

ESSENTIAL MEDICINES

- Essential medicines are those that satisfy the priority health care needs of the population.
- Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

Core list is the list of minimum medicine needed for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions.

Complementary list-Essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities and or specialist medical care and or specialist training are needed.

Selection criteria of essential medicines in national list [UQ]

- The medicine should be approved/licensed in India.
- The medicine should be useful in disease which is a public health problem in India.
- It should have proven efficacy and safety profile based on valid scientific evidence.
- It should be cost effective.
- It should be aligned with the current treatment guidelines for the disease.
- It should be stable under the storage conditions in India.
- Price of the total treatment to be considered and not the unit price of a medicine.

- Choose drug which provides the most favourable benefit/risk ratio
- Selection of dosage forms on the basis of general utility & wider availability
- Fixed dose combination is generally not included unless the combination has unequivocally proven advantage over individual ingredients administered separately in terms of increasing efficacy, reducing side effects and/or improving compliance.
- The list of essential medicines is based according to the level of health care i.e. Primary (P), Secondary (S) and tertiary (T) because the treatment facility, training, experience and availability of health care personnel differ at these levels.
- Available Financial resources to purchase drugs by the health system.
- Genetic, Demographic & Environmental factors.
- Mortality and morbidity statistics.

384 medicines and 22 FDCs are included in national list of essential medicines 2022.

Advantages

- More cost-effective drug control, management, purchase, storage and distribution.
- Improved drug use in terms of safety, simplified and more efficient drug information including training to health workers
- Identification & avoidance of adverse drug reaction and interaction
- Stimulation of local drug formulation and production.

Disadvantages

- Reduced freedom of choice.
- Creation of monopolies favouring a single drug product.

- Reduced possibilities for gaining episodic experience e.g., new application of old drugs
- Lack of interest in drug innovation.

COUNTERFEIT MEDICINES

- Counterfeit medicines as those medicines that are described as "deliberately and fraudulently mislabelled with respect to identity and/or source.
- Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging.

Harm to the patients

- Adverse reactions due to consumption of adulterated substances
- Counterfeit medicines can also be life threatening
- Increased disease transmission.
- Development of antibiotic resistance.
- Credibility of a national healthcare system is harmed if counterfeit medicines get into the legitimate supply chain.

Financial implications

- Legitimate manufacturers of pharmaceutical products suffer from patent and copyright infringement
- Loss of taxation revenue for the government
- Considerable resources are required to combat the practice of counterfeiting.
- Health programmes are being defrauded and compromised

Factors associated with increased counterfeiting

- Lack of appropriate drug legislation
- Absence of or weak drug regulatory system
- Weak enforcement and penal sanctions
- Demand exceeding supply
- High price of medicines When price differentials between identical products exist there is a greater incentive to supply cheap counterfeit medicines
- Inefficient cooperation between stakeholders (regulatory authorities, police, and customs services and the judiciary)
- Lack of regulation by exporting countries and within free trade zones
- Online pharmacies - Illegal or unethical pharmacies send outdated, substituted, or counterfeit medications
- Lack of public awareness.
- Ignorance and increase in self-medication culture.
- High demand of quality products.

Identifying a sub-standard or falsified medical product

- Examining the packaging for condition, spelling mistakes or grammatical errors.
- Checking the manufacture and expiry dates and ensuring any details on the outer packaging match the dates shown on the inner packaging.
- Ensuring the medicine looks correct, is not discoloured, degraded or has an unusual smell;
- Discussing with your pharmacist, doctor or other healthcare professional as soon as possible if you suspect the product is not working properly or you have suffered an adverse reaction.

- Reporting suspicious medical products to your National Medicines Regulatory Authority.

Prevention of Counterfeit Medicines

- Legislation forms the basis for drug regulation. Creation of competent national drug regulatory authorities to control the manufacture, importation, distribution and sale of medicines.
- Legislation must be complemented with effective law enforcement. Governments need to develop strategies to reduce corruption and criminal activity and promote intersectoral co-operation between regulatory authorities, police custom services & judiciary.
- Education and awareness among all stakeholders.
- Preventing shortages by assuring access to quality products at affordable prices
- Promoting the rational use of medicines to maximizing the success of treatment & minimizing antimicrobial resistance.
- Quality standards should be ensured at both manufacturers and distributors level by a strong Pharmacovigilance system.
- Pre-qualification of manufacturers and laboratories by WHO
- Comprehensive legal framework for the inspection, investigation, and enforcement
- Supply chain integrity through a track and trace system with an authentication process
- Coordinating international surveillance for fake and sub-standard drugs
- Educating patients and healthcare workers.