NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

सत्यमेव जयते

NATIONAL PHARMACEUTICAL PRICING AUTHORITY
DEPARTMENT OF PHARMACEUTICALS
MINISTRY OF CHEMICALS & FERTILIZERS
GOVERNMENT OF INDIA

Azadi Ka Amrit Mahotsav

AUSHADH SANDESH

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A Bi-monthly e-Newsletter

दवा वही
दाम सही

Committed Towards Accessibility, Availability & Affordability of Medicines for All

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About NPPA...

The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals was constituted by the Government of India vide resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia, includes fixation and revision of prices of scheduled formulations under the Drugs Prices Control Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

The Authority is a multi-member body consisting of a Chairperson, a Member Secretary and three ex-officio members. Two of the three ex-officio members are from Department of Economic Affairs and Department of Expenditure respectively and third member is Drug Controller General of India.

The Drugs (Prices Control) Order, 2013(DPCO, 2013) was notified on 15.05.2013 under the Essential Commodities Act, 1955(EC Act, 1955) and is based on the broad guidelines of the National Pharmaceutical Pricing Policy (NPPP), 2012. The three key principles of the NPPP-2012 are as below:

a) Essentiality of Drugs: The regulation of prices of drugs is on the basis of essentiality of drugs as per the medicines under NLEM-2011, NLEM-2015 as amended vide S.O. th 701(E) dated 10 March, 2016 has been incorporated as the First Schedule of DPCO 2013.

b) Control of Formulations prices only: The prices of formulations only are to be regulated and not the prices of the Bulk Drugs and the resulting formulations as adopted in the Drug Policy 1994.

c) Market Based Pricing: The ceiling prices of medicines are fixed on Market Based Pricing (MBP) methodology.

DISCLAIMER:

This is an initiative by NPPA to report current affairs and events related to Pharmaceutical industry and the NPPA. This newsletter has been curated purely for informative purposes and do not reflect the official policy or position of NPPA. This newsletter is not intended to be used for any commercial/official purposes.

You can also give your suggestions/ feedback at: monitoring-nppa@gov.in

सत्यमेव जयते

From CHAIRMAN'S DESK

Shri Kamlesh Kumar Pant, IAS
Chairman
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

I am happy to bring to you the third issue of the NPPA bi-monthly e-Newsletter.

This edition has an article penned by Dr. Rajeev Singh Raghuvanshi Secretary cum Scientific Director, Indian Pharmacopoeia Commission wherein he explains role of the Indian Pharmacopoeia Standards for Ensuring Quality of Medicines in India as Pharmacopoeia is a legally binding collection of written standards on quality of drugs.

In this issue, insights on the Union Budget 2022, wherein some major changes have been done in the customs duty structure that have bearing on pharmaceutical structure have been included. Besides, observations on Fifteen Finance Commission (15th FC) and fund allocations for Health Sector over 15th FC award period of 2021-26 have been included in brief.

I am also happy to share that NPPA has expanded its presence with the opening of another PMRU in Union Territory of Ladakh in February 2022. With this the number of PMRUs in the country have reached 22.

NPPA wishes good health to all its readers; stay safe, stay healthy and follow all COVID appropriate behavior.

With best wishes

(Kamlesh Kumar Pant)

ROLE OF THE INDIAN PHARMACOPOEIA STANDARDS FOR ENSURING QUALITY OF MEDICINES IN INDIA

(**Rajeev Singh Raghuvanshi,** Indian Pharmacopoeia Commission
(Ministry of Health and Family Welfare, Government of India),
Sector 23, Raj Nagar, Ghaziabad 201 002, India. Email: rajeevr.ipc@gov.in)

1. Indian Pharmacopoeia Commission

Indian Pharmacopoeia Commission (IPC) came into existence on January 1, 2009 as an autonomous Institution under the Ministry of Health & Family Welfare, Government of India and is entrusted with the mandates of:

- Publication of the Indian Pharmacopoeia (IP) and its addenda having official standards of the drugs marketed in India,
- Establishment and distribution of IP Reference Standards (IPRS) to the stakeholders,
- Publication of the National Formulary of India for rational prescription of medicines,
- working as the National Coordination Centre for Pharmacovigilance Programme of India

The Commission has a three-tier structure (Fig. 1), comprising the General Body, the Governing Body and the Scientific Body, which are supported by the IPC Secretariat and the Indian Pharmacopoeia Laboratory (IPL). IPC has the vision "to promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacturing and analysis" and 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". In order to realise its vision and mission, the IPC Secretariat and the scientists of IPL work closely with different advisory Expert Working Groups and the Scientific Body.

2. Indian Pharmacopoeia (IP)

IP and its recommendations ensure that patients have uninterrupted access to the critical medicines that extend and improve their lives. Pharmacopoeia is a legally binding collection of written standards, prepared by a national or regional authority, of standards and quality specifications for medicines used in that country or region. A quality specification is composed of a set of appropriate tests that will confirm the identity and purity of the product, ascertain the strength (or potency) of the active substance and, when needed, its performance characteristics. The role of a modern pharmacopoeia is to furnish quality specifications for active pharmaceutical ingredients (APIs), finished dosage forms or drug product (DP), excipients, herbs and chapters on general definitions, explanations and requirements. The existence of such specifications and requirements is, on one hand, necessary for the

(Fig. 1)

proper functioning or regulatory control of medicines and on the other hand help manufacturers and analysts in producing quality medicines. Pharmacopeial requirements form a base for establishing quality requirements for individual pharmaceutical preparations in their final form. Public quality standards are used by the manufacturers, regulators and other stakeholders for quality control of the APIs and DPs as per recommended specifications. Pharmacopeial requirements in countries form part of national legislation, defining the specifications which pharmaceutical products circulating on their market must fulfil.

