

The key initiatives/achievements/events of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers during the year are as under

## **1. Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)**

*Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) is a flagship scheme of the Department whereby quality generic medicines are made available at affordable prices to all through dedicated outlets known as *Jan Aushadhi Kendras* (JAKs). The Scheme is being implemented through the Pharmaceuticals & Medical Devices Bureau of India (PMBI). As of 30.11.2024, a total of 14,320 Jan Aushadhi Kendras have been opened nationwide.

### **Objectives of the Scheme**

- (a) To make available quality medicines and surgicals/medical consumables/devices at affordable prices for all and thereby reduce out of pocket expenditure of consumers/patients.
- (b) To popularize generic medicines among the masses and dispel the prevalent notion that low-priced generic medicines are of inferior quality or are less effective.
- (c) Generate employment by engaging individual entrepreneurs in the opening and running of Jan Aushadhi Kendras.

### **Salient features**

- Incentive to Jan Aushadhi Kendra owners is given @ 20% of monthly purchases made up to Rs.20,000/- per month subject to certain conditions such as maintenance of stock of specified medicines.
- One-time incentive of Rs.2.00 lakh is provided to the Jan Aushadhi Kendras opened in NE States, Himalayan areas, island territories & backward areas (aspirational districts) or opened by women entrepreneur, Divyang, SC & ST in the form of support for furniture & fixtures etc.
- Prices of the Jan Aushadhi medicines are generally 50%-80% less than that of branded medicines prices which are available in the open market.
- Medicines are procured from World Health Organization–Good Manufacturing Practices (WHO-GMP) certified suppliers only for ensuring the quality of the products.
- Each batch of the drug after its receipt at the warehouses is tested at laboratories accredited by ‘National Accreditation Board for Testing and Calibration Laboratories (NABL) to ensure best quality.

### **Product basket**

Product basket of PMBJP comprises 2047 medicines & 300 surgicals/medical consumables/devices covering all major therapeutic groups such as Anti-infectives, Anti-diabetics, Cardiovascular, Anti-cancers, Gastro-intestinal medicines, etc. In the year 2024, 288 medicines & 20 other items have been added to the product basket.

## Suvidha Sanitary Napkins

To ensure easy availability of menstrual health services at affordable prices for women, Jan Aushadhi Suvidha Sanitary Napkins at Rs.1/- per pad are made available through Jan Aushadhi Kendras, across the country. Till 30.11.2024, over 64.55 crore Jan Aushadhi Suvidha Sanitary Pads have been sold through these Kendras. Out of this, over 13.82 crore Jan Aushadhi Suvidha Sanitary Pads have been sold in the year 2024 till 30.11.2024.

## Savings to the citizens

In 2023-24, PMBI registered sales of Rs.1470 crore which led to savings of approximately Rs.7350 crore to the citizens. In the current financial year 2024-25, till 30.11.2024, PMBI has made sales of Rs.1255 crore, which has led to savings of approximately Rs.5020 crore to the citizens. In the last ten years approximately Rs.30,000 crore has been saved under this *Pariyojana*.

## Progress Report

Financial Year	Number of JAKs functional		Sales at MRP Value in Rs. crore
	Yearly addition	Cumulative	
2023-24	1957	11261	1470
2024-25 (As on 30.11.2024)	3059	14320	1255

## Steps taken for increasing viability of kendras

- Product basket is continuously expanded to provide complete range of medicines covering almost all chronic and acute disease conditions.
- State Health Departments and associated government authorities have been requested to open Jan Aushadhi Stores in various government hospitals by providing rent free spaces for opening of JAKs.
- To ensure awareness among masses, various media platforms like print, outdoor, radio & social media, etc. are being used regularly. Government is also adopting an integrated approach for spreading awareness about PMBJP with State Governments. Promotion workshops are also being organized across India with stores owners, doctors and various important dignitaries.
- Minimum stocking mandate has been implemented with stocking of fast moving 200 drugs as eligibility condition for disbursement of incentives to Jan Aushadhi Kendras for better availability.

## Initiatives in 2024:

- MoU was signed between PMBI and HLL Lifecare Ltd on 8<sup>th</sup> January 2024 for export of Jan Aushadhi generic medicines to other nations.
- MoU was signed between SIDBI and PMBI on 12<sup>th</sup> March 2024 in New Delhi for project loan at competitive rates to applicants wanting to open new Kendras and credit facility of working capital to existing Kendras, across the country.

- First overseas Jan Aushadhi Kendra in Mauritius was opened in Mauritius in presence of Hon'ble Minister for External Affairs, Government of India and Prime Minister of Mauritius on 17.07.2024.
- A five-member delegation from Burkina Faso and Embassy, visited the PMBI Head Office on 21<sup>st</sup> August 2024 to understand the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). During the meeting, CEO, PMBI explained the concept of Jan Aushadhi in India and how it can be adopted internationally. The delegates had detailed discussions about the PMBJP model regarding availability of affordable quality medicines and expressed keen interest to implement the scheme in Burkina Faso.
- An international delegation from Fiji Pharmaceuticals and Biomedical Services (FPBS) visited Jan Aushadhi Kendra at Ghaziabad, Uttar Pradesh on 27th August 2024. The delegation got the opportunity to understand the working of the Jan Aushadhi outlet in India. They appreciated Government of India's efforts and showed keen interest in implementing the scheme in their country.
- In the august presence of Governor Shri Mangubhai Patel and Chief Minister Dr. Mohan Yadav, Jan Aushadhi Kendras were virtually launched in 50 district hospitals at Kushabhau Thackeray International Auditorium, Bhopal, Madhya Pradesh on 17th September 2024. These Jan Aushadhi Kendras will be operated by the Red Cross Society. Quality generic medicines will be made available to the people at these centers at very affordable prices.
- Hon'ble Prime Minister Shri Narendra Modi inaugurated new Jan Aushadhi Kendras in the campuses of AIIMS New Delhi, AIIMS Bilaspur (Himachal Pradesh), and AIIMS Kalyani (Paschim Bengal) on 29th October'24, marking a significant step towards affordable healthcare access across India. Under the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP), these centers aim to provide quality generic medicines at affordable prices, benefiting millions nationwide.
- PMBI participated in the 19th International Conference of Drug Regulatory Authorities (ICDRA) organized by the Central Drugs Standard Control Organisation (CDSCO) from October 14 to 15, 2024 in New Delhi, Yashobhoomi, ICC, Delhi to spread awareness amongst the officials of the 150 participating nation and the WHO officials from across the world about Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). Hon'ble Union Health Minister Shri J. P. Nadda inaugurated the PMBJP mock-up stall and penned best wishes to Janaushadhi for the remarkable work of providing high-quality medicines at affordable prices for all.
- Hon'ble Prime Minister virtually inaugurated 18 new Jan Aushadhi Kendras in various zones of Indian Railways. So far, Jan Aushadhi Kendras have been opened at 69 railway stations, and the inauguration of these 18 new centers signifies the success of Jan Aushadhi Pariyojana, which will make medicines available to more and more passengers at affordable prices.
- PMBJP signed a Memorandum of Understanding (MoU) with Central Armed Police Forces, National Security Guard & Assam Rifles (CAPFs, NSG & AR), under the Ministry of Home Affairs (MHA), Govt. of India on 29th November 2024 for enhancing healthcare accessibility by bringing Jan Aushadhi medicines to CAPFs, NSG & AR (MHA) Hospitals and other medical establishments.
- PMBJP participated in 43rd India International Trade Fair (IITF) 2024 and exhibited Jan Aushadhi model shop in Hall No. 4, Stall No. 4H-01-B from 14th Nov to 27th Nov 2024 at Pragati Maidan, New Delhi. The general public was made aware of the process for

