सत्यमेव जयते

Government of India

Ministry of Chemicals & Fertilizers

DEPARTMENT OF PHARMACEUTICALS

Annual Report

2023-24

Annual Report

2023-24

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

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CHAPTER 1

An Overview

1.1 Pharmaceutical Industry

1.2 Medical Device Industry

1.3 Foreign Direct Investment

CHAPTER 1

An Overview

1.1 Pharmaceutical Industry

The Indian pharmaceutical industry is the world's 3rd largest by volume of production and plays a significant role globally. India is a global leader in the supply of DPT, BCG, and Measles vaccines and one of the largest suppliers of low-cost vaccines in the world. Indian manufacturers account for 60 percent of the vaccine supplies to UNICEF, contributing 40 to 70 percent of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine.

India has the highest number of United States Food and Drug Administration (USFDA) compliant pharma plants outside of the USA. There are 500 API manufacturers contributing about 8% to the global API Industry. India is the largest supplier of generic medicines, with a 20% share in the global supply by manufacturing 60,000 different generic brands across 60 therapeutic categories.

Access to affordable HIV treatment from India is one of the greatest success stories in medicine. Due to the low price and high quality, Indian medicines are preferred worldwide, rightfully making the country the 'pharmacy' of the world.

The sector has been growing at a healthy rate. The total annual turnover of pharmaceuticals in 2023-24 was Rs. 4,17,345 crore, registering a growth of 10 per cent over 2022-23. The trend in annual turnover in the sector over the last five years may be seen in Table 1A

Table 1A

(Pharma Sector's Growth at Current Prices)

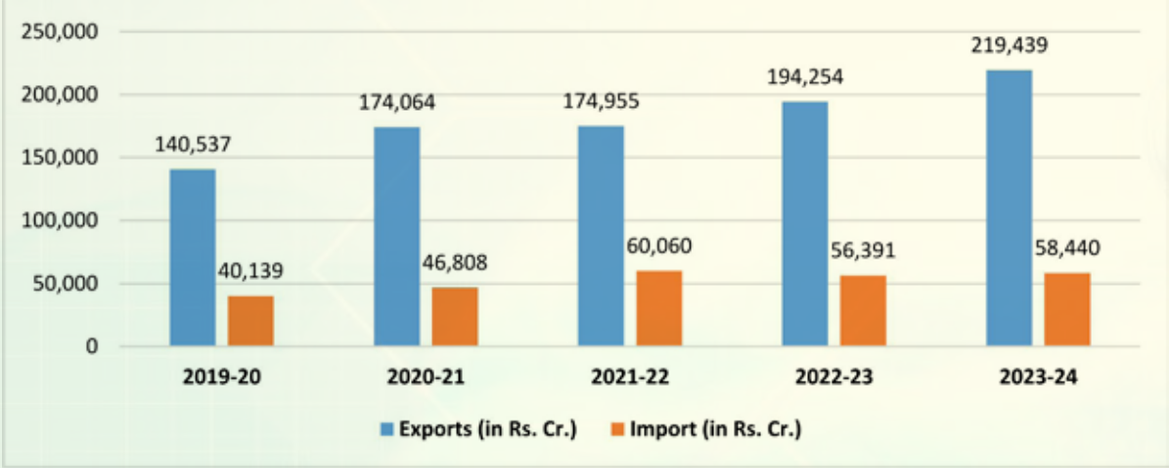
Financial Year	Turnover (Rs. in crore)	Growth Rate %
2019-2020	2,89,998	12
2020-2021	3,28,054	13
2021-2022	3,44,125	5
2022-2023	3,79,450	10
2023-2024	4,17,345	10

Source: Pharmatrac/NPPA/DGCIS, Kolkata

The sector is one of the important sectors in terms of exports and in 2023-24 the total exports of pharmaceuticals was Rs. 2,19,438.60 crore while the total imports of pharmaceuticals was Rs. 58,440.37 crore.

Graph 1A

(Export-Import of Pharmaceuticals)



(Source: DGCI&S, Ministry of Commerce and Industry)

(Data includes Bulk Drugs, Drug Intermediates, Drug Formulations, Biologicals)

1.2 Medical Device Industry

1.2.1 Medical Devices

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for the prevention, diagnosis, treatment and management of all medical conditions and disabilities. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and healthcare insurance industry, thereby helping achieve the key objectives of the National Health Policy (NHP), 2017. Medical devices constitute a multi-disciplinary sector, with the following broad classification: (a) Electronic equipment (b) Implants (c) Consumables and Disposables (d) Surgical instruments and (e) In-Vitro Diagnostic Re-agents.

Several segments in the medical device industry are highly capital intensive, with long gestation period, require continuous induction of new technologies, continuous training of healthcare professionals to adapt to new technologies, and involve rapid innovation. The medical devices have to demonstrate their safety, quality and efficacy through processes defined by the Regulator before they get placed in the market for sale.

1.2.2 Indian Medical Device Market

India is one of the fastest growing markets in the global medical devices industry, expected to grow at a CAGR of 15 per cent. The current market share in global market is estimated to be 1.5%**.** India is the 4th largest Asian medical devices market after Japan, China, and South Korea and among the top 20 global medical devices markets in the world. Export and Import of Medical Devices over past five financial years is given in Table 1B and 1C respectively.

(A) Export data- Category wise

Table 1B

(Category wise Export data)

(USD Million)

S. No.	Segment	FY 2019-20	FY 2020-21	FY 2021-22	FY 2022-23	FY 2023-24
1	Consumables & Disposables	1083	1290	1378	1605	1752
2	Surgical Instruments	50	54	71	72	79
3	Electronics Equipment	999	985	1163	1335	1472
4	Implants	94	99	135	188	266
5	IVD Reagents	68	104	176	191	216
	TOTAL	**2293**	**2532**	**2923**	**3391**	**3785**

Source: DGCI&S, Ministry of Commerce and Industry

(B) Import data- Category wise

Table 1C

(Category wise Import data)

(USD Million)

S. No.	Segment	FY 2019-20	FY 2020-21	FY 2021-22	FY 2022-23	FY 2023-24
1	Consumables & Disposables	1076	1471	1624	1091	1185
2	Surgical Instruments	180	104	169	210	205
3	Electronics Equipment	3647	3569	5441	4884	5408
4	Implants	415	226	423	540	586
5	IVD Reagents	527	872	883	767	804
	TOTAL	**5845**	**6241**	**8540**	**7492**	**8188**

Source: DGCI&S, Ministry of Commerce and Industry

Graph 1B

(EXIM DATA)

1.3 Foreign Direct Investment

Pharmaceutical sector has emerged as a favourite destination for the foreign investors and is one of the top ten attractive sectors for foreign investment in India. The Government has put in place an investor-friendly Foreign Direct Investment (FDI) policy to promote investment in the sector. 100% foreign investment is allowed under automatic route in Medical Devices. In pharmaceuticals, up to 100% FDI in greenfield projects and up to 74% FDI in brownfield projects is allowed under the automatic route. Foreign investment beyond 74% in brownfield projects requires Government approval. After the abolition of the Foreign Investment Promotion Board (FIPB) in May 2017, the Department of Pharmaceuticals 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 the pharmaceutical sector and medical devices sector arising out of Press Note 3 dated 17.04.2020 wherein investors/ ultimate beneficiaries in the investment proposals are from the countries sharing land border with India.

The sector contributes about 3.80% of total FDI inflows in the country across various sectors. Total FDI inflows in Pharma and MediTech Sectors has been ₹ 1,57,087 crore from April 2000 to March 2024. During the financial year 2023-24, Department of Pharmaceuticals approved 14 FDI proposals that would result in foreign investment inflow of ₹ 11,858 crore in the brownfield projects of pharmaceutical sector.

The Department monitors the progress of FDI inflows received by the Indian Companies in the sector as well as compliances of FDI linked performance conditions as required under the extant FDI Policy through an online Portal, namely, *"FDI linked Compliance Monitoring Portal."* The web-link of the portal is http://fdi.pharmaceuticals.gov.in. Activity-wise break-up of the FDI inflows i.e. in pharmaceutical and meditech activities, separately may be seen at Table 1D.

Table 1D

(FDI inflows in Drugs & Pharmaceuticals and Meditech Activities)

Financial Year	FDI Inflows Drugs & Pharmaceuticals (Amount in ₹ crore)	FDI Inflows MediTech Sector (Amount in ₹ crore)
2019-20	3,650	2,196
2020-21	11,015	511
2021-22	10,552	1,545
2022-23	16,654	3,123
2023-24	8,844	3,978

CHAPTER 2

Functions and Organisational Set-Up

2.1 Mandate of Department of Pharmaceuticals

2.2 Vision

2.3 Mission

2.4 Organisational set-up

2.5 Attached Office

2.6 Registered Society

2.7 Autonomous Institutes

2.8 Public Sector Undertakings

CHAPTER 2

Functions and Organisational Set-Up

2.1 Mandate of Department of Pharmaceuticals

The Department of Pharmaceuticals was created on 1st July, 2008 under the Ministry of Chemicals & Fertilizers with the objective of giving greater focus and thrust on the development of pharmaceuticals sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to pharmaceuticals sector, which required integration of work with other ministries.

The following works have been allocated to the Department of Pharmaceuticals:

i. Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.

ii. Medical Devices Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.

iii. Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceuticals sector.

iv. Development of infrastructure, manpower and skills for the pharmaceuticals sector and management of related information.

v. Education and training including high-end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.

vi. Promotion of public- private-partnership in pharmaceutical related areas.

vii. International co-operation in pharmaceuticals research, including work related to international conferences in related areas in India and abroad.

viii. Inter-sectoral coordination including coordination between organisations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.

ix. Technical support for dealing with national hazards in pharmaceutical sector.

x. All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.

xi. All matters relating to National Institutes of Pharmaceuticals Education and Research.

xii. Planning, development and control of, and assistance to all industries dealt with by the Department.

xiii. Bengal Chemicals and Pharmaceuticals Limited.

xiv. Hindustan Antibiotic Limited.

xv. Karnataka Antibiotics and Pharmaceuticals Limited.

2.2 Vision

To promote Indian Pharma as the global leader for quality medicines; and to ensure availability, accessibility and affordability of drugs and medical devices in the country.

2.3 Mission

- Investment for Make in India in Pharma sector,
- Make in India in critical APIs and medical devices,
- Industry expansion, skilling, R&D and innovation,
- Stable and effective price regulation, and
- Generic medicines by expanding Jan Aushadhi scheme

2.4 Organisation Set Up

Department of Pharmaceuticals is the nodal Department for policy making, sectorial planning, promotion and development of pharmaceutical and meditech industries. Administrative control of the Public Sector Undertakings of the Department, National Pharmaceutical Pricing Authority (NPPA) and Pharmaceuticals & Medical Devices Bureau of India (PMBI) is also vested with the Department.

The Department is headed by Secretary to the Government of India who is assisted by one Senior Economic Adviser, two Joint Secretaries and one Economic Adviser.

(Dr. Arunish Chawla is holding the charge of Secretary of the Department w.e.f. 01.11.2023)

2.4.1 Divisions of the Department

The Department has 15 Divisions to carry out various mandated functions and responsibilities. The summary of the main functions of the 15 Divisions is given below:

(i) **Integrated Finance Division (IFD) -** Exercising expenditure control and management, ensuring rationalization of expenditure and compliance of economy measures in accordance with the instructions of the Department of Expenditure including regular monitoring of expenditure through monthly/ quarterly reviews and submission of reports to the concerned. IFD also prepares the budget of the Department in consultation with various Divisions and the Department of Expenditure.

(ii) **Pricing Division -** All matters relating to National Pharmaceutical Pricing Authority (NPPA) including administrative/establishment budgetary matters/fund release; Review cases against NPPA's orders; Administration of Drug Price Equalisation Account (DPEA) funds; Administration of Drug (Prices Control) Order (DPCO) and all issues relating to Pharmaceutical Pricing Policy & pricing of drugs.

(iii) **Policy Division -** All policy matters related to the promotion of pharmaceutical industry; all matters of pharmaceutical industry received from other Departments/Ministries; all references received from pharmaceutical industry; all tax related proposals of Pharmaceuticals for annual Budget; Project Development Cell; Matters related to Pharma Bureau; Implementation of PLI Scheme for Pharmaceuticals; Implementa-

tion of Scheme for Promotion of Bulk Drug Parks; all matters related to Uniform Code for Pharmaceuticals Marketing Practices (UCPMP).

(iv) **Public Sector Undertakings (PSUs) -** All matters relating to five Central Public Sector Enterprises (CPSEs) under the administrative control of the Department of Pharmaceuticals.

(v) **NIPER Division -** All matters related to National Institutes of Pharmaceutical Education & Research (NIPERs) under the administrative control of the Department of Pharmaceuticals, Administration of NIPER Act, R&D matters-promotion & coordination of basic, applied and other research related to Pharmaceutical and Medical Devices sector.

(vi) **Scheme Division -** Implementation of PLI Scheme for APIs/KSMs and DIs; Implementation of PLI Scheme for Medical Devices; Implementation of Strengthening of Pharmaceutical Industry scheme; Implementation of Pharmaceuticals & Medical Devices Promotion and Development (PMPDS) scheme; and Implementation of Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP).

(vii) **Medical Device Division -** All policy matters related to the promotion of Medical Device industry; all matters of Medical Device industry received from other Departments/Ministries; all references received from Medical Device industry; all tax related proposals of Medical Device for annual Budget; Implementation of Public Procurement Order (Make in India), 2017; Implementation of Scheme for Promotion of Medical Device Parks; all matters related to Uniform Code for Medical Devices Marketing Practices (UCMDMP).

(viii) **International Cooperation -** All matters related to International Co-operation including Free Trade Agreements, WTO, WHO, G20 and all Joint Working Groups (JWGs) and MoUs on Pharma and Medical Devices.

(ix) **Foreign Direct Investment -** Processing and monitoring of all Foreign Direct Investment (FDI) proposals.

(x) **Rajbhasha -** Implementation of various provisions of the Official Language Policy of the Union of India including those of Official Languages Act, 1963 as well as Official Languages (Use for Official Purposes of the Union) Rules, 1976 and orders issued there under.

(xi) **Establishment & Cash Division -** All matters related to Establishment i.e. all service-related matters of officers/officials of the Department of Pharmaceuticals, outsourcing of services for support staff, pay & allowances etc.

(xii) **Administration Division -** All matters related to administration including procurement and distribution of day-to-day articles needed for smooth running of the office, housekeeping services, maintenance of office equipment including computers, printers, photocopiers, air conditioners, printing of annual report and other event-specific banners, posters, standees and hospitality services, etc.

(xiii) **IT Division -** All matters related to Information Technology (IT), website of Department of Pharmaceuticals, liaison with NIC for maintenance of various portals of the Department, cyber security and security audit etc.

(xiv) **Parliament & Coordination -** All matters related to Parliament and Coordination of all intra and inter-ministerial work.

(xv) **Vigilance Division -** All matters related to Vigilance including interaction with Central Vigilance Commission (CVC).

2.4.2 Employment of Scheduled Castes / Scheduled Tribes / Physically Handicapped in the Main Secretariat of the Department of Pharmaceuticals

The status of employment of Scheduled Castes / Scheduled Tribes / Other Backward Classes / Physically handicapped in the main Secretariat of the Department of Pharmaceuticals, as on 01.01.2024 is given in Table 2A.

Table 2A

(Status of employment of Scheduled Castes / Scheduled Tribes / Other Backward Classes / Physically handicapped in the main Secretariat of the Department of Pharmaceuticals)

Group	Total No. Of Posts	In position	Scheduled Castes	Scheduled Tribes	Other Backward Classes	Physically Handicapped	EWS
A	28	25	2	3	3	-	0
B	47	32	5	2	8	-	0
C	21	18	7	0	4	-	2
Total	**96**	**75**	**14**	**5**	**15**	**-**	**2**

Officers in Group A include officers belonging to Central Secretariat Service besides officers on deputation from All India Services, Central Services and other Departments/ Undertakings including Lateral Entry Mode. Appointment to posts in Group B and C is largely done on the basis of nominations made by the Department of Personnel & Training.

The Department also monitors the progress of filling up of the posts reserved for the members of Scheduled Castes, Scheduled Tribes and other Backward Classes in the Public Sector Undertaking under the administrative control of the Department.

2.4.3. Organisation Chart

The Organisation chart of the Department is given at Annexure 2A.

2.5 Attached Office

National Pharmaceutical Pricing Authority - an attached office of the Department and the functions, inter-alia, include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of various provisions of DPCO. NPPA also provides inputs to Government on Pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

2.6 Registered Society

Pharmaceuticals & Medical Devices Bureau of India (PMBI) – erstwhile known as Bureau of Pharma Public Sector Undertakings of India (BPPI) was set up on 01.12.2008 by the Department of Pharmaceuticals with the objective to have focused and empowered structure to implement the Jan Aushadhi Scheme launched by Department of Pharmaceuticals.

2.7 Autonomous Institutions

National Institute of Pharmaceutical Education & Research (NIPER) – NIPERs are institutes of National Importance set up to promote and nurture quality and excellence in pharmaceutical education and research. NIPER at SAS Nagar (Mohali) was set up as a registered society under the Societies Registration Act, 1860. Subsequently the Institute was given statutory recognition by an Act of Parliament, NIPER Act, 1998 and was declared as an Institute of National Importance. Six more new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Rae Bareli with the help of Mentor Institutes during 2007-08.

2.8 Public Section Undertakings

The Department has 5 Central Public Sector undertakings under its administrative control. They are:

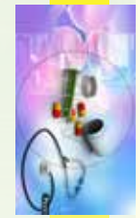
(a) Indian Drugs & Pharmaceuticals Ltd. (IDPL), Gurugram, Haryana,

(b) Hindustan Antibiotics Ltd, Pimpri, Pune, Maharashtra,

(c) Karnataka Antibiotics & Pharmaceuticals Limited, Bangalore, Karnataka

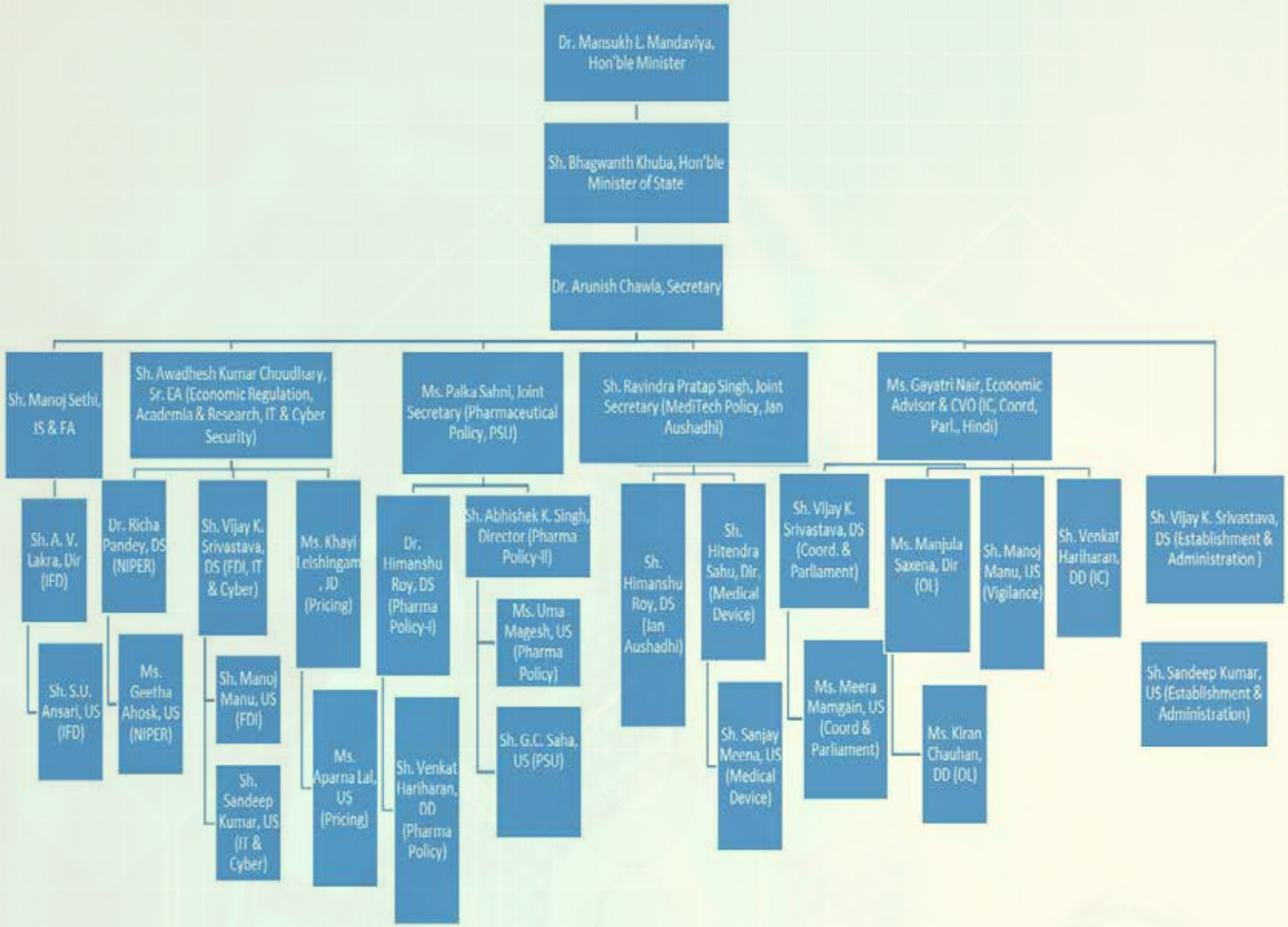
(d) Bengal Chemicals & Pharmaceuticals Ltd, Kolkata, West Bengal, and

(e) Rajasthan Drugs and Pharmaceuticals Limited, Jaipur, Rajasthan



ANNEXURE – 2A

ORGANISATION CHART – DEPARTMENT OF PHARMACEUTICALS.