IPC exclusively deals with matters relating to timely publication of the IP which is the official book of standards for drugs included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder so as to specify the standards of identity, purity and strength for the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. The IP Standards are authoritative in nature and are enforced by the regulatory authorities for quality control of medicines in India. During quality assurance and at the time of dispute in the court of law, IP standards are legally acceptable.

In 1948, the Indian Pharmacopoeia Committee was constituted with the mandate of publication of IP and the journey of publication of IP editions in chronological order is given below (Fig. 2).

Currently, the eighth edition of the IP (IP 2018) is official in India. The standards prescribed in IP adhere to the concept of harmonization, keeping in view the technological advancements in manufacturing and analysis of the drugs and pharmaceuticals in the country and abroad without compromising with the quality of the products. On one hand, it strives to update the existing monographs based on the context and advancement in the field and on the other hand it incorporates new monographs of APIs and DPs as per the specified inclusion and exclusion criteria. The current IP consists of four volumes. Volume 1 consists of General Chapters, Volume 2 and 3 consists of individual monographs and volume 4 is exclusively for veterinary products. The quality specifications and the methods of analysis is provided in the form of Monograph.

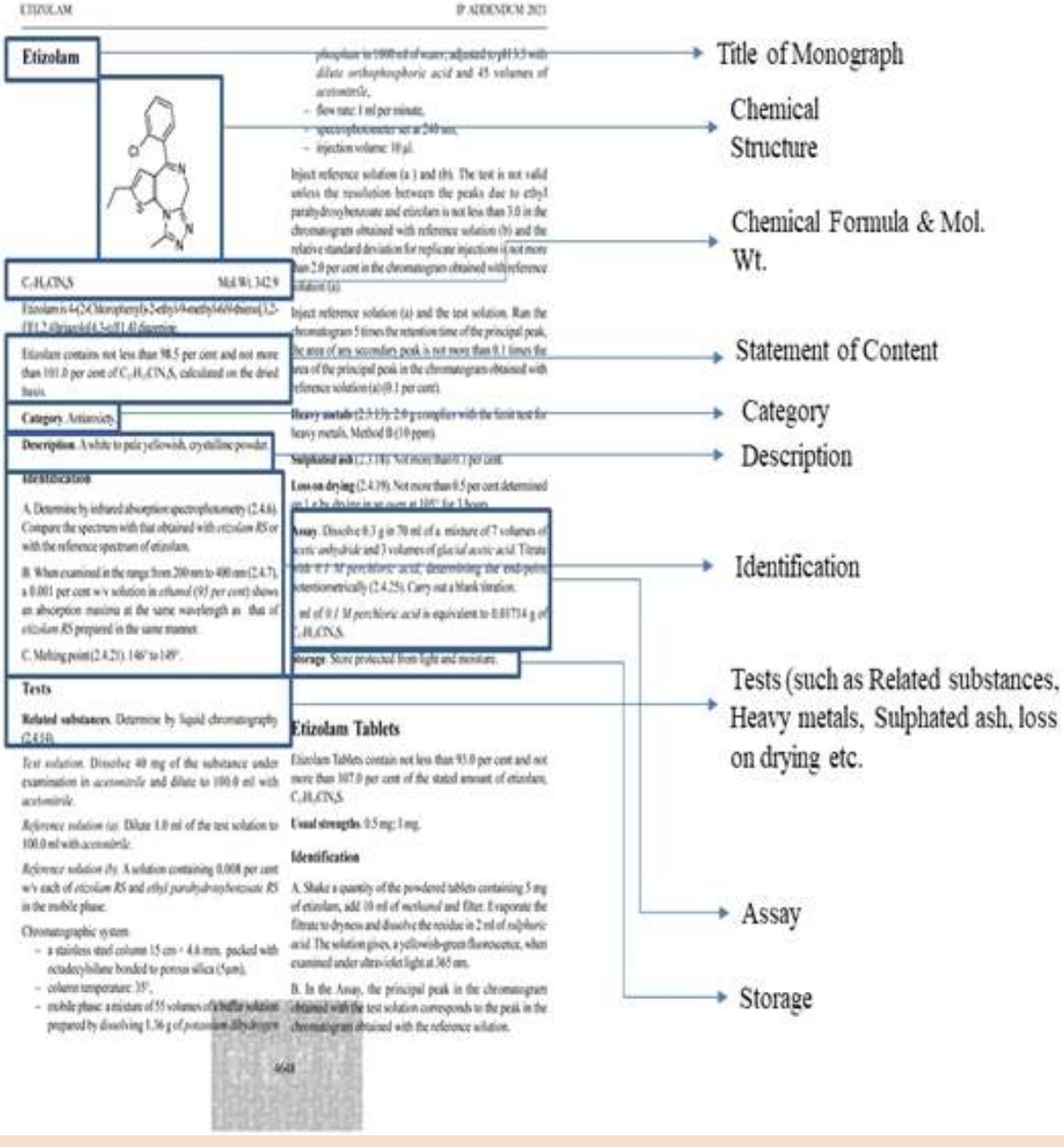
For understanding, structure of typical monograph of an API is being presented (Fig. 3) which shows the content of a monograph under different sub-headings like Description, Identification, Assay, Impurities and Storage. On similar lines, IP has DP monographs also. Invariably, one will find one monograph of API followed by multiple DP monographs. e.g., the common drug Paracetamol has one API monograph followed by 5 different DP

(Fig. 2) **Journey of the publications of IP editions**

monographs – Paracetamol Infusion, Paracetamol Oral Solution, Paracetamol Paediatric Oral Suspension, Paracetamol Paediatric Syrup and Paracetamol Tablets. A point to be noted is that the pharmacopoeia does not provide strength specific monographs for DP. A monograph, has both qualitative e.g., identification and description and quantitative tests e.g., assay and dissolution. The quantitative test results are always represented in percent and therefore it is not required to have strength specific monograph. Only in exceptional cases, where different strengths of one drug are completely different products based on technology used and having different clinical profile, we may have strength specific monographs.