opening Jan Aushadhi Kendra and high-quality medicines available at affordable prices to all.

### **Central Warehouse of PMBJP, Gurugram, Haryana**



### **Jan Aushadhi Kendra**



### **Jan Aushadhi Kendra in AIIMS, New Delhi**



### **Jan Aushadhi Kendra at Mauritius**



**Jan Aushadhi Kendra at Tiruchirappalli Junction Railway Station, Tamil Nadu**



**2. Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs), Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India:**

The objective of Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in India is to promote domestic manufacturing of 41 identified bulk drugs to address their high import dependence. The total outlay of the scheme is Rs 6,940 crore and the scheme duration is from 2020-21 to 2029-30. The scheme provides for financial incentive for six years to eligible manufacturers of 41 bulk drugs on their incremental sales over the base year. For fermentation based eligible products, rate of incentive for the first four years (2023-2024 to 2026-2027) is 20%, for the fifth year (2027-28) it is 15% and for the sixth year (2028-2029) it is 5%. For chemical synthesis products, rate of incentive for entire six years (2022-2023 to 2027-2028) is 10%.



Industrial Finance Corporation of India (IFCI) Ltd. is the Project Management Agency (PMA) for the scheme.

A total 249 applications across all four categories of products were received. Out of 249 applications, 48 applications have been approved with committed investment of Rs.3,938.57 crore and expected employment generation of around 9,618 persons. It is expected that in the coming years, the import dependence in the notified bulk drugs will get reduced over the implementation period of the scheme.

**Progress made under the scheme as of September 2024 is as follows:**

Out of 48 approved projects, 34 projects have been commissioned. Investment of Rs.4155.80 crore have been grounded and employment for 4241 persons have been generated. The sales made by the commissioned projects is worth Rs.1330.82 crore which includes exports of Rs. 403.59 crore.

Glimpses of some of the commissioned projects:

	
Plant: Lyfius Pharma Pvt. Ltd., Kakinada, Andhra Pradesh	Product: Penicillin-G (Antibiotic)
	

Plant: Kinvan Pvt. Ltd., Nalagarh, Himachal Pradesh	Product: Clavulanic Acid (a beta-lactamase inhibitor used with antibiotics)
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Under the PLI scheme for Bulk Drugs, fermentation-based projects for Penicillin G and Clavulanic acid have been inaugurated by the Honourable Prime Minister in October 2024. The Penicillin G antibiotic project established in Kakinada, Andhra Pradesh with an investment of Rs.1,910 crore is the largest fermentation-based facility in the country and is expected to cause an import substitution of Rs.2700 crore per annum. The project of Clavulanic Acid, a beta-lactamase inhibitor used with antibiotics, established in Nalagarh Himachal Pradesh with an investment of Rs.450 crore is expected to cause an import substitution of Rs.600 crores per annum.

Centrient Pharmaceuticals India Private Limited has established its plant at Nawanshahr, Punjab for product Atorvastatin with an investment of Rs.137.74 crore in October 2021. Atorvastatin belongs to a group of medicines called statins. It is used to lower cholesterol.

Andhra Organics Limited has established its plant at Srikakulam, Andhra Pradesh for three products Olmesartan (treats high blood pressure) with an investment of Rs.30.50 crore in July 2024, Sulfadiazine (antibiotic) with an investment of Rs.38.70 crore in June 2021 and Telmisartan (treats high blood pressure) with an investment of Rs.40.00 crore in November 2022.

### **3. Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices:**

The domestic medical devices industry faces challenges related to considerable cost of manufacturing disability, among other things, on account of lack of adequate infrastructure, domestic supply chain and logistics, high cost of finance, limited design capabilities and low investments in R&D and skill development. With a view to address these challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies, a scheme called “Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of Medical Devices” was approved by the Government of India on 20.03.2020. The guidelines for implementation of the scheme were issued on 29.10.2020.

The scheme is applicable only to greenfield projects and intends to boost domestic manufacturing and attract large investments in the medical devices sector. The period of the scheme is from financial year 2020-21 to financial year 2027-28 with total financial outlay of Rs. 3,420 crore. Under the scheme, financial incentive is given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the target segments of the scheme, for a period of five years. The details of incentive under the scheme are as follows:

Category of applicant	Incentive Period	Incentive rate
Category A	FY 2022-23 to FY 2026-27	5% limited to Rs.121 crore per applicant
Category B	FY 2022-23 to FY 2026-27	5% limited to Rs.40 crore per applicant

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The products under the scheme have been categorized under following four categories-

- I. Cancer care / Radiotherapy medical devices
- II. Radiology & imaging medical devices (both ionizing & non -ionizing radiation products) and nuclear imaging devices
- III. Anaesthetics & cardio-respiratory medical devices including catheters of cardio respiratory category & renal care medical devices
- IV. All implants including implantable electronic devices

Industrial Finance Corporation of India (IFCI) Ltd. is the Project Management Agency (PMA) for the scheme.

