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

AUSHADH SANDESH

Vol.-XVIII | AUGUST, 2024

A Bi-monthly e-Newsletter

दवा वही
दाम सही

Committed Towards Accessibility, Availability & Affordability of Medicines for All

CONTENTS

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 and NLEM-2022 as amended vide S.O. 5249 dated 11.11.2022 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 events and affairs 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

From
CHAIRMAN, NPPA'S DESK

सत्यमेव जयते

Dr Arunish Chawla, IAS
Chairman
National Pharmaceutical Pricing Authority
Department of Pharmaceutical
Ministry of Chemical and Fertilizers
Government of India

It is with immense pleasure I present to you the Eighteenth issue of the NPPA bi-monthly e-Newsletter, the **AUSHADH SANDESH**. Our objective of bringing out the newsletter remains steadfast - to disseminate information that caters to the diverse interests of our stakeholders, thereby fostering informed decision-making and collaboration within the pharmaceutical and med-tech landscape.

3rd August, every year is celebrated as Indian Organ Donation day and I am happy to note that an insightful article titled "Understanding Basics of Organ Donation and Transplantation" has been contributed by Dr Gaurav Sharma, Faculty, Department of Translational & Regenerative Medicine Postgraduate Institute of Medical Education & Research Chandigarh. Knowing about organ donation and transplantation is crucial for improving lives and health outcomes as it helps advance donor selection, immunological assessment, and overcoming challenges, ultimately fostering a culture of generosity and awareness.

In continuation of our webinar series, Sixty (60) State and District level Events/ Seminars were organized by 17 PMRUs in their respective States/ UTs viz. Puducherry, Telangana, Andhra Pradesh, Jammu & Kashmir, Kerala, Uttar Pradesh, Goa, Jharkhand, Ladakh, Meghalaya, Maharashtra, Chhattisgarh, Haryana, Punjab, Odisha, Himachal Pradesh and Tripura PMRU's.

These events were aimed at imparting awareness among people about the role of NPPA in making the Drugs affordable and available for all; promotion and use of Pharma Sahi Daam App & IPDMS 2.0; and carrying out monitoring of prices of medicines through PMRUs.

I extend my gratitude to Dr Gaurav Sharma for his insight article on various facets of Organ donation and the editorial team for their relentless efforts in curating this newsletter, which I trust will serve as a valuable resource to keep stakeholders abreast of the latest regulatory news, policies, events, and more.

NPPA wishes good health to all its readers; stay safe, stay healthy.

With best wishes

(Dr. Arunish Chawla)

UNDERSTANDING BASICS OF ORGAN DONATION AND TRANSPLANTATION

Dr Gaurav Sharma
Faculty, Department of Translational & Regenerative Medicine
Postgraduate Institute of Medical Education & Research, Chandigarh

Every year, August 03, 2024 is observed as Indian Organ Donation Day to commemorate country's first successful deceased donor heart transplant on August 03, 1994 after promulgation of the "Transplantation of Human Organs Act" on July 08, 1994.

Clinical Cure through Tissue and Organ Transplantation

Transplantation is the surgical process in which an organ/s, tissue or group of cells are removed from one person (the donor) and transplanted into another person (the recipient), or moved from one site to another in the same person. Organs such as kidneys, liver, heart, lungs, intestines and pancreas could be transplanted from one individual to another, while tissue transplants chiefly involve skin, cornea transplant.

a) Tissues are basically group of cells that work together to perform a specific function in the body and therefore can be used therapeutically to cure damaged tissues e.g. cornea (regain sight), tendons (rebuild joints), valves (repair cardiac defects), veins (re-establish circulation), skin (healing burn patients), bones (prevent the need for amputation).

b) Organs are collection of tissues that structurally form a functional unit specialized to perform a particular function and can be used therapeutically to cure end stage organ failures e.g. heart (for curing heart failure), lungs (for treating terminal lung illnesses), kidneys (kidney failure), liver (liver failure), pancreas (diabetes), intestines.

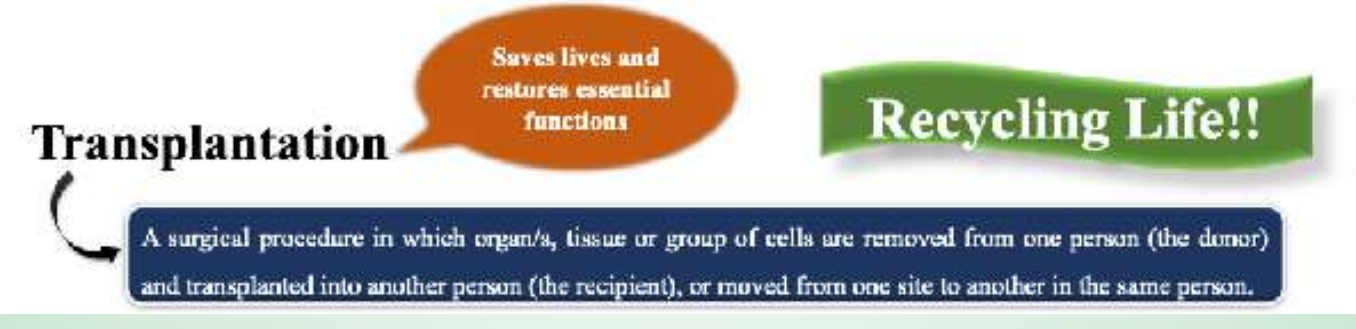


Figure 1: Organs and Tissues Transplantation for Clinical Cure

Based on donors, organ transplantation is broadly classified into following four categories:

i. Autologous i.e., donor is self
ii. Isotopic/ syngeneic i.e., transplant between identical twins
iii. Allogenic involves a histocompatible donor belonging to same species
iv. Xenogeneic transplant is a cross-species transplant, which is an alternative for human organs and still in ascent stage and yet to be clinically approved

Types of Organ/Tissue Donors

1. Living Donors: These donors can donate one kidney as body can sustain physiological function with remaining one kidney, a portion of pancreas and a part of the liver which is highly regenerative in nature.

a) Near Relative Donor (mother, father, son, daughter, brother, sister, spouse, grandchildren and grandparents).
b) Other than near relative donor who can donate only for the reasons of affection and attachment or for any special reason with the approval of authorization committee.
c) By swapping of near relative donors between unmatched donor and recipient.