Creation of monographs is a collaborative process. Since it is a post drug approval activity, monograph development starts only after the drug has been approved by CDSCO. Post approval of a product, IPC evaluates a candidate as per its inclusion criteria framework and once the candidate fits in

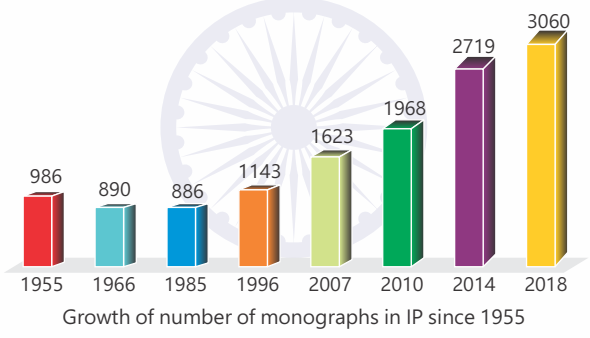
(Fig. 3) Monograph structure of IP



the framework, monograph development process starts. The process involves intense discussion among manufacturers, regulators, subject matter experts and other stakeholders before finalization and publication in IP.

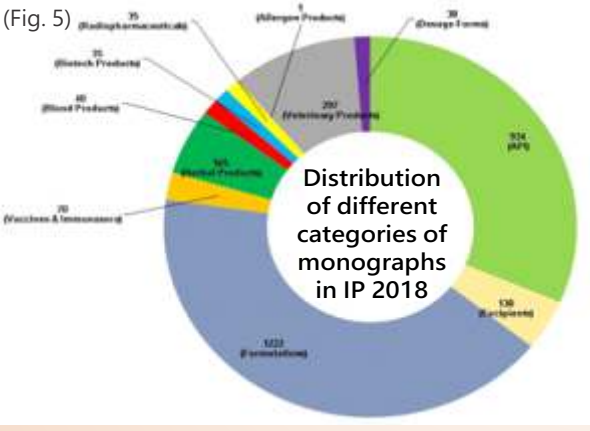
In the current edition of IP, there are 3060 monographs in total. Out of this, the largest chunk goes to the DP monographs with 1222 numbers followed by API with 934 and then veterinary monographs with 297 of them. For more details, the following two figures (Fig. 4 & Fig. 5) will be helpful.

(Fig. 4) IP MONOGRAPH DEVELOPMENT



Growth of number of monographs in IP since 1955

(Fig. 5)



3. IP Reference Substances (IPRS)

IPC also has the mandate to accelerate the process of preparation, certification and distribution of IPRS. IPRS is highly characterized substance that is used in the official methods prescribed in IP for the purpose of comparison to ensure the identity, purity, strength and quality of drug substances and drug products being analysed. IPRS characterization involves collaborative processes and additional procedures other than those used in routine testing. There is IPRS for Active Ingredient, Impurity Standards, Microbiological Culture, Herbal Extracts, Vaccines etc. Currently, IPC has an inventory of IPRS for 642 Active Ingredients and 272 Impurity Standards. The information on the IPRS and impurities available with the IPC and the procedure for their purchase is displayed on our website (www.ipc.gov.in). Pharmacopeial documentary standards and RSs could help shrink product development timelines, decrease risk, and reduce capital equipment utilization.

(Fig. 6) **Reference standards of the IPC**

A pharmaceutical analyst routinely uses the IP monograph and the IP reference standards for analysing the drug manufactured by a manufacturer. The analysis could be done at their in-house QC labs or can be out sourced to an analytical lab. Wherever the analysis happens, for an "IP" designated drug, the analysis has to happen as per the methods given in the monograph and using the IP reference standard (Fig. 6). It's a legal obligation as per D & C Act 1940 and Rule 1945. On the other hand, when samples are picked either from market or manufacturing locations by regulators, their analysis by govt. laboratories is done as per the IP monograph for compliance. Thus, monograph provides an opportunity to unify the quality testing parameters and brings consistency in the specifications and methods of testing. Through this, it helps in maintaining uniform minimal acceptable quality of medicines throughout the country, irrespective of the manufacturer. Monographs in IP also helps in rationalizing the cost of medicines. Research has shown that once monographs are published in pharmacopoeia, it promotes genericization of the drug and thereby reduces the cost. MSMEs can pick up the specifications and methods of analysis from IP and start using them in testing and maintaining the quality which, considering their infrastructure, may be difficult for them in absence of the monograph.

