Essential Medicines List (EML):

As per the World Health Organisation (WHO), Essential Medicines are those that satisfy the priority health care needs of the population. The list is made with consideration to disease prevalence, efficacy, safety and comparative cost-effectiveness of the medicines. Such medicines are intended to be available in adequate amounts, in appropriate dosage forms and strengths with assured quality. They should be available in such a way that an individual or community can afford.
Drawing an essential medicines list (EML) is expected to result in better quality of medical care, better management of medicines and cost-effective use of health care resources. This is especially important for a resource limited country like India. The list of essential medicines is intended to have a positive impact on the availability and rational use of medicines

The WHO Model List of Essential Medicines, published by the World Health Organization, contains the medications considered to be most effective and safe to meet the most important needs in a health system. The list is frequently used by countries to help develop their own local lists of essential medicines.

The WHO Model Lists of Essential Medicines are updated every two years by the Expert Committee on Selection and Use of Essential Medicines. The first Essential Medicines List was published in 1977, and the first Essential Medicines List for Children was published in 2007. The current versions, updated in September 2021, are the 22nd Essential Medicines List (EML) and the 8th Essential Medicines List for Children (EMLc).

Essential medicines are those that satisfy the priority health care needs of a population. They are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost-effectiveness. They are intended to be available in functioning health systems at all times, in appropriate dosage forms, of assured quality and at prices individuals and health systems can afford.

The WHO Model List of Essential Medicines and Model List of Essential Medicines for Children are updated and published every two years, intended as a guide for countries or regional authorities to adopt or adapt in accordance with local priorities and treatment guidelines for the development and updating of national essential medicines lists. Selection of a limited number of essential medicines as essential, taking into consideration national disease burden and clinical need can lead to improved access through streamlined procurement and distribution of quality-assured medicines, support more rational or appropriate prescribing and use and lower costs for both health care systems and for patients.

National List of Essential Medicines (NLEM)

The WHO EML is a model list. The decision about which medicines are essential remains a national responsibility based on the country's disease burden, priority health concerns, affordability concerns etc. Ministry of Health and Family Welfare, Government of India hence prepared and released the first National List of Essential Medicines of India in 1996 consisting of 279 medicines. This list was subsequently revised in 2003 and had 354 medicines. Later in 2011, the list was revised and had 348 medicines. Till June 2018, 851 medicines (including 4 medical devices i.e. Cardiac stents, drug eluting stents, condoms and intra uterine devices) are regulated under Revised Schedule - I based on National List of Essential Medicines, 2015 (NLEM, 2015).

Purpose of the National List of Essential Medicines:

The NLEM may have multiple uses. It can:

- Guide safe and effective treatment of priority disease conditions of a population
- Promote the rational use of medicines
- Optimize the available health resources of a country It can also be a guiding document for:
    - State governments to prepare their list of essential medicines
    - Procurement and supply of medicines in the public sector
    - Reimbursement of cost of medicines by organizations to its employees
    - Reimbursement by insurance companies
    - Identifying the 'MUST KNOW' domain for the teaching and training of health care professionals

Considerations for Framing the NLEM 2015:

- **Essentiality** - Every medicine may be necessary or even critical for specific disease conditions for which it is indicated. But in the context of NLEM, a medicine may be essential considering the population at large and should fit into the definition mentioned earlier. Hence, a medicine which is critical for a specific condition may not be listed in the list of essential medicines if the disease condition for which it is indicated has low prevalence or is rare. This does not mean that if a particular medicine is not included in the list of essential medicines, it is not necessary. In no way, exclusion of such medicines from the list undermines their importance in therapeutics and need of their availability at an affordable cost.
- **Changing Disease Burden** - Disease burden is an important consideration for identifying the essential medicines. Medicines needed to manage diseases that are highly prevalent or are emerging diseases in the population will qualify for inclusion in the NLEM. For example, MDR tuberculosis is increasing in incidence and is a public health issue. Similar is the case with increasing prevalence of resistant malaria. These necessitate the inclusion of medicines in NLEM to address the above issues.
- **Efficacy and Safety** - Safety and efficacy are the most important criteria for considering essentiality of a medicine. For a medicine to be considered essential, it should have an unequivocal evidence of efficacy and wider acceptance in medical science. The medicine

should have a safety profile which is acceptable in terms of risk benefit assessment. The safety profile of a medicine may change over time as new adverse effects may be discovered after wider use of the drug. This may change the risk benefit assessment and a drug once preferred may no longer remain so. For example, pioglitazone is an effective and cheap antidiabetic drug but it recently came under the scanner because of the safety concern of bladder cancer. Though the drug finds its use in specific diabetic conditions, the same is with various safety restrictions. Therefore, pioglitazone has not been considered essential in spite of being effective for a specific diabetic condition.