2. **Deceased donors:** Organ donation is not always dependent on living donors and deceased donors are even more important. These donors may include:

a) Donor after brain stem death where the person cannot breathe and maintained through ventilator to keep organs functional e.g. a victim of road accident where the brain stem is dead. Such a donor can donate multiple organs and tissues after brain stem death, for example, one such donor can donate up to eight life saving organs including heart, two lungs, liver, pancreas, two kidneys and intestines.
b) Donor after cardiac death where tissues can be donated, however, recently PGIMER Chandigarh has started organ donation from controlled cardiac death donors.

Key steps in the organ donation process involve registering the donor, brain death testing in case of brain stem death, authorization and consent for donation, matching process, recovering/retrieval of organ/s / tissues, transportation and transplantation.

Each organ has a different timeframe between recovery/retrieval from donor to recipient's transplant, for example: ~4 hours for heart and lungs, ~8-12 hours for liver and 24-36 hours for kidneys. Hence, retrieval of organs and tissues for transplantation is done in Retrieval Centers which are primarily involved in organ procurement, tissue banking handling and transportation aspects. On the other hand, transplant centres perform organ and tissue transplants to treat patients with end stage organ failure. These centres are specialized in pre transplant evaluation, surgical procedures and post-transplant care and follow-ups for monitoring.

Framework of National Organ Transplantation Programme (NOTP)

Organ and tissue transplantation can save lives and cure end stage organ specific diseases e.g. heart, kidney and liver failure etc., which require planning through a strong organizational structure addressing the ethical and moral concerns too. To achieve this, Transplantation of Human Organs Act 1994 (THOA) was promulgated, which was subsequently amended to Transplantation of Human Organs and Tissues Act (THOTA, 2011). It meant for regulation, storage, and transplantation of human organs and tissues for therapeutic purpose only while preventing their commercial dealings. National Organ Transplant Program (NOTP) was implemented by the Government of India to enforce THOTA wherein National biomaterial Centre and National human organ and tissue removal and storage network were established.

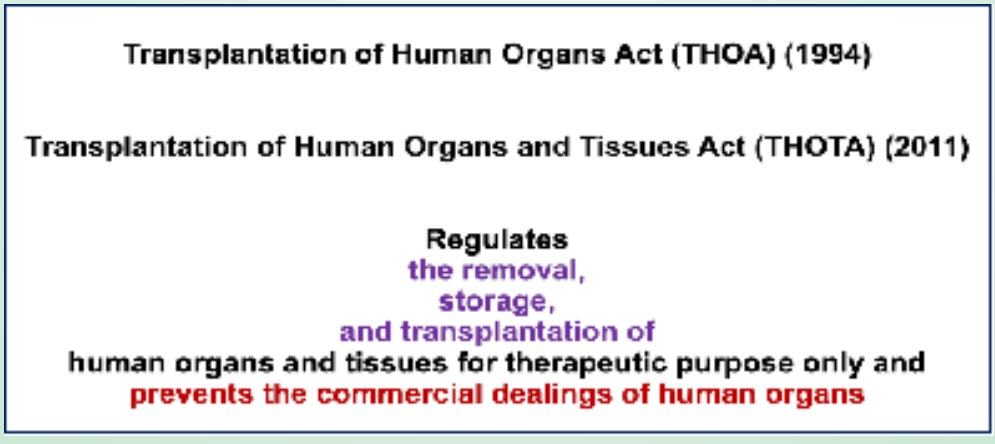


Figure 2: Laws governing transplantation of Human Organs and Tissues

ARTICLE BY PHARMA EXPERT

Briefly, the directorate of General of health Services (DGHS), Ministry of health and welfare established National Organ and Tissue Transplant Organization(NOTTO) for directly monitoring and coordinating all transplant related activities through five Regional Organ and Tissue Transplant Organizations (ROTTO) and ~35 State Organ and Tissue Transplant Organizations(SOTTO) all over India. The apex organisation NOTTO is located at the 4th and 5th floor of National Institute of Pathology, Safdarjung Hospital, New Delhi.

Success of organ and tissue donation and transplantation relies on extensive collaboration of NOTTO, ROTTO and SOTTO at the national, regional and state levels. Together these organizations form the corner stone of India's organ donation and transplantation system and maintain the distribution of organ and tissues. So, by working in a coordinated manner these organizations saved numerous lives and enhanced the wellbeing of a number of patients.

Waiting list Protocol for organ allocation

As per the protocol, patients requiring cadaver organs are put in the waiting list. Broadly, there are two types of waiting lists as stated below:

a) **Urgent waiting list:** For patients who require an organ urgently to save their lives as otherwise they may not survive.
b) **Regular waiting list:** This list is based on clinical criteria which differ based on different organs. For example, for renal transplant, a criterion is based on the time spent on regular dialysis.

According to THOTA, sequence of allocation of organs shall be in the following order: 1) State list followed by 2) Regional list which is followed by 3) National list, subsequently 4) Person of Indian Origin and 5) Foreigner.

Is there any age limit for organ donation?

- In living donation, person should be >18 year of age, and for most organs it's the donors physical condition and not merely the age.
- Healthcare professionals decide suitability on case to case basis. Organs and tissue from donors in 70s-80s have been transplanted successfully globally.
- In the case of tissues and eyes, age usually does not matter.

