

NATIONAL FORMULARIES

❖ Formulary:

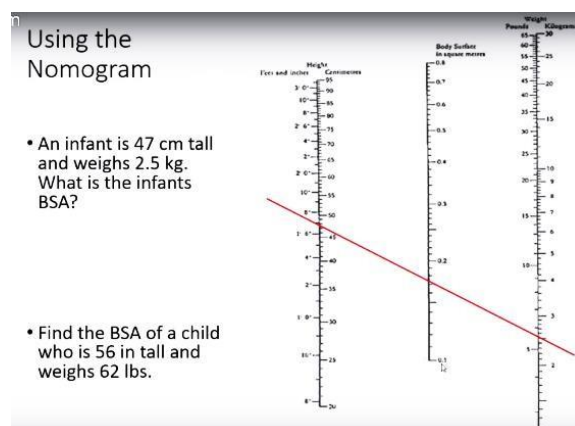
- At its most basic level, a formulary is a list of medicines(essential medicine list, EML)
Or

Manual contains clinically oriented pharmacological information summaries about selected drugs. It also includes administrative and regulatory information related to the prescribing and dispensing of drugs.

- It provides information on use, dosage, adverse effects, contraindications and warnings, supplemented by guidance on selecting the right medicine for a range of conditions.

❖ Purpose

- NF is not a regulatory document.
- NF would serve as a guidance document to medical practitioners, pharmacists, nurses, medical and pharmacy students, and other healthcare professionals and stakeholders in healthcare system.
- To provide unbiased information to health care professionals in a country and to promote safe, effective and rational use of medicines
- To help in the eliminating the unsafe, ineffective or poor quality medicinal products by identifying effective and safe medications
- To support cost-effective utilization of drug budgets and improve access to essential medicines
- Information to be included in National formulary
- General advice to prescribers
- Individual drug information
- Therapeutic information, recommendations
- Medicine prices – Brand names
- Availability at health facilities
- National policies on prescribing/dispensing
- Brief summary of local guidelines
- Specific information on drug interactions, prescribing in pregnancy, breastfeeding, hepatic and renal impairment
- Forms for reporting of adverse drug reactions and product quality problems
- Nomograms, dose calculators or other tools



❖ The formulary list (essential medicine list)

- The formulary process is critical to good health care and consists of developing and implementing:
- a formulary list (essential medicines list) consisting of the most cost- effective, safe, locally available drugs of assured quality that will satisfy the health care needs of the majority of the patients
- a formulary manual containing summary information on medicines
- Standard treatment guidelines containing essential information on how to manage common diseases.
- **The formulary list (essential medicines list)**
 - Essential medicines are those that satisfy the priority health care needs of the population.
 - they are selected with due regard to disease prevalence, evidence of efficacy, safety and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.
 - the implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility

❖ **Criteria for Inclusion of drugs in NFI**

- Drugs in National List of Essential medicine (NLEM) 2011, India
- Drugs used in National Health Programmes
- Drugs listed in Indian Pharmacopoeia
- Drugs not covered but recommended by panel of experts
- Any drug(s) considered appropriate by the IPC

❖ **Criteria for Exclusion of drugs from NFI**

- Drugs banned in India
- Obsolete Drugs
- Drugs considered inappropriate by IPC

❖ **Difference between NF, HF & Pharmacopoeia**

National Formulary	Hospital Formulary	Pharmacopoeia
Generally concentrates on available and affordable medicines that are relevant to the treatment of diseases in a particular country	<ul style="list-style-type: none"> ➤ Generally concentrates on medicines that are relevant to the particular hospital ➤ The hospital formulary system is a method whereby the medical staff of a hospital with the help of pharmacy and therapeutic committee, selects and evaluates medicinal agents and their dosage forms which are considered to be most useful in the patient care. ➤ it provides information for <ul style="list-style-type: none"> • Procuring, • Prescribing, • Dispensing And • Administration of drugs under brand names where the drug have both names. 	legally recognized book of standards for monitoring the quality of Drugs and Pharmaceuticals

❖ **National Formulary of India-History**

- Ministry of Health and Family Welfare, Govt. of India assigned responsibility to the Indian Pharmacopoeia Commission (IPC), Ghaziabad to publish NFI on regular basis.
- History of National Formulary of India (NFI):
- National Formulary of India 1960 –The first edition
- National Formulary of India 1966 –The Second edition
- National Formulary of India 1979 –The Third edition
- National Formulary of India 2011 – The Fourth Edition
- National Formulary of India 2016 – The Fifth Edition
- National formulary of India 2021- The Sixth(current) edition

❖ **Table of content NFI 2016**

- Preface, introduction, Acknowledgments
- List of medicines monographs included and deleted
- Abbreviations
- General advice to prescribers
- Monographs
- Appendices- NHP, Calculation, advisories, disposal of unused medicines, poison information centers in India, drug interactions, special conditions, and drug banned, NLEM, PvPI etc.