CHAPTER 3

Programmatic Interventions

3.1 Production Linked Incentive (PLI) Schemes

3.2 Umbrella Scheme for Development of Pharmaceutical Industry

3.3 Schematic and Non-schematic interventions for Promotion of Medical Devices Sector

3.4 Pharma Bureau

CHAPTER 3

Programmatic Interventions

The Department of Pharmaceuticals is implementing the following central sector schemes with the objective to increase efficiency and competitiveness of domestic pharmaceutical and medical devices industry so as to enable them to play a lead role in the global market and to ensure accessibility, availability and affordability of quality pharmaceuticals and medical devices for mass consumption. The scheme-wise details are as follows:

3.1 Production Linked Incentive (PLI) Schemes

The Department implements three PLI schemes as Central Sector Schemes, out of the total 14 PLI schemes, being implemented by the Government of India and they are as below:

a) PLI Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (Dis)/ Active Pharmaceutical Ingredients (APIs) in India

b) PLI Scheme for Promoting Domestic Manufacturing of Medical Devices

c) PLI Scheme for Pharmaceuticals

The Guidelines for implementation of the sub-schemes are available on the Department's website at https://pharmaceuticals.gov.in/schemes. All the above three PLI schemes are being implemented, to achieve the intended objectives as per the timeline and to increase the domestic manufacturing of Bulk Drugs, Pharmaceuticals and Medical Devices.

3.1.1 Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Material (KSMs)/Drug Intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) in India

With a view to attain self-reliance and reduce import dependence in critical APIs, a scheme called "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" was approved by the Government of India on 20.03.2020. The scheme intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs.

The scheme covers 41 products under following four categories:

Table 3A

(Categories under the Scheme)

Sl No.	Target Segment	Name
1	I	Key fermentation based KSMs/drug intermediates
2	II	Key fermentation based niche KSMs/drug intermediates
3	III	Chemical synthesis based KSMs/drug intermediates
4	IV	Other chemical synthesis based KSMs/ drug intermediates/ APIs

The period of the scheme is from financial year 2020-2021 to 2029-30 with total financial outlay of Rs.6,940 crore. The financial incentive under the scheme will be provided on sales of 41 identified products for six (06) years at the rates given below:

Table 3B

(Details of Incentive)

Product Category	Incentive Period	Rate of Incentive
For fermentation based products	Incentive for Financial Year 2023-24 to Financial Year 2026-27	20%
	Incentive for 2027-28	15%
	Incentive for 2028-29	5%
For chemical synthesis based products	Incentive for Financial Year 2022-23 to Financial Year 2027-28	10%

The Government has received a good response to the scheme. In total 249 applications were received under the scheme for the 41 products spread across the 4 Target Segments for the scheme from all over the country.

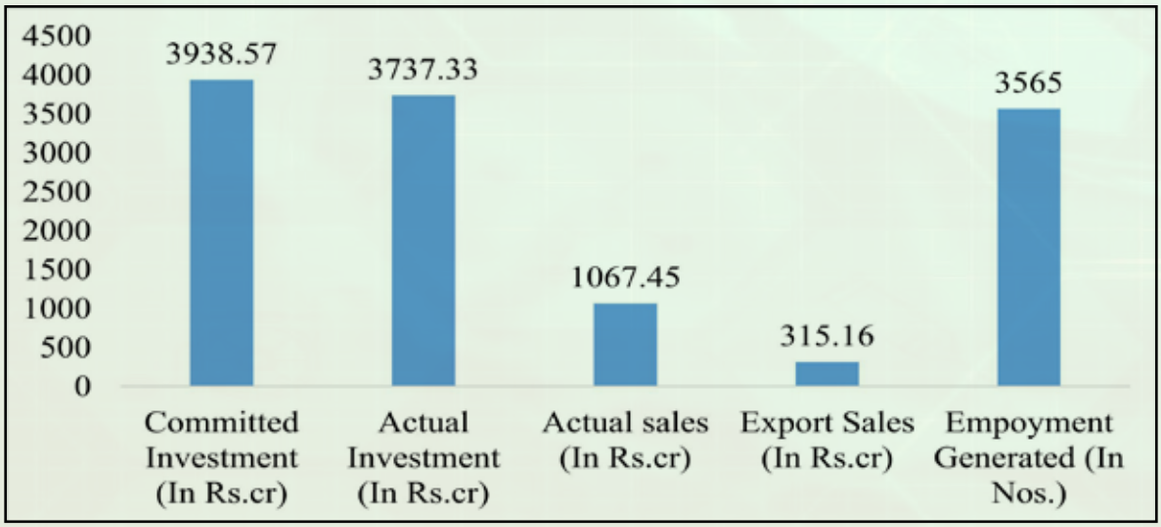
48 projects have been approved with committed investment of Rs. 3,938.57 crore, and expected employment generation for around 9,618 persons. Investment of Rs. 3,737.33 crore have been realized and employment for 3,565 persons have been generated. The sales made by the commissioned projects is worth Rs.1067.45 crore which includes export of Rs.315.16 crore. The scheme is expected to create capacity for manufacturing of critical import dependent bulk drugs/drug intermediates.

Financial Year 2022-23 is the first year of performance/sales, and an incentive amount of Rs.14.74 crore has been released to the applicants on achieving the eligible criteria for quarterly/half-yearly incentive claims and verification by the Project Management Agency.

Status of Projects, as of March 2024, is given in Graph 3A.

Graph 3 A

(Status of Projects)



Glimpse of some of the commissioned projects:

Plant: Meghmani LLP -Dahej, Gujarat

Product: Para Amino Phenol

Plant: Centrient Pharmaceuticals India (P) Ltd -Nawanshahr,

Punjab Product: Atorvastatin

Plant: Andhra Organics Limited - Srikakulam, Andhra Pradesh

Product: Sulfadiazine

3.1.2 Production Linked Incentive (PLI) 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:

Table 3C

(Details of Incentive)

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

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. AII implants including implantable electronic devices

Total 64 (Category – A: 42 and Category – B: 22) applications across all four categories of products were received. Out of 64 applications, 26 applications (Category – A: 19 and Category – B: 7) have been approved with committed investment of Rs. 1,330.44 crore and expected employment generation for around 7,950 persons. Upto March, 2024 investment of Rs.958.72 crore have been grounded and employment generated for 5,396 persons. The sales made by the commissioned projects is worth Rs.5986.56 crore which includes export of Rs.2806.37 crore.

Financial Year 2022-23 was the first year of performance/sales, and incentive amount of Rs.48.85 crore has been released to the applicants on achieving the eligible criteria for quarterly/half-yearly incentive claims and verification by the Project Management Agency.

Status of Projects, as of March 2024, is given in Table 3D.

Table 3D

(Status of Projects)

Sl. No.	Target Segment	Total approved Applicants		Total Committed Investment (₹ in crore)		Actual Investment up to March 2024 (₹ in crore)	Actual Employment up to March 2024 (No. of Persons)
		Cat A	Cat B	Cat A	Cat B		
1	Cancer care / Radiotherapy medical devices	1	0	24.50	-	22.75	375
2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	6	2	332.14	177.82	387.02	1,206
3	Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardiorespiratory Category & Renal Care Medical Devices	6	3	300.64	140.61	297.10	1,500
4	All Implants including implantable electronic devices	6	2	307.83	46.90	251.85	2,315
Total		**19**	**7**	**965.11**	**365.33**	**958.72**	**5,396**

Glimpse of some of the commissioned projects:

Plant: Philips Global Business Services LLP - Taluka KHED, Pune, Maharashtra

Product: MRI Coils

Plant: WIPRO GE Healthcare Private Limited
Bengaluru, Karnataka

Product: CT-Scan

Plant: Siemens Healthcare Private Limited
Hosur Road, Bengaluru, Karnataka

Product: CT-Scan and MRI

3.1.3 Production Linked Incentive (PLI) scheme for Pharmaceuticals

The Union Cabinet on 24.02.2021 approved this scheme with the objective to enhance 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 scheme covers pharmaceutical goods under following three categories:

Category 1: Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.; Complex excipients; Phyto-pharmaceuticals; Other drugs as approved.

Category 2: Active Pharmaceutical Ingredients(APIs) / Key Starting Materials(KSMs) / Drug Intermediates(DIs).

Category 3 : **(Drugs not covered under Category 1 and Category 2):** Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs; In vitro diagnostic (IVD) devices; Other drugs as approved; Other drugs not manufactured in India.

The period of the Scheme is from financial year 2020-21 to financial year 2028-29. The scheme provides for incentives on incremental sales to selected participants for a period of 6 years at the rate of 10% for financial year 2022-23 to financial year 2025-26, 8% for financial year 2026-27 and 6% for financial year 2027-28.

Table 3E

(Details of Incentive)

Group	Incentive ceiling per applicant	Ceiling of additional incentive per applicant, if any	Total Incentive Ceiling for the group
A	1000 crore	200 crore	11000 crore
B	250 crore	50 crore	2250 crore
C	50 crore	10 crore	1750 crore

Product category	Incentive rate	Incentive period
1 & 2:	10% (first 4 years), 8% (5th year) & 6% (6th year)	2022-23 to 2027-28
3:	5% (first 4 years), 4% (5th year) & 3% (6th year)	2022-23 to 2027-28

The total financial outlay of the scheme is Rs.15,000 crore. 55 applicants have been selected under the scheme including 20 MSMEs.

- Total incremental sales worth Rs.2,94,000 crore is estimated during six years from financial year 2022-23 to 2027-28.
- Employment for 71,763 persons have been generated. The sales made by the selected applicants is worth Rs.1,61,209 crore, which includes export of Rs.98,837 crore.
- Financial year 2022-23 is the first year of performance/sales, and incentive amount of Rs.2,201.53 crore have been released to the scheme participants.

Status of Projects, as of March 2024, given in Graph 3B.

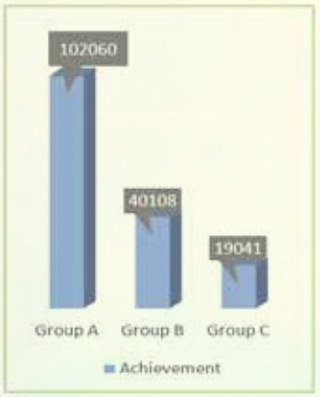
Graph 3B

(Status of Projects)

Investment

Committed- Rs. 17275 crores
Achieved- Rs. 29268 crores

Total locations where investment done- 443 across India.



Sales

Achieved-Rs. 161209 crores
Exports- Rs. 98837 crores

Incentive Disbursed Rs 2201.53 cr.

Employment

Projected- 39915
Actual- 71763

Glimpse of some of the commissioned projects:

Cipla Ltd. (Plants-Bengaluru and Sikkim)

Dr. Reddy's Lab (Plants-Hyderabad and Solan)

3.2 Umbrella Scheme for Development of Pharmaceutical Industry

3.2.1 Scheme for Promotion of Bulk Drug Parks

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 and in order to significantly bring down the manufacturing cost of bulk drugs, the scheme "Promotion of Bulk Drug Parks" was approved by Union Cabinet on 20.03.2020. The scheme aims to make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry as well as to minimize country's dependence on imports and to give fillip to indigenous manufacturing.

The Scheme envisages creation of world class infrastructure facilities in order to make Indian bulk drug industry a global leader. The scheme further envisages - (i) Easy access to world class common infrastructure facilities to bulk drug units located in the parks, (ii) To help industry meet the standards of environment at a reduced cost through innovative methods of common waste management system, and (iii) To exploit the benefits arising due to optimization of resources and economies of scale.

Under the scheme, financial assistance is provided for creation of Common Infrastructure Facilities (CIF) like the following.

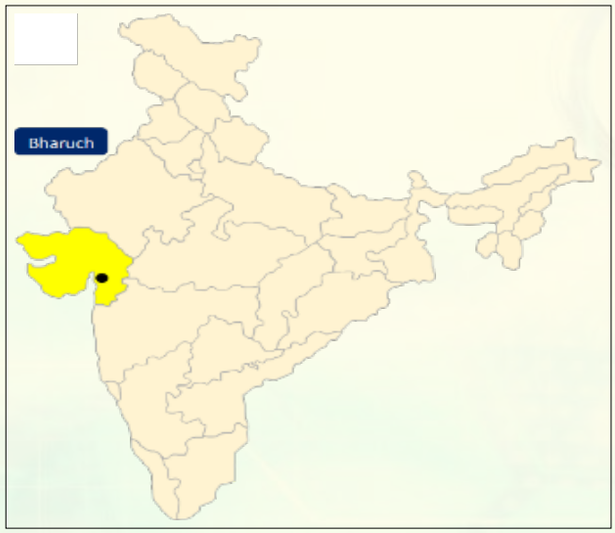
i. Central Effluent Treatment Plant(s) (CETP)	viii. Steam generation and distribution system
ii. Solid waste management	ix. Common cooling system and distribution network
iii. Storm water drains network	x. Common logistics
iv. Common Solvent Storage System, Solvent recovery and distillation plant	xi. Advanced laboratory testing Centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers
v. Common Warehouse	x. Emergency Response Centre
vi. Dedicated power sub-station and distribution system with the necessary transformers at factory gate	xi. Safety/ Hazardous operations audits centre and
vii. Raw, Potable and Demineralized Water	xii. Centre of Excellence

- The total financial outlay of the scheme is Rs.3000 crore. The period of the scheme is from FY 2020-2021 to FY 2024-2025. Financial assistance to a selected Bulk Drug Park is 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance is 90% of the project cost. Maximum assistance under the scheme for one Bulk Drug Park is limited to Rs.1000 crore.
- Gujarat, Himachal Pradesh and Andhra Pradesh were selected for providing grant-in-aid for creation of common infrastructure facilities in the Bulk Drug Park.
- Establishment of Bulk Drug Parks was approved in the States of Gujarat on 08.10.2022, Himachal Pradesh on 11.10.2022 and Andhra Pradesh initially on 07.11.2022 and to a new location on 07.12.2023.
- During 2022-23, first instalment of Rs.300 crore was released to Gujarat, Rs.225 crore to Himachal Pradesh and Rs. 225 crore to Andhra Pradesh.

The salient features of the CIF project of **Gujarat** are: -

- Total Project Cost – Rs.2507.02 crore
- Area: 2015.02 acres

Major Common Infrastructure facilities being developed under the scheme include:
Steam Generation and supply
Common Effluent Treatment Plant (CETP)
Centre of Excellence
Solvent recovery facility
Treatment, Storage & Disposal Facilities (TSDF)
Raw water supply and effluent collection pipeline
Internal roads
Internal drains
Common Infrastructure of Marine Discharge
Power infrastructure



The salient features of the CIF project of **Himachal Pradesh** are: -

- Total Project Cost – Rs.1923 crore
- Area: 1405.41 acres

Major Common Infrastructure facilities being developed under the scheme include:
Common Effluent Treatment Plant with ZLD (Zero Liquid Discharge) 5 MLD (Minimum Liquid Discharge)
Solid Waste Management
Storm water drains network
Common solvent storage system
Solvent recovery and distillation plant
Common Warehouse
Dedicated Power sub-station
Steam generation and distribution system
Raw, potable and demineralized water
Emergency response centre
Safety / hazardous operations audit centre
Internal road network
Advanced Laboratory testing centre
Centre of Excellence

The salient features of the CIF project of **Andhra Pradesh** are:

- Total Project Cost- 1876.66 crore
- Area: 2001.80 acres

Major Common Infrastructure facilities being developed under the scheme include:
Internal roads
Drainage network
Water supply
Wastewater conveyance network system (CETP)
Power Supply
Emergency Response centre
Steam Co-generation plant
Common solvent recovery system
Solid Waste Management
Storm water drains network
Common Warehouse
Advanced Laboratory testing centre
Centre of Excellence

3.2.2 Scheme for Promotion of Medical Devices Parks

- The medical device industry is highly capital intensive with a long gestation period and requires development and induction of new technologies. It also requires continuous training of health providers to adapt to new technologies. Most of the hi-tech innovative products originate from a well-developed eco-system and innovation cycle which is yet to be fully developed in India. The industry depends on imports up to an extent of 70 to 80%.
- To promote setting up of Medical Device parks in the country for providing easy access to world class common infrastructure facilities to Medical Device units located in the parks and in order to significantly bring down the manufacturing cost of Medical Device and thereby make India self-reliant, the scheme “Promotion of Medical Device Parks” was approved by Union Cabinet on 20.03.2020.
- The Scheme envisages creation of world class infrastructure facilities in order to make Indian medical device industry a global leader. The scheme further envisages - (i) Easy access to world class common infrastructure facilities to medical device units located in the parks, (ii) To help industry to significantly reduce the cost of production of medical devices leading to better availability of medical devices in the domestic market (iii) To exploit the benefits arising due to optimization of resources and economies of scale.
- Under the scheme, financial assistance is provided for creation of Common Infrastructure Facilities (CIF) like (i) Component Testing Centre/ESDM/PCB/Sensors facility (ii) Electro-magnetic interference & Electro Magnetic Compatibility Centre (iii) Biomaterial/ Biocompatibility/Accelerated Aging testing centre (iv)

Medical grade moulding/milling/injection moulding/ machining/ tooling centre (v) 3D designing and printing for medical grade products (vi) Sterilization/ ETO/ Gamma Centre (vii) Animal Lab and Toxicity testing centre (viii) Radiation testing centre (ix) Radiology Tube/ Flat Panel Detectors/MRI Magnets/ Piezo electrical crystals (x) Solid waste management (xi) Common Warehouse & Logistics (Clearing and Forwarding, Insurance, Transportation, Customs, Weighbridges, etc) centre (xii) Emergency Response Centre/ Safety/ Hazardous Operations audit centre (xiii) Centre of Excellence/ Technology Incubator/ ITI/ Training Centres

- The total financial outlay of the scheme is Rs.400 crore. The period of the scheme is from FY 2020-2021 to FY 2024-2025. Financial assistance to a selected Medical Device Park is 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance is 90% of the project cost. Maximum assistance under the scheme for one Medical Device Park is limited to Rs.100 crore.

- Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh were selected for providing grant-in-aid for creation of common infrastructure facilities in the Medical Device Park.

The salient features of the CIF project of **Himachal Pradesh** are:

- Total Project Cost – Rs.157.64 crore
- Area: 265.75 acres
- Location – BBN Area, Nalagarh, Baddi, Solan
- Common infrastructure facilities include 3D Design, Rapid Prototyping & Tooling Lab, Haptic Mechatronics and Medical Robotic Lab; Component, ESDM, EMC & EMI component Testing and Design Facility Lab; Sensor Testing Integration Facility; and Biocompatibility and Biomaterial testing Lab

The salient features of the CIF project of **Madhya Pradesh** are:

- Total Project Cost – 155.63 Rs. crore
- Area: 360 acres
- Location – Vikram Udhyogpuri, Ujjain
- Major Common infrastructure facilities being developed under the scheme include Biocompatilbility Testing Facility; Histopathology and Hemocompatibility Lab; 3D printing & Prototyping facility, Plastics Processing, Tool Room for Mould, Dies Manufacturing, PC board manufacturing including component insertion and wave soldering; Ethylene Oxide Sterilization, Incubation HUB, Waste management service for Plastic and Metal Chemicals & Biomedical waste

The salient features of the CIF project of **Tamil Nadu** are:

- Total Project Cost- 153.33 crore
- Area: 350 acres
- Location – Orgadam Industrial Area, Kanchipuram
- Major Common infrastructure facilities being developed under the scheme include EMI/EMC Center, Gamma Irradiation Centre, Calibration Centre, Accelerated Ageing Testing Centre, Microbiology lab, Medical grade Molding, Rapid Prototyping, 3D Designing and printing for medical grade products, Innovation hub and Technology Bridging Centre, Warehouse, Cold Storage and Metal Finishing Facility.

The salient features of the CIF project of **Uttar Pradesh** are:

- Total Project Cost- 186.63 crore
- Area: 350 acres
- Location – Sector 28, YEIDA, Gautam Buddha Nagar
- Major Common infrastructure facilities being developed under the scheme include Common commercial facilities; central warehouses, convention and exhibition centre, 3D design, rapid prototyping & tooling lab, Bio material testing facility; and Gamma irradiation zone

3.2.3 Strengthening of Pharmaceutical Industry (SPI)

Department of Pharmaceuticals has released the guidelines for the scheme "Strengthening of Pharmaceutical Industry" (SPI), with a total financial outlay of Rs.500 crores for the period from financial year 2021-22 to financial year 2025-26 on 11.03.2022. The scheme will address the rising demand in terms of support required to existing Pharma clusters and MSMEs across the country to improve their productivity, quality, and sustainability. The objectives of the scheme "Strengthening of Pharmaceutical Industry" (SPI) are to strengthen the existing infrastructure facilities in order to make India a global leader in the Pharma Sector.

