapy:

1. **Advisory Role:**
   - Counsel patients about **correct drug use** and possible side effects.
   - Provide **evidence-based information** to prescribers.
2. **Collaborative Role:**
   - Work closely with physicians to encourage **generic prescribing** and **formulary compliance**.
   - Monitor **drug interactions** and prevent duplication.
3. **Clinical Role:**
   - Evaluate prescriptions for appropriateness, dose, and duration.
   - Promote **adherence** and **monitor therapeutic outcomes**.
4. **Managerial Role:**
   - Ensure **quality procurement and storage** of drugs.
   - Prevent wastage and ensure **continuous supply** of essential medicines.
5. **Pharmacovigilance:**
   - Detect and report **adverse drug reactions**.
   - Contribute to post-marketing surveillance.

Requirements for Rational Drug Use in Healthcare System

1. **Availability** of essential and life-saving medicines.
2. **Unbiased drug information** (preferably in generic name).
3. **Quality control** of drug manufacture and supply.
4. **Withdrawal of hazardous and irrational drugs.**

5. **Strong drug regulatory authority.**
6. **Continuing education** for prescribers and pharmacists.
7. **Patient education** to encourage adherence and understanding.

Key Takeaways

- Rational use ensures **effective, safe, economical**, and **patient-centered** therapy.
- Irrational use wastes resources, increases resistance, and harms patients.
- **Pharmacists**, through education, monitoring, and collaboration, are the **guardians of rational drug use**.
- Implementation of **Essential Drug Lists** and **Standard Treatment Guidelines (STGs)** strengthens rational prescribing.
- **Patient awareness** is essential for achieving rational use at community level.

Professional Responsibilities of the Community Pharmacist

WHO and FIP Guidelines

The **World Health Organization (WHO)** and the **International Pharmaceutical Federation (FIP)** have defined the **professional responsibilities** of the community pharmacist to ensure **safe, rational, and effective use of medicines**.

According to these bodies, a community pharmacist's role extends beyond dispensing — it includes **direct patient care**, **public health promotion**, and **drug information services**.

2. Main Areas of Pharmacist Responsibility

The WHO consultative group classifies pharmacist responsibilities into **four broad categories:**

1. **Central Pharmacist Responsibilities**
2. **Direct Patient Care Responsibilities**
3. **Patient Care Area Responsibilities**
4. **General Responsibilities**

Each of these plays a crucial role in ensuring medication safety and optimizing patient outcomes.

Central Pharmacist Responsibilities

These are **administrative and supervisory duties** that ensure smooth operation of the pharmacy and compliance with regulations.

Key Functions:

- Enforce **policies and procedures** related to drug use and storage.
- Ensure **accuracy of doses** prepared, especially for:
    - **Intravenous admixtures**

    - **Unit dose systems**
- Maintain **proper drug control** — especially for **narcotics and investigational drugs**.
- Ensure **drugs are stored and dispensed properly** under appropriate environmental conditions.
- Comply with **all legal and regulatory requirements** (state and federal drug laws).

 Example:
A central pharmacist verifies that an investigational cancer drug is kept under refrigeration and dispensed only under proper authorization.

Direct Patient Care Responsibilities

Pharmacists today are not only dispensers but also **medication therapy experts** who provide individualized care.

Responsibilities Include:

- **Collect and integrate patient drug history:**
  Review all prescription, OTC, and herbal medicines a patient uses.
- **Clarify patient understanding:**
  Ensure the patient knows how to take the medication and for what purpose.
- **Advise on drug precautions:**
  Inform about possible side effects, interactions, food restrictions, or special administration techniques.
- **Evaluate therapeutic response:**
  Monitor patient progress and communicate with physicians if therapy needs modification.

Example:
A pharmacist identifies a patient on warfarin who also takes aspirin and warns about bleeding risk.

Patient Care Area Responsibilities

These involve **clinical participation** in direct patient management, often in hospital or clinic-based settings.

Pharmacist Activities:

- Assist nursing staff in patient monitoring, including **vital signs**.
- **Participate in drug selection** (therapeutic interchange, formulary decisions).
- **Monitor entire drug therapy**, focusing on:
    - Adverse drug reactions (ADRs)
    - Toxicities
    - Allergic responses
    - Drug–drug or drug–food interactions
- Assess achievement of **therapeutic outcomes**.

- **Counsel patients** on their discharge medications and follow-up therapy.
- Participate in **cardiopulmonary emergencies (CPR/Code Blue)** — assist with emergency drugs.

 Example:
A pharmacist ensures appropriate antidote use during a cardiac arrest emergency.

