NFI

National Formulary of India

5th Edition

2016

Government of India
Ministry of Health & Family Welfare

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare
Government of India

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Website: www.ipc.gov.in
E-mail: ipclab@vsnl.net

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Disclaimer

NFI is not a regulatory document. It is a reference document for health professionals. Physicians are supposed to use their professional experience, judgment etc while prescribing medicines or adopting treatment regimes. Treatment regimes in respect of the diseases and ailments included in this document may also change from time to time and users are advised to adopt the changed regimes. The references to statutory provisions/ requirements etc are based on the status of such provisions at the time of compilation of this document. Users are advised to refer to the statutory document concerned for updates. The contents such as 'Indications', 'Strength' etc included are based on the inputs available to the IPC. These shall not form the basis for any user or stakeholder to seek immunity under the "New Drug" status as specified in the Drugs and Cosmetics Act and Rules. In the event of any dispute in any of the content of these document and the statutes, the statutory provisions shall prevail. Where the use of any drug is banned in the country by the authority concerned, the monograph or other content of this document shall stand deleted or modified as the situation may demand. Where there is any anomaly between the content of NFI and any other non-statutory Official document exists, the decision of the Government or the implementing authority will prevail.

Indian Pharmacopoeia Commission

Mission

To promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers.

Vision

To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis.

Objectives

- To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, pharmaceutical aids and dosage forms as well as medical devices and to keep them updated by revision on a regular basis.
- To develop monographs for herbal drugs, both raw drugs and extracts/formulations therefrom.
- To accord priority to monographs of drugs included in the National Essential Medicines List and their dosage forms.
- To take note of the different levels of sophistication in analytical testing/instrumentation available while framing the monographs.
- To accelerate the process of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products.
- To collaborate with pharmacopoeias like the Ph Eur, BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing with global standards.
- To review existing monographs periodically with a view to deleting obsolete ones and amending those requiring upgrading/revision.
- To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles/materials.
- To publish the National Formulary of India for updating medical practitioners and other healthcare professionals.
- To act as a National Coordination Centre for Pharmacovigilance Programme of India.

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Preface

The first, second and third editions of National Formulary of India (NFI) were published in 1960, 1966 and 1979 respectively by the Ministry of Health, Govt. of India. In the past 3 decades there has been vast expansion in the range of new drugs and their formulations. To address the need of publication of an updated version of NFI, Ministry of Health and Family Welfare, Govt. of India vide their Notification No. F.No.X.11035/2/06- DFQC dated 8th May, 2008 assigned this mandatory responsibility to the Indian Pharmacopoeia Commission (IPC), Ghaziabad and hence the NFI is being published by the IPC on behalf of the Govt. of India, Ministry of Health and Family Welfare. The fourth edition of NFI was brought out by the IPC in 2011. To publish the 5th Edition of NFI 2016, a High Power Committee was constituted by the Ministry of Health & Family Welfare, Govt of India vide letter No 11020/4/2012- DFQC dated 23rd Jul 2012, to identify the experts. The Committee consisted of:

HIGH POWER COMMITTEE

1. Dr V. M. Katoch, Ex-Secretary, Department of Health Research (DHR) and Director General, Indian Council of Medical Research, New Delhi.
2. Prof. Y. K. Gupta, Head, Department of Pharmacology, AIIMS, New Delhi.
3. Prof. K.K. Talwar, Ex-Chairman, Board of Governors, Medical Council of India, New Delhi.
4. Dr G.N. Singh, Secretary-cum-Scientific Director, IP Commission, Ghaziabad and DCG(I), FDA Bhawan, New Delhi.

Other Important Committees for NFI, 5th Edition, 2016

APEX BODY

Chairman: Secretary (*Ex-officio*), Ministry of Health & Family Welfare, Govt. of India.

Members

1. Dr V. M. Katoch, Ex-Secretary, DHR and Director General, Indian Council of Medical Research, New Delhi.
2. Dr Jagdish Prasad, Director General, Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of India, Nirman Bhawan, New Delhi.
3. Additional Secretary and DG (*Ex-officio*), Ministry of Health and Family Welfare, Govt. of India, Nirman Bhawan, New Delhi.
4. Joint Secretary, Regulation (*Ex-officio)*, Ministry of Health and Family Welfare, Govt. of India, Nirman Bhawan, New Delhi.
5. Prof. B. Suresh, Chairman, Scientific Body, Indian Pharmacopoeia Commission, Ghaziabad.
6. Prof. Y. K. Gupta, Head, Department of Pharmacology AIIMS, New Delhi.
7. Mr. P. D. Sheth, Ex-Vice President, The International Pharmaceutical Federation, The Hague, The Netherlands.
8. Prof. T. M. Mohapatra, Ex-Director & Dean, Institute of Medical Sciences, BHU, Varanasi.
9. Dr Nitya Anand, Ex-Director, CDRI, Lucknow.
10. Dr G. N. Singh, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad and DCG(I), FDA Bhawan, New Delhi.

CORE GROUP

Chairpersons: Prof. B. Suresh and Prof. Y.K. Gupta

Member Secretary: Dr. G. N. Singh

1. Director (Drugs) (*Ex-officio)*, Ministry of Health and Family Welfare, Govt. of India, New Delhi.
2. Prof. Praveen Aggarwal, Department of Emergency Medicine, AIIMS, New Delhi.
3. Dr Veena Gupta, Consultant, Department of Radiotherapy, Safdarjung Hospital, New Delhi.
4. Dr Jai Prakash, Senior Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad.
5. Dr G.C. Khilnani, Ex-Professor, Department of Medicine, AIIMS, New Delhi.
6. Prof. Lalit Kumar, Dr. B R Ambedkar Institute – Rotary Cancer Hospital, AIIMS, New Delhi.
7. Mr P.D. Sheth, Ex-Vice President, The International Pharmaceutical Federation, The Hague, The Netherlands.
8. Dr Pramil Tiwari, Professor and Head, Department of Pharmacy Practice, National Institute of Pharmaceutical Education & Research, Mohali, Punjab.
9. Mr A.K. Pradhan, Deputy Drugs Controller (India), CDSCO North Zone, Ghaziabad.
10. Dr Bishwa Mohan Padhy, Assistant Professor, Department of Pharmacology, AIIMS, Bhubaneswar.
11. Dr Bikash Medhi, Additional Professor, Department of Pharmacology, PGIMER, Chandigarh.
12. Dr D. Roy, Deputy Drugs Controller (India) (Retd), CDSCO, North Zone, Ghaziabad.
13. Mr Ramesh Adige, Ph.D. Chamber of Commerce & Industry, New Delhi.
14. Mr Pradeep Mishra, Professional Secretary, SEARPharm, Forum, New Delhi.