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

i. **Assistance to Pharmaceutical Industry for Common Facilities (API-CF)**
ii. **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)**
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.

ii. **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), interest subvention or capital subsidy on their capital loans will be provided, which will further facilitate the growth in volumes as well as in quality; and

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.

The above three sub-schemes are already approved in the Department of Pharmaceuticals as part of scheme for 'Development of Pharmaceutical Industries' (DPI). Now, the DoP has combined the above schemes into a single scheme namely 'Strengthening of Pharmaceutical Industry (SPI)' with modification in the scheme guidelines, after stakeholder consultations for effective intervention.

It is expected that the units supported under this scheme will act as Demonstration Firms for the pharma clusters and MSMEs Pharma Industries, to develop on quality and technology upgradation fronts.

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

Under the sub scheme **Assistance to Pharmaceutical Industry for Common Facilities (API-CF)**, application window was opened for inviting applications for project proposals. Accordingly, total 20 applications/project proposals have been received from seven States and Union Territories. Out of 20 applications/project proposals, 17 applications/project proposals have been found eligible under the scheme. During 2023-24, 6 projects have been given final approval and 1 project have been given 'in-principle' approval.

Under Sub-Scheme **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)** promotional outreach events were held in 11 States and UTs. During 2023-24, 03 projects have been given final approval for capital subsidy on loan.

Under Sub-Scheme **Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS),-** During 2023-24, 09 studies have been awarded, out of which, 03 studies have been completed and 6 studies are under finalization. Also 14 events/workshops were organized under this Scheme including 02 mega events i.e. "India Pharma 2023 and India Medical Device 2023" and "India MedTech Expo.

The sub-scheme 'Pharmaceuticals Technology Upgradation Assistance Scheme'(PTUAS) was revised and renamed as 'Revamped Pharmaceuticals Technology Upgradation Assistance Scheme' (RPTUAS) on 11.03.2024 with a view to better uptake and to help upgrade the 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.

Under RPTUAS, the 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. 1.00 crore :

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

(a) India Pharma and India Medical Devices 2023

Department of Pharmaceuticals in association with Federation of Indian Chambers of Commerce & Industry (FICCI) organized the 8th edition of the International Conference on Pharmaceuticals & Medical Devices Industry i.e. – **INDIA PHARMA 2023 & INDIA MEDICAL DEVICE 2023 from 26th to 27th May, 2023 at The Ashok, New Delhi**. The Union Minister for Chemicals and Fertilizers Dr. Mansukh Mandaviya inaugurated the 8th edition of the International Conference on *'India Pharma & India Medical Device 2023* in the presence of Shri Bhagwanth Khuba, Minister of State for Ministry of Chemicals & Fertilizers.

Hon'ble Minister launched the National Medical Devices Policy, 2023, as well as the Export Promotion Council for Medical Devices. He also launched a new scheme named 'Assistance for Medical Devices clusters for Common Facilities (AMD-CF) with the objective to strengthen or establish common infrastructure facilities in the medical devices clusters and also to strengthen or establish testing facilities for medical devices.

The annual flagship conference was conducted over two days; First day (26.05.2023) dedicated for India Medical Device sector on the theme "Sustainable MedTech 5.0: Scaling and Innovating Indian MedTech," and Second day (27.05.2023) dedicated for the Pharmaceutical sector on the theme "Indian pharma industry: Delivering Value through Innovation".

Over 100 CEOs of the pharmaceutical and medical device industries participated in several thematic sessions during the two days, bringing participation from all over the world to the event. Several dignitaries attended the event including Member, Industry, NITI Aayog; Secretaries of Departments of Pharmaceuticals, Health, DPIIT &

Higher Education; Chairman NPPA; senior officials of MeitY, MoEFCC, BIS, AERB, National Bio-pharma Commission; Drug Controller General of India, and representatives from IIT Delhi, IIT Kanpur, NIPER Mohali, BIRAC, Healthcare Sector Skill Council.

Glimpse of the India Medical Devices and Pharma 2023 Event

(b) India Med-Tech Expo (IMTE) 2023

India Med-Tech Expo (IMTE) 2023, 1st edition, was organized by Department of Pharmaceuticals, from **17th-19th August 2023 at Helipad Exhibition Center, Gandhinagar**, on the theme "India: The Next Med-Tech Global Hub Future of Devices, Diagnostics and Digital". The event showcased the strength and potential of Indian Medical Devices ecosystem. Some of the major features of the event are as below:

(i) The event brought all stakeholders on one platform, creating opportunities to network and explore collaborations for sector's growth in India.

(ii) In the event, more than 4000 Buyer-Seller meetings were organized and more than 10000+ visitors visited the EXPO-2023.

The Expo witnessed large participation from Global and Indian companies including MSMEs, Startups, Academic and Research Institutions, State Governments, Central and State procurement agencies and Regulatory agencies

Glimpse of the India MedTech Expo 2023 Event

3.2.4 Assistance to Medical Device Clusters for Common Facilities (AMD-CF)

The SFC on 20.03.2022 approved the scheme, Assistance to Medical Device Clusters for Common Facilities (AMD-CF). The scheme aims to provide assistance to 12 clusters and 12 testing labs. The total financial outlay of the scheme is Rs.300 crore. The period of the scheme is from financial year 2023-24 to financial year 2025-26.

AMD-CF Scheme aims to strengthen Medical Device clusters by providing financial assistance and to strengthen and / or establish more Testing Laboratories for Medical Devices to improve quality and sustainable growth.

The guidelines were issued on 09.05.2023. SIDBI has been appointed as Project Management Agency (PMA) for implementation of Scheme.

3.3 Non-schematic interventions for Promotion of Medical Devices Sector

(i) Preference to local suppliers in public procurement

Department of Pharmaceuticals is the nodal department for implementation of Department for Promotion of Industry and Internal Trade (DPIIT) Order for providing purchase preference in public procurement. In accordance with the revised Public Procurement (Preference to Make in India) Order dated 16.09.2020, the Department has issued revised guidelines for implementation of the order for medical device sector on 16.02.2021

The Department vide Order dated 16.02.2021 and 25.03.2021 has also notified 135 & 19 medical devices respectively where there is sufficient local capacity and local competition available in the country, under Para 3(a) of PPO Order dated 16.09.2020. This will enable procurement of these notified medical devices only from the "Class-I local suppliers".

(ii) National Medical Device Policy

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for the prevention, diagnosis, treatment and management of medical conditions, diseases, illnesses, and disabilities. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and health insurance industry, thereby helping achieve the key values enshrined in the National Health Policy (NHP) 2017 in terms of provision of good quality, affordable, and comprehensive healthcare to all citizens.

The Union Cabinet approved the National Medical Device Policy, 2023 on 26.04.2023. Policy aims to facilitate medical devices sector and guide it to achieve its missions through a set of strategies that cover six broad areas of interventions.

- Regulatory Streamlining
- Enabling Infrastructure
- Facilitating R&D and Innovation
- Attracting investments in the Sector
- Human Resources Development
- Brand Positioning and Awareness Creation

Regular meetings are being held in the Department to review progress as per the Action Plan.

(iii) Other initiatives for the medical device industry

Constitution of Standing Forum of Medical Devices: The Medical Device sector has seen significant activity in recent years with increase in exports and production of Medical Devices like CT Scan & MRI within the country under the Production Linked Incentive Scheme. The Department has constituted a Standing Forum of Medical Devices Associations to deliberate upon different issues related to Medical Devices that are referred to it by the Department and arrive at a set of inputs from Industry for policy and program formulation which, in turn, would enable the Department to undertake consultation with the wider range of stakeholders including regulatory authorities.

Reconstitution of *"National Medical Devices Promotion Council (NMDPC)":* National Medical Devices Promotion Council (NMDPC) was set up by DPIIT vide OM dated 03.03.2020. Since the Department of Pharmaceuticals has the mandate for the promotion of the Medical Device industry and has created dedicated institutional mechanisms such as Standing Forum of Medical Device Associations, the DPIIT communicated its concurrence to reconstitute the NMDPC under the chairpersonship of Secretary, Department of Pharmaceuticals. Accordingly, *National Medical Devices Promotion Council (NMDPC)* was reconstituted under the Department of Pharmaceuticals since 05.08.2022. 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.

Setting up of the Export Promotion Council for Medical Devices: Export Promotion Council for Medical Devices was established on 22.05.2023 with headquarters in YEIDA, Greater Noida, Uttar Pradesh, under the aegis of Department of Pharmaceuticals. The primary objective of EPC-MD is to promote and facilitate exports of medical devices and related products from India.

3.4 Pharma Bureau

Pharma Bureau provides facilitation to investors and resolution of their inter-departmental coordination issues in the Pharmaceutical and Medical Device sector. It consists of technical experts in the area of:

(i) Pharmaceuticals
(ii) Medical Devices
(iii) Project Management
(iv) Legal
(v) FDI
(vi) Media

- Pharma Bureau also provides policy support to Department of Pharmaceuticals for framing incentive schemes for the industry.
- Pharma Bureau is committed to its goal of engagement with the stakeholders of pharmaceutical and medical devices sector and address the critical issues of the sector.
- It also works as the Project Development Cell of the Department.

CHAPTER 4

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARI-YOJANA (PMBJP)

4.1 Background of the Scheme

4.2 Progress of the Scheme

4.3 Achievements during 2023-24

4.4 Jan Aushadhi Diwas Celebration

4.5 Swachhata Special Campaign 3.0

4.6 PMBI Exploration of International Market with HLL

4.7 MoU between Pharmaceuticals and Medical Devices Bureau of India (PMBI) and Small Industrial Development Bank of India (SIDBI)

Chapter 4

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

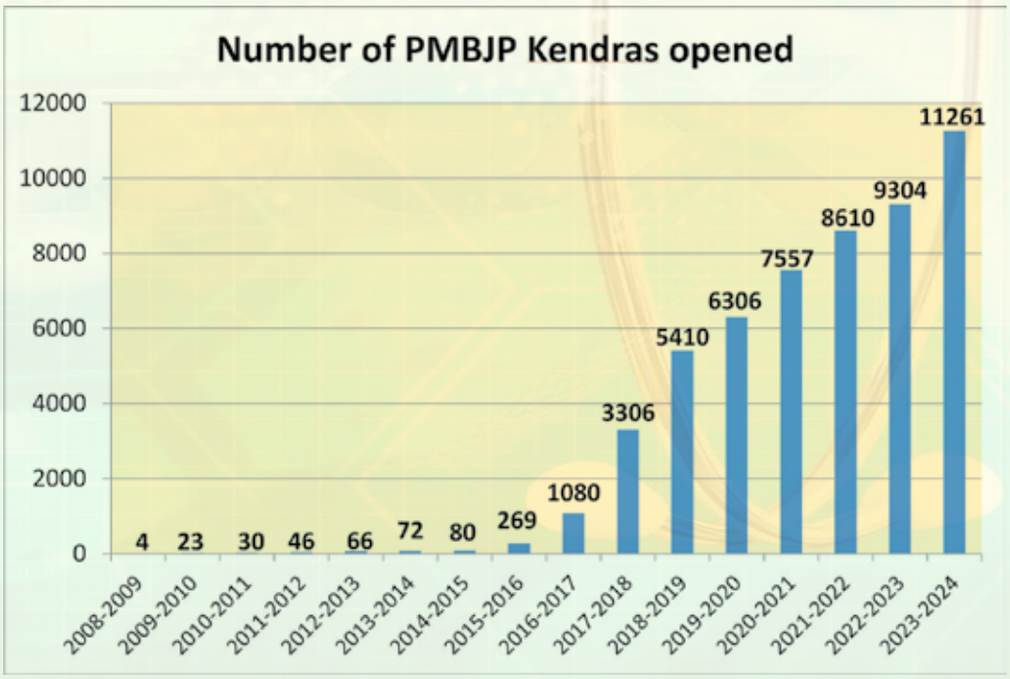
4.1 Background

The *Pradhan Mantri Bhartiya Janaushadhi Pariyojna (PMBJP),* an important initiative by the Government of India which aims at providing affordable and high-quality generic medicines to the masses was launched by the Department in 2008. Since 2015, after impetus from the Hon'ble Prime Minister, PMBJP has shown a highly progressive trend and by 31st March, 2024, 11,261 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) have been opened across India.

Since December 2017, individual entrepreneurs have come forward in large numbers to open PMBJP Jan Aushadhi Kendras, with continual efforts by the Government to motivate them through intensive media campaigns. Year-wise progress in the total number of PMBJP Kendras is shown in Graph 4A.

Graph 4A

(Year-wise total number of PMBJP Kendras)



PMBJP is expanding its product basket and as on 31.03.2024, 2047 drugs and 300 surgicals/ equipment are being sold through PMBJKs.

Implementing Agency

This Scheme is implemented by Pharmaceuticals & Medical Devices Bureau of India (PMBI), earlier known

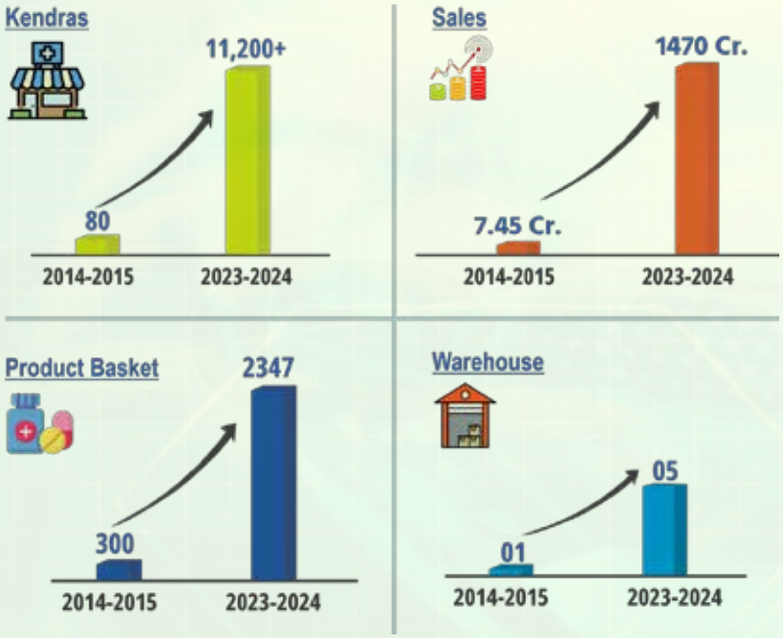
as the Bureau of Pharma Public Sector Undertakings of India (BPPI). The Bureau is headed by a Chief Executive Officer (CEO). The policy decisions are taken by Governing Council, which is set up under the Chairmanship of the Secretary, Department of Pharmaceuticals.

Journey so far

Based on the five year Plan from 2020 to 2025, a target of 10,500 PMBJKs was envisaged. This was later revised to 10,000 PMBJKs by 31.12.2023. Pharmaceuticals & Medical Devices Bureau of India (PMBI), achieved the target before time and as on 31st March, 2024, 11,261 PMBJK's have been opened across the country. Key achievements under the scheme are shown in Graph 4B.

Graph 4B

(Key achievements under the Scheme)



Objectives

- To ensure access to quality medicines for all the sections of the population, especially for the poor and the deprived ones.
- To create awareness about generic medicines through education and publicity to counter the perception that quality is synonymous with high price only.
- To generate employment by engaging individual entrepreneurs in opening of PMBJP Kendra.

Highlights of the Scheme

Incentive under the scheme is being provided as follows:-

Normal Incentive: A margin of 20% on the Retail Price and an incentive @ 15% of monthly purchases, subject to

a ceiling of Rs. 15,000/- per month is given to the Kendra owners (As per Revised Business Plan approved in 45th Governing Council Meeting held on 16.11.2023).

Additional Incentive: - In order to popularize the scheme amongst women, Divyang, Ex-servicemen, SC&ST entrepreneurs and entrepreneurs opening stores in aspirational districts, Himalayan states, Island territories and North-Eastern States, PMBI offers an amount of ₹ 2 lakh, in addition to normal incentives, as under:

i. ₹ 1.50 lakh reimbursement of furniture and fixtures.

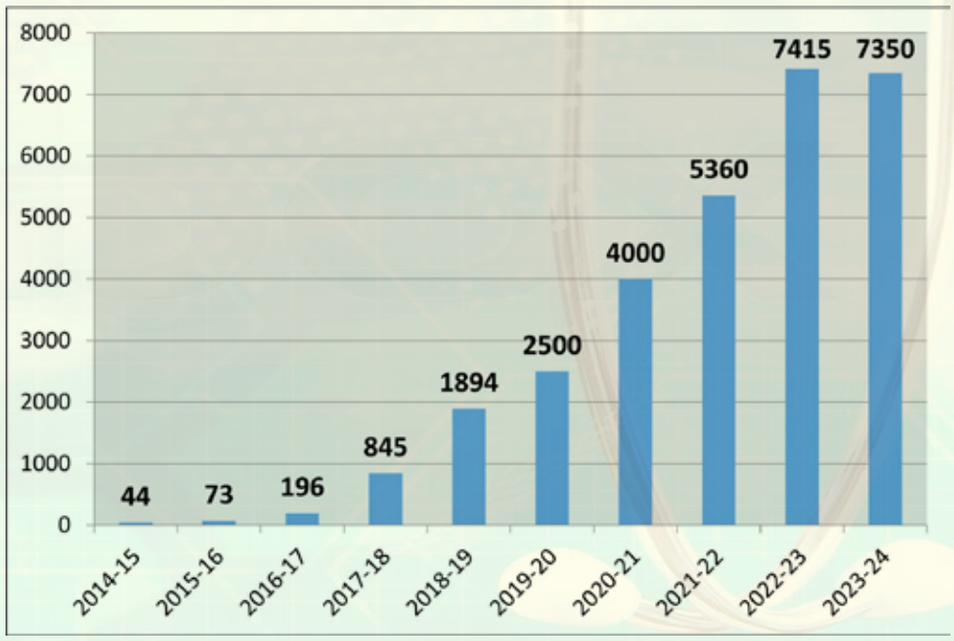
ii. ₹ 0.50 lakh as reimbursement for computer, internet, printer, scanner etc.

Savings to the masses

The scheme is doing justice to its tagline *"Janaushadhi - Seva Bhi, Rozgar Bhi."* PMBJP's affordable healthcare initiative has brought down expenses on healthcare significantly, thereby leading to substantial savings. The details of estimated savings under PMBJP are shown in Graph 4C.

Graph-4C

(Estimated Savings to the People under PMBJP (in Rs. Crore)



Procurement of Medicines

The medicines are procured only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers for ensuring the quality of the products. Apart from this, each batch of drug is tested at laboratories accredited by 'National Accreditation Board for Testing and Calibration Laboratories' (NABL). Only after passing the quality tests, the medicines are dispatched to PMBJP Kendras.

Implementation of IT Enabled Warehousing/Supply Chain System

For smooth supply and products availability, a 360-degree IT-enabled End to End Supply Chain system has

been implemented.

- It comprises one central warehouse at Gurugram and four regional warehouses at Chennai, Bengaluru, Guwahati & Surat.
- Further, it has been planned to open two more warehouses in Western and Central India.
- 36 distributors have also been appointed across States/UTs to strengthen the supply chain system.

Implementation of SAP and POS System

All billing and ordering activities are being carried out with single IT enabled system (SAP)/POS to ensure monitoring at every step in the process. Thus it is ensured that all JAKs are provided with this software to have smooth and transparent ordering and billing process.

Jan Aushadhi SUGAM Mobile App

A mobile application "Janaushadhi Sugam" is a facility for the general public which provides a digital platform by virtue of which they can avail a host of user-friendly services like locating nearby PMBJK (direction guided through Google Maps), searching Janaushadhi medicines and product comparison of generic vs branded medicine in the form of MRP saving

The process is as follows:

Women's Empowerment with PMBJP

Pharmaceuticals and Medical Devices Bureau of India (PMBI), the implementing agency of Pradhan Mantri

Bhartiya Jan Aushadhi Pariyojana (PMBJP), has always given priority to women of the country by giving them special opportunities to open Jan Aushadhi Kendras and become self-dependent. Under the PMBJP, out of 11,261 Jan Aushadhi Kendras, more than 3565 Jan Aushadhi Kendras have been opened by women till March, 2024.

Also, for ensuring their health security and menstrual health wellness, Jan Aushadhi Suvidha Oxo-biodegradable Sanitary Napkins are sold at Rs.1/ per sanitary pad only by Jan Aushadhi Kendras. Jan Aushadhi Suvidha Sanitary Napkins are environment friendly, as these pads are made with Oxo-biodegradable material complying with ASTM D-6954 (biodegradability test) standards. In last four years, over Rs. 53.50 crore Jan Aushadhi Suvidha Sanitary pads have been sold through these Kendras.

