# Report

## Introduction

As per World Health Organization (WHO), Essential Medicines are those that satisfy the priority health care needs of any population. These medicines should have established safety, efficacy, and comparative cost effectiveness. The aim behind formulating essential medicine list (EML) is to ensure that these medicines are available in adequate amounts, in appropriate dosage forms and strengths with assured quality. EML is expected to aid in improving quality and accessibility of health care while ensuring cost effective use of resources. This has obvious importance for resource limited country like India. Further, EML is intended to promote rational use of medicines.

## Evolution of Essential Medicines List

Tanzania was the first country to compose its own country specific EML in 1970. In 1975, the World Health Assembly requested WHO to assist member states in identifying essential medicines specific to them and assuring their availability, assuring good quality at reasonable cost. WHO published first model list of essential medicines in 1977 which contained 186 medicines. It was intended to be used as a template by member countries. It stated that *essential medicines* were "of utmost importance, basic, indispensable and necessary for the health and needs of the population" and criteria for selection were based on efficacy, safety, quality, and total cost. The emphasis was laid on disease burden and treatment guidelines as basis for selecting essential medicines.

In 1985, the list of essential medicines of the WHO was recognized as important, mainly for the public sector and its scope was to guide the procurement, distribution, rational use, and quality assurance of medicines. As the disease diversity and burden grew, the number of medicines in the WHO EML increased over the years, a trend that has also been seen with National List of Essential Medicines (NLEM) of India.

**Requirement for Country Specific EML**

The essential medicines list prepared by WHO is a prototype list that can be used as a template by individual countries. Since priority health care needs of countries differ, it is logical that each country shall have its own country specific EML. Socio-demographic factors and economy are other factors that are likely to influence composition of EML for any country.

**Disease burden may vary in different countries**

The central concept of Essential medicines is to address the "priority health care needs" specific to a country. It is therefore important to take into consideration the 'burden' of diseases in that population. For example, HIV, tuberculosis, malaria and diarrheal diseases are priority health care concerns in low- and middle- income countries including India, but it may not be so for evolved economies. On the same line, trypanosomiasis and yellow fever may be a priority health care concern in some countries but not in our country.

**Variations in Priority Health Care Concerns within a country**

For our country, which has a large geographical area with huge diversity in climate, food habits, culture etc., there are differences in health care priorities within the states, across different regions. For example, kala-azar is more prevalent in Bihar whereas Japanese encephalitis is more prevalent in Bihar and Assam. Therefore, medicines for priority health care conditions for different regions of the country have been considered for inclusion in NLEM 2022. Indian healthcare needs are also peculiar as they involve not only problems of low-income countries but that of high-income countries also, such as hypertension, diabetes mellitus and other lifestyle diseases.

## What makes Indian NLEM different

### Disease Prevalence Patterns in India

With the improvement in public health care and the socioeconomic status, India faces the twin epidemic of continuing/ emerging infectious diseases as well as non-communicable, lifestyle diseases. The temporal landscape of India's health care priorities makes an intriguing study.

The current disease prevalence scenario is unique with an increase in the burden of non- communicable diseases and resurgence of certain communicable diseases either due to emergence of drug resistance, like in tuberculosis and malaria, or occurrence of certain co-infections like HIV and TB, and HIV and sexually transmitted diseases, or due to evolution of the pathogens as in case of dengue, influenza like H1N1, etc.

The essential medicines selection for various therapeutic areas have been considered taking into view the larger perspective of current demographic profile of disease burden as well as likely future trends.

### Meeting the healthcare needs of a common man in India

India's public health expenditure has been steadily rising over the last decade. In fiscal year 2018-19, the value of public health expenditure by states and union territories together amounted to around 1.58 trillion Indian rupees. This was estimated to be around 1.28 percent of the country's GDP. Urgent need has now been felt to enhance the budgetary allocation in health sector. Huge funding support has been provided by government to meet the healthcare needs. Overall, India's per capita expenditure on health amounted to over 1,600 Indian Rupees that same year[1]. The past decade has also seen a rise in the public

[1] *Reference - India - estimated public health expenditure 2017-2020 | Statista [Internet]. Statista. 2021 [cited 9 July 2021]. Available from: https://www.statista.com/statistics/684924/india-public-health-expenditure/

adoption of insurance schemes. Nevertheless, the health insurance schemes are often underutilized in India. Very-small subset of the Indian population is covered through health insurance, most of it being government employees and organized sectors. The most vulnerable groups like workers of unorganized sectors, migrant workers and agriculture dependent population are left out of the insurance coverage and are dependent on the out of the pocket or public spending for purchase of medicines. Various programmes like the Ayushman Bharat,
Jan Aushadhi Yojana, AMRIT Pharmacies and the National Health Mission have been implemented to provide affordable healthcare to the common man of India.

The National Health Policy 2017 emphasized on the vision of health for all and universal health coverage. To fulfill this objective, the Government of India conceived Ayushman Bharat, an initiative led by Honorable' Prime Minister. It aims to provide financial protection (Swasthya Suraksha) to 10 crore poor and deprived rural families and identified categories of urban worker's families. It is world's largest healthcare programme and insurance scheme that aims to provide free healthcare access to low income population of the country.

Out-of-pocket expenditure constitutes over 60% of total health expenditure, with a substantial 40% being incurred on medicines. With this background, it is of paramount importance that accessibility and affordability of medicines be enhanced in order to reduce the financial burden on the households. Access to safe, effective, quality, and affordable essential medicines can be achieved with the use of NLEM. It provides the framework for judicious use of medicines as all the drugs listed are based on criteria of efficacy, safety, cost-effectiveness data. The drugs listed in NLEM are considered scheduled drugs under Drugs Price Control Order (DPCO) and their

prices are regulated by National Pharmaceutical Pricing Authority (NPPA) to ensure affordability. India is a resource limited country, and the allocated budget has to be used judiciously so that maximum number of beneficiaries can be covered. NLEM is an important tool to achieve this goal, not only by rationalizing the therapeutics but also by economizing the resources. The NLEM will also help in optimization of State's budget on account of medicines.

**Balance of affordability and essentiality in NLEM**

There may be situations where certain medicines or formulations may have some advantage over others in similar class, but the high cost differential may not merit their inclusion in NLEM. For example – the injectable iron preparations used for iron deficiency anemia include iron dextran, iron sucrose, and ferric carboxymaltose. Iron dextran is the cheapest of the three but has substantial safety concerns due to risk for anaphylaxis. Iron sucrose is though relatively bit expensive but is safer. Ferric carboxymaltose has the least safety concern and can deliver the maximum amount of iron. Ferric carboxymaltose is however, very expensive and hence it does not justify inclusion. Considering comparative efficacy, safety and cost, out of the three, iron sucrose has been included in the NLEM.

As a corollary, there may also be a situation where a medicine/ formulation are included in NLEM despite it being more expensive as it has significant advantage of safety and/or efficacy. However, considering the socioeconomic conditions, the less expensive, other formulation may also find a place in the list. For example – three formulations of amphotericin B (conventional, relatively expensive lipid formulations as well as the much expensive liposomal) have been included.

**Issues related to Price Control of Medicines and NLEM 2022**

To make medicines affordable, the government promulgated the National Pharmaceutical Pricing Policy, 2012, to bring 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.

The issue related to price control sometimes became the main focus of discussions. However, committee ensured that the critical 'go/no go' decision regarding the inclusion of medicines in NLEM was taken considering the main themes of safety, efficacy, and disease burden in the country, their affordability and accessibility.

**NLEM – a dynamic process that needs a standing committee**

As the health and science are dynamic, the usefulness of medicines is also dynamic. The list of essential medicines cannot be static but must be ever dynamic. It needs to be updated/ revised periodically. The approval of newer and better medicines may lead to change in treatment practices/ guidelines for various disease conditions. For example, ergot alkaloids (dihydroergotamine) were commonly used for the treatment of acute attack of migraine. However, with the introduction of safer alternatives of 5-$HT_{1b/d}$ agonists like medicines of this class are now preferred over the existing ones. Among various 5-$HT_{1b/d}$ agonists, sumatriptan has been considered as essential in place of dihydroergotamine. Similarly, availability of rituximab for NHL has changed the treatment regimen for this disease.

Further, some medicines may become obsolete whereas some may become the drug of choice. Thus, monitoring and evaluation of benefit-risk, availability, affordability needs to be continuous over time. This philosophy

formed the basis for constitution of a Standing Committee. This will preserve the relevance of NLEM for the Indian population.

During the process of revision of NLEM, there were several practical questions were which need to be answered through simple observational studies. The data generated through such studies will support evidence-based decisions. Some examples of such questions are listed as a separate chapter. The academic institutions can take up these studies

**Various purposes that can be served by National List of Essential Medicines**

The NLEM may serve multiple purposes as under:

- Promote the rational use of medicines
- Guide safe and effective treatment of priority disease conditions of a population and optimize the available health resources of the country.
- It can also serve as a guiding document for:
    - State governments to prepare their list of essential medicines
    - Developing Standard Treatment Guidelines
    - Help in preparing hospital formularies
    - Procurement and supply of medicines in the public sector as well as private sector hospitals
    - Reimbursement of cost of pharmaceutical products by employers
    - Reimbursement by insurance companies
- Identifying the 'MUST KNOW' domain for the teaching and training of health care professionals (medical, dental, pharmacy and nursing).

## Salient features of NLEM 2022

The current National List of Essential Medicines (NLEM 2022) contains 386 medicines. The NLEM 2015 contained 376 medicines. In 2015, 70 medicines were deleted, and 106 medicines were added. In NLEM 2022, 34 medicines have been added and 26 medicines have been deleted. Thus, the current list contains a total of 384 medicines. Out of these 384 medicines, 342 appear in single therapeutic category, 41 drugs appear in two therapeutic categories, 11 appear in three therapeutic categories and 4 drugs appear in four therapeutic categories. Hence, the total list is 440 items long. There are relatively lesser number of deletions and additions in the current list.

**Table: Addition, deletion and total number of medicines in successive NLEMs**

| Year | 2011 | 2015 | 2022 |
|---|---|---|---|
| **Number of medicines added** | 47 | 106 | 34 |
| **Number of medicines deleted** | 43 | 70 | 26 |
| **Total number of medicines** | 348 | 376 | 384 |

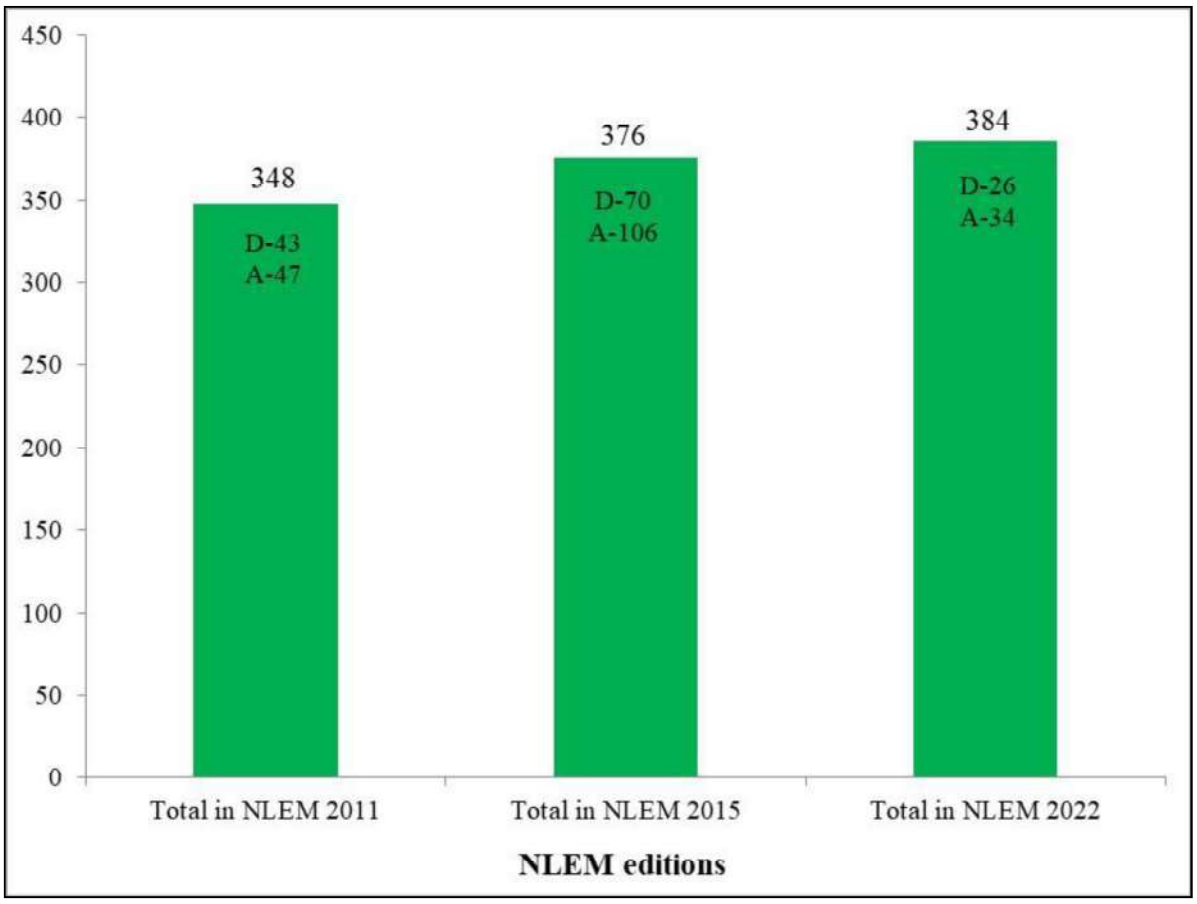



**Figure: Number of medicines in successive NLEMs**

## Therapeutic Categories of medicines

In NLEM 2015, the medicines were listed in 30 therapeutic categories in. In NLEM 2022, it was decided to merge four categories (Antiepileptic medicines, Antiparkinsonism medicines, Antimigraine and Medicines used in Dementia) into a single therapeutic category and name it as 'Medicines for Neurological Disorders'. Similarly, erstwhile category of 'Muscle relaxants and cholinesterase inhibitors' was merged into one category and named as 'Medicines used in Anaesthesia'. Further, a new section of Medicines for COVID-19 Management has been added. Thus, NLEM 2022 contains 27 therapeutic categories as opposed to 30 in NLEM 2015.

Each deletion/ addition of medicines/ formulations was carried out after extensive deliberation among the experts, considering published evidence

(papers, meta-analysis, national and international guidelines, safety data from published reports, and reports from Pharmacovigilance Programmed of India), seeking inputs from stakeholders and also assessing the availability in the market. This nationwide rigorous consultative process has led to a consensus decision in all modifications.

- The medicines in various National Health Programmes have been considered for inclusion in NLEM. Any medicine/ vaccine, as and when recommended under any National Health Programmes will be deemed included in NLEM.

- More than 130 suggestions/ inputs, from Pharmaceutical Industries, Associations/ Bodies, non-governmental organizations (NGOs), Ministries were received. After deliberations on each, wherever considered appropriate, the viewpoints have been included.

The major deletions and additions in NLEM 2015 list were in the therapeutic category of anti-infective medicines (deletion 16 and additions 33) as compared to 09 deletions and 18 additions in NLEM 2022.

Maximum numbers of additions in anti-infective therapeutic category of medicines. In this category 18 medicines have been added and 09 have been deleted. The second maximum numbers of medicine 63 (including duplication) are in anti-cancer agents including Immunosuppressive and Medicines used in Palliative care therapeutic category.

**Details of changes made in NLEM from 2011 till 2022 are given in the table below:**

| Section | Therapeutic Category | Total in NLEM 2011 | Deleted | Added | Total in NLEM 2015 | Deleted | Added | No. of Medicines* |
|---|---|---|---|---|---|---|---|---|
| 1. | Medicines used in Anaesthesia | 23 | 4 | 2 | 21 | 1 | 0 | 20(6) |
| 2. | Analgesics, antipyretics, non-steroidal anti-inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders | 14 | 0 | 1 | 15 | 1 | 0 | 14(8) |
| 3. | Antiallergics and medicines used in anaphylaxis | 9 | 2 | 0 | 7 | 1 | 0 | 6(3) |
| 4. | Antidotes and Other Substances used in Management of Poisonings/Envenomation | 14 | 1 | 1 | 14 | 1 | 0 | 13(4) |
| 5 | Medicines used in neurological disorders | 14 | 2 | 5 | 17 | 0 | 0/3 | 20(8) |
| 6. | Anti-Infective Medicines | 69 | 16 | 33 | 86 | 09 | 18/32 | 109 (34) |
| 7. | Anti-cancer agents | 40 | 6 | 25 | 59 | 1 | 4/5 | 63 |

| Section | Therapeutic Category | Total in NLEM 2011 | Deleted | Added | Total in NLEM 2015 | Deleted | Added | No. of Medicines* |
|---|---|---|---|---|---|---|---|---|
| | including Immunosuppressives and Medicines used in Palliative Care | | | | | | | (16) |
| 8. | Medicines affecting blood | 10 | 3 | 6 | 13 | 0 | 0 | 13 (3) |
| 9. | Blood products and Plasma substitutes | 10 | 4 | 2 | 8 | 0 | 0 | 8(0) |
| 10. | Cardiovascular medicines | 29 | 5 | 5 | 30 | 2 | 2/5 | 30(8) |
| 11. | Dermatological medicines (Topical) | 16 | 6 | 5 | 15 | 3/2 | 0 | 12 (2) |
| 12. | Diagnostic agents | 11 | 6 | 2 | 7 | 1/1 | 0/1 | 7(2) |
| 13. | Dialysis components (Hemodialysis and Peritoneal Dialysis) | 1 | 0 | 1 | 2 | 0 | 0 | 2(0) |
| 14. | Antiseptics and Disinfectants | 12 | 3 | 0 | 9 | 2 | 0 | 7(1) |
| 15. | Diuretics | 4 | 0 | 0 | 4 | 0 | 0 | 4(2) |
| 16. | Ear, nose, throat medicines | 0 | 0 | 4 | 4 | 0 | 0 | 4(3) |
| 17. | Gastrointestinal medicines | 16 | 3 | 3 | 16 | 2 | 0 | 14(4) |
| 18. | Hormones, other endocrine medicines and contraceptives | 24 | 4 | 3 | 23 | 2 | 4/5 | 25(5) |
| 19. | Immunological | 13 | 0 | 4 | 17 | 0 | 1/1 | 18(1) |

| Section | Therapeutic Category | Total in NLEM 2011 | Deleted | Added | Total in NLEM 2015 | Deleted | Added | No. of Medicines* |
|---|---|---|---|---|---|---|---|---|
| 20. | Medicines for Neonatal Care | 0 | 0 | 3 | 3 | 0 | 0 | 3(0) |
| 21. | Ophthalmological Medicines | 17 | 5 | 6 | 17 | 2/1 | 1/1 | 16(8) |
| 22. | Oxytocics and Antioxytocics | 7 | 1 | 1 | 7 | 0 | 0 | 7(0) |
| 23. | Medicines in treatment of Psychiatric Disorders | 11 | 5 | 7 | 13 | 0 | 3/4 | 17(6) |
| 24. | Medicines acting on the Respiratory tract | 6 | 3 | 3 | 6 | 0 | 1/1 | 7(2) |
| 25. | Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances* | 10 | 0 | 0 | 8 | 0 | 0 | 8(2) |
| 26. | Vitamins and Mineral | 10 | 2 | 1 | 9 | 1 | 0 | 8(1) |
| 27. | Medicines in management of COVID-19 | - | - | - | - | - | 0/5 | 5(5) |
| | **Total Number of Medicines** | **348/390** | | | **376/ 430** | | | **384** ** **460#** **(56)** |

* Total in NLEM 2022 (No of medicines appearing more than once)

** Actual Number of medicines, i.e. Medicines appearing at more than one category is counted once only

# Total Number of medicines i.e. the medicines repeating in more than one category have been counted for each category. For example – Hydroxyurea appearing at two places is counted as two. Morphine appearing at 3 places is counted as three.

## The process of revision of NLEM

Ministry of Health & Family Welfare (MoHFW), Government of India, constituted Standing National Committee on Medicines (SNCM) under the chairmanship of Prof. Balram Bhargava, Secretary, Department of Health Research (DHR) and Director General, Indian Council of Medical Research (ICMR), and Prof. Y.K. Gupta, Formerly Head, Department of Pharmacology and Dean, All India Institute of Medical Sciences (AIIMS), New Delhi as its Vice Chairman.

The notification provided the list of experts of different disciplines from across the country with a provision that the chairman may consult other experts as and where required.

The committee deliberated on the criteria of inclusion and exclusion for the current revision of NLEM and decided that the criteria adopted in NLEM 2015 will largely be followed since the principle of essentiality remains unchanged. The committee paid special attention to antimicrobial resistance while deliberating on the essentiality of antibiotics. It also noted the availability issues of certain formulations listed in NLEM 2015 and considered this aspect while listing them in the current NLEM. Enlisting of medicines in NLEM was stratified according to the level of health care, i.e. Primary (P), Secondary (S) and Tertiary (T) because the requirements, treatment facilities, training, experience and availability of health care personnel differ at these levels.

**Criteria for inclusion and deletion**

The criteria for inclusion of a medicine are listed below:

- The medicine should be approved/ licensed in India.
- The efficacy and safety profile of the medicine should be based on robust scientific evidence.
- The medicine should be useful in disease which is a public health problem in India.
- All medicines enlisted in National Health Programmes/ National Disease Control Programmes are as such essential and hence included in the NLEM 2022.
- The medicine should be affordable to the community in the Indian context.
- The medicine should be readily accessible at P, S, T healthcare levels
- When more than one medicine are available from the same therapeutic class, preferably one prototype/ best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, availability and affordability.
- Overall cost of therapy was considered and not just the unit cost of the medicine.
- A Fixed Dose Combination (FDC) was generally not included unless the combination had unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.

The criteria for deletion of a medicine from the existing NLEM are listed below:

- The medicine has been banned in India by the regulatory authority.
- There are reports of serious concerns on the safety profile of a medicine.
- Another medicine with better efficacy or favourable safety profile or better accessibility and affordability is now available.
- The disease burden, for which a medicine is indicated, is no longer a national health concern for India.
- In case of antimicrobials, if the resistance pattern has rendered an antimicrobial ineffective in the Indian context.

**Reference documents to guide the revision process**

The NLEM 2015 was treated as the base document for drafting NLEM 2022. Any suggestions regarding addition to the list were discussed within the cornerstones of essentiality. Other documents such as WHO EML 2019, Indian Pharmacopoeia, National Formulary of India 2016, Drug compendia including online drug information sources and formularies of other countries (like British National Formulary) were also perused before taking a decision regarding suggested inclusion. Guidelines drawn from major National Health Programmes/ Disease Control Programmes were also referred to. Any additions of medicines in these were also included in NLEM 2022.

To consider the safety issue of the drugs, the available literature, the safety reports from WHO and other countries as well as information from Pharmacovigilance Programme of India (PvPI) were considered. If there was any emerging safety issue which tilted adversely the risk benefit assessment, the medicine was considered for deletion.

## Involvement of Experts and stakeholders

The NLEM revision process involved nation-wide, transparent consultation process. For this, the subject experts were drawn from different medical institutions, including those situated in peri-urban and rural areas. A country wide representation (including North-East and Jammu Kashmir regions) was ensured. The experts were of different subject domain. Representatives of different national health Programme such as National TB Elimination Program (NTEP), National AIDS Control Programme (NACP), and National Vector Borne Disease Control Programme (NVBDCP); were invited.

To get the inputs and opinions of pharmaceutical industry and NGOs, an advertisement was placed in national newspapers and on the ICMR website. Representatives from pharmaceutical industry and NGOs presented their viewpoints in stakeholder meetings. Inputs from the experts were also received through emails. The committee deliberated on online and offline submissions from stakeholders.

### Transparent approach in NLEM meetings and deliberations

The meetings with experts were earlier planned as National consultative meetings in various parts of the country i.e. Delhi, Kolkata, Mumbai, Chennai and Guwahati. The initial few meetings were held face-to-face in DHR/ ICMR. However, due to the onset of Covid-19 pandemic, from April 2020 the subsequent meetings were conducted through online video conferencing. The meetings were conducted according to the therapeutic categories and the subject experts were invited accordingly. To reiterate the concept and principles of NLEM, a briefing session was organized before the start of each consultation meeting, highlighting the need for NLEM, its philosophy, principles and practices to be kept in mind while deliberating the matter. Key considerations for framing NLEM 2022 were explained to the experts with the help of real-world

examples.

Four consultative meetings were held with pharmaceutical industry, NGOs, pharmaceutical associations along with subject experts to get their inputs. The dates and venue of these consultation meetings are given below:

- 25.07.2019 at Department of Health Research, MoHFW, Delhi
- 04.11.2019 at Department of Health Research, MoHFW, Delhi
- 17.08.2020 at Indian Council of Medical Research, Delhi
- 19.02.2022 at Indian Council of Medical Research, Delhi

The committee received more than 60 representations from institutions, industry associations, pharmaceutical companies, NGOs, as well as individual experts. All these representations were carefully considered and deliberated upon.

Proceedings of all the meetings were audio recorded after obtaining verbal consent. The recordings have been archived. More than 130 meetings were held subject wise and therapeutic category wise in which 120 meetings were expert group meetings, 4 national stakeholders' consultation meetings, 8 SNCM meetings and 18 drafting group meetings.

**Evidence Based Additions and Deletions**

The experts were requested to support their recommendations with suitable evidence. If their opinion was based on their clinical judgment and experience, it was recorded as such. A summary sheet providing evidence-based justification for each addition and deletion of medicines listed in the NLEM was documented.

# The process of revision of NLEM 2022

**Constitution of the Standing National Committee on Medicines by Ministry of Health and Family Welfare to review and revise NLEM 2015**

Chairman: Prof. Balram Bhargava, Secretary, DHR & DG, ICMR
Vice Chairman: Prof. Y.K. Gupta, Formerly HOD, Pharmacology, AIIMS, Delhi

**Outline of NLEM revision process**

Review of criteria for inclusion/ deletion of medicines
Identification of subject experts from across the country
Reorganization of therapeutic categories

**Consulting various source documents of medicines**

Source documents of medicines with dosage forms and strengths referred to:

- NLEM 2011 and 2015
- WHO EML 2019 and EMLc 2019
- National Formulary of India 2016
- National Health Programmes
- Standard Treatment Workflows, Treatment guidelines of associations and professional bodies
- Newsletters of Pharmacovigilance Programme of India

**Stakeholders' meetings with officials from:**

Ministry of Health and Family Welfare, Ministry of AYUSH, Department of Consumer Affairs, Department of Pharmaceuticals, NPPA, CDSCO , IPC, NGOs, pharmaceutical industry, associations and patient groups

Stakeholders were informed through print media and website of ICMR, IPC and CDSCO. Total four stakeholders meetings were held.

Online/offline submissions from stakeholders were received.

**Therapeutic category wise meetings of experts**

Video conferencing/face to face meetings
Total meetings more than 130
Audio-visual recording and minutes have been archived.

**Meetings of SNCM Core Committee** to review the recommendations of all subject experts meetings, deliberations on the submissions of NGOs, pharmaceutical associations, patient groups and other stakeholders.

**Drafting the report of NLEM 2022**
**Submission to the Ministry of Health and Family Welfare**

## General Considerations for preparing the NLEM 2022

### Essentiality

Any medicine may be necessary or even critical for specific disease conditions for which it is indicated. However, in the context of national list of essential medicines, a medicine should be essential considering the population at large and should fit into the definition of essentiality of a medicine. 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 not necessarily means that if a particular drug is not included in the list of essential medicines, it is not necessary in therapeutics. Non-inclusion of such drugs in the list of essential medicines does not undermine their importance in therapeutics.

Some examples are:

- Plerixafor is the medicine which is used for stem cell mobilization prior to stem cell transplant. Since the drug serves a very small group of population, it may not find a place in the national list of essential medicines.
- For the prevention of vertical transmission of *Toxoplasma gondii* infection, spiramycin is the only treatment available. However, toxoplasmosis is relatively less prevalent and hence, spiramycin is not an essential medicine in the Indian context.
- For the treatment for diabetes insipidus, desmopressin is required but considering the rarity of the condition it may not find a place in the essential medicines list.

For effective healthcare delivery, the NLEM can serve as a reference document for medicines of national priority so that administrative, scientific, pharmaceutical and logistic efforts are appropriately directed towards optimum utilization of the available resources.

**Efficacy and Safety**

The most important parameters for considering essentiality of a medicine are efficacy and safety. For a medicine to be considered essential, it should have an unequivocal evidence of efficacy and wider acceptance in medical science. It should also 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.

**Considerations of comparative costs of treatment**

This issue is important when selecting from more than one medicine from the same therapeutic category which do not differ significantly in their efficacy and safety. Sometimes per unit price of a medicine may be more but it may be prescribed at a lesser frequency. Other costs involved in drug administration such as cost of injection, hospitalization if required, etc., may differ between two equi-effective medicines of the same category. Thus, the total price of the treatment schedule including direct and indirect costs should be taken into consideration and not only the unit price of a medicine.

**Feasibility in the context of advantage in storage**

An essential medicine should be available in a form in which adequate quality can be assured throughout its shelf-life under recommended storage conditions. However, it may not always be feasible to ensure the recommended storage conditions for a particular medicine. In such conditions, alternate forms of the medicine suited to the available storage conditions should be considered. For example, liquid formulation of antisnake venom is cheaper and equi-efficacious as compared to the lyophilized preparation albeit requiring cold chain, which is sometimes difficult to maintain in its distribution channel. On the other hand, lyophilized polyvalent offers the advantage of longer shelf-life and less

stringent storage requirements. Therefore, both lyophilized and liquid formulations have been included in the list.

**Consideration of inclusion of Fixed Dose Combinations (FDCs)**

In essential medicines list as a principle, single medicines are preferred. An FDC is included only if the combination is rational and has a proven advantage in terms of improved therapeutic efficacy, safety and compliance or in decreasing the emergence of drug resistance. For example, FDCs for the treatment of diseases such as malaria and Human Immunodeficiency Virus (HIV) infection/ Acquired Immunodeficiency Syndrome (AIDS) offer dual advantage of improving therapeutic outcomes and limiting the emergence of antimicrobial resistance. In these therapeutic categories, certain FDCs have been considered as essential and are included in the list. In certain other cases, FDCs are required to achieve optimal therapeutic efficacy, and are thus considered essential. For example, FDCs of levodopa and carbidopa, and amoxicillin and clavulanic acid.

FDCs which do not have strong published evidence of their merit in therapeutics have not been included.

**High Sales of a medicine does not necessarily indicate essentiality**

The high sales of a drug with reference to Moving Annual Total (MAT) volume and MAT value do not necessarily mean essentiality. The sale of a medicine is likely to be impacted by factors such as market forces, physician's preferences, and influence 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. Sometimes, such FDCs may not even be rational and need attention of regulator to assess their continued

marketing. Such formulations do not meet the essentiality criteria and therefore have not been included.

**Hierarchical Healthcare Structure in India**

In India, the health care system is categorized as 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, medicines for critical care settings, for specialized treatments like organ transplantation and for inpatient setup.

At the primary care center, the health care facilities do not carry out certain sophisticated therapeutic interventions (such as dialysis, neonatal intensive care, palliative care, treatment of malignant diseases) and therefore do not have such special facilities and personnel. Therefore, such medicines are not essential for primary care however; they may essentially be required at secondary and tertiary healthcare level. Similarly, use of high-end antimicrobials, medicines for conditions like systemic fungal infections, resistant tuberculosis, resistant malaria, kala-azar, etc., will be required more in secondary and tertiary care. Thus, the essentiality of medicines also depends upon the hierarchy of the health care system, and hence there is need to stratify the recommendation for inclusion of medicines at:

(P) = Primary care facility

(S) = Secondary care facility and

(T) = Tertiary care facility

## Specific issues addressed in NLEM 2022

### Dosage form of the medicines

Formulation of medicines may be available in different dosage forms as under:

- **Oral solid dosage** forms which include tablet, capsule, sachet, granules, powder, etc.
  - Tablets which include conventional, enteric coated, film coated, sugar coated tablet, etc.
  - Capsules include hard gelatin and soft gelatin capsules. (Unless specified, capsules mentioned in the NLEM are considered as hard gelatin capsules).
- **Oral liquid dosage** forms include syrup, suspension, elixir, etc.
- **Injectable dosage** forms include conventional liquid injection or powder for injection, as well as delivery system like depot, liposomal/ lipid complex, etc.
- **Topical dosage forms** include ointment, cream, lotion, drops etc.