SUBJECT REVIEW COMMITTEE

Chairman : Prof. Y. K. Gupta

Member Secretary : Dr Jai Prakash

The manuscript was reviewed and the contents updated to align with Indian context by the Subject Review Committee.

1. Dr Sridhar Dwivedi, Professor of Medicine/Preventive Cardiology, Hamdard Institute of Medical Sciences and Research, Associated Hakeem Abdul Hameed Centenary Hospital, Jamia Hamdard (Hamdard University), New Delhi-110062.
2. Mr S. S. Venkatakrishnan, Drugs Controller (Retd), Kerala State, Thiruvananthapuram.
3. Dr Pooja Gupta, Assistant Professor, Department of Pharmacology, AIIMS, New Delhi.
4. Dr Sheffali Gulati, Professor, Department of Pediatric Neurology, AIIMS, New Delhi.
5. Dr Pramil Tiwari, Professor and Head, Department of Pharmacy Practice, National Institute of Pharmaceutical Education & Research, Mohali, Punjab.
6. Dr Prafull Kumar, Senior Resident, Department of Pharmacology, AIIMS, New Delhi.
7. Dr N. Harivenkatesh, Senior Resident, Department of Pharmacology, AIIMS, New Delhi.
8. Dr Ekta Arora, Senior Resident, Department of Pharmacology, AIIMS, New Delhi.
9. Dr Guruprasad, Senior Resident, Department of Pharmacology, AIIMS, New Delhi.
10. Dr Harmanjit Singh, Senior Resident, Department of Pharmacology, AIIMS, New Delhi.
11. Dr Shyam Sunder Sharma, Professor, Department of Pharmacology and Toxicology, National Institute of Pharmaceutical Education & Research, Mohali, Punjab.
12. Dr V Kalaiselvan, Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad.

13. Dr Biswa Mohan Padhy, Assistant Professor, Department of Pharmacology, AIIMS, Bhubaneswar.
14. Dr R K Sanghavi, Chairman, Medical Sub-Committee, IDMA, Mumbai.
15. Dr Madhur Gupta, Technical Officer, WHO-India (Country Office), New Delhi.
16. Dr R.N. Gupta, Professor, Birla Institute of Technology (BITS), Mesra, Ranchi.
17. Dr Vijaylaxmi Nag, Professor and Head, Department of Microbiology, AIIMS, Jodhpur.
18. Dr Rajat Ray, Ex-Professor and Head, Department of Psychiatry, & Chief, National Drug Dependence Treatment Centre , All India Institute Medical Sciences, New Delhi.
19. Dr Alka Beotra, Scientific Director, National Dope Testing Laboratory, Min. of Youth Affairs and Sports, New Delhi.
20. Dr Vijay Mathur, Additional Professor, Department of Dental Research AIIMS, New Delhi.
21. Dr Neena Valecha, Director, National Institute of Malaria Research, Dwarka, New Delhi.
22. Dr Deepali Anvikar, Scientist C, National Institute of Malaria Research, Dwarka, New Delhi.
23. Prof. Anoop Mishra, Chairman, Fortis-C-DOC Centre of Excellence for Diabetes, Metabolic Diseases and Endocrinology, Fortis Hospital, Vasant Kunj and SDA, New Delhi.
24. Dr Ritesh Gupta, Fortis-C-DOC Centre of Excellence for Diabetes, Metabolic Diseases and Endocrinology, Fortis Hospital, Vasant Kunj and SDA, New Delhi.
25. Dr Bikash Medhi, Additional Professor, Department of Pharmacology, PGIMER, Chandigarh.

26. Dr B. Gupta, Professor and Head, Department of Medicine, Safdarjung Hospital, New Delhi.

27. Dr Jatinder Dhillon, Assistant Professor, Maulana Azad Institute of Dental Sciences, New Delhi.

IPC Scientific team

Dr Jai Prakash (Chief Coordinator), Dr V. Kalaiselvan, Dr Manoj Kumar Pandey, Dr M. Kalaivani, Mr K. K. Singh Ms Amandeep Bhatia, Mr Ashish Kushwaha, Ms Shruti Rastogi, Ms Neha Singh, Dr Divya Kaushik, Mr Hariom Singh.

The Criteria for Inclusion of Drugs in NFI:

- Drugs in National List of Essential Medicines 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

The Criteria for Exclusion of Drugs from NFI:

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

NFI Review Process

To fulfil the mandate of publishing the NFI, the following process has been adopted:

To Fulfil the mandate of publishing the NFI,
the following has been adopted:

High Powered Committee
(for identification of experts and major policy decision)
↓
Policy Framework by Apex Body
↓
NFI 4th Edition & WHO Model Formulary as base document
↓
Review by Core Group
↓
Modification suggested by Subject Review Committee
↓
Review by Core group
↓
Approval by Apex Body
↓
Draft content of NFI uploaded on the website of
IPC for public comments and comments requested
individually also from the targeted experts
↓
Review and incorporation of public comments
↓
Adoption for NFI

NFI is not a regulatory document. Physicians are supposed to use their professional judgment. Inclusion/Exclusion of monographs in NFI is a dynamic process. The drugs contained in NFI have been chosen for rational and economic prescribing. NFI would serve as a guidance document to medical practitioners, pharmacists, nurses, medical and pharmacy students, and other healthcare professionals and stakeholders in healthcare system. The feedback from stakeholders will be useful for further improvement.