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HEALTH SYSTEM IN BRAZIL

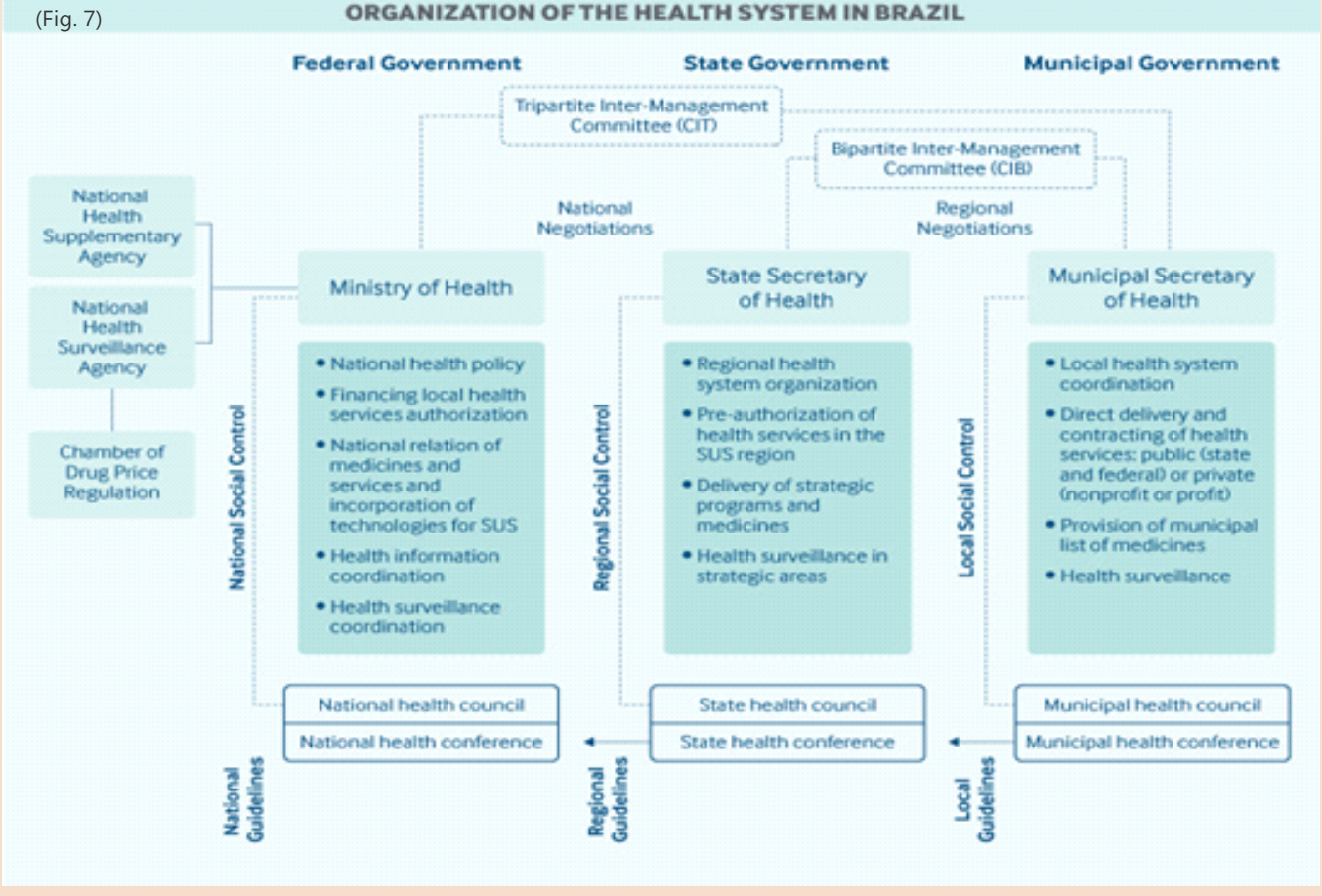
The constitution of Brazil defines health as a universal right and a state responsibility. The Brazilian health system, known as SUS (Sistema Único de Saúde), was conceived during the 1980s as part of the social movement aimed at Brazil's re-democratization. SUS was officially created in 1988 by the new Brazilian constitution (Fig. 7). Three principles underpin SUS:

- The universal right to comprehensive health care at all levels of complexity (primary, secondary, and tertiary).
- Decentralization with responsibilities given to the three levels of government: federal, state, and municipal.
- Social participation in formulating and monitoring the implementation of health policies through federal, state, and municipal health councils.

Since 1990, the incremental expansion of SUS has enabled substantial progress toward achieving universal health coverage. Brazil's decentralized, universal public health system is funded with tax revenues and contributions from federal, state, and municipal governments. The administration and delivery of care are handled by municipalities or states. All residents and visitors, including undocumented individuals, can access free, comprehensive services, including primary, outpatient specialty, mental health, and hospital care, as well as prescription drug coverage. No application process is necessary. There is no cost-sharing for health care services. Nearly 25 percent of Brazilians, mostly middle- and higher-income residents, have private health insurance to circumvent bottlenecks in accessing care. Private health insurance costs, as well as health-related purchases, qualify as tax deductions.

Read more

(Fig. 7)



HEALTH OUTCOMES: PERFORMANCE OVER TIME

Fifteenth Finance commission in its Report has observed that India has made some notable gains on the health front since independence. Life expectancy at birth has increased, infant mortality and crude death rates have been greatly reduced, diseases such as smallpox, polio and guinea worm have been eradicated, and leprosy is on the verge of getting eliminated.

The sex ratio in the country has improved from 933 in 2001 to 943 in 2011. The estimated birth rate declined from 25.8 per 1,000 population in 2000 to 20.4 per 1,000 population in 2016 while the death rate declined from 8.5 per 1,000 population to 6.4 per 1,000 population over the same period. The natural growth rate declined from 17.3 per 1,000 population in 2000 to 14 per 1,000 population in 2016, according to the National Health Profile 2018-19. In recent years, India has made progress in reducing the maternal mortality ratio (MMR) from 556 per 100,000 live births in 1990 to 130 in 2016. The long-prevailing urban-rural divide in institutional births has largely been bridged. Overall, 75 per cent of rural births are now supervised as compared to 89 per cent in urban areas.

National health programmes have played a crucial role in tackling several serious health concerns. The malarial death rate in India declined to 0.02 deaths per 100,000 population in 2018 from 0.10 deaths in 2001 and the country has achieved the Millennium Development Goal (MDG) of halting and reversing the incidence of tuberculosis (TB) by 2015. There has been significant progress in achieving immunisation coverage through the Universal Immunisation Programme (UIP) which provides protection from six vaccine-preventable diseases

While all this reflects significant achievements, it cannot deflect attention from the fact that India lags behind many similarly placed countries. At 130 per 100,000 live births, the MMR is almost double the 2030 Sustainable Development Goal (SDG) target of 70. India ranked 94 out of 107 countries in the Global Hunger Index 2020. Childhood stunting rates of 38 per cent are among the highest in the world. Data on nutritional outcomes also show that 35.8 per cent of children are underweight and 58.6 per cent are anaemic. Since all this has long-term implications for health as well as for learning, employability and economic performance, it is a development challenge of first-order importance.