The cumulative sales made by the applicants under the scheme is Rs 8039.63 crore (which includes exports worth Rs 3,844.01 crore) up to September, 2024.

Glimpse of some of the commissioned projects:





	
Plant: <b>WIPRO GE Healthcare Private Limited</b>	Product: CT-Scan and MRI
	
Plant: <b>Siemens Healthcare Private Limited</b>	Product: CT-Scan and MRI

**Glimpse of the projects virtually inaugurated by Hon'ble Prime Minister of India on 9th Ayurveda Day i.e. 29.10.2024 under the scheme**



Plant and Location	Total Investment (In Rs.cr)	Approved Products
Meril Group - Medical Device Manufacturing Facility at Vapi-Gujarat	1,400	Heart Valves, Stents, PTCA Ballon Catheter, Hip Implants, Knee Implant and Trauma Implant, Hernia Surgical Mesh Implants, Endocutter, Linear Stapler, Linear Cutter, Trocar, Litigation Clip, Hemostates, Impella, Vascular Closure Device etc.

#### **Body Implants Manufacturing Facility at Sultanpur, Hyderabad**



Plant and Location	Total Investment (In Rs.cr)	Approved Products
BPL Technologies - Medical Devices Park Sultanpur, Telangana	317	Surgical X-Ray C-Arm, Fixed LF and HF X-Ray Products, X-Ray Panels, Ultrasound Products, Anesthesia Workstation, Automated External Defibrillators (AEDs), ECG, Patient Monitoring, Syringe Pump, Defibrillators, Stress Test System,

#### **4. Production Linked Incentive Scheme for Pharmaceuticals:**

PLI Scheme for pharmaceuticals is being implemented with an objective of enhancing India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. The total outlay of the scheme is Rs.15,000 crore and the scheme duration is from 2020-2021 to 2028-29.

Under the scheme, financial incentive is provided for production of identified products under three product categories. Category 1 includes drugs such as - bio-pharmaceuticals, complex generics, patented drugs or drugs nearing patent expiry, orphan drugs etc., Category-2 includes active

pharmaceutical ingredients, key starting materials, drug intermediates etc., and Category-3 includes auto-immune drugs, anti-cancer drugs, anti-diabetic drugs, anti- infective drugs, cardiovascular drugs, psychotropic drugs, anti-retroviral drugs, in-vitro diagnostic medical devices etc. These products are expected to give an impetus to innovation, R&D and product diversification of Indian Pharmaceutical industry. In addition, investment by the anchor industries of the pharmaceutical sector shall play a vital role in development and growth of MSMEs down the value chain in the forthcoming years.

The Scheme provides for financial incentives on incremental sales (over base year) of pharmaceutical goods and in-vitro diagnostic medical devices to selected applicants, depending upon the threshold investments and sales criteria to be achieved by the applicants, at the rate of 10% for FY 2022-23 to FY 2025-26, 8% for FY 2026-27 and 6% for FY 2027-28 for product categories 1 & 2. The incentive for product category 3 is at the rate of 5% for FY 2022-23 to FY 2025-26, 4% for FY 2026-27 and 3% for FY 2027-28.

Small Industries Development Bank of India (SIDBI) is the Project Management Agency for the Scheme.

Under the Scheme, 55 applicants have been selected, which includes five applicants of In-vitro Diagnostics (IVD) devices with committed investment of Rs.17,275 crore.

**Progress made under the scheme as of September 2024 is as follows:**

Investment worth Rs. 33344.66 crore have been grounded and employment for 87,535 persons have been generated. The sales made by the selected applicants is worth Rs. 2,26,992 crore which includes exports of Rs. 1,44,428 crore. The scheme envisages manufacturing of specialized category of pharmaceuticals/ IVD devices.

FY 2022-23 is the first year of performance/sales, and cumulative incentive amount of Rs. 3384.75 crore till November 2024 has been released to the applicants based on achieving the eligible criteria for Quarterly/Half-yearly/Annual incentive claims and verification by the Project Management Agency.

**Glimpses of some of the commissioned projects:**



## 5. Strengthening of Pharmaceutical Industry (SPI):

Department of Pharmaceuticals implements the scheme “Strengthening of Pharmaceutical Industry” (SPI), with a total financial outlay of Rs.500 crore. The implementation period of the scheme is from FY 21-22 to FY 25-26. The scheme aims to provide support to existing pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability to strengthen the existing infrastructure facilities in the Pharma MSME clusters.

SIDBI has been appointed as the Project Management Consultant (PMC) for the SPI scheme.

This Scheme is a Central Sector Scheme and comprises the following sub-schemes:

- (i) Assistance to Pharmaceutical Industry for Common Facilities (API-CF)
- (ii) Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS)
- (iii) Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

(i) Assistance to Pharmaceutical Industry for Common Facilities (API-CF), to strengthen the existing pharmaceutical clusters’ capacity for their sustained growth by creating common facilities. This will not only improve the quality but also ensure the sustainable growth of clusters.

The illustrative list of eligible activities under this sub-scheme in order of priority is as under:

- a) Research and Development Labs
- b) Testing Laboratory for Pharma Products
- c) Effluent Treatment Plants

- d) Logistic Centers
- e) Training Centers

Under the Scheme, as on date, 07 projects have been given final approval.

**(ii) Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS)** The scheme was originally launched as Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) to facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards (WHO-GMP or Schedule-M) through upgrade of technology. The scheme provided for interest subvention for loan component eligible under the scheme taken to the upper limit of Rs. 10 cr.

The PTUAS been revised and renamed as ‘Revamped Pharmaceuticals Technology Upgradation Scheme’ (RPTUAS) on 11.03.2024 with a view to better uptake and to help upgrade technological capabilities of our pharmaceutical industry to ensure its alignment with global standards. The revised guidelines were issued on 14.03.2024 with a view to facilitate existing pharma units to upgrade to ‘Revised Schedule M’ and ‘WHO-GMP’ standards, enhancing the quality and safety of pharmaceutical products manufactured in our country. The scheme has been further liberalized on 17.09.2024 to boost participation of pharma units by increasing the maximum incentive amount under the scheme from Rs. 1 crore to Rs. 2 crore and including the expenditure incurred on “Production Equipment” under eligible activities in the scheme.