On the other hand, a deceased donor can generally donate the Organs & Tissues with the age limit of:

- **Kidneys, liver:** up-to 70 years
- **Heart, lungs:** up-to 50 years
- **Pancreas, Intestine:** up-to 60-65 years
- **Corneas, skin:** up-to 100 years
- **Heart valves:** up-to 50 years
- **Bone:** up-to 70 years

Statistics of Organ Transplantation

Recent clinical and technological advancements have significantly improved organ transplantation protocols. Nevertheless, increasing burden of metabolic disorders has resulted in a concomitant rise in the waiting list of patients requiring organ transplant. As per the global statistics report for the year 2022, a total of 157,494 organ transplants were performed globally, of which 102,090 were for kidney, 37,436 for liver, 8,988 for heart, 6,784 for lungs, 2,026 for pancreas and 170 were intestine transplants. India ranks third globally with approximately 17,000-18,000 solid organ transplants performed annually3. In 2020 > 1,12,000 Indians were waiting for a transplant, and a new name was added to the national transplant waiting list every 10 minutes. As per the

reports from NOTTO, there were ~15,561 organ transplants performed across Indian subcontinent including both living (~12,791) and deceased donor (~2,765) transplants. Among the top five states, Delhi NCR leads with 3,623 living donor transplants while Telangana leads with 194 deceased donor transplants4. Moreover, in year 2022, living and deceased donor kidney transplants in India have increased to 9,834, and 1,589 respectively. Similar trends were observed for liver transplants with 2,957 transplants from living donors and 761 from deceased donors (Table 1). These statistics of transplants for each of these organs is indicative of: the efficient transplant network on one side, while increasing disease burden advocating need for organ donation, on the other side.

Table 1: Organ transplantation statistics in India as per National Organ and Tissue Transplant Organization (2013-2022)

Year	Total Tx	Total Living Tx	Total Deceased Tx	Living Donor Renal Tx	Deceased Donor Renal Tx	Living Donor Liver Tx	Deceased Donor Liver Tx	Heart Tx	Lung Tx	Pancreas Tx
2013	4990	4153	837	3495	542	658	240	30	23	2
2014	6916	5886	1030	4884	628	1002	325	53	15	7
2015	8348	6689	1659	5571	984	1118	498	118	51	6
2016	9022	6756	2265	5697	1261	1059	694	216	73	20
2017	9539	7429	2110	6165	1169	1264	579	237	106	18
2018	10340	8085	2254	6772	1164	1313	631	241	191	25
2019	12666	10604	2060	8613	1138	1991	599	187	114	22
2020	7443	6457	984	4970	516	1487	291	89	67	14
2021	12259	10638	1619	8275	830	2363	482	151	133	19
2022	15561	12791	2765	9834	1589	2957	761	250	138	24

Basic Immunological Aspects in Transplantation

Transplantation involves complex immuno-biological process regulating histocompatibility through antigen recognition and presentation by major histocompatibility complex (MHC) and generation of cytotoxic responses by T cells. The MHC molecules also known as Human leukocyte antigen (HLA) in humans is encoded by a highly polymorphic gene dense region mapped to a short arm of chromosome 6 (6p21.3), and are classified into three classes viz., HLA class I, II and III. The major biological role of HLA class I molecules is to present antigen (peptide/epitopes) to CD8+ T cells while HLA class II molecules regulate the adaptive immune responses through antigen (peptide/epitopes) presentation to CD4+ T cells (Sharma et al. 2020).Briefly, the more genetically compatible the donor and the recipient, the more tolerant the recipient's immune system towards the graft. Ideally, a donor matched for 6 loci i.e., HLA-A, -B, -C, -DRB1, -DQB1 and –DPB1 is considered an HLA-identical donor, suitable for transplant1.

Graft rejection is major life-threatening risk post organ transplantation, apart from other non-immunologic risks including infectious complications, metabolic disorders and ischemia. The risk of graft rejection is negligible for autologous and syngeneic transplants while it's highest for the xenogeneic cases. Rejection is broadly grouped into three categories i.e.,

a) **Hyperacute:** The hyperacute rejections appear within minutes of transplant due to preformed antibodies which destroy the graft.
b) **Acute:** The acute rejections occur after few days to months of transplant involving the role of donor-specific antibodies (DSA) and humoral as well as cell-mediated immune system.
c) **Chronic:** The chronic rejection develops over a longer period of time with adverse immunologic symptoms like inflammation, fibrosis etc.

To regulate all the immune responses against graft for long term survival of the transplant immunosuppressant drugs are used. These drugs majorly including Tacrolimus, Mycophenolate mofetil, Cyclosporine, Sirolimus, Mycophenolic acid, and Azathioprine2. Table 2 summarises some basic details about common immunosuppressant drugs and their mechanistic action. On the other hand, these immunosuppressive regimens render the recipient susceptible to an array of microbial infections (bacterial, viral and fungal) for which routine clinical monitoring is supported by infection prophylaxis designed to protect against these infectious complications. It majorly includes drugs like Septrin, Valtrex, Valganciclovir, Mycostatin, Flucanazole among others2. These post-transplant regimens are crucial in development of immune kinetics, preventing rejection and fighting infection.

Table 2: Immunosuppressant drugs for organ transplantation recipients2

S. No.	Name of Immunosuppressant	Mechanism of Action
1	Prednisolone	Corticosteroid binding to glucocorticoid receptor reducing inflammation in the body
2	Tacrolimus	Inhibits T-lymphocyte signal transduction and IL-2 transcription
3	Mycophenolate Mofetil	Depletes guanosine nucleotides preferentially in T and B lymphocytes and inhibits their proliferation
4	Mycophenolic Acid	Inhibits the de novo pathway of guanosine nucleotide synthesis without incorporation to DNA
5	Azathioprine	Inhibits purine synthesis in white blood cells
6	Cyclosporine	A calcineurin inhibitor, and inhibits IL-2 synthesis essential for activation and differentiation of T-cells
7	Sirolimus	Blocks signal transduction and inhibits cell cycle progression