- **Comparative Cost-effectiveness** - This is especially important when selecting more than one medicine from the same therapeutic category and when they do not differ significantly in their efficacy & safety. Sometimes per unit price of the medicine may be more but it may be required to be given at a lesser frequency. Thus the total price of the treatment schedule should be taken into consideration and not the unit price alone.
- **Feasibility in context of advantage and cost-effectiveness** - An essential medicine should be available in a form in which adequate quality throughout its shelf-life under recommended storage conditions is ensured. For example, liquid formulation of antisnake venom is cheaper and equi-efficacious as compared to the lyophilised preparation. However, lyophilisation involves use of technology and cost. Whereas, liquid formulation requires cold chain, which is sometimes difficult to maintain in its distribution channel. Considering the advantage of one and the costeffectiveness of the other, both lyophilized and liquid formulations have been included in the List. They have been listed as separate items and should be considered differently by the user of NLEM.
- **Fixed Dose Combinations (FDCs)** - As a principle, single medicines are to be preferred. FDCs are included only if the combination is rational and has a proven advantage with respect to therapeutic effect, safety and compliance or in decreasing the emergence of drug resistance. Some examples are, diseases such as malaria, Human Immunodeficiency Virus (HIV) infection/ Acquired Immunodeficiency Syndrome (AIDS), where the emergence of antimicrobial resistance is an important issue, which may be partly caused by poor compliance. In these therapeutic categories, certain FDCs have been considered as essential. In certain other cases where FDCs are critical for their optimal efficacy, such FDCs are also considered as essential. For example, FDC of levodopa and carbidopa, and FDC of amoxicillin and clavulanic acid.
- **Sales Turnover** - The sales of a medicine in terms of moving annual total (MAT) volume and MAT value may not be criteria for essentiality. A medicine with high volume of sales may or may not qualify as essential since the sales of a medicine is likely to be impacted by factors such as market forces, physician's preferences, and influences of Key Opinion Leaders etc especially for countries like India where there is lack of universally acceptable treatment guidelines for many disease conditions. For example, several multivitamin preparations such as Vitamin B complex, Vitamin C with minerals like zinc etc are widely consumed and figure very high on the MAT list. But considering the criteria for inclusion in NLEM, these preparations do not qualify for their inclusion. Some FDC which figure very high may not be even rational and need attention of regulator to assess their continued marketing. Such formulations obviously, will not meet the essentiality criteria.
- **Hierarchy of Health Care Structure** - The health care system in India is essentially a three-tier system with primary, secondary and tertiary levels having different health care

concerns and medicine requirements. While a primary health care level setup may require medicines prescribed in an outpatient setup like basic antibiotics, analgesics and anti-inflammatory drugs; a tertiary level setup might need more parenteral medicines and medicines used in an inpatient setup. The health care facility at the primary care center may not be adequate for use of medicines which require special facilities and techniques for their administration. Therefore, infrastructure at the PHC might preclude use of such medicines. The use of high-end antimicrobials, and medicines for conditions like resistant tuberculosis, malaria, kala-azar; oncology medicines etc will be required more in tertiary care. Thus, the essentiality of the medicine will also depend upon the hierarchy of the health care system, and hence the need to bucket the essentiality as:

- (P) = Primary care facility
- (S) = Secondary care facility and
- (T) = Tertiary care facility

Criteria for inclusion of a medicine in NLEM 2015:

The criteria are as follows

- The medicine should be approved/licensed in India.
- The medicine should be useful in disease which is a public health problem in India.
- The medicine should have proven efficacy and safety profile based on valid scientific evidence.
- The medicine should be cost effective.
- The medicine should be aligned with the current treatment guidelines for the disease.
- The medicine should be stable under the storage conditions in India.
- 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.
- Fixed Dose Combinations (FDCs) are generally not included unless the combination has unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.
- The listing of medicine in NLEM is based according to the level of health care, i.e. Primary (P), Secondary (S) and Tertiary (T) because the treatment facilities, training, experience and availability of health care personnel differ at these levels.

Criteria for deletion of a medicine from NLEM 2015:

- The medicine has been banned in India.
- There are reports of concerns on the safety profile of a medicine.
- A medicine with better efficacy or favorable safety profiles and better cost-effectiveness is now available.

- The disease burden for which a medicine is indicated is no longer a national health concern in India.
- In case of antimicrobials, if the resistance pattern has rendered a medicine ineffective in Indian context

NLEM and Related Price Control Issue 2015:

In order to make medicines affordable, Government of India promulgated the National Pharmaceutical Pricing Policy, 2012 bringing all medicines with specified dosage and strength included in NLEM under price control. Accordingly, Drug Price Control Order, 2013 was issued by Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers for fixing the ceiling price of medicines included in NLEM, 2011.