Under RPTUAS, pharmaceutical units with following average turnover criterion for the last three years will receive incentive ranging from 10% to 20% subject to a maximum of Rs. 2.00 crore:

- Turnover 1 Cr. to 50 Cr.- 20% of investment
- Turnover 50 Cr. to 250 Cr.- 15% of investment
- Turnover 250 Cr. to 500 Cr.- 10% of investment

Under the scheme, promotional outreach events have been held in various States and UTs. Application window has been opened w.e.f. 11.04.2024 and as of November 2024, 210 registrations have been done, of which Scheme Steering Committee (SSC) has already approved 62 applications in its meetings held on 07.11.2024, 12.11.2024 and 25.11.2024.

**(iii) Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)** to facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry.

Under Sub-Scheme **PMPDS**, **twelve** (12) events/workshops have been organized under the Scheme in 2024-25 (as on 10.12.2024). Further, nine (09) studies were awarded in 2023-24, out of which five (05) studies have been completed and two (02) new studies have been awarded in F.Y. 2024-25.

## **6. Scheme for Promotion of Bulk Drug Parks:**



The scheme for Promotion of Bulk Drug Parks has been approved by the Government of India on 20th March 2020 and notified on 21<sup>st</sup> July 2020. The tenure of the scheme is from FY 2020-2021 to FY 2025-2026. The objective of the scheme is to promote setting up of bulk drug parks in the country for providing easy access to world class common infrastructure facilities to bulk drug units located in the parks to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry.

Under the scheme for Promotion of Bulk Drug Parks, the Department had received proposals from 13 states. After evaluation, proposals of Gujarat, Himachal Pradesh and Andhra Pradesh were approved.

The financial assistance by the Central Govt. is subject to a maximum limit of Rs.1000 crore per park or 70% of the project cost of Common Infrastructure Facilities (CIF) (90% in case of Northeastern States and Hilly States i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), whichever is less. The fund allocated for the scheme is Rs. 3000 crores. Rs. 1000 crores grant has been approved for each of the selected State, i.e. Gujarat, Himachal Pradesh and Andhra Pradesh. Construction activities are in progress in all 3 selected parks. The status of funds released and utilized in the selected Bulk Drug parks is as under-

<b>States</b>	<b>Total Project Cost (in Rs. Crore)</b>	<b>Total CIF Cost (in Rs. Crore)</b>	<b>Central Grants released (in Rs. crore)</b>	<b>Funds utilized till November 2024 including State Share (in Rs. Crore)</b>
Gujarat	2507.02	1457.01	299.25	150.60
Himachal Pradesh	1923	1118.46	225	41.55
Andhra Pradesh	1876.66	1438.89	225	24.60

## **7. FDI performance in pharmaceutical sector:**

Pharmaceuticals is one of the top ten attractive sectors for foreign investment in India. 100% foreign investment is allowed under automatic route in Medical Devices. Foreign investments in pharmaceuticals in Greenfield projects are allowed upto 100% under the automatic route and for brownfield pharmaceutical projects, foreign investment beyond 74% to 100% Government's approval is required.

After abolition of Foreign Investment Promotion Board (FIPB) in May 2017, the Department of Pharmaceutical has been assigned the role to consider the foreign investment proposals under the Government approval route. Apart from this, the Department considers all FDI proposals of pharmaceutical sector and medical devices sector arising out of Press Note 3 of 2020 dated 17.04.2020 wherein investors/ultimate beneficiaries in the proposals are from the countries sharing land border with India.

During 2023-24, FDI inflows in pharmaceutical sector (in both pharmaceuticals and medical devices) was ₹12,822 crore. During the current financial year of 2024-25 from April 2024 upto September, 2024, FDI inflows (in both pharmaceuticals and medical devices) has been ₹8,103 crore, which was ₹ 4,456 crore during the corresponding period of FY 2023-24. Further, the Department of Pharmaceuticals has approved Eleven (11) FDI proposals worth ₹4,253.53 crore for brownfield projects during 1st April, 2024 to 31st October 2024.

#### **8. National Institutes of Pharmaceutical Education and Research (NIPERs):**

- The First National Institute of Pharmaceutical Education and Research (NIPER) was set up in the year 1998 at SAS Nagar (Mohali), Punjab as an institution of national importance vide NIPER Act, 1998.
- After amendment of the Act in the year 2007 six more NIPERs were set up at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli. All these seven NIPERs have been identified as **institutes of national importance**.
- In accordance with NIPER (Amendment) Bill 2021, NIPER Council has been set up under the Chairmanship of Hon'ble Minister of Chemicals & Fertilizers. The Council inter alia would lay down policies and ensure uniformity and coordination among NIPERs.
- As on November, 2024 a total of about 10,960 students have passed out from these NIPERs since their inception, facilitating availability of professional manpower to the industry as well as R&D and academic institutions. NIPERs have published more than 8096 research papers in various reputed journals and filed more than 428 patents. As part of academia-industry collaboration and exchange, NIPERs have signed more than 303 MOUs with industries and other academic institutions.
- As per the 2024 National Institutional Ranking Framework (NIRF), issued by the Ministry of Education in India, of the seven NIPERs, five have been ranked within the top 15, with two of them securing positions within the top ten ranks and NIPER Hyderabad achieving the 2nd rank in the 'Pharmacy' category.
- **Construction of NIPER Campus:**  
In EFC meeting held in September, 2021, the Ministry of Finance has approved Rs.1500 crore for strengthening of existing 7 NIPERs. EFC has approved the construction of campuses of six NIPERs at Guwahati, Ahmedabad, Hyderabad, Kolkata, Raebareli and Hajipur. NIPER Mohali already had a well-functioning campus. The construction of campus at Guwahati and Ahmedabad has been completed. The construction of campuses of the other four NIPERs at Hyderabad, Kolkata, Raebareli and Hajipur are in progress.