When the solid oral dosage form of a medicine is available both as tablet and capsule, the more commonly available dosage form (between tablet and capsule), is listed in NLEM. If both the formulations i.e. tablet and capsule are available in almost equal proportions, the formulation as included in Indian Pharmacopoeia, has been listed in NLEM. For example, ibuprofen which is included in IP as tablet, is listed in NLEM as tablet though it is also available as capsule. Similarly, tramadol is mentioned in IP as capsule, but is also available as tablet. In NLEM, it has been listed as capsule only. If more than one solid oral dosage form is mentioned in IP, the more commonly used form is listed in NLEM.

Oral liquid formulations (syrups, suspensions, solutions, etc.) are listed in the NLEM as oral liquid unless the specific formulations which require identification such as – doxycycline, amoxicillin (A) + clavulanic acid (B) have been included as dry syrups. Similarly, many medicines intended for topical use are available as cream, ointment, lotion, etc. If the formulation is included in the IP, the same dosage form as mentioned in IP is listed in NLEM. For example, fusidic acid and silver sulfadiazine are available as cream and ointment, but only cream is mentioned in IP. Hence, in NLEM they are listed as cream. Where, more than one dosage form is mentioned in IP, the more commonly used form is listed in NLEM. However, in case the medicine is not included in IP, the commonly available form is mentioned in NLEM.

For pricing and policy decisions, only the similar dosage forms of a medicine should be grouped together. However, if different technology is involved, which confers significant difference in pharmacokinetics/ pharmacodynamics/ efficacy/ safety over the dosage form mentioned in the list, such technologically different dosage forms should not be grouped together. They should be considered separately for purposes of pricing, procurement, etc.

Any dosage form of a medicine other than that included in NLEM but in same strength and route of administration, which does not demonstrate significant difference in terms of pharmacokinetics/ pharmacodynamics/ efficacy /safety over the dosage form mentioned in the list, should be considered as included. To elaborate, if tablet is included, other oral solid dosage form such as capsule is considered as included. However, such different dosage forms should be considered differently for purposes of procurement policy, pricing etc. This principle also applies to all other dosage forms e.g. oral liquid dosage forms, injectables, topical dosage forms etc.

**Strengths of a Medicine**

Formulations of a medicine are usually available in many strengths. The committee deliberated that where more than one strength(s) is/ are available, the strength(s) which is/ are appropriate and meet the need of most, are to be considered for inclusion in the NLEM. Some strengths of a particular formulation, presently available in the market, do not appear to be appropriate or not commonly required, have not been considered for inclusion in NLEM.

**Where multiple salts of medicines are available**

The committee decided that in general, medicines should be mentioned in the NLEM in terms of their active moieties, without mentioning the salts. In case, a medicine is available in more than one salt without any significant difference in potency/ pharmacokinetics/ pharmacodynamics/ efficacy-safety profile aspects, it indicates that these salts are therapeutically similar. Therefore, all salts of such medicines with specified dosage form and strength are considered included in NLEM 2022. For example, diclofenac is available as diclofenac sodium or diclofenac potassium and there is no significant difference in the above-mentioned aspects, between the two salts. Hence, mention of only diclofenac implies that both its sodium and potassium salts are included and it suffices for the purpose of procurement and other policy decisions.

However, in case, where the different salts of a medicine have significant difference in potency/ pharmacokinetics/ pharmacodynamics/ efficacy-safety profile, the medicine has been mentioned in the list with respect to its specific salt. In case of topical betamethasone, its valerate salt has been specifically mentioned, because it has lower potency and has fewer systemic adverse effects as compared to its dipropionate salt.

**Isomeric forms wherever applicable**

Different isomers of a molecule may differ with respect to potency/ pharmacodynamics/ safety-efficacy profile. For example, S-amlodipine is an optical isomer of amlodipine. These two forms have been considered as separate entities and approved as two different medicines. Therefore, inclusion of amlodipine in NLEM does not imply that S-amlodipine is also included in NLEM.

**Prodrugs/ Analogues / Derivatives of medicines wherever applicable**

Prodrugs/ analogues/ derivatives of one active moiety are available as different medicines. They may differ with respect to potency/ pharmacokinetics/ pharmacodynamics/ safety-efficacy profile. For example, valganciclovir which is a prodrug of ganciclovir should be considered differently from ganciclovir for the purpose of pricing, policy, etc. Similarly, oxcarbazepine is a derivative of carbamazepine and both oxcarbazepine and carbamazepine have been considered and licensed as different medicines. Inclusion of carbamazepine in NLEM does not imply that oxcarbazepine is also included. Thus, wherever, such different forms exist, which have been considered as different entities and licensed as different medicines, inclusion of one form of such medicines in NLEM will not automatically imply inclusion of other forms.

**Biological Products**

Vaccines, sera and immunoglobulins are complex biological products, which may be manufactured from various sources, by using different processes and technologies. In such cases, irrespective of variation in source, composition, or strengths, all the products of the same vaccine/ sera/ immunoglobulin, as approved by licensing authority are considered as included in NLEM. However, considering the source, process, technology and other relevant aspects, different products of a biologic should be considered differently by the user.

**Medicines under patent protection**

Most of the medicines that are listed in the NLEM are off-patent. The generic version of the drugs which after patent expiration become cheaper because of market competition. In addition, market availability of such medicines is improved given the multitude of manufacturers.

Whether a drug which is under patent protection can be included in NLEM, the issue was deliberated at length in the stakeholders' meeting where the representatives of industry, academia, Department of Pharmaceuticals (DoP), NPPA, ICMR, Directorate General of Health Services (DGHS) were present. It was appreciated that new drug development is a complex, lengthy, expensive and risky process and the innovator company invests significant amount of capital, time and expert human resource for the development of a new molecule. The committee deliberated the issue whether a new patented drug to be considered essential or not. This needs to be determined in individual cases with consideration of several aspects like essentiality criteria for inclusion /exclusion, need of such drug in Indian scenario, urgency, special situations like public health emergencies, etc. The committee was of the opinion that, even when a drug is patented, if it meets the requirements of essentiality from public health perspective, the drug may be considered 'essential' and included in the list. This issue has been considered in the past on the same lines and sofosbuvir which is a patented drug was listed in NLEM in 2015, considering that the drug met all the criteria of essentiality in view of its favourable safety, efficacy profile and unmet therapeutic needs for hepatitis C patients in the country. This principle is in line with WHO principles[2]. Based on this principle, the patented medicines like bedaquiline, delamanid, dolutegravir, etc. have been considered essential and included in the NLEM 2022.

[2] https://www.who.int/healthsystems/topics/health-law/chapter15.pdf

**NLEM and the need to encourage innovations**

Considering the huge disease burden in India, research and development is of paramount importance for bringing new medicines for the patients. Discovery and development of new drug molecules is a complex, knowledge intensive activity requiring involvement of expertise from various fields, considerable time and resources. However, Indian pharmaceutical industry being strong in manufacture of generic medicines and Novel Drug Delivery Systems (NDDS) should be encouraged for innovations including incremental innovations in therapeutics and medicine.

The committee deliberated in detail about the issue of inclusion of improved formulations of a medicine developed through radical/ incremental innovation involving technology. The committee considered that such formulations including novel drug delivery systems like lipid/ liposomal formulations, modified release formulations of a medicine, which are developed to overcome certain disadvantages associated with the use of conventional formulations, will be considered included only if specified in the list against the medicine.

An innovation could be an incremental innovation leading to some ease of administration improving compliance or better packaging for stability; or it could provide a significant therapeutic advantage in drug delivery system, significant reduction in the cost of therapy, significant reduction in adverse effects. Whereas minor incremental innovation may not merit separate class of drug in NLEM, but the significant advantage should entitle them to be considered as a separate class. The differential pricing policy will promote innovation and help the pharmaceutical sector of India to remain contemporary to the world's pharmaceutical sector.

**Market availability of the formulations across the country**

The availability of medicines listed in National List of Essential Medicines at all times and all places needs to be ensured. From the different feedbacks of NLEM 2015, it was noted that some strengths/ formulations of medicines have very little availability in the market. This information was also received from NPPA. An intense exercise was conducted to further confirm the availability of these medicines and their formulations across the country. The information regarding availability was also gathered from doctors of primary, secondary and tertiary care hospitals across the country. The medicines which were poorly available or unavailable were deliberated by experts for their essentiality.

Based on deliberation, many formulations which were present in 2015 and are now not available in the market or have very poor availability, and their alternative dosage form and strength are available have been deleted. For example – sodium thiosulphate injection 100 mg/mL, morphine tablet 20 mg etc.

**National List of Essential Medicines 2022 and Anti-microbial Resistance**

Management of infectious diseases is heading from a pre-antibiotic era to a post-antimicrobial era due to the threat of antimicrobial resistance. Tuberculosis has gone from drug sensitive to isoniazid – resistant to multidrug resistant (MDR) to extensively resistant (XDR). Other bacterial infections have progressed from being penicillin sensitive to penicillin resistant to even carbapenem resistant.

Most of the old antimicrobials have increasingly become ineffective e.g. tetracycline and nalidixic acid are effective in only 57% and 50% cases of *Shigella* respectively. Similarly, *Pseudomonas* has become resistant to amikacin

and ciprofloxacin in 20% cases (4)[3,4.] Even relatively newer drugs like piperacillin – tazobactam, cefepime and meropenem are not effective in 28.6%, 21.8% and 8.5% cases, respectively (5)[3,5.] It is also considered that the anti-microbial resistance is becoming a silent pandemic which if not addressed effectively today, will be catastrophic tomorrow.

Several antimicrobial agents such as tetracycline, chloramphenicol, streptomycin, penicillin was first line of treatment at one point of time. These once very useful antimicrobial agents gradually became resistant and almost ineffective in most of the conditions in which they were once drugs of choice. Development of antibiotic resistance is dynamic and at times a swift process. For example, tetracycline resistance to *Vibrio cholera* increased from 1-76% between 2004 to 2007 before decreasing to 50% in 2009 [6]. Even after widespread development of resistance, some microorganisms may still remain susceptible and hence, this antibiotic may retain its effectiveness in certain conditions. For example, tetracycline is still effective in rickettsial infections, as is chloramphenicol in conjunctival infections. However, their clinical utility is limited and therefore, these antimicrobials were deleted from NLEM 2011 (tetracycline, clarithromycin, ketoconazole, mebendazole, norfloxacin) and NLEM 2015 (sulphadiazine, ofloxacin, nelfinavir).

An expert group from different disciplines i.e. medicine, pediatrics, neonatology, pulmonology, critical care, microbiology, community health physicians from different parts of the country and health programme officials met on several occasions and deliberated the issue of growing anti-microbial

[3] Kakkar M, Walia K, Vong S, Chatterjee P, Sharma A. Antibiotic resistance and its containment in India BMJ 2017; 358 :j2687 doi:10.1136/bmj.j2687.
[4] Bhattacharya, K., Kanungo, S., Sur, D., Lal Sarkar, B., Manna, B., Lopez, A. L., Bhattacharya, M., Nandy, S., & Kumar Niyogi, S. (2011). Tetracycline-resistant Vibrio cholerae O1, Kolkata, India. Emerging infectious diseases, 17(3), 568–569. https://doi.org/10.3201/eid1703.101176.
[5] Vazquez-Guillamet MC, Vazquez R, Micek ST, Kollef MH. Predicting Resistance to Piperacillin-Tazobactam, Cefepime and Meropenem in Septic Patients With Bloodstream Infection Due to Gram-Negative Bacteria. Clin Infect Dis. 2017 Oct 30;65(10):1607-1614. doi: 10.1093/cid/cix612. PMID: 29020294.
[6] Antiobiotics. (2021). Retrieved 6 May 2021, from https://www.nhsinform.scot/tests-and-treatments/medicines-and-medical-aids/types-of-medicine/antibiotics

resistance in India. The inputs from other stakeholders were also considered. The issue was discussed in the context of the AWaRe (Access, Watch and Reserve) classification of antimicrobial agents in WHO EML 2021.

A. **ACCESS** – are those drugs "that have activity against a wide range of commonly encountered susceptible pathogens which also showing lower resistance potential than antibiotics in the other groups. Selected access group antibiotics are recommended as essential first or second choice empiric treatment options for infectious syndromes as reviewed by the Expert Committee of EML of WHO and are listed as individual medicines on the Model Lists to improve access and promote appropriate use. They are essential antibiotics that should be widely available, affordable and quality assured."

From the 20 antibiotics listed in the Access Category of WHO EML 2021, the following 16 antimicrobial agents are present in the NLEM 2021:

- Amikacin
- Amoxicillin
- Amoxicillin + clavulanic acid
- Ampicillin
- Benzathine benzylpenicillin
- Benzylpenicillin
- Cefazolin
- Clindamycin
- Cloxacillin
- Doxycycline
- Gentamicin
- Metronidazole
- Nitrofurantoin
- Phenoxymethylpenicillin
- Procaine benzylpenicillin
- Sulfamethoxazole + trimethoprim

B. **WATCH** – are those drugs "that have higher resistance potential and includes most of the highest priority agents among the Critically Important Antimicrobials for Human Medicine and/or antibiotics that are at relatively high risk of selection of bacterial resistance. These medicines should be prioritized as key targets of stewardship programmes and monitoring. Selected Watch group antibiotics are recommended as essential first or second choice empiric treatment options for a limited number of specific infectious syndromes and are listed as individual medicines on the Model Lists." of WHO.

From the 11 antibiotics listed in the Watch Category of WHO EML 2021, the following 11antimicrobial agents are present in the NLEM 2022:

- Azithromycin
- Cefixime
- Cefotaxime
- Ceftriaxone
- Cefuroxime
- Ciprofloxacin
- Clarithromycin
- Meropenem
- Piperacillin + Tazobactam
- Vancomycin
- Ceftazidime

C. **RESERVE** – are those drugs "that should be reserved for treatment of confirmed or suspected infections due to multi-drug-resistant organisms. Reserve group antibiotics should be treated as "last resort" options. Selected Reserve group antibiotics are listed as individual medicines on the Model

Lists when they have a favourable risk-benefit profile and proven activity against "Critical Priority" or "High Priority" pathogens identified by the WHO Priority Pathogens List, notably carbapenem resistant Enterobacteriaceae. These antibiotics should be accessible, but their use should be tailored to highly specific patients and settings, when all alternatives have failed or are not suitable. These medicines could be protected and prioritized as key targets of national and international stewardship programmes involving monitoring and utilization reporting, to preserve their effectiveness."

From the 7 antibiotics listed in the Reserve Category of WHO EML 2021 the following 1antimicrobial agents are listed in the NLEM 2022:

- Linezolid

The antimicrobial agents which are useful in majority of the situations/ conditions to combat the common infections have been listed in NLEM. The antimicrobial agents which, in recent years, are showing development of resistance but may still be useful in many situations have been retained in NLEM.

It was argued in the meetings that, many antimicrobial agents have shown pattern of high resistance. Some antimicrobial agents have shown resistance, albeit in limited studies, which may not be truly representative of the country due to huge variability in the demography, and also may not represent the difference / variability in resistance pattern in rural, semi urban and urban populations. There may also be differences in the level of healthcare delivery in the primary, secondary and tertiary setups.

The committee also noted that certain microorganisms have been reported to rapidly develop resistance against specific antimicrobials e.g. *Pseudomonas* resistance in 42% of cases against piperacillin – tazobactam and in 50% of cases

against meropenem[7]. This observation is based on a few studies and the data may be skewed towards the urban tertiary care setups. The committee decided that despite increasing incidence of resistance, some of these drugs are still life-saving and thus essential in the treatment of serious bacterial infections, for example, penicillin G and V in sexually transmitted infections[8].

It was argued by some experts that antimicrobials for which some studies show high resistance should be deleted from the NLEM. This will reduce the access to these antibiotics thus reducing their overuse and might help in preserving their effectiveness and perhaps reversing their resistance pattern. However, majority of the experts opined that making such antimicrobial agents less available by removing them from the NLEM may in fact deprive the patients having serious bacterial infections of the beneficial effects of these drugs. Therefore, the committee opined that a strong antimicrobial stewardship programme and continuous education to the prescribers /doctors would be a better and effective strategy rather than restricting their availability. With this background, the drugs like piperacillin – tazobactam have been retained in NLEM 2022.

In the Indian context, although antimicrobials are not classified as Access, Watch and Reserve in NLEM 2022, but the philosophy similar to WHO AWaRe antimicrobial classification was kept in mind. The antimicrobial agents which have less possibility for development of resistance and are commonly needed should also be judiciously prescribed. These drugs can be considered akin to ACCESS category in WHO EML 2021.

The other group of drugs which have high potential for development of resistance should also be prescribed cautiously. Continuous education regarding appropriate antibiotic prescribing and use in a correct manner (dose, frequency,

[7] Kakkar M, Walia K, Vong S, Chatterjee P, Sharma A. Antibiotic resistance and its containment in India BMJ 2017; 358 :j2687 doi:10.1136/bmj.j2687.
[8] Antibiotics. (2021). Retrieved 6 May 2021, from https://www.nhsinform.scot/tests-and-treatments/medicines-and-medical-aids/types-of-medicine/antibiotics

duration) must be emphasized in undergraduate and post graduate curriculum, as well as in routine clinical practice. The resistance pattern of these antimicrobial agents should be carefully monitored and their use should be appropriately tailored. These drugs can be considered akin to WATCH category in WHO EML 2021.

Special emphasis is being made on the philosophy of classification of WHO reserving antibiotics like linezolid in specific conditions where their use is strongly justified and should be given only by the concerned specialist. Their prescription should also be governed through appropriate, strong oversight programme of hospitals. Their availability should also be strongly regulated. These can be considered akin to the RESERVE class of drugs in WHO category.

The antimicrobial resistance is a dynamic process and depends on several factors namely, genetic mutation in bacteria, overuse/ misuse (dose, frequency, duration, etc), inadequate evidence for use in prophylaxis, use in viral conditions like, common cold, flu and most upper respiratory tract infections[9,10.]

In current times of COVID-19, misuse and overuse of antimicrobial agents is being witnessed, with little/no evidence of benefit. Making antimicrobial agents unavailable in the market, perhaps, is not an appropriate strategy. Rather, continuous sensitization of prescribers, strict prescription audit and antimicrobial stewardship programmes will go a long way in discouraging irrational antimicrobial prescribing and prevent antimicrobial resistance.

Thus, to preserve the therapeutic effectiveness of existing antimicrobial agents, a multi-pronged approach comprising of education, audits, surveillance and regulatory oversight is essential.

[9] Shiley, K. T., Lautenbach, E., & Lee, I. (2010). The use of antimicrobial agents after diagnosis of viral respiratory tract infections in hospitalized adults: antibiotics or anxiolytics?. Infection control and hospital epidemiology, 31(11), 1177–1183. https://doi.org/10.1086/656596.

[10] Antibiotics. (2021). Retrieved 6 May 2021, from https://www.nhsinform.scot/tests-and-treatments/medicines-and-medical-aids/types-of-medicine/antibiotics

### Fixed Dose Combination (FDC) of Antibiotics

The committee also specifically wanted to highlight the increasing and continued need of educating the healthcare professionals/ doctors against the use of FDCs of antibiotics, unless there is convincing evidence of therapeutic superiority over individual drugs. Although, many antibiotic FDCs with multiple antibiotics, analgesics, vitamins, minerals, etc have been banned by regulator in India, still many combinations with unestablished rationality are available in the market and physicians/doctors tend to prescribe many of these. Though, the committee wishes to publish a list of such irrational FDCs, it is restricting itself because preparation of such a list will require, separate extensive exercise.

## Essentiality of 42 anticancer drugs which were subjected to Trade Margin Rationalization (TMR) by NPPA

### Background of the notification by NPPA, DoP, Govt. of India

Considering the representations and several other issues, the NPPA issued the notification on 27 February, 2019 to put a cap on trade margins of 42 anti-cancer medicines.

The relevant para 9 of the notification is reproduced below:

*"And whereas, considering the **High trade margin** in sale of drugs leading to **high out of pocket expenses** on healthcare, the Government hereby, seeks to undertake the matter of price control through a '**Trade Margin Rationalisation Approach'**. And therefore, in order to bring in regulation of drugs in the 'non-scheduled' segment the Government hereby seeks to undertake a Pilot for Proof of Concept by capping prices of **select Anti-Cancer drugs, identified by the MoHFW** as being essential for the treatment of this disease."*

To further quote relevant para 12, para 13, para 14 and para 15-

*"The NLEM 2015 had 376 medicines out of which 59 drugs are already under the category of Anti-neoplastic/immunosuppressive, Hormones & Antihormones and medicines used for palliative care. Pricing of these medicines are controlled through Drug Pricing Control Order (DPCO) 2013 as amended from time to time."*

*"And whereas, the Expert Committee of Ministry of Health and Family Welfare (MoHFW) after examining in detail, deliberating and considering all available information/data/viewpoints and all relevant options for ensuring affordability of essential drugs to the patients, in case of Anti-cancer Medicines, had recommended 42 Anti-Cancer medicines for price control on pilot basis*

*And accordingly, NPPA had put a cap on trade margin of 30% and directed vide notification, manufacturers to fix their retail price based on price at first point of sale of product (hereinafter referred as Price to Stockist), as formulated in Table A, of the non-scheduled formulations containing any of the 42 drugs vide notification on 27th Feb 2019. The list of the 42 drugs is as below:*

**Table: List of anticancer drugs under TMR by NPPA**

| ***Sl. No.*** | ***Name of the Drug*** | ***Sl. No*** | ***Name of the Drug*** |
|---|---|---|---|
| *1.* | *Azacitidine* | *22.* | *Nilotinib* |
| *2.* | *Bendamustine Hydrochloride* | *23.* | *Plerixafor* |
| *3.* | *Bortezomib* | *24.* | *Carfilzomib* |
| *4.* | *Crizotinib* | *25.* | *Cladribine* |
| *5.* | *Cytarabine* | *26.* | *Triptorelin* |

| | | | |
|---|---|---|---|
| *6.* | *Dasatinib* | *27.* | *Pomalidomide* |
| *7* | *Decitabine* | *28.* | *Osimertinib* |
| *8.* | *Doxorubicin HCI Pegylated Liposomal Injection* | *29.* | *Pegasperagase* |
| *9.* | *Enzalutamide* | *30.* | *Regorafenib* |
| *10.* | *Epirubicin* | *31.* | *Ribociclib* |
| *11.* | *Eribulin mesylate* | *32.* | *Clofarabine* |
| *12.* | *Erlotinib HC* | *33.* | *Sunitinib* |
| *13.* | *Estramustine phosphate* | *34.* | *Olaparib* |
| *14.* | *Everolimus* | *35.* | *Paclitaxel (Protein-bound particles)* |
| *15.* | *Exemestane* | *36.* | *Olaratumab* |
| *16.* | *Fulvestrant* | *37.* | *Cabazitaxel* |
| *17.* | *Irinotecan HCI Trihydrate* | *38.* | *Bevacizumab* |
| *18.* | *Lapatanib* | *39.* | *Lenalidomide* |
| *19.* | *Leuprolide acetate depot for inj* | *40.* | *Pegfilgrastim* |
| *20.* | *Lomustine* | *41.* | *Mitomycin* |
| *21.* | *Mitoxantrone* | *42.* | *Pemetrexed* |

SNCM examined all the 42 drugs under Trade Margin Rationalization (TMR) to assess if they meet the criteria of essentiality. In a series of meetings, with

oncology and related experts from across the country and stakeholders, SNCM deliberated on the abovementioned list of anticancer drugs. The committee agreed on the following criteria to be considered while discussing inclusion of these anticancer drugs in NLEM –

- Unequivocal proof of benefit versus previous comparator.
- Higher priority to drugs that have the potential to cure a fraction of patients versus those that have been proven to only prolong lives in metastatic settings.
- Marginal advantage in limited number of patients.

Further, committee also considered that medicines which are established to have cure rate of >90% for certain cancer even though the incidence of such cancer is low, should be included in the NLEM.

After consultations and detailed deliberations, the following anticancer drugs were recommended for inclusion in NLEM 2022.

- Bendamustine hydrochloride
- Irinotecan HCl Trihydrate
- Lenalidomide

**Assessment of availability and essentiality of specific formulations in NLEM 2015**

The last NLEM was published in 2015 which had 376 medicines and their formulations. The medicines listed in NLEM are referred to as scheduled drugs under Drug Price Control Order (DPCO), 2013 and their prices are fixed by the National Pharmaceutical Pricing Authority (NPPA) using a defined methodology. The NPPA could not fix the price for some formulations of NLEM 2015 as their market data could not be found. This list was shared by

NPPA with SNCM for assessment of their essentiality and availability. The SNCM decided to review each of these formulations considering the following:

- Availability –
  - In the market
  - Through hospital supplies
  - Through National Health Programmes (GOI)
- Essentiality as per eligibility criteria of the NLEM

The following methodology was adopted:

The list was shared with subject experts from different specialities, public health professionals and medical professionals across different parts of the country. A group of experts and officials examined the inputs received and deliberated on the formulations based on the available evidence. In case, a particular dosage form or strength of a drug had limited /no availability, its essentiality was deliberated in detail and decision was taken to retain/replace/delete the drug from the NLEM.

The group consisted of the following:

- Prof. Y.K. Gupta, Vice- Chairman, SNCM
- Prof. Santanu Tripathi, Professor & Head, Department of Clinical & Experimental Pharmacology, School of Tropical Medicine, Kolkata
- Prof. Lalit Gupta, Professor, Dept. of Pharmacology, LHMC, Delhi
- Col. (Dr.) Prafull Mohan, Professor, Dept. of Pharmacology, AFMC, Pune
- Dr. Biswa Mohan Padhy, Associate Professor, Dept. of Pharmacology, AIIMS, Bhubaneswar
- Dr. Pooja Gupta, Associate Professor, Department of Pharmacology, AIIMS, Delhi
- Dr. Ashish Kakkar, Assistant Professor, Dept. of Pharmacology, PGIMER, Chandigarh

**SNCM Secretariat**

- Dr. Monika Pahuja, Scientist – D, Division of BMS, ICMR, Delhi
- Amal Verma, Govind Singh– Technical Assistant

**National Pharmaceutical Pricing Authority (NPPA)**

- Mr. N.I. Choudhary, Advisor
- Mr. Prasenjeet Das, Deputy Director

**CDSCO**

- Mr. A.K. Pradhan, Joint Drug Controller (I)

**IPC, Ghaziabad**

- Dr. Jai Prakash, Senior Principal Scientific Officer

**Programme officers of National Public Health Programmes**

Availability of the formulations was enquired from the following sources:

- National disease control programmes
- Jan Aushadhi stores and pharmacies of various hospitals
- Rate contract, AIIMS, Bhubaneshwar
- DGAFMS rate contract
- Online drug information sources
- Speciality experts from different institutions

The group decided to deliberate and recommend the formulations for retention/deletion based on the following criteria:

a. Specific formulations to be retained in NLEM 2022 on the basis of essentiality.

b. Specific formulations to be deleted because of non-availability/limited availability and non-essentiality in the present context.

c. Specific formulations to be retained because they are listed in various national health programmes and their procurement is done through the programme although these may not be available in the open market.

d. Special formulations like – blood products and other biologicals to be retained as these are supplied through designated supply chain and may not be available in the open market.

It was noted that in some situations there was change in the prescription practices. Such changes may be because of non-availability of certain formulations and/or availability of alternate formulations with claimed ease of administration, better patient compliance and may be influence of sales promotion.

In addition, the group also noted that sometimes, to circumvent the NLEM and subsequent price capping, there may be possibility that alternate formulations may be manufactured and marketed which over a period of time may change the prescribing habit of the practitioners. It was felt that, in order to discourage such practices that dilute the importance and applicability of NLEM in letter and spirit, continuous sensitization of prescribers and treating physicians is required. The Group after due deliberation and consideration of above-mentioned criteria made recommendations as detailed in the table below, for retention/deletion/replacement of the formulations.

It is envisaged that these recommendations will give a message to the stakeholders including the manufacturers as well as the prescribing physicians and policy makers, regulators to make the best use of NLEM. The Group was also of the opinion that such exercise should be undertaken periodically to assess the trend in prescription practices, marketing strategy vis-à-vis the availability of the formulations.

## Assessment of specific formulations listed in NLEM 2015 referred by NPPA for availability and essentiality

| S. No | Details | Total No. | Annexure no. |
|---|---|---|---|
| a. | Specific formulations to be retained in NLEM 2022 on the basis of essentiality. | 18 | 2.1 |
| b. | Specific formulations to be retained because they are listed in various national health programs and their procurement is done through the program although these may not be available in the open market. | 12 | 2.2 |
| c. | Special formulations like – blood products and other biologicals to be retained as these are supplied through designated supply chain and may not be available in the open market | 9 | 2.3 |
| d. | Specific formulations to be deleted because of non-availability/limited availability and non-essentiality in the present context. | 46 | 2.4 |
| | **Total** | **85** | |

**Issue of essentiality of Desferrioxamine referred by NPPA**

The NPPA also referred the case of desferrioxamine powder for injection 500 mg. This is listed in NLEM 2015 under the heading of chelating agent. NPPA informed that it is imported and marketed by only one company and as per the information there is negligible sale in last two years. The committee deliberated on its essentiality and noted the following:

- Desferrioxamine is mainly indicated as iron chelator in thalassemia.
- The numbers of cases of thalassemia in India are 1 lakh and it is an important disease.
- Desferrioxamine is an affordable and time-tested injectable drug. In contrast, the newer oral preparations (Deferiprone and Deferasirox) are relatively expensive.
- There are some patients who show less response to oral chelator and thus, injectable chelator is required.

Drugs listed in the "Prevention and Control of Hemoglobinopathies in India – Thalassemias, Sickle Cell Disease and Other Variant Haemoglobins – 2016", are Injectable – Desferrioxamine and oral preparations of Deferiprone and Deferasirox. In WHO EML 2019 list, deferoxamine injection 500 mg which is same as desferrioxamine powder for injection 500mg is the only preparation that is included for this indication.

The committee noted that injectable desferrioxamine is also indicated in iron overload because of sickle cell anaemia and iron toxicity by iron overload.

After considering the above aspects, the committee opined that for thalassemia programme all 3 drugs are important but for NLEM purpose, only injectable desferrioxamine merits inclusion.

## Important changes in NLEM 2022

### Addition of new sections/sub sections

In consultation with the programme in-charge of National AIDS Control Programme (NACP) the following two sub sections have been added.

### Medicines for treating opportunistic infections in People Living with HIV (PLHIV)

HIV infection leads to AIDS and opportunistic infections are the major cause of morbidity and mortality in such patients, which considerably affect the health and quality of life of such infected people. The common opportunistic infections are tuberculosis, oral candidiasis and diarrhoea etc. The total number of PLHIV in India is estimated around 21.40 lakhs in 2017. Children (<15 years) account for 0.61 lakh while females (15+ years) accounts for 8.79 lakh PLHIV in India[11]. Considering this, a separate sub section – 6.7.5 has been added in the NLEM 2022 for opportunistic infections in PLHIV.

### Additional medicines for syndromic management of sexually transmitted infections

Sexually transmitted infections are commonly associated with HIV infection. After the consultation with the programme officers, a subsection – 6.7.6 of additional medicines for syndromic management of sexually transmitted infections has been added.

### Addition of new section for management of Covid-19 pandemic

January 2020 witnessed the starting of COVID 19 pandemic in India. The symptomatology of the illness caused by this new virus was evolving, the etiopathogenesis was poorly understood and since no available antiviral drug

[11] Chapter - 24 National AIDS Control Organization (NACO) [Internet]. Main.mohfw.gov.in. [cited 9 August 2022]. Available from: https://main.mohfw.gov.in/sites/default/files/24%20Chapter%20496AN2018-19.pdf

was able to successfully contain the virus, no specific guidelines were available. Being a novel pathogen, vaccine was also not available. Soon COVID 19 pandemic turned into a serious public health emergency globally. Initial response was focused on containing the spread by community interventions. Meanwhile, scientific community initiated a massive effort to find out an effective answer for this catastrophic problem.