4.2 Progress of the Scheme

Table 4A

(Progress of the Scheme)

Financial Year	Number of PMBJP Kendras functional		Sales at MRP (Value in Cr.)
	Net Yearly Addition	Cumulative	
2016-17	811	1080	33
2017-18	2226	3306	141
2018-19	1834	5140	315
2019-20	1166	6306	434
2020-21	1251	7557	666
2021-22	1053	8610	894
2022-23	694	9304	1236
2023-24	1957	11261	1470

4.3 Achievements during 2023-2024

Coverage of the Scheme - As of 31.03.2024, **11,261** PMBJP Kendras are functional across the country. The Pariyojana has marked its presence in almost every district of India.

Creation of new department in PMBI: International Assistance Division (IAD)- Since Covid-19, PMBI has initiated philanthropic activities by supplying medicines to Ministry of External Affairs (MEA) for distribution to other countries. Now with the introduction of a new department in PMBI, this operation is being carried forward with HLL and till March 2024 goods worth more than Rs.1.38 crores have been supplied to Jeddah (for Haj) and to more than 8 countries.

Growth in Therapeutic Categories- PMBJP is progressively increasing its therapeutic categories to cover all major diseases, so that the benefit may be passed on to each and every citizen. The product basket of PMBJP comprises of 2047 drugs and 300 surgicals/ consumables/ equipment.

Launch of new range of Products- Realising the increase in non-communicable diseases burden across the country, PMBJP has launched some new products in Diabetic Range and Protein Range (specially designed for Diabetes and Renal care). These are being sold at 50%-90% lower prices than the similar products on offer in the market. Some other special products like Janaushadhi Protein Bar, Malt based protein named as POSHAN and Janaushadhi Madhurak (Stevia natural sweetener) in form of liquid, tablets/pellets have also been introduced. In the PMBJP product basket under surgicals/equipment, new products, such as Electrical Nebulizer Machine, Digital Blood Pressure Monitor and Medical Steam Vaporiser have also been added.

Steps taken for increasing viability of kendras

i. PMBJP product basket is being expanded, to provide complete range of medicines, covering almost all chronic and acute disease conditions. 288 drugs and 20 surgical equipment have been included in the product basket in last one year.

ii. In order to ensure easy availability of the menstrual health services at affordable prices for women, Jan Aushadhi Suvidha Sanitary Napkins at Rs. 1/- per pad are being made available through PMBJKs across the country. Over 53.50 Crore Jan Aushadhi Suvidha Sanitary Pads have been sold through these Kendras.

iii. Department has taken various steps to ensure market expansion. State Health Departments and associated government authorities have been requested to open Jan Aushadhi Stores in various government hospitals by providing rent free spaces to private individuals.

iv. To ensure awareness among masses, various media platforms like print, outdoor, TV & social media, etc. are being used regularly. Promotion workshops are also being organized across India with stores owners, doctors and other important dignitaries.

PACS (Primary Agricultural Credit Society)

- For rural coverage, PMBJP is being integrated with the cooperative sector to maximize benefits of PMBJP Kendras in interior parts of the country.
- This is aimed at passing the benefits of PMBJP to both consumers and entrepreneurs who wants to start their own business.
- Till 31st March 2024, 2600+ PACS have been given initial approval letter to open Janaushadhi Kendra.

4.4 Jan Aushadhi Diwas Celebration

The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) celebrated 5th Jan Aushadhi Diwas 2023 on 7th March 2023 with the theme "जन औषधि - सस्ती भी अच्छी भी". The weeklong awareness program kickstarted with Jan Aushadhi Jan Chetna Abhiyan on 1St March 2023 and ended with the celebrations of Jan Aushadhi Diwas on 7th March 2023, with grand events conducted at State / UT level across the country.

All activities and celebrations were conducted with close coordination of PMBJK owners, Beneficiaries, State/UT officials, Public Representatives, Doctors, Health Workers, Nurses, Pharmacists, Jan Aushadhi Mitras and other stakeholders.

All the Jan Aushadhi Kendras owners were motivated to participate in the weeklong celebrations with focus on day wise theme to cover all the sections of the society including women, children, senior citizens, volunteers and health professionals.

Flagging of the Chattisgarh Sampark Kranti Express from Hazrat Nizamuddin Railway Station, taking the message of Jan Aushadhi to the masses.

4.5 Swachhata Special Campaign 3.0

PMBI along with its all its Kendras (Pradhan Mantri Bhartiya Janaushadhi Kendra) enthusiastically participated in Swachhata Special Campaign 3.0, demonstrating a strong commitment to cleanliness and hygiene. During the campaign period from 1st Oct-31st Oct, 2023, all employees/officials and Kendra owners engaged in various activities, such as clean-up drives, awareness programs, and waste management initiatives, to contribute to a cleaner and healthier environment. PMBI also used social media to conduct outreach programmes with the

public and highlighted its efforts under Special Campaign 3.0 and spread it through social media platforms of the Ministry.

Cleaning Work Undertaken During Special Campaign 3.0

4.6 PMBI exploration of International Market with HLL

Carrying forward the vision of Hon'ble Prime Minister to implement the PMBJP scheme in other countries, a Memorandum of Understanding (MoU) was signed between Pharmaceuticals & Medical Devices Bureau of India (PMBI) and HLL Lifecare Ltd on 8th January 2024 to work together to export Jan Aushadhi generic medicines to other nations.

Signing of MoU Between PMBI & HCL

4.7 MoU between Pharmaceuticals and Medical Devices Bureau of India (PMBI) and Small Industrial Development Bank of India (SIDBI)

MoU was also signed between SIDBI and PMBI on 12th March 2024 in New Delhi to provide financing to applicants, who want to open Jan Aushadhi Kendras through project loan at competitive terms and to the existing Jan Aushadhi Kendras by way of invoice based financing, across the country.

Lounch of Credit Program for Jan Aushadhi Kendra

CHAPTER 5

National Institutes of Pharmaceutical Education & Research (NIPERs)

5.1 Background

5.2 NIPER SAS Nagar (Mohali)

5.3 NIPER Kolkata

5.4 NIPER Raebareli

5.5 NIPER Hyderabad

5.6 NIPER Hajipur

5.7 NIPER Guwahati

5.8 NIPER Ahmedabad

CHAPTER 5

National Institutes of Pharmaceutical Education & Research (NIPERs)

5.1 Background

Indian pharma industry is a global leader in generic drugs. To acquire a leadership position in drug discovery and development and to continue to excel in formulations, the Government recognized that human resources/ talent pool is very critical. In order to nurture and provide skilled resources to the pharma and meditech sector, National Institute of Pharmaceutical education and Research were established. National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar (Mohali) was set up as a registered society under the Societies Registration Act, 1860 and given statutory recognition by an Act of Parliament, viz., NIPER Act, 1998 and was declared as an Institute of National Importance.

After the amendment of the Act in 2007, six more NIPERs were set up at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli. The present status of allotment of land and construction of campuses of the NIPERs is as under:

Table 5A

Status of allotment of land and construction of campuses of the NIPERs

Name of NIPER	Estt.	Status of allotment of land and construction
Ahmedabad	2007	About 60 acres land in Gandhinagar, Gujarat has been allocated for NIPER, Ahmedabad and M/s Hindustan Steelworks Corporation Limited (HSCL) is selected as Project Management Consultant (PMC). Hon'ble Home Minister inaugurated the permanent campus of NIPER-Ahmedabad on 30.09.2023 and dedicated to the nation.
Guwahati	2008	About 66.02 acres land at Village Sila, Changsari Dist, Kamrup was allocated for NIPER Guwahati and M/s Engineering Projects India Limited (EPIL) was selected as Project Management Consultant (PMC). Construction of NIPER-Guwahati campus has been completed and the institute has started functioning from its new campus. Institute dedicated to Nation on 12.01.2024.
Hajipur	2007	About 12.5 acres of land at EPIP Campus, Industrial Area at Hajipur has been allocated by Government of Bihar for NIPER, Hajipur. MoU has been signed with CPWD for construction of campus. The work for construction of campus at NIPER-Hajipur awarded to M/s Tribeni Constructions Limited by CPWD, the PMC.
Hyderabad	2007	About 50 acres of IDPL's land has been transferred to NIPER-Hyderabad for construction of its permanent campus. M/s NPCC has been appointed as PMC for construction of permanent campus. The work for construction of campus of NIPER-Hyderabad has been awarded to M/s NJR Constructions Private Limited by NPCC. Foundation stone laying ceremony was organised on January 12, 2024.
Kolkata	2007	About 10 acres of land at Mouza-Gopalpur, P.S. Kalyani, Dist Nadia has been allocated by Government of West Bengal. Further, the Department has allotted 20.55 acres of land of BCPL's plant at Kolkata for construction of permanent campus of NIPER, Kolkata. MoU has been signed with CPWD for construction of campus. The work for construction of campus of NIPER, Kolkata is awarded to M/s Jupiter International by CPWD. Foundation stone for the campus was laid by Hon'ble Minister (C&F) on 25.08.2023.

Raebareli	2008	About 49 acres land at Village Vinayakpur, Pargana Bachrawan, Tehsil Maharajganj, Raebareli has been allocated for NIPER, Raebareli. MoU has been signed with CPWD for construction of campus. The work for construction of campus of NIPER-Raebareli awarded to M/s R.K. The Aluminium People by CPWD, the PMC. Foundation stone laying ceremony of NIPER, Raebareli was organised on January 12, 2024.

5.1.1 Chairpersons of the Board of Governors and Directors of NIPERs

The details of the Chairpersons of the Board of Governors (BoGs) and Directors of NIPERs are as under:

Table 5B

Details of Chairpersons of the Board of Governors and Directors of NIPERs

NIPER	Chairperson, BoG	Director
Ahmedabad	To be nominated	Dr. Shailendra Saraf
Guwahati	To be nominated	Dr. USN Murty
Hajipur	Prof. Samit Chattopadhyay, Chair Professor, BITS-Pilani, Goa Campus	Dr. V. Ravichandiran (Additional Charge)
Raebareli	Dr. (Ms.) Madhu Dikshit, Former Director, CSIR-CDRI	Prof. Shubhini A. Saraf
Kolkata	Prof. P Balaram, Former Director, IISc, Bengaluru	Dr. V. Ravichandiran
Hyderabad	Dr. Satyanarayana Chava, CEO, Laurus Labs, Hyderabad	Dr. Shailendra Saraf (Additional Charge)
Mohali	Dr. Girish Sahni, Former DG, CSIR	Prof. Dulal Panda

5.1.2 Aims and objectives

Aims and objectives of the NIPERs are:

(i) To nurture and promote quality and excellence in pharmaceutical education and research.

(ii) To concentrate on courses leading to master's degree, doctoral and post-doctoral courses and research in pharmaceutical education.

(iii) To hold examinations and grant degrees.

(iv) To confer honorary awards or other distinctions.

(v) To cooperate with educational or other institutions having objectives wholly or partly similar to those of the institute by exchange of faculty members and scholars and generally in such manner as may be conducive to their common objective.

(vi) To conduct courses for teachers, pharmaceutical technologies, community and hospital pharmacists and other professionals.

(vii) To collect and maintain world literature on pharmaceutical and related sciences and technology so as to develop an information centre of its own kind for other institutions within the country and in the developing world.

(viii) To create a central faculty of pharmaceutical instrumentation and analysis for use by the research within and outside the institute.

(ix) To have a centre to experiment and innovate and to train teachers and other workers in the art or science or pharmaceutical teaching.

(x) To develop a world level centre for the creation of new knowledge and transmission of existing information in pharmaceutical areas with focus on national, educational, professional, and industrial commitments.

(xi) To develop a multi-disciplinary approach in carrying out research and training of pharmaceutical manpower so that the larger interests of the profession, academia and pharmaceutical industry are better served and a pharmaceutical work culture is evolved which is in tune with the changing world trends and patterns of pharmaceutical education and research.

(xii) To organize national or international symposia, seminars and conferences in selected areas of pharmaceutical education, from time to time.

(xiii) To arrange courses catering to the special needs of developing countries.

(xiv) To act as nucleus for interaction between academics and industry by encouraging the exchange of scientist and other technical staff between the institute and the industry and by undertaking sponsored and funded research as well as consultancy projects by the institute and

(xv) To pay due attention to studies on the distribution and usage of drugs by the rural masses, considering the socio-economic spectrum in the country.

5.1.3 National Institutional Ranking Framework (NIRF)

As per National Institutional Ranking Framework of the Ministry of Education, under the 'Pharmacy' category, NIPERs have remained amongst the top pharmacy institute in the country. The details of the year-wise National Institutional Ranking Framework (NIRF) issued by Ministry of Education are as under:

Table 5C

(Details of year-wise NIRF Ranking of NIPERS)

NIPERs	2017	2018	2019	2020	2021	2022	2023
Mohali	2nd	1st	3rd	3rd	4th	4th	6th
Hyderabad	5th	6th	6th	5th	6th	2nd	**1st**
Ahmedabad	-	14th	9th	8th	10th	10th	13th
Guwahati	-	-	-	11th	19th	13th	12th
Raebareli	-	-	-	18th	13th	27th	14th
Kolkata	-	-	-	27th	33rd	-	32nd
Hajipur						75th	44th

5.1.4 Funds released during last 5 years

The details of funds released to NIPERs during last 5 years are as under:

Table 5D

Release of Funds to NIPERs during last 5 years

In Rs crore

NIPERs	2019-20	2020-21	2021-22	2022-23	2023-24	Total
Mohali	30.60	60.55	51.00	84.05	58.00	284.20
Ahmedabad	18.50	60.50	54.00	76.10	33.42	242.52
Guwahati	43.90	79.45	59.45	106.49	22.88	312.17
Hajipur	5.00	26.00	41.00	37.00	18.00	127.00
Hyderabad	27.00	44.50	72.91	69.54	34.00	247.95
Kolkata	18.00	34.82	47.64	45.45	43.50	189.41
Raebareli	17.01	28.00	46.00	32.50	19.00	142.51
Total	**160.01**	**333.82**	**372.00**	**451.13**	**228.8**	**1545.76**

5.1.5 Admission process and fellowships:

The admissions to various branches in MS/PhD in all the seven NIPERs are made through a common Joint Entrance Examination (JEE) held every year in the month of June/July. The applicants, who have qualified Graduate Pharmacy Aptitude Test (GPAT), are eligible to appear in the common JEE examination. Successful candidates of JEE get admission in NIPERs through counselling. All students receive fellowship, as under:

MS (Pharma): ₹12,400/- per month

PhD: ₹ 37,000- 42,000/ - per month

5.1.6 Amendment of the NIPER Act:

Some amendments have been made recently in the NIPER Act, 1998 which, inter-alia, include:

(a) Clarifying that existing NIPERs and similar institutes set up subsequently would be institutes of national importance;

(b) Rationalizing strength of BoG of individual NIPERs from 23 members to 12 members;

(c) Widening the nature and scope of courses to include undergraduate, integrated courses and other short-term courses, etc.;

(d) Setting up of a NIPER Council under Hon'ble Minister and indicating its composition, power and functions etc.; and

(e) Incorporating a provision to issue directions by the Central Government.

Pursuant thereto, NIPER Council has been constituted under the chairmanship of Hon'ble Minister of Chemicals & Fertilizers. First NIPER Council meeting was held on 28.02.23 in the Conference Hall, National Institute of Health and Family Welfare, New Delhi, under the chairmanship of the Hon'ble Minister for Chemicals & Fertilizers.

5.2 NIPER S.A.S. Nagar (Mohali)

NIPER S.A.S. Nagar was set up vide NIPER Act, 1998 as an "Institute of National Importance". The Institute has been conceptualized, planned and set up to provide leadership in pharmaceutical sciences and related areas not only within the country, but also to the countries in South East Asia, South Asia and Africa. It is only one of its kind in its domain and is highly valued for its outcomes, namely well trained and focused human resources (students/researchers); publications of high impact and novel processes/outputs of industrial relevance in its chosen areas of working.

NIPER S.A.S. Nagar has a campus that caters for research facilities, three boys' hostels with intake capacity of 472 and a girls' hostel with intake capacity of 220, a married students' hostel with intake capacity of 18, 133 quarters (Type–II – 12, Type-III – 36, Type-IV – 30, Type-V – 42, Type-VI – 12, Director Bungalow – 1) for NIPER staff. Board of Governors has been constituted to oversee its functioning. NIPER offers Masters', integrated Masters-Ph.D. and Ph.D. degrees in 17 streams and caters to the various needs of pharmaceutical industry.

5.2.1 Achievements:

Academic excellence: In 2023-24, the Institute has published 202 articles in journals of repute. Institute has filed 237 patents out of which 131 have been granted. Since the inception of academic programme, 4572 students have passed out (Masters 3397, MBA 777 & Ph.D. 398).

5.2.2 Research areas in NIPER S.A.S. Nagar:

A. **Neglected diseases** - Research is carried out in the areas of Leishmaniasis, tuberculosis, and malaria. New molecules are being synthesized and their mechanisms of action are being worked out.

B. **Other diseases-** Metabolic pathways in diseases like inflammation, infection, cancer, diabetes, obesity, Parkinson's disease, neurodegeneration is being worked out. Mitochondrial dysfunction and its involvement in the pathophysiology of diseases, exploring newer druggable targets for diabetic nephropathy/ End-stage renal disease (ESRD), mitigating chemotherapy-induced neuropathic pain, etc.

C. **Drug development and formulation**

i. Improvement of oral bioavailability, synergistic anticancer efficacy and reduced toxicity of drugs New formulations and Novel Drug Delivery System (NDDS).

ii. Green sustainable synthesis of Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs) and intermediates

iii. Standardization of Herbal drugs and formulations

iv. Toxicological studies of in-house developed molecules and those received from the industry

D. Other areas

i. Biopharmaceuticals
ii. Herbal medicines and Nutraceuticals
iii. Epigenetics
iv. Chemo-enzymatic synthesis of drugs
v. Monograph on herbals is being developed
vi. Study of the effect of aptamers on stabilization of misfolded proteins
vii. Assessment of an appropriate and reliable method to diagnose neuropathic pain
viii. Artificial intelligence, Machine Learning, Big data Analytics
ix. Utility of Physiology Based Pharmacokinetic (PBPK) Modelling in prediction of PK of drugs in special populations and in the study of food effects on drug PK
x. Health Economics and Outcomes Research (HEOR) and pharmacovigilance

5.2.3 Academic and Non –academic Staff

Table 5E

(Details of Academic and Non-academic staff)

Manpower	In Position
Academic	28+1(Director)
Non-Academic	118

5.2.4 Total funds allocated by the Government during the last 5 years

Table 5F

Details of funds allocated during the last 5 years

(Rs in crores)

Heads of Allocation	2019-20	2020-21	2021-22	2022-23	2023-24
GIA-SALARY	17.60	29.55	25.00	24.00	29.00
GIA- GENERAL	13.00	16.00	22.00	30.00	29.00
GIA-CCA (Creation of Capital Assets)	-	15.00	4.00	30.05	-
TOTAL	**30.60**	**60.55**	**51.00**	**84.05**	**58.00**

5.2.5 Students

Degrees/programmes offered and Subjects offered year-wise with currently enrolled status:

Table 5G

(Year-wise details of Degrees/Programmes offered and subjects offered)

Level Masters/ Doctoral	Degree MS/ MBA/ M.Tech/ Ph. D	Discipline	Admission Year							
YEARS			2016-17	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24
Masters'	M.S. (Pharm.)	Medicinal Chemistry	42	32	25	28	26	28	28	29
Doctoral	PhD		5	8	2	2	0	6	13	9
Masters+ Ph.D	Integrated PhD		-	-	-	-	-	-	1	-
Masters'	M.S. (Pharm.)	Pharma-co-informatics	18	16	19	17	17	20	20	20
Doctoral	PhD		1	2	2	0	1	6	4	6
Masters'	M.S. (Pharm.)	Natural Products	12	10	12	13	13	14	15	23
Doctoral	PhD		1	2	2	4	0	7	6	9
Masters'	M.S. (Pharm.)	Traditional Medicine	5	3	2	5	5	5	5	5
Masters'	M.S. (Pharm.)	Pharmaceutical Analysis	9	9	8	9	9	9	9	11
Doctoral	PhD		0	1	0	0	0	0	3	3
Masters + Ph.D	Integrated PhD		-	-	-	-	-	-	1	-
Masters'	M.S. (Pharm.)	-	23	24	18	18	18	20	24	30
Doctoral	PhD	-	6	3	3	4	1	7	9	11

Masters + Ph.D	Integrated PhD	Pharmacology & Toxicology	-	-	-	-	-	-	1	-
Masters'	M.S. (Pharm.)	Regulatory Toxicology	10	8	8	9	9	9	9	10
Masters + Ph.D	Integrated PhD		-	-	-	-	-	-	-	1
Masters'	M.Tech. (Pharm.)	Pharmaceutical Technology (Formulations)	7	6	6	7	7	7	7	9
Masters'	M.Tech. (Pharm.)	Pharmaceutical Technology (Process Chemistry)	14	16	16	17	17	16	17	18
Doctoral	PhD		0	2	4	1	1	4	4	6
Masters'	M.Tech. (Pharm.)	Pharmaceutical Technology (Biotechnology)	9	10	8	10	11	10	11	12
Doctoral	PhD		0	0	2	0	0	0	0	3
Masters'	M.S. (Pharm.)	Pharmaceutics	17	19	18	20	20	22	24	24
Doctoral	PhD		6	6	1	3	1	7	0	9
Masters + Ph.D	Integrated PhD		-	-	-	-	-	-	-	1
Masters'	M.S. (Pharm.)	Biotechnology	30	30	31	35	35	35	39	28
Doctoral	PhD		2	7	5	0	3	9	9	12
-	Integrated PhD		-	-	-	-	-	-	-	1
Masters'	M.Pharm.	Pharmacy Practice	7	8	8	9	9	9	9	9
-		Clinical Research	8	8	7	9	9	9	9	9
Doctoral	PhD	Pharmacy Practice	1	2	1	1	1	5	4	4
Masters + Ph.D	Integrated PhD		-	-	-	-	-	-	-	1

Masters	M. Tech	Medical Devices	-	-	-	-	11	11	10	9
Doctoral	PhD		0	0	0	0	0	0	0	0
Masters	M. Tech	Bio-pharmaceuticals	-	-	-	-	-	-	-	11
Masters'	MBA	Pharm. Management	40	42	42	44	46	47	48	49
Doctoral	PhD		0	0	0	2	1	0	0	1

Total Currently Enrolled-

Ph.D	**: 213**
Masters (2022+2023)	**: 489**
MBA (2022+2023)	**: 96**
Masters + Ph.D	**: 9**
Total	**: 807**

5.2.6 Teacher-Student ratio

Table 5H

(Teacher-Student ratio)

Course/Ratio	
	Total Ratio (S:F)
Ph.D.	213/28=7.60:1
Masters' (Science)	489/26=18.81:1
MBA (Pharm.)	96/2=48:1
Total	**807/28=28.82:1**

5.2.7 Placement

Table 5I

(Placements status: in campus/off-campus)

Academic Year	Total Students	No. of students Interested	No. of students placed	% of Students placed	Average Package Rs. in lakh
2017-19	242	232	155	66.81%	4.73
2018-20	224	188	153	81.38%	5.03
2019-21	248	218	158	72.47%	5.54
2020-22	252	243	200	82.30%	7.26
2021-23	268	254	213	83.86%	7.16

Most of the students, who are interested, get placements in industry. Some master's students prefer to get admission in PhD within country or outside the country. Few other students are interested in setting up their own businesses.