#### **Ongoing policy/programs/schemes (NIPER/R&D Division):**

(i) **National Policy on Research & Development and Innovation in the Pharma-MedTech Sector in India:** The Department has constituted Indian Council for Pharmaceuticals and Medtech Research and Development (ICPMR) vide DOP O.M. dated 05.03.2024 with the approval of the Hon'ble Minister of Chemical & Fertilizer. The Department has developed a portal for monitoring the implementation of the R&D Policy, and the portal has been operational since April 2, 2024.

(ii) **Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP):** Cabinet has approved **PRIP (Promotion of Research and Innovation in Pharma**

**MedTech Sector)** scheme with a budget outlay of **Rs. 5000 crores** over a period of 5 years (FY 23-24 to 27-28). The aim of the scheme is to promote industry-academia linkage for R&D in priority areas and to inculcate the culture of quality research and nurture our pool of scientists. This will lead to sustained global competitive advantage and contribute to quality employment generation in the country.

**The scheme has two components:**

**Component A:** Strengthening of research infrastructure by establishment of 7 CoEs at NIPERs- These CoEs would be set up in pre-identified areas with a financial outlay of Rs 700 Crores. The Steering Committee in its 1<sup>st</sup> meeting held in March 2024 approved the proposal for setting up of CoEs with an outlay of Rs 700 Cr, to be released over a period of 5 years, with an allocation of Rs 243 Cr for FY 2024-25. The virtual foundation stone laying ceremony for the COEs at NIPER Mohali, NIPER Ahmedabad, NIPER Guwhati and NIPER Hyderabad by Hon'ble PM was held on 29.10.2024. Rs.20.46 Cr (approx) has been released to NIPERs as first installment.

**Component B:** Component B is for promoting research in pharmaceutical sector by encouraging research in six priority areas like New chemical/biological Entities, Complex generics including biosimilars, medical devices, stem cell therapy, orphan drugs, Drugs against Anti-microbial resistance etc., wherein financial assistance will be provided to the large industries, MSMEs, SMEs, Startups for both In-house research and research in collaboration with Government institutes. The financial outlay of this component is Rs 4250 crore. The Component B is further divided into 3 categories based on the kind and level of research. A Consulting Firm to work as PMA (Project Management Agency) for component B of the scheme has been selected through open tendering in two bid system.

**Achievements of the 7 NIPERs during 2024 are as follows:**

**NIPER Ahmedabad**

(i) NIPER-Ahmedabad has secured the 15th rank in the NIRF-2024 (National Institutional Ranking Framework-2024) under the pharmacy category.

(ii) NIPER Ahmedabad organized one-day hands-on training program on “Hot Melt Extrusion in Manufacturing of Implants/ Inserts (23<sup>rd</sup> July 2024).



(iii) Applied Pharmaceutical Analysis (APA)-2024, an International conference organized by The Boston Society and NIPER Ahmedabad (22nd September 2024)



(iv) Hon'ble Prime Minister Shri Narendra Modi laid the foundation stone for the Centre of Excellence for Medical Devices at NIPER Ahmedabad on the auspicious day of Dhanvantari Jayanti and 9th Ayurveda Day, October 29, 2024.



## NIPER Guwahati

(i) NIPER Guwahati secured 12<sup>th</sup> position in the NIRF ranking 2024 under pharmacy category.

(ii) NIPER Guwahati organized Pharmaceutical Additive Manufacturing workshop which aims to train the faculty members of nearby institute/college/university with cutting-edge 3D/4D Printing Technology including CAD models for Pharmaceutical Applications.



(iii) NIPER Guwahati has signed an MoU with Nalanda University (Nodal Institution of ASEAN-India Network of Universities) that will enable NIPERG to participate in faculty exchange programs, doctoral student exchange and joint research programs among higher education institutions of the ASEAN countries.

(iv) Department of Pharmacy Practice, NIPER Guwahati was identified as a Technical Resource Centre for the Centre for Evidence for Guidelines, Department of Health Research, Ministry of Health and Family Welfare, Government of India (MoH&FW), Govt. of India for conducting Systematic Reviews and Meta-analyses to develop and promote Evidence-Based Guidelines and enhance the adoption of evidence-based practices in healthcare.

(v) Hon'ble Prime Minister Shri Narendra Modi laid the foundation stone for the Centre of Excellence for Phytopharmaceuticals at NIPER Guwahati on the auspicious day of Dhanvantari Jayanti and 9th Ayurveda Day, October 29, 2024.





## **NIPER Hajipur**

- (i) NIPER-Hajipur is setting up the Centre of Excellence (CoE) in Biological Therapeutics as approved by the Department of Pharmaceuticals.
- (ii) NIPER Hajipur organized symposium on Involvement of Peripheral organ dysfunction in the development of the cognitive disease on 19 September 2024.
- (iii) NIPER Hajipur organized a hybrid symposium titled “Pharmaceutical Product Development: From R&D to Registration” on Oct 04th, 2024.



- (iv) NIPER Hajipur has developed several state-of-the-art research facilities, including Central Instrumentation Facility, Confocal microscope facility, Cell Culture Facility and Pilot Formulation Unit. These additions are designed to foster research excellence and academic growth.

## **NIPER Hyderabad**

- (i) NIPER Hyderabad secured 2<sup>nd</sup> position in the NIRF ranking 2024 under pharmacy category.
- (ii) NIPER Hyderabad organized International Conference on Drug Discovery, Delivery and Diagnostics (ICD-4) on 9-10<sup>th</sup> August, 2024.



(iii) Biosafety Level 3 (BSL-3) laboratory facility was dedicated by Sh. Awadesh Kumar Choudhary, Sr. Economic Adviser, DoP in the presence of Dr. Shailendra Saraf, Director, NIPER Hyderabad and faculty/ Staff of NIPER Hyderabad on 18<sup>th</sup> October, 2024.



(iv) Hon'ble Prime Minister Shri Narendra Modi laid the foundation stone for the Centre of Excellence for Bulk Drugs at NIPER Hyderabad on the auspicious day of Dhanvantari Jayanti and 9th Ayurveda Day, October 29, 2024.



## **NIPER Kolkata**

(i) NIPER Kolkata organized seminar cum workshop on “Recent advances in gene editing and next-generation sequencing technologies.