Recognising the need for improvement in India's healthcare system, fifteenth finance commission has recommended grants for the health sector, divided into two parts: (i) grants aggregating to Rs. 70,051 crores through local governments and (ii) sectoral grants aggregating to Rs. 31,755 crores to States. 15th Finance Commission have also recommended State-specific grants for health amounting to Rs. 4,800 crores. The total grants-in-aid support to the health sector over the award period 2021-26 works out to be Rs. 1,06,606 crore which is 10.3 per cent of the total grants-in-aid recommended by FC. This forms about 0.1 per cent of GDP. The grants for the health sector will be unconditional.

[Source: 15th Finance Commission Report (Para 9.4,9.5,9.6,9.7 and 9.49)]

BUDGET 2022 ANNOUNCEMENTS

- **Item 89 and 90 of Budget Speech**

Supportive policies, light-touch regulations, facilitative actions to build domestic capacities, and promotion of research & development will guide the governments approach. For R&D in these sunrise opportunities, in addition to efforts of collaboration among academia industry and public institutions, government contribution will be provided

- **Item 109 of Budget Speech**

Government backed Funds NIIF and SIDBI Fund of Funds have provided scale capital creating a multiplier effect. For encouraging important sunrise sectors such as Climate Action, Deep-Tech, Digital Economy, Pharma and Agri-Tech, the government will promote thematic funds for blended finance with the government share being limited to 20 per cent and the funds being managed by private fund managers.

- **Changes in Basic Custom Duty on Drugs**

a. Vide S. No. 166 of notification No. 50/2017-Customs, concessional BCD rate of 5% is prescribed on "Drugs, medicines, diagnostic kits or equipment and Bulk drugs used in the manufacture of drugs or medicines" falling under Chapters 28, 29 or 30. On review, this entry and associated List-3 is being rationalized and accordingly,

- 35 items have been omitted from the associated List-3 w.e.f. 02.02.2022 [IV (ix)(i) of notification No. 02/2022-Customs dated 02.02.2022 refers]- (Table 3)

- 1 item [item no. 95 Influenza Vaccine of List-3] would be omitted w.e.f. 1st October, 2023. [IV (ix)(ii) of notification No. 02/2022-Customs dated 02.02.2022 refers]
- 3 items have been transferred to this List from List 4 w.e.f. 2.2.2022. [IV (ix)(iii) of notification No. 02/2022-Customs dated 02.02.2022 refers]

b. A new entry at S. No. 166A would be inserted w.e.f. 1st April 2024 providing concessional rate of 5% for bulk drugs falling under Chapters 28, 29 or 30 used in the manufacture of Poliomyelitis Vaccine or Monocomponent insulins subject to importer following IGCR Rules 2017. [S. No. 42 of notification No. 02/2022 dated 1st February 2022 refers]

c. Vide S. No. 167 of notification No. 50/2017-Customs, concessional BCD rate of Nil is prescribed on"Lifesaving drugs, medicines, diagnostic kits or equipment and Bulk drugs used in the manufacture of lifesaving drugs or medicines"falling under Chapters 28, 29, 30 or 38. On review, this entry is being rationalized and accordingly

- Entry at S. No. 167 (C) which provides exemptions to other life-saving drugs or medicines subject to the condition No. 16 has been omitted. This exemption is already available vide entry at S. No. 607 of notification No. 50/2017-Customs.
- 39 items have been removed from the List-4. [IV(x) of Notification No. 02/2022- Customs dated 02.02.2022 refers]- (Table 4)
- For 2 medicines namely Poliomyelitis Vaccine (inactivated and live) and of Monocomponent Insulin, the formulations are being omitted from List-4. Further, bulk drugs for manufacture of these formulations have been granted exemptions till 31.03.2024. W.e.f. 01.04.2024 these bulk drugs would attract 5% rate under newly created entry at S. No. 166A of 50/2017-Customs [S. No. 43 (b) of notification No. 02/2022-Customs dated 1st February 2022 refers]

d. A new entry S. No. 167A is being inserted in the notification No. 50/2017-Customs, to exempt drugs or medicines, falling under Chapter 30 or Heading 9804 of the First Schedule to the

Customs Tariff Act, 1975, which are used for the treatment of rare diseases, when imported by 8 Centers of Excellence (CoE) listed in the associated List 2 (inserted) or any other person/ institution on their recommendation and Condition No. 112 is also being inserted. [S. No. 44 of notification No. 02/ 2022-Customs dated 1st February 2022 refers]

- **Changes in Basic Custom Duty on Medical Devices**

a. BCD increase to give effect to PMP for X-Ray Machines and Parts (Table 1):

Table 1

S. No.	Chapter, heading, subheading, or tariff item	Commodity	From	To
1	90	Following items used in manufacture of X-ray items: a) X-Ray grid b) Multi Leaf Collimator/ Iris c) Static User Interface	5%	10%
2	90	X-Ray Machines	7.5%	10%

b. BCD exemption withdrawn for the following

- artificial kidney and disposable sterilized dialyzer and micro-barrier of artificial kidney. (Applicable BCD rate now is 7.5% with 5% Health Cess)
- raw materials, parts or accessories for use in manufacture of on artificial kidney and disposable sterilized dialyzer and micro barrier of artificial kidney. (Applicable BCD rate now is 2.5% with no health cess)

c. Health Cess exemption

reduced from 5% to'Nil'on needles for suture (tariff item 9018 32 10) used in manufacture of surgical sutures

d. Rates Notified under Custom Tariff Act and correspondingly deleted from Notification (No effective change in Budget) (Table 2)

- **Concessional Rate of Corporate Tax under section 115 BAB for new manufacturing firms, extended by one year**

Extension of the last date for commencement of manufacturing or production, under section 115BAB, from 31.03.2023 to 31.03.2024. Section 115BAB of the Income-tax Act provides for an option of concessional rate of taxation @ 15 % for new domestic manufacturing companies provided that they do not avail of any specified incentives or deductions and fulfil certain other conditions.