The research for developing drugs for combating the COVID-19 pandemic could be categorized into following broad areas:

1. **Repurposing of drugs:** Use of established drugs or drugs under development for other indications for the prevention/treatment of COVID-19 infection. This category contained some established drugs albeit for different indications such as hydroxychloroquine (HCQS), ivermectin, azithromycin, doxycycline to name a few. These drugs were tried both for prevention as well as for treatment of COVID 19. Some other drugs approved for other indications (such as baricitinib) were also tried in COVID 19. Extensive multicentric clinical trials (such as SOLIDARITY – (remdesivir, hydroxychloroquine, lopinavir/ritonavir and interferon) were undertaken. Some trials are still continuing, and data continues to emerge. Of these, HCQS was recommended in India as a prophylactic agent (subject to certain conditions). Baricitinib (Janus kinase inhibitor, approved for RA), itolizumab (anti CD 6 Mab, approved for acute psoriasis) Pegylated Interferon alfa-2b Injection (anti-cancer drug) were given approval in India for restricted use under emergency situation in COVID 19. Examples of some other drugs for which several clinical trials have been conducted and are still going on alone or in combination are nitazoxanide, colchicine, etc. Some drugs have also been tried as off label.

2. **Development of new chemical entity (NCE) for COVID 19 treatment based on the etiopathology:** several new chemical entities were also investigated and for some, clinical trials are still ongoing. Favipiravir, remdesivir, 2-Deoxy-D-Glucose, casirivimab and imdevimab Injection (combination therapy) and bamlanivimab and etesevimab injection (combination therapy), have received approval for restricted use under emergency situation in India.

The conditional approval/emergency use approval with respect to above drugs and some other drugs (not mentioned in para 1 and 2 above) were guided on the basis of potential benefit exceeding the potential risk (risk benefit ratio) on the basis of the available in vitro, non-clinical and clinical trial data. The data of all these medicines is still not conclusive and complete in the regulatory perspective. Thus, specific precautions and emphasis on post marketing surveillance (PMS) studies have been advised.

The Pharmacovigilance Program of India has developed a specific Adverse Drug Reaction (ADR) reporting form for COVID-19 drugs. The Ministry of Health and Family Welfare has also constituted a national pharmacovigilance committee under the chairmanship of Prof. Y.K. Gupta for monitoring of ADRs of drugs used in COVID-19. The collection, collation, and causality assessment of the ADRs collected from different centers is ongoing. The safety and efficacy data regarding these interventions are still emerging and their exact status in treating COVID-19 will become clear with completion of trials, analysis of data and meta-analysis.

Therefore, the committee was of the opinion that in absence of unequivocal evidence of efficacy and safety, the medicines mentioned above do not pass the muster of 'essentiality' and hence not recommended for inclusion in the NLEM 2022.

3. **Management of pathophysiological phenomenon associated with COVID-19 infection (such as cytokine storm, coagulopathy, inflammatory response etc.).** In this category some drugs such as steroids, Low Molecular Weight Heparin (LMWH) and tocilizumab are being extensively used. Among them there is strong evidence regarding the use of steroids and LMWHs in improving clinical outcomes. Along with medical oxygen and antipyretics, these therapeutic interventions have a clear role in COVID-19 management. These four medicines are already included in NLEM 2022 in other therapeutic categories. Considering the above aspects, the committee recommended that these interventions meet the criteria of essentiality of COVID-19 management and accordingly such medicines have been included in a separate section of COVID-19 category in the list.

   Other drugs from para 1 and 2 shall be added to this category once more convincing data is available. Extensive research and development activities are ongoing all over the world for finding reliable/evidence-based medicines for COVID 19. As and when such convincing data for specific medicines is available, they will be considered for inclusion based on the criteria of essentiality.

4. **Use of some drugs without unequivocal evidence** – Some medicines have been used in COVID-19 patients with the expectation/ inconclusive evidence to offer some advantage such as, antiviral, anti-inflammatory and immune boosting. These medicines are already in use for other indications; examples are zinc, vitamin cholecalciferol, etc. The committee did not find evidence for them to be included in NLEM.

5. **Development of COVID-19 vaccine** – It has been another massive global effort to develop COVID-19 vaccines to fight the COVID-19 pandemic. As on date five COVID-19 vaccines have been approved in India for restricted

use under emergency situation (COVAXIN, Covishield, Sputnik V, MODERNA and Johnson & Johnson). All available COVID-19 vaccines have established their protective effect and also, favorable risk-benefit ratio. However, factors such as duration of protection, protection against various mutants, requirement of boosters, use in special population and longterm sequelae of vaccination are yet to be established with these vaccines. Considering these aspects, the committee was of the opinion that with availability of further long-term efficacy and safety data, these vaccines may be considered for inclusion in future.

Some medicines have however been considered essential for supportive management of COVID and accordingly, a separate section containing the list of such medicines has been added in the NLEM 2022.

On the basis of definitive evidence for benefits the following drugs have been listed in the COVID-19 category in NLEM 2022: Paracetamol, Methylprednisolone, Dexamethasone, Enoxaparin and Oxygen. All these drugs are also listed in other indications.

The committee also recommended that to encounter public health emergencies in future for such pandemic, government research bodies (such as ICMR) articulate suitable, flexible recommendations on the basis of emerging data. This way, medical response to emergencies is likely to be more responsive and quicker.

## Consideration of immunotherapeutic agents for cancer

Immune checkpoint inhibitors represent an important development in cancer immunotherapy. Anti-CTLA-4 monoclonal anti-body ipilimumab has been found to be useful in advanced melanoma. Anti-PD1 monoclonal antibodies, nivolumab and pembrolizumab, are other immune checkpoint inhibitors that have demonstrated higher efficacy than conventional anti-cancer drugs in clinical trials for a variety of advanced solid tumors including melanoma, non-small cell lung carcinoma and renal carcinoma. These studies have indicated that the enhancement of anti-cancer immunity by controlling the immune suppressive environment within the cancer tissues is important for the development of cancer immunotherapy.

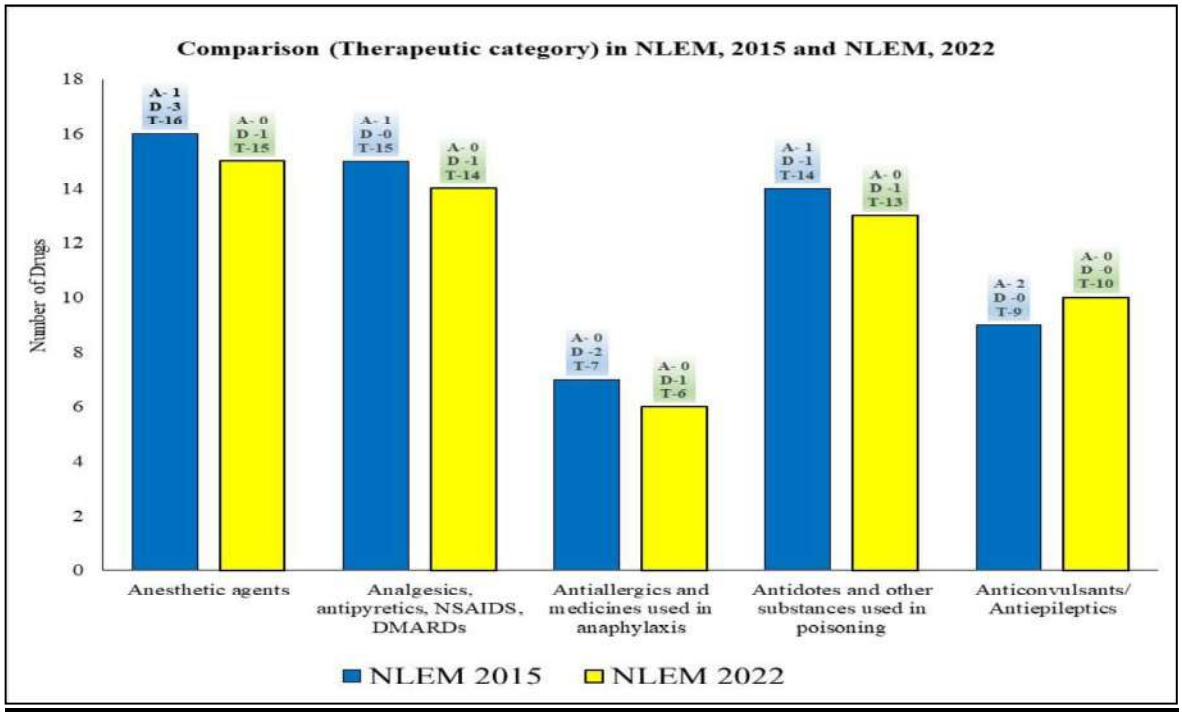
The committee deliberated in detail the immunotherapeutic agents for the treatment of various malignancies. It was noted that immunotherapy is useful as a therapeutic tool mainly in renal cell cancer, head and neck cancer, bladder cancer and lung cancer. The immunotherapeutic agents are used only in very limited cases where the other anti-cancer agents have failed. However, the cost of immunotherapy is exorbitant and overall therapeutic response is less predictable. Several clinical trials are still ongoing to demonstrate their efficacy in different stages of cancer patients.

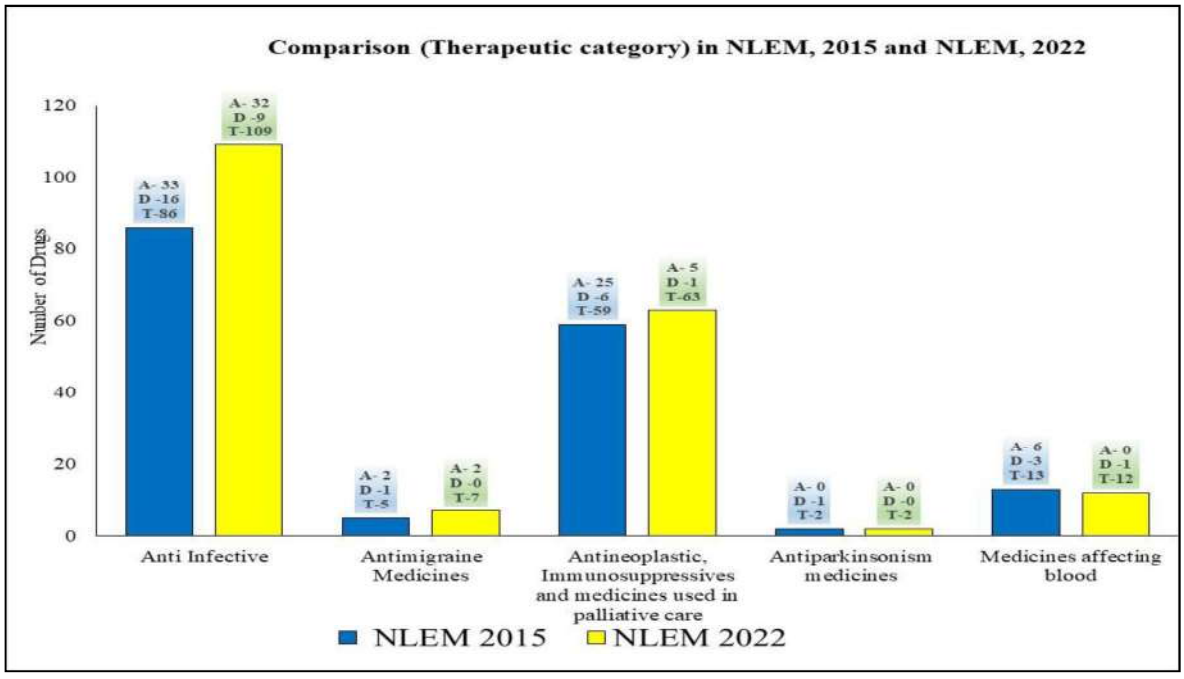
Targeted oncology therapies are suitable for a specified and small subgroup of cancer patients. In these patients, presence of specific genetic markers is often required for predicting their response to the treatment. This was considered an additional challenge in the use of certain targeted oncology therapy in India.

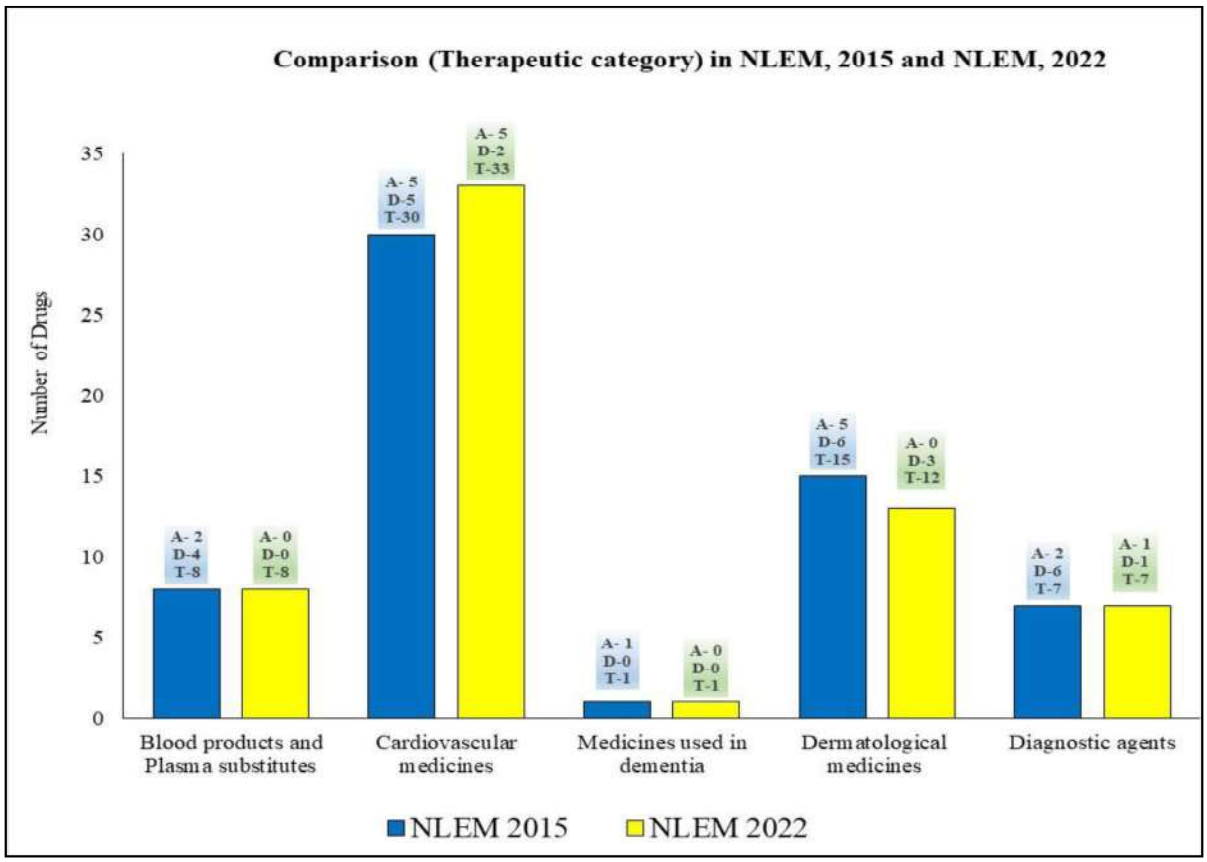
Considering the above aspects, the experts including oncologists were unanimously of the opinion that, as on date immunotherapeutic agents for

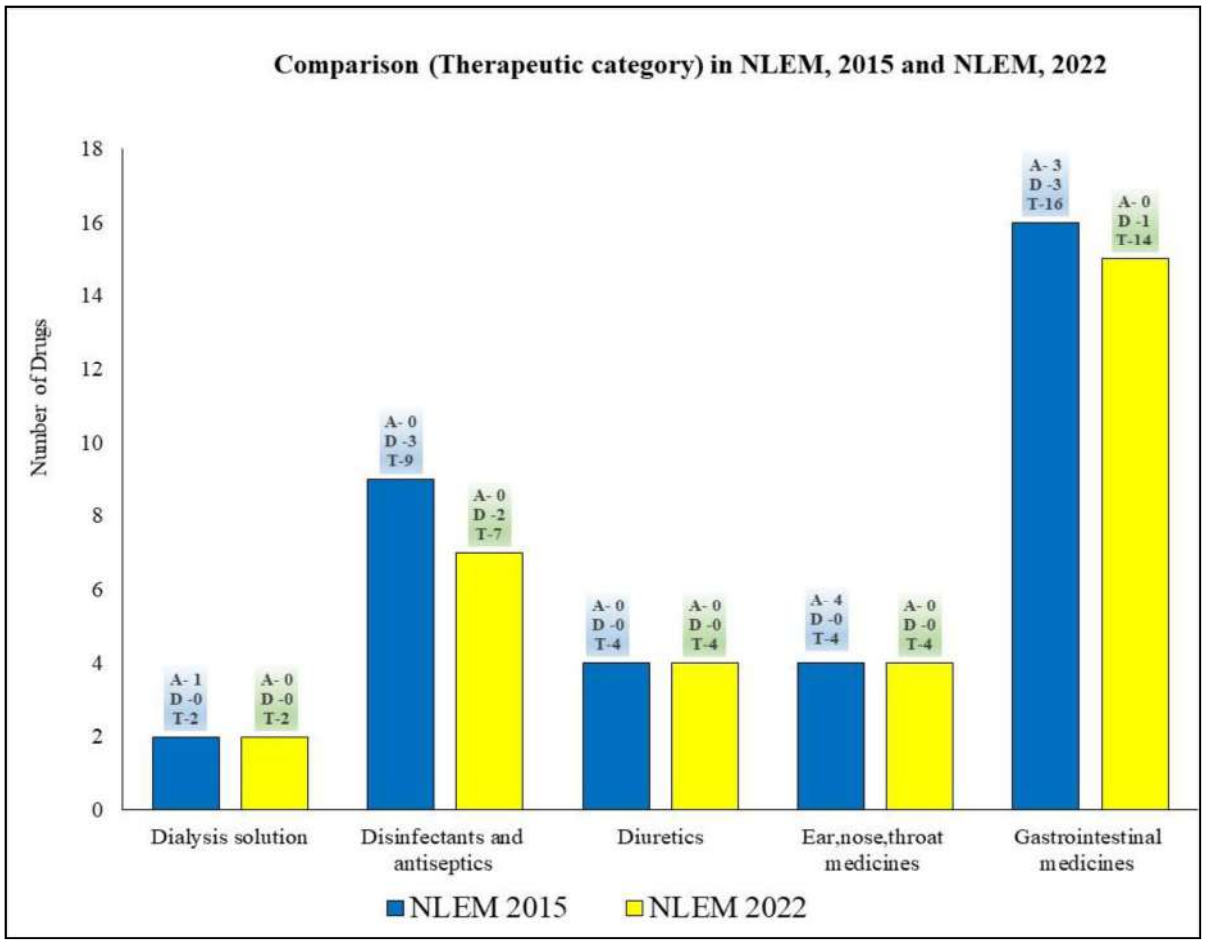
cancer do not meet the criteria of their usefulness for majority of cases of cancer patients, risk benefit ratio, cost- effectiveness, established therapeutic efficacy, availability in India and hence such immunotherapeutic agents are not included in NLEM at present.

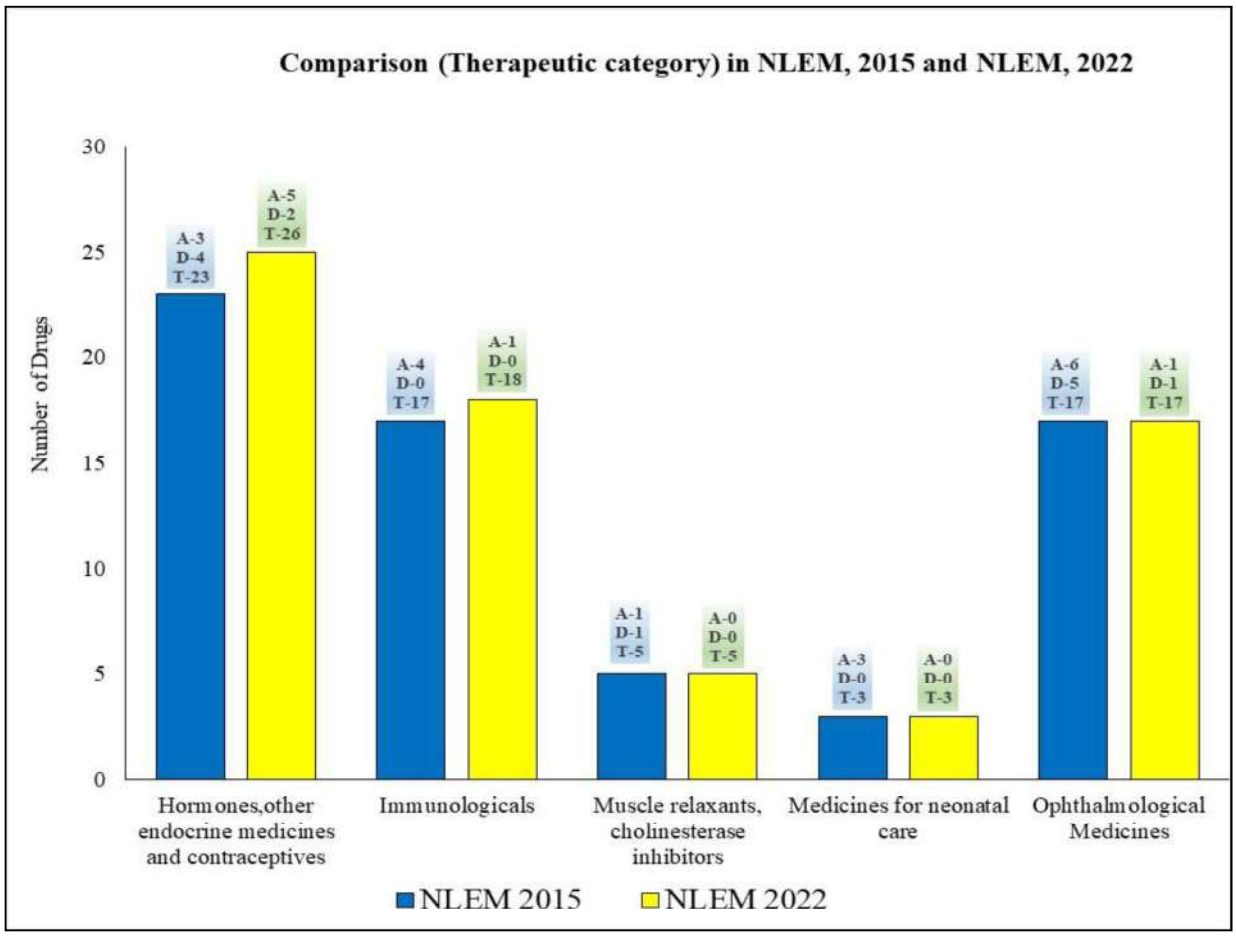
**Graphical representation of addition and deletion of medicines in each therapeutic category**

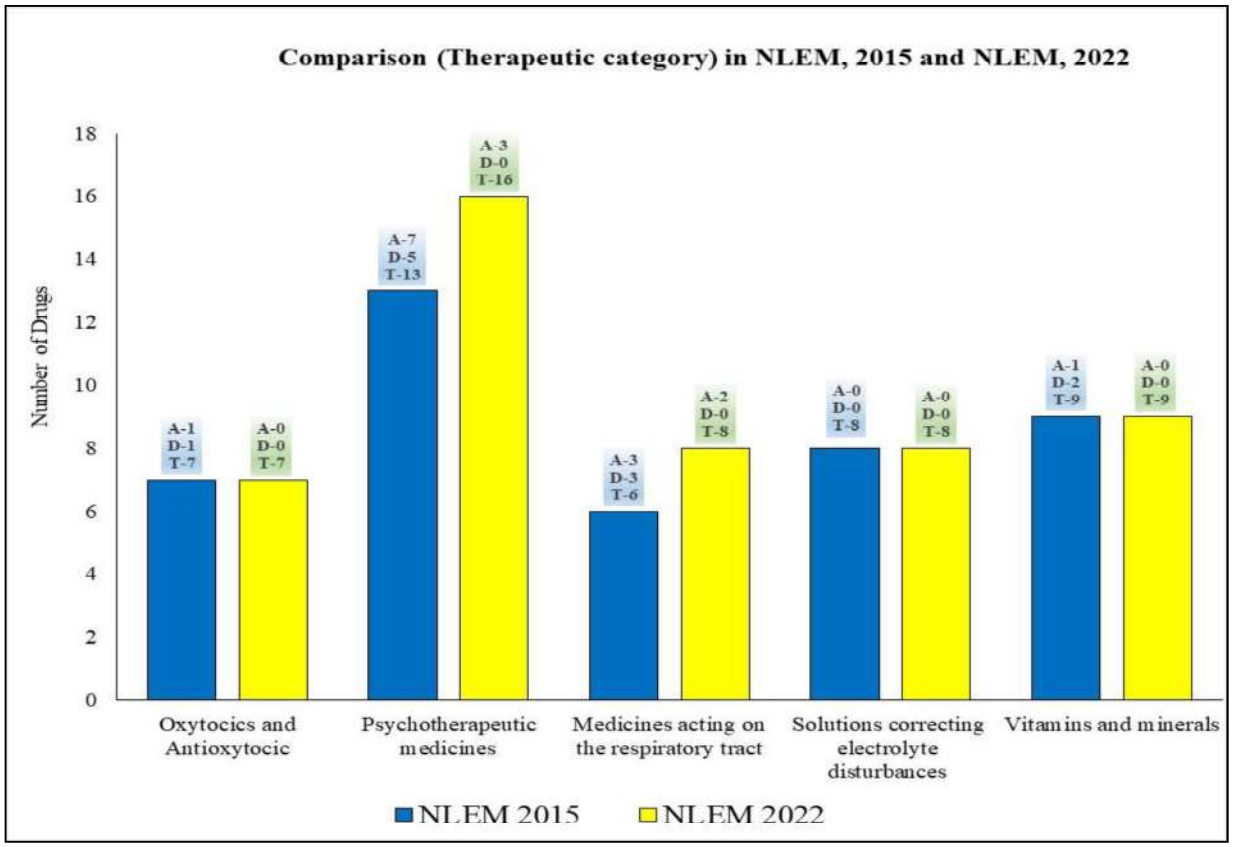



Comparison (Therapeutic category) in NLEM, 2015 and NLEM, 2022
Number of Drugs
35
30
25
20
15
10
5
0
A- 2 D-4 T-8
A- 0 D-0 T-8
A- 5 D-5 T-30
A- 5 D-2 T-33
A- 1 D-0 T-1
A- 0 D-0 T-1
A- 5 D-6 T-15
A- 0 D-3 T-12
A- 2 D-6 T-7
A- 1 D-1 T-7
Blood products and Plasma substitutes
Cardiovascular medicines
Medicines used in dementia
Dermatological medicines
Diagnostic agents
NLEM 2015
NLEM 2022


Comparison (Therapeutic category) in NLEM, 2015 and NLEM, 2022
Number of Drugs
18
16
14
12
10
8
6
4
2
0
A- 1 D -0 T-2
A- 0 D -0 T-2
A- 0 D -3 T-9
A- 0 D -2 T-7
A- 0 D -0 T-4
A- 0 D -0 T-4
A- 4 D -0 T-4
A- 0 D -0 T-4
A- 3 D -3 T-16
A- 0 D -1 T-14
Dialysis solution
Disinfectants and antiseptics
Diuretics
Ear,nose,throat medicines
Gastrointestinal medicines
NLEM 2015
NLEM 2022


Comparison (Therapeutic category) in NLEM, 2015 and NLEM, 2022
Number of Drugs
30
25
20
15
10
5
0
A-3 D-4 T-23
A-5 D-2 T-26
A-4 D-0 T-17
A-1 D-0 T-18
A-1 D-1 T-5
A-0 D-0 T-5
A-3 D-0 T-3
A-0 D-0 T-3
A-6 D-5 T-17
A-1 D-1 T-17
Hormones,other endocrine medicines and contraceptives
Immunologicals
Muscle relaxants, cholinesterase inhibitors
Medicines for neonatal care
Ophthalmological Medicines
NLEM 2015
NLEM 2022


Comparison (Therapeutic category) in NLEM, 2015 and NLEM, 2022
Number of Drugs
18
16
14
12
10
8
6
4
2
0
A-1 D-1 T-7
A-0 D-0 T-7
A-7 D-5 T-13
A-3 D-0 T-16
A-3 D-3 T-6
A-2 D-0 T-8
A-0 D-0 T-8
A-0 D-0 T-8
A-1 D-2 T-9
A-0 D-0 T-9
Oxytocics and Antioxytocic
Psychotherapeutic medicines
Medicines acting on the respiratory tract
Solutions correcting electrolyte disturbances
Vitamins and minerals
NLEM 2015
NLEM 2022

## Changes in writing the names of the medicines

Some changes in writing the names of the medicines have been done to bring better clarity. Such changes will now better reflect specific salts, isomers, formulation and specific property of the pharmaceutical/biological products. Such changes made in NLEM 2022 are listed below:

**Table: Changes in writing the names of the medicines**

| S.No | In NLEM 2015 | In NLEM 2022 |
|---|---|---|
| 1 | Penicillamine | **D – Penicillamine** |
| 2 | Amphotericin B<br>a) Amphotericin B (conventional)<br>b) Lipid/ Liposomal Amphotericin B | **Amphotericin B**<br>**a) Amphotericin B (conventional)**<br>**b) Lipid Amphotericin B**<br>**c) Liposomal Amphotericin B** |
| 3 | Protamine | **Protamine Sulphate** |
| 4 | Platelet rich plasma | **Platelet rich plasma / Platelet concentrates** |
| 5 | Red blood cells | **Red blood cells / Packed RBCs** |
| 6 | Betamethasone | **Betamethasone valerate** |
| 7 | Gadobenate | **Gadobenate dimeglumine** |
| 8 | Intraperitoneal dialysis solution | **Peritoneal dialysis solution** |
| 9 | 5-aminosalicylic acid | **5-aminosalicylic acid (Mesalazine/ Mesalamine)** |
| 10 | Clomiphene | **Clomiphene citrate** |

**Use of term 'Modified release' with respect to tablets/ capsules**

Modified release dosage forms are drug delivery systems (DDS) that, by virtue of their formulation and product design, provide drug release in a modified form which is different from that of the conventional/ immediate release dosage forms. The oral modified release (MR) dosage forms are developed by altering the rate/kinetics and site of drug release and absorption to confer advantages like improved patient compliance, optimized efficacy and/or reduced adverse events. This may be achieved through specialized formulation design or innovative manufacturing methods. The various types of delivery technologies could be as extended, delayed, controlled, prolonged, multiphasic release system, etc.

The modified release dosage forms may sometimes offer following advantages over conventional formulations e.g. improved patient compliance- by reducing the frequency of drug administration, the reduction in the total cost of therapy as lesser number of pills may be required. The MR forms may also offer better bioavailability. Another advantage that modified release dosage forms may offer is to minimize the fluctuations in drug plasma concentrations and facilitating continuous levels above minimum effective concentrations. This may also avoid certain adverse drug reactions.

In NLEM 2015, various modified release solid oral dosage forms were listed as sustained release, controlled release, delayed release, extended release, prolonged release, etc. However, the drug delivery systems are evolving rapidly, and the pharmaceutical industry is increasingly focusing on novel drug delivery systems. Many of these are often introduced with incremental innovation. To broadly reflect all such modified release dosage forms, in NLEM 2022, the term Modified Release has been used to represent controlled release, sustained release, prolonged release, extended release etc. with respect to tablets and capsules as the case may be.

Medicines where modified release formulations have been mentioned are Carbamazepine, Levetiracetam, Phenytoin, Sodium Valproate, Levodopa + Carbidopa, Morphine, Diltiazem, Isosorbide – 5 – Mononitrate, Metoprolol, Metformin, etc.