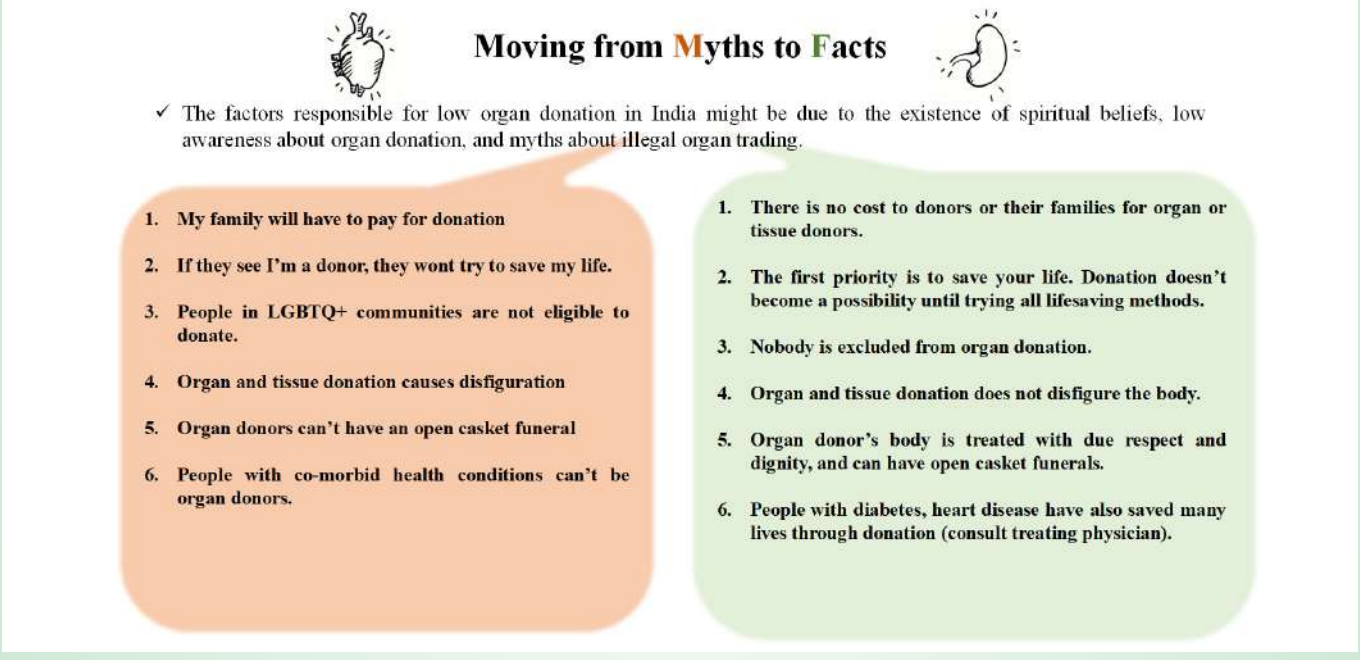
Major Issues and Challenges in Organ Donation and Transplantation

- High number of organ failure cases
- Poor availability of donors (Demand Vs. Supply gap)
- Lack of awareness on concept of Brain Stem Death and Less number of such Certification by Hospitals
- Non availability of adequate Infrastructure
- Lack of awareness and attitude towards organ donation

- Transportation of Donated Organs (especially inter State)
- Gaps in Data Reporting especially online entry by hospitals/ States in National Registry
- High Cost (especially for uninsured and poor)
- Maintenance of Standards in Transplantation
- Potential Organ Trading

Doctors Against Forced Organ Harvesting (DAFOH)

Global organ trafficking and forced organ harvesting, the removal of organs from a donor, without obtaining prior free and voluntary consent, is considered a crime against humanity, as well as a threat to medical science in general. Different forms of organ theft are reported worldwide, scattered across various regions and countries. Hence, DAFOH was established as an organization founded by medical doctors across the world to voluntarily serve to maintain the dignity of human beings and promote the highest ethical standards in medicine. DAFOH aims to provide the medical community and society with objective findings of unethical and illegal organ harvesting.



Pledge/register to be an Organ Donor

Anyone may pledge for organ donation by simply signing up with NOTTO website i.e. www.notto.nic.in and register as donor. For registering offline one can download Form 7 from and send signed copy of filled form to NOTTO at below mentioned address:

NATIONAL ORGAN AND TISSUE TRANSPLANT ORGANISATION
4th Floor, NIOP Building, Safdarjung Hospital Campus, New Delhi-110029

Key References:

1) http://www.beaumont.ie/ accessed on August 1, 2024
2) www.statista.com accessed on August 1, 2024
3) https://notto.mohfw.gov.in/ accessed on August 1, 2024
4) Sharma G, Baranwal A, Mehra NK., (2020), The human leukocyte antigen system in human disease and transplantation medicine. Clinical Molecular Medicine, Elsevier

REGULATORY NEWS

News related to pricing of drugs

- Ceiling prices for 742 scheduled formulations (National List of Essential Medicines, 2022) and Retail prices for 2964 non-scheduled formulations have been fixed under DPCO, 2013 till 28th August 2024.
- As on 31st August 2024, 257 Authority meeting have been conducted of which 125 is under DPCO 2013. The details of the recent meetings are given as below:

Meeting No.	Held on	Prices Approved & Notified
257th (overall) & 125th Meeting under DPCO 2013	25.07.2024	(i) Retail prices for 70 formulations notified vide S.O. 3169 (E) & 3170 (E) dated 06.08.2024.
		(ii) Revised Ceiling price of 4 scheduled formulations of Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 vide S.O. 3216(E) dated 08.08.2024 based on Review Orders issued by DoP.