Introduction

The Indian Pharmacopoeia Commission is pleased to present the 5th edition of National Formulary of India 2016. This edition follows the 4th edition which was published in 2011.

The principal objective of the 5th edition continues to be promotion of rational use of medicines. To achieve this objective, the monographs of drugs comprise the clinical indications, strengths of formulations and major adverse drug reactions. This edition includes medicines listed in the National List of Essential Medicines, other medicines frequently prescribed by clinicians and medicines for use in India's public health programs and National Health Missions.

The scope of this edition has been expanded substantially by incorporating several important Chapters. Some of these are:

A total of 33 chapters by therapeutic categories, 521 total drug monographs including 33 fixed dose combinations, 20 immunologicals and 12 vitamins form an integral part of this Formulary. Introductory parts of all chapters are fully revised. The specific drug monographs are arranged in alphabetical order. The drugs listed in National List of Essential Medicines, 2011 can be easily identified from the superscripted asterisk. The change of the regulatory status of a drug under the Drugs and Cosmetics Rules - Schedule H into Schedule H and H_1 - has been reflected under the specific drug monographs.

The chapter on diabetes mellitus has been updated according to current treatment scenario. Similarly, chapters on drugs used in treatment of psychiatric disorders, substance use and antiepileptic/anticonvulsant drugs have been updated.

Athletes and other sports persons may be prescribed – inadvertently – drugs banned in sports. To avoid the situation, a chapter on medicines banned in sports is incorporated.

Malaria has become one of the major challenging health problems and therefore the chapter on Antimalarial drugs is thoroughly revised keeping in view the current national guidelines.

Fixed dose combinations of various therapeutic categories are available in the market. The scope of fixed dose combinations is expanded, but limited to those falling under the categories of drugs included as mentioned earlier with a view to promote their rational use. The additional FDCs incorporated in this edition are :

Additional Fixed-Dose combinations

1. Acriflavin + Glycerin
2. Aluminium Hydroxide + Magnesium Hydroxide
3. Artemether + Lumefantrine
4. Arterolane + Piperaquine
5. Artesunate + Mefloquine
6. Artesunate + Sulfadoxine + Pyrimethamine
7. Etophylline + Theophylline
8. Iron Salts + Folic Acid
9. Lignocaine Hydrochloride + Adrenaline
10. Lignocaine + Prilocaine
11. Stavudine + Lamivudine

Keeping in view the drugs which do not stand the test of time in their safety and efficacy and withdrawn from the market or have become obsolete based on clinical evidence are omitted. Likewise, a list of banned drugs in India since 2008 onwards has been included in this edition.

The 5th edition contains unique supplementary information through appendices thereby adding further value for the users. There are 22 appendices in all including the appendices on reporting of adverse drug reactions and their causality assessment. Common drugs causing severe allergic reactions have been clubbed together in a new appendix. For the healthcare professionals, relevant information on Basics of medical emergencies is included. For protecting and promoting oral health a new chapter “Drugs for oral health” is also incorporated.

Improper storage conditions lead to deterioration of drug products, therefore, appropriate information is provided in the chapter on Storage of medicines. The information on poison centers and general advice to prescribers have been updated. Advisories related to medicines add further value in this edition.

NFI 2016 also covers important medicines which are useful in management of some rare diseases. The list of life saving drugs may be accessed at www.cghs.nic.in. Many life saving drugs are covered in this edition.

The stakeholders of NFI which include clinicians, pharmacists, nurses, patients, trainers, students and other health care providers both in the rural and urban settings will find the 5th edition highly informative and useful.

Acknowledgements

We are pleased to present the 5th Edition of National Formulary of India. It has been brought out after a gap of 5 years since last edition in 2011. This edition incorporates the changes, new chapters, specific drug monographs and the appendices based on the current knowledge.

Valuable inputs that emerged during the meetings of the Core Group, Subject Review Committee and the feedback on the 4th Edition of NFI have given this edition a unique feature by incorporating value added informations. The Commission is greatly indebted to the Members of the High Power Committee for identifying the experts for this edition.

The Commission expresses its deep gratitude to the chairman(s) and the members of the Apex body, Core Group and the Subject Review Committee from diverse fields who consented to review the manuscript of the Formulary. The services of all these experts are appreciated.

Dr Jai Prakash, Senior Principal Scientific Officer, Indian Pharmacopoeia Commission played a key role in every step in bringing out this edition of NFI including coordination with different Expert Committees, contributing in updating and editing of NFI. He was supported by Dr Manoj Kumar Pandey, Dr M Kalaivani, Mr Ashish Kushwaha, Ms Amandeep, Ms Shruti Rastogi, Ms Neha Singh, Dr Divya Kaushik, Ms Geetika Nirmal, Mr Arun Kumar Dahiya, Mr Hariom Singh. Special thanks go to the members who prepared new appendices and updated the previous appendices.

Prof Y. K. Gupta deserves a special mention and thanks for his crucial role in preparing and enriching the contents of the formulary and by closely coordinating with his colleagues throughout the course of preparation of this formulary.

The vision and encouragement received from Padma Shri Dr Nitya Anand is highly acknowledged.

This National Formulary has been thoroughly updated for its content considering WHO Model Formulary and NFI, 4th Edition 2011 as the base document, especially keeping in view the end user in India for which we wish to thank profusely Dr Y. K. Gupta, Dr Praveen Aggarwal, the Resident Clinicians/Scientist team of Dr Y. K. Gupta of the Department of Pharmacology – Dr N. Harivenktesh, Dr Prafull Mohan, Dr Ekta Arora, Dr Guruprasad, Dr Harmanjit Singh, Dr S Venkatesan at the All India Institute of Medical Sciences, New Delhi.

The Commission is highly appreciative of the encouragement and support received from the Secretary, Mr B P Sharma, Ex-Secretary, Mr Lov Verma, Ex-Additional Secretary and DG (CGHS), Mr R K Jain, Additional Secretary and DG(CGHS), Mr Navneet Singh Kang, Ex-Joint Secretary (Regulations), Dr Arun Kumar Panda, Joint Secretary (Regulations), Mr K L Sharma, Ex-Director (Drugs), Mr Sanjay Prasad, Director (Drugs), Dr Shailendra Kumar and other officials of Ministry of Health & Family Welfare, Government of India.