**Modifications in Names of Therapeutic Categories (Sections and Sub-sections)**

In NLEM 2022, names of some therapeutic categories (Sections and Sub-sections) have been modified. This has been done to bring better clarity regarding the medicines listed therein. The changes in names of therapeutic categories are listed below:

**Table: Changes in names of Therapeutic categories**

| Therapeutic Categories in NLEM 2015 | Therapeutic Categories in NLEM 2022 |
|---|---|
| Section 1<br>Anaesthetic Agents | Section 1<br>Medicines used in Anaesthesia |
| Section 2<br>Analgesics, antipyretics, non-steroidal anti-inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders | Section 2<br>Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders |
| Section 4<br>Antidotes and other substances used in poisoning | Section 4<br>Antidotes and Other Substances used in Management of Poisonings/ Envenomation |
| Section 7<br><br>Antineoplastic/ immunosuppressives and medicines used in palliative care | Section 7<br>Anti-cancer agents including Immunosuppressives and Medicines used in Palliative Care |

| | |
|---|---|
| Section 6.5.1<br><br>Antiamoebic and antigiardiasis medicines | Section 6.9.1<br><br>Medicines used for amoebiasis and other parasitic infections |
| Section 12.5<br><br>Antithrombotic medicine (Cardiovascular/ Cerebrovascular) | Section 10.5<br><br>Antiplatelet and antithrombotic medicines |
| Section 14.2<br><br>Anti-infective medicines | Section 11.2<br><br>Antibacterial medicines |
| Section 14.4<br><br>Medicines affecting skin differentiation and proliferation | Section 11.4<br><br>Keratolytic agents |
| Section 16<br><br>Dialysis solutions | Section 13<br><br>Dialysis components (haemodialysis and peritoneal dialysis) |
| Section 17<br><br>Disinfectants and antiseptics | Section 14<br><br>Antiseptics and disinfectants |
| Section 27<br><br>Psychotherapeutic medicines | Section 23<br><br>Medicines used in treatment of psychiatric disorders |

## Merging of Therapeutic Categories (Sections and sub-sections)

In NLEM 2022, some therapeutic categories which were listed as individual sections have been merged. The medicines belonging to one disease have been listed as sub section. For example – In NLEM 2015, there were different sections for antiepileptic drugs, Antimigraine drugs, Antiparkinsonism drugs and drugs for Dementia. In NLEM 2022, these four sections have been merged as Section 5 – i.e. Medicines used in neurological disorders.

**Table: Merging of Therapeutic Categories (Sections and sub-sections)**

| In NLEM 2015 | In NLEM 2022 |
|---|---|
| **Section – 5,7,9,13** | **Section 5**<br>**Medicines in used neurological disorders** |
| Section 5<br>Anticonvulsants / Antiepileptics | Section 5.1<br>Anticonvulsants / Antiepileptics |
| Section 7<br>Antimigraine Medicines | Section 5.2<br>Antimigraine Medicines |
| Section 9<br>Antiparkinsonism Medicines | Section 5.3<br>Antiparkinsonism Medicines |
| Section 13<br>Medicines used in Dementia | Section 5.4<br>Medicines used in Dementia |
| **Section 23**<br>**Muscle Relaxants and cholinesterase inhibitors** | **Section 1**<br>**Medicines used in Anaesthesia** |
| | Section 1.1<br>General anaesthetics and oxygen |
| | Section 1.2<br>Local anaesthetics |
| | Section 1.3<br>Perioperative medications |
| | Section 1.4<br>Muscle relaxants and cholinesterase inhibitors |
| **Section 25.6**<br>**Ophthalmic surgical aids** | **Section 21.6**<br>**Miscellaneous** |

**Splitting of Therapeutic Categories (Sections and sub-sections)**

In NLEM 2015, the section 6 describes anti-infective medicines. The two important therapeutic category drugs i.e. antileprosy and anti-tubercular drugs were mentioned as two sub sections, (6.2.3 and 6.2.4) respectively of a sub section i.e. antibacterial (Section 6.2).

In NLEM 2022, the rationalization of therapeutic categories has been done and antileprosy has been made a sub section as 6.2 and anti-tubercular has been made sub section 6.3. Similarly, antiretroviral drugs are now listed as separate sub-section (6.7) which was earlier placed as 6.4.3 in NLEM 2015.

**Table: Splitting of Therapeutic Categories (Sections and sub-sections)**

| In NLEM 2015 | In NLEM 2022 |
|---|---|
| Section 6<br>Anti- Infective medicines | Section 6<br>Anti- Infective medicines |
| 6.1–Anthelminthics<br>6.2–Antibacterials<br>6.2.1–Beta-lactam medicines<br>6.2.2–Other antibacterials<br>6.2.3–Antileprosy medicines<br>6.2.4–Antituberculosis medicines<br>6.3–Antifungal medicines<br>6.4–Antiviral medicines<br>6.5–Antiprotozoal Medicines | 6.1-Anthelminthics<br>6.2-Antibacterials<br>6.3-Antileprosy medicines<br>6.4-Antituberculosis medicines<br>6.5-Antifungal medicines<br>6.6-Antiviral medicines<br>6.7-Medicines used in the management of HIV<br>6.8- Medicines used in Hepatitis B and Hepatitis C<br>6.9-Antiprotozoal Medicines<br>6.10-Antimalarial medicines |

## Change in therapeutic categories of medicines

In NLEM 2015, certain drugs were listed in therapeutic categories which did not accurately reflect their indication/ therapeutic use. In NLEM 2022, these medicines have now been placed under therapeutic categories which are better indicative of their use.

These changes in therapeutic categories are listed below:

**Table: Change in therapeutic categories of medicines**

| Drug | In NLEM 2015 | In NLEM 2022 |
|---|---|---|
| **Mesna** | Section 8.1<br>Antineoplastic Medicines | Section 8.4<br>Palliative Care |
| **Human Chorionic Gonadotropin** | Section 21.1.2<br>Adrenal Hormones and Substitutes | Section 18.5.2<br>Ovulation Inducers |
| **Levonorgestrel** | Section 21.3.2<br>Estrogens | Section 18.2.2<br>Hormonal Contraceptives |
| **Clopidogrel** | Section 12.1.2<br>Medicines used in angina | Section 10.5.2<br>Antiplatelet and Antithrombotic Medicines |

**Changes in Level of Healthcare for drugs**

In NLEM, the medicines have been categorized as P – Primary, S – Secondary, T – Tertiary. Over the years, some drugs which were only used in tertiary care setups are now being commonly used in secondary care setups also.

The list of such changes in level of healthcare for drugs is given in Annexure 3.1.

**Changes in Dosage form(s) of Medicines**

Over the years, new dosage forms have been introduced into the market which have shown advantage in terms of safety, efficacy, bioavailability and ease of administration, etc. Where such dosage forms found merit, have been added.
The list of such changes in dosage form(s) of medicines is given in Annexure 3.2.

**Changes in Strength(s) of Medicines**

For some medicines, it was noted that some strengths listed in NLEM 2015 have limited availability. Their availability was checked from multiple drug information sources and obtained feedback from physicians, pharmacists/chemist shops across the country. Such strengths with limited availability were deleted from the list considering that alternate essential strengths are included.
The list of such changes in strength(s) of Medicines is given in Annexure 3.3.

**Medicines listed in more than one therapeutic category**

There are 56 drugs which are listed in more than one therapeutic category because they are indicated in more than one conditions. In these indications, dosage form and strength may be same or different. Some representative examples are given below:

- Aspirin is used as analgesic in 325 mg strength whereas 75 mg is used as anti-platelet.
- Lignocaine 2% injection is used as antiarrhythmic agent and 1% injection as topical anaesthetic agent.
- Diazepam is used as 2 mg tablet in palliative care and as 5 mg/mL injection is used as anticonvulsant.

Out of 386 medicines in NLEM 2022, 342 appear in single therapeutic category, 41 drugs appear in two therapeutic categories (Annexure 4.1), 11 appear in three therapeutic categories (Annexure 4.2) and 4 drugs appear in four therapeutic categories (Annexure 4.3).

## SNCM's vision for revision of NLEM: The way forward

Therapeutics and pharmaceutical landscape have changed rapidly with the advent of newer technologies and incremental innovations, globally as well as in India. Rapid advances in point of care diagnostics, molecular biology platforms, monoclonal antibodies, biosimilars, nanomedicine, radioprotective agents, special drug delivery systems, wearable devices, etc have driven the therapeutics arena significantly. While drug therapy has become safer, predictable and more personalized, there has been a sustained increase in cost and in affordability/accessibility, as a consequence. Furthermore, real world

data about their effectiveness and long-term safety continues to emerge, which shall determine their exact place in therapeutics some years down the line.

Till that happens, continuous and critical analysis of such technologies is warranted in the form of standardized and validated HTA protocols for ensuring their accessibility in Indian context so as to harness their prowess for larger public good. There is a need to identify the 'therapeutic game changers' early on and fast track their development. It is equally important to identify and weed out 'less than cost effective' interventions and technologies. Either way, continuous HTA remains important and it is recommended that this be taken up on priority as part of SNCM activity. Indian healthcare ecosystem is cost sensitive due to minimal insurance coverage and lesser public spending on healthcare. Though the cost of medicines in India are much cheaper than the western world, still the expenditure incurred by an average individual is unbearable as he has to shell out about 80% of the medicine cost as out of pocket expenses.

One of the cornerstones of SNCM is to identify drugs/medicines of public importance so as to improve their accessibility through suitable executive interventions. Such identification, needless to say is a dynamic process, based on regular accrual of country specific data and is subject to continuous refinement. Such refinement cannot take place in silo and has to factor in simultaneous advancements in other related fields. Analysis of associated factors that affect cost (such as cost of therapy taken in-toto, cost of ADRs, cost of diagnostic tests, loss of wages, hospital admission costs, cost of travel etc) have to be taken in cognizance and incorporated into pharmacoeconomic decision making process. The NLEM is essentially linked to rational use of medicines which is influenced by multiple factors. Therefore, the committee deliberated on the following related issues:

**NLEM for rational therapeutics**

The NLEM should not remain the only dear/fear for pharmaceutical industry but should become an important tool for improving rational therapeutics in Indian healthcare system so that the limited resources of the health care sector can be optimized and majority of the population gets benefited.

**Need for Capacity Building for Pharmacoeconomics as a discipline in India**

The committee recommends that the discipline of pharmacoeconomics must be formally encouraged/practiced/included in the UG and PG curriculum of medical, dental and nursing courses for optimum financial and therapeutic benefits. The important purpose of NLEM is to ensure adequate and regular access to the essential medicines.

The concept of essential medicines is one of the pharmacoeconomic tools to economize/ optimize the purchase/ procurement of medicines. The pharmacoeconomics particularly focuses on cost and benefits of drug therapy. Medicines account for a significant proportion of total healthcare cost and prescription can be considered as important therapeutic intervention in practice of medicine. It is therefore important that each prescribing doctor is empowered with right knowledge to practice effectively the principles of pharmacoeconomics which will help promote rational prescribing.

The committee, therefore, recommends that the basic training in pharmacoeconomic principles should be mandatory in MBBS and post graduate curriculum. Advanced pharmacoeconomic courses should be made available for those involved in committees like hospital formulary committee, drug and therapeutic committee, making of essential medicines list and preparing standard treatment guidelines, medical superintendents, directors, etc. This will also curtail irrational use of medicines. By applying the pharmacoeconomic principles, the substantial government exchequer can also be saved.

**Strengthening translational value of Pharmacovigilance Programme of India (PvPI) and NLEM**

Periodic dissemination of signals and alerts generated by IPC through PvPI to the practicing clinicians will significantly improve the therapeutic outcomes. Any new treatment which is adopted in country needs to be specially monitored.

The committee, therefore, recommends that Pharmacovigilance Programme of India needs to be strengthened by inculcating the practice of Adverse Drug Reaction (ADR) reporting during early clinical exposure of medical, dental, nursing and paraclinical students.

**NLEM India to become global guidance document for developing world**

NLEM 2022 has been drafted after detailed countrywide deliberations and is based on robust scientific evidence, accessibility considerations and healthcare needs of the country. This approach can be adopted by other countries. This is especially pertinent to geographically proximate nations as they share similar health issues. Therefore, the committee recommends that necessary measures should be taken to disseminate the NLEM 2022to other countries especially to the geographically proximate nations.

**Discouraging irrational formulations of medicines**

In order to appear different, many pharmaceutical houses make formulations of different strengths, dosage forms, and fixed dose combinations of medicines claiming some advantage. However, many of such formulations are without robust scientific evidences. Incidentally, such medicines are also prescribed. These often create confusion, unnecessary economic burden and sometimes more adverse reactions because of multiple drugs in FDC. The committee recommends that such formulations of medicines should be discouraged by the physicians, regulators, pharmaceutical industry and policy makers.

Similarly, many formulations which are almost similar in active principle but have combinations of not relevant medicines. There are several *me too* drugs with marginally or sometimes significantly higher costs. There are several strengths of a medicine/formulation, however, for these medicines, only few strengths may serve the purpose of majority. Innumerable fixed dose combinations of medicines particularly of vitamins and minerals are available in the market. Addition of probiotics to other drugs is necessity only in limited cases whereas these are used in many formulations without any scientific justifications. Similar is the case with several antioxidants which are available in different combinations with different medications. The education of concept of essential medicines to post graduate medical students, nursing students, pharmacy students would discourage such formulations. Sometimes their use can be confusing and do not offer any advantage to the patients. The experts engaged with the regulators while approving such formulations can also act as gatekeeper of not flooding *me too* formulations in the market.

**Need for impact assessment of NLEM**

NLEM is in existence in India since 1996. After 2015, its visibility and popularity increased primarily because of its implication on pricing of essential medicines in India. Though the basic philosophy of NLEM is to ensure accessibility, availability of quality medicines even in resource limited settings, sometimes, its influence on pricing becomes more prominent feature. It is important that there should be mechanism to carry out impact assessment of NLEM on rational use of medicines, improvement in their accessibility and affordability to the society as well as impact on optimization of healthcare budget of the country.

**Issue of FDC of multiple drugs iron, vitamin and calcium preparations**

In some cases, FDC of two drugs, particularly in cases of iron, calcium were included in NLEM 2015. For example-

a) Oral Liquid – Ferrous Salt (20 mg elemental iron) + Folic Acid (100 mcg)

b) Tablet – Ferrous Salt (45 mg elemental iron) + Folic Acid (400 mcg).

However, NPPA could not fix the ceiling price in some of these formulations as these formulations are not available in the market. These formulations are listed in national programme – "*National Iron + Initiative*" and supplied by the programme.

The reason for non-availability of these formulations in the market may be due to shifting of the market to other FDCs containing iron and folic acid along with other multiminerals and multivitamins. Several similar examples are with vitamin, minerals and calcium. These are examples where essentiality of the drugs is taken over by the marketing strategies and become the pen of physicians.

The concerned department/organization should ensure that the formulations which have little scientific rationale should be discouraged during licensing by the regulator and practice by the physicians.

**NLEM and self-reliant India (आत्मनिर्भर भारत) for Active Pharmaceutical Ingredients (APIs)/ Key Starting Materials (KSMs)**

India today has emerged as pharmacy of the world with its pharmaceutical industry ranking third largest in terms of medicines produced by volume and accounts for 20% of global generic medicines. However, the Indian pharmaceutical industry has over the years become significantly dependent on import of basic raw materials that are used to produce the finished dosage

formulations. The import dependence of APIs, KSMs and intermediates for many medicines which are in NLEM create a vulnerable situation for Indian healthcare system. This could be on account of multiple factors: a) Unpredictable fluctuations of import cost affecting the affordability; b) Uncertainty about the import in the time of conflicts/emergencies; c) Extra expenditure to ascertain and verify the quality of imported material; d) High dependency on the limited number of importers. The challenges for ensuring availability and affordability of API for several pharmaceutical products which are listed in NLEM were realized during recent COVID-19 times.

Several deliberations were held in Ministry of Commerce, Ministry of Health and Family Welfare, Indian Council of Medical Research and CDSCO to address the issue of availability and affordability of APIs/KSMs for medicines listed in the NLEM, particularly those which are critical. Pharmaceutical manufacturing associations, NPPA and Department of Pharmaceuticals jointly identified specific APIs / KSMs for which the import dependency was very high (even up to 100%). Out of these, the SNCM further identified some APIs as critical and essential. It is important that the manufacturing of these APIs in India be taken up on top priority so as to become self-reliant (**आत्मनिर्भर भारत**) for formulations of essential medicines. Other strategies for competitive import from multiple sources be explored and kept in readiness. The Department of Pharmaceuticals has launched a scheme named as Production Linked Incentive scheme for APIs/KSMs to promote production of APIs in India. This will go a long way to ensure the availability of key medicines in the country at all times.

## Conclusion

While the extended mandate of the Standing National Committee on Medicines (SNCM) to revise NLEM 2015. i.e. including medical devices, medical disposables, medical consumables and other products used for Health and Hygiene used for general public in NLEM, is being deliberated, the SNCM has finalized the recommendations of essential medicines and NLEM 2022 has been prepared and placed in this report.

An important dimension deliberated by SNCM is anti-infective agents in the light of antimicrobial resistance and the classification of antimicrobial agents as AWaRe (Access, Watch and Reserve) in WHO EML 2022. It is recommended that continuous sensitization of prescribers, strict prescription audit, anti-microbial stewardship programmes and adherence to NLEM 2022 will go a long way in promoting rational antimicrobial prescribing and prevent antimicrobial resistance.

The COVID-19 pandemic has been a challenge globally as well as for India. The SNCM deliberated on essentiality of medicines for COVID-19 and opined that the data of new medications are still not conclusive and complete in regulatory perspective. Therefore, in absence of unequivocal evidence of efficacy and safety, the new COVID-19 medicines have not been included as of now. However, the supportive management has been added in a separate section.

The medicines and their formulations (dosage form and strength) which had limited availability and not commonly used by the physicians have been deleted after considering their essentiality. Innovation for improving therapeutics and vaccines for Indian patients must be encouraged. The ecosystem needs to be developed so that inclusion of innovative products in NLEM gives a boost rather than the apprehension of commercial sustainability.

Innovations, changes in disease burden, revision in treatment guidelines, changing pharmacoeconomics and pharmacovigilance dimensions make the NLEM revision process dynamic. Continuous feedback and suggestions from all stakeholders to the Standing National Committee on Medicines is crucial in keeping the NLEM up-to-date.

It is reiterated that addressing all the issues is difficult but the basic principles of essentiality, i.e. efficacy, safety, cost of treatment, need to address public health problems and common diseases prevalent in India were adhered to. Thus, the NLEM remains a Best Fit list. More application of important tools like Health Technology Assessment, pharmacovigilance, pharmacoeconomics and disease epidemiology will be useful for addressing the several challenges faced during the process of revision of NLEM.

# Annexures

## Annexure 1 – Order of Ministry of Health and Family Welfare for constitution of SNCM for revision of NLEM

F.No X.11035/923/2017-DRS
Government of India
Ministry of Health and Family Welfare
Department of Health & Family Welfare
(Drugs Regulation Section)

Nirman Bhawan, New Delhi,
Dated 03 July, 2018

**ORDER**

Subject:- Constitution of Standing National Committee on Medicines (SNCM) for revision of National List of Essential medicines (NLEM).

The Government has decided to constitute a Standing National Committee on Medicines (SNCM) to review and revise the National List of Essential Medicines (NLEM) by way of additions and deletions in the existing NLEM in the context of contemporary knowledge of use of therapeutic products in health & hygiene of general public. The composition of the Committee shall be as follows:

| | | |
|---|---|---|
| 1. | Secretary, DHR and DG, ICMR | Chairperson |
| 2. | Prof. Y.K. Gupta, Former Prof. & Head Department of Pharmacology, AIIMS, New Delhi | Vice-Chairperson |
| 3. | A representative of Director General Health Services (DGHS), Ministry of Health & Family Welfare | Member |
| 4. | A representative of Department of Pharmaceuticals, Ministry of Chemical & Fertilizers | Member |
| 5. | A representative of National Vector Borne Diseases Control Programme, Ministry of Health & Family Welfare | Member |
| 6 | Director, National Institute of Biologicals, (NIB) NOIDA (U.P), Ministry of Health & Family Welfare | Member |
| 7 | Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Ghaziabad | Member |
| 8 | Additional Director General (Stores), Directorate General Health Services, Ministry of Health & Family Welfare | Member |
| 9 | Director, National Institute of Malaria Research, Ministry of Health & Family Welfare | Member |
| 10 | Director, National Institute of Pharmaceuticals Education and Research (NIPER), Guwahati. | Member |

| | | |
|---|---|---|
| 11 | Director-General, Employees' State Insurance Corporation, Ministry of Labour or his nominee | Member |
| 12 | Representative of Ministry of AYUSH | Member |
| 13 | Director, Central Government Health Scheme (CGHS), Ministry of Health & Family Welfare | Member |
| 14 | Representative of Department of Consumer Affairs | Member |
| 15 | Five Experts as nominated by the Chair | Member |
| 16 | Drugs Controller General (India), Ministry of Health & Family Welfare, or his representative | Member |
| 17 | Principal Secretary, Health, Tamil Nadu | Member |
| 18 | Principal Secretary, Health, Uttar Pradesh | Member |

2. Representative of NPPA, D/o Pharmaceuticals will be special Invitee.

3. The Chairperson of the Committee may co-opt the subject experts as deemed fit from the list as enclosed in the Annexure.

4. The Terms of Reference of the Committee will be as follows:

(i) While the SNCM would be a standing committee, the non-officials members and the members by name will have a tenure of three years unless extended by the Government.

(ii) SNCM will prepare detailed guidelines and procedures for revision of National List of Essential Medicines and suggest additions and deletions in the NLEM, including, but not limited to the following:

- Revision of NLEM 2015, inclusion of Medical Devices, Medical Disposables, Medical Consumables and other products used for Health & Hygiene of general public in NLEM.
- While preparing the list, the Committee shall consider the list of drugs included in the Indian Pharmacopoeia (IP), the National Formulary of India (NFI), the essential drug list of the World Health Organisation (WHO) and the drugs included in various health programmes of the Ministry of Health and Family Welfare and other relevant resource materials.

(iii) Before finalizing the list, the SNCM shall obtain views from experts/stakeholders by organizing consultative workshops or meetings.

(iv) If considered necessary, the Committee can interact with the stakeholders like Civil Society, drug manufacturing associations and individual experts on the subject etc.

(v) The Committee shall also look into the issue of Anti Microbial Resistance (AMR) while recommending drugs for inclusion/deletion.

(vi) The Committee shall meet at least once every 06 months from the date of its constitution and submit its recommendations within one month of meeting.

(vii) TA/DA/honorarium for non-official members and other logistic support will be paid / provided from the budget of the Indian Pharmacopoeia Commission, Ghaziabad (U.P.) as per rules.

(viii) The members / experts should sign prior declaration on conflict of interest.

Encl: **Annexure**.

(R.G. Singh)
Under Secretary to the Govt. of India
Tele:-23063019

To:

The Chairperson and all members of the Committee.

Copy to:

1. Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi- with request for arranging meetings and communications with the committee.
2. Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Ghaziabad.
3. Member Secretary, NPPA, New Delhi.
4. PS to HFM / PS to MoS (AKC)/PS to MoS (AP)/PPS to Secretary(HFW) / PPS to DGHS / PS to AS&DG(CGHS) / PPS to JS (R).

Annexure

| S.No. | Name of Expert/Member | Position / Designation/ Organisation |
|---|---|---|
| | **Pharmacology** | |
| 1. | Dr. Samir Malhotra | Prof. Department of Pharmacology PGIMER Chandigarh |
| 2. | Dr. Vijay M Motghare | Prof & Head Department of Pharmacology, Govt Medical College, Nagpur |
| 3. | Dr. Santanu Tripathi | Prof. & Head, Department of Clinical and Experimental Pharmacology, School of Tropical Medicines, Kolkata |
| 4. | Dr. H S Rehana, | Director Professor, Lady Harding Medical College |
| | **Oncology** | |
| 5. | Dr. Sameer Bakshi | Prof. Department of Oncology, AIIMS, New Delhi |
| 6. | Dr Rajesh Kumar Grover | Director and Chief Executive officer, Delhi State Cancer Institute, New Delhi |
| 7. | Dr Prantar Chakraborty | Prof Dept of Oncology NRS Medical college, kolkatta |
| 8. | Dr Lalit Kumar | Prof of Medical oncology, AIIMS, New Delhi |
| 9. | Dr. Amita Aggarwal | Prof. Department of Clinical Immunology, SGPGI, Lucknow |
| 10. | Dr. Renu Saxena | Prof. & Head of Department of Haematology, AIIMS, New Delhi |
| 11. | Dr. Renen Chakraborty, | Dr, RML Hospital, New Delhi. |
| | **Cardiology CTVS** | |
| 12. | Dr. (Prof.) Neeraj Pandit | Consultant & Head of Cardiology, RML Hospital |
| 13. | Dr. Rakesh Yadav | Prof. of Cardiology, AIIMS, New Delhi |
| 14. | Dr. Sandeep Bansal | Prof & Head of Cardiology VMMC and Safdurjung Hospital , New Delhi |
| 15. | Dr V K Gupta | Prof. and Head Dept of CTVS , PGIMER Dr RML Hospital, New Delhi |
| 16. | Dr Shiv Chaudhary | Prof of CTVS. AIIMS, New Delhi |
| 17. | Dr. Abid Jilani | Prof of CTVS, G B Pant Institute of Medical Sciences, New Delhi |
| | **Gynae** | |
| 18. | Dr Vinita Suri | Prof Department of Gyane & Obstrectic. PGIMER Chandigarh |
| 19. | Dr. Alka Kriplani | Prof. & Head Department of Gynaecology, AIIMS, New Delhi |
| 20. | Dr Pinkee Saxena | Prof of Gynaecology LHMC, New Delhi |
| 21. | Dr. Sunesh Kumar | Professor, AIIMS, New Delhi |
| 22. | Dr. Neerja Bhatla | Professor, AIIMS, New Delhi |
| 23. | Dr. H P Anand | Consultant, Safdarjung Hospital, New Delhi |
| 24. | Dr. Rupali Diwan | Consultant, Safdarjung Hospital, New Delhi |
| 25. | Dr. Abha Singh | HoD, Lady Harding, Hospital, New Delhi |
| 26. | Dr. Pratima Mittal | Head, Gynaecology, Safdurjung Hospital, New Delhi. |
| 27. | Dr. Manju Puri | Professor, Lady Harding, Hospital, New Delhi |

| | | |
|---|---|---|
| 28. | Dr. Ajay Dudeja | Paediatric, Kalawati Saran Hospital |
| | **Paediatric** | |
| 29. | Dr Surjit Singh | Prof of Paediatric, PGIMER, Chandigarh |
| 30. | Dr T P Yadav | Prof & Head Dept of Paediatric PGIMER Dr RML Hospital, New Delhi |
| 31. | Dr. Ajay Dudeja | Paediatric, Kalawati Saran Hospital |
| 32. | Dr. Ashok. K. Deorari, | Prof.& Head, Dept of Paed, AIIMS |
| 33. | Dr Rashmi Kumar | Prof.& Head, Paed. Neurology, KGMU, Lucknow |
| 34. | Dr Vijaylakshmi Bhatia | Paed. Endocrinologist, SGPGI, Lucknow |
| 35. | Dr Suman Rao | Prof.&Head, Neonatology, St. John's Hospital, Bangalore |
| | **Medicine & allied** | |
| 36. | Dr. S.P. Singh | Medicine, Head, CGHS, Safdurjung Hospital, New Delhi. |
| 37. | Prof. Sanjeev Sinha | Prof. Department of Medicine, AIIMS, New Delhi |
| 38. | Dr. Rakesh Aggarwal | Prof. Department of Gastroenterology, SGPGI, Lucknow |
| 39. | Dr. Sudir Gupta | Prof. & Head, Department of Gastroenterology, Government Medical College, Nagpur |
| 40. | Dr. Vineet Ahuja | Prof. Department of Gastroenterology, AIIMS, New Delhi |
| 41. | Dr. Nikhil Tandon | Prof. & Head of Endocrinology and Metabolism, AIIMS, New Delhi |
| 42. | Dr. Krishna Biswas | Prof. & Head, Department Endocrinology, Safdarganj Hospital, New Delhi |
| 43. | Dr. J. C. Suri | Head, Department of Respiratory ,Medicine, VMMC & Safdarganj Hospital, New Delhi |
| 44. | Dr. Anant Mohan | Addl. Prof. Pulmonary Medicine, AIIMS, New Delhi |
| 45. | Dr. M K Sen | Prof. Medicine, Consultant, Safdarganj Hospital, New Delhi |
| 46. | Dr. Neelam Marwaha | Professor of Transfusion Medicine, PGIMER Chandigarh |
| 47. | Dr Praveen Agarwal | Prof of Emergency Medicine, AIIMS, New Delhi |
| | **Nephrology + Urology** | |
| 48. | Dr. S. K. Agarwal | Prof. & Head, Department of Nephrology, AIIMS, New Delhi |
| 49. | Dr. R. K. Sharma | Prof. & Head, Department of Nephrology, SGPGI, Lucknow |
| 50. | Dr. Anup Kumar Kundu | Prof. & Head, Department of Urology, IPGMER & SSKM Hospital, Kolkata |
| 51. | Dr. Anup Kumar | Prof & Head, Dept. of Urology Safdurjung Hospital, New Delhi |
| | **Surgery + allied (ENT & Ophthalmology)** | |
| 52. | Dr C K Durga | Prof & Head Dept of Surgery , PGIMER, Dr RML Hospital, New Delhi |
| 53. | Dr S V Arya | Professor & HoD Surgery, Safdurjung |

| | | |
|---|---|---|
| | | Hosp and VMMC, New Delhi |
| 54. | Dr. A.K. Rai | Prof. & Head, ENT, PGIMER &Dr RML Hospital New Delhi |
| 55. | Dr. Rohit Saxena | Prof. of Ophthalmology, Dr R P Centre for Opthalmic Sciences, AIIMS, New Delhi |
| 56. | Dr. Raj Sekhar | Eye Specilist, Safdurjung Hospital, New Delhi |
| 57. | Dr Ramanuj Bansal | Prof & Head Dept of ENT, MAMC Hospital, New Delhi |
| 58. | Dr. Ram Chander | Director & Prof Dermatology, LHMC. |
| 59. | Dr. Anil Agarwal, | Gastro Surgery, G B Pant Hospital |
| 60. | Dr. Kamlesh | Prof & Head, Ophthalmology Gurunanak Eye Hospital, New Delhi. |
| 61. | Dr. Pawanendra Lal | General Surgery, MAMC Hospital, New Delhi |
| | **Orthopedics** | |
| 62. | Dr. Rajesh Malhotra | Prof. & Head, Department of Orthopedics, AIIMS, New Delhi |
| 63. | Dr. Ramesh Chander | Head Ortho, Safdarjung Hospital, New Delhi |
| 64. | Dr. Lalit Maine | Prof Orthopaedics, Lok Nayak Jaiparkash Hospital |
| | **Anaesthesia** | |
| 65. | Dr G D Puri | Professor dept of Anaesthesiology, PGIMER Chandigarh |
| 66. | Dr. D.B.V. Madhusudhaa Rao | Associate Prof. Department of Anaesthesiology, Visakhapatnam, A.P. |
| 67. | Dr Rajesh Sood | Prof of Anasthesiology, PGIMER &bDr RML Hospital, New Delhi |
| 68. | Dr. D S Meena, | Professor, **Anaesthesia, Safdarjung Hospital, New Delhi** |
| | **Neurology + Psychiatry** | |
| 69. | Dr. Debashish Chowdhary | Prof., Department of Neurology, MAMC, New Delhi |
| 70. | Dr. Kameshwar Prasad | Prof. & Head of Neurology, AIIMS, New Delhi |
| 71. | Dr. Smitha Deshpandey | Prof. & Head, Department of Psychiatry, RML Hospital, New Delhi |
| 72. | Dr. Shruti Srivastava | Prof., Department of Psychiatry, UCMS, New Delhi |
| 73. | Dr Ajit Awasthi | Prof of Psychiatry, PGIMER, Chandigarh |
| | **Miscellaneous** | |
| 74. | Dr. R. R. Gangakhedkar | Director, National AIDS Research Institute, ICMR, Pune |
| 75. | Dr. R.S. Gupta | Dy. Director General, NACO |
| 76. | Dr. Varsha Gupta | Prof. Department of Microbiology, Government medical College Chandigarh |
| 77. | Dr. D.C. Katoch | Advisor, (Ayurveda) Ministry of AYUSH |
| 78. | Dr. Ram Vishwakarma | Director, Indian Institute of Integrative Medicine, Jammu |
| 79. | Dr Kamini Walia | Focal point for Antibiotic stewardship Programme ICMR, New Delhi |
| 80. | Dr. Alok Dhawan | Director, CDRI Lucknow |

*******

## Annexure 2 – Assessment of specific formulations listed in NLEM 2015 referred by NPPA for availability and essentiality