Table 2 **Tariff rate changes (without any change in the effective rates of Basic Customs Duty)**

S. No.	Chapter, heading, subheading, or tariff item	Commodity	From	To
1	62071910	Of synthetic fibres	25% or Rs. 30 per piece, whichever is higher	20% or Rs.30 per piece, whichever is higher
2	621020	Outer garments, of fabrics impregnated, coated, covered or laminated with preparations of cellulose derivatives and other artificial plastic materials	25% or Rs. 365 per piece, whichever is higher	20% or Rs. 365 per piece, whichever is higher
3	6217	For articles of apparel of synthetic fibres	25%	20%
4	6307	Other	25%	10%
5	9018 32 30, 9018 50 20, 9018 90 21, 9018 90 24, 9018 90 43, 9018 90 95, 9018 90 96, 9018 90 97, 9018 90 98	Specific instruments and appliances used in medical, surgical, dental or veterinary sciences like tonometer, tubular needles for medical sutures etc.	10%	5%
6	9018 (other than items in entry at Sr. No. 407. above and 9018 90 99)	Other medical equipment and medical related goods used in medical, surgical, dental or veterinary sciences like catheters, cannulae, defibrillator etc	10%	7.5%
7	9019 (except 9019 10 20)	Mechano-therapy appliances such as massage apparatus, psychological aptitude testing apparatus etc	10%	7.5%
8	9020	Breathing appliance other than protective masks not having replaceable filters or mechanical parts	10%	7.5%
9	9021	Orthopaedic appliances like crutches, surgical belts and trusses, splints etc	10%	7.5%

(Table 3) - 35 items omitted from List-3 of S.No 166 of Customs Notification 50/2017

Entry No in Notification	Name of the drug
3	Amrinone
7	Busulphan
8	BCG Vaccine, Iopromide, Iotrolan
12	Cyclophosphamide
22	Isoprenaline
25	Lomustine
27	Melphalan
28	Mesna
30	MMR (Measles, mumps and rubella) vaccine
33	Praziquantel
38	Somatostatin
39	Strontium Chloride (85 Sr.)
43	Typhoid Vaccines: (i) VI Antigen of Salmonella Typhi, and (ii) Ty 2la cells and attenuated non-pathogenic strains of S. Typhi
44	Tretinoin
49	Vasopresssin
50	Vecuronium Bromide
53	Pegulated Liposomal Doxorubicin Hydrochloride injection
54	Ketoanalogue preparation of essential amino acids
61	Haemophilus Influenzae Type b Vaccine
62	Mycophenolate Sodium
68	Muromonab Cd3
70	Valganciclovir
80	Everolimus tablets/dispersible tablets
86	Injection Exenatide
88	Pneumococcal-7 Valent Conjugate Vaccine (Diphtheria CRM197 Protein)
93	Entacevir
97	Lapatinib
99	Suntinib Malate
102	Anidulafungin
107	Maraviroc
109	Sorafenib tosylate
110	Varenciline tartrate
115	Bevacizumab
117	Rotavirus Vaccine (Live Oral Pentavalent)
121	Octreotide

(Table 4) - 39 items omitted from List-3 of S.No 167 of Customs Notification 50/2017

Entry No in Notification	Name of the drug
1	Aurothiomalate Sodium
3	Agglutinating Sera
4	Anti-Diphtheria Normal Human Immunoglobulin
7	Anti-Pertussis Normal Human Immunoglobulin
8	Anti-Plague serum
9	Anti-Pseudomonas Normal Human Immunoglobulin
13	Botulinum Toxin Type "A"
17	Bretyleum Tossylate
18	Calcium Disodium Edetate
19	Carmustine
26	Cyanamide
27	Diagnostic Agent for Detection of Hepatitis B Antigen
28	Diagnostic kits for detection of HIV antibodies
29	Diphtheria Antitoxin sera
30	Diazoxide
32	Enzyme linked Immunoabsorbent Assay kits FLISA KITS
37	Flecainide
42	Gasgangrene Anti-Toxin Serum
45	Hexamethylmelamine
46	Hydralazine
50	Inactivated rabies vaccine Human diploid cell
51	Inactivated rabies vaccine Vero-cell
58	Levodopa with benserazine
60	Meningococoal A and C combined vaccine with diluant solvent
61	Methicillin
63	Monocomponent insulins
71	Penicillinase
72	Poliomyelitis vaccine (inactivated and live)
73	Potassium Aminobenzoate
74	Porcine Insulin Zinc Suspension
76	Porcine and Bovine insulin
77	Purified Chick Embryo Cell Rabies Vaccine
78	Pyridostigmine
81	Radio-immunoassay kit for hormones (T3, T4, TSH Insulin, Glucogen, Growth Hormone Cortisol, L.H., FSH and Digoxin)
89	Freeze Dried Form of Human Follicle Stimulating and Luteinising Hormones
91	Specific Desensitizing Vaccine
98	Ticarcillin
99	Tranexamic Acid
110	Zoledronic Acid

News related to pricing of drugs

- Ceiling prices for 886 scheduled formulations (National List of Essential Medicines, 2015) and Retail prices for 1817 non-scheduled formulations have been fixed under DPCO, 2013 till 31st January, 2022.
- As on 31.01.2022, over all 227 Authority meetings have been conducted and out of which 95 are under DPCO 2013. The 227th (Overall) and the 95th meeting of the Authority under DPCO 2013 was held on 28.01.2022.
- Retail prices of 19 new drugs for various pharmaceutical companies were fixed in the 95th meeting of the Authority under DPCO 2013 respectively.