- Details of retail prices notified for various formulations based on the decision taken in 125th Authority Meetings are as follows:

Year	Therapeutic group	Total Number	Type of formulation	Retail Price fixed Range (Rs.) (Excl. GST) per tablet/per ml
(1)	(2)	(3)	(4)	(5)
1	Anti Diabetic	31	Tablets	6.49 – 20.73
2	Analgesic & anti-inflammatory	3	Tablets/Infusion	2.38 – 4.08
3	Anti-bacterial	4	Infusion/Tablet	14.13 – 1620.01
4	Anti-hypertensive	7	Tablet	5.80 – 16.48
5	Cardiovascular	12	Tablet / Capsule	4.95 – 33.63
6	Vitamins/Minerals/ Nutrients	2	Tablet/Solution	11.02 – 13.92
7	Anti-Infective	4	Tablet/ Infusion/Kit	29.21 – 1572.59
8	Others	7	Tablet/ Injection / Gel / Eye drops	4.83 – 95.06

- Ceiling prices of 926 formulations are effective as on date of which details of ceiling prices notified for various formulations under NLEM, 2022 till date are as follows:

Therapeutic Category	No. of Medicines	No. of Formulations
Anti-infective Medicines	62	169
Anticancer Medicines	59	119
Neurological Disorder Medicines	18	59
Psychiatric Disorder Medicines	14	41
Cardiovascular Medicines	25	59
HIV Management Medicines	20	23
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs)	8	24
Anti-Diabetic drugs	16	11
Hormones, other Endocrine Medicines and Contraceptives	106	33
Others	321	204
Unique Drugs / Formulations	**321***	**742**

*Some medicines are listed in various sections. The medicines are counted in both sections, but the formulation is counted only once in one of the sections.

Ceiling Prices of medicines used in Organ transplantation procedures

NPPA has fixed the ceiling prices of around 37 essential formulations, which lie in the therapeutic categories as mentioned below and also used in cases of organ transplantation. The details of these ceiling prices effective as on 28.08.2024 are as under-

S. No	Section under NLEM	Formulation	Current Ceiling price (in Rs.)
1	**A. Section 3.6** - Antiallergics and Medicines used in Anaphylaxis **B. Section 7.2.4** - Hormones and anti- hormones used in cancer therapy **C. Section 21.2.1** -Anti-inflammatory medicine **D. Section 18.1.4** -Adrenal Hormones and Synthetic substitutes	Prednisolone Tablet 5mg	0.68 per tablet
2		Prednisolone Tablet 10mg	1.20 per tablet
3		Prednisolone Tablet 20mg	2.40 per tablet
4		Prednisolone Tablet 40mg	3.41 per tablet
5		Prednisolone Drops 1%	5.76 per ml
6		Prednisolone Oral liquid 5mg/ml (p)	0.49 per ML
7		Prednisolone Oral liquid 15mg/ml (p)	0.86 per ML
8		Prednisolone Injection 20mg/2ml	4.46 per ML*
9	**Section 7.3 - Immunosuppressive Medicines**	Tacrolimus Capsule 0.5mg	20.66 per capsule
10		Tacrolimus Capsule 1mg	40.62 per capsule
11		Tacrolimus Capsule 2mg	84.34 per capsule
12		Tacrolimus Tablet 0.5mg	20.97 per tablet
13		Tacrolimus Tablet 1mg	39.98 per tablet
14		Tacrolimus Tablet 2mg	77.69 per tablet

15		Mycophenolate Mofetil Tablet 250mg	49.60 per tablet
16		Mycophenolate Mofetil Tablet 500mg	74.59 per tablet
17		Cyclosporine Capsule 25mg	28.04 per capsule
18		Cyclosporine Capsule 50mg	55.11 per capsule
19		Cyclosporine Capsule 100mg	103.12 per capsule
20		Cyclosporine Injection 50mg/ml	335.80 per ML*
21		Cyclosporine Oral liquid 100mg/ml (p)	80.58 per ML
22	**A. Section 7.3**-Immunosuppressive Medicines **B. Section 2.4** - Disease Modifying Agents used in Rheumatoid Disorders	Azathioprine Tablet 50mg	11.26 per tablet
23		Azathioprine Tablet 25mg(p)	7.24 per tablet
24	**A. Section 6.9.3.2** – Anti-pneumocystosis and antitoxoplasmosis medicines **B. Section 6.2.2.6** - Other antibacterials	Co-trimoxazole Oral liquid 200 mg (A) + 40 mg(B)/5mL(p)	0.35 per ML
25		Co-trimoxazole Tablet 400 mg (A) + 80 mg (B)	0.90 per tablet
26		Co-trimoxazole Tablet 800 mg (A) + 160 mg (B)	2.30 per tablet
27	**A. Section 6.6.2** - Anti-cytomegalovirus (CMV) medicines **B. Section 6.7.5** - Medicines for treating Opportunistic Infections in People living with HIV	Valganciclovir Tablet 450mg	408.27 per tablet
28	**Section 6.5**- Antifungal Medicines	Fluconazole Tablet 50mg	9.68 per tablet
29		Fluconazole Tablet 100mg	7.62 per tablet
30		Fluconazole Tablet 150mg	12.06 per tablet
31		Fluconazole Tablet 200mg	17.46 per tablet
32		Fluconazole Tablet 400mg	29.75 per tablet
33		Fluconazole Capsule 150mg	19.22 per capsule
34		Fluconazole Capsule 200mg	40.11 per capsule
35		Fluconazole Capsule 100mg	21.40 per capsule
36		Fluconazole Injection 200mg/100ML	92.33 per 100ML vial
37		Fluconazole Oral Liquid 50mg/5ml (p)	3.25 per ML*

*Fixed under NLEM 2015

IPDMS 2.0:

Integrated Pharmaceutical Database Management System (IPDMS) is an integrated responsive cloud-based application. It is a system for online information collection, processing and communication portal to monitor and regulate the prices of medicines and medical devices, to ensure availability and affordability of drugs and medical devices in the country. The upgraded IPDMS 2.0 was launched on

Chart1: Total number of registered companies at the end of August 2024.