## Annexure 2.1

## A. Specific formulations to be retained in NLEM 2022 on the basis of essentiality

| S.No. | Drug Name Strength | Recommendations of Experts |
|---|---|---|
| **1.** | Acetylsalicylic acid<br><br>Effervescent/ Dispersible/ Enteric coated<br><br>Tablet 300 mg to 500 mg | The committee noted that commonly marketed preparations are Disprin and Disprin Plus available as 325 mg and 500 mg. Therefore, expert committee recommended that Effervescent/ Dispersible/ Enteric coated – Tablet 300 mg to 500 mg be retained in NLEM 2022. |
| **2.** | Acetylsalicylic acid Tablet 300 mg to 500 mg (351 mg to 500mg) | Different formulations of acetylsalicylic acid are available as effervescent / plain/ effervescent/ dispersible/ enteric coated. Therefore, expert committee recommended that Tablet 300 mg to 500 mg to be retained in NLEM 2022. |
| **3.** | Activated charcoal Powder (as licensed) | The committee noted that it is less commonly sold in market. But the drug is essential as a universal antidote for poisoning cases. Therefore, expert committee recommended that Activated charcoal – Powder (As licensed) to be retained in NLEM 2022. |
| **4.** | Calcium carbonate | The committee noted that calcium carbonate is available in the market and is commonly used by |

| | | |
|---|---|---|
| | Tablet 250 mg | clinicians. Therefore, expert committee recommended that Calcium carbonate Tablet 250 mg to be retained in NLEM 2022. |
| **5.** | Calcium folinate<br>Injection 3 mg/ml | The committee noted that calcium folinate is available in the market and is commonly used by clinicians. Therefore, expert committee recommended that calcium folinate injection 3mg/mL be retained in NLEM 2022. |
| **6.** | Cloxacillin<br>Oral Liquid 125 mg/5 ml | The committee noted that Cloxacillin Oral liquid is available in the market and is commonly used by clinicians. Therefore, expert committee recommended that Oral Liquid 125 mg/5 ml be retained in NLEM 2022. |
| **7.** | Doxycycline<br>Dry syrup 50 mg/5 ml | The committee noted that –<br>• Doxycycline is in National Malaria Elimination Programme.<br>• Earlier there was concern for toxicity, but recent reports show no toxicity.<br>Therefore, expert committee recommended that Dry syrup 50 mg/5mL be retained in NLEM 2022. |
| **8.** | Hydroxocobalamin<br>Injection 1 mg/ml | Vitamin B12 (cobalamin) is used in cases of deficiency which is at times supported by low blood levels also. The deficiency could be due to factors like pernicious anaemia, megaloblastic anaemia, inflammatory bowel disease, short bowel syndrome, inherited disorders like methylmalonic aciduria, strict vegetarian diet especially in elderly, |

| | | |
|---|---|---|
| | | and worm infestation. It is common in India and hence warrants inclusion of vitamin B12, particularly parenteral preparation in the NLEM. Parenteral preparation is needed when the deficiency is severe and blood levels are very low, leading to either anaemia or its specific secondary effects such as peripheral or central neurological symptoms.<br><br>Vitamin B12 supplementation is available in 3 different forms: hydroxo-; cyano- and methyl-cobalamin. Hydroxo- is parenteral only and cyano- and methyl- are both oral and parenteral. Hydroxo- and cyano- are storage forms in the blood and methyl- is the intracellular active form as cyano- is converted to hydroxo- which is then converted to methyl- (https://en.wikipedia.org/wiki/Hydroxocobalamin). Hydroxo-cobalamin, in addition is useful for treatment of cyanide poisoning as well (https://www.ncbi.nlm.nih.gov/books/NBK557632)<br><br>All three forms are available and used, based on regional preferences, market forces and personal choices. Hydroxocobalamin is more commonly used in Europe and cyanocobalamin is more commonly used in USA (https://www.ncbi.nlm.nih.gov/books/NBK557632). As per British National Formulary, for maintenance therapy, hydroxocobalamin requires once in three months dosing as compared to once a month for cyano- (https://www.bmj.com/content/349/bmj.g5389). It directs that when vitamin B12 injection is prescribed |

| | | |
|---|---|---|
| | | or demanded hydroxocobalamin injection shall be dispensed or supplied (https://bnf.nice.org.uk › drug › cyanocobalamin). Hydroxocobalamin is included in the WHO EML also.<br><br>Thus, the above information supports the inclusion of hydroxocobalamin 1 mg/ml injection in the NLEM. Therefore, expert committee recommended that Injection 1mg/mL to be retained in NLEM 2022. |
| **9.** | Iohexol<br><br>Injection 140 to 350 mg iodine/ml | The information from AIIMS Bhubaneshwar – procured through rate contract (GE Healthcare). Other hospitals also may be procuring through rate contract. The availability of this product was checked and it was found that the whole spectrum from 140 – 350 mg iodine/ml is available.<br><br>Therefore, expert committee recommended that Injection 140 mg to 350 mg iodine /mL be retained in NLEM 2022. |
| **10.** | Medroxyprogesterone acetate<br><br>Tablet 5 mg | Subject experts opined that Tablet medroxyprogesterone acetate 10 mg is commonly used, but some patients are started on 5 mg and the dose is increased depending on the tolerability and clinical response. Therefore, expert committee recommended that both 5 mg and 10 mg be retained in NLEM 2022. |
| **11.** | Methylthioninium chloride (Methylene blue) Injection 10 | The committee noted that Injection 10 mg/ml is an essential drug for management of cases leading to drug induced methemoglobinemia. Therefore, the |

| | | |
|---|---|---|
| | mg/ml | committee recommended that it should continue as essential in NLEM 2022. |
| **12.** | Nystatin<br><br>Pessary 100,000 IU | Nystatin was approved by the FDA in 1971 and is currently widely used in the treatment of superficial candida infections of the skin, mucous membranes and gastrointestinal tract, including oropharyngeal candidiasis.<br><br>https://www.ncbi.nlm.nih.gov/books/NBK548581/<br><br>Nystatin is available in multiple forms such as tablets, troches, powder for suspension, creams and ointments and varying concentrations which are usually measured in units.<br><br>The committee deliberated regarding different formulations of nystatin. The following were noted:<br><br>• The nystatin formulation has limited availability.<br><br>• Purportedly more efficacious with better safety profile antifungals are commonly used now a days. For example–<br><br>○ Fluconazole for GI candidiasis.<br><br>○ Clotrimazole for vulvovaginal candidiasis<br><br>Both agents are listed in NLEM 2022<br><br>The committee appreciated that the chances of resistance with nystatin is low. It is also the most economical antifungal agent as compared to newer |

| | | |
|---|---|---|
| | | antifungal agents. This drug is locally effective and not absorbed systemically. The formulations are also listed in WHO EML 2019. The committee therefore recommends that Pessary 100000 IU and Oral Liquid 100000 IU/mL should be retained and Tablet 500000 IU be deleted in NLEM 2022, even though there are other anti-fungal agents in the list.<br><br>The committee recommended that there should be a reassessment after one year for efficacy, safety and resistance. The use pattern, resistance, efficacy should be kept in watch. |
| **13.** | Nystatin<br><br>Oral Liquid 100, 000 IU/ml | Nystatin was approved by the FDA in 1971 and is currently widely used in the treatment of superficial candida infections of the skin, mucous membranes and gastrointestinal tract, including oropharyngeal candidiasis<br><br>https://www.ncbi.nlm.nih.gov/books/NBK548581/<br><br>Nystatin is available in multiple forms such as tablets, troches, powder for suspension, creams and ointments and varying concentrations which are usually measured in units.<br><br>The committee deliberated regarding different formulations of nystatin. The following were noted:<br><br>• The availability of nystatin formulation has limited availability.<br><br>• More efficacious with better safety profile antifungals are commonly used now a days. |

| | | |
|---|---|---|
| | | Commonly used examples are –<br>○ Fluconazole for GI candidiasis<br>○ Clotrimazole for vulvovaginal candidiasis<br>Both of these agents are listed in NLEM 2022<br>The committee appreciated that the chances of resistance with nystatin is low. It is also the most economical antifungal agent as compared to newer antifungal agents. This drug is locally effective and not absorbed systemically. The formulations are also listed in WHO EML 2019. The committee therefore recommends that Pessary 100000 IU and Oral Liquid 100000 IU/mL should be retained and Tablet 500000 IU be deleted in NLEM 2022. Even though there are other anti-fungal agents in the list.<br>The committee recommended that there should be a reassessment after one year for efficacy, safety and resistance. The use pattern, resistance, efficacy should be kept in watch. |
| **14.** | Podophyllin resin<br>Solution 10% to 25% | The committee deliberated and noted that Podophyllum resin (Podophyllin) is commonly used for warts. Though different strengths from 10 to 25% are available, commonly used and available strength in India is 20%. Therefore, the committee recommended Podophyllin resin 20% should be retained. |
| **15.** | Povidone iodine<br>Drops 5% | The committee noted that it is available as 5% drops and has limited availability. In clinical practice, Povidone-iodine (PVI) solutions have |

| | | |
|---|---|---|
| | | been widely used for several decades with adequate tolerability and safety. It is a universally accepted antiseptic agent used in ophthalmic surgery with strong evidence for its efficacy.<br><br>https://www.nature.com/articles/s41433-021-01447-8<br><br>Therefore, the committee recommended that it should continue as essential in NLEM 2022. |
| **16.** | Pyridoxine<br><br>Tablet 50 mg | Several formulations are available and commonly used. Thus, the committee recommended to retain it in NLEM 2022. |
| **17.** | Sodium chloride<br><br>Injection 3% | Both 3% and 5% hypertonic saline (HS) are currently FDA-approved for use in hyponatremia and increased intracranial pressure (ICP).<br><br>https://www.sort.nhs.uk/Media/Guidelines/Hypertonicsaline3sodiumchlorideguideline.pdf<br><br>The committee deliberated and noted the following:<br><br>1. 3% hypertonic saline is commonly used in management of hyponatremia, raised ICP, cerebral oedema.<br><br>2. It is also available in the market, few of the manufacturers are listed above.<br><br>3. USFDA also recommends use of 3% hypertonic saline (HS) in hyponatremia and increased intracranial pressure (ICP).<br><br>Therefore, the committee recommended retention of |

| | | |
|---|---|---|
| | | 3% sodium chloride. |
| **18.** | Vitamin A<br><br>Oral liquid 100000 IU/ml | The capsules of 50000 IU can meet dose titration needs for most of the indications. The expert committee thus recommended deletion of Capsule 1 Lac IU and retention of oral liquid 100000 IU/mL. |

**Annexure – 2.2**

**B. Specific formulations recommended to be retained –**

The formulations which were referred by NPPA for limited/non-availability in the market were assessed by the expert group. The nationwide feedback was also collected on the availability. It was noted that these formulations are poorly available or not available in the market. However, these formulations are directly procured and provided by the respective programmes. Thus, after deliberation the committee, on the basis of essentiality, recommended retention of these formulations in NLEM 2022.

The formulations of medicines and name of the National Health Programme is given in the following table:

| S.No. | Drug Name and Strength | Name of the National Health Programme in which the drug is mentioned |
|---|---|---|
| 1. | Abacavir<br>Tablet 60 mg | National AIDS Control Programme |
| 2. | Cycloserine<br>Capsule 125 mg | National TB Elimination Programme |
| 3. | Dapsone<br>Tablet 50 mg | National Leprosy Elimination Programme |
| 4. | Ethionamide<br>Tablet 125 mg | National TB Elimination Programme |

| | | |
|---|---|---|
| 5. | Ferrous salt (A) + Folic acid (B)<br>Oral liquid 20 mg elemental iron (A) + 100 mcg | National Iron + Initiative<br>The committee also noted that several preparations of Oral liquid 20 mg elemental iron (A) + 100 mcg (B) as FDC are available in the market with additional constituents such as zinc, vitamin B12. These FDCs are commonly sold. Therefore, the experts recommended retention of this formulation in NLEM 2022. |
| 6. | Ferrous salts<br>Tablet equivalent to 60 mg of elemental iron | National Iron + Initiative |
| 7. | Lamivudine (A) + Zidovudine (B)<br>Tablet 30 mg (A) + 60 mg (B) | National AIDS Control Programme |
| 8. | Miltefosine<br>Capsule 50 mg | National Vector Borne Disease Control Programme (NVBDCP) |
| 9. | Nevirapine<br>Dispersible Tablet 50 mg | National AIDS Control Programme |
| 10. | Paromomycin<br>Injection 375 mg/ml | National programme for Kala Azar (NVBDCP) |
| 11. | Zidovudine<br>Oral liquid 50 mg/5 ml | National AIDS Control Programme |
| 12. | Zidovudine (A) + Lamivudine (B) + Nevirapine (C)<br>Tablet 60 mg (A) + 30 mg (B) + 50 mg (C) | National AIDS Control Programme |

**Annexure – 2.3**

## C. Special formulations like – blood products and other biologicals to be retained as these are supplied through designated supply chain and may not be available in open market

| S.No. | Drug Name | Recommendations of experts |
|---|---|---|
| **1.** | Condom<br><br>As per the standards prescribed in Schedule R of Drugs and Cosmetics Rules, 1945 | NPPA informed that ceiling price has been fixed based on NLEM 2011. Presently this is under litigation as informed by regulator.<br><br>The data for Condom is available on the online source. |
| **2.** | Cryoprecipitate<br><br>As licensed | There are certain biological products which are special in nature in terms of their availability and use and thus are not expected to be available in the general/open market. |
| **3.** | Fresh frozen plasma<br><br>As licensed | There are certain biological products which are special in nature in terms of their availability and use. These are not expected to be available in the general/open market. |
| **4.** | Inactivated polio Vaccine<br><br>As licensed | Inactivated Polio Vaccine is not yet included in Universal Immunization Programme of India and thus it is not enlisted in NLEM. |
| **5.** | Intraperitoneal dialysis solution<br>As licensed | There are certain biological products which are special in nature in terms of their availability and use. These are not expected to be available in the general/open market. |

| | | |
|---|---|---|
| **6.** | Platelet rich plasma<br><br>As licensed | There are certain biological products which are special in nature in terms of their availability and use. These are not expected to be available in the general/open market. |
| **7.** | Red blood cell<br><br>As licensed | There are certain biological products which are special in nature in terms of their availability and use. These are not expected to be available in the general/open market. |
| **8.** | Tuberculin, Purified Protein derivative<br><br>As licensed | There are certain biological products which are special in nature in terms of their availability and use. These are not expected to be available in the general/open market. This Tuberculin, Purified Protein Derivative might be procured by the laboratories. |
| **9.** | Whole blood<br><br>As licensed | There are certain biological products which are special in nature in terms of their availability and use. These are not expected to be available in the general/open market. |

## Annexure – 2.4

## D. Specific formulations deleted because of non-availability/limited availability and / or non-essentiality in the present context

| S.No. | Drug Name and Strength | Recommendations of Experts |
|---|---|---|
| 1. | Atropine<br><br>Injection 1 mg/ml | Injection 0.6 mg/ml is commonly used. Experts from different parts of the country could not confirm the availability of Injection 1 mg/ml in their hospitals.<br><br>Therefore, expert committee recommended that the strength of 1mg/ml strength is being deleted in NLEM 2022.<br><br>The high dose of atropine will be required in Organophosphorus poisoning cases where Injection 0.6mg/ml (although high volume) can also serve the purpose. |
| 2. | Barium sulphate<br><br>Oral liquid 100% w/v | Barium Sulphate Oral Liquid 250 % w/v and 100% w/v are very less used. Although different strengths are available. Thus, availability in the market is not there.<br>Most commonly used strength is oral liquid 95 % w/v as confirmed by most of the radiologists who responded. This strength (95%w/v) meets requirement of majority of the cases.<br>Hence, the strengths of 100% w/v and 250% w/v are deleted from NLEM 2022 and are replaced with one strength i.e. oral liquid 95% w/v. |

| | | |
|---|---|---|
| **3.** | Barium sulphate<br><br>Oral liquid 250% w/v | Barium Sulphate Oral Liquid 250 % w/v and 100% w/v are very less used. Although different strengths are available. Thus, availability in the market is not there<br><br>Most commonly used strength is oral liquid 95 % w/v as confirmed by most of the radiologists who responded. This strength (95%w/v) meets requirement of majority of the cases.<br><br>Hence, the strengths of 100% w/v and 250% w/v are deleted from NLEM and are replaced with one strength i.e. oral liquid 95% w/v. |
| **4.** | Bleaching powder<br>Containing not less than 30% w/w of available | The experts noted that as it is not used by clinicians and the fact that this can better fit into category of hygiene and healthcare products. This is recommended for deletion in NLEM 2022. |
| **5.** | Carbamazepine<br><br>Oral Liquid 200 mg/5ml | Experts from different parts of the country could not confirm availability of 200mg/5ml. Oral Liquid 100mg/5ml is freely available and is commonly used.<br><br>The subject expert group recommended that 200mg/5ml to be deleted from NLEM 2015.<br><br>Therefore, the committee recommended deletion of 200mg/5ml as the purpose will be solved with 100mg/5ml. |
| **6.** | Chlorpheniramine<br><br>Oral liquid 2 mg/5 ml | The committee noted the following regarding the oral liquid 2mg/5mL formulation of chlorpheniramine:<br><br>1. Not in WHO EML 2019<br><br>2. Not available in market |

| | | |
|---|---|---|
| | | 3. Alternative oral liquid antihistaminic is Cetirizine – Oral Liquid 5mg/5mL is present in NLEM.<br><br>4. The literature review also suggests the superiority of cetirizine over other second generation.<br><br>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7043022/<br><br>In view of the above, expert committee recommended chlorpheniramine oral liquid 2mg/5mL for deletion. |
| **7.** | Coal tar Solution 5% | Coal Tar solution has limited availability in the market as a single agent. Coal Tar is rather used commonly in the form of an FDC with Salicylic Acid – Coal Tar Solution 1% coal tar + 3% Salicylic Acid is commonly used formulation.<br><br>The expert recommended that coal tar solution is replaced by Coal tar (A) + Salicylic Acid (B) solution – Solution 1% (A) + 3% (B) in NLEM, 2022. |
| **8.** | Cyclophosphamide Tablet 200 mg | Feedback from subject experts concluded that tablet 200 mg is not used where high dose is used, it is given as injectable for which 500 mg ampoule is already present in NLEM.<br><br>Therefore, the expert committee were of the opinion that higher doses are used only for injection and not as oral dose/tablet. And also, WHO EML 2019 enlisted Tablet 25 mg and 50 mg only. Thus, it is recommended to delete Tablet 200 mg in NLEM 2022. |

| | | |
|---|---|---|
| **9.** | Cyclosporine<br><br>Capsule10 mg | Experts from different parts of the country could not confirm the availability of Cyclosporine Capsule 10 mg. This strength (capsule 10 mg) is not commonly used. The starting dose is 10 mg but, the liquid preparation can serve the purpose which is also in NLEM, therefore, capsule 10 mg is recommended to be deleted. |
| **10.** | Dapsone<br><br>Tablet 25 mg | The anti – Leprosy drug Dapsone tablet 25 mg is not listed in the National Leprosy Eradication Programme (NLEP). The committee noted that in the National Leprosy Eradication Programme (NLEP) 50 mg and 100 mg dose is recommended for children and adults respectively. Once a day tablet of 50 and 100 mg (daily dose). In any situation where 25 mg is to be given of tablet 50 mg can serve the purpose.<br><br>The experts from different parts of the country informed that 25 mg is not commonly available. Therefore, the committee recommended its deletion in NLEM 2022. |
| **11.** | Efavirenz<br><br>Tablet 50 mg | The anti-HIV drug Efavirenz tablet 50 mg is not listed in the National AIDS Control Programme (NACP). Other formulations Tablet 200 mg for children and Tablet 600 mg for adults are listed in the (NACP). Therefore, the expert committee recommended deletion of Tablet 50 mg in NLEM 2022. |
| **12.** | Erythromycin<br><br>Ointment 0.5% | The expert group confirmed the non-availability of this formulation. They further noted that erythromycin is not superior to existing ophthalmic antibiotics. Therefore, the committee recommended for its |

| | | |
|---|---|---|
| | | deletion in NLEM, 2022. |
| **13.** | Ethinylestradiol (A) + Norethisterone<br><br>Tablet 0.035 mg (A) + 1 mg (B) | Experts informed that FDC of Ethinylestradiol (A) + Norethisterone (B) is not commonly prescribed. The NLEM 2015 already has alternative combination of hormonal contraceptives which is commonly used.<br><br>The FDC is:<br><br>Ethinylestradiol (A) + Levonorgestrel (B) –<br><br>Tablet 0.03 mg (A) + 0.15 mg (B)<br><br>The expert committee thus recommended its deletion from NLEM 2022. |
| **14.** | Etoposide<br><br>Capsule 100 mg | Capsule 100 mg is less commonly used, wherever 100 mg dose is required, two Capsules of 50 mg can serve the purpose. Thus, the expert committee recommended that 100 mg be deleted from NLEM, 2022. For higher dose, Injection 200mg/ml is available. |
| **15.** | Ferrous salt (A) + Folic acid (B)<br><br>Tablet 45mg elemental iron (A) + 400 mcg (B) | The formulation of Ferrous Salt and Folic acid are available with various combinations of vitamins. The reason may be, due to promotion and shifting of market to other FDCs containing iron and folic acid along with multimineral and multivitamins.<br><br>The preparations available have additional constituents like zinc, Vitamin B12.<br><br>The committee recommended addition of<br><br>a. Iron dextran 50 mg/ml in 2 ml ampoules<br><br>b. Iron sorbitol citrate complex 50 mg/ml in 2 ml |

| | | |
|---|---|---|
| | | ampoules<br><br>This will also align with the Iron + Initiatives it is indicated for the treatment of anaemia.<br><br>Therefore it is recommended for S,T levels of healthcare. |
| **16.** | Ferrous salts<br><br>Oral liquid equivalent to 25 mg of elemental iron/ml | The experts noted that this formulation is<br><br>1. Is listed in Iron + initiative<br><br>2. Is formulation is not available in market<br><br>3. It is not listed in WHO EML 2019<br><br>However, the committee noted that this formulation is available in FDC with folic acid, Vit B12, as Tonoferon and recommended its deletion in NLEM 2022. |
| **17.** | Fluorescein<br>Eye drop 1% | The expert committee noted the following:<br>1. Cost of the strip per patient compared to drops is higher. However, the drops have limitation that it has to be used in multiple patients once the vial is opened. So, the drops are useful in hospitals with high patient load.<br>2. There is issue of drug wastage in drops as once the vial is opened, it is to be used for multiple patients in one sitting.<br>3. Drops have Economic advantage over strips<br>4. There is ease of use in case of strips.<br>5. Cost of the strips is higher than the drops which is the only limitation of strips.<br>6. Most of the clinicians shifted from drops to strips and market availability could not be confirmed.<br>Therefore, the expert committee recommended |

| | | |
|---|---|---|
| | | deletion of eye drops 1% and addition of strips in NLEM 2022. |
| **18.** | Framycetin<br><br>Cream 0.5% | The expert group noted that Framycetin Cream 0.5% is not used and is not available. Instead, Framycetin Cream 1% is available and commonly used. Therefore, the experts recommended to delete 0.5% and replace it with Framycetin Cream 0.5% with 1% in NLEM, 2022. |
| **19.** | Isoniazid<br><br>Tablet 50 mg | The committee perused NTEP and noted that 50 mg tablet is not mentioned whereas oral liquid 50mg/5ml is mentioned. Therefore, the committee recommended the deletion of tablet 50 mg. (Oral Liquid 50mg/5ml has been added). |
| **20.** | Isoniazid<br><br>Oral Liquid 100mg/5ml | The committee noted the following:<br>1. Other formulations of 100mg/5ml are in combination with other ingredients.<br>2. The more commonly available formulation is 50 mg/5ml.<br>3. 50 mg/5ml is also commonly used as per subject experts' inputs.<br>4. 50mg/5ml is also listed in WHO EML 2019.<br>5. 50mg/5ml is also listed in Guidelines for programmatic management of drug resistant TB in India 2022. (https://tbcindia.gov.in/showfile.php?lid=3590)<br><br>Therefore, the committee recommended the deletion of 100mg/5ml and inclusion of 50mg/5ml strength. |
| **21.** | Lignocaine<br><br>Eye drop 4% | The subject experts informed that at present Lignocaine 4% drops are not available and are not being used in current practice. They have been |

| | | |
|---|---|---|
| | | replaced by Proparacaine 0.5% eye drops which are easily available. One bottle of Proparacaine costs approx. Rs 50 and is manufactured by a large number of companies in India. As lignocaine drops 4% is no more essential, it can be dropped from the list.<br><br>Considering the above, the expert committee recommended to delete Lignocaine eye drops 4 % and addition of Proparacaine eye drops 0.5% in NLEM 2022. |
| **22.** | Lopinavir (A) + Ritonavir (B)<br><br>Oral liquid 400 mg (A) + 100 mg (B)/ 5ml | As per the inputs received from NACP, the formulation Lopinavir + Ritonavir – Oral liquid 400 mg (A) + 100 mg (B)/ 5mL is not part of the programme. Therefore, the expert committee recommended deletion of this formulation in NLEM, 2022. |
| **23.** | Mefenamic acid<br><br>Capsule 250 mg | The committee noted that there is more frequent availability of tablet formulation. Therefore, expert committee recommended replacement of Ccapsule 250 mg by Tablet 250 mg. |
| **24.** | Mefenamic acid<br><br>Capsule 500 mg | The committee noted that usually the daily dose is 500mg to start with followed by maintenance dose of 250mg oral. The commonly available and used form is tablet but capsules are also available. Therefore, expert committee recommended deletion of Capsule 500 mg in NLEM 2022. |
| **25.** | Methyl prednisolone<br><br>Tablet 32 mg | The committee noted the following:<br><br>1. 32 mg methylprednisolone has limited availability<br><br>2. Cost difference<br><br>3. Not commonly used |

| | | |
|---|---|---|
| | | 4. Equivalent efficacy can be achieved with equipotent doses of prednisolone which is much cheaper. (http://rc.rcjournal.com/content/63/6/655)<br>5. This deletion of all oral formulations of methylprednisolone also aligns with WHO EML 2019.<br><br>Therefore, the expert committee recommended deletion of Tablet 32 mg in NLEM 2022. |
| **26.** | Midazolam<br><br>Oral liquid 2 mg/ml | The expert committee noted that the oral liquid 2 mg/mL formulation of midazolam is not used while nasal spray is used. Midazolam nasal spray is acceptable and is a good alternative to oral midazolam as premedication in the pediatric population.<br><br>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6545947/<br><br>Therefore, the committee recommended addition of midazolam nasal sprays 0.5 mg and 1.25 mg and deletion of oral liquid 2mg/mL. |
| **27.** | Midazolam<br><br>Tablet 15 mg | The committee noted that 15 mg tablet is rarely used instead nasal spray is preferred. The cost effectiveness of nasal spray to be assessed after 1 year for the purpose of inclusion in NLEM.<br><br>Though this is less commonly available, committee recommended the deletion of tablet 15 mg in NLEM 2022. |
| **28.** | Miltefosine<br><br>Capsule 10 mg | The currently recommended dose for miltefosine as monotherapy for either CL or VL is 2.5 mg/kg/day for a total of 28 days. However, due to regular unavailability of the 10 mg capsule in clinical |

| | | |
|---|---|---|
| | | practice, other dosages are being administered. National programme for elimination of Elimination of Leishmania recommends 100 mg/day miltefosine for patients with a body weight ≥25 kg (corresponding to ~1.7–4 mg/kg/day) and 50 mg/day for body weights <25 kg (corresponding to ~2–5.5 mg/kg/day).<br><br>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393397/<br><br>The miltefosine dose is 2.5 mg/kg. For better titration, 10 mg/kg is useful. However, 10 mg capsules are not available. Therefore, the national programme recommends that patient with less than 25 kg be given one capsule of 50 mg and patient with more than 25 kg be given a capsule of 100 mg.<br><br>The above-mentioned reference also indicates similar dosing strategy i.e. less than 45 kg – 50mg twice daily and ≥ 45 kg – 50 mg thrice daily.<br><br>Considering the above, the committee recommended deletion of 10 mg capsule. |
| **29.** | Morphine<br><br>Tablet 20 mg | The committee noted that the availability of 20 mg is not reliable and also not commonly used. Most of the needs are fulfilled by 10 mg and SR 30 mg. Therefore, the committee recommended deletion of morphine tablet 20 mg from the NLEM, 2022. |
| **30.** | Moxifloxacin<br><br>Tablet 200 mg | Although the dose 200 mg is listed in Programmatic management of Drug Resistant Tuberculosis in India – 2022. Considering the non-availability of 200 mg tablet and the fact that half tablet of 400 mg serves the purpose, the 200mg tablet is recommended for |

| | | |
|---|---|---|
| | | deletion.<br><br>The committee recommended that all 400 mg tablet should be manufactured as scored tablet to align with programmatic recommendations. |
| **31.** | Nicotinamide<br><br>Tablet 50 mg | Nicotinamide 50 mg had been included in the NLEM for the management of nutritional deficiency of Vitamin B3 – pellagra.<br><br>Until the late 1950s, pellagra was considered as an endemic disease in India. Research reports revealed that people who consumed millet jowar (sorghum) as their staple diet were more prone to pellagra. The high leucine content in millet decreases the absorption of nicotinic acid. But scientists did not resort to nicotinic acid supplementation. Instead, they advised these populations not to rely solely on jowar but to vary their diets by including other cereals and millets. Meanwhile, when the Green Revolution arrived in the late 1960s, the price of rice and wheat supplied through ration shops fell to low and readily affordable levels. People switched to eating rice, and soon thereafter pellagra perished. Over the past two decades, only a few pellagra cases have been reported. By the year 2011, Pellagra had almost disappeared due to public distribution system.<br><br>(https://www.cdriadvlkn.org/article.asp?issn=2542-551X;year=2019;volume=3;issue=2;spage=126;epage=129;aulast=Brahmaiah)<br>(https://www.ijmr.org.in/article.asp?issn=0971-5916;year=2013;volume=138;issue=3;spage=392;epage=397;aulast=Gopalan) |

| | | |
|---|---|---|
| | | It is pertinent to note that in 2007, the WHO EMLc (children) Subcommittee noted that most of the listed indications for nicotinamide, including nicotinamide deficiency, are now rare in children and therefore decided not to include nicotinamide in the EMLc.<br><br>The online survey of available formulations in the Indian market also revealed limited availability of this dosage strength. Therefore, in view of its limited utility, it was opined by the expert group that the formulation no longer meets the criteria for inclusion in the NLEM and it was decided to delete it from the revised list.<br><br>The committee noted the following:<br><br>1. The tablet of 50 mg nicotinamide is not available. However, nicotinamide in varying amount is available in different multivitamin formulations.<br><br>2. Nicotinamide is drug of choice as replacement therapy in pellagra. Pellagra is no more a public health concern in India.<br><br>Considering the above, the committee recommended deletion of nicotinamide 50 mg in NLEM 2022. |
| **32.** | Nystatin<br><br>Tablet 500,000 IU | Nystatin was approved by the FDA in 1971 and is currently widely used in the treatment of superficial candida infections of the skin, mucous membranes and gastrointestinal tract, including oropharyngeal candidiasis.<br><br>Nystatin is available in multiple forms such as tablets, troches, powder for suspension, creams and ointments |

| | | |
|---|---|---|
| | | and varying concentrations which are usually measured in units.<br><br>The committee deliberated regarding different formulations of nystatin. The following were noted:<br><br>1. The availability of nystatin formulation has limited availability.<br><br>2. More efficacious with better safety profile antifungals are commonly used now a days. Commonly used examples are –<br><br>Fluconazole for GI candidiasis<br><br>Clotrimazole for vulvovaginal candidiasis<br><br>Both of these agents are listed in NLEM 2022<br><br>The committee appreciated that the chances of resistance with nystatin is low. It is also the most economical antifungal agent as compared to newer antifungal agents. This drug is locally effective and not absorbed systemically. The formulations are also listed in WHO EML 2019.<br><br>The committee therefore recommended Pessary 100000 IU and Oral Liquid 100000 IU/mL should be retained and Tablet 500000 IU be deleted in NLEM 2022. Even though there are other anti-fungal agents in the list.<br><br>The committee also recommended that there should be reassessment after 1 year for efficacy, safety and resistance. The use pattern, resistance, efficacy should |