The Commission appreciates the comments offered by the stakeholders on the draft of NFI, 5th Edition. The inputs received from the institutions, state governments and stakeholders have helped to shape the 5th Edition.

The Commission acknowledges the significant contribution of Prof. Y. K. Gupta and his team in critically analysing the stakeholders comments received on draft of 5th Edition of NFI and suggesting appropriate action.

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IPC also places on record thanks to the services of IPC employees and subject experts who from time to time provided their valuable inputs.

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Dr G. N. Singh
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission

List of Medicines Monographs in NFI

FIXED DOSE COMBINATIONS

IMMUNOLOGICALS

VITAMINS

List of medicines monographs deleted from NFI

1. Amodiaquine
2. Emtricitabine
3. Formaldehyde
4. Mexiletine
5. Proguanil
6. Propyliodone
7. Strontium Ranelate
8. Tacrine

Common Abbreviations

ACCORD	Action to Control Cardiovascular Risk in Diabetes
ACE	Angiotensin Converting Enzyme
ACE Inhibitors	Angiotensin Converting Enzyme Inhibitors
ACP	Amorphous Calcium Phosphate
ACT	Artemisinin based Combination Therapy
ADR	Adverse Drug Reaction
ADVANCE	Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Control Evaluation
AE	Adverse Event
AEFI	Adverse Events Following Immunization
AIDS	Acquired Immuno Deficiency Syndrome
ALT	Alanine Amino transferase (ALAT)
APD	Automated Peritoneal Dialysis
ARB	Angiotensin Receptor Blocker
BCG	Bacillus Calmette Guerin
ASA	Aminosalicylic Acid
ASV	Antisnake venom
ATP	Adenosine Triphosphate
BNF	British National Formulary
BP	British Pharmacopoeia
BSA	Body Surface Area
CAPD	Continuous Ambulatory Peritoneal Dialysis
CD4	Cluster of Differentiation 4
CDSCO	Central Drugs Standard Control Organization
CFC	Chloro Fluoro Carbon
CIOMS	Council for International Organization of Medical Sciences

CKD	Chronic Kidney Disease
CMC	Carboxy Methyl Cellulose
CMV	Cytomegalo Virus
CNS	Central Nervous System
COLD	Chronic Obstructive Lung Disease
COPD	Chronic Obstructive Pulmonary Disease
CPP	Casein Phosphopeptide
CR	Controlled Release
CSF	Cerebrospinal Fluid
CTZ	Chemoreceptor trigger zone
DCCT	Diabetes Control and Complications Trials
DCG(I)	Drugs Controller General (India)
DMARDs	Disease Modifying Anti-Rheumatic Drugs
DOTS	Directly Observed Treatment Short-course
DT	Dispersible Tablet/Diphtheria Tetanus
DPT	Diphtheria Pertussis Tetanus
DTaP	Diphtheria Tetanus Acelluar Pertussis Vaccine
DTwP	Diphtheria Tetanus Whole Cell Pertussis Vaccine
ECG	Electro Cardiogram
ECT	Electroconvulsive Therapy
EMA	European Medicines Agency
EMS	Emergency Medical Services
EPS	Extrapyramidal Symptoms
ER	Extended Release
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FEV1	Forced Expiratory Volume in one second
FFP	Fresh Frozen Plasma
G-6-PD	Glucose-6-Phosphate Dehydrogenase
HAART	Highly Active Anti-Retroviral Therapy
HD	Hemodialysis

GCP	Good Clinical Practice
GERD	Gastro–oesophageal Reflux Disease
GFR	Glomerular Filtration Rate
GI	Gastrointestinal
GLP	Glucagon Like Peptide
HBsAg	Hepatitis B surface Antigen
HCV	Hepatitis C Virus
Hep-A	Hepatitis A Vaccine
Hep-B	Hepatitis B Vaccine
Hib	Haemophilus Influenza b
HIV	Human Immunodeficiency Virus
HPA	Hypothalamic Pituitary Adrenal Axis
HPMC	Hydroxy Propyl Methyl Cellulose
HT	Hormone Therapy
ICD	International Classification of Disease
ICMR	Indian Council of Medical Research
ICS	Inhaled glucocorticosteroids
ICU	Intensive Care Unit
ID	Intra Dermal
IgA	Immunoglobulin A
IM	Intramuscular
INR	International Normalized Ratio
IP	Indian Pharmacopoeia
IPC	Indian Pharmacopoeia Commission
IPV	Inactivated Poliomyelitis Vaccine
IU	International Units
IV	Intravenous
JE	Japanese Encephalitis Vaccine
LFT	Liver Function Test
LGS	Lennox–Gastaut Syndrome
MAO	Mono Amine Oxidase
MD	Mouth Dissolving

MDR	Multi Drug Resistance
mEq	MilliEquivalent
MDI	Metered Dose Inhaler
MI	Myocardial Infarction
mMol	Millimole
MMR	Measles, Mumps and Rubella
MOHFW	Ministry of Health and Family Welfare
MR	Modified Release
NACO	National AIDS Control Organization
NCC	National Coordination Centre
NFI	National Formulary of India
NHPs	National Health Programmes
NHM	National Health Mission
NIMR	National Institute of Malaria Research
NIMS	National Institute of Medical Statistics
NLEM	National List of Essential Medicines
NMS	Neuroleptic Malignant Syndrome
NRI	Nicotine Replacement Therapy
NS	Normal Saline
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OCD	Obsessive Compulsive Disorders
ODT	Oral Dispersible Tablet
OPV	Oral Polio Vaccine
ORS	Oral Rehydration Salts
PCI	Pharmacy Council of India
PD	Peritoneal Dialysis
PEF	Peak Expiratory Flow
PFS	Pre-Filled Syringes
PK/PD	Pharmacokinetic/Pharmacodynamic
PPAR	Peroxisome Proliferator Activated Receptor
PT	Prothrombin Time
PvPI	Pharmacovigilance Programme of India