SR NO	NFI 2011	NFI 2016
1	377 drug monographs, 22 FDCs, 20 immunological, 12 vitamins	521 drug monographs, 33 FDCs, 20 immunological, 12 vitamins, 8 drug monographs deleted
2	Schedule H	Schedule H and H1
3	30 chapters by therapeutic categories	3 categories added- Basics of medical emergency, drugs for oral health, medicines banned in sports
4		All chapter revised as per latest guidelines
5	15 appendices	22 appendices- focused on ADR reporting and causality assessment, drugs causing severe allergic reactions, drugs banned in India since 2008, NLEM 2011
6	ADR reporting form Health care professional	ADR reporting form for Health care professional and consumers

❖ **National formulary of India 2021- The Sixth (current) edition**

- Union Minister for Health and Family Welfare Dr. Mansukh Mandaviya launched the Sixth Edition of National Formulary of India (NFI) on 28 OCT 2021.
- NFI has been published by Indian Pharmacopoeia Commission (IPC) to promote rational use of medicines in the country.
- NFI, 2021 would act a guidance document for all the healthcare professionals such as clinicians, pharmacists, nurses, dentists etc. It will play a crucial role in daily clinical practices.
- The 6th Edition of NFI 2021 has been drafted by adopting the principle 'do not miss critical and do not overload' the information by revising the appendices, chapters and drug monographs.
- The chapters such as Analgesics, Antipyretics and Anti-inflammatory drugs, Antiepileptics, Antacids and Antiulcer Drugs, Antiallergics and Drugs Used in Anaphylaxis, Antidiarrhoeals and Laxatives, Antidotes and Substances Used in Poisoning, Antimigraine drugs, Basics of Medical Emergencies, Dermatological Drugs, Disease Modifying Anti-Rheumatic Drugs (DMARDs) and Drugs for Gout, Diuretics, Drugs in Osteoporosis, Drugs for Inflammatory Bowel Disease, Drugs for Respiratory Diseases, Ophthalmological Preparations and Psychotherapeutics Drugs were revised thoroughly by involving the subject specific experts/specialist in the country.

❖ **The salient feature of 2021 edition includes:**

- 34 therapeutic categories chapters including 591 drug monographs and 23 appendices are included in this edition.
- The NFI is aligned with National Health Programmes and National List of Essential Medicines (NLEM).
- Important Weblinks related to NLEM, Drugs banned in India, national health portal (NHP), Drugs banned in sports, Immunization schedule, wherever necessary are provided for information to readers.
- Special note on "How to use NFI?" and Salient Features of NFI are added in this edition.
- Only indications approved by the Indian drug regulator (*Central Drugs Standard Control Organization (CDSCO)*), clinically relevant and as per standard care are included
- the term 'availability' is now replaced with 'dosage forms and usual strength'
- Only the clinically relevant precautions and contraindications are included
- the common or the serious and clinically relevant adverse effects are included
- Storage conditions for medicines are included for special cases only
- Chapter on Medicines banned in sports in previous edition has been considered under appendices in this edition
- Considering the prevalence of diabetes in the country a separate Chapter on Management of Diabetes is included after revising completely
- New appendix on Good Distribution Practices is incorporated
- Appendix on National Immunization Schedule and Indian academics of pediatrics (IAP) Immunization Schedule is revised as per current schedule.

❖ **British National Formulary**

- It also covers brand names and pricing information
- Updated twice in a year (print edition- March and September), monthly (online)
- Separate formulary for children
- Current version March 71

❖ **Other Formularies**

- WHO model formulary 2008, model formulary for children 2010
- New Zealand formulary online version updated every monthly, separate for children
- United States Pharmacopoeia-National Formulary (39,34)

❖ **Rational drug use**

- The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and their community.
- It consist of
 - Correct drug
 - Appropriate indication
 - Appropriate drug considering efficacy, safety, suitability for the patient, and cost
 - Appropriate dosage, administration, duration
 - No contraindications
 - Correct dispensing, including appropriate information for patients
 - Patient adherence to treatment