| | | |
|---|---|---|
| | | be kept in watch. |
| **33.** | Oxaliplatin<br><br>Injection 5 mg/ml | The experts noted the following:<br><br>1. This drug is useful and commonly used in advanced colorectal cancer as Folfox regimen.<br><br>2. 5mg/mL concentrate for solution for infusion – 10 mL and 20 mL vials are commonly used.<br><br>3. These formulations are manufactured by many reputed pharmaceutical companies.<br><br>Considering the above, the expert committee recommended oxaliplatin to be retained in NLEM 2022 as follows:<br><br>Injection 50 mg/10 mL in 10- mL vial<br>Injection 100 mg/20 mL in 20- mL vial |
| **34.** | Para-aminosalicylic acid<br>Tablet 500 mg | The committee noted that Para-aminosalicylic acid (PAS) is listed in Guidelines for Programmatic management of Drug resistant TB in India – 2022 (pg-239) and mentioned as 4g sachet granules and PAS sodium salt – (equivalent to 4 g PAS acid) sachet and 60% w/w (9.2 g; equivalent to 4 g PAS acid) sachet are mentioned.<br><br>Immediate release PAS tablets produce substantial GI intolerance.<br>(https://pubmed.ncbi.nlm.nih.gov/8159600/ )<br><br>The committee therefore recommended that Tablet 500 mg be deleted and only granules be kept. |
| **35.** | Paracetamol | Paracetamol Oral liquid formulations are available in different dosage forms such as suspension/syrup/ |

| | | |
|---|---|---|
| | Suspension 156.25 mg/5 ml | solution, and in different strengths.<br><br>The committee noted that multiple dosage forms such as suspension/solution/syrup in multiple strengths of paracetamol are available in the market/. The commonly used strengths are following:<br><br>Oral liquid 120mg/5mL<br><br>Oral Liquid 125 mg/5mL<br><br>Oral Liquid 250 mg/5mL<br><br>The 120 mg/5mL and 125 mg/5mL are also listed in WHO EML 2019. The committee therefore recommended that above mentioned three formulations for inclusion in NLEM 2022. |
| **36.** | Pentamidine<br><br>Powder for Injection 200 mg | Pentamidine – Powder for Injection 200 mg is no longer used for Kala-azar under NVBDCP. Therefore, the committee recommended its deletion in NLEM 2022. |
| **37.** | Povidone iodine<br><br>Drops 0.6 % | The experts noted that Povidone iodine 0.6% w/v (6% w/w) has limited availability and not commonly used. Whereas more commonly used strength is 0.5% w/v (5% w/w). The committee therefore recommended Povidone iodine 0.6% w/v for deletion in NLEM 2022. |
| **38.** | Povidone iodine<br><br>Drops 0.6 % | The experts noted that Povidone iodine 0.6% w/v (6% w/w) has limited availability and not commonly used. Whereas more commonly used strength is 0.5% w/v (5% w/w). The committee therefore recommended Povidone iodine 0.6% w/v for deletion in NLEM 2022. |

| | | |
|---|---|---|
| **39.** | Prednisolone<br><br>Drops 0.1% | Experts from different parts of the country could not confirm the availability of prednisolone drops and the expert committee deliberated and got the feedback from subject experts also that prednisolone drops are used but in 1 % strength. Drops of 0.1% are not used. Therefore, the committee recommended deletion of drops 0.1% in NLEM, 2022. |
| **40.** | Riboflavin<br><br>Tablet 5 mg | Riboflavin supplements come in 25 mg, 50 mg, and 100 mg tablets. According to the National Institute of Health, the recommended daily nutrient intake of riboflavin is 1.3 mg for men, 1.1 mg for women, 1.3 mg for male adolescents (age 14 to 18), and 1.0 mg for female adolescents (age 14 to 18). Recommendations are that pregnant women take 1.4 mg, and breastfeeding women take 1.6 mg. Its dose for infants of age 0 to 6 months old is 0.3 mg, 7 to 12 months is 0.4 mg, 1 to 3 years old is 0.5 mg, 4 to 8 years old is 0.6 mg, and 9 to 13 years is 0.9 mg.<br><br>https://www.ncbi.nlm.nih.gov/books/NBK470460/<br><br>A few Indian studies show biochemical evidence of riboflavin deficiency in >70% of children from low-income groups,6 largely attributed to the inadequacy of riboflavin in the diet<br><br>Bamji MS, Lakshmi AV. Less recognised micronutrient deficiencies in India. NFI Bull 1998; 19: 5–8.<br><br>The committee noted that riboflavin is required to be retained in NLEM, as riboflavin deficiency continues to be a problem in India (Swaminathan, S., Edward, |

| | | |
|---|---|---|
| | | B. & Kurpad, A. Micronutrient deficiency and cognitive and physical performance in Indian children. Eur J Clin Nutr 67, 467–474 (2013). https://doi.org/10.1038/ejcn.2013.14). However, the availability of 5 mg is limited and this strength is also less commonly used while 10 mg is widely available and commonly prescribed. National Health Mission also listed riboflavin tablet 10 mg in its guideline – Guideline for District Hospitals (Revised 2012).<br><br>Therefore, the committee recommended deletion of Tablet 5 mg and addition of Tablet 10 mg. |
| **41.** | Sodium chloride<br><br>Injection 0.45% | The committee noted the following:<br><br>1. 0.45% sodium chloride (half normal saline) has limited utility in cases of hypernatremia.<br><br>2. This strength is not commonly available in the market and if required, it is locally made by diluting 0.9% solution.<br><br>3. 0.45 % is not listed in WHO EML 2019.<br><br>The committee therefore recommended deletion of 0.45% strength in NLEM 2022. |
| **42.** | Sodium thiosulphate<br>Injection 100 mg/ml | The expert committee noted the following:<br><br>1. Injection 100mg/ml is not commonly used and has limited availability. The strength of 250mg/ml is commonly used.<br><br>2. This has indication in cyanide poisoning and cisplatin extravasation and nephrotoxicity.<br><br>According to some experts, the drug is very less used, |

| | | |
|---|---|---|
| | | its usefulness needs to be studied. The status to be reviewed after 1 year. And also, the discussion with WHO to be done.<br><br>Therefore, the committee recommended deletion of 100 mg/mL and addition of 250 mg/mL. |
| **43.** | Stavudine (A) + Lamivudine (B) Dispersible Tablet 6 mg (A) + 30 mg (B) | Stavudine has been reported to be hepatotoxic therefore all formulations containing stavudine are recommended for deletion in NLEM, 2022. |
| **44.** | Sumatriptan<br><br>Injection 6 mg/ 0.5 ml | Triptans are often considered the best choice for first-line therapy. The most rapidly effective treatment in the class is 6 mg subcutaneous (SC) sumatriptan, which reaches peak plasma concentration ($t_{max}$) in 12 min, has an onset of action of 10 min, and relieves migraine pain in 82% of patients at 2 h post dose. Despite its excellent efficacy profile, fewer than 10% of migraineurs who might benefit from SC sumatriptan use it to treat their condition [18]. This may be because most (59%) SC sumatriptan-treated patients have injection site reactions, and many (42%) experience triptan sensations (e.g., tingling, warm/hot, tightness/pressure) that appear to be dose-related [19]. Concerns about drug-related adverse events have caused two thirds of migraine patients to delay or avoid treating an attack<br><br>https://thejournalofheadacheandpain.biomedcentral.com/articles/10.1186/s10194-018-0881-z<br><br>The expert committee consulted subject experts who informed that injectable sumatriptan is rarely used. Therefore, the committee recommended the deletion |

| | | |
|---|---|---|
| | | of injection 6 mg/ 0.5 ml in NLEM 2022. |
| **45.** | Vitamin A<br><br>Capsule 100000 IU | The committee noted that capsules of 50000 IU can meet dose titration needs for most of the indications. Therefore, the expert recommended deletion of Capsule 1 Lac IU. |
| **46.** | Vitamin A<br><br>Capsule 5000 IU | The committee noted that capsules of 50000 IU can meet dose titration needs for most of the indications. Therefore, the expert recommended deletion of Capsule 5000 IU. |

## Annexure 3 – Changes in NLEM 2022 from NLEM 2015

### Annexure 3.1: Changes in Level of Healthcare for drugs

| Medicine | In NLEM 2015 | | In NLEM 2022 | |
|---|---|---|---|---|
| | Level of Health care | Dosage form(s) and strength(s) | Level of Health care | Dosage form(s) and strength(s) |
| **Section 1.1- General Anaesthetics and Oxygen** | | | | |
| Sevoflurane | T | Inhalation | S,T | Liquid for inhalation |
| **Section 2.4-Disease Modifying Agents used in Rheumatoid Disorders** | | | | |
| Hydroxychloroquine | S,T | Tablet 200 mg<br>Tablet 400 mg | P,S,T | Tablet 200 mg<br>Tablet 400 mg |
| Methotrexate | S,T | Tablet 5 mg<br>Tablet 7.5 mg<br>Tablet 10 mg<br>Injection 25 mg/ mL | P,S,T | Tablet 2.5 mg<br>Tablet 5 mg<br>Tablet 10 mg |

| | | | | |
|---|---|---|---|---|
| **Section 5.1-Anticonvulsants/ Antiepileptics** | | | | |
| Sodium Valproate | P,S,T | Tablet 200 mg<br>Tablet 300 mg<br>CR Tablet 300 mg<br>Tablet 500 mg<br>CR Tablet 500 mg<br>Oral liquid 200 mg/5ml | P,S,T | Tablet 200 mg<br>Tablet 300 mg<br>Tablet 500 mg<br>Modified Release<br>Tablet 300 mg<br>Tablet 500 mg<br>Oral liquid 200 mg/5mL (p) |
| | T | Injection 100 mg/mL | S,T | Injection 100 mg/mL |
| **Section 6.2.1 – Beta-lactam medicines** | | | | |
| Vancomycin | T | Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Powder for Injection 1000 mg | S,T | Capsule 125 mg<br>Capsule 250 mg<br>Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Powder for Injection 1000 mg |
| **Section 6.4-Antituberculosis medicines** | | | | |
| Cycloserine | P,S,T | Capsule 125 mg<br>Capsule 250 mg | S,T | Capsule 125 mg<br>Capsule 250 mg |

| | | | | |
|---|---|---|---|---|
| Ethionamide | P,S,T | Tablet 125 mg<br>Tablet 250 mg | S,T | Tablet 125 mg<br>Tablet 250 mg |
| Kanamycin | P,S,T | Powder for Injection 500 mg<br>Powder for Injection 750 mg<br>Powder for Injection 1000 mg | S,T | Powder for Injection 500 mg<br>Powder for Injection 750 mg<br>Powder for Injection 1000 mg |
| Para-aminosalicylic acid | P,S,T | Tablet 500 mg<br>Granules (As licensed) | S,T | Granules (As licensed) |
| **Section 6.5-Antifungal medicines** | | | | |
| Nystatin | P,S,T | Tablet 500,000 IU<br>Pessary 100,000 IU<br>Oral Liquid 1 Lac IU/mL | S,T | Pessary 1 Lac IU<br>Oral Liquid 1 Lac IU/mL (p) |
| **Section 6.7.2 Non-nucleoside reverse transcriptase inhibitors** | | | | |
| Nevirapine | S,T | Tablet 200 mg<br>Dispersible Tablet 50 mg<br>Oral liquid 50 mg/5 mL | P,S,T | Tablet 200 mg<br>Dispersible Tablet 50 mg (p)<br>Oral liquid 50 mg/5 mL (p) |

| Section 7.1 – Antineoplastic medicines | | | | |
|---|---|---|---|---|
| Methotrexate | T | Tablet 2.5 mg<br>Tablet 5 mg<br>Tablet 10 mg<br>Injection 50 mg/mL | S,T | Tablet 2.5 mg<br>Tablet 5 mg<br>Tablet 10 mg<br>Injection 50 mg/mL |
| Allopurinol | T | Tablet 100 mg | S,T | Tablet 100 mg |
| Amitriptyline | T | Tablet 10 mg<br>Tablet 25 mg | S,T | Tablet 10 mg<br>Tablet 25 mg |
| Dexamethasone | T | Tablet 0.5 mg<br>Injection 4 mg/mL | S,T | Tablet 0.5 mg<br>Tablet 4 mg<br>Injection 4 mg/mL |
| Diazepam | T | Tablet 2 mg<br>Tablet 5 mg<br>Injection 5 mg/mL | S,T | Tablet 2 mg<br>Tablet 5 mg<br>Injection 5 mg/mL |
| Fluoxetine | T | Capsule 20 mg | S,T | Capsule 20 mg |
| Haloperidol | T | Tablet 1.5 mg<br>Tablet 5 mg<br>Injection 5 mg/mL | S,T | Tablet 1.5 mg<br>Tablet 5 mg<br>Injection 5 mg/mL |
| Lactulose | T | Oral liquid 10 g/15 mL | S,T | Oral liquid 10 g/15 mL |
| Loperamide | T | Tablet 2 mg | S,T | Tablet 2 mg |

| | | | | |
|---|---|---|---|---|
| Metoclopramide | T | Tablet 10 mg<br>Oral liquid 5 mg/5 mL (p)<br>Injection 5 mg/mL | S,T | Tablet 10 mg<br>Oral liquid 5 mg/5 mL (p)<br>Injection 5 mg/mL |
| Midazolam | T | Injection 1 mg/mL | S,T | Injection 1 mg/mL |
| Morphine | T | Tablet 10 mg<br>Tablet 20 mg<br>SR Tablet 30 mg | S,T | Tablet 10 mg<br>Modified Release<br>Tablet 30 mg |
| **Section 8.1-Antianaemia medicines** | | | | |
| Hydroxyurea | P,S,T | Capsule 500 mg | S,T | Capsule 500 mg |
| **Section 8.2-Medicines affecting coagulation** | | | | |
| Enoxaparin | T | Injection 40 mg/0.4 mL<br>Injection 60 mg/0.6 mL | S,T | Injection 40 mg/0.4 mL<br>Injection 60 mg/0.6 mL |
| **Section 10.1-Medicines used in angina** | | | | |
| Diltiazem | P,S,T | Tablet 30 mg<br>Tablet 60 mg<br>SR Tablet 90 mg | P,S,T | Tablet 30 mg<br>Tablet 60 mg<br>Modified Release<br>Tablet 180 mg |
| | T | Injection 5 mg/mL | S, T | Injection 5 mg/mL |

| | | | | |
|---|---|---|---|---|
| Metoprolol | P,S,T | Tablet 25 mg<br>Tablet 50 mg<br>SR Tablet 25 mg<br>SR Tablet 50 mg | P,S,T | Tablet 25 mg<br>Tablet 50 mg<br>Tablet 100 mg<br>Modified Release<br>Tablet 100 mg |
| | | | S, T | Injection 1 mg/mL |
| **Section 10.3-Antihypertensive medicines** | | | | |
| Labetalol | P,S,T | Injection 5 mg/ml | P,S,T | Tablet 50 mg<br>Tablet 100 mg |
| | | | S,T | Injection 5 mg/mL |
| Sodium nitroprusside | T | Injection 10 mg/mL | S, T | Injection 10 mg/mL |
| **Section 18.5-Ovulation Inducers** | | | | |
| Human chorionic gonadotropin | T | Injection 1000 IU<br>Injection 5000 IU | S,T | Injection 2000 IU<br>Injection 5000 IU<br>Injection 10000 IU |
| **Section 22.1-Oxytocics and abortifacient** | | | | |
| Mifepristone | T | Tablet 200 mg | P,S,T | Tablet 200 mg |
| Misoprostol | T | Tablet 100 mcg<br>Tablet 200 mcg | P,S,T | Tablet 100 mcg<br>Tablet 200 mcg |

| | | | | |
|---|---|---|---|---|
| Oxytocin | S,T | Injection 5 IU/mL<br>Injection 10 IU/mL | P,S,T | Injection 5 IU/mL<br>Injection 10 IU/mL |
| **Section 23.1-Medicines used in psychotic disorders** | | | | |
| Fluphenazine | S,T | Depot Injection 25 mg/mL | P,S,T | Injection 25 mg/mL |
| **Section 25-Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances** | | | | |
| Potassium chloride | P,S,T | Oral liquid 500 mg/5 mL<br>Injection 150 mg/mL | P,S,T | Oral liquid 500 mg/5 mL |
| | | | S,T | Injection 150 mg/mL |

## Annexure 3.2: Modification(s) in Dosage form(s) of Medicines in NLEM 2022

| Medicine | In NLEM 2015 | | In NLEM 2022 | |
|---|---|---|---|---|
| | Level of Health care | Dosage form(s) | Level of Health care | Dosage form(s) |
| **Section 1.1- General Anaesthetics and Oxygen** | | | | |
| Halothane | S,T | Inhalation | S,T | Liquid for inhalation |
| Isoflurane | S,T | Inhalation | S,T | Liquid for inhalation |
| Nitrous oxide | P,S,T | Inhalation | P,S,T | As licensed for medical purpose |
| Oxygen | P,S,T | Inhalation (Medicinal gas) | P,S,T | As licensed for medical purpose |
| Sevoflurane | T | Inhalation | S, T | Liquid for inhalation |
| **2.1-Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines** | | | | |
| Mefenamic acid | P,S,T | Capsule 250 mg<br>Capsule 500 mg<br>Oral liquid 100 mg/5 ml | P,S,T | Tablet 250 mg<br>Oral liquid 100 mg/5 mL (p) |

| | | | | |
|---|---|---|---|---|
| **Section 2.4-Disease modifying agents used in rheumatoid disorders** | | | | |
| **Section 4.2 – Specific** | | | | |
| D – Penicillamine | P,S,T | Capsule 250 mg | P,S,T | Capsule 150 mg (p)<br>Capsule 250 mg |
| Snake venom antiserum<br>a) Soluble/ liquid polyvalent<br>b) Lyophilized polyvalent | P,S,T | a) Injection<br>b) Powder for Injection | P,S,T | a) Soluble/ liquid polyvalent – Injection<br>b) Lyophilized polyvalent – Powder for Injection |
| **Section 5.1-Anticonvulsants/ Antiepileptics** | | | | |
| Carbamazepine | P,S,T | Tablet 100 mg<br>Tablet 200 mg<br>CR Tablet 200 mg<br>Tablet 400 mg<br>CR Tablet 400 mg<br>Oral liquid 100 mg/5 ml<br>Oral liquid 200 mg/5 ml | P,S,T | Tablet 100 mg<br>Tablet 200 mg<br>Tablet 400 mg<br>Modified Release<br>Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 100 mg/5 mL (p) |

| | | | | |
|---|---|---|---|---|
| Levetiracetam | S,T | Tablet 250 mg<br>Tablet 500 mg<br>Tablet 750 mg<br>ER Tablet 750 mg<br>Oral liquid 100 mg/ml Injection 100 mg/ml | S,T | Tablet 250 mg<br>Tablet 500 mg<br>Tablet 750 mg<br>Modified Release<br>Tablet 750 mg<br>Oral liquid 100 mg/mL (p)<br>Injection 100 mg/mL |
| Phenytoin | P,S,T | Tablet 50 mg<br>Tablet 100 mg<br>Tablet 300 mg<br>ER Tablet 300 mg<br>Oral liquid 30 mg/5 ml<br>Oral liquid 125 mg/5 ml Injection 25 mg/ml<br>Injection 50 mg/ml | P,S,T | Tablet 50 mg<br>Tablet 100 mg<br>Tablet 300 mg<br>Modified Release<br>Tablet 300 mg<br>Oral liquid 30 mg/5 mL (p)<br>Oral liquid 125 mg/5 mL (p)<br>Injection 25 mg/mL<br>Injection 50 mg/mL |

| | | | | |
|---|---|---|---|---|
| Sodium Valproate | P,S,T | Tablet 200 mg<br>Tablet 300 mg<br>CR Tablet 300 mg<br>Tablet 500 mg<br>CR Tablet 500 mg<br>Oral liquid 200 mg/5ml | P,S,T | Tablet 200 mg<br>Tablet 300 mg<br>Tablet 500 mg<br>Modified Release<br>Tablet 300 mg<br>Tablet 500 mg<br>Oral liquid 200 mg/5mL (p) |
| | T | Injection 100 mg/mL | S,T | Injection 100 mg/mL |
| **Section 5.3- Antiparkinsonism medicines** | | | | |
| Levodopa (A) + Carbidopa (B) | P,S,T | Tablet 100 mg (A) + 10 mg (B)<br>Tablet 100 mg (A) + 25 mg (B) CR<br>Tablet 100 mg (A) + 25 mg (B)<br>CR Tablet 200 mg (A) + 50 (B) mg<br>Tablet 250 mg (A) + 25 mg (B) | P,S,T | Tablet 100 mg (A) + 10 mg (B) Tablet 100 mg (A) + 25 mg (B)<br>Tablet 250 mg (A) + 25 mg (B)<br>Modified Release<br>Tablet 100 mg (A) + 25 mg (B)<br>Tablet 200 mg (A) + 50 mg (B) |
| **Section 6.1.1 - Intestinal anthelminthics** | | | | |

| | | | | |
|---|---|---|---|---|
| Albendazole | P,S,T | Tablet 400 mg<br>Oral liquid 200 mg/5 mL | P,S,T | Tablet 400 mg<br>Chewable Tablet 400 mg<br>Oral liquid 200 mg/5 mL<br>(p) |
| **Section 6.5-Antifungal medicines** | | | | |
| Amphotericin B<br><br>a)Amphotericin B (conventional)<br><br>b) Lipid/Liposomal Amphotericin B | S,T | Powder for Injection 50 mg | S,T | a) Amphotericin B (conventional) - Injection 50 mg/vial<br><br>b) Lipid Amphotericin B - Injection 50 mg/vial<br><br>c) Liposomal Amphotericin B - Injection 50 mg/vial |
| **Section 6.10 - Antileishmaniasis medicines** | | | | |
| Amphotericin B<br>a) Amphotericin B (conventional)<br>b) Lipid/Liposomal Amphotericin B | S,T | Powder for Injection 50 mg | S,T | a) Amphotericin B (conventional) -<br>b) Lipid Amphotericin B - Injection 50 mg<br>c) Liposomal Amphotericin B - Injection 50 mg |

| | | | | |
|---|---|---|---|---|
| Cytosine arabinoside | T | Injection 100 mg/ mL<br>Powder for Injection 500 mg<br>Powder for Injection 1000 mg | T | Injection 100 mg/Vial<br>Injection 500 mg/Vial<br>Injection 1000 mg/vial |
| **Section 7.3-Immunosuppressive medicines** | | | | |
| **7.4-Medicines used in palliative care** | | | | |
| Morphine | T | Tablet 10 mg<br>Tablet 20 mg<br>SR Tablet 30 mg | S,T | Tablet 10 mg<br>Modified Release<br>Tablet 30 mg |
| **Section 10.1-Medicines used in angina** | | | | |
| Diltiazem | P,S,T | Tablet 30 mg<br>Tablet 60 mg<br>SR Tablet 90 mg | P,S,T | Tablet 30 mg<br>Tablet 60 mg<br>Modified Release<br>Tablet 180 mg |
| | T | Injection 5 mg/mL | S, T | Injection 5 mg/mL |
| Isosorbide-5-mononitrate | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>SR Tablet 30 mg<br>SR Tablet 60 mg | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>Modified Release<br>Tablet 60 mg |

| | | | | |
|---|---|---|---|---|
| Metoprolol | P,S,T | Tablet 25 mg<br>Tablet 50 mg<br>SR Tablet 25 mg<br>SR Tablet 50 mg | P,S,T | Tablet 25 mg<br>Tablet 50 mg<br>Tablet 100 mg<br>Modified Release Tablet 100 mg |
| | | | S, T | Injection 1 mg/mL |
| **Section 10.3-Antihypertensive medicines** | | | | |
| **Section 10.5- Antiplatelet and Antithrombotic Medicines** | | | | |
| Acetylsalicylic acid | P,S,T | Tablet 75 mg<br>Effervescent/ Dispersible/ Enteric coated Tablet 75 mg<br>Tablet 100 mg<br>Effervescent/ Dispersible/ Enteric coated Tablet 100 mg<br>Tablet 150 mg<br>Effervescent/ Dispersible/ Enteric coated Tablet 150 mg | P,S,T | Conventional/Effervescent / Dispersible/ Enteric coated Tablets 150 mg<br>Conventional/Effervescent / Dispersible/ Enteric coated Tablets 325 mg<br>Enteric coated Tablet 75 mg<br>Enteric coated Tablet 100 mg |

| | | | | |
|---|---|---|---|---|
| **Section 11.6-Miscellaneous** | | | | |
| Glycerin (as mentioned in IP) | P,S,T | Oral Liquid | P,S,T | As Licensed |
| **Section 12.1-Ophthalmic Medicines** | | | | |
| Fluorescein | S,T | Eye drop 1 % | S,T | Ophthalmic strips |
| **Section 14.2 – Disinfectants** | | | | |
| Glutaraldehyde | S,T | Solution 2 % | S,T | As Licensed |
| **Section 18.1 - Adrenal Hormones and synthetic substitutes** | | | | |
| Hydrocortisone | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Injection 100 mg/mL | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Powder for Injection 100 mg |
| **Section 18.2.3 - Barrier methods** | | | | |
| Condom | P,S,T | As per the standards prescribed in Schedule R of Drugs and Cosmetics rules,1945 | P,S,T | As Licensed – as per the standards of Drugs Rules, 1945 |

| | | | | |
|---|---|---|---|---|
| **Section 18.4.1 - Insulins and other antidiabetic agents** | | | | |
| Metformin | P,S,T | Tablet 500mg<br>Tablet 750mg<br>Tablet 1000 mg<br><br>(Immediate and controlled release) | P,S,T | Tablet 500mg<br>Tablet 1000 mg<br><br>Modified release<br>Tablet 1000 mg |
| **Section 19.1-Diagnostic agents** | | | | |
| Tuberculin, Purified Protein derivative | P,S,T | | P,S,T | As Licensed |
| **Section 19.2-Sera and immunoglobulins (Liquid/ Lyophilized)** | | | | |
| Anti-rabies immunoglobulin | P,S,T | | P,S,T | As Licensed |
| Anti-tetanus immunoglobulin | P,S,T | | P,S,T | As Licensed |
| Anti-D immunoglobulin | S,T | | S,T | As Licensed |
| Diphtheria antitoxin | P,S,T | | P,S,T | As Licensed |
| Hepatitis B immunoglobulin | S,T | | S,T | As Licensed |

| | | | | |
|---|---|---|---|---|
| Human normal immunoglobulin | T | | T | As Licensed |
| Snake Venom Antiserum<br><br>a) Soluble/ liquid polyvalent<br><br>b) Lyophilized polyvalent | P,S,T | | P,S,T | a) Soluble/ liquid polyvalent - As Licensed<br><br>b) Lyophilized polyvalent - As Licensed |
| **Section 19.3.1 - For universal immunization** | | | | |
| BCG vaccine | P,S,T | | P,S,T | As licensed |
| DPT+ Hib+ Hep B vaccine | P,S,T | | P,S,T | As licensed |
| DPT vaccine | P,S,T | | P,S,T | As licensed |
| Hepatitis B vaccine | P,S,T | | P,S,T | As licensed |
| Japanese encephalitis vaccine | P,S/,T | | P,S/,T | As licensed |
| Measles vaccine | P,S,T | | P,S,T | As licensed |
| Oral poliomyelitis vaccine | P,S,T | | P,S,T | As licensed |
| Tetanus toxoid | P,S,T | | P,S,T | As licensed |

| | | | | |
|---|---|---|---|---|
| **Section 23.1-Medicines used in psychotic disorders** | | | | |
| Fluphenazine | S,T | Depot Injection 25 mg/mL | P,S,T | Injection 25 mg/mL |
| Section 23.2.1 - **Medicines used in Bipolar disorders** | | | | |
| Sodium valproate | P,S,T | Tablet 200 mg<br>Tablet 500 mg | P,S,T | Tablet 200 mg<br>Tablet 300 mg<br>Tablet 500 mg<br>Modified Release<br>Tablet 300 mg<br>Tablet 500 mg |
| **Section 24.1 - Antiasthmatic Medicines** | | | | |
| Hydrocortisone | P,S,T | Injection 100 mg<br>Injection 200 mg | P,S,T | Powder for Injection 100 mg<br>Powder for Injection 200 mg |
| **Section 26-Vitamins and Minerals** | | | | |
| Cholecalciferol | P,S,T | Tablet 1000 IU<br>Tablet 60000 IU<br>Oral liquid 400 IU/mL | P,S,T | Solid oral dosage form 1000 IU<br>Solid oral dosage form 60000 IU<br>Oral liquid 400 IU/mL |

| | | | | |
|---|---|---|---|---|
| Vitamin A | P,S,T | Capsule 5000 IU<br>Capsule 50000 IU<br>Capsule 100000 IU<br>Oral liquid 100000 IU/ml Injection 50000 IU/ml | P,S,T | Capsule/Tablet 50000 IU (including Chewable tablet)<br>Oral liquid 100000 IU/mL<br>Injection 50000 IU/mL |