RDT	Rapid diagnostic test
RNTCP	Revised National TB Control Programme
RV	Rotavirus Vaccine
SAE	Serious Adverse Event
SC	Subcutaneous
SL	Sublingual
SLE	Systemic Lupus Erythematosus
SNRI	Serotonin Norepinephrine Reuptake Inhibitor
SR	Sustained Release
SSRI	Selective Serotonin Reuptake Inhibitor
SWI	Sterile Water for Injection
T1DM	Type 1 Diabetes Mellitus / Insulin Dependent Diabetes
T2DM	Type 2 Diabetes Mellitus /Non- Insulin Dependent Diabetes
TCA	Tricyclic Antidepressant
TCD	Transcranial Doppler Ultrasonography
TdaP	Tetanus Diphtheria Acellular Pertussis Vaccine
TDM	Therapeutic Drug Monitoring
TNF	Tumour Necrosis Factor
TT	Tetanus Toxoid
USFDA	United States Food and Drug Administration
USP	United States Pharmacopoeia
W/V	Weight/Volume
W/W	Weight/Weight
WHO	World Health Organization

*****Drugs listed in National List of Essential Medicines 2011, India

Schedule H and H1:	List of drugs that to be sold by retail on the prescription of a Registered Medical Practitioner only (Prescription Drugs).
Schedule X:	List of drugs for which the retailer is to preserve prescription for a period of 2 years.
Schedule G:	List of drugs that could be dangerous to take except under medical supervision.

Notes:

1. *Wherever Schedule H and H1, as well as X are stated, it means that the drug is specified in that Schedule of Drugs and Cosmetics Rules, 1945.*
2. *Substances specified in Schedule H and H1 or X shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner; and in the case of substances specified in Schedule X, the prescriptions shall be in duplicate, one copy of which shall be retained by the licensee for a period of two years.*
3. *The supply of drugs specified in Schedule H and H1 or X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years.*
4. *The supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.*

General Advice to Prescribers

Rational Approach to Therapeutics

Drugs should be prescribed or used only when necessary, and in all cases the benefit of administering the medicine should be considered in relation to the risks involved. Bad prescribing habits lead to ineffective and unsafe treatment, exacerbation or prolongation of illness, distress and harm to the patient, and higher cost. *The Guide to Good Prescribing* (WHO, Geneva; 1994) provides important tools for training in the process of rational prescribing.

The following steps will help prescribers to follow the rational approach to therapeutics:

1. Define the Patient's Problem

Whenever possible, making the right diagnosis is based on integrating many pieces of information: the complaint as described by the patient; a detailed history; physical examination; laboratory tests; X-rays and other investigations. This will help in rational prescribing, always bearing in mind that diseases are evolutionary processes.

2. Specify the Therapeutic Objective

Doctors must clearly state their therapeutic objectives based on the pathophysiology underlying the clinical situation. Very often, physicians are required to select more than one therapeutic goal for each patient.

3. Selecting Therapeutic Strategies

The selected strategy should be agreed with the patient; this agreement on outcome, and how it may be achieved, is termed concordance.

The selected treatment can be non-pharmacological and/ pharmacological; it also needs to take into account the total cost of all therapeutic options.

a) Non-Pharmacological treatment

It is very important to bear in mind that the patient does not always need a medicine for treatment of the condition. Very often, health problems can be resolved by a change in lifestyle or diet, use of physiotherapy or exercise, provision of adequate psychological support, and other non-pharmacological treatments; these have the same importance as a prescription medicine, and instructions must be written, explained and monitored in the same way.

b) Pharmacological treatment

Selecting the Correct Group of Drugs

Knowledge about the pathophysiology involved in the clinical situation of each patient, pharmacokinetics and pharmacodynamics of the chosen group of drugs, are fundamental principles for rational therapeutics.

Selecting the Medicine from the Chosen Group

The selection process must consider benefit/risk/cost information. This step is based on evidence about maximal clinical benefits of the medicine (efficacy) for a given indication with the minimum production of adverse effects (safety).

It must be remembered that every medicine has some adverse effects and it is estimated that up to 10% of hospital admissions in industrialized countries are due to adverse effects. Not all medicine-induced injury can be prevented but much of it is caused by inappropriate selection of drugs.

In cost comparison between drugs, the cost of the total treatment and not only the unit cost of the medicine must be considered.

Verifying the Suitability of the Chosen Pharmaceutical Treatment for Each Patient

The prescriber must check whether the active substance chosen, its dosage form, standard dosage schedule and

standard duration of treatment are suitable for each patient. Medicine treatment should be individualised to the needs of each patient.

Prescription Writing

The prescription is the link between the prescriber, the pharmacist (or dispenser) and the patient, so it is important for the successful management of the presenting medical condition.

Giving Information, Instructions and Warnings

This step is important to ensure patient compliance and is covered in detail in the following section (refer 11. Adherence (compliance) with medicine treatment).

Monitoring Treatment

Evaluation of the follow up and the outcome of treatment allow the stopping of it (if the patient's problem is solved) or to reformulate it when necessary. This step gives rise to important information about the effects of drugs contributing to building up the body of knowledge of pharmacovigilance, needed to promote the rational use of drugs.

Factors Affecting Medicine Response

1. Variation in Dose

Success and effectiveness of medicine therapy depends not only on the correct choice of medicine but also on the correct dose regimen. Unfortunately, treatment frequently fails because either the dose is too small or it is too large that it produces adverse effects amongst other factors. The concept of a standard or 'average' adult dose for every medicine is firmly rooted in the mind of most prescribers. After the initial 'dose ranging studies on new drugs', manufacturers recommend a dosage that appears to produce the desired response in the majority of subjects. These studies are usually done on healthy, young male volunteers, rather than on older men and women with illnesses and of different ethnic and

environmental backgrounds. The use of standard doses in the marketing literature suggests that standard responses are the rule, but in reality there is considerable variation in medicine response. There are many reasons for this variation such as medicine formulation, body weight and age, variation in pharmacokinetics (absorption, distribution, metabolism and excretion), variation in pharmacodynamics, disease variables, environmental and genetic variables, adherence to instructions and adverse effects and interactions etc. Some of them are described below.

