Essential Medicines

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No.	Competency
CM 19.1	Define and describe the concept of Essential Medicine List (EML)
CM 19.2	Describe roles of essential medicine in primary health care
CM 19.3	Describe counterfeit medicine and its prevention

LEARNING OBJECTIVES

At the end of the class, the student should be able to-

- Define Essential Medicine.
- Describe the Guideline for establishing a list of essential drugs.
- Describe Criteria for selection of Essential Drugs.
- Describe the role of Essential Medicines in Primary Health care.
- Describe about Counterfeit Medicines & measures to prevent them.

“The desire to take medicines is one feature which distinguishes man, the animal from his fellow creatures. It is one of the most serious difficulties with which we have to contend”

William Osler

Introduction

- Globally, India ranks
- 3rd in terms of manufacture of pharmaceuticals by volume
- 17th in terms of export of pharmaceutical products to almost 200 countries
- including highly regulated markets of the United States of America, Europe, Japan, and Australia

Introduction

- The following issues determine the actual availability and effectiveness of medicines at the consumer end point:
  1. Inappropriate prescription
  2. Professional competence of the prescriber
  3. Quality: *(Counterfeit Medicines)*
  4. Affordability: *(purchasing power)*
  5. Availability
  6. Accessibility

Essential Medicines

Essential medicines are defined by WHO as those medicines that satisfy the priority health care needs of the population.

It is very important that all countries should develop their own “Essential Medicines List” (EML) relevant to them, and this list would be an important and essential factor in developing the national drug policy.

Essential drug list is same as limited drug list. (Synonymous terms)

Essential Medicines

The national list of essential drugs should be based on the following considerations:

- All common diseases which are important causes of mortality and morbidity should be covered while developing the list.
- An essential drug list of any country should allow a doctor to treat most (at least 90%) diseases that he/she encounters in a community.
- As far as possible, medicines should be listed as single compounds and not as combinations.
- Generic names (and not brand or trade names) should be used in the list.

Essential Medicines (contd.)

The national list of essential drugs should be based on the following considerations:

- Indigenously manufactured drugs should be given priority.
- The list should be developed on evidence-based “standard treatment guidelines.”
- The medicines should be graded according to their requirement at the primary, secondary, or tertiary levels of health care.
- The list should be regularly updated on the basis of technological advancements.

India's Essential Medicines List (EML)

- EML was first drawn by the Government of India in 2003.
- Subsequently, extensive revisions were undertaken and the latest National List of Essential Medicines (NLEM), has been released in September, 2022 and has got a total of 384 Medicine.
- Each of these medicines has been identified as per its requirement at the three levels of health care, namely,
- "P" (drug required at primary health care level),
- "S" (drug required at secondary health care level), and
- "T" (drug required at tertiary health care level).

India's Essential Medicines List (EML)

- Thus, if only "P" is written in front of the drug, it means that it is required only at the primary level,
- whereas if only "S" or "T" is written it means that it is required only at the secondary or tertiary level, respectively.
- If a drug is categorized as P, S and T, it means that the drug is required at all the three levels.

India's Essential Medicines List (EML) : Present Categories

- Section 1 Medicines used in Anesthesia
- Section 2 Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid
- Section 3 Antiallergics and Medicines used in Anaphylaxis
- Section 4 Antidotes and Other Substances used in Management of Poisonings/Envenomation
- Section 5 Medicines used in Neurological Disorders
- Section 6 Anti-infective Medicines (AMR – AWaRe)

India's Essential Medicines List (EML) : Present Categories

- Section 7 Anti-cancer agents including Immunosuppressives and Medicines used in Palliative Care
- Section 8 Medicines affecting Blood
- Section 9 Blood products and Plasma substitutes
- Section 10 Cardiovascular Medicines
- Section 11 Dermatological Medicines (Topical)
- Section 12 Diagnostic agents
- Section 13 Dialysis components (Hemo and Peritoneal Dialysis)
- Section 14 Antiseptics and Disinfectants

India's Essential Medicines List (EML) : Present Categories

- Section 15 Diuretics
- Section 16 Ear, Nose and Throat Medicines
- Section 17 Gastrointestinal Medicines
- Section 18 Hormones, other Endocrine Medicines and Contraceptives
- Section 19 Immunologicals
- Section 20 Medicines for Neonatal Care
- Section 21 Ophthalmological Medicines

India's Essential Medicines List (EML) : Present Categories

- Section 22 Oxytocics and Antioxytocics
- Section 23 Medicines used in treatment of Psychiatric Disorders
- Section 24 Medicines acting on the Respiratory tract
- Section 25 Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances
- Section 26 Vitamins and Minerals
- Section 27 Medicines for COVID 19 management

Criteria for including a medicine in India's NLEM

- should be approved/licensed in India.
- should be useful in disease which is a public health problem in India.
- should have proven efficacy and safety profile based on valid scientific evidence.
- should be cost effective.
- should be aligned with the current treatment guidelines for the disease.
- should be stable under the storage conditions in India.

Criteria for including a medicine in India's NLEM

- When more than one medicine are available from the same therapeutic class, preferably one prototype/ medically best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, cost-effectiveness.