5.2.8 Innovation/knowledge transfer

i. Patents and Commercialization: 237(filed)/131 (granted)/07 (licensed) since inception.

ii. Total revenue generated in the F.Y. 2022-23 - Rs 13.30 Cr; in the F.Y.2023-24 - Rs 12.42 Cr (tentative).

iii. H Index - NIPER S.A.S. Nagar is 137.

iv. H Index and Citation per faculty for NIPER S.A.S. is one of the highest among the premier research institutes of India.

v. 11 current faculty members and 5 former faculty members are listed in the Top 2 % list of Stanford University in 2023.

5.2.9 Impact of NIPER

- The success of NIPER, S.A.S. Nagar has encouraged the GoI to set up more NIPERs across the country to meet the growing demands of the pharmaceutical sector. NIPER S.A.S. Nagar was ranked 1st in India, 7th in Asia, and 54th in the world in the 2023 QS World University Rankings in Pharmacy and Pharmacology category and 6th Rank in Pharmacy category in MoE NIRF rankings.
- NIPER S.A.S. Nagar has carried out training programmes for personnel from India and abroad under ITEC capacity building programmes (World Bank- sponsored) and Small and Medium Pharmaceuticals Industry Centre (SMPIC).
- NIPER S.A.S. Nagar organized a special ITEC program on "Developing Training and Capacity Model ITEC Program on Pradhan Mantri Bhartiya Janaushadhi Pariyojna" from August 28 to September 1, 2023
- Skill development training under Skill Vigyan Program was sanctioned under Punjab State Council for Science & Technology (PSCST) & Department of Biotechnology (DBT) program for different roles in pharmaceutical industry.
- Training and analytical services provided to small and medium-scale enterprises (SMEs): Setting up of a Centre for SMEs
- Member of Committee evaluating or monitoring 'Investigational New Drugs'(IND) applications, PLI scheme, Assistance to Pharmaceutical Industry for Common Facilities (APICF), etc
- NIPER S.A.S. Nagar is the knowledge partner for Department of Industry, Himachal Pradesh for establishing the Medical Devices Park.
- The institute is working with the Department of Industry, Himachal Pradesh as part of SIA to establish Bulk Drug Park at Himachal Pradesh.
- Member of Committee revising Indian pharmacopeia
- Contribution of monographs to Ayurvedic pharmacopeia of India
- 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 MHFW (GOI)

Photographs and details of events (seminar / webinar / other events) conducted at NIPER, S.A.S. Nagar


14th Convocation of NIPER SAS Nagar organized on 14.10.23


Foundation Day-2024 celebration on 15.02.2024

A Conclave "SAMPRABHAV – Union of Magnates" (3rd edition) organized by the Dept. of Pharma Management from 17 to 18.02.2024 attended by 1000 participants nationwide

5.3 NIPER Kolkata

National Institute of Pharmaceutical Education & Research Kolkata (NIPER-Kolkata) was established in 2007 vide NIPER Act as an Institute of National Importance and is presently functioning from its interim campus at Kolkata to promote excellence in the field of pharmaceutical education and research and contribute to the growth of the pharmaceutical industry in India through teaching, research, and scholarship. The Institute aspires to serve as a premium institute for pharmaceutical education and allied research and to start a new era of pharmaceutical development in India. Currently, NIPER Kolkata is offering eight disciplines out of which new discipline of Biopharmaceuticals (M. Tech Program) was introduced in the Academic Session 2023.

5.3.1 Achievements:

5.3.2 Academics

- A total of 75 students completed their Master's degree in 2023.
- A total of 9 research scholars were awarded PhD degrees in 2023.
- In 2023, a total of 112 students were admitted for Master's degrees, 2 in integrated PhD,
- and 26 research scholars were admitted to PhD.
- NIPER Kolkata ranked 32nd in the NIRF Ranking 2023.

5.3.3 Teacher-Student Ratio: 1:14

The academic and research activities of the institute are strengthened by regular and contractual faculty.

5.3.4 Placements Statistics:

For FY-2023-24, out of 75 students, 58 students (77%) were placed, and 13 students (17%) opted for higher studies.

5.3.5 Recruitment of Regular Faculty and Staff

- The Institute recruited 2 faculties (1- regular; 1- on contract) and 4 non-teaching staff during the year.
- By the end of Calendar Year 2023, the strength of the Teaching and Non-Teaching staff is as follows
    - Regular Faculty: 16
    - Regular Non-Teaching Staff: 19
    - Contractual Faculty: 03
    - DST Inspire Faculty: 01
    - Contractual Research Staff: 11
    - Contractual Non-Teaching Staff: 0

5.3.6 Campus Development:

- Land measuring 20.55 acres at Panihati has been allocated by Department of Pharmaceuticals (DoP), and 78.56 crores has been sanctioned & approved for establishing permanent campus (10972 sq.m) of NIPER Kolkata.
- Foundation Stone Laying Ceremony at Panihati, Kolkata, was held on 25th August 2023 by the Hon'ble Minister, Dr. Mansukh Mandaviya, Union Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India.
- The construction work of the permanent campus of NIPER-Kolkata at Panihati is in progress, and 34% of the construction work has been completed.

5.3.7 Awards & Honors:

Faculty:

- Dr. Pallab Datta, Assistant Professor, NIPER Kolkata has been recognized as one of the world's top 2% of scientists, according to the latest profile review conducted by Stanford University and Elsevier.
- Dr. Subramanian Natesan, Professor, received a Marshall Award for Researcher from Indian Chitin and Chitosan Society, December 2023.

Students:

- Two students from NIPER Kolkata bagged prizes at International Conference on New Horizons in Drugs, Devices & Diagnostics on 14th - 16th September 2023, held at NIPER Hyderabad.
- Mr. Tapasvi Patel from NIPER Kolkata got a prize in the International Conference cum Workshop on Artificial Intelligence Solutions for Pharmaceutical Research and Knowledge (AI-SPARK 2023) from 9th - 11th October 2023.
- Ms. Superna Banerjee from NIPER Kolkata received Best Poster Award in PHARMACON 2023 at NIPER Hyderabad.
- Mr. Victor Hmingthansanga from NIPER Kolkata received Best Poster Presentation Award in international conference on chitosan and 10th Indian Chitin and chitosan symposium held at Kolkata.
- Ms. Superna Banerjee from NIPER Kolkata received 3rd prize in oral presentation in international conference on chitosan and 10th Indian Chitin and chitosan symposium held at Kolkata.
- Ms. Iram Saba from NIPER Kolkata won first prize in poster presentation at 3rd international conference on new horizon in drug discovery and development process, Admas University, Kolkata.
- Ms. Sujatha Das from NIPER Kolkata won third prize in poster presentation at 3rd International conference on newhorizon in drug discovery and development process, Admas University, Kolkata.

5.3.8 Major Events

36 online/offline events were conducted from April, 2023 to March, 2024 in which 4990 participants attended the events from all over India. The experts were invited from various prestigious institutions across the world.

Table 5J

List of Major Events held during 2023-24

Date	Event Title
12.04.2023	Symposium on Pharmacological Approaches for Chronic Inflammation and its Complications
21.07.2023 & 22.07.2023	International Symposium on "Recent Advances in Cancer Therapeutics"
28.07.2023	11th Convocation of NIPER Kolkata
25.08.2023	NIPER Kolkata Foundation Stone Laying Ceremony at Panihati, Kolkata
20.12.2023	16th Foundation Day of NIPER Kolkata
26.12.2023	Special Invited Talk on Proteomics and its Applications in Biopharmaceuticals
03.01.2024 & 04.01.2024	Academia-Industry Meeting on Development of Biopharmaceuticals
11.01.2024	Empowering Future Entrepreneurs: Unveiling the Startup Spectrum in India, Bridging Knowledge Gaps, and Navigating Current Trends
08.12.2023 & 09.12.2023	International Conference on Chitosan & 10th Indian Chitin Chitosan Symposium

5.3.9 Research:

- Institute has received a project for Efficient Process Development Strategies for Prevalent "Rare Disease" Drugs to address Duchenne Muscular Dystrophy (DMD) such as Exondys51, Eliglustat and Tezacaftor with a fund of Rs. 15 crores from the Department of Science & Technology, New Delhi.
- The institute has published 107 international peer-reviewed publications during 2023-2024. Since its inception, the institute has 497 publications.
- Total 7 patents have been filed during 2023-2024. Since its inception, the institute hasfiled 11 patents.
- The institute is coordinating the Common Research Program (CRP) of NIPERs and the following projects are being carried out by NIPER Kolkata.

CRP - Biological Sciences

- Phytopharmaceutical Product development for IBD and colon pain using Terminalia chebula.
- Development of antibiofilm and antimicrobial molecules (enhanced probiotics and antibiotic quantum dots) to tackle S. aureus and E. faecalis infections
- Anti-Snake venom antibodies development against four major snake venoms, which are involved in most of the cases of snake bites, as an adjuvant therapy with currently available antivenins.

CRP – FORMULATION DEVELOPMENT

- Development of delayed-release metformin tablets to deliver to the later part of the intestine to improve the efficacy and decrease the toxicity in kidney-diseased patients

CRP – API/PROCESS CHEMISTRY

- Process Development for API/KSM such as OTBN, Clopidogrel, Tavaborole, Oxcarbazepine

Funded Projects:

Consultancy Projects:

- A project titled "Probiosimilarity of Bifilac Clausi with Enterogermina and other Bacillus Clausii formulations available in the market" from Tablets India Pvt Ltd, Chennai worth Rs. 8 lakhs has been completed.

Research Projects

- Rs. 30 crores have been sanctioned by DoP and DST, New Delhi, for establishing the Centre for Marine Therapeutics.
- Rs. 3.5 crores have been sanctioned for developing Rare Diseases/ Orphan Drugs by DST, New Delhi.
- 16 research projects undertaken by the faculty members of NIPER Kolkata in 2023-24 and currently ongoing.

Ongoing Research

- Novel drug delivery system and 3D bioprinting
- Biomaterial optimization for Medical Devices
- Biosensor development
- Advanced manufacturing of dosage forms.
- Nucleosides as therapeutics agents
- Development of sphingosine inhibitors
- Green Chemistry & Flow Chemistry for API synthesis
- Targeting biofilms and quorum sensing.
- Development of DNA-based therapeutics and diagnostic tools.
- Structural bioinformatics: new drug discovery/repurposing for Infectious Diseases and Metabolic disorders.
- Computational designing of anti-microbial agents.
- Metabolic bio-engineering for the production of small molecules
- Transcriptomics and Proteomic profiling of phytopharmaceuticals and herbal formulations
- Diabetes mediated non-alcoholic steatohepatitis and hepatocellular carcinoma: Pharmacological and biochemical characterization.
- Diabetes-associated neurological complications
- Genome editing in immune biotechnology

- Phytochemistry; chemicals transformation: herbal products analysis
- Network Pharmacology of herbal medicines in respiratory diseases.
- Phytopharmaceuticals development
- Standardization & fingerprinting of natural products
- Metabolite Profiling, Pharmacokinetics of herbal drugs and herb-drug interactions studies
- Method development and Validation (Analytical & Bioanalytical)

Research Initiatives:

(a) NIPER Kolkata Research Council: The institute has established a Research Council with Eminent Scientists in order to provide a roadmap and facilitate the faculty research activities, First meeting of the Council was conducted on 10th November 2023.

(b) Centre of Excellence in Flow Chemistry and Continuous Manufacturing: Institute is in the process of establishing the CoE in Flow Chemistry and Continuous Manufacturing to undertake research and provide expertise, technical consultancy, skilled personnel, and product management technology for the small and big pharmaceutical companies in their adoption of flow chemistry and continuous manufacturing.

(c) Development of anti-aging and anti-cancer agent: Urolithin A

(d) Antibody development for Dengue

(e) Vaccine development for Salmonella infections in poultry farms

(f) Anti-obesity small molecule development

(g) Organoid development

5.3.10 Visit by eminent people

- Hon'ble Minister, Dr. Mansukh Mandaviya, MoHFW and MoCF, Govt. of India for attending foundation stone laying ceremony 2023.
- Prof. Gary Piazza, Auburn University, USA for attending International Symposium On "Recent Advances in Cancer Therapeutics.
- Prof. Murali Dhanasekaran, Auburn University, USA for attending International Symposium On "Recent Advances in Cancer Therapeutics.
- Prof. Deepak K. Saini, IISC Bengaluru for attending Symposium on Pharmacological Approaches for Chronic Inflammation and its Complications.
- Prof. Hiroshi Tamura, Kansai University, Osaka, Japan for attending International Conference on Chitosan & 10th Indian Chitin Chitosan Symposium.
- Prof. Makoto Anraku, Sojo University, Kumamoto, Japan for attending International Conference on Chitosan & 10th Indian Chitin Chitosan Symposium.
- Dr. Wanpen Tachaboonyakiat, Chulalongkorn University, Bangkok, Thailand for attending International Conference on Chitosan & 10th Indian Chitin Chitosan Symposium.

5.3.11 Total funds allocated by the Government during the last 5 years

Table 5K

Details of Funds allocated during the last 5 years

(Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2019-20	16.00	18.00	18.00
2020-21	23.00	34.82	34.82
2021-22	27.64	47.64	47.64
2022-23	50.45	50.45	45.45
2023-24	69.00	43.50	43.50

Table 5L

(Degrees/Programs and disciplines offered Year-Wise with admission status)

Masters/ Doctoral	Courses	Discipline	No. of Students admitted in 2023-24
Masters	M.S. (Pharm.)/ M Tech	Medicinal Chemistry	19
		Natural Products	10
		Pharmacoinformatics	10
		Pharmacology & Toxicology	19
		Pharmaceutics	21
		Pharmaceutical Analysis	13
		Medical Devices	10
		Biopharmaceuticals	10
		Total	**112**
Doctorate	Ph.D.	Medicinal Chemistry	09
		Natural Products	06
		Pharmacoinformatics	01
		Pharmacology & Toxicology	02
		Pharmaceutics	06
		Pharmaceutical Analysis	01
		Medical Devices	01
		Total	**26**
	I-PhD	Pharmacology & Toxicology	02
Total			**140**

5.3.12 Innovation/ Knowledge transfer/ MoUs / MoA signed

- Memorandum of Understanding signed on 13/04/2023 with CSIR-IICB Kolkata and NIPER Kolkata. The

purpose of the MoU is to jointly work on IPR or on the patent.

- Memorandum of Agreement made on 19/06/2023 with National Research Development Corporation, New Delhi and NIPER Kolkata. The purpose of the MoA is providing technology commercialization services.
- Memorandum of Agreement made on 07/08/2023 with NIPER S.A.S Nagar Mohali and NIPER Kolkata. The objective of this MoU is participation in the research and development projects and formulation development for therapeutic use.
- Memorandum of Understanding made on 22/09/2023 between CSIR-Central Leather Research Institute (CSIR) and NIPER Kolkata. The MoU aims to validate the findings on synthetic trachea work carried out at NIPER Kolkata. The MoU is valid for 2 years.
- Memorandum of Agreement made on 27/09/2023 with Chittaranjan National Cancer Institute, Kolkata, and NIPER Kolkata. The objective of the MoU is to undertake collaborative research on developing cancer organoids for drug discovery and theragnostics.
- Memorandum of Agreement made on 11/01/2024 with Jawaharlal Nehru Centre for Advance Scientific Research, Bangalore, and NIPER Kolkata. The objective of the MoU is to undertake collaborative research between both parties.
- Memorandum of Understanding made on 24/01/2024 between Beyond Antibody LLP, Bangalore and NIPER Kolkata. The objective of the MOU is the antibody development for Dengue Virus NS1 protein.
- Memorandum of Understanding made on 20/03/2024 between Central Council for Research in Ayurvedic Sciences – Central Ayurveda Research Institute, Kolkata and NIPER Kolkata. The purpose of this MoU is to carry out the collaborative research project entitled “Preclinical Evaluation and the Molecular Mechanism of Ayush-64 against Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatitis (NASH) in murine model”

5.3.13 Filed Patent Details in 2023-2024

Table 5M

(Patent Details)

Application No.	Dated	CBR No.	Title
202331075837	06.11.2023	15551	A single-step process-scale synthesis of urolithine-A.
202331058995	02.09.2023	12095	Noval Process of Tavaborole
202331058996	02.09.2023	12095	Novel Process of Crisaborole
202311039884	09.06.2023	-	3, 3’- Biindole based florescence dye probe and application thereof
202023102215	10.05.2023	-	A system for synthesizing 4-aminoquinaldine derivatives for treatment of malignancies and infectious diseases
202331025089	01.04.2023	5237	Novel Maleimide derivative Antibody recruiting Molecule to target *E. faecalis*
202331025085	01.04.2023	5236	Benzo [1,4] thiazin-3-one bis-amide derivatives and methods for the preparation thereof

5.3.14 Institution Leadership Impact of NIPER Kolkata

NIPER Kolkata is reaching out to various undergraduate and post-graduate institutions helping them with various research projects. The Institute has undertaken a major research drive towards developing new strategies to tackle infectious disease, metabolic disorders, and neurodegenerative disorders.

Glimpses of the Events organized at NIPER Kolkata

Hon'ble Minister for Health and Family Welfare and Chemicals and Fertilizers visited the Institute

Foundation stone laying ceremony of NIPERK new campus graced by Hon'ble Minister for Health and Family Welfare and Chemicals and Fertilizers, Govt. of India.

International Symposium on recent advances in cancer therapeutics

11th Convocation of NIPER Kolkata graced by Hon'ble Governor of West Bengal

International Conference on Chitosan & 10th Indian Chitin Chitosan Symposium

NIPER Kolkata Foundation Stone Laying Ceremony at Panihati, Kolkata

5.4 NIPER Raebareli

National Institute of Pharmaceutical Education and Research (NIPER), Raebareli was established in 2008. It offers doctoral and masters programs in Medicinal Chemistry, Pharmaceutics, Pharmacology & Toxicology, Regulatory Toxicology and Biotechnology and there are **311** students currently enrolled in the institute. It is currently running from its transit campus in Lucknow with a world class central Instrumentation facility within its premises and an animal house to perform pre-clinical studies.

5.4.1 Achievements: -

- The Division of Pharmaceutics at NIPER-Raebareli developed new technologies for nano-based drug-delivery systems for better delivery of anti-psychotic and anti-tubercular drugs.
- The Institute filed 6 patents during 2022-23.
- The Institute received Rs. 4.36 Crore as extramural research grant for research in the thematic areas of the Institute.
- The Institute has more than 329 publications in last 3 years to its credit with publications in the journals of international repute and contributed 86 Books and Chapters in reputed publications.
- NIPER- Raebareli has various centralized State of Art facilities like Cell Culture Facility, Central Animal Facility, Imaging facility (FT-IR spectrometer, Cary Eclipse, 12-Cell Cary 100 UV and Multi-Mode Plate Reader) and Central Instrumentation Facility.
- Central Instrumentation Facility was created housing sophisticated instruments such as Nuclear Magnetic Resonance (NMR), Zetasizer, , HPLC, Bio analyzer, DSC, DSC for molecules, LC-MS (QTOF-HRMS), Hot Stage Microscope, Flow-cytometry, Animal imaging system, Lyophilizer, Calorimeter, CD Spectrometer, Digital Polarimeter, Probe Sonicator, Confocal system etc.

