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National List of Essential Medicines (NLEM)

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What's in News?

After 7 years, the National List of Essential Medicines (NLEM) was revised recently.

Essential Medicines:

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.

National List of Essential Medicines (NLEM):

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 and subsequently it was revised thrice earlier in **2003, 2011, and 2015**.

The essential medicines list is categorised based on medicines at primary, secondary and tertiary healthcare levels.

The drugs in the NLEM are included in the schedule category and their **price is regulated by the National Pharmaceutical Pricing Authority (NPPA)**

National Pharmaceutical Pricing Authority (NPPA) caps medicine prices and **changes only based on wholesale price index-based inflation**

Typically, once NLEM is released, the department of pharmaceuticals under the ministry of chemicals and fertilisers adds them in the Drug Price Control Order, after which NPPA fixes the price.

It is based on **World Health Organisation's (WHO) Model List of Essential Drugs**.

It is a dynamic list that takes into account any changing profile of diseases, newer drugs available in the market, and changing treatment protocols.

Purpose of NLEM:

The NLEM may have multiple uses. It can:

Guide safe and effective treatment of priority disease conditions of a population

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Promote the rational use of medicines

It promotes prescription by generic names

Optimize the available health resources of a country

It can also be a guiding document for:

- a) State governments to prepare their list of essential medicines
- b) Procurement and supply of medicines in the public sector
- c) Reimbursement of cost of medicines by organizations to its employees
- d) Reimbursement by insurance companies
- e) Identifying the 'MUST KNOW' domain for the teaching and training of health care professionals

News Summary:

Twenty-six drugs, including the common gastrointestinal medicines ranitidine and sucralfate, have been deleted from the revised National List of Essential Medicines (NLEM) 2022

Deletion of Drugs:

i) Drugs deleted from the NLEM include medicines banned in India and those having reports of concerns on the safety profile.

ii) Drugs also go off the list if medicine with better efficacy or favourable safety profile and better cost-effectiveness become available.

iii) Also if the disease burden for which a medicine is indicated is no longer a national health concern, it is deleted from the NLEM

iv) In case of antimicrobials, if the resistance pattern has rendered them ineffective, the drugs are taken off the list.

The new list also includes four drugs that are still under patent - used in the treatment of multiple drug-resistant tuberculosis, human immunodeficiency virus (HIV) infection and viral infections such as Hepatitis C

None of the drugs for COVID-19 was added in the list, since the clinical trials to check the efficacy of the drugs were not yet conclusive

Also, several antibiotics, vaccines and anti-cancer drugs are set to become more affordable with their addition to the list

Inclusion of a drug in the NLEM mandates that it is sold at prices fixed by the NPPA.

Significance:

Several antibiotics, vaccines, anti-cancer drugs and many other important drugs would become **more affordable**, and the "out-of-pocket expenditure" on health care would come down.

This is critical because the recently released National Health Accounts Estimates 2018-19 points to a high burden on households to pay for healthcare, which is a key reason pushing Indians into poverty.

This is also aligned with the vision of PM's **Sabko Dawai, Sasti Dawai** (medicine for all, cheap medicine)

Drugs (Prices Control) Order (DPCO):

The Drugs Prices Control Order, 1995 is an order issued by the Government of India under Sec. 3 of Essential Commodities Act, 1955 to regulate the prices of drugs.

The Order inter alia provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Govt., penalties for contravention of provisions etc

For the purpose of implementing provisions of DPCO, powers of Govt. have been vested in NPPA.

Later, the Drugs (Prices Control) Order (DPCO) 2013 was notified.

National Pharmaceutical Pricing Authority (NPPA):

National Pharmaceutical Pricing Authority (NPPA), was established on **29th August 1997** as an independent body of experts as per the decision taken by the Cabinet committee in September 1994 while reviewing Drug Policy.

It is an **attached office of the Department of Pharmaceuticals (DoP)**, Ministry of Chemicals & Fertilizers.

It is an **independent authority** that has been entrusted with the task of fixation/revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the Drugs (Prices Control) Order and monitoring of the prices of controlled and decontrolled drugs in the country.