## Annexure 3.3: Modification(s) in strength(s) of Medicines in NLEM 2022

| Medicine | In NLEM 2015 | | In NLEM 2022 | |
|---|---|---|---|---|
| | Level of Health care | Strength(s) | Level of Health care | Strength(s) |
| **2.1-Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines** | | | | |
| Mefenamic acid | P,S,T | Capsule 250 mg<br>Capsule 500 mg<br>Oral liquid 100 mg/5 ml | P,S,T | Tablet 250 mg<br>Oral liquid 100 mg/5 mL (p) |
| Paracetamol | P,S,T | Tablet 500 mg<br>Tablet 650 mg<br>All licensed oral liquid dosage forms and strengths<br>Injection 150 mg/ml<br>Suppository 80 mg<br>Suppository 170 mg | P,S,T | Tablet 500 mg<br>Tablet 650 mg<br>Oral liquid 120 mg/5mL<br>Oral Liquid 125mg/5ml (p)<br>Oral Liquid 250 mg/5mL<br>Injection 150 mg/mL<br>Suppository 80 mg<br>Suppository 170 mg |
| **Section 2.4-Disease Modifying Agents used in Rheumatoid Disorders** | | | | |
| Azathioprine | S, T | Tablet 50 mg | S,T | Tablet 25 mg (p)<br>Tablet 50 mg |
| Methotrexate | S,T | Tablet 5 mg<br>Tablet 7.5 mg<br>Tablet 10 mg<br>Injection 25 mg/mL | P,S,T | Tablet 2.5 mg<br>Tablet 5 mg<br>Tablet 10 mg |

| | | | | |
|---|---|---|---|---|
| Chlorpheniramine | P,S,T | Tablet 4 mg<br>Oral liquid 2 mg/5 mL | P,S,T | Tablet 4 mg |
| Dexamethasone | P,S,T | Tablet 0.5 mg<br>Injection 4 mg/mL | P,S,T | Tablet 0.5 mg<br>Tablet 2 mg<br>Tablet 4 mg<br>Oral liquid 0.5 mg/5 mL (p)<br>Injection 4 mg/mL |
| Hydrocortisone | P,S,T | Powder for Injection 100 mg | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Powder for Injection 100 mg<br>Powder for Injection 200 mg |
| **Section 4.2 – Specific** | | | | |
| Atropine | P,S,T | Injection 1 mg/mL | P,S,T | Injection 0.6 mg/mL |
| D – Penicillamine | P,S,T | Capsule 250 mg | P,S,T | Capsule 150 mg (p)<br>Capsule 250 mg |
| Sodium thiosulphate | S,T | Injection 100 mg/mL | S,T | Injection 250 mg/mL |
| **Section 5.1-Anticonvulsants/ Antiepileptics** | | | | |

| | | | | |
|---|---|---|---|---|
| Carbamazepine | P,S,T | Tablet 100 mg<br>Tablet 200 mg<br>CR Tablet 200 mg<br>Tablet 400 mg<br>CR Tablet 400 mg<br>Oral liquid 100 mg/5 ml<br>Oral liquid 200 mg/5 ml | P,S,T | Tablet 100 mg<br>Tablet 200 mg<br>Tablet 400 mg<br>Modified Release<br>Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 100 mg/5 mL (p) |
| Lorazepam | P,S,T | Tablet 1 mg<br>Tablet 2 mg<br>Injection 2 mg/mL | P,S,T | Tablet 1 mg<br>Tablet 2 mg<br>Injection 2 mg/mL<br>Injection 4 mg/mL |
| **Section 5.2- Antimigraine medicines** | | | | |
| Paracetamol | P,S,T | Tablet 500 mg<br>Tablet 650 mg | P,S,T | Tablet 500 mg<br>Tablet 650 mg<br>Oral liquid 120mg/5mL (p)<br>Oral Liquid 125 mg/5mL (p)<br>Oral Liquid 250 mg/5mL (p) |
| Sumatriptan | P,S,T | Tablet 25 mg Tablet 50 mg Injection 6 mg/ 0.5 ml | P,S,T | Tablet 25 mg<br>Tablet 50 mg |
| Propranolol | P,S,T | Tablet 10 mg<br>Tablet 40 mg<br>Tablet 80 mg | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>Tablet 40 mg |
| **Section 5.3- Antiparkinsonism medicines** | | | | |

| | | | | |
|---|---|---|---|---|
| **Section 6.1.1 - Intestinal anthelminthics** | | | | |
| Albendazole | P,S,T | Tablet 400 mg<br>Oral liquid 200 mg/5 mL | P,S,T | Tablet 400 mg<br>Chewable Tablet 400 mg<br>Oral liquid 200 mg/5 mL (p) |
| **Section 6.2.1 Beta-lactam antibacterials** | | | | |
| Amoxicillin | P,S,T | Capsule 250 mg<br>Capsule 500 mg<br>Oral liquid 250 mg/5 mL | P,S,T | Capsule 250 mg<br>Capsule 500 mg<br>Oral liquid 125 mg/5 mL (p)<br>Oral liquid 250 mg/5 mL (p)<br>Powder for Injection 250mg<br>Powder for Injection 500 mg<br>Powder for injection 1000 mg |
| Benzathine Benzylpenicillin | P,S,T | Powder for injection 6 lac units<br>Powder for injection 12 lac units | P,S,T | Powder for injection 6 lac units<br>Powder for injection 12 lac units<br>Powder for injection 24 lac units |
| Benzyl penicillin | P,S,T | Powder for injection 10 lac units | P,S,T | Powder for injection 5 lac units<br>Powder for injection 10 lac units |
| **Section 6.2.2 – Other antibacterials** | | | | |

| | | | | |
|---|---|---|---|---|
| Doxycycline | P,S,T | Capsule 100 mg<br>Dry Syrup 50mg/5 mL | P,S,T | Capsule 100 mg<br>Dry Syrup 50mg/5 mL (p)<br>Power for Injection 100 mg |
| Vancomycin | T | Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Powder for Injection 1000 mg | S,T | Capsule 125 mg<br>Capsule 250 mg<br>Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Powder for Injection 1000 mg |
| **Section 6.3-Antileprosy medicines** | | | | |
| Dapsone | P,S,T | Tablet 25 mg<br>Tablet 50 mg<br>Tablet 100 mg | P,S,T | Tablet 50 mg<br>Tablet 100 mg |
| **Section 6.4 - Antituberculosis medicines** | | | | |
| Capreomycin | P,S,T | Powder for Injection 1000 mg | P,S,T | Powder for Injection 500 mg<br>Powder for Injection 750 mg<br>Powder for Injection 1000 mg |
| Isoniazid | P,S,T | Tablet 50 mg<br>Tablet 100 mg<br>Tablet 300 mg<br>Oral liquid 100 mg/5 mL | P,S,T | Tablet 100 mg<br>Tablet 300 mg<br>Oral Liquid 50 mg/5 mL (p) |
| Moxifloxacin | P,S,T | Tablet 200 mg<br>Tablet 400 mg | P,S,T | Tablet 400 mg |

| | | | | |
|---|---|---|---|---|
| **Section 6.5-Antifungal medicines** | | | | |
| Fluconazole | P,S,T | Tablet 100 mg<br>Tablet 150 mg<br>Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 50 mg/5 mL | P,S,T | Tablet 50 mg<br>Tablet 100 mg<br>Tablet 150 mg<br>Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 50 mg/5 mL (p) |
| | S,T | Injection 200 mg/100 mL | S,T | Injection 200 mg /100 mL |
| Nystatin | P,S,T | Tablet 5,00,000 Lac IU<br>Pessary 1,00,000 IU<br>Oral Liquid 1,00,000 IU/mL | S,T | Pessary 1 Lac IU<br>Oral Liquid 1 Lac IU/mL (p) |
| **Section 6.6.1 Antiherpes medicines** | | | | |
| Acyclovir | P,S,T | Tablet 200 mg<br>Tablet 400 mg<br>Powder for Injection 250 mg<br>Powder for Injection 500 mg Oral liquid 400 mg/5 mL | P,S,T | Tablet 200 mg<br>Tablet 400 mg<br>Tablet 800 mg<br>Powder for Injection 250 mg<br>Powder for Injection 500 mg Oral liquid 400 mg/5 mL (p) |
| **Section 6.7.2 – Non -nucleoside reverse transcriptase inhibitors** | | | | |
| Efavirenz | S,T | Tablet 50 mg<br>Tablet 200 mg<br>Tablet 600 mg | S,T | Tablet 200 mg (p)<br>Tablet 600 mg |

| | | | | |
|---|---|---|---|---|
| **Section 6.7.4 - Protease inhibitors** | | | | |
| Lopinavir (A) + Ritonavir (B) | S,T | Tablet 100 mg (A) + 25 mg (B) Tablet 200 mg (A) + 50 mg (B) Oral liquid 400 mg (A) + 100 mg (B)/ 5ml | S,T | Tablet 100 mg (A) + 25 mg (B)<br>Tablet 200 mg (A) + 50 mg (B)<br>Oral Liquid 80 mg (A) + 20 mg (B) /mL (p)<br>Capsule/ Sachet (containing Pellets/Granules) 40 mg (A) +10 mg (B) (p) |
| **Section 6.8 -Medicines for Hepatitis B and Hepatitis C** | | | | |
| Entecavir | S,T | Tablet 0.5 mg<br>Tablet 1 mg | S,T | Tablet 0.5 mg<br>Tablet 1 mg<br>Syrup 0.05 mg/mL (p) |
| **Section 6.10 - Antileishmaniasis medicines** | | | | |
| Miltefosine | P,S,T | Capsule 10 mg<br>Capsule 50 mg | P,S,T | Capsule 50 mg |
| **Section 6.10 - Antimalarial medicines** | | | | |
| Artemether (A) + Lumefantrine (B) | P,S,T | Tablet 20 mg (A) + 120 mg (B) Tablet 40 mg (A) + 240 mg (B) Tablet 80 mg (A) + 480 mg (B)<br>Oral liquid 80 mg (A) + 480 mg (B)/5 mL | P,S,T | Tablet 20 mg (A) + 120 mg (B)<br>Tablet 40 mg (A) + 240 mg (B)<br>Tablet 80 mg (A) + 480 mg (B) |
| **Section 7.1-Antineoplastic medicines** | | | | |
| Cyclophosphamide | T | Tablet 50 mg<br>Tablet 200 mg<br>Powder for Injection 500 mg | T | Tablet 50 mg<br>Powder for Injection 500 mg |

| | | | | |
|---|---|---|---|---|
| Etoposide | T | Capsule 50 mg<br>Capsule 100 mg<br>Injection 20 mg/mL | T | Capsule 50 mg<br>Injection 20 mg/mL |
| Cyclosporine | T | Capsule10 mg<br>Capsule 25 mg<br>Capsule 50 mg<br>Capsule 100 mg<br>Oral liquid 100 mg/mL<br>Injection 50 mg/mL | T | Capsule 25 mg<br>Capsule 50 mg<br>Capsule 100 mg<br>Oral liquid 100 mg/mL (p)<br>Injection 50 mg/mL |
| Oxaliplatin | T | Injection 5 mg/mL | T | Injection 5mg/mL in 10 mL and 20 mL vial |
| **Section 7.3-Immunosuppressive medicines** | | | | |
| Cyclosporine | T | Capsule 10 mg<br>Capsule 25 mg<br>Capsule 50 mg<br>Capsule 100 mg<br>Oral liquid 100 mg/mL<br>Injection 50 mg/mL | T | Capsule 25 mg<br>Capsule 50 mg<br>Capsule 100 mg<br>Oral liquid 100 mg/mL (p)<br>Injection 50 mg/mL |
| **7.4-Medicines used in Palliative Care** | | | | |
| Dexamethasone | T | Tablet 0.5 mg<br>Injection 4 mg/mL | S,T | Tablet 0.5 mg<br>Tablet 4 mg<br>Injection 4 mg/mL |
| Morphine | T | Tablet 10 mg<br>Tablet 20 mg<br>SR Tablet 30 mg | S,T | Tablet 10 mg<br>Modified Release Tablet 30 mg |

| | | | | |
|---|---|---|---|---|
| **Section 8.1-Antianaemia medicines** | | | | |
| Ferrous salts<br><br>(a) Iron Dextran<br>(b) Iron sorbitol citrate complex | P,S,T | Tablet equivalent to 60mg of elemental iron<br>Oral liquid equivalent to 25mg of elemental iron/mL | P,S,T | Tablet equivalent to 60 mg of elemental iron<br><br>Injection 50 mg/mL<br>Injection 50 mg/mL |
| Folic Acid | P,S,T | Tablet 5 mg | P,S,T | Tablet 1 mg<br>Tablet 5 mg |
| **Section 10.1-Medicines used in angina** | | | | |
| Diltiazem | P,S,T | Tablet 30 mg<br>Tablet 60 mg<br>SR Tablet 90 mg | P,S,T | Tablet 30 mg<br>Tablet 60 mg<br>Modified Release<br>Tablet 180 mg |
| | T | Injection 5 mg/mL | S, T | Injection 5 mg/mL |
| Isosorbide-5-mononitrate | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>SR Tablet 30 mg<br>SR Tablet 60 mg | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>Modified Release<br>Tablet 60 mg |
| Metoprolol | P,S,T | Tablet 25 mg<br>Tablet 50 mg<br>SR Tablet 25 mg<br>SR Tablet 50 mg | P,S,T | Tablet 25 mg<br>Tablet 50 mg<br>Tablet 100 mg<br>Modified Release<br>Tablet 100 mg |
| | | | S, T | Injection 1 mg/mL |
| **Section 10.2-Antiarrhythmic medicines** | | | | |
| Lignocaine | S,T | Injection 2%<br>(Preservative free for IV use) | S,T | Injection 2% |
| **Section 10.3-Antihypertensive medicines** | | | | |
| Labetalol | P,S,T | Injection 5 mg/mL | P,S,T | Tablet 50 mg<br>Tablet 100 mg |
| | | | S,T | Injection 5 mg/mL |

| | | | | |
|---|---|---|---|---|
| **Section 10.5- Antiplatelet and Antithrombotic Medicines** | | | | |
| Acetylsalicylic acid | P,S,T | Tablet 75 mg<br>Effervescent/ Dispersible/ Enteric coated Tablet 75 mg<br>Tablet 100 mg<br>Effervescent/ Dispersible/ Enteric coated Tablet 100 mg<br>Tablet 150 mg<br>Effervescent/ Dispersible/ Enteric coated Tablet 150 mg | P,S,T | Conventional/Effervescent/ Dispersible/ Enteric coated Tablets 150 mg<br>Conventional/Effervescent/ Dispersible/ Enteric coated Tablets 325 mg<br>Enteric coated Tablet 75 mg<br>Enteric coated Tablet 100 mg |
| Clopidogrel | P,S,T | Tablet 75 mg | P,S,T | Tablet 75 mg<br>Tablet 150 mg |
| **Section 10.6-Hypolipidemic medicines** | | | | |
| Atorvastatin | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>Tablet 40 mg | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>Tablet 40 mg<br>Tablet 80 mg |
| **Section 11.1 - Antifungal medicines** | | | | |
| Clotrimazole | P,S,T | Cream 1% | P,S,T | Cream 1%<br>Lotion 1% |
| **Section 11.2 - Antibacterial medicines** | | | | |
| Framycetin | P,S,T | Cream 0.5% | P,S,T | Cream 1% |
| **Section 11.4-Keratolytic agents** | | | | |
| Benzoyl peroxide | P,S,T | Gel 2.5% | P,S,T | Gel 2.5% - 5% |

| | | | | |
|---|---|---|---|---|
| Coal tar (A) + Salicylic Acid (B) | P,S,T | Solution 5% (A) | P,S,T | Solution 1% (A) + 3% (B) |
| Podophyllin resin | S,T | Solution 10 % to 25 %<br>Solution 20% | S,T | Solution 20% |
| **Section 11.6-Miscellaneous** | | | | |
| Glycerin (as mentioned in IP) | P,S,T | Oral Liquid | P,S,T | As Licensed |
| **Section 12.2-Radiocontrast media** | | | | |
| Barium sulphate | S,T | Oral liquid 100 % w/v<br>Oral liquid 250 % w/v | S,T | Oral Liquid 95% w/v |
| **Section 17.2 – Antiemetics** | | | | |
| Metoclopramide | P,S,T | Injection 5 mg/mL | P,S,T | Tablet 10 mg<br>Injection 5 mg/mL |
| **Section 18.1 - Adrenal Hormones and synthetic substitutes** | | | | |
| Hydrocortisone | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Injection 100 mg/mL | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Powder for Injection 100 mg |
| Methylprednisolone | S,T | Tablet 8 mg<br>Tablet 16 mg<br>Tablet 32 mg<br>Injection 40 mg/mL | S,T | Injection 40 mg/mL |

| | | | | |
|---|---|---|---|---|
| Prednisolone | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Oral liquid 5 mg/5 mL (p)<br>Oral liquid 15 mg/5 mL |
| **Section 18.4.1 - Insulins and other antidiabetic agents** | | | | |
| Metformin | P,S,T | Tablet 500 mg<br>Tablet 750 mg<br>Tablet 1000 mg<br>(Immediate and controlled release) | P,S,T | Tablet 500 mg<br>Tablet 1000 mg<br>Modified release<br>Tablet 1000 mg |
| **Section 18.5-Ovulation Inducers** | | | | |
| Human chorionic gonadotropin | T | Injection 1000 IU<br>Injection 5000 IU | S,T | Injection 2000 IU<br>Injection 5000 IU<br>Injection 10000 IU |
| **Section 18.6 - Progestogens** | | | | |
| Medroxyprogesterone acetate | P,S,T | Tablet 5 mg<br>Tablet 10 mg | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Injection 150 mg/ mL |
| **Section 18.7-Thyroid and antithyroid medicines** | | | | |
| Carbimazole | P,S,T | Tablet 5 mg<br>Tablet 10 mg | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg |

| | | | | |
|---|---|---|---|---|
| **Section 21.1 - Anti-infective medicines** | | | | |
| Povidone iodine | P,S,T | Drops 0.6%<br>Drops 5% | P,S,T | Drops 5% |
| **Section 21.2 - Anti-inflammatory medicine** | | | | |
| Prednisolone | P,S,T | Drops 0.1%<br>Drops 1% | P,S,T | Drops 1% |
| **Section 23.1-Medicines used in psychotic disorders** | | | | |
| Haloperidol | S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Oral liquid 2 mg/5 mL | S,T | Tablet 2 mg<br>Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Oral liquid 2 mg/5 mL<br>Injection 5 mg/mL |
| Risperidone | P,S,T | Tablet 1 mg<br>Tablet 2 mg<br>Tablet 4 mg<br>Oral liquid 1 mg/mL | P,S,T | Tablet 1 mg<br>Tablet 2 mg<br>Tablet 4 mg<br>Oral liquid 1 mg/mL<br>Injection (Long acting) 25 mg<br>Injection (Long acting) 37.5 mg |

| | | | | |
|---|---|---|---|---|
| **Section 23.2.1 - Medicines used in Bipolar disorders** | | | | |
| Sodium valproate | P,S,T | Tablet 200 mg<br>Tablet 500 mg | P,S,T | Tablet 200 mg<br>Tablet 300 mg<br>Tablet 500 mg<br>Modified Release<br>Tablet 300 mg<br>Tablet 500 mg |
| **Section 25 - Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances** | | | | |
| Sodium chloride | P,S,T | Injection 0.9% | P,S,T | Injection 0.9% |
| | S,T | Injection 0.45%<br>Injection 3% | S,T | Injection 3% |
| **Section 26-Vitamins and minerals** | | | | |
| Calcium carbonate | P,S,T | Tablet 250 mg<br>Tablet 500 mg | P,S,T | Tablet 1250 mg (equivalent to elemental calcium 500 mg) |
| Riboflavin | P,S,T | Tablet 5 mg | P,S,T | Tablet 10 mg |
| Vitamin A | P,S,T | Capsule 5000 IU<br>Capsule 50000 IU<br>Capsule 100000 IU<br>Oral liquid 100000 IU/ml Injection 50000 IU/ml | P,S,T | Capsule/Tablet 50000 IU (including Chewable tablet)<br>Oral liquid 100000 IU/mL<br>Injection 50000 IU/mL |

## Annexure 4 – Drugs figuring in more than one therapeutic category

## Annexure 4.1: Drugs figuring in two therapeutic categories

| Drugs Figuring in Two Therapeutic Categories | | |
|---|---|---|
| **S.No.** | **Drug** | **Therapeutic Category** |
| 1. | Albendazole | Sub Section 6.1.2 – Antifilarial |
| | | Sub Section 6.1.1- Intestinal Anthelminthics |
| 2. | Allopurinol | Sub Section 2.3 - Medicines used to treat gout |
| | | Sub Section 7.4 - Medicines used in palliative care |
| 3. | Amphotericin B | Sub Section 6.5.1- Antifungal medicines |
| | | Sub Section 6.9.3- Antileishmaniasis medicines |
| 4. | Azathioprine | Sub Section 2.4 - Disease Modifying Agents used in Rheumatoid Disorders |
| | | Sub Section 7.3- Immunosuppressive medicines |
| 5. | Azithromycin | Sub Section 6.2.14- Other antibacterials |
| | | Sub Section 6.7.26- Additional Medicines for Syndromic Management of Sexually Transmitted Infections |
| 6. | Budesonide | Sub Section 16- Ear, Nose and Throat Medicines |
| | | Sub Section 24.1 -Antiasthmatic Medicines |

| | | |
|---|---|---|
| 7. | Calcium Gluconate | Sub Section 4.2.2 - Antidotes and Other Substances used in Management of Poisonings/Envenomation- Specific |
| | | Sub Section 26.3 - Vitamins and Minerals |
| 8. | Carbamazepine | Sub Section 5.1.1 –Anticonvulsants/antiepileptics |
| | | Sub Section 23.2.6-Medicines used in Bipolar disorders |
| 9. | Cefotaxime | Sub Section 6.2.9 – Beta Lactam medicines |
| | | Sub Section 6.7.21- Medicines for treating Opportunistic Infections in People living with HIV |
| 10. | Clarithromycin | Sub Section 6.2.17-Other antibacterials |
| | | Sub Section 6.4.4 – Anti-tuberculosis medicines |
| 11. | Clofazimine | Sub Section 6.3.1- Antileprosy medicines |
| | | Sub Section 6.4.5– Anti-tuberculosis medicines |
| 12. | Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B) | Sub Section 6.2.19- Other antibacterials |
| | | Sub Section 6.9.7-Antipneumocystosis and antitoxoplasmosis medicines |

| | | |
|---|---|---|
| 13. | Diazepam | Sub Section 5.1.3- Anticonvulsants/ Antiepileptics |
| | | Sub Section 7.4.4 - Medicines used in palliative care |
| 14. | Digoxin | Sub Section 10.2.3- Antiarrhythmic medicines |
| | | Sub Section 10.4.1- Medicines used in Shock and Heart Failure |
| 15. | Doxycycline | Sub Section 6.2.20- Other antibacterials |
| | | Sub Section 6.10.8 – For prophylaxis |
| 16. | Glucose | Sub Section 18.4.8- Medicines used to treat hypoglycemia |
| | | Sub Section 25.1-Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances |
| 17. | Haloperidol | Sub Section 7.4.7 - Medicines used in Palliative Care |
| | | Sub Section 23.1.3 - Medicines used in psychotic disorders |
| 18. | Heparin | Sub Section 8.2.2 - Medicines affecting coagulation |
| | | Sub Section 10.5.3 -Antithrombotic medicine (Cardiovascular/Cerebrovascular) |

| | | |
|---|---|---|
| 19. | Hydrochlorothiazide | Sub Section 10.3.3 - Antihypertensive medicines |
| | | Sub Section 15.2 - Diuretics |
| 20. | Hydroxyurea | Sub Section 7.1.6 Antineoplastic medicines |
| | | Sub Section 8.1.6 - Antianaemia medicines |
| 21. | Ibuprofen | Sub Section 2.1.3- Non-opioid Analgesics, Antipyretics and Non-steroidal Anti-inflammatory Drugs |
| | | Sub Section 5.3.2 – Medicines used in Neurological disorders- Antimigraine medicines |
| 22. | Lactulose | Sub Section – 7.4.8 –Medicines used in Palliative Care |
| | | Sub Section 17.5.3 – Gastrointestinal medicines - Laxatives |
| 23. | Lignocaine | Sub Section 1.2.2- Local Anaesthetics |
| | | Sub Section 10.2.5 –Antiarrhythmic medicines |
| 24. | Methotrexate | Sub Section 2.4.3- Disease Modifying Agents used in Rheumatoid Disorders |
| | | Sub Section 7.1.33 -Antineoplastic medicines |
| 25. | Methylprednisolone | Sub Section 18.1- Adrenal Hormones and Synthetic |

| | | |
|---|---|---|
| | | substitutes |
| | | Section 27 - Medicines for COVID– 19 management |
| 26. | Metoclopramide | Sub Section 7.4.10 –Medicines used in Palliative Care |
| | | Sub Section 17.2.2 –Antiemetics |
| 27. | Metronidazole | Sub Section 6.2.22 – Other antibacterials |
| | | Sub Section 6.9.2 – Medicines used for amoebiasis and other parasitic infections |
| 28. | Neostigmine | Sub Section 6.9.2 – Medicines used for amoebiasis and other parasitic infections |
| | | Sub Section 4.2.10 – Antidotes and Other Substances used in Management of Poisonings/Envenomation- Specific |
| 29. | Ondansetron | Sub Section 7.4.15- Medicines used in Palliative Care |
| | | Sub Section 17.2.3 – Anti-ulcer medicines |
| 30. | Oral Rehydration Salts | Sub Section 17.6.1 – Medicines used in diarrhoea |
| | | Sub Section 25.3 – Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances |
| 31. | Oxygen | Sub Section 1.1.5 - General Anaesthetics and Oxygen |

| | | |
|---|---|---|
| | | Sub Section 27.5- Medicines for COVID– 19 management |
| 32. | Povidone iodine | Section 14.1.5 – Antiseptics and Disinfectants- Antiseptics |
| | | Sub Section 21.1.5 - Anti-infective medicine |
| 33. | Proparacaine | Sub Section 12.1.2 - Diagnostic agents - Ophthalmic Medicines |
| | | Sub Section 21.3.1 - Local anaesthetic |
| 34. | Rifampicin | Sub Section 6.3.3- Antileprosy medicines |
| | | Sub Section 6.4.17 – Anti-tubercular medicines |
| 35. | Snake Venom Antiserum | Sub Section 4.2.12 – Antidotes and Other Substances used in Management of Poisonings/Envenomation- Specific |
| | | Sub Section 19.2.7 – Sera and immunoglobulins (Liquid/ Lyophilized) |
| 36. | Sodium Valproate | Sub Section 5.1.9 –Anticonvulsants /antiepileptics |
| | | Sub Section 23.2.5- Medicines used in mood disorders |
| 37. | Spironolactone | Sub Section 10.4.5 - Medicines used in shock and heart failure |
| | | Sub Section 15.4 - Diuretics |
| 38. | Tenofovir Disproxil Fumarate (TDF) | Sub Section 6.7.4 – Nucleoside reverse transcriptase inhibitors |

| | | |
|---|---|---|
| | | Sub Section 6.8– Medicines for Hepatitis B and Hepatitis C |
| 39. | Tramadol | Sub Section 2.2.- Opioid Analgesics |
| | | Sub Section 7.4.- Medicines used in Palliative Care |
| 40. | Tropicamide | Sub Section 12.1.- Ophthalmic Medicines |
| | | Sub Section 21.5. - Mydriatics |
| 41. | Valganciclovir | Sub Section 6.6.2- Anti Cytomegalovirus (CMV) Medicines |
| | | Sub Section 6.7.5- Medicines for treating Opportunistic Infections in People living with HIV |

## Annexure 4.2: Drugs Figuring in Three Therapeutic Categories

| Drugs Figuring in Three Therapeutic Categories | | |
|---|---|---|
| **S.No.** | **Drug** | **Therapeutic Category** |
| 1. | Acetylsalicylic acid | Sub Section 2.1. - Non-opioid Analgesics, Antipyretics and Non-steroidal Anti-inflammatory Drugs |
| | | Section 5.2- Antimigraine Medicines |
| | | Sub Section 10.5- Antiplatelet and Antithrombotic Medicines |
| 2. | Acyclovir | Sub Section 6.6.1 - Anti-herpes medicines |
| | | Sub Section 6.7.5- Medicines for treating Opportunistic Infections in People living with HIV |
| | | Sub Section 21.1- Anti-infective medicine |
| 3. | Amitriptyline | Sub Section 5.2.1 - For Prophylaxis |
| | | Sub Section 7.4 - Medicines used in Palliative Care |
| | | Sub Section 23.2.1 - Medicines used in Depressive Disorder |

| | | |
|---|---|---|
| 4. | Atropine | Sub Section 1.3- Preoperative Medication and Sedation for Short Term Procedures |
| | | Sub Section 4.2.1- Antidotes and Other Substances used in Management of Poisonings/Envenomation- Specific |
| | | Sub Section 21.5.1 - Ophthalmological Medicines- Mydriatics |
| 5. | Ciprofloxacin | Sub Section 6.2.2 - Anti-infective medicines- Antibacterials -Other Antibacterials |
| | | Sub Section 16.2 - Ear, Nose and Throat Medicines |
| | | Sub Section 21.1-Anti-infective Medicines |
| 6. | Enoxaparin | Sub Section 10.5.4 - Antiplatelet and Antithrombotic Medicines |
| | | Sub Section 8.2.1- Medicines affecting coagulation |
| | | Section 27 - Medicines for COVID– 19 management |
| 7. | Fluoxetine | Sub Section 7.4 -Medicines used in Palliative Care |
| | | Sub Section 23.2.1 - Medicines used in Depressive Disorders |
| | | Sub Section 23.4 - Medicines used in Obsessive Compulsive Disorders and Panic attacks |
| 8. | Hydrocortisone | Sub Section 3.5- Antiallergics and Medicines used in |

| | | |
|---|---|---|
| | | Anaphylaxis |
| | | Sub Section 18.1.3- Adrenal hormones and synthetic substitutes |
| | | Sub Section 24.1 -Antiasthmatic Medicines |
| 9. | Midazolam | Sub Section 1.3- Preoperative Medication and Sedation for Short Term Procedures |
| | | Sub Section 5.1- Anticonvulsants/ Antiepileptics |
| | | Sub Section 7.4- Medicines used in Palliative Care |
| 10. | Morphine | Sub Section- 1.3- Preoperative Medication and Sedation for Short Term Procedures |
| | | Sub Section 2.2- Opioid Analgesics |
| | | Sub Section - 7.4-Medicines used in Palliative Care |
| 11. | Paracetamol | Sub Section 2.1 - Non-opioid Analgesics, Antipyretics and Non-steroidal Anti-inflammatory Drugs |
| | | Sub Section 5.2- Antimigraine Medicines |
| | | Section 27- Medicines for COVID– 19 management |

## Annexure 4.3: Drugs Figuring in Four Therapeutic Categories

| Drugs Figuring in Four Therapeutic Categories | | |
|---|---|---|
| **S.No.** | **Drug** | **Therapeutic Category** |
| 1. | Clindamycin | Sub Section 6.2.- Other antibacterials |
| | | Sub Section 6.7.5- Medicines for treating Opportunistic Infections in People living with HIV |
| | | Sub Section 6.9.3- Antipneumocystosis and antitoxoplasmosis medicines |
| | | Sub Section 6.10.1 - For curative treatment |
| 2. | Clotrimazole | Sub Section 6.5- Antifungal medicines |
| | | Sub Section 6.7.5- Medicines for treating Opportunistic Infections in People living with HIV |
| | | Sub Section 11.1. - Antifungal medicines |
| | | Section 16- Ear, nose and throat medicines |
| 3. | Dexamethasone | Section 3 - Antiallergics and Medicines used in |

| | | |
|---|---|---|
| | | Anaphylaxis |
| | | Sub Section 7.4 - Medicines used in Palliative Care |
| | | Sub Section 18.1- Adrenal Hormones and Synthetic substitutes |
| | | Section 27 - Medicines for COVID– 19 management |
| 4 | Prednisolone | Sub Section 3.- Antiallergics and medicines used in anaphylaxis |
| | | Sub Section 7.2.- Hormones and anti-hormones used in cancer therapy |
| | | Sub Section 18.1- Adrenal hormones and synthetic substitutes |
| | | Sub Section 21.1- Anti-inflammatory medicine |