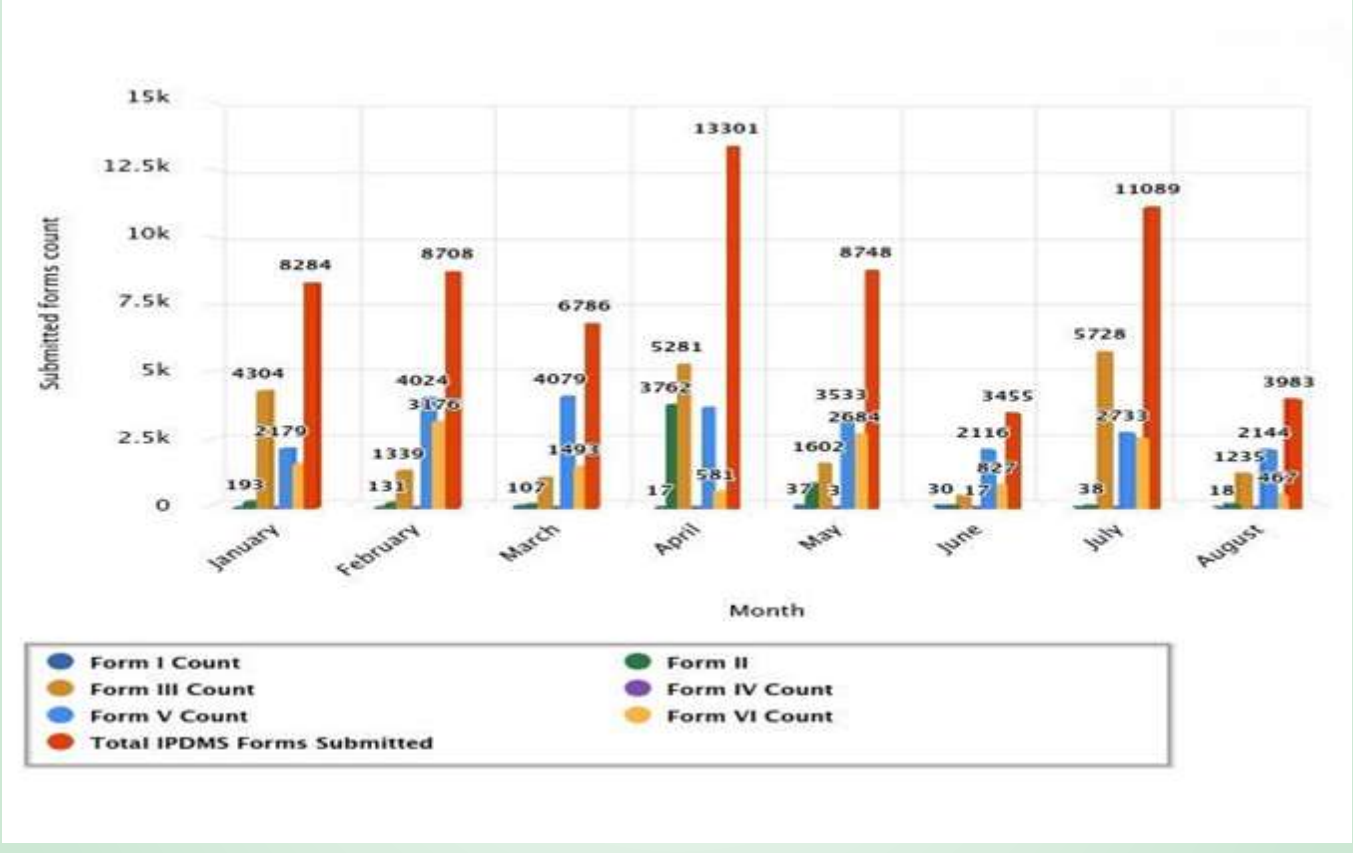


Chart 2: Number of statutory forms filed on IPDMS as on 31st August 2024

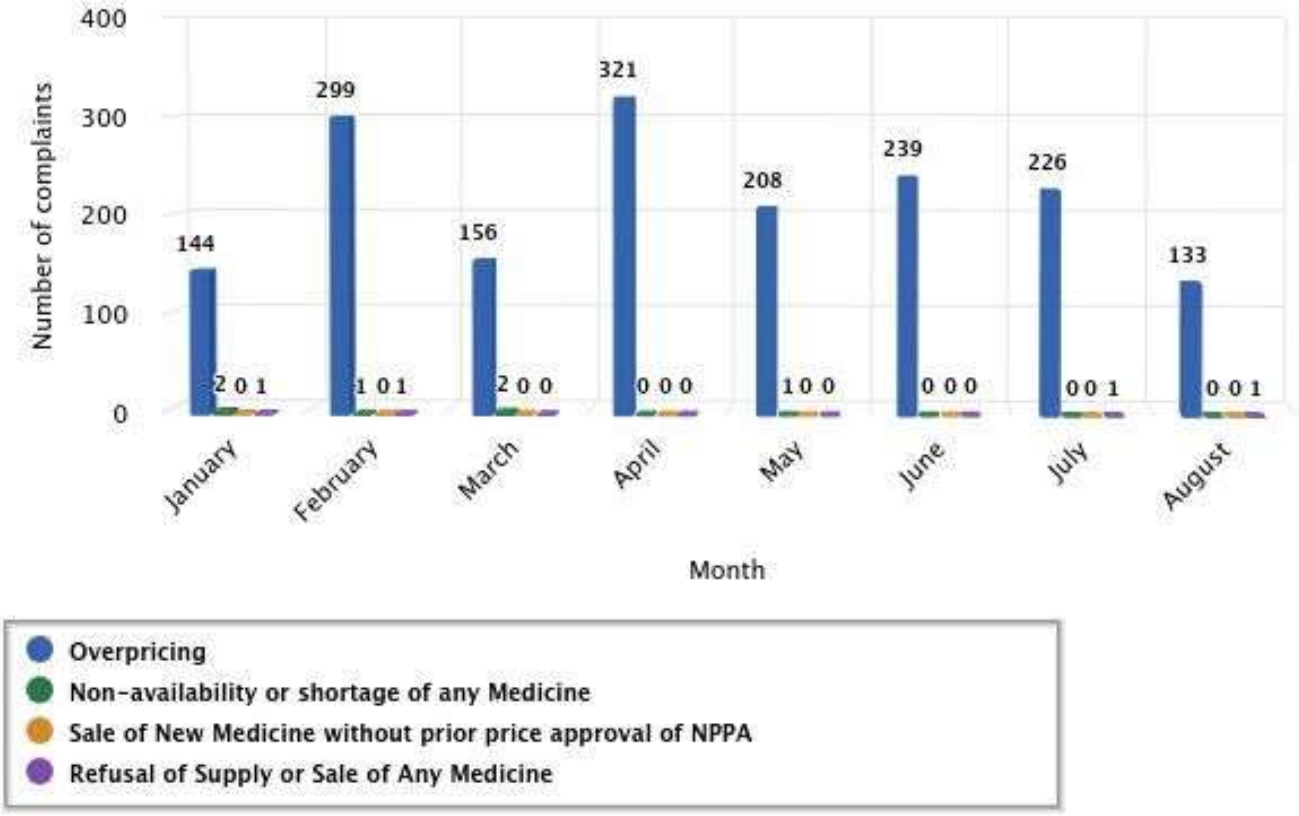


Chart 3: Number of complaints received on IPDMS/ Pharma Jan Samadhan

Chart 4: Number of Pharma Sahi Daam Mobile app downloads

Chart 5: Number of User logins in IPDMS 2.0

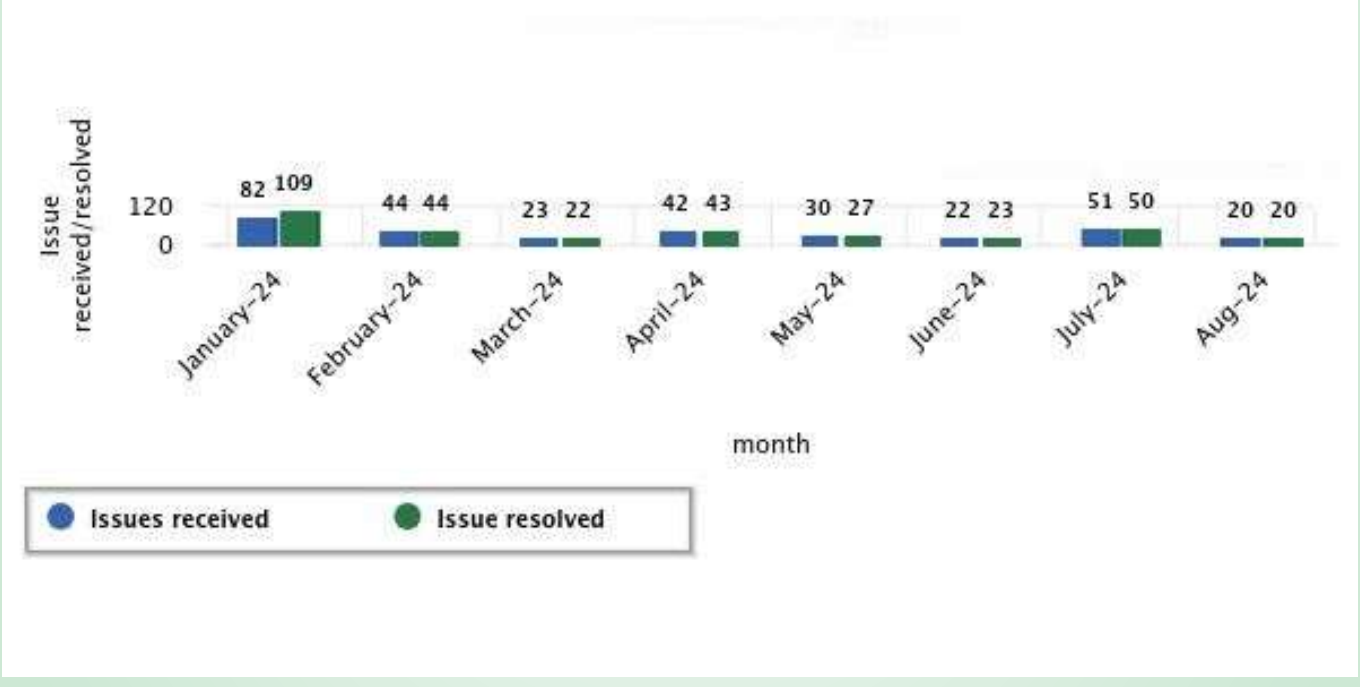


Chart 6: Number of tickets raised/ resolved at IPDMS help-desk

INTERNATIONAL NEWS

FDA Updates Guidance to Further Empower Companies to Address the Spread of Misinformation (July 08, 2024)

The U.S. Food and Drug Administration is advancing its mission of ensuring that the public has access to accurate, up-to-date science-based information to inform decisions about FDA-regulated medical products to maintain and improve their health. The agency is providing updated recommendations to empower industry seeking to voluntarily address misinformation about or related to their approved/cleared medical products. In today's health care system, health care providers and consumers often turn to the internet to obtain health and medical- related information. However, not all information found online about medical products is reliable. There are many false statements and conclusions shared online and the structure and popularity of social media platforms have meant that false, inaccurate and/or misleading information about medical products can spread rapidly to a broad audience.

Read more

FDA Approves First Gene Therapy to Treat Adults with Metastatic Synovial Sarcoma (August 02, 2024)

The U.S. Food and Drug Administration approved Tecelra (afamitresgene autoleucel), a gene therapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA antigen(s) A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive, and whose tumor expresses the MAGE-A4 antigen as determined by FDA authorized companion diagnostic devices.

Synovial sarcoma is a rare form of cancer in which malignant cells develop and form a tumor in soft tissues of the body. This type of cancer can occur in many parts of the body, most commonly developing in the extremities. The cancerous cells may also spread to other parts of the body. Each year, synovial sarcoma impacts about 1,000 people in the U.S. and most often occurs in adult males in their 30s or younger. Treatment typically involves surgery to remove the tumor and may also include radiotherapy and/or chemotherapy if the tumor is larger, returns after being removed or has spread beyond its original location.