- price of total treatment to be considered and not the unit price of a medicine.

Criteria for including a medicine in India's NLEM

- Fixed Dose Combinations (FDCs) are generally not included unless the combination has proven advantage over individual ingredients administered separately (higher efficacy, lower adverse effects and/or better compliance).

- Listing is based according to the level of healthcare, i.e., Primary (P), Secondary (S) and Tertiary (T) because the treatment facilities, training, experience, and availability of healthcare personnel differ at these levels.

Are all the drugs not figuring in essential drugs list useless or redundant?

- List of essential drugs does not imply that no drugs outside it are useful.
- These drugs may be more expensive alternatives or useful only for uncommon ailments.
- May be harmful or hazardous.
- May be irrational fixed dose combination.

Drug Utilization

WHO DEFINITION

The marketing, distribution, prescribing and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences.

Benefits of essential drug list

- More cost effective drug control, management, purchase, storage, turnover and distribution. More patients treated per unit cost.

- Improved drug use in terms of safety, simplified and more efficient drug information including training to health workers.

- Able to define real health needs and to perform programme evaluation more effectively.

Benefits of essential drug list (contd.)

- Easy identification and avoidance of adverse drug reactions and interactions with fewer drugs.

- Stimulation of local drug formulation and production depending on the requirement.

Essential Drug List

- Who should prepare it?
- How many drugs?

  (WHO Model list, National, regional level, Hospital and primary health centre)
- Which drugs? (effective, safe, cheap, for common ailments)
- Revision and updating of the list yearly.

National Drug Policy 2002

- The National Drug Policy in India was first enunciated in 1986
- as Drug Policy, modified in 1994,
- and last revised in 2002 as Pharmaceutical Policy.
- In India, the drug policy is formulated by the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

Pradhan Mantri Bhartiya Janaushadhi Pariyojana

Sample List of Medicines Available Under PMBJP				
Drug Code	Generic Name	Strip/Unit	MRP	Category
1	Aceclofenac + Paracetamol (100 mg + 325 mg) Tab	10's	8.00	Analgesic and Antipyretic/Muscle relaxants
97	Meropenem Injection IP 1 g vial and wfi (water for injection)	Vial	214.60	Anti-infective
122	Ketoconazole 2% w/w lotion 100 ml bottle	100 ml bottle	41.15	Dermatology/Topical/External
142	Insulin Injection (Human) (40 iu/ml)	10 ml vial	71.50	Anti-diabetic
152	Bleomycin 15 mg Injection	vial	300.00	Anti-cancer/Oncology
208	Ondansetron 2 mg/ml Injection	2 ml vial	3.60	Gastrointestinal
255	Salbutamol 100 mcg/puff Inhaler	200 md	38.00	Respiratory

Counterfeit Medicine

WHO defines counterfeit medicines as those medicines which are deliberately and fraudulently mislabelled with respect to identity and/or source.

Counterfeiting can apply to both branded and generic medical products and include any of the following:

- products which do not contain any of the specified active ingredients despite such declarations on the labels
- products which contain active ingredients other than those specified on their labels

Counterfeit Medicine (contd.)

- products which contain the correct strength of the specified active ingredients but whose source is different from the one declared
- products which contain the specified active ingredients but in strengths different to those declared; they may also contain different quantities of impurities
- products with fake packaging

Measures to Control Counterfeit Medicines

- Global surveillance and monitoring system for counterfeit drugs
- Strong national political will and commitment
- Appropriate legislation and effective enforcement
- An effective National Drug Regulatory Agency
- Training of Drug Inspectors and presence of SOPs and guidelines
- Effective judiciary

Measures to Control Counterfeit Medicines (contd.)

- Coordination between producers, importers, distributors, wholesalers, retailers, health professionals and community
- Mandatory barcoding for all genuine drugs
- Blockchain-based computer technology for traceability of drugs, such as the one being considered by NITI Aayog
- Monthly Counterfeit Drugs List as being published by CDSCO (Central Drugs Standard Control Organisation)

Generic vs. Branded Medicines

Any drug has three types of names.

i. The *chemical name*, which describes the chemical structure of the drug

ii. The *non-proprietary (generic) name*, or the "molecular" name, for example, "propranolol"

iii. The *brand name* by which a particular manufacturer markets a particular drug, for example, "Inderal" (generic/molecular name: propranolol).

Each manufacturer markets the generic drugs under its own brand name

Take Home Message ….

- E - efficacy
- S - safety
- S - storage and stability.
- E - ease of administration (dosage form).
- N – need of population.
- T - total cost.
- I - irrational combination to avoid
- A - available
- L - listing regularly (updating)

Summary

- Definition of Essential Medicine
- Types of Essential Medicines
- Guidelines for selecting essential medicines
- Role of Essential Medicines in Primary health care
- Counterfeit Medicines

Questions

- Define Essential Medicines
- Describe Guidelines for selecting Essential Medicines
- Define Counterfeit Medicines. Add a note on measures to control the counterfeit medicines.

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THANK YOU