2. Formulation

The type of drug formulation is an important factor affecting its response, apart from its lipid solubility and so many other factors. Pharmaceutical dosage forms such as tablets, capsules, emulsions, ointments, injectables, liposomes, etc, provide a mechanism for safe, effective, accurate, and convenient delivery of drugs to the target site. Poorly formulated drugs may fail to disintegrate or dissolve. Enteric-coated drugs are particularly problematic, and have been known to pass through the gastrointestinal tract intact. Some drugs like digoxin or phenytoin have track records of formulation problems, and dissolution profiles can vary not only from manufacturer to manufacturer but also from batch to batch manufactured by the same manufacturer. Lately, biogeneric products (off patent biopharmaceuticals) have also been available in the pharmaceutical market. The production of biogenerics involves complex processes.

3. Body Weight and Age

Although the concept of varying the dose with the body weight or age of children has a long tradition, adult doses have been assumed to be the same irrespective of size or shape. Yet, adult weights vary two to threefold, while a large fat mass can store large excess of highly lipid soluble drugs compared to lean patients of the same weight. Age changes are also important. Adolescents may oxidize some drugs relatively more rapidly than adults, while the elderly may have reduced renal function and eliminate some drugs more slowly.

4. Sex

Females usually require smaller doses than males. Iron preparations and other haematinics are exceptions to this rule because of the blood lost by women during menstruation. There is a possibility that males metabolize benzodiazepines, estrogen containing preparations and salicylate at a faster rate than females.

5. Route of Administration

It governs the speed and intensity of drug response. The indications for a drug may vary when route of administration varies.

Example: Magnesium sulphate when administered orally—acts as a purgative; when administered topically—decreases swelling on sprained joints; and when administered intravenously—CNS depression and hypotension occur.

6. Tolerance

The therapeutic effects of some medications are lessened in individuals over a prolonged period of use. Thus, a patient who has been using a drug for longer time, requires a higher dose so as to obtain the same therapeutic effect as produced by the drug when taken for the first time. This is called tolerance. Opioids, benzodiazepines, β_2 agonists, caffeine, cocaine, amphetamines and barbiturates fall into this category. Cross-tolerance develops when use of one drug causes a tolerance to another. Alcoholics, barbiturate and narcotic addicts develop a cross-tolerance to sedatives and anaesthetics. These individuals require very large amounts of anaesthetics before surgical anaesthesia can be attained.

7. Synergistic Effect

Several drugs when combined may show synergistic action in the form of either additive or supra-additive action or potentiation. A few examples are:

a) trimethoprim + sulphamethoxazole

b) ACE inhibitor + angiotensin receptor blocker + diuretic

c) long acting β_2 agonists + inhaled steroids (e.g., salmeterol + fluticasone)

8. Resistance

Development of resistance to drugs is a common problem with antimicrobial agents (antituberculosis drugs, antileprotic drugs, antimalarial drugs etc.). Rational prescribing and in turn compliance by the user will prevent the emergence of resistance.

9. Pharmacokinetic Variables

a) Absorption

Absorption of a medicine is possible when it is present in solution form. Medicine absorption rates may vary widely between individuals and in the same individual at different times and in different physiological states. Drugs taken after a meal are delivered to the small intestine much more slowly than in the fasting state, leading to much lower medicine concentrations. In pregnancy, gastric emptying is also delayed, while some drugs may increase or decrease gastric emptying and affect absorption of other drugs.

b) Distribution

Medicine distribution varies widely— fat soluble drugs are stored in adipose tissue, water soluble drugs are distributed chiefly in the extracellular space, acidic drugs bind strongly to plasma protein albumin and basic drugs to muscle cells. Hence, variation in plasma–albumin levels, fat content or muscle mass may all contribute to dose variation. With very highly albumin bound drugs like warfarin, a small change of albumin concentration can produce a big change in free medicine concentration and a dramatic change in therapeutic action of a medicine.

c) Metabolism

Medicine metabolic rates are determined both by genetic and environmental factors. Medicine acetylation shows genetic polymorphism, whereby individuals fall clearly into either fast or slow acetylator types. Medicine oxidation, however, is polygenic, and although a small proportion of the population can be classified as very slow oxidizers of some drugs,

for most drugs and most subjects there is a normal distribution of medicine metabolizing capacity, and much of the variation is under environmental control. Also see section 10 (Environmental factors and genetic factors).

d) Excretion

Many drugs are eliminated by the kidneys without being metabolised. Renal disease or competitive tubular secretion of drugs can, therefore, slow down the excretion of certain drugs.

10. Pharmacodynamic Variables

There are significant variations in receptor response to some drugs, especially central nervous system responses, for example, pain and sedation. Some of these are genetic, some due to tolerance, some due to interactions with other drugs and some due to addiction, for example, morphine and alcohol.

a) Disease Variables

Both liver and kidney diseases can have major effects on medicine response, chiefly by the effect on metabolism and elimination respectively (increasing toxicity), and also by their effect on plasma albumin (increased free medicine also increasing toxicity). Heart failure can also affect metabolism of drugs with rapid hepatic clearance (e.g., lidocaine, propranolol). Respiratory disease and hypothyroidism can both impair medicine oxidation.

b) Environmental Factors and Genetic Factors (Pharmacogenetics)

Many drugs and environmental toxins can induce the hepatic microsomal enzyme oxidizing system (MEOS) or cytochrome P450 oxygenases, leading to more rapid metabolism and elimination and ineffective treatment. Environmental pollutants, carcinogens, tobacco smoke, alcohol, anaesthetic drugs and pesticides may also induce metabolism. Diet and nutritional status also have an impact on pharmacokinetics. For example, in infantile malnutrition and in malnourished elderly populations medicine oxidation rates are decreased,

while high protein diets, charcoal cooked foods and certain other foods act as metabolising enzyme inducers. Sedative and hypnotics induce sleep better in calm environment and when administered at night. Pharmacogenetic variation will affect the medicine response, by 4 to 6 fold among different individuals. All major determinants of medicine response such as transporters, metabolising enzymes, and receptors are controlled genetically. These factors in certain cases may result in toxicity—for example toxicity caused by inhibi- tory effect of isoniazid on phenytoin metabolism seems to be more significant in slow acetylators of isoniazid than in those patients who metabolise the drug more rapidly. The Appendix 16 summarises the pharmacogenetic variation, the frequency of occurrence, drugs involved and the outcome.