(ii) NIPER Kolkata signed a MoU with DNDi Geneva, Switzerland. The objective of the MoU is to engage in a collaboration wherein DNDi is exploring the concept of open-source drug discovery by contemplating the implementation of a student crowd-sourcing model for a chemistry project.

(iii) NIPER Kolkata signed MoU with CSIR-IICT Hyderabad. The objective of the MoU is to evaluate the anti-obesity activity of NIPER-K923 in db/db mice.

### **NIPER Mohali**

(i) NIPER Mohali carried out study on “Impact of TRIPS on pharmaceutical prices with special focus on generics in India”, under the work plan of WHO biennium and MoHFW (GOI).

(ii) A MoU between Patanjali Research Foundation and NIPER, SAS NAGAR was signed on 09-11-2024 for bringing ayurveda and modern science together, taking a step forward towards a healthier India.



(iii) Hon'ble Prime Minister Shri Narendra Modi laid the foundation stone for the Centre of Excellence for Bulk Drugs at NIPER Mohali on the auspicious day of Dhanvantari Jayanti and 9th Ayurveda Day, October 29, 2024.

(iv) NIPER Mohali conducted a special capacity building ITEC Program on “Pradhan Mantri Bhartiya Janaushadhi Pariyojan” to make ITEC countries understand about the working model of PMBJP for affordable medicines to common people worldwide.

### **NIPER Raebareli**

(i) NIPER - Raebareli organized Certificate Course and Hands-on Training on “Design and Characterization of Nanomaterials” From 17th–21th July, 2024



(ii) NIPER Raebareli organized a two-day workshop and hands-on training program on the Design of Experiments and Biostatistics. Dr. Muralidhara A, Ph.D., Global JMP Team trained MS Pharma of MS Pharm. and Ph.D. on 12 August and 13 August 2024.



(iii) Department of Pharmaceutical & Toxicology and Regulatory Toxicology of NIPER Raebareli organized a four day workshop on Hands on Training on Histology Techniques and Staining. Dr. Muralidhara A, Ph.D., Global JMP Team trained MS Pharma of MS Pharm. and Ph.D on 17-20 September 2024.





## 9. National Pharmaceutical Pricing Authority (NPPA):

The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals (DoP), 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 the Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

Followings are the major achievement and initiatives for the period of January, 2024 to December, 2024:

**Fixation of Ceiling Price of drugs:** NPPA fixes the ceiling price of formulation listed in Schedule-I of DPCO, 2013. Under the market-based approach adopted in DPCO, 2013, NPPA has fixed the ceiling prices of 926 formulations (742 formulations under NLEM 2022 & 184 under NLEM 2011 and 2015) under DPCO, 2013 till date (12.12.2024). Ceiling prices of 37 formulations have been fixed in the current calendar year. The average price reduction due to refixation of prices is about 16.82% leading to savings of around Rs. 3740 crore to the consumers. In addition to this, ceiling prices of 13 formulations under NLEM, 2022 have been approved by the Authority in 128<sup>th</sup> meeting held on 12.12.2024, however, notification in this regard is yet to be issued.

**Price Revision of Anti-Cancer Drugs under NLEM 2022:** As on 12.12.2024, ceiling prices of 131 anti-cancer formulations (including palliative care) are effective. The ceiling prices of 120 anti-cancer formulations (including palliative care) have been fixed under NLEM, 2022. Further, ceiling prices of 11 formulations fixed under NLEM, 2015 are also effective. This has resulted in an annual savings of around Rs. 294.34 crore on account of fixation of ceiling prices of Anti-cancer formulation under NLEM, 2022.

**Fixation of Retail Price of drugs:** NPPA fixes the retail price of 'new drugs' as per DPCO, 2013 which are applicable only to the applicant manufacturing/ marketing companies. NPPA notified retail prices of around **3046 'new drugs'** as on date. Out of these retail prices of 440 new drugs have been fixed in current calendar year. In addition to this, retail prices of approximately 60 new



drugs have been approved by the Authority in 128<sup>th</sup> meeting held on 12.12.2024, however, notification in this regard is to be issued.

### **Price revision under Para 19 of DPCO, 2013**

NPPA received applications in respect of 77 formulations from various pharmaceutical manufacturing/marketing companies and industry associations requesting for upward revision of price for their formulation(s). This request was made on the grounds that ensuring continued availability of these drugs at existing rates was not viable due to reasons like increase in cost of production, increase in cost of active pharmaceutical ingredients (APIs), changes in exchange rate, request for discontinuation of some of the formulations etc. After detailed scrutiny, NPPA approved increase in the price of 11 formulations of 8 drugs to ensure their continued availability so that the public is not forced to switch to expensive alternatives due to non-availability of these drugs in the market. Most of these drugs are low-cost and generally used as first line treatment crucial to the public health programmes of the country. These drugs are used for treatment of Asthma, Glaucoma, Thalassemia, Tuberculosis, mental health disorders, etc. Similar increase has been earlier allowed in other few drugs in 2019 and 2021 to ensure the availability of the drugs.

**Monitoring availability of drugs through weekly surveys:** The availability of key medicines at the retail level is being monitored through regular surveys conducted by Price Monitoring Resource Units (PMRUs) in their respective States/ UTs at chemist shops at various locations across the country.

**Monitoring & Enforcement Activities** The Government is effectively monitoring the prices of scheduled as well as non-scheduled medicines under DPCO, 2013 and takes action against companies found overcharging the consumers based on the references received from the State Drugs Controllers; individuals; samples purchased from the open market; reports from market based data; and complaints reported through the grievance redressal websites, 'Pharma Jan Samadhan' and 'Centralized Public Grievance Redress and Monitoring System (CPGRAMS)'. During the year 2024 (01-01-2024 to till 30.11.2024), 1878 samples were collected and 856 cases were found *prima facie* price violation.

**E-initiatives:** NPPA has undertaken the following e-initiatives for better disposal of grievances of general public:

#### **A. Pharma Sahi Daam and Pharma Jan Samadhan APP**

The Pharma Sahi Daam App 2.0 available on Android as well as iOS platform has features like searching of prices for medicines (brand wise or formulation wise), search latest ceiling prices of scheduled drugs, etc. Users can compare the prices of different brands of same formulation; and share price detail on messages etc. The app or search medicine facility tool facilitates consumers to verify whether medicines are being sold within the approved price range and also to detect any case of overpricing by pharmaceutical company/chemist.