Details of retail prices fixed for various formulations in 95th Authority Meetings are as follows:

S. No.	Therapeutic group	Total Number	Type of formulation	Retail Price fixed Range (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Anti-Diabetic	4	Tablet	6.25 - 8.54
2	Antihypertensive	3	Tablet	8.92 - 9.79
3	Cardio Vascular	2	Tablet	10.68 – 12.95
4	Hypolipidemic drugs	2	Capsules	12.55-16.70
5	Anti-Pyretic	3	Tablet/Infusion	3.05 – 16.94
6	Pain Analgesic	3	Tablet/Patch	2.93 - 31.25
7	Others	2	Tablet	14.74 – 15.55

News related to pricing of Medical devices

NPPA vide S.O. 2808 (E) dated 13.07.2021 rationalised the Trade margin for five Medical Devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer upto 31.01.2022. This has been further extended upto 31st July 2022 vide S.O. 401(E) dated 30.01.2022 in view of ongoing pandemic.

OTHER NEWS AND EVENTS

NPPA sets up 22nd PMRU in Union Territory of Ladakh in February, 2022

NPPA under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has so far set-up Price Monitoring and Resource Units (PMRU) in 22 States/ UTs. The 22nd PMRU was established in Union Territory of Ladakh on 09.02.2022. With this NPPA is one step closer to establish its presence at pan- India basis. Now, NPPA has set-up PMRUs in following states/ UTs viz. Kerela, Gujarat, Odisha, Rajasthan, Punjab, Nagaland, Tripura, Uttar Pradesh, Mizoram, Jammu & Kashmir, Andhra Pradesh, Haryana, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, West Bengal, Puducherry and Ladakh. This will help NPPA trickle down the benefits of DPCO at grassroot level with the help of PMRU to ensure that consumer at large is benefitted.

Activities done by PMRU's

One day workshop was organized by PMRU, Haryana on 15.12.2021 on "Activities of PMRU and Enforcement of DPCO", which was chaired by Commissioner, Food and Drugs Administration, Haryana and was attended by Drug Control Officers. Also, Drug Control Officers are conducting workshop about activities of PMRU and menace of medical intoxicants. Such workshops have been organized in Karnal on 30.12.2021, Ambala on 05.01.2022 and Faridabad on 25.01.2022.

INTERNATIONAL NEWS

WHO announces first technology recipients of mRNA vaccine hub with strong support from African and European partners

At the European Union - African Union summit in Brussels, WHO Director-General, Dr Tedros Adhanom Ghebreyesus, announced the first six countries that will receive the technology needed to produce mRNA vaccines on the African continent. Egypt, Kenya, Nigeria, Senegal, South Africa and Tunisia all applied and have been selected as recipients. The global mRNA technology transfer hub was established in 2021 to support manufacturers in low- and middle-income countries to produce their own vaccines, ensuring that they have all the necessary operating procedures and know-how to manufacture mRNA vaccines at scale and according to international standards.

Read more

Novavax COVID-19 vaccine Nuvaxovid approved by MHRA

Nuvaxovid, the COVID-19 vaccine developed by Novavax, has been given regulatory approval by the Medicines and Healthcare products Regulatory Agency (MHRA). Nuvaxovid becomes the fifth COVID-19 vaccine authorised by the UK's independent medicines regulator. The approval authorises the use of this vaccine in people aged 18 and over for a first and second dose. As with all vaccines, People with an allergy to one of the components of the vaccine listed in the patient information leaflet should not receive the vaccine.

Read more

Oral COVID-19 antiviral, Paxlovid, approved by UK regulator

A COVID-19 treatment called Paxlovid (PF-07321332 and ritonavir) has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) after it was found to be safe and effective at reducing the risk of hospitalisation and death in people with mild to moderate COVID-19 infection who are at an increased risk of developing severe disease. This follows a rigorous review of its safety, quality and effectiveness by the UK regulator and expert advice from the government's independent scientific advisory body, the Commission on Human Medicines. Developed by Pfizer, Paxlovid is an antiviral medicine with a combination of active ingredients, PF-07321332 and ritonavir, that works by inhibiting a protease required for virus replication.

Read more

FDA Authorizes New Monoclonal Antibody for Treatment of COVID-19 that Retains Activity Against Omicron Variant

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for a new monoclonal antibody for the treatment of COVID-19 that retains activity against the omicron variant. The EUA for bebtelovimab is for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms, which is about 88 pounds) with a positive COVID-19 test, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

Read more

FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant

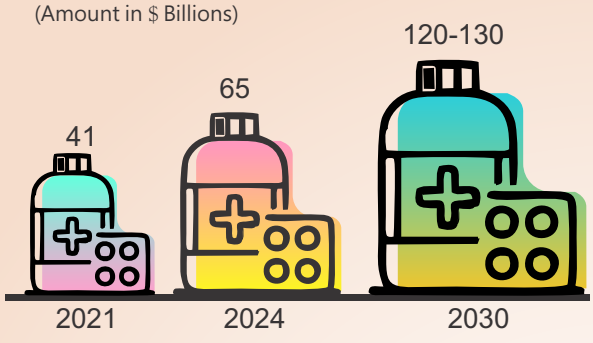
Ensuring that healthcare providers on the frontlines have the best tools available to treat patients is a top priority for the agency. In light of the most recent information and data available, today, the FDA revised the authorizations for two monoclonal antibody treatments – bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) – to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.