11. Adherence (Compliance) with Medicine Treatment

It is often assumed that once an appropriate medicine is chosen, the prescription correctly written and the medication correctly dispensed, that it will be taken correctly, then the treatment will be successful. Unfortunately, this is very often not the case, and physicians overlook one of the most important reasons for treatment failure that is poor adherence (compliance) with the treatment plan. There are sometimes valid reasons for poor adherence. The medicine may be poorly tolerated, may cause obvious adverse effects or may be prescribed in a toxic dose. Failure to adhere with such a prescription has been described as 'intelligent non-compliance'. Bad prescribing or a dispensing error may also create a problem, and regarding which patients may have neither the insight nor the courage to question. Even with good prescribing, failure to adhere to treatment is common. Factors may be related to the patient, the disease, the doctor, the prescription, the pharmacist or the health system and can often be avoided. Low-cost strategies for improving adherence increase effectiveness of health interventions and reduce costs. Such strategies must be tailored to the individual patient. Healthcare providers should be familiar with techniques for improving adherence and they should employ systems to assess adherence and to determine what influences it.

a) Patient Reasons

In general, women tend to be more adherent than men, younger patients and the very elderly are less adherent, and people living alone are less adherent than those with partners or spouses. Specific education interventions have been shown to improve adherence. Patient disadvantages such as illiteracy, poor eyesight or cultural attitudes (e.g., preference for traditional or alternative drugs and suspicion of modern medicine) may be very important in some individuals or societies, as may economic factors. Such disabilities or attitudes need to be discussed and taken account of.

b) Disease Reasons

Conditions with a known worse prognosis (e.g., cancer) or painful conditions (e.g., rheumatoid arthritis) elicit better adherence rates than asymptomatic 'perceived as benign' conditions such as hypertension. Doctors should be aware that in most settings less than half of patients initiated on antihypertensive medicine treatment are still taking it a year later. Similarly, in epilepsy, where events may occur at long intervals, adherence is notoriously unsatisfactory.

c) Doctor Reasons

Doctors may cause poor adherence in many ways–by failing to inspire confidence in the treatment offered, by giving too little or no explanation, by thoughtlessly prescribing too many drugs, by making errors in prescribing by prescribing very costly drugs, or by their overall attitude towards the patient.

d) The Doctor–Patient Interaction

There is considerable evidence that this is crucial to concordance. 'Satisfaction with the interview' is one of the best predictors of good adherence. Patients are often well informed and expect a greater say in their healthcare. If they are in doubt or dissatisfied they may turn to alternative options including 'complementary medicine'. There is no doubt that the medicine 'doctor' has a powerful effect to encourage confidence and perhaps contribute directly to the healing process.

e) Prescription Reasons

Many aspects of the prescription may lead to non-adherence (non-compliance). It may be illegible or inaccurate; it may get lost; it may not be refilled as intended or instructed for a chronic disease. Also, the prescription may be too complex; it has been shown that the greater the number of medications the poorer the adherence, while multiple doses also decrease adherence, if more than two doses per day are given. Not surprisingly, adverse effects like drowsiness, impotence or nausea reduce adherence and patients may not admit to the problem.

f) Pharmacist Reasons

The pharmacist's behaviour and professionalism, like the doctor's, may have a positive impact, supporting adherence, or a negative one, raising suspicions or concerns. This has been reported in relation to generic drugs when substituted for brand-name drugs. Pharmacist information and advice can be a valuable reinforcement, as long as it agrees with the doctor's advice.

g) The Healthcare System

The healthcare system may be the biggest hindrance to adherence. Long waiting times, uncaring staff, uncomfortable environment, exhausted medicine supplies and so on, are all common problems in developing countries, and have a major impact on adherence. An important problem is the distance and accessibility of the clinic from the patient. Some studies have confirmed the obvious, that patients farthest from the clinic are least likely to adhere to treatment in the long term.

h) Summary of Common reasons of medication and prescription errors

The medication errors are of concern for patient safety. They can cause significant ADRs/adverse events and many even lead to morbidity and mortality. They impact the quality of life of a patient. Majority of medication errors are preventable. The common reasons of medication errors and their possible solutions are listed below. The list is not exhaustive.

1. Legibility of contents of prescription including medical abbreviations, symbols errors and spelling errors
2. Inadequate direction /guidance to the patient on the use of drugs
3. Irrational prescription of antibiotics, steroidal anti-inflammatory drugs, antihistamines and fixed dose combinations etc.
4. Polypharmacy practice such as administration of more than one drug for the same ailment when it is not indicated (such as antiepileptics or not adopting multiple drug therapy where it is needed (eg. Antituberculosis agents, antileprotics, anti-HIV drugs)
5. Concomitant use of medicines of different systems such as Modern system, Ayurvedic system, Homeopathic system, Unani system for the same disease
6. Poor pharmacy and dispensing practices –
   - Improper storage of drugs
   - Substitution of drugs
7. Miscalculation of dose and strengths of drugs
8. Wrong route of drug administration
9. Transcription errors
10. Use of contaminated syringes and needles and re-use of these
11. Poor compliance by the patient
    - Non-adherence to prescribed dosage regimen, timing and duration
    - Improper storage of drugs
    - Lack of easy accessibility to the medicines prescribed
12. Communication gap which may be due to
    - Transcription
    - Legibility
    - Inability / Failure to explain the patient
13. Self medication

14. Lack of continuing education about the new uses/ adverse effects/dosage of old drugs and about new drugs at different levels of healthcare delivery system.