Users can also register a complaint or view the status of the complaint, which was raised earlier (OTP authentication). If there is any ceiling price violation, the buyer will be able to lodge a complaint against company/ chemist through Pharma Jan Samadhan/ Pharma Sahi Daam

(<http://www.nppaindia.nic.in/redressal.html>). There were over one lakh downloads of the App with rating of 3+.

NPPA launched Pharma Jan Samadhan (PJS) with an objective to provide complaint redressal system. Any stakeholder can lodge an on-line complaint relating to non-availability of medicines; overpricing of medicines; sale of drugs without prior price approval; and, refusal of supply or sale of medicines to NPPA through PJS. The complaint can be lodged in the PJS through the NPPA's website on the URL: <https://nppaipdms.gov.in/NPPA/PharmaJanSamadhan/registration>.

Action on the complaint received through PJS with the complete information is initiated within 48 hours by the NPPA. As soon as the complaint is lodged on PJS portal, an acknowledgement regarding receipt of complaint along with the registration number is sent to the complainant's mobile/ email ID. The complainant can track the status of his/her complaint by using that reference number on the portal. In case of overcharging and selling of medicines without price approval etc., further action is taken after detailed examination of documents provided by the complainant as per provisions of the Drugs (Prices Control) Order, 2013.

## **B. Integrated Pharmaceutical Database Management System (IPDMS)**

Integrated Pharmaceutical Database Management System is an integrated system which was launched by NPPA in 2015. However, an upgraded, responsive cloud-based version, IPDMS 2.0 was launched on 29<sup>th</sup> August, 2022. 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. During this calendar year, as on 05.12.2024, 191 companies and 29039 products are registered in IPDMS.

## **Consumer Awareness, Publicity and Price Monitoring (CAPP) Scheme**

CAPP Scheme has two components, viz. (i) Assistance to set-up Price Monitoring and Resource Units (PMRUs), and (ii) Advertisement and Publicity for CAPP. PMRUs are societies registered under the Societies Registration Act having its own Memorandum of Association/ Bye laws and they function under the direct supervision of the concerned State Drug Controllers for increasing outreach of NPPA. As on 13.12.2024, PMRUs have been set-up in 31 States/UTs.

### **(i) IEC (Information, Education and Communication) Activities under CAPP by NPPA:**

(a) NPPA has organized eleven (11) online webinars in 2024. The main aim of these webinars/ campaigns was on awareness and guidance regarding monitoring of price movement of scheduled/ non-scheduled formulations; weekly survey; collection/ purchase of test samples of medicines; reporting of likely violation cases through IPDMS; guidance on incurring of Expenditure through PFMS; and maintenance of records/ supporting documents and submission of Monthly report including Static and dynamic reports.

(b) Participation in 19<sup>th</sup> International Conference of Drug Regulatory Authorities (ICDRA) held at 14<sup>th</sup>-15<sup>th</sup> October at Yashobhoomi, Delhi:

NPPA participated as an exhibitor at the 19<sup>th</sup> International Conference of Drug Regulatory Authorities (ICDRA) (held on 14<sup>th</sup>–15<sup>th</sup> October at Yashobhoomi, Delhi) organised by the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, in collaboration with the World Health Organization (WHO) that brought together regulatory authorities, policymakers, and health officials from over 194 WHO member states. Around 100 delegates viz regulators from different countries, manufactures, State drug controllers, marketers, students, researchers and news media persons visited NPPA stall.



**(ii) State Level Events/ Seminars organised by PMRUs:**

Webinars for Price Monitoring and Resource Units in the States/ UTs: Interactive webinars were organized by PMRU Division for Price Monitoring and Resource Units in the States/ UTs as follows:

- A webinar on the topic ‘Activities undertaken by PMRUs during April 2023 to December 2023’ was held on 07.02.2024. The main aim of meeting was to discuss and review the progress of activities undertaken by the PMRUs during the period from April 2023 to December 2023.
- A webinar on the topic ‘Methodology for assessing overcharging in violation cases’ was held on 28.03.2024. The main aim of the webinar was to provide comprehensive guidance and sharing of knowledge with PMRUs regarding methodology for assessing overcharging in violation.
- A webinar on the topic 'Monitoring the Prices of ‘Scheduled and Non-scheduled formulations’ was held on 21.05.2024. The main aim of the webinar was to provide comprehensive guidance

and sharing of knowledge with PMRUs regarding Methodology for Price Monitoring activities of Scheduled and Non-scheduled formulations.

- An interactive webinar was organized by PMRU Division along with Overcharging Division on 01.08.2024 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.
- 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.
- A webinar on the proper submission of necessary documents related to Overcharging cases through IPDMS 2.0 was held on 20.09.2024. The main aim of the above webinar was to provide information regarding submission of documents related to activities performed by PMRUs with the help of IPDMS 2.0.
- 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.

### **(iii) IEC Activities by PMRUs:**

One hundred and sixteen (116) IEC Activities were conducted by 22 PMRUs in their respective States/ UTs viz. Puducherry, Jharkhand, Ladakh, Maharashtra, Punjab, Arunachal Pradesh, Uttarakhand, Meghalaya, Kerala, Jammu & Kashmir, Tripura and Uttar Pradesh, Goa, Gujarat, KIHT, Karnataka, Madhya Pradesh, Chhattisgarh, Mizoram, Odisha, Rajasthan PMRUs. These events were aimed for imparting awareness among people about role of NPPA in making the drugs affordable and available for all, Promotion and use of Pharma Sahi Daam App & IPDMS 2.0, monitoring of prices of medicines through PMRUs.