5.4.2 Academic/Non-Academic staff:

Administrative Staff			: 15
Academic Staff:			
		Associate Professors	: 05
		Assistant Professors	: 10
		Research Associate	: 03
Staff	:	Technical	: 06
		Multi-Tas Staff	: 00

5.4.3 Total funds allocated by the Government during the last 5 years:

Table 5N

(Year-wise Fund allocated to NIPER, Raebareli)

(Rs. in Crore)

Year	Allocation BE	Allocation RE	Total Release
2019-20	16.00	17.01	17.01
2020-21	22.00	28.00	28.00
2021-22	17.00	29.00	46.00
2022-23	46.00	46.00	32.50
2023-24	74.00	22.00	19.00

5.4.4 Students: -

Table 5O

(Degrees/programs and subjects offered year-wise with admission status

Year	M.S. (Pharm)		PhD			Integrated PhD (Started in session 2022-27)	
	Admission	Completion	Admission	Completion		Admission	Completion
2017-19	36	36	05	Completed	**05**	-	-
2018-20	56	56	06 -1= 05	Pursuing		-	-
2019-21	62	60	06	Pursuing		-	-
2020-22	74	74	06 -1= 05	Pursuing		-	-
2021-23	88-1=87	87	19-1=18	Pursuing		-	-
2022-24	113-5=108	Pursuing	28	Pursuing		03	Pursuing
2023-25	112-2=110	Pursuing	26	Pursuing		01	Pursuing
Current Status	**533**	**313**	**93**		**05**	**04**	

5.4.5 Teacher: Student Ratio - **1:16**

5.4.6 Employability/ Placements Status:-

Table 5P

(Year-wise placement status of NIPER-Raebareli)

Year	M.S. (Pharm.)	
	No. of students	Placement (in %)
2015-17	36	25
2016-18	35	100
2017-19	36	98
2018-20	58	90
2019-21	60	90
2020-22	73	92

5.4.7 Awards/ Teachers:

Table 5Q

(Details of Awards received by Teachers)

S.No.	Name	Discipline	Recognition
1	Dr. Sandeep Chaudhary	Associate Professor, Department of Medicinal Chemistry	Honored with Honorary Professor by Perm State University, Perm, Russia.
2	Dr. Rakesh Kumar Singh	Associate Professor, Department of Pharmacology and Toxicology	Secured a place in Stanford University's prestigious global list of top 2 percent scientists
3	Dr. Keerti Jain	Assistant Professor, Department of Pharmaceutics	Secured a place in Stanford University's prestigious global list of top 2 percent scientists
4	Dr. Rahul Shukla	Assistant Professor, Department of Pharmaceutics	Secured a place in Stanford University's prestigious global list of top 2 percent scientists

5.4.8 Research

a. Active Research Areas:

- Neurodegenerative diseases
- Heavy Metal Toxicity
- Japanese Encephalitis
- Tuberculosis
- Development and evaluation of drugs using nano formulations.

b. Development of green and eco-friendly synthetic methods

c. Projects: Ongoing: 13 worth Rs. 4.36 Cr. Approx.

5.4.9 Impact of NIPER

NIPER-Raebareli has emerged as an institution of significance both in academics and research particularly in Central India and has achieved a number of milestones. The pharma industries have shown interest in collaborating with the institute besides providing training to students on short term and long term basis. The institute initiated collaborative projects/ work with national and international academic and research institutes in the area of immediate importance such as *Japanese Encephalitis*, Tuberculosis and Neurodegenerative diseases. An online portal has been created to facilitate seamless sample analysis for drug discovery. The institute plays a valuable role in providing highly skilled human resources for the Indian Pharmaceutical Industry.

Various events/workshops carried out by the institute: -

The 8th Convocation of NIPER, Raebareli was held on 23-09-2023

NIPER, Raebareli celebrated the Swachhata pakhwada.

5.5 NIPER Hyderabad

NIPER Hyderabad is an autonomous body established under the aegis of the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers as a Centre of Excellence for higher education, research, and development in pharmaceutical sciences. The institute has been declared as an "Institute of National Importance" by the Government of India through an Act of Parliament. In pursuance of the decision of the Government of India, NIPER Hyderabad started functioning as one of the six new NIPERs in September 2007, in the premises of IDPL, R&D centre, Balanagar, Hyderabad. The Institute has been serving to develop human resources with excellence through conducting Postgraduate and Ph.D. courses. The students are selected through a Joint Entrance Examination for all the NIPERs every year.

NIPER Hyderabad offers M.S. (Pharm.) in Medicinal Chemistry, Pharmaceutical Analysis, Pharmacology and Toxicology, Pharmaceutics, Regulatory Toxicology, Natural Product, Regulatory Affairs, Pharmacoinformatics & M.Tech (Process Chemistry, Medical Devices), and MBA (Pharmaceutical Managment). In the recent NIRF ranking 2023 given by MHRD, GoI, NIPER-Hyderabad has secured 1st rank in the Pharmacy' category.

The Institute has well-experienced faculty, spacious, ventilated, and well-furnished classrooms and modern laboratories, an excellent auditorium for seminars/conferences, and an extensive library within the campus. Furnished hostel rooms are available for the accommodation of students. Lectures by eminent guest faculty on specialized subjects in the concerned disciplines are also arranged for the benefit of students. Several conferences/workshops have been organized to acquaint the students and faculty with the latest advances in pharmaceutical sciences. Participation of students in the seminars organized by professional bodies is also encouraged for enhancing interaction with researchers in the field of their expertise.

5.5.1 Achievements:

Table 5R

Details of Achievements

S.No.	Particular	Achievements
1	Master Students Passed Out	1552
2	Master Students pursuing course	180
3	Students pursuing Ph.D course	138
4	Doctoral degree awarded	110
5	Patents (filed)	10
6	Research Publications	234
7	Sanctioned extramural research projects	Ongoing Projects: 44

5.5.2 Details of Faculty & Staff:

Regular Faculty	: 19
Regular Staff	: 25
Contractual Faculty	: 05
Contractual Administrative and Technical Staff	: 01

5.5.3 Total funds allocated by the Government during the last 5 years

Table 5S

(Allocation of funds to NIPER, Hyderabad)

(Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2019-20	25.00	27.00	27.00
2020-21	30.50	44.50	44.50
2021-22	38.00	72.91	72.91
2022-23	72.50	72.50	69.54
2023-24	90.00	34.00	34.00

5.5.4 Teacher-Student ratio:

Presently 1:13

5.5.5 Employability/ Placements Status: -

Every year students are placed in reputed companies' like Dr Reddy's Laboratories, Pfizer, Genpact, Troikaa pharmaceuticals, Sanofi Healthcare India Pvt Ltd, Hetero Pharma Pvt Ltd, Novartis Healthcare Private Limited, Aragen Life Sciences Pvt. Ltd., Biocon Biologics Ltd, Aurobindo Pharma, Jodas Pharma, Zydus Pharmaceuticals Limited, Stryker, Sun Pharma, IQVIA, Emcure and Tech Mahindra

Table 5T

Year-wise Placement Status

Year	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Incampus Placements (%)	88	85	82	82	80	83	100	99	90	100	100	100

5.5.6 Teachers

NIPER Hyderabad has some of the most talented and dedicated faculty who came from reputed institutions and have received advanced training abroad as post-doctoral fellows in their specializations. The performance of the faculty is assessed periodically. The assessment is based on the student feedback, output from the research activities and contributions to institutional growth assessed by subject experts.

5.5.7 Core Research areas:

- Integrated Drug Discovery & Product Development Programmes
- Cancer, Inflammation and related proliferative diseases
- Diabetes and other metabolic disorders
- Neurodegenerative diseases
- Infectious diseases
- Psoriasis
- In vitro and in vivo screening
- Development of novel process for NCEs, Bulk Drugs and Intermediates
- Development of Analytical Methods, Impurity Profiling and Stability studies
- Solid state characterization
- Targeted drug delivery systems

5.5.8 Innovation / knowledge transfer

Patents and commercialization - 5 patents filed and 5 granted in areas of Cancer Drug Discovery, Formulation Development and Analytical Method Development

5.5.9 Impact of NIPER:

NIPER Hyderabad has helped in developing skilled human resources in pharmaceutical sciences for the pharmaceutical industry. It serves as a research institute focusing on thrust areas of national and international relevance. The institute has helped in fostering academic and industrial collaborations to address some of the key issues in the pharma sector and the needs of pharmaceutical industry in the country.

5.5.10 Collaborations / MoUs

NIPER-Hyderabad has signed three MoUs with national and international bodies to promote multidimensional research. The principal collaborators are:

i. MoU signed with National Institute of Sowa Rigpa (NISR), Leh, Ministry of Ayush on 19.1.2024

ii. MoU signed with CCRUM, New Delhi, Ministry of Ayush, Govt. of India on 14.12.2023

iii. MoU signed with SVNIT, Surat, Gujarat, India on 10.4.2023

5.5.11 Various events/ Workshops carried out by the Institute: -

NIPER Hyderabad conducted various scientific events and workshops training for students. Following are some photographs of the various events in NIPER, Hyderabad.

Parliamentary Standing Committee Visit to Hyderabad on 26.05.2023

PHARMACON 2023: International Conference on New Horizons in Drugs, Devices & Diagnostics at Kanha Shanti Vanam from 14-16th September, 2023.

5.6 NIPER Hajipur

NIPER Hajipur, established in 2007, was under the mentorship of ICMR-Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna till 31.10.2018. Regular Director assumed charges with effect from 01.11.2018. As Institute of National Importance under the aegis of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, for higher education, research and development in pharmaceutical sciences, the institute provides quality education in pharmaceutical sciences and other related areas. It imparts postgraduate (MS) in pharmacy education and doctoral degree (PhD) in seven (07) specializations, namely

i. M.S and PhD. in Biotechnology,

ii. M.Pharm. and PhD in Pharmacy Practice

iii. M. S. and PhD in Pharmacology & Toxicology

iv. M.S. and PhD in Pharmaceutical Analysis (From 2021-22)

v. M.S. and PhD in Pharmaceutics (From 2021-22)

vi. M.S. and PhD in Regulatory Toxicology (From 2022-23)

vii. M.Tech in Biopharmaceuticals

Table 5U
Annual intake of students- Coursewise

Sr. No.	Department	P.G.	Ph.D.	I.Ph.D.	Total Intake
1	Biotechnology	18	5	-	23
2	Pharmacy Practice	18	2	-	20
3	Pharmacology & Toxicology	18	5	3	26
4	Pharmaceutical Analysis	16	2	2	20
5	Pharmaceutics	16	5	4	25
6	Regulatory Toxicology	14	-	-	14
7	Biopharmaceuticals	10	2	-	12

5.6.1 Achievements

Since its inception, a total of 566 students have passed out (M. Pharm- 546 and PhD- 20), 269 research papers have been published and 20 MoUs have been signed so far, out of those four MoUs were signed during this academic year (2023-24). Out of total 11 patents filed by the Institute, one Indian Patent was filed in 2023.

5.6.2 Details of faculty & staff

Academic : Director & 12 (regular)

Non-Academic : 20 (regular)

5.6.3 Total funds allocated by the Government during the last 5 year

Table 5V

(Fund allocation by the Government to NIPER Hajipur during the last 5 years)

Year	Budget Estimated	Revised Estimated	Total Release (Rs. in Crores)
2019-20	10.50	10.50	5.00
2020-21	15.00	26.00	26.00
2021-22	21.00	41.00	41.00
2022-23	43.00	43.00	37.00
2023-24	63.00	18.00	18.00

5.6.4 Students details

Table 5W

(Category wise details of students)

Students	Male	Female	General	OBC	SC	ST	EWS + PH	Total
PG-II (current) (Batch 2022-24)	49	42	29	38	17	06	01	91
PG-I (current) (Batch 2023-25)	68	41	57	24	12	5	11	109
I.Ph.D. (on roll)	4	3	3	3	1	0	0	7
Ph.D. (on roll)	29	27	27	16	9	3	1	56

5.6.5 Teacher-Student ratio

1:18

5.6.6 Placements

NIPER-Hajipur established the “Training and Placement Cell” in 2021 to cater to the needs of student’s/ research scholars for right career / placement, required knowledge, skill, and aptitude to meet the requirements of the industry. The P&TC is functioning with well-defined objectives and policies on recruitment, internship and training. This cell is responsible for continuous improvement in quality system through maintaining the database of students/scholars and feedback mechanism from time to time.

Objectives of P&TC

- To assist the scholars to choose their career through interactive sessions.
- To arrange career guidance/counseling sessions, and personality development sessions.
- To train the scholars for on/off campus recruitment through mock interview, guidance on interview skills, soft-skills, communication skills.

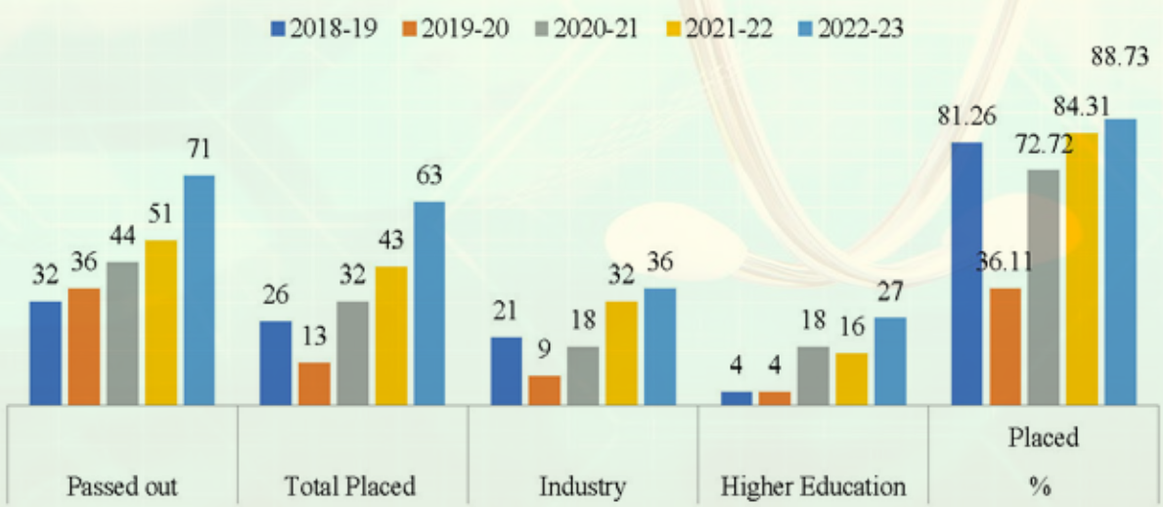
- To connect the current students/ scholars to alumni through alumni interactive sessions.
- To establish industry linkage for placing the students /scholars for training as a part of curricular requirement/ specific skill requirement in coordination with the department in-charge.
- To assure the participation of industry experts/ personnel in interactive sessions/events, seminars, workshops, guest lectures and conferences.
- To maintain the placement data base as required for regulatory submissions and rankings.

Placement Record details of campus placement (as on 31st March 2024) is provided in Table 5X.

Table 5X
(Placement Record details of campus placement)

Year	Total Graduated	Total Placed	Placed in Industry, JRF/project fellow	Opted Higher studies	% Placed
2018-19	32	26	21	4	81.26
2019-20	36	13	9	4	36.11
2020-21	44	32	18	18	72.72
2021-22	51	43	32	16	84.31
2022-23	71	63	36	27	88.73

Graph 5A
(Placement Data of NIPER Hajipur)



The recruiters include reputed companies such as Novartis, Aurobindo, Fryer solutions, IQVIA, Indigene, Taj Pharma, Johnsons & Johnsons, ICMR-RMRIMS (JRF), AIIMS (JRF), Panacea Biotech, Mankind Pharma, TCS, GeneSys, Cognizant, Delveinsight, Cadila, APCER, and Parexel.

5.6.7 Research

Departmental Research Activities: Dept. of Biotechnology

- Nano-medicine based drug delivery for fungal, parasitic and liver diseases
- 3D organ development for replacement of animal models in drug screening
- Nanozyme development for biomedical application against oxidative stress-mediated diseases
- Quantum dots –based drug delivery for antimicrobial resistance
- Novel approaches to regenerative medicine (tissue engineering) and nano-engineering of stem cells
- Recombinant DNA technology using bacterial and Pichia pastoris expression system for enzyme assays and antibody development

Departmental Research Activities: Dept. of Pharmacy Practice

- Pharmacovigilance and Materiovigilance
- Medication safety and drug utilization evaluation including affordability and accessibility
- Infectious diseases & AMR: HIV, TB and Leishmaniasis
- Clinical efficacy and safety studies
- Pharmacogenetic and biomarker studies

Departmental Research Activities: Dept. of Pharmacology & Toxicology and Regulatory Toxicology

- Developing pharmacologic, genetic, and stem cell-based interventions for reversing the mood and cognitive deficits ageing, Alzheimer's disease, and cancer or chemotherapy-induced brain disorders.
- Identify the simple, cost-effective, and easy-to-use biomarkers for detection, prognosis, and therapeutic assessment of neurological disorders, cancer, diabetes, and infectious diseases.
- Pharmacokinetic based studies of herbal, synthetic and biological products for establishing its ADMET profile.
- Toxicological studies of plant based, synthetic and biological product for establishing its safety profile.

Departmental Research Activities: Dept. of Pharmaceutics

- Development of conventional, modified-release, site-specific and targeted drug delivery systems.
- Development of nanotechnology-based formulations.
- Particle engineering and solubility enhancement of poor water-soluble drugs.
- Integrating QbD (DoE) and computer-aided approach in formulation development.
- In-vitro & ex-vivo / in-vivo characterization of API & formulations.

Department of Pharmaceutical Analysis

- LC-HRMS-based proteomics profiling of microbial, animal tissue, and human serum,
- Metabolomics database development of C. elegans,
- Natural product profiling/identification secondary metabolite (Common Research Plan with NIPER-G)
- Nitrosamine control in Pharmaceutical products (Common research plan with NIPER-Kolkata)

- Proteomics-based target identification, and mechanism study of microbial/ cancer drug resistance
- Food-omics in cancer therapeutics,
- Industry-relevant analytical method development using LC-HRMS, HPLC/Prep. HPLC by AQbD/QSRR/ ICHQ14 principles

Department of Biopharmaceuticals

- Cloning, expression and purification of proteins from bacterial, fungal and baculovirus expression systems
- Phage display, yeast surface display and antibody engineering
- Biochemical engineering, Fermentation technology, and downstream processing
- Generation of hybridoma technology for monoclonal antibody preparation

5.6.8 Impact and achievements

- The Institute continually strives to improve its position in NIRF ranking. NIPER Hajipur is ranked 44th in NIRF 2023, which was a significant improvement from previous years.
- Since inception, 564 post graduate degree and 21 PhD degree has been awarded.
- Research output of 335 publications, 21MoUs and 11 patents has been recorded.
- Total of 7 funded extra-mural research grants have been sanctioned to the faculty by various funding bodies including, ICMR, DST-SERB, DST (Rare disease), DNDi, etc.
- Central Instrumentation Facility (CIF) of the Institute has collaboration with clinicians for bio analysis (ICPMS, LCHRMS)
- 5 best research presentations/awards has been bagged by NIPER-Hajipur scholars at national level.
- The institute has developed Animal house facility, Central instrumentation facility, and Cell Culture facility, Pilot formulation unit facility for fostering the research and academic standards of the institute. Expansion of infrastructure with new building is under progress.
- Separate hostels for Boys and Girls, PhD scholars, Campus Medical facility, has been created adequately, further expansion of infrastructure is under process.
- In academic year 2023, Biopharmaceuticals branch was introduced with Masters Course.

5th Convocation of NIPER Hajipur conducted on 31 July, 2023

5.7 NIPER Guwahati

NIPER Guwahati started functioning in 2008 under the Mentor Institute, Guwahati Medical College, up to July 2017. The first regular Director took over the charge of the Institute on 3rd November 2016. NIPER Guwahati has been functioning from its permanent campus at Changsari, Kamrup (Rural), since January 2020. The Institute has been dedicated to the Nation on January 12, 2024. This institute has ten (10) National Centers identified by premium funding agencies of Government of India, namely:

i. National Centre for Pharmacoengineering funded by Technology Development Transfer Board, DST

ii. BioNEST Incubation Centre, BIRAC, DBT

iii. Centre of Excellence Tribal Health Care from Ministry of Tribal Health Care

iv. GMP accredited pilot scale-up extraction facility, DBT

v. Quality assessment & value addition Centre for herbal industry in the North-Eastern states of India Under TIES (Trade infrastructure for Export Scheme), Ministry of Commerce

vi. GLP accredited animal house facility from Ministry of DoNER

vii. Advanced Centre for Drug Design from, Ministry of Electronics & IT

viii. Pharmacovigilance Centre from Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare.

ix. ATAL Incubation Centre, ATAL Innovation Mission, Niti-Aayog, and

x. Centre of Excellence on Phyto-pharmaceuticals

5.7.1 Achievements

i. Ph.D. – 144 (enrolled), Degrees Awarded – 39 (since inception),

ii. Total M.S. (Pharm.) /M.Pharm/M.Tech (since inception),

Students enrolled	:	1023
Graduated	:	679

328 students are currently pursuing their P.G Programmes and 29 students are currently pursuing their Integrated PG Ph.D. Programmes

iii. Publications: In total, 716 articles have been published in peer-reviewed national and international journals out of which 177 articles were published in 2023-24.

iv. Institute has a total of 21 patents including 03 design patents, 2 copyrights and 03 process patents.