15. Medical Reconciliation: Failure to reconcile the present prescription with prescription history of the patient

Possible Solutions

1. Proper diagnosis of the ailment before prescribing drug therapy
2. Proper reading of the prescription before dispensing the medicines
3. Proper patient counseling to secure compliance
4. Accessibility and affordability of medicines
5. Computer generated prescriptions
   (CPOE- Computerized Physician Order Entry)
6. Compliance of 5R rule that is
   - Right Drug
   - Right Route
   - Right Time
   - Right Dose
   - Right Patient
7. Greater emphasis on correct prescription writing practices during undergraduate training and sensitization towards WHO Guide to Good Prescribing.

12. Adverse Effects and Interactions

An Adverse Drug Reaction (ADR) may be defined as 'any response to a medicine which is noxious, unintended and occurs at doses normally used for prophylaxis, diagnosis or therapy'. ADRs are, therefore, unwanted or unintended effects of a medicine, including idiosyncratic effects, which occur during its proper use. These differ from accidental to deliberate excessive dosage or medicine maladministration. ADRs may be directly linked to the properties of the medicine in use, the so-called 'A' type reactions. An example is hypoglycaemia induced by an antidiabetic medicine. ADRs may also be unrelated to the known pharmacology of the medicine, the

'B' type reactions including allergic effects, for example, anaphylaxis with penicillins. Thalidomide marked the first recognised public health disaster related to the introduction of a new medicine. It is now recognised that clinical trials, however thorough, cannot be guaranteed to detect all adverse effects likely to be caused by a medicine and hence, necessitating post-marketing surveillance. Health workers are thus encouraged to record and report to the nearest ADR Monituring Centre for any unexpected adverse effects with any medicine to achieve faster recognition of serious related problems. The National Regulatory Authority takes appropriate action on drugs showing serious ADRs.

a) Major Factors Predisposing to Adverse Effects

It is well known that different patients often respond differently to a given treatment regimen. For example, in a sample of 2422 patients who had been taking combinations of drugs known to interact, only 7 (0.3%) showed any clinical evidence of interactions. Therefore, in addition to the pharmaceutical properties of the medicine, the characteristics of the patients may be responsible for causing predisposition to ADRs.

b) Extremes of Age

The very old and the very young persons are more susceptible to ADRs. Drugs which commonly cause problems in the elderly include hypnotics, diuretics, non-steroidal anti-inflammatory drugs, antihypertensives, psychotropics, digoxin, etc. All children, and particularly neonates, differ from adult in their response to drugs. Some drugs are likely to cause problems in neonates (e.g. morphine), but are generally tolerated in children. Valproic acid is associated with increased risk of ADRs in children of all ages. Other drugs associated with problems in children include chloramphenicol (grey baby syndrome), antiarrhythmics (worsening of arrhythmias) and acetylsalicylic acid (Reye's syndrome etc).

c) Intercurrent Illness

If besides the condition being treated, the patient concomitantly suffers from another disease, such as kidney, liver or

heart disease, special precautions may be necessary to prevent ADRs. Remember also, that apart from the above factors, the genetic make-up of the individual patient may also predispose to ADRs.

d) Drug Interactions

Interactions (*see* Appendix 10) may occur between drugs which compete for the same receptor or act on the same physiological system. These may also occur indirectly when a medicine- induced disease or a change in fluid or electrolyte balance alters the response to another medicine. Interactions may occur when one medicine alters the absorption, distribution, metabolism or elimination of another medicine, such that the amount which reaches the site of action is increased or decreased. Medicine–medicine interactions are some of the commonest causes of adverse effects. When two drugs are administered to a patient, these may either act independent of each other, or interact with each other. Interactions may increase or decrease the effects of the drugs concerned and may cause unexpected toxicity. As newer and more potent drugs become available, the number of serious medicine interactions is likely to increase. Remember that interactions which modify the effects of a medicine may involve non-prescription drugs, non-medicinal chemical agents, and social drugs such as alcohol, marijuana, tobacco and traditional remedies, as well as certain types of food. The physiological changes in individual patients, caused by such factors as age and gender, also influence the predisposition to ADRs resulting from medicine interactions.

e) Pharmaceutical Interactions

Certain drugs, when added to intravenous fluids, may be inactivated by pH changes, by precipitation or by chemical reaction. Benzylpenicillin and ampicillin lose potency after 6–8 h if added to dextrose solutions, due to the acidity of these solutions. Some drugs bind to plastic containers and tubing, for example, diazepam and insulin. Aminoglycosides are incompatible with penicillins and heparin. Hydrocortisone is incompatible with heparin, tetracycline and chloramphenicol.

f) Adverse Effects Caused by Traditional Drugs

Patients who have been or are taking traditional herbal reme- dies may develop ADRs. It is not always easy to identify the responsible plant or plant constituent. For further details, refer to the Medicine and Toxicology Information Service, if available, and/or to suitable literature. Appendix 10d summarises the drug–food interactions.

g) The Effect of Food on Medicine Absorption

Food delays gastric emptying and reduces the rate of absorption of many drugs; the total amount of medicine absorbed may or may not be reduced. However, some drugs are preferably taken with food, either to increase absorption or to decrease the irritant effect on the stomach. Appendix 10d summarises the drug–food interactions.

Recommendations

- Review the prescription to make sure that it is correct.
- Spare time explaining the health problem and the reason for the medicine.
- Provide counselling to patients.
- Establish good rapport with patients.
- Explore problems, for example difficulty with reading the label or getting the prescription filled.
- Encourage patients to bring their medication to the clinic, so that tablet/capsule counts etc., can be done to monitor compliance.
- Encourage patients to learn the names of their drugs, and review their regimen with them. Write notes for them.
- Keep treatment regimens simple and consider socioeconomic background of the patient while selecting the drugs.
- Communicate with other healthcare professionals, to develop a team approach and to collaborate on helping and advising the patient.
- Involve the partner or another family member in eliciting clinical history of patients and explaining the advice.
- Listen to patients.

Pharmacist plays an important role as a connecting link between the physician and patient.