Read more

KNOW YOUR REGULATOR/SECTOR

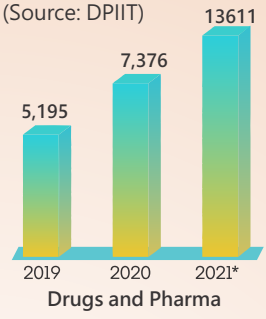
Size of Pharma Industry

(Source: Economic Survey 2020-21)
(Amount in $ Billions)



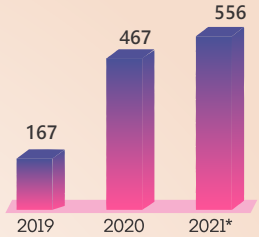
Investment Intentions in Terms of IEMs Filed

(Source: DPIIT)



Drugs and Pharma

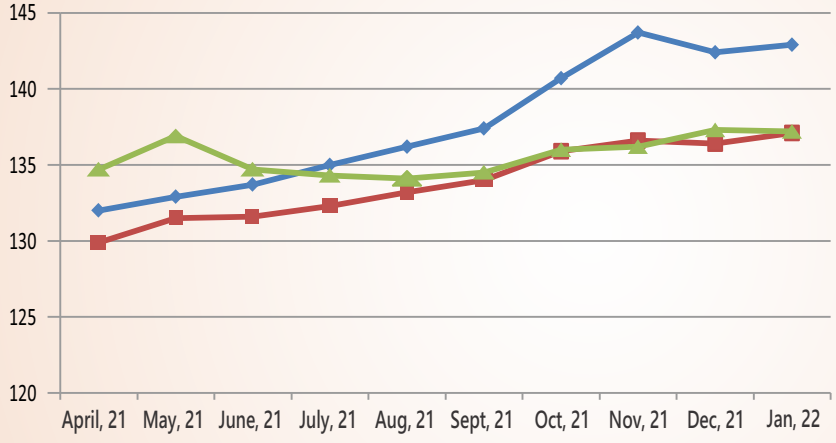
(Amount in Rs. crore)



Medical & Surgical Instruments

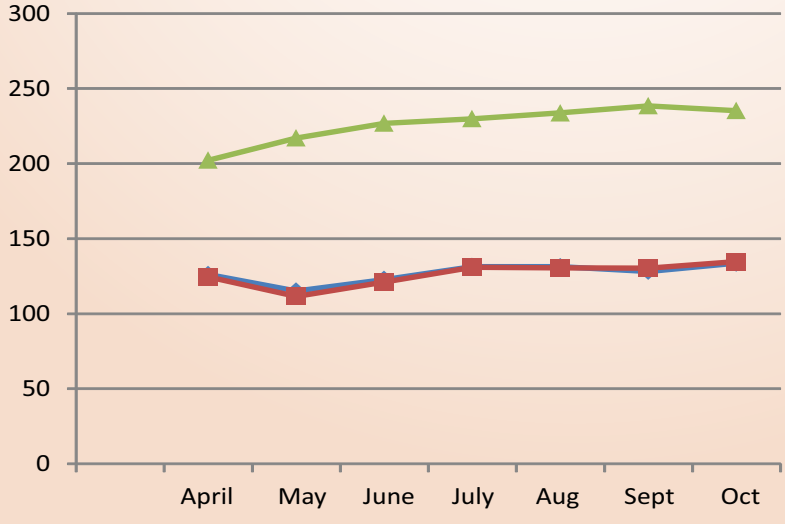
(*Till December, 2021)

Wholesale Price Index (Base 2011-12) (source: DPIIT)



- All commodities
- Manufacturing
- Manufacture of pharmaceuticals, medicinal chemical and botanical products

Index of Industrial Production (Base 2011-12) (Source: MoSPI)



- All commodities
- Manufacturing
- Manufacture of pharmaceuticals, medicinal chemical and botanical products

FREQUENTLY ASKED QUESTIONS

- **Does Government fix prices of all drugs?**

  The Government fixes the Ceiling Price of Scheduled drugs. The maximum MRP that can be kept for a Scheduled drug is Ceiling Price plus applicable taxes. Scheduled drugs are mentioned at Schedule-I of DPCO, 2013, which is based on the National List of Essential Medicines (NLEM). However, the prices of other drugs can also be fixed by Govt., if warranted in public interest.

- **Are non-scheduled drugs out of price control?**

  No. Although the Govt. does not fix the prices of non-scheduled drugs but there is a limit on annual increase in prices of drugs. The manufacturers cannot increase the MRP of a drug by more than ten percent in a year.

- **Is there any control on increase in prices of Scheduled drugs also?**

  Yes. The manufacturers cannot increase the MRP of a scheduled drug by more than the WPI rate. Further, the price increase can be taken only in the month of April every year.

- **Is approval of NPPA required for increasing the price of non scheduled drugs?**

  No. the approval of NPPA is not required for increasing the prices of non scheduled drugs. The manufacturers can increase the prices on their own, but the increase should not beyond 10% in 12 months period.

- **What if a manufacturer increases the prices beyond the specified limit?**

  In such a case, the overcharged amount shall be recovered from the manufacturer along with interest and penalty. Further, action can also be taken under Section 7 of the Essential Commodities Act, 1955.

Feedback and Complaint Redressal

Grievance Redressal

Pharma Jan Samadhan: A web enabled system for grievance redressal – catering to consumers, distributors, dealers, retailers.

Information Dissemination

Pharma Sahi Daam: One can easily search brand name, composition, ceiling price and MRP of the formulation – available to public.

Seminars and Workshops conducted by NPPA and by PMRUs

Collaboration with State Governments

PMRU: To help NPPA to monitor notified prices and ensure availability of medicines.

To spread awareness regarding the pricing of drugs, etc.

NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

3rd / 5th Floor, YMCA Cultural Center Building 1, Jai Singh Road, New Delhi, India
www.nppaindia.nic.in | Helpline No.: 1800 111 255 (10 am to 6 pm on working hours)

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