5.7.2 Details of faculty & staff

Administrative Staff	:	24
Academic Staff	:	26
Professors	:	03
Associate Professors	:	5

Assistant Professors	:	18 (2 ad hoc)
Research Associate	:	09
Technical Staff	:	16
Multi-Task Staff	:	35
Ramalingaswami Fellow	:	01

5.7.3 Total funds allocated by the Government during the last 5 years.

Table 5Y

(Allocation of fund to NIPER, Guwahati)

(Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2019-20	36.90	43.90	43.90
2020-21	34.45	79.45	79.45
2021-22	38.70	59.45	59.45
2022-23	35.00	103.53	106.49
2023-24	50.00	22.88	22.88

5.7.4 Students

Details of degrees/programmes offered and subjects offered year-wise is provide in Table 5Z.

Table 5Z

Status of Admissions in various disciplines

Level- Masters/ Doctoral	Degree MS/ MBA/ M.Tech/ Ph.D	Discipline	Year					
			2018-19	2019-20	2020-21	2021-22	2022-23	2023-24
Masters	M.S. (Pharm.)	Pharmacology and Toxicology	15	15	15	18	19	24
Masters	M.S. (Pharm.)	Biotechnology	10	10	10	10	15	17
Masters	M.S. (Pharm.)	Pharmaceutical Analysis	15	18	19	25	26	29
Masters	M.S. (Pharm.)	Pharmaceutics	15	18	18	20	24	28
Masters	M.S. (Pharm.)	Medicinal Chemistry	Not started	Not started	11	12	15	19
Masters	M. Pharm.	Pharmacy Practice	10	9	10	12	14	20

Masters	M. Pharm.	Pharmaceutical Technology (Formulations)	Not started	Not started	11	12	14	22
Masters	M. Tech.	Medical Devices	Not started	Not started	9	16	16	18
Masters	M. Tech.	Biopharmaceuticals	Not started	Not started	Not started	Not started	Not started	12
Integrated PG-PhD	Integrated PG-PhD	Pharmacy Practice	Not started	Not started	Not started	Not started	Not started	3
Integrated PG-PhD	Integrated PG-PhD	Pharmacology and Toxicology	Not started	Not started	Not started	Not started	01	5
Integrated PG-PhD	Integrated PG-PhD	Biotechnology	Not started	Not started	Not started	Not started	Not started	3
Integrated PG-PhD	Integrated PG-PhD	Pharmaceutical Analysis	Not started	Not started	Not started	Not started	Not started	4
Integrated PG-PhD	Integrated PG-PhD	Pharmaceutics	Not started	Not started	Not started	Not started	01	3
Integrated PG-PhD	Integrated PG-PhD	Medicinal Chemistry	Not started	Not started	Not started	Not started	Not started	4
Integrated PG-PhD	Integrated PG-PhD	Pharmaceutical Technology (Formulations)	Not started	Not started	Not started	Not started	01	4
Integrated PG-PhD	Integrated PG-PhD	Medical Devices	Not started	Not started	Not started	Not started	Not started	1
Doctoral	Ph.D.	Pharmacy Practice	1	1	1+1*	3	1+1 #	1
Doctoral	Ph.D.	Pharmacology and Toxicology	2+2*	1+2*	2	3	7	3
Doctoral	Ph.D.	Biotechnology	1	0	2	3	6+1*	1
Doctoral	Ph.D.	Pharmaceutical Analysis	1*	1+1*	2+1*	5	6	5+1*
Doctoral	Ph.D.	Pharmaceutics	2*	1+3*	4+1*	7	8	3+2*
Doctoral	Ph.D.	Medicinal Chemistry	Not started	Not started	2	4	4	2
Doctoral	Ph.D.	Medical Devices	Not started	Not started	Not started	Not started	Not started	4
Doctoral	Ph.D.	Pharmaceutical Technology (Formulations)	Not started	Not started	Not started	Not started	Not started	3

***Ph.D. Project Seats**

#Ph.D. DST Inspire Fellow

5.7.5 Teacher-Student ratio

Pharmacy Practice	: 1:23
Pharmacology and Toxicology	: 1:16
Biotechnology	: 1:16
Pharmaceutics	: 1:20
Pharmaceutical Analysis	: 1:16
Pharmaceutical Technology (Formulations)	: 1:15
Medicinal Chemistry	: 1:17
Medical Devices	: 1:17

5.7.6 Employability/ Placements Status

Out of 120 students in 2022–23, 78 students were placed in reputed pharmaceutical industries during on- or off-campus placements. A few companies to mention are Dr. Reddy's, Viatris, Pinnacle Life Sciences, Mu Sigma, Gland Pharma, MacLeod's, Aragen, Sai Lifesciences, Syngene, MC Analytics, Serum Institute of India, Maven Prof-con Services, and AMTZ. The remaining 42 students opted for higher education and joined for a Ph.D. in national and international institutes.

5.7.7 Research

Biotechnology:

- Target-based and phenotype-based drug discovery in cancer and cardiometabolic disorder
- Genetically modified bacteria for therapeutic intervention
- Identifying novel targets and developing an assay system
- Pharmacogenetics and personalized medicine
- Disease mechanisms: Inflammation and energy metabolism
- Developmental defects and cardiac reprogramming
- Breast cancer biology and drug resistance mechanisms
- Novel peptide-based anticancer targeted therapeutics for ovarian cancers
- Biology of clonal evolution in cancer proregression
- Basic Biology – Stem cell biology and Signal Transduction
- Biopharmaceutical Technology – Therapeutically important proteins and peptides
- Screening small molecules and plant-derived products

Pharmacology and Toxicology:

- Cancer and its complications
- Inflammatory conditions: Rheumatoid arthritis, Ulcerative colitis, and psoriasis
- Respiratory diseases: Asthma, COPD, and Lung fibrosis

- Neurodegenerative diseases: Alzheimer's and Parkinson's disease, Epilepsy
- Fibrotic disorders like renal fibrosis, hepatic fibrosis
- Cardio-Renal Pharmacology
- Diabetes and its complications, mainly nephropathy, cardiomyopathy, and neuropathy
- Infectious diseases: Malaria
- Toxicological studies as per OECD guidelines
- Theranostic approaches

Pharmacy Practice:

- Clinical and Translational Research
- Biomarkers Discovery
- Pharmacogenomics
- Clinical Studies to Diseases Management Programs
- Medication Utilization Evaluation
- Medication Safety Evaluation
- Tribal Population Health Outcomes Evaluation
- Health Economics and Outcomes Research
- Evidence Synthesis

Pharmaceutics:

- Dosage form design, development, optimization, and evaluations for BCS-II & III drugs
- Micro-and nanotheragnosis concepts for the early detection and treatment of malignant diseases and other life-threatening diseases
- Eradication of biofilm-producing microorganisms from the surfaces of implanted or inserted medical devices into the human body
- Ligand-anchored lipid/polymer-mediated nanoarchitectonics
- Pharmacoengineering approaches to fight against neglected diseases
- Pharmaceutical Additive Manufacturing Engineering / 3D-4D Printing Technology
- Nanomedicines for organ/lymphatic delivery with deep molecular insights
- Extrusion based filaments processing for fused filaments applications
- Translational cutting-edge pharmaceutical research & development

Pharmaceutical Analysis:

- Metabolomics and lipidomic profiling of various cancer, cardiovascular and metabolic disorders
- Enantiomeric separation of Chiral pharmaceutical compounds by using chiral chromatography technique
- Enantiomeric stability, Pharmacokinetics, and Metabolic profiling of chiral drugs

- Biomonitoring of endocrine disruptors and other emerging environmental contaminants for characterizing human exposure by using LC-MS/MS and GC/MS
- Impact of aggravated environment on the stability of pharmaceuticals
- Phyto-metabolomics study of the plant from the Northeast Region of India
- Analytical and bioanalytical method development and validation
- Pharmacokinetic studies of drugs and metabolites
- Identification and characterization of drug metabolites.
- Solid State Characterization - Reference material development
- Nanotechnological based product development

Medicinal Chemistry:

- Active Pharmaceutical Ingredients (APIs)/ KSMs/ Intermediates Synthesis
- Sustainable development: Atom-efficient, cost-effective, and environmentally benign new synthetic routes to access bio-active compounds and NCEs
- Carbohydrate chemistry, heterocyclic chemistry, and multistep synthesis
- Applications of Organic electrochemistry for drug synthesis
- Natural Product API (Extraction, Isolation, Purification, and Characterization)
- Drug Discovery Therapeutic Targets: Microorganisms (Hepatitis C Virus and Bacteria), Cancer (HCA, mRNA binding protein-HuR, HDAC), Neurological Disorders (Epilepsy and Alzheimer's dis- ease), ulcerogenic wound healing, etc.
- AI-guided Drug Design and Drug metabolism

Pharmaceutical Technology (Formulations):

- Preformulation screening
- Developing prototype formulations for improved deliverability of BCS class II and IV molecules including natural bio-actives.
- Dosage form optimization based on QbD principles
- Amorphous drug delivery technology (amorphous solid dispersions, co-amorphous systems)
- Reverse engineering of a product's formulation to create generic drugs
- Herbal product developments
- Osmotic drug delivery systems
- Multiparticulate drug delivery systems

Medical Devices:

- Biosensors
- Ultrathin sensors paper based diagnostics
- Nanobiotechnology
- Microfluidics devices

- Multiplexed detection of cancer biomarker
- Scaffold based tissue engineering
- Biomaterials, 3D spheroids
- Design and fabrication of bioreactors
- Mechanical characterization of hypodermic needles, Single use syringes, catheters and Class A & B Medical Devices
- Medical Electronic Devices Calibration and performance measurements as per IS/ISO and regulatory standards.

Biopharmaceuticals:

- Cell line development and engineering for expression of recombinant proteins
- Process Development - Scale-Up and Scale-Down Approaches for Production of Biotherapeutics
- Downstream Processing for Production of Biotherapeutics
- Post-translational Modification characterization of biotherapeutics through MS
- FTIR for high-order structure analysis of biotherapeutics
- Formulation development for Biotherapeutics

5.7.8 Student's enrolment

Current strength of Ph.D. students : 88

(Pharmacology & Toxicology-16; Biotechnology-13; Pharmacy Practice-08; Pharmaceutics-21; Pharmaceutical Analysis-16; Medicinal Chemistry-11 and Pharmaceutical Technology (Formulations)- 03.

Current strength of Masters Students : 328

(Pharmacology & Toxicology- 42 ; Biotechnology- 32; Pharmacy Practice- 34; Pharmaceutics -51; Pharmaceutical Analysis- 53 ; Medicinal Chemistry- 34; Pharmaceutical Technology (Formulations)- 36 ; Medical Devices- 34 and Biopharmaceuticals-12)

Current strength of Integrated PG Ph.D. Students : 29

(Pharmacology & Toxicology- 05 ; Biotechnology- 03; Pharmacy Practice- 03; Pharmaceutics -04; Pharmaceutical Analysis- 04 ; Medicinal Chemistry- 04; Pharmaceutical Technology (Formulations)- 05 and Medical Devices- 01)

Table 5AA

(Year wise status of students enrolled/received Degree)

Sl. No	Batch	Number of students enrolled	Number of students received degree
1	2015-17	26	26
2	2016-18	35	35
3	2017-19	39	39
4	2018-20	65	65

5	2019-21	70	70
6	2020-22	100	100
7	2021-23	120	120
8	**Total**	**455**	**455**

5.7.9 Patents and Commercialization

Institute has a total of 21 patents including 03 design patents, 2 copyrights and 03 process patents

5.7.10 Collaboration

NIPER-Guwahati has entered into 35 Memorandum of Undertandings. NIPER-Guwahati has exchanged MoUs with pioneer institutes/organizations like NRDC, IISc Bangaluru, CIPET-Guwahati, NPL-New Delhi, CSIR-CDRI, Lucknow, CSIR-National Physics Laboratory (NPL), AIIMS Guwahati, Sankardev Nethralaya, Guwahati, Assam, Rajiv Gandhi University, Itanagar, Arunachal Pradesh, AIIMS-Bibinagar, Telengana, Indian Pharmacopoeia Mission and BVG Life Sciences etc.

5.7.11 Impact of NIPER

NIPER Guwahati is the first & foremost National Institute of Pharmaceutical Education & Research in the entire North East region of India. It has helped in fostering and nurturing an innovation and entrepreneurship eco-system in the region. The institute is running 10 National Centres apart from the regular 09 departments funded by different agencies and several external funded research projects from funding bodies like DBT, ICMR, SERB, DST, BIRAC. In 2023 NIRF rankings, the institute secured 12th position under the pharmacy category.

NIPER-Guwahati campus dedicated to Nation on January 12, 2024.

5.8 NIPER- Ahmedabad

NIPER Ahmedabad was established in 2007 and is currently located at Gandhinagar. The institute is offering MS (Pharm.), MBA(Pharm), Integrated PhD and PhD programmes in 08 disciplines (Pharmaceutics, Pharmaceutical Analysis, Pharmacology & Toxicology, Biotechnology, Natural Products, Medicinal Chemistry, and Medical Devices and Pharmaceutical Management). The location of the Institute ensures a symbiotic association with pharmaceutical and medical devices industries, hospitals, and other universities. The Institute aspires to strengthen holistic research ecosystem in pharma sector and provide affordable and quality drugs and devices to the country.

The new building of NIPER Ahmedabad was inaugurated by Shri Amit Shah, Hon'ble Minister for Home & Minister for Cooperation in the gracious presence of Dr. Mansukh Mandaviya, Hon'ble Minister of Chemical & Fertilizers and Minister of Health & Family Welfare and Shri Bhupendra Patel, Hon'ble Chief Minister of State of Gujarat on 30th September, 2023.

5.8.1 Achievements:

National Institute Ranking Framework-2023 (NIRF) :-NIPER Ahmedabad is ranked 13th in All India Ranking of all Pharmacy Educational and Research Institutions in India as per NIRF 2023 released by Ministry of Education, Government of India.

Publications - The Institute has published 1052 articles in peer reviewed journals of repute with total citations of 21812

Patents - Institute has filed 30 patents till now wherein faculty or students of NIPER Ahmedabad are inventors. The Institute filed 12 patent and has been granted one patent during the financial year 2023-24

MoU Signed - Institute has signed 30 MoUs till now with different academic institutes and industry.

Students in Master Programme

i. 1007 master students have graduated from NIPER Ahmedabad and are well placed in various pharma industries in India and abroad.

ii. Presently, 360 students are pursuing their M.S. (Pharm), Integrated PG- PhD and MBA (Pharm) course in 8 disciplines.

Students in PhD Programme

i. 39 students have been awarded Ph.D. Degree till date.

ii. 129 students are continuing for their PhD studies.

Placement of Students - 100% placement of willing students has been achieved

Details of Faculty and Staff :

In addition to the post of Director, following posts are filled up:

Table 5AB

(Details of faculty positions)

Position	Regular	Contractual
Faculty Position	22	0
Non Faculty Position	22	0

5.8.2 Total Funds allocated by the Government during the last 5 years

Table 5AC

(Year-wise allocation of fund to NIPER, Ahmedabad)

(Rs in Crore)

Year	Allocation BE	Allocation RE	Total release
2019-20	15.00	18.50	18.50
2020-21	60.50	60.50	60.50
2021-22	54.00	54.00	54.00
2022-23	74.00	74.00	76.10
2023-24	78.00	33.42	33.42

5.8.3 Students

Table 5AD

(Degrees/programmes offered and Subjects offered (with year) with admission status)

Masters/ Doctoral	MS /PhD	Discipline	No. of students admitted			
			2020-21	2021-22	2022-23	2023-24
Masters	M.S.(Pharm.)	Biotechnology	15	15	15	16
Integrated PG-PhD			-	-	-	2
Doctoral	PhD		4	4	3	4
Masters	M.S.(Pharm.)	Medicinal Chemistry	22	22	22	24
Integrated PG-PhD			-	-	-	६
Doctoral	PhD		5	5	9	3
Masters	M.S.(Pharm.)	Medical Devices	15	15	15	15
Integrated PG-PhD			-	-	-	1
Doctoral	PhD		3	3	3	2
Masters	M.S.(Pharm.)	Natural Products	12	12	16	17
Integrated PG-PhD			-	-	-	4
Doctoral	PhD		3	3	1	9

Masters	M.S.(Pharm.)	Pharmaceutical Analysis	22	22	24	27
Integrated PG-PhD			-	-	-	3
Doctoral	PhD		5*1	5	8	5
Masters	M.S.(Pharm.)	Pharmacology & Toxicology	22	22	22	24
Integrated PG-PhD			-	-	-	5
Doctoral	PhD		5	5	8	0
Masters	M.S.(Pharm.)	Pharmaceutics	22	22	25	25
Integrated PG-PhD			-	-	-	3
Doctoral	PhD		5	5	7	12
MBA (Pharm)	MBA (Pharm)		25	25	26	30
			186	**185**	**204**	**235**

5.8.4 Teacher-Student ratio:

Presently 1: 23 (22 Faculties: 489 students)

5.8.5 Employability/ Placements Status: Last 3 years placements status: in Campus/off campus

Table 5AE

(Last 3 years placements status: in Campus/off campus)

Batch	Total no of student	Total no of student placed	Students pursing higher studies
2019-21	107	85	22
2020-22	142	116	25
2021-23	151	124	26

5.8.6 Teachers: International Research Collaboration

NIPER Ahmedabad has established an International Research Collaboration with faculties from Harvard Medical School, Boston, USA, University of Miami, USA, University of Copenhagen, Denmark, University of Washington, Seattle, USA; the University of Newcastle, School of Biomedical Sciences and Pharmacy, Australia; University of Mississippi School of Pharmacy, USA; Wayne State University Use-inspired Biomaterials & Integrated Nano Delivery Systems Laboratory, USA; and National University of Ireland, Galway, Ireland. Under this initiative, research faculties from these foreign Universities/Institutes have agreed to establish future research collaborations and academic partnerships with the faculty members from NIPER Ahmedabad.

5.8.7 MoUs signed during 2023-24

Table 5AF

(Details of MoUs signed)

Sr.No	MoU	Date
1	Indian Institute of Public Health, Gandhinagar (IIPH) Gujarat	18-04-2023
2	Leicester School of Pharmacy, De Montfort University Leicester (DMU), UK	07-08-2023
3	Pfizer Ltd	16-11-2023
4	Zydus	25-01-2024

5.8.8 Research Areas :

Department of Biotechnology:

- Genetic profile and biomarker identification of OSCC patients through transcriptome analysis
- Dissecting the molecular mechanisms by which healthy cells become cancerous and metastasize
- Epigenetic modulation in diabetic nephropathy through mRNA
- Modulating breast cancer stem cells using exogenous hyaluronic acid induction
- Combining experimental and computational approaches to design and validation of anticancer molecules
- Structural and Functional Evaluation of Indole Based Anti-cancer Compounds targeting Histone deacetylases (HDACs)
- Molecular characterization of hippocampal sAHP modulation in temporal lobe epilepsy
- Role of ER-PM connecting junctional proteins in the potentiation of sAHP in aging
- Molecular identification of the regulatory mechanisms that control the differential excitability pattern of dorsoventral hippocampal neurons
- Differential regulation of L-type calcium channels in ischemic brain injury
- Development of targeted therapeutics for acute myeloid leukemias (AMLs)

Department of Medicinal Chemistry:

- Target based bioactive scaffold explorations towards oral cancer and Alzheimer's' disease.
- Peptides and peptidomimetics based soft material for biomedical applications and tissue engineering
- Borrowing Carbonate-Enabled Allylic Amination Reactions under Additive- and Reductant-Free Nickel Catalysis Employing Allylic Alcohols
- Green chemical process toward the synthesis of pharmaceuticals (drugs)
- Inhibition of Glycolytic enzyme Pyruvate Kinase M2 (PKM2) results in tumor regression
- Synthesis of imidazopyri(mi)dines and their derivatives to achieve anticancer molecules
- Design of protacs targeting pyruvate kinase isoform m2.