# National List of Essential Medicines (NLEM), 2022

# List of Experts

# National List of Essential Medicines (NLEM) 2022

## List of Experts Participated in NLEM 2022 Deliberation

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 1. | A K Rai | E.N.T. | Principal Consultant | Dr. Ram Manohar Lohia Hospital, Delhi |
| 2. | Abha Singh | Obstetrics &Gynaecology | Professor | Lady Hardinge Medical College, Delhi |
| 3. | Abhinav Kumar | Surgery | Associate Professor | JPN Trauma Centre AIIMS, Delhi |
| 4. | Abhinav Sinha | Malaria Epidemiology | Scientist E | ICMR-NIMR Delhi |
| 5. | Abid Jilani | Cardiology | Professor | Govind Ballabh Pant Hospital, Delhi |
| 6. | Ajay Kumar Dudeja | Paediatrics | Senior Paediatrician | Kalawati Saran Children Hospital, Delhi |
| 7. | Ajay Mahajan | Cardiology | Professor | Lokmanya Tilak Municipal Medical College, Mumbai |
| 8. | Ajay Shukla | Pharmacology | Assistant Professor | All India Institute of Medical Sciences, Bhoapl |
| 9. | Ajit Avasthi | Psychiatry | Professor | PGIMER, Chandigarh |
| 10. | Alka Kriplani | Obstetrics & Gynaecology | Professor | All India Institute of Medical Sciences, Delhi |
| 11. | Alok Dhawan | Toxicology | Director | CSIR-Central Drug Research Institute, Lucknow |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 12. | Alok Thakkar | Otorhinolaryngology | Professor | All India Institute of Medical Sciences, Delhi |
| 13. | Amit Kumar Satpathy | Pediatrics | Associate Professor | All India Institute of Medical Sciences, Bhubaneswar |
| 14. | Amita Aggarwal | Clinical Immunology | Professor | SGPGI, Lucknow |
| 15. | Anant Mohan | Pulmonary Medicine & Sleep Disorder | Professor | All India Institute of Medical Sciences, Delhi |
| 16. | Anil Aggarwal | Gastrointestinal Surgery | Professor | Govind Ballabh Pant Hospital, Delhi |
| 17. | Anil Bhansali | Endocrinology | Professor | PGIMER, Chandigarh |
| 18. | Animesh Ray | Medicines | Assistant Professor | All India Institute of Medical Sciences, Delhi |
| 19. | Anirban Biswas | Neurotology | Founder &Head | Vertigo & Deafness Clinic, Kolkata |
| 20. | Anju Seth | Paediatrics | Professor | Kalawati Saran Children's Hospital, Delhi |
| 21. | Anoop Misra | Endocrinologist | Chairman | National Diabetes, Obesity & Cholesterol Foundation |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 22. | Anubhav Gupta | CTVs | Professor | All India Institute of Medical Sciences, Delhi |
| 23. | Anup Anvikar | Malaria Field | Scientist-F | ICMR-NIMR, Delhi |
| 24. | Anup Kumar | Urology | Professor | All India Institute of Medical Sciences, Delhi |
| 25. | Anup Kumar Kundu | Urology | Professor | IPGMER, Kolkata |
| 26. | Anupam Prakash | Medicines | Professor | Lady Hardinge Medical College, Delhi |
| 27. | Anuradha H V | Pharmacology | Head | M.S. Ramaiah Medical College, Bengaluru |
| 28. | Anushree D. Patil | Clinical Research | Scientist-D | ICMR-NIRRH, Mumbai |
| 29. | Arti Kapil | Microbiology | Professor | All India Institute of Medical Sciences, Delhi |
| 30. | Arun Aggarwal | Otorhinolaryngology | Former Head | Maulana Azad Medical College, Delhi |
| 31. | Aruna Kekre | Obstetrics and Gynecology | Professor | Christian Medical College ,Vellore |
| 32. | Arvind Kumar | Medicines | Associate Professor | All India Institute of Medical Sciences, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 33. | Ashish Kakkar | Pharmacology | Assistant Professor | PGIMER, Chandigarh |
| 34. | Ashok K. Deorari | Paediatric | Professor | All India Institute of Medical Sciences, Delhi |
| 35. | Ashok Vaid | Medical Oncology | Chairman | Medanta Hospital, Gurugram |
| 36. | Asith Mittal | Dermatology | Professor | RNT Medical College, Udaipur, Rajasthan |
| 37. | Atul Sharma | Oncology | Professor | All India Institute of Medical Sciences, Delhi |
| 38. | Awadesh Kumar Jha | Pharmacology | Professor | Government Medical College, Bihar |
| 39. | B Ghosh | Ophthalmology | Former Director | Guru Nanak Eye Centre, Delhi |
| 40. | B N Gangadhar | Psychiatry | Director | NIMHANS, Bengaluru |
| 41. | Bani Sarcar | Obstetrics and Gynaecology | Professor | Dr. Ram Manohar Lohia Hospital, Delhi |
| 42. | Bikash Medhi | Pharmacology | Professor | PGIMER, Chandigarh |
| 43. | Biswa Mohan Padhy | Pharmacology | Associate Professor | All India Institute of Medical Sciences, Bhubaneswar |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 44. | Biswaroop Chakrabarty | Paediatrics | Assistant Professor | All India Institute of Medical Sciences, Delhi |
| 45. | C K Durga | Surgery | Professor | Dr. Ram Manohar Lohia Hospital, Delhi |
| 46. | C.D. Tripathi | Pharmacology | Professor | VMMC & Safdarjung Hospital, Delhi |
| 47. | Chayna Sarkar | Pharmacology | Professor | NEIGRIHMS, Shillong, Meghalaya |
| 48. | Chetna Desai | Pharmacology | Head | BJ Medical College, Asarwa, Gujarat |
| 49. | Chinmoyee Das | Public Health | Deputy Director | National AIDS Control Organization, Delhi |
| 50. | D C Katoch | Ayurveda | Advisor | Ministry of AYUSH |
| 51. | D S Meena | Anaesthesia | Professor | VMMC & Safdarjung Hospital, New Delhi |
| 52. | DBV Madhusudan Rao | Anaesthesia | Associate Professor | Andhra Medical Rao College, Visakhapatnam |
| 53. | Debashish Chowdhury | Neurology | Professor | G.B. Pant Hospital, Delhi |
| 54. | Deepika Saraf | Epidemiology | Scientist-E | Indian Council of Medical Research, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 55. | Dennis Xavier | Pharmacology | Professor | St John's Medical College, Bangalore |
| 56. | Devi Dayal Gupta | Pharmacology | Professor | Indira Gandhi Medical College, Shimla |
| 57. | Digambar Behera | Pulmonary | Professor | PGIMER, Chandigarh |
| 58. | Dinesh Kumar Badyal | Pharmacology | Head | Christian Medical College, Ludhiana |
| 59. | Dipankar Bhowmik | Nephrology | Professor | All India Institute of Medical Sciences, Delhi |
| 60. | Forhad Zaman | Community Medicines | Professor | Sikkim Manipal Institute of Medical Sciences, Sikkim |
| 61. | G D Puri | Anaesthesia | Professor | PGIMER, Chandigarh |
| 62. | G.C. Khilnani | Critical Care & Sleep Medicine | Chairman | PSRI Hospital, Delhi |
| 63. | Gagandeep Singh | Microbiology | Assistant Professor | All India Institute of Medical Sciences, Delhi |
| 64. | Gajanan D Velhal | Community Medicine | Head | Seth G S Medical College, Mumbai |
| 65. | Garima Kachhawa | Obstetrics & Gynaecology | Additional Professor | All India Institute of Medical Sciences, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 66. | H P Anand | Obstetrics and Gynaecology | Professor | VMMC & Safdarjung Hospital, Delhi |
| 67. | Harender Kumar | Medicine | Professor | BSA Medical College &Hospital, Delhi |
| 68. | Harivansh Chopra | Community Medicines | Professor | Govt. Medical college, Meerut , Uttar Pradesh |
| 69. | Harmeet Singh Rehan | Pharmacology | Professor | Lady Hardinge Medical College,Delhi |
| 70. | J C Suri | Pulmonary Medicine and Sleep Disorder | Professor | VMMC & Safdarjung Hospital, Delhi |
| 71. | Jhuma Sankar | Paediatrics | Assistant Professor | All India Institute of Medical Sciences, Delhi |
| 72. | Justin Paul | Cardiology | Professor | Apollo Medical Centre, Chennai |
| 73. | K H Srinivasa | Cardiology | Professor | SICSR, Bangalore |
| 74. | K K Talwar | Cardiology | Professor | Max Hospital, Delhi |
| 75. | K. Chandra Kala | Pharmacology | Associate Professor | Guntur Medical College, Guntur, Andhra Pradesh |
| 76. | K.V. Siva Prasad | Pharmacology | Professor | Rangaraya Medical College, Kakinada, Andhra Pradesh |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 77. | Kamal Krishnu Kundu | Pharmacology | Professor | Agartala Government Medical College, Tripura |
| 78. | Kameshwar Prasad | Neurology | Professor | All India Institute of Medical Sciences, Delhi |
| 79. | Kamini Walia | Antimicrobial Diseases | Scientist F | Indian Council of Medical Research, Delhi |
| 80. | Kamlesh | Ophthalmology | Professor | Guru Nanak Eye Hospital, Delhi |
| 81. | Krishna Biswas | Endocrinology &Metabolism | Professor | VMMC & Safdarjung Hospital, Delhi |
| 82. | Krishna Panday | Clinical Medicine | Director | ICMR- RMRIMS Patna |
| 83. | Lalit Kumar | Medical Oncology | Professor | All India Institute of Medical Sciences, Delhi |
| 84. | Lalit Kumar Gupta | Pharmacology | Professor | Lady Hardinge Medical College, Delhi |
| 85. | Lalit Maine | Orthopaedics | Professor | LNJP Hospital, Delhi |
| 86. | Lyla K. N | Pharmacology | Head | Travancore Medical College and Hospital, Kollam, Kerala |
| 87. | M K Lal | Medicine | Senior Physician | VMMC & Safdarjung Hospital, Delhi |
| 88. | M K Sen | Pulmonary Medicine &Sleep Disorder | Consultant | VMMC & Safdarjung Hospital, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 89. | M Ramesh | Pharmacology | Head | JSS Medical College Hospital, Mysore, Karnataka |
| 90. | M.C. Gupta | Pharmacology | Head | PGIMS, Rohtak,Haryana |
| 91. | Mahipal Sachdev | Ophthalmology | Chairman & Medical Director | Centre For Sight Group of Eye Hospitals, Delhi |
| 92. | Manik Mahajan | Radio-Diagnosis | Lecturer | Govt. Medical college Jammu, Jammu & Kashmir |
| 93. | Manish Soneja | Medicines | Associate Professor | All India Institute of Medical Sciences, Delhi |
| 94. | Manjari Tripathi | Neurology | Additional Professor | All India Institute of Medical Sciences, Delhi |
| 95. | Manju Puri | Obstetrics and Gynaecology | Professor | Lady Hardinge Medical College, Delhi |
| 96. | Manju Sengar | Medical Oncology | Professor | Tata Memorial Hospital, Mumbai |
| 97. | Manoj Kumar Dash | Community Medicine | Assistant Professor | Pt. Raghunath Murmu Medical College, Baripada, Odisha |
| 98. | Manoj Kumar Saurabh | Pharmacology | Professor | All India Institute of Medical Sciences, Deoghar, Jharkhand |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 99. | Mira Desai | Pharmacology | Professor | Nootan Medical College and Research Centre, Gujrat |
| 100. | Mohit Gupta | Cardiology | Professor | G.B. Pant Hospital, Delhi |
| 101. | N. Poorana Ganga Devi | General Medicine | Scientist C | ICMR- NIRT, Chennai |
| 102. | N.N. Mathur | ENT | Director | Lady Hardinge Medical College, Delhi |
| 103. | Narendra Kumar Bagri | Paediatrics | Associate Professor | All India Institute of Medical Sciences, Delhi |
| 104. | Naresh Gupta | Medicines | Former Director | Maulana Azad Medical College, Delhi |
| 105. | Naresh Kumar Gill | Public Health | Deputy Director | National Vector Borne Disease Control Programme, MoHFW |
| 106. | Neelam Marwaha | Transfusion Medicine | Professor | PGIMER, Chandigarh |
| 107. | Neena Khanna | Dermatology | Professor | All India Institute of Medical Sciences, Delhi |
| 108. | Neeraj Pandit | Cardiology | Professor | Dr. Ram Manohar Lohia Hospital, Delhi |
| 109. | Neerja Bhatla | Obstetrics and Gynaecology | Professor | All India Institute of Medical Sciences, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 110. | Nikhil Tandon | Endocrinology &Metabolism | Professor | All India Institute of Medical Sciences, New Delhi |
| 111. | Nilima Kshirsagar | Pharmacology | National Chair | Clinical Pharmacology, ICMR, Delhi-Mumbai |
| 112. | Nimesh Desai | Psychiatrist | Professor | Institute of Human Behaviour and Allied Sciences, Delhi |
| 113. | Nithya Gogtay | Pharmacology | Head | Seth GS Medical Mumbai, Maharashtra |
| 114. | Niyati Trivedi | Pharmacology | Head | Medical college, Baroda, Gujrat |
| 115. | Nusrat Shafiq | Pharmacology | Professor | PGIMER, Chandigarh |
| 116. | P Lakshminarayana | Ophthalmology | Head | ESIC Model Hospital, Noida |
| 117. | P Usha Rani | Pharmacology | Professor | Nizam Institute of Medical Sciences, Hyderabad, Telangana |
| 118. | Padma Srivastava | Neurology | Head | Neurosciences Centre, AIIMS, Delhi |
| 119. | Pankaj Kumar Masare | Pharmacology | Assistant Professor | Belgaum Institute of Medical Sciences, Belgaum, Karnataka |
| 120. | Pawanindra Lal | General Surgery | Professor | Maulana Azad Medical College, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 121. | Pikee Saxena | Obstetrics and Gynaecology | Professor | Lady Hardinge Medical College, Delhi |
| 122. | Pooja Agrawal | Pharmacology | Head | GSVM Medical College, Kanpur, Uttar Pradesh |
| 123. | Pooja Gupta | Pharmacology | Associate Professor | All India Institute of Medical Sciences, Delhi |
| 124. | Pradeep Kumar Saha | Psychiatry | Professor | Government of West Bengal, Kolkata |
| 125. | Prafull Mohan | Pharmacology | Associate Professor | Armed Forces Medical College, Pune |
| 126. | Pramod Kumar Manjhi | Pharmacology | Assistant Professor | All India Institute of Medical Sciences, Patna |
| 127. | Prantar Chakrabarti | Hematology | Professor | Nil Ratan Sircar Medical College and Hospital, Kolkata |
| 128. | Prashant Ganeshan | Medical Oncology | Additional Professor | JIPMER, Puducherry |
| 129. | Pratibha Kale | Microbiology | Assistant Professor | Institute of Liver and Biliary Sciences, Delhi |
| 130. | Pratima Mittal | Obstetrics and Gynaecology | Professor | VMMC & Safdarjung Hospital, Delhi |
| 131. | Pratima Murthy | Psychiatry | Professor & Head | NIMHANS, Bengaluru |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 132. | Praveen Aggarwal | Emergency | Professor | All India Institute of Medical Sciences, Delhi |
| 133. | Pravin G. Dhone | Pharmacology | Professor | Govt. Medical College, Chhattisgarh |
| 134. | Puneet Dhamija | Pharmacology | Addition Professor | All India Institute of Medical Sciences, Rishikesh |
| 135. | Purva Mathur | Laboratory Medicine | Assistant Professor | JPN Trauma Center AIIMS, Delhi |
| 136. | Pushpa G Kini | Paediatrics | Professor | Kasturba Medical College, Manipal |
| 137. | R K Arya | Orthopaedics | Professor | VMMC & Safdarjung Hospital, Delhi |
| 138. | R K Sharma | Nephrology | Professor | S.G.P.G.I. Lucknow |
| 139. | R S Gupta | Epidemiologist | Deputy Director | National AIDS Control Organization, Delhi |
| 140. | R. Manikandan | Urology | Head | JIPMER, Puducherry |
| 141. | Radhika Tandon | Ophthalmology | Professor | All India Institute of Medical Sciences, Delhi |
| 142. | Raj Kanwar Yadav | Nephrology | Professor | All India Institute of Medical Sciences, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 143. | Rajeev Sood | Anaesthesiology | Professor | Dr. Ram Manohar Lohia Hospital, Delhi |
| 144. | Rajesh Khadgawat | Endocrinology & Metabolism | Additional Professor | All India Institute of Medical Sciences, Delhi |
| 145. | Rajesh Kumar Grover | Medical Oncology | Director | Delhi State Cancer Institute, Delhi |
| 146. | Rajesh Malhotra | Orthopaedics | Professor | All India Institute of Medical Sciences, Delhi |
| 147. | Rajni Gaind | Microbiology | Associate Professor | VMMC & Safdarjung Hospital, Delhi |
| 148. | Rakesh Aggarwal | Gastroenterologist | Professor | JIPMER, Puducherry |
| 149. | Rakesh Lodha | Paediatrics | Professor | All India Institute of Medical Sciences, Delhi |
| 150. | Rakesh Yadav | Cardiology | Professor | All India Institute of Medical Sciences, Delhi |
| 151. | Ram Chander | Dermatology | Professor | Lady Hardinge Medical College, Delhi |
| 152. | Ram Vishwakarma | Pharmaceutical Sciences | Professor | CSIR-Indian Institute of Integrative Medicine, Jammu |
| 153. | Raman R. Gangakhedkar | Epidemiologist | Former Division Head, ECD | Indian Council of Medical Research, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 154. | Ramanuj Bansal | ENT | Consultant | LNJP Hospital, Delhi |
| 155. | Ramesh Agarwal | Neonatology | Professor | All India Institute of Medical Sciences, Delhi |
| 156. | Ramesh Kumar | Orthopaedics | Professor | VMMC & Safdarjung Hospital, Delhi |
| 157. | Ranen Chakraverty | Oncology | Professor | Dr. Ram Manohar Lohia Hospital, Delhi |
| 158. | Rangeel Singh Raina | Pharmacology | Professor | Government Doon Medical College, Dehradun |
| 159. | Rashmi Kumar | Paediatrics | Professor | King George Medical College, Lucknow |
| 160. | Rashmi Kundapur | Community Medicine | Professor | AII India Institute of Medical Sciences, Telangana |
| 161. | Rashmi Ramchandran | Anaesthesiology | Professor | All India Institute of Medical Sciences, Delhi |
| 162. | Rashmi Ranjan Das | Pediatrics | Additional Professor | All India Institute of Medical Sciences, Bhubaneswar |
| 163. | Rashmiranjan Mohanty | General Medicine | Additional Professor | All India Institute of Medical Sciences, Bhubaneswar |
| 164. | Ratinder Jhaj | Pharmacology | Additional Professor | All India Institute of Medical Sciences, Bhopal |
| 165. | Reeja R | Pharmacology | Professor | Govt. Medical College, Kollam, Kerla |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 166. | Renu Saxena | Haematology | Professor | All India Institute of Medical Sciences, Delhi |
| 167. | Rohit Saxena | Ophthalmology | Professor | All India Institute of Medical Sciences, Delhi |
| 168. | Ruchika Mittal | Ear Nose &Throat | Technical Assistant | Mittal Clinic, Delhi |
| 169. | Rupak Singla | Respiratory | Professor | National Institute of T.B.&Respiratory Diseases, Delhi |
| 170. | Rupali Dewan | Obstetrics and Gynaecology | Professor | VMMC & Safdarjung Hospital, Delhi |
| 171. | S Jayachandran | Oral Medicines and Radiology | Professor | Tamilnadu Dental College & Hospital, Chennai |
| 172. | S K Agarwal | Nephrology | Professor | All India Institute of Medical Sciences, Delhi |
| 173. | S K Jain | Medicines | Professor | Lady Hardinge Medical College, Delhi |
| 174. | S K Kabra | Pediatrics | Professor | All India Institute of Medical Sciences, Delhi |
| 175. | S K Maulik | Pharmacology | Professor | All India Institute of Medical Sciences, Delhi |
| 176. | S P Kataria | Medical Oncology | Consultant | VMMC & Safdarjung Hospital, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 177. | S P Singh | Medicine | Professor | VMMC & Safdarjung Hospital, Delhi |
| 178. | S V Arya | Surgery | Professor | VMMC & Safdarjung Hospital, Delhi |
| 179. | Sachidanand Jee Bharati | Palliative Medicine | Associate Professor | All India Institute of Medical Sciences, Delhi |
| 180. | Sadhna Kaushik | Pharmacology | Professor | Maharani Laxmi Bai Medical College Hospital, Jhansi |
| 181. | Sadishkumar Kamalanathan | Endocrinology | Additional Professor | JIPMER, Puducherry |
| 182. | Sameer Bakhshi | Medical Oncology | Professor | All India Institute of Medical Sciences, Delhi |
| 183. | Sameer Sethi | Anaesthesia | Additional Professor | PGIMER, Chandigarh |
| 184. | Samir Malhotra | Pharmacology | Professor | PGIMER, Chandigarh |
| 185. | Sandeep Bansal | Cardiology | Professor | VMMC & Safdarjung Hospital, Delhi |
| 186. | Sandeep Kaushal | Pharmacology | Head | Dayanand Medical College & Hospital, Ludhiana |
| 187. | Sandeep Singh | Cardiology | Professor | All India Institute of Medical Sciences, Delhi |
| 188. | Sandip Kumar Panda | Nephrology | Assistant Professor | All India Institute of Medical Sciences, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 189. | Sandya Kamar | Pharmacology | Professor | Seth G.S. Medical College, Mumbai |
| 190. | Sanjeev Kumar Bhoi | Neurology | Assistant Professor | All India Institute of Medical Sciences, Bhubaneswar |
| 191. | Sanjiv Sinha | Medicine | Professor | All India Institute of Medical Sciences, Delhi |
| 192. | Sanjiv Sinha | Medicines | Professor | All India Institute of Medical Sciences, Delhi |
| 193. | Santanu Kumar Tripathi | Department of Clinical & Experimental | Professor | Calcutta School Of Tropical Medicine, Kolkata |
| 194. | Sarman Singh | Microbiology | Director | All India Institute of Medical Sciences, Bhopal |
| 195. | Saubhagya Kumar Jena | Obstetrics & Gynaecology | Professor | All India Institute of Medical Sciences, Bhubaneswar |
| 196. | Savita Verma | Pharmacology | Professor | PGIMER, Rohtak, Haryana |
| 197. | Shantanu Guha | Cardiology | Professor | Kolkata Medical College, Kolkata |
| 198. | Sheffali Gulati | Pediatrics | Professor | All India Institute of Medical Sciences, Delhi |
| 199. | Shiv Kumar Choudhary | Cardiology | Professor | All India Institute of Medical Sciences, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 200. | Shivani Aggarwal | Otolaryngology | Technical Assistant | All India Institute of Medical Sciences, Delhi |
| 201. | Shivkumar Halkude | Community Medicine | Additional District Health Officer | District Osmanabad, Maharashtra |
| 202. | Shobini Rajan | Pathology | Chief Medical Officer | National Aids Control Organisation, Delhi |
| 203. | Shruti Srivastava | Psychiatry | Professor | University College Of Medical Sciences, University of Delhi |
| 204. | Siddhartha Sathpathy | Hospital Administration | Professor | All India Institute of Medical Sciences, Delhi |
| 205. | Smita Deshpande | Phychiatry | Professor | Dr. Ram Manohar Lohia Hospital, Delhi |
| 206. | Sneha Ambwani | Pharmacology | Head | All India Institute of Medical Sciences, Jodhpur |
| 207. | Sonali Sarkar | Preventive and Social Medicine | Assistant Professor | JIPMER, Puducherry |
| 208. | Soumitra S Datta | Palliative Care | Senior Consultant Psychiatrist | Tata Medical Center, Kolkata |
| 209. | Sudeep Gupta | Medical Oncology | Professor | ACTREC, Mumbai |
| 210. | Sudhir Chandra Sarangi | Pharmacology | Associate Professor | All India Institute of Medical Sciences, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 211. | Sudhir Gupta | Gastroenterology | Professor | Government Medical College, Nagpur |
| 212. | Sujith J Chandy | Pharmacology | Professor | Christian Medical College, Vellore |
| 213. | Sukant Pandit | Clinical Pharmacology | Senior Resident | Seth G.S Medical College,Mumbai |
| 214. | Suman Rao | Neonatology | Professor | St. John's Hospital, Bangalore |
| 215. | Sumitra Dutta | Psychiatrist | Consultant | Tata Medical Centre, Kolkata |
| 216. | Sunesh Kumar | Obstetrics and Gynaecology | Professor | All India Institute of Medical Sciences, Delhi |
| 217. | Suparna Chatterjee | Pharmacology | Professor | IPGMER, Kolkata |
| 218. | Surbhi Vyas | Radiology | Additional Professor | All India Institute of Medical Sciences, Delhi |
| 219. | Surjit Singh | Pediatrics | Professor | PGIMER, Chandigarh |
| 220. | Sushma Bhounsule | Pharmacology | Professor | Goa Medical College, GOA |
| 221. | Swarnamoni Das | Pharmacology | Professor | TRIHMS, Arunachal Pradesh |
| 222. | Swopna Phukan | Pharmacology | Professor | Gauhati Medical College & Hospital, Assam |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 223. | Syed Mohammad Naser | Pharmacology | Associate Professor | Calcutta School of Tropical Medicine, Kolkata |
| 224. | T P Yadav | Pediatrics | Principal Consultant | Dr. Ram Manohar Lohia Hospital, Delhi |
| 225. | T.S. Ganeshan | Medical Oncology | Professor | Cancer Institute (WIA) Chennai |
| 226. | Thangarajan Rajkumar | Molecular Oncology | Professor | Cancer Institute (WIA) Chennai |
| 227. | Uma Maheswari Krishnaswamy | Pulmonary Medicine | Professor | St. Johns National Academy of Health Sciences, Bengaluru |
| 228. | Urmi Choudhary | Pharmacology | Associate Professor | Govt. Medical College, Guwahati, Assam |
| 229. | Usha Joshi | Pharmacology | Professor | Pt. JNM Medical College, Chhattisgarh |
| 230. | V K Gupta | Cardiology | Professor | PGIMER, Chandigarh |
| 231. | V Rajshekhar | Ophthalmology | Specialist Gr-II | VMMC & Safdarjung Hospital, Delhi |
| 232. | Vandana Roy | Pharmacology | Head | Maulana Azad Medical College Hospital, Delhi |
| 233. | Vanlalhruai | Pharmacology | Professor | Zoram Medical College, Mizoram |
| 234. | Varkung Valte | Pharmacology | Head | JNIMS, Imphal, Manipur |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 235. | Varkung Valte | Pharmacology | Professor | JNIMS, Imphal, Manipur |
| 236. | Varsha Gupta | Microbiology | Professor | Government Medical College & Hospital Chandigarh |
| 237. | Vijay Hadda | Pulmonary, Critical Care & Sleep Medicine | Associate Professor | All India Institute of Medical Sciences, Delhi |
| 238. | Vijay Kher | Nephrology | Chairman | Medanta Hospital, Gurugram |
| 239. | Vijay Motghare | Pharmacology | Professor | Govt. Medical College Nagpur |
| 240. | Vijya lakshmi Bhatia | Endocrinology | Professor | SGPGI, Lucknow |
| 241. | Vikrant Gupta | Radiology | Assistant Professor | Govt. Medical college Jammu, Jammu & Kashmir |
| 242. | Vineet Ahuja | Gastroenterology | Professor | All India Institute of Medical Sciences, Delhi |
| 243. | Vinita Suri | Obstetrics and Gynaecology | Professor | PGIMER, Chandigarh |
| 244. | Vinod Kumar Bhardwaj | Pharmacology | Professor | SHKM Medical College, Mewat, Haryana |
| 245. | Vivekanand Jha | Nephrology | Executive Director | The George Institute for Global Health, Delhi |

| S. No. | Name | Speciality | Designation | Institution |
|---|---|---|---|---|
| 246. | Yashpal Sharma | Cardiology | Professor | PGIMER, Chandigarh |
| 247. | Yatin Mehta | Anesthesiology | Chairman | Medanta Hospital, Gurugram |
| 248. | Zubair Ashai | Pharmacology | Associate Professor | Govt. Medical College, Srinagar, Jammu and Kashmir |

**List of Ministry & Regulatory officials**
**Participated in**
**NLEM 2022 Deliberation**

| S. No. | Name | Designation | Ministry/Regulatory Office |
|---|---|---|---|
| 1. | A Raghu | Joint Adviser (Ayurveda) | Ministry of AYUSH |
| 2. | A.K. Gadparde | Additional Director General | Directorate General Of Health Services, MoHFW |
| 3. | Alka Ahuja | Additional Director (Medical Store) | Central Government Health Scheme, MoHFW |
| 4. | Arun Kumar Gupta | Dy. Medical Commissioner (Medical Service-I) | ESIC, Ministry of Labour & Employment |
| 5. | Arun Kumar Pradhan | Deputy Drugs Controller (India) | CDSCO, MoHFW |
| 6. | Arvind R Himwale | Assistant Drugs Controller (India) | CDSCO, MoHFW |
| 7. | Baljeet Singh | Assistant Director | National Pharmaceutical Pricing Authority, DoP |
| 8. | D C Katoch | Joint Advisor | Ministry of AYUSH |
| 9. | G N Singh | Secretary-cum-Scientific Director | Indian Pharmacopoeia Commission |
| 10. | Gulshan Taneja | Deputy Drugs Controller(India) | CDSCO, MoHFW |
| 11. | J Radhakrishnan | Principal Secretary | Department of Health & Family Welfare, Government of Tamil Nadu |
| 12. | Jai Prakash | Principal Scientific Officer | Indian Pharmacopoeia Commission |

| S. No. | Name | Designation | Ministry/Regulatory Office |
|---|---|---|---|
| 13. | M Kalaivani | Senior Scientific Officer | Indian Pharmacopoeia Commission |
| 14. | Navdeep Rinwa | Joint Secretary (Policy) | DoP, Ministry of Chemicals & Fertilizers |
| 15. | Pradeep Dua | Research Officer (Ay.) Nodal Officer | Central Council for Research in Ayurvedic Sciences (CCRAS) |
| 16. | Prakash Hemani | Additional Director | National Pharmaceutical Pricing Authority, DoP |
| 17. | Pramod Kumar | Drugs Inspector | CDSCO, MoHFW |
| 18. | Ravi Kant Sharma | Deputy Drugs Controller(I) | CDSCO, MoHFW |
| 19. | Remya Prabha G | Deputy Director | DoP, Ministry of Chemicals & Fertilizers |
| 20. | Ritu Dhillon | Member Secretary | National Pharmaceutical Pricing Authority, DoP |
| 21. | Ritu Mathur | Additional Director (Delhi-MSD) | CGHS, MoHFW |
| 22. | S Eswara Reddy | Joint Drugs Controller (India) | CDSCO, MoHFW |
| 23. | Sher Singh | Joint Director (Public Health) | National Vector Borne Disease Control Programme, MoHFW |

| S. No. | Name | Designation | Ministry/Regulatory Office |
|---|---|---|---|
| 24. | Shubhra Singh | Chairperson | National Pharmaceutical Pricing Authority, DoP |
| 25. | Sita Ram Meena | Director (Public Grievances) | Ministry of Consumer Affairs, Food & Public Distribution |
| 26. | Sunil Kumar | Director General of Health Services | DGHS, MoHFW |
| 27. | Thiru K Sivabalan | Director of Drugs Control | Food Safety and Drug Administration Department, Government of Tamil Nadu |
| 28. | USN Murthy | Director | National Institute of Pharmaceutical Education and Research, Guwahati |
| 29. | V G Somani | Drugs Controller General of India | CDSCO, MoHFW |
| 30. | Vineet Mathur | Joint Secretary | Ministry of Consumer Affairs, Food & Public Distribution |
| 31. | Alok Ranjan | Director- Medical Device | National Pharmaceutical Pricing Authority, DoP |
| 32. | S S Ojha | Director- Pricing | National Pharmaceutical Pricing Authority, DoP |
| 33. | Vinod Choudhary | Director | National Vector Borne Disease Control Programme, MoHFW |
| 34. | Somnath Basu | Assistant Drugs Controller (India) | CDSCO, MoHFW |

## List of NGOs, Patient Groups

## Participated in NLEM 2022 Deliberation

1. All India Drug Action Network
2. Cancer Patients Aid Association (CPAA)
3. Dakshayani & Amaravati Health and Education
4. Disease Management Association of India
5. Expert Public Health Group
6. Indian Medical Association
7. Institute for Studies in Industrial Development (ISID)
8. Lepra Society
9. Médecins Sans Frontières (MSF)
10. Population Health Services (India)
11. Third World Network

## List of Pharmaceuticals Association

## Participated in NLEM 2022 Deliberation

1. Advanced Medical Technology Association
2. American Chamber Of Commerce In India
3. Association of Indian Medical Device Industry
4. Confederation of Indian Industry (CII)
5. Federation of Indian Chambers of Commerce & Industry
6. Federation of Pharma Entrepreneurs
7. Indian Drug Manufacturers' Association
8. Indian Pharmaceutical Alliance (IPA)
9. Karnataka Drugs & Pharmaceuticals Manufacturers' Association
10. Medical Technology Association of India
11. Organisation of Pharmaceutical Producers of India
12. The Associated Chambers of Commerce and Industry of India
13. The Council of Soft Gelatin Manufacturers
14. US India Strategic Partnership Forum
15. US-India Business Council
16. Federation of Pharma Entrepreneurs

## SNCM SECRETARIAT

**Prof. Balram Bhargava, Secretary DHR & DG ICMR, Chairman, Standing National Committee on Medicines**

**Prof. Y.K. Gupta, Former Head, Department of Pharmacology & Dean, AIIMS, New Delhi, Vice-Chairman, Standing National Committee on Medicines**

**Dr. Monika Pahuja, Scientist D and Coordinator, Division of BMS, ICMR**

## Acknowledgement

SNCM is thankful to **Dr. Nabendu Sekhar Chatterjee, Head of Division, BMS, ICMR headquarters, New Delhi** for providing all the required support. We are thankful to **Late. Dr. Vijay Kumar, Former Head of Division, BMS, ICMR headquarters, New Delhi** for his support in the endeavour. We acknowledge the support of **Dr. Rajni Kaul, Former Head of Division, BMS, ICMR headquarters** and **Dr. Jerin Jose Cherian**, Scientist D, Division of **BMS, ICMR Headquarters, New Delhi** to SNCM.

We also acknowledge the support of project staff **Dr. Kritika Mathur**, Scientist B, **Dr. Renu Arora**, Research Associate and technical staff of SNCM, **Mr. Amal Verma,** Assistant, **Mr. Amit Kumar Yadav,** Data Entry Operator, **Mr. Govind Singh,** Data Entry Operator and **Mr. Kunal,** Multi-Tasking Staff**.**

# NLEM 2022 REPORT DRAFTING GROUP

| | |
|---|---|
| **Prof. Y.K. Gupta** | ***Former Head, Pharmacology & Dean, AIIMS, New Delhi, Vice-Chairman, SNCM*** |
| **Mr. A.K. Pradhan** | ***Deputy Drugs Controller (India), CDSC, New Delhi*** |
| **Dr. Santanu K Tripathi** | ***Professor & Head of Pharmacology, School of Tropical Medicine, Kolkata*** |
| **Dr. Lalit Kumar Gupta** | ***Professor, Department of Pharmacology, Lady Hardinge Medical College, New Delhi*** |
| **Col. (Dr.) Prafull Mohan** | ***Professor, Department of Pharmacology, Armed Forces Medical College, Pune*** |
| **Dr. Biswa Mohan Padhy** | ***Additional Professor, Department of Pharmacology, AIIMS, Bhubaneswar*** |
| **Dr. Pooja Gupta** | ***Associate Professor, Department of Pharmacology, AIIMS, New Delhi*** |
| **Dr. Ashish Kakkar** | ***Associate Professor, Department of Pharmacology, PGIMER, Chandigarh*** |
| **Dr. Monika Pahuja** | ***Scientist-D, Division of BMS, ICMR headquarters, New Delhi*** |