Read more

FDA Approves First Nasal Spray for reatment of Anaphylaxis (August 09, 2024)

The U.S. Food and Drug Administration approved neffy (epinephrine nasal spray) for the emergency treatment of allergic reactions (Type I), including those that are life-threatening (anaphylaxis), in adult and pediatric patients who weigh at least 30 kilograms (about 66 pounds).

Allergic reactions happen when a person's immune system reacts abnormally to a substance that normally does not cause symptoms. Anaphylaxis is a severe, life-threatening allergic reaction that typically involves multiple parts of the body and is considered a medical emergency. Common allergens that can induce anaphylaxis include certain foods, medications and insect stings. Symptoms usually occur within minutes of exposure and include, but are not limited to, hives, swelling, itching, vomiting, difficulty breathing and loss of consciousness. Epinephrine is the only life-saving treatment for anaphylaxis and has previously only been available for patients as an injection.

Read more

FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants (August 22, 2024)

The U.S. Food and Drug Administration approved and granted emergency use authorization (EUA) for updated mRNA COVID-19 vaccines (2024-2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2. The mRNA COVID-19 vaccines have been updated with this formula to more closely target currently circulating variants and provide better protection against serious consequences of COVID-19, including hospitalization and death. Today's actions relate to updated mRNA COVID-19 vaccines manufactured by ModernaTX Inc. and Pfizer Inc.

Read more

FDA Clears First Device to Enable Automated Insulin Dosing for Individuals with Type 2 Diabetes Agency Supports Broader Access to Innovative Technology in Diabetes Management (August 26, 2024)

Today, the U.S. Food and Drug Administration expanded the indications of the Insulet Smart Adjust technology, an interoperable automated glycemic controller previously indicated for the management of type 1 diabetes in individuals two years and older, to also include management of type 2 diabetes in individuals 18 years and older. An interoperable automated glycemic controller is software that automatically adjusts insulin delivery to a person with diabetes by connecting to an alternate controller-enabled insulin pump (ACE pump) and integrated continuous glucose monitor (iCGM).

Read more

NPPA's initiative for disposal of waste/expired medicine

Webinars for Price Monitoring and Resource Units in the States/ Uts

An interactive webinar was organized by PMRU Division along with Overcharging division for Price Monitoring and Resource Units in the States/ UTs as follows:

Sr. No.	Date	Webinar
01	01.08.2024.	A webinar on the topic 'Generation of Utilization Certificate in PFMS'.

The main aim of the webinars was to provide comprehensive guidance and sharing of knowledge with PMRUs regarding Procedure of Generation of Utilization Certificates on PFMS portal.

PMRUs participated in the webinar and all queries were answered. The procedure of Generation of Utilization Certificates on PFMS portal was demonstrated using live example so that the PMRUs can generate the Utilization Certificates properly so that the records on PFMS portal are properly aligned with the required compliances in this regard.

State Level Events/ Seminars by PMRUs

Sixty (60) State and District level Events/ Seminars have been organized by 17 PMRUs in their respective States/ UTs viz. Puducherry, Telangana, Andhra Pradesh, Jammu & Kashmir, Kerala, Uttar Pradesh, Goa, Jharkhand, Ladakh, Meghalaya, Maharashtra, Chhattisgarh, Haryana, Punjab, Odisha, Himachal Pradesh and Tripura PMRU. Major glimpse of the activities are as follows: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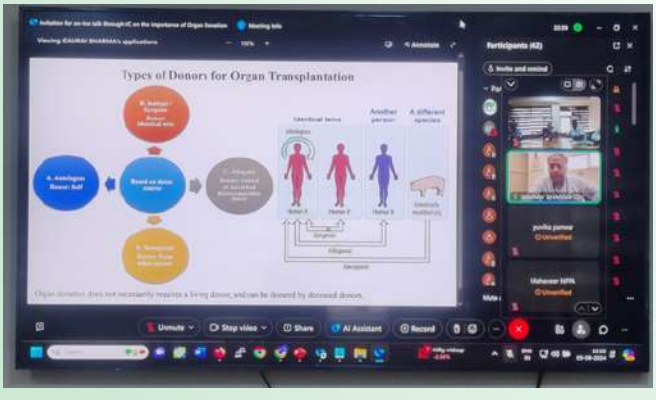
OTHER NEWS AND EVENTS

Webinar on the importance of Organ Donation

As part of Indian Organ Donation Day celebration, a webinar was held on the importance of Organ Donation on 05.08.2024. Dr Gaurav Sharma, Faculty, Department of Translational & Regenerative Medicine Postgraduate Institute of Medical Education & Research, Chandigarh presented some insights on the Critical Role of Organ Donation and Transplantation. The webinar was participated by NPPA, PMRU and SDC officials.



FREQUENTLY ASKED QUESTIONS

➲ **Whether any approval is required from NPPA for launching a Drug?**

Ans. No, approval of NPPA is not required for launching a Drug. However, where an existing manufacturer of a Scheduled drug launches a new drug, such existing manufacturer shall apply to NPPA for obtaining Retail Price, prior to the launch of such new drug.

➲ **Does New Drug mean all newly launched drugs?**

Ans. No. Under DPCO, 2013, New Drug means a formulation launched by an existing manufacturer by combining a scheduled drug with another drug or by changing the strength or dosages or both of a scheduled drug.

➲ **Is Retail Price and Maximum Retail Price (MRP) one and the same thing?**

Ans. No. Retail Price under DPCO, 2013 means the Price given by NPPA for a New Drug. The manufacturer of a New Drug can fix the MRP up to Retail Price plus local taxes and duties as applicable.

➲ **Whether Retail Price is to be obtained by an existing manufacturer in case NPPA has already fixed the Retail Price of such formulation for some other manufacturer?**

Ans. Yes, Retail Price needs to be obtained by all existing manufacturers in respect of all New Drugs separately.

➲ **What if a manufacturer launches a New Drug without obtaining Retail Price from NPPA?**

Ans. In such a case, the Retail Price shall be fixed by NPPA and 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

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