### **e-Newsletter of NPPA: Aushadh Sandesh**

During the year, five issues of e-Newsletter were released. It contained information on the latest developments in the pharmaceutical sector in India as well as globally including regulatory activities of NPPA. In addition, an article by a pharma expert is also been included in these issues and following expert articles were carried in these five issues:

<b>Month</b>	<b>Topic of Article</b>
February, 2024	An analysis of Antibiotics use as per WHO AWaRe classification
April, 2024	Antimicrobial Resistance (AMR)- A critical challenge to healthcare
June, 2024	Epidemiological perspective on emerging disease profile in India

August, 2024	Understanding basics of organ donation and transplantation
October, 2024	Use of Artificial Intelligence in Pharmaceuticals

### Other Activities:

(i) Participation in India Healthcare Conference ‘Navigating the Future of Healthcare: From Vision to Reality’: Member Secretary, NPPA participated and delivered a keynote address at the GS1 India Healthcare conference ‘Navigating the Future of Healthcare: From Vision to Reality’ on Thursday, 19<sup>th</sup> September’24.



(ii) 10<sup>th</sup> International Day of Yoga was celebrated by NPPA on 21<sup>st</sup> June, 2024, wherein NPPA officials participated enthusiastically, promoting health and well-being. The theme of Yoga Day was “Yoga for Self and Society”.







(iii) With the objective of ensuring proper disposal of expired/unused medicines, the NPPA in association with Lady Hardinge Medical College (LHMC)/Hospital, Delhi, and Mediflo, continued its initiative this year by placing a collection box in the office premises of NPPA at the YMCA Cultural Centre Building for the collection and subsequent proper disposal of expired/unused medicines.



## 10. Medical Device:

### Scheme for Promotion of Medical Devices Parks

Scheme for Promotion of Medical Devices Parks: The scheme “Promotion of Medical Device Parks” was approved on 20th March, 2020 for providing easy access to world class common infrastructure facilities to medical device units located in the parks. The total financial outlay of the scheme is Rs. 400 crore and the implementation period is from FY 2020-2021 to FY 2024-2025. Under the scheme, Department had received proposals from 16 States. After evaluation of



the proposals, Govt. of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh were conveyed final approval for creation of common infrastructure facilities in the proposed medical device parks in these four states. Civil works in all the other three parks (except Himachal Pradesh) has progressed well with most of the structures for housing equipment for Common Infrastructure Facility (CIF) constructed, while procurement of equipment is in progress.

### **Strengthening of Medical Device Industry**

In order to provide support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion, a new scheme "Strengthening of Medical Device Industry" with five sub-schemes has been launched on 08.11.2024 with financial outlay of Rs. 500 crore. Sub-scheme of the scheme is as given below:-

(i) Common Facilities for Medical Device Clusters: To strengthen existing infrastructure by providing financial assistance to medical device clusters for creating Common Infrastructure Facilities, boosting domestic manufacturing capacity and improving cluster quality and to strengthen availability of more Medical Device Testing Laboratories in order to boost manufacturing of quality medical devices. Total outlay of the scheme is Rs. 110 crore.

Under the scheme in-principle approval has been granted for 4 proposals to set up common facilities and 6 proposals to set up testing facilities.

(ii) Marginal Investment Scheme for Reducing Import Dependence: To promote domestic production of key components, raw materials and accessories used in manufacturing of medical devices, including in-vitro diagnostic devices, in order to reduce dependence of Indian medical device manufacturers on imported key components and raw materials and increase the depth of our value chains. Total outlay of the Scheme is Rs 180 crore.

(iii) Capacity Building and Skill Development in Medical Device Sector: The main objective of the component is to fill the gap existing in the education and research in medical devices sector and to ensure quality teaching, training and nurturing excellence in Medical Technology education for generating critical mass of trained human resource to meet the requirements of rapidly innovating multidisciplinary areas of Medical Technology and create R&D ecosystem for the sector. Total outlay of the Scheme is Rs 100 crore. Under the sub-scheme, in-principle approval has been granted to 13 proposals for Component-A and 5 proposals for Component-B.

(iv) Medical Device Clinical Studies Support Scheme: To support the medical device industry by fostering development of devices supported by clinical evidence and generation of clinical data that demonstrates the safety and efficacy of the devices manufactured in India. This will promote manufacturing of quality products with better efficacy and safety. It will also enhance credibility of domestic manufacturers to produce high quality products, opening up opportunities for them in markets outside the country. Total outlay of the Scheme is Rs 100 crore.

(v) Medical Device Promotion Scheme: To promote Medical Device Industry by bringing

industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the sector as well as to facilitate growth and development of the sector through conducting studies, organizing awareness programs, creation of databases and promotion of industry. Total outlay of the Scheme is Rs 10 crore.

#### **Glimpse of launching of the scheme-**



The Union Cabinet approved the National Medical Device Policy, 2023 on 26.04.2023. The Policy envisions to place the Indian medical devices sector on an accelerated growth path with a patient-centric approach to meet the evolving healthcare needs of patients by building an innovative and globally competitive industry in India, enabling ecosystem, streamlined regulatory framework and quality manpower. This will ensure access to patent-centric, innovative and affordable healthcare products of excellent quality for better healthcare outcomes.

Export Promotion Council for Medical Devices (EPC-MD) was established on 22.05.2023 with headquarters in Yamuna Expressway Industrial Development Authority (YEIDA), Greater Noida, Uttar Pradesh, under the aegis of D/o Pharmaceuticals. The primary objective of EPC-MD is to promote and facilitate exports of medical devices and related products from India.

The National Medical Devices Promotion Council (NMDPC) was set up by DPIIT vide OM dated 03.03.2020. Since the D/o Pharmaceuticals has the mandate for the promotion of the medical device industry, the NMDPC was reconstituted and functioning under the chairpersonship of Secretary, D/o Pharmaceuticals since 5.08.2022. The council consists of stakeholders from Government and industry and provides a platform to discuss and resolve various regulatory issues for ease of doing business and promotion of the Medical Device sector.

**Meditech Stackathon 2024 :** The Department of Pharmaceuticals organised Meditech Stackathon, 2024 in two rounds on 07.05.2024 and 29.08.2024 respectively. This initiative aimed to analyze the value chain of selected medical devices and identify opportunities for growth and innovation in the Indian MedTech sector. The stackathon involved a series of focused group discussions on various medical device segments, including cancer therapy, imaging, critical care, and others. The

goal was to develop recommendations for policy and regulatory changes, as well as industry best practices, to boost the Indian MedTech sector. By addressing the issues of duty inversion, manufacturers can enhance their competitiveness and maintain sustainable operations.

### Glimpse of the events



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**MV/AKS**