General Responsibilities of a Community Pharmacist

These are day-to-day duties ensuring safe and rational medication dispensing and public health participation.

The Core Responsibilities Include:

1. **Processing of Prescriptions**
2. **Dispensing of Medicines**
3. **Health Promotion**
4. **Drug Information Services**
5. **Patient Counselling**

Let's review these in detail

(A) Processing the Prescription

Before dispensing, the pharmacist must:

- Verify **legality, safety, and appropriateness** of the prescription.
- Check **patient medication record** for drug duplication, allergy, or contraindications.
- Evaluate **dose, route, and duration** for rationality.
- Identify and correct **incompatibilities or interactions** before preparing the product.

(B) Dispensing of Medicines

Dispensing means *preparing and supplying medicines according to a prescription.*

Steps in Dispensing:

1. Select the **correct container and closure**.
2. Prepare **label** with correct drug name, strength, dosage, and instructions.
3. Prepare or compound (if needed) and transfer into the container.
4. Affix the label correctly and check the **final preparation**.
5. **Record the details** in the dispensing register.
6. Counsel the patient about **dose, timing, and precautions.**

Example:
Compounding a pediatric syrup and labeling it "Shake well before use."

(C) Health Promotion Role

Community pharmacists contribute to **public health education and preventive health** through:

- **Local and national health campaigns**
- **Health awareness programs** in schools, workplaces, and communities

Topics include:

- Rational use of medicines
- Prevention of alcohol and tobacco abuse
- Poison prevention
- Importance of vaccination
- Safe motherhood and family planning
- Common diseases (diarrhea, tuberculosis, leprosy, HIV/AIDS)

Example:
Pharmacist conducts a "Quit Smoking" awareness week, counseling visitors on nicotine patch use.

(D) Drug Information Services

Pharmacists provide **evidence-based information** to:

- Physicians (on drug selection, dosage, interactions)
- Nurses (on drug administration)
- Patients (on safe use)

Services Include:

- Promoting **Adverse Drug Reaction (ADR) awareness**.
- Participating in **ADR reporting** to pharmacovigilance programs.
- Reporting **defective or substandard drugs** (e.g., discolored tablets, particulate matter in IV fluids).
- Maintaining a **drug information center (DIC)** for quick reference.

Example:
Reporting color change in an antibiotic injection to the regulatory authority.

(E) Patient Counselling

Pharmacists must provide direct, understandable advice to patients about:

- Purpose of each medication.
- Correct dosage and timing.
- Duration of therapy.

- What to do in case of a missed dose.
- Possible side effects and when to seek help.
- Lifestyle modifications (diet, exercise, avoiding alcohol or certain foods).

Example:
Advising a diabetic patient on timing of insulin injection and diet restrictions.

Dialogue on Non-Prescription Drugs (NPDs)

- Pharmacists play an important role in guiding patients regarding **Over-the-Counter (OTC)** or **non-prescription drugs**.
- Dialogue between patient and pharmacist should focus on:
  - **Indications and correct use**
  - **Side effects and interactions**
  - **When to refer to a doctor**

As healthcare costs rise, pharmacists may suggest **cost-effective OTC alternatives** — but only when clinically appropriate.

Example:
Recommending an antacid for mild heartburn but referring the patient if symptoms persist beyond 2 days.

Professional Ethics and Communication

Pharmacists must:

- Maintain **confidentiality** of patient information.
- Communicate respectfully with patients and other health professionals.
- Base all recommendations on **scientific evidence**.
- Avoid **commercial bias** or conflicts of interest.
- Continuously **update knowledge** through continuing education.

Summary Table — Roles of a Community Pharmacist

Category	Key Activities	Examples
Central responsibilities	Enforce policies, legal compliance, drug control	Check storage of narcotics
Direct patient care	Review drug history, monitor therapy, advise precautions	Evaluate diabetic patient's medication plan
Patient care area	Clinical monitoring, emergencies, discharge counselling	Participate in CPR or ward rounds
General responsibilities	Dispensing, counselling, health promotion, ADR reporting	Process prescriptions, promote rational drug use

Summary and Importance

- Community pharmacists are **front-line healthcare professionals**.
- Their work ensures **safe, effective, and rational use of medicines**.
- They bridge the gap between **physician and patient** through counselling, monitoring, and follow-up.
- They also play a vital role in **public health education**, **disease prevention**, and **pharmacovigilance**.

Thus, the pharmacist's mission is to ensure that **each patient receives the right medicine, in the right way, for the right reason.**

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