Department of Medical Devices:

- Biomaterial platforms in developing medical devices & biotechnology products
- Bioengineered three-dimensional aligned scaffold for intervertebral disc repair

- Polymeric conduit for spinal cord regeneration
- Smart 3D smart scaffolds for musculoskeletal tissue regeneration and repair
- Paper-based diagnostic biosensor for swine flu detection
- Development of biosensor towards non-invasive detection of oral cancer
- Development of biosensor for detection of liver cancer
- Development of bioengineered 3D disease models with a focus on cancer
- Fabrication of in vitro biophysical microenvironment to understand disease biology
- Non-invasive screening platforms for early detection of cancer

Department of Natural Product:

- LC-MS based dereplication strategy for isolation of novel bioactivenatural products from plant sources
- Bio-prospecting of endolichenic fungi to discover novel bioactive scaffolds
- Identification of plant-derived natural products possessing GLP-1R agonist activity
- Process optimization for large scale purification/enrichment of selected natural products
- C-H activation strategy for the total synthesis and/or semi-synthesis of natural products
- Isolation, Characterization of Undescribed Alkaloids, and Semisynthetic Modifications of Cytotoxic Pyrano-acridone Alkaloids from Glycosmispentaphylla
- Establishment of Q-Marker system for standardization of traditional Ayurvedic polyherbal formulations
- Microbial bioprospecting for production of novel 20s proteosome inhibitor
- Endophytic fungi as a source of ecofriendly, sustainable and cost-effective way to produce valuable plant-based chemicals: Case study for rosmarinic acid production by endophytes isolated from Thymus vulgaris
- Establishing the targeted and untargeted metabolomic technology pipeline for natural product and cancer metabolomics

Department of Pharmaceutical Analysis:

- Drug-excipient compatibility studies
- Forced degradation studies of APIs and NCEs using HPLC, LC-MS/MS and qNMR
- Drug-Device compatibility and drug release study
- Bioanalysis, drug metabolism, and pharmacokinetics
- Analytical Approaches for polymer characterization
- Synthetic peptide characterization
- Complex injectable, ophthalmic formulation characterization
- Analytical method development for genotoxic and nitrosamine impurities quantification
- Extractable and Leachable study of drug product
- Biosimilars characterization

Department of Pharmacology and Toxicology:-

- Mitochondrial protection in ischemic stroke using intra-arterial mesenchymal stem cell treatment
- Stem Cell Therapy to Counteract Endoplasmic Reticulum Stress in Ischemic stroke

- Therapeutic strategy based on targeting growth hormone-releasing hormone (GRH) receptors for mitochondrial protection in ischemic stroke
- Investigating the role of inosine on inflammasome signaling in animal model of ischemic stroke
- Exploring the effect of endoplasmic reticulum stress in exacerbation of stroke pathology in chronic kidney disease
- Statins for stroke: Deciphering the involvement of endoplasmic reticulum
- Exacerbation of ischemic stroke pathology in CKD: Involvement of mitochondrial dysfunction
- Exploring the role of statins in protecting mitochondria following ischemic stroke
- Investigating the role of inosine in cerebral ischemia via pi3k/akt pathway
- Neuroprotective role of apelin-13 in post-stroke depression
- Development of progressive mouse model of Parkinson's disease targeting olfactory bulb
- Parkinson's Disease
- Exploring the role of miR 128 3p in the breast cancer metastasis by regulating PKM2 and CD98 expression
- Examining whether enteric neuronal inflammation is a starting point of Parkinson's Disease pathogenesis
- Exploring the role of glycated α-Syn on Receptor for Advanced GlycationEndproducts (RAGE) signaling pathway in development of Parkinson's disease
- Evaluation of the therapeutic potential of Swertiamarin in rotenone-induced mouse model of Parkinson's disease
- Exploring the effect of indole-benzothiazole and aminoindane derivatives as selective MAO-B inhibitors in mouse model of Parkinson's disease
- Exploring the role of LIM Kinase(s) on Microtubule stabilization and Actin microfilaments dynamics in experimental model(s) of Spinal cord injury
- Tomographic imaging and correlation to quantify vascular changes and inflammation after experimental spinal cord injury
- Evaluating the role of Ethamsylate on fibrotic scar formation after spinal cord injury
- Investigating the multimodal action of phenserine after spinal cord injury in mice
- Deciphering the activity of coumarin derivatives in attenuation of inflammatory pain
- Exploring the role of Pyruvate Kinase M2 inhibitor (PKM2) in relieving neuropathic pain:
- Evaluation of the therapeutic potential of Swertiamarin in rotenone-induced mouse model of Parkinson's disease
- Exploring the effect of indole-benzothiazole and aminoindane derivatives as selective MAO-B inhibitors in mouse model of Parkinson's disease
- Exploring the role of LIM Kinase(s) on Microtubule stabilization and Actin microfilaments dynamics in experimental model(s) of Spinal cord injury
- Tomographic imaging and correlation to quantify vascular changes and inflammation after experimental spinal cord injury
- Evaluating the role of Ethamsylate on fibrotic scar formation after spinal cord injury
- Investigating the multimodal action of phenserine after spinal cord injury in mice
- Deciphering the activity of coumarin derivatives in attenuation of inflammatory pain
- Exploring the role of Pyruvate Kinase M2 inhibitor (PKM2) in relieving neuropathic pain:
- Evaluation of the role of exosomal miR-155 inhibitor on cisplatin resistance in oral cancer xenograft mouse model

Department of Pharmaceutics:

- Development of novel polymeric nanomaterial for effective cytosolic delivery of anticancer bioactive
- Formulation development of injectable RNA interfering nanoparticle for targeted therapy of diabetic nephropathy
- Tripartite approach for the treatment of triple-negative breast cancer (TNBC) using graphene oxide wrapped polymeric nanoparticles
- NIR laser activatableNanoplates for the treatment of resistant tumors
- NIR laser activatableNanoseeds for the prevention of post-surgical relapse of the resectable tumor
- Electrospraying Vs Lyophilization: Impact on solid-state properties of drug Nanosuspension
- Formulating the poorly soluble drugs in conventional dosage forms for bio-enhancement
- Exploiting the oral route for delivery of macromolecular therapeutics using penetration enhancer(s)
- Minicapsules encapsulating nanoparticles for targeting, apoptosis induction, and treatment of colon cancer

5.8.9 Impact of NIPER :

NIPER Ahmedabad is committed to building human resource for promoting research and development in the country and contribute towards 'Make in India' initiative as part of its national responsibility. The Institute has established itself as one of the top technological pharmacy research institutes in the country with research collaboration as an integral part of the growth strategy. It has expanded its outreach to the industry as well as collaborated with the best academic institution of USA, UK, Australia, Ireland and Malaysia for collaborating research, faculty visit, syllabus up-gradation and regulatory reforms with several industries and leading institutes. The Institute has conducted various conferences, symposiums, discussions which were attended by masters' students, PhD, Post Docs and researchers from academia and industry.

5.8.10 Awards/Achievement

i. National Institute Ranking Framework (NIRF) 2023: NIPER Ahmedabad is ranked 13th among all Pharmacy Educational and Research Institutions in India as per NIRF 2023 released by Ministry of Education, Government of India

ii. Recognition with BSCIC Certificate for Medical Devices: NIPER Ahmedabad has been recognized with the distinguished BSCIC certificate for Medical Devices, demonstrating its dedication to providing exceptional education and research in the field of medical devices to students and stakeholders

iii. Awarding of BSCIC Certificate for Quality Management: NIPER-Ahmedabad has been awarded the prestigious BSCIC certificate for Quality Management, acknowledging its commitment to providing the highest quality education and research students and stakeholders.

iv. Dr. Pallab Bhattacharya was an invited speaker to deliver a talk on "Stroke and Sickle Cell Disease" at World Stroke Congress 2022 at Singapore

v. Top 2% World Scientist: Dr. Rakesh K. Tekade was listed as Top 2% World Scientist by a recent list published by Stanford University, USA

vi. NIPER Ahmedabad students actively participated in various scientific activities of 6th Bharatiya Vigyan Sammelan held at Science City, Ahmedabad. Ms.Aishika Datta from Deptt of Pharmacology and Toxicology bagged 2nd prize in oral presentation and Mr. Shaikh Ayyaz Shaikh Idris from Deptt of Biotechnology bagged 2nd prize in poster presentation at the event.

vii. Ms. Dhwani Rana, a student at NIPER Ahmedabad, achieved second rank in the Shri B.V. Patel Essay Competition-2023 on the subject "Increasing role and importance of advanced technologies like artificial intelligence, block chain technology, 3-D Printing in drug and pharmaceutical industries".

viii. #SCiDD lab Ph.D scholars Mr. Aditya A. Singh and Ms. Zarna Pathak won the "Young Researcher Award" at 4th National Biomedical Research Competition, ESIC Medical College, Alwar. Dr. Hemant Kumar Aditya A. Singh won 1st prize in Pharmaceutical Sciences (Oral presentation) with a cash prize of Rs. 50,000 and Zarna Pathak won 5th prize in Life Sciences (Oral presentation) with a cash prize of Rs. 5,000.

ix. Mr. Amit Sharma, PhD student of NIPER Ahmedabad received a fund support of Rs 3 lakhs for his idea, "Ghritozenge." This idea was supported by the Biopharma Incubation Center under the GSBTM's Entrepreneurship Capacity Building Scheme.

x. Ms. Sonali Jain, PhD student of NIPER Ahmedabad received a fund of Rs 5 lakhs for her idea, "RS4DEC." This idea was supported and mentored by the Biopharma Incubation Center under the Gujarat Student Startup and Innovation Hub (i-Hub)'s Startup Srujan Seed Support Grant (S4).

xi. Ms. Parusu Kavya Teja and Mr. Sayan Chatterjee students of NIPER Ahmedabad secured first prize in poster presentation in NIPER Students Research Symposium (NSRS)-2023 held at NIPER SAS-Nagar, Mohali on 10-12 August 2023. The symposium was held on the occasion of 25 years of NIPER Act (Silver Jubilee Celebration).

xii. Dr. Harpreet Kaur, a Ph.D. scholar from NIPER-Ahmedabad (Department of Pharmacology and Toxicology). get selected as a Post-Doctoral Fellow at the LSU Health Shreveport, Department of Pathology and Translational Pathobiology, USA.

xiii. Ms. Bharathi K. won third prize in MS category for poster presentation in Disso Research Presentations India (DRPI) 2023 (M.Pharm/Pharm D. category), an annual flagship conference of the Society for Pharmaceutical Dissolution Science (SPDS).

xiv. Mr. Sagar Salave, a Ph.D. scholar from NIPER-A (Department of Pharmaceutics). selected as a Post-Doctoral Fellow at the prestigious Vaccine Analytics and Formulation Center, the University of KANSAS, USA.

xv. Ms. Sonali Jain, selected for the prestigious Females in Mass Spectrometry Empowerment Award Q2, 23.

5.8.11 Events/ Workshops carried out by the institute

NIPER Ahmedabad conducted various events, conference workshops/seminar/webinar/ training for students.

Hon'ble Union Home Minister & Cooperation Minister, Government of India Shri. Amit Shah inaugurated the permanent campus of NIPER-Ahmedabad on September 30, 2023

The Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, Government of India, organised the Chintan Shivir to promote collaboration and innovation in the pharmaceutical industry on the 12th and 13th of May, 2023 at the Statue of Unity in Kevadiya, Gujarat.

10th convocation at NIPER-Ahmedabad on February 27, 2024

On 10th January 2024, Secretary, Department of Pharmaceuticals, visited NIPER Ahmedabad, its laboratories, and various equipment facilities.

CHAPTER 6

Public Sector Undertakings (PSUs)

6.1 Central Public Sector Undertakings

6.2 Indian Drugs & Pharmaceuticals Ltd. (IDPL)

6.3 Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)

6.4 Hindustan Antibiotics Ltd. (HAL)

6.5 Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL)

6.6 Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)

Chapter 6

Public Sector Undertakings (PSUs)

6.1 Central Public Sector Undertakings (PSUs)

There are five Central Public Sector Enterprises (CPSEs) under the administrative control of the Department of Pharmaceuticals.

- Of the five PSUs, Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) is a profit making CPSE. BCPL has started making profits since last few years.
- Other three PSUs viz. Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and referred to Board for Industrial & Financial Reconstruction (BIFR).
- Rajasthan Drugs & Pharmaceuticals Limited (RDPL) has reported losses since 2013-14 and is incipient sick.

Table 6A
(Details of PSUs)

(As on 31st March 2024)
(Rupees in Crores)

	HAL	IDPL	RDPL	BCPL	KAPL
Established in	1954	1961	1978	1981	1981
Classification	Sick	PSU (Under Closure)	Incipient sick	Profit Making since 2016-17	Profit Making
Net worth (incr.)	-704.12	-7624.94	-103.20	179.31	275.91
Turnover (incr.)	197.00	38.87	Nil	130.65 (provisional)	462.09#
Operating profit/ loss (in Cr.)	4.45	40.57*	-1.80	21.55 (provisional)	18.00# (Profit after Tax)
Liabilities (incr.)	1295.59	332.58	142.03	84.50	125.00#
Referred to BIFR	1997	1992	No	1992	NA

 # Provisional figures (KAPL).

*Notes:

1. Total liabilities & all other financials are derived from 2018-19 Balance Sheet
2. Lease hold land has already been resumed by respective State Government and/or taken over by Liquidator (Orissa Drugs & Chemicals Ltd (ODCL)- Joint Venture) / Lease period is over (Rishikesh)

6.1.1 Policy Decisions on Pharma PSUs

The Union Cabinet has taken a decision on 28.12.2016, which was modified subsequently on 17.07.2019, to close the two Pharma PSUs, namely Indian Drugs & Pharmaceuticals Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL) and strategically disinvest the other two, viz., Hindustan Antibiotics Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL). Separately, the Cabinet Committee on Economic Affairs (CCEA) on 01.11.2017 has decided to strategically disinvest 100% central government equity in the fifth PSU, viz., Karnataka Antibiotics & Pharmaceutical Limited (KAPL). However, Cabinet vide its decision dated 01.03.2023 has approved RDPL for transfer to State Government of Rajasthan.

6.2 Indian Drugs and Pharmaceuticals Ltd (IDPL)

6.2.1 Background

Indian Drugs & Pharmaceuticals Limited (IDPL) was incorporated as a public limited company on 5th April, 1961 under the Companies Act, 1956. The main objectives of the company were to create self-sufficiency in respect of essential life-saving medicines, to free the country from dependence on imports and to provide medicines to the people at affordable prices. IDPL was basically conceived and established as part of healthcare infrastructure of the country and has played a pioneering infrastructural role in the growth of the Indian drugs industry base.

The Registered Office of the Company is located at IDPL Complex, Dundahera, Gurgaon. The company has three main plants at Rishikesh (Uttarakhand), Gurugram (Haryana) and Hyderabad (Telangana).

6.2.2 Present Status

The Union Cabinet decided on 28.12.2016 decided for the closure of the company. In view of the Cabinet decision, the company is in the process of closure. The company signed a Memorandum of Understanding (MoU) with M/s National Buildings Construction Corporation (NBCC) to act as Land Management Agency (LMA) on 22nd October, 2019 for disposal of its land /immovable properties and with M/s Metal Scrap Trade Corporation Limited (MSTC) to function as Auctioning Agency (AA) for the sale of its movable and immovable properties by e-auction. The valuation of land of IDPL Gurugram Plant and Hyderabad Plant (including the building) has been done by Land Management Agency (LMA) – NBCC and approved by the Board. The lease period of the land of Rishikesh plant has already expired and the same is being returned to the Government of Uttarakhand.

The valuation of movable assets (plants & machinery) of all plants and subsidiaries have been done. The company has disposed of the same through approved auctioning agency, viz., M/s MSTC Limited.

All units have stopped production in view of closure decision of the Union Cabinet taken on 28.12.2016. Presently, the company has no regular employees as all the regular employees of IDPL have been given VRS as per DPE Guidelines dated 14.06.2018.

6.3 Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)

6.3.1 Background:

Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) was founded in 1901 by Acharya Prafulla Chandra Ray, a renowned scientist and academician. Government of India took over its management in 1977, subsequently, the Company was nationalized in 1980 and registered as Bengal Chemicals & Pharmaceuticals Limited (BCPL) under

the Companies Act in 1981. The company was declared sick in 1992 and was sanctioned scheme for revival in 1995 by the erstwhile Board for Industrial & Financial Reconstruction (BIFR).

6.3.2 Business Operations:

BCPL is a Kolkata-based company and is engaged in the business of Industrial Chemicals (Ferric Alum), Drugs & Pharmaceuticals, and Disinfectants such as Phenol, Naphthalene balls, Bleaching powder, Toilet cleaners, and Floor cleaners. Cantharidine Hair oil, a reputed brand of Bengal Chemicals, is being manufactured at Maniktala Unit.

6.3.3 Manufacturing Locations:

At present, BCPL has three factories which are situated at Maniktala (Kolkata), Panihati(North 24 Parganas) in West Bengal and Kanpur(U.P.).

i. **Maniktala Unit:**

This unit was set up in 1905 and primarily produces Pharmaceutical Formulations which include branded as well as unbranded generic medicines. Commercial production of Tablets, Capsules, Ointments and Cosmetics is going on. Maniktala Unit of BCPL also produces Cantharidine Hair Oil. Bengal Chemicals launched its Hand Sanitizer "BENSANI+" on 2nd August, 2020, to prevent the spread of Corona Virus Disease (COVID-19).

ii. **Panihati Unit:**

Panihati unit was set up in 1920 and is located in North-24 Parganas, West Bengal. Panihati unit primarily produces Industrial Chemicals and Disinfectants such as Phenol, Naphthalene balls, Bleaching powder, Toilet cleaners, and Floor cleaners. During the pandemic situation, BCPL touched an all-time record of manufacturing 60,680 bottles of Phenol 450 ml. in a single day (26th September, 2020) as against an average daily production of 30,000 bottles.

iii. **Kanpur Unit:**

Kanpur Unit was set up in1949. It primarily produces tablets for acute disorders.

iv. **Mumbai Unit:**

Mumbai unit was set up in 1938 and presently the commercial space developed (in February, 2000) has been leased out, for generation of additional sources of revenue.

6.3.4 Past Achievements:

The Company has retained its brand position in home products/ disinfectants even during the crisis period and is well set to capitalize on these brands.

6.3.5 Financial Status of BCPL

The Company was referred to erstwhile BIFR in 1992. The revival package for BCPL was approved by the Government in December 2006. The approved package of ₹440.60 crore comprised of restructuring of existing debts of BCPL, capital investments, support for development of marketing infrastructure and promotional measures, grant for wage revision and implementation of VRS and funds for payment of non-Government dues. Even after restructuring efforts in 2006, it was running into losses and its operational performance had come down drastically in 2013-14.

However, from the financial year 2016-17 onwards, the company turned around and reported a Net Profit of ₹4.51 Crores and a Gross Margin of ₹24.05 Crores. Details of profit of the company over the past few years is given in Table 6 B.

Table 6B
(Details of year wise profit)

(₹ in crore)

S.No.	Financial Year	Profit
1	2017-18	10.06
2	2018-19	25.26
3	2019-20	13.07
4	2020-21	6.08
5	2021-22	7.47
6	2022-23	10.19
7	2023-24	15.57

Further, it may be noted that BCPL has repaid the entire bank loan of ₹28 crore to United Bank of India (which was taken in 1983 by mortgaging Registered Office building) and now BCPL is a debt free company. After repayment of Government of India loans of ₹23.73 crore, as on 31.03.2021, there was balance in Plan Loan & Non-Plan Loan including accrued interest amounting to ₹193.71 crore. Government of India vide Order dated 09.09.2021 has given waiver of Government of India loans along with accrued interest amounting to ₹.193.71 crore against transfer of physically available 19.78 acres of surplus land at Panihati factory to NIPER, Kolkata. The Government of India loan is Nil as on 31.03.2024.

6.3.6 Product profile and range

The products manufactured under different business segments are mentioned in Table 6C.

Table 6C
(Details of products)

Division-I	Division–II		Division-III		
Industrial Chemicals	Pharma Generics	Pharma Branded	Disinfectants	Hair Oil	Other Products
Alum, Bleaching Powder	Tablets, Capsules, Injectables, Ointments, Liquids, External-Liquids, ASVS,BENSANI+	Aqua Ptychotis, Kalmegh, Eutheria, Benflam Gel	Phenol, White Tiger, Klin Toilet, Lysol	Cantharidine Hair Oil	Naphthalene Balls Liquid Soap Aguru Essence

Popular brands: Lamp brand Phenol, White Tiger, Bleaching Powder, Naphthalene Balls, Cantharidine Hair Oil, Bensani+ etc.

6.3.7 Manpower

Table 6D
(Details of category- wise manpower)

Particulars	Manpower (As on 31.03.2024)
Executives	45
Supervisors	27
Workers	43
Grand Total	**115**

6.3.8 Distribution network

The company has a strong distribution network pan India with 10 Depots and 6 C&F Agencies. BCPL has also opened 3 exclusive retail stores in Kolkata and 1 in Mumbai.

6.3.9 Performance

Details of production, Turnover and Financial Performance of BCPL from 2021-22 onwards given in Table 6E.

Table 6E
(Year - wise Financial Status of BCPL)

(₹ in Crore)

Particulars	2023-24 (Provisional)	2022-23	2021-22
Production	148.94	137.13	84.73
Sales / Turnover	130.65	112.82	72.05
Gross Margin	21.55	16.28	15.23
Interest & Financial Expenses(Finance cost)	0.09	0.04	0.03
Depreciation	5.89	5.90	6.15
Net Profit(Loss)	15.57	10.19	7.47
Net Worth	179.31	163.74	153.55

6.3.10 DPE Rating:

Table 6F

(Details of year wise DPE rating)

Year	MOU Assessment	Corporate Governance
2016-17	"Very Good"	"Excellent"
2017-18	"Not applicable"	"Excellent"
2018-19	"Not applicable"	"Excellent"
2019-20	"Not applicable"	"Excellent"
2020-21	"Not applicable"	"Excellent"
2021-22	"Not applicable"	"Excellent"
2022-23	"Not applicable"	"Excellent" as per Internal Assessment
2023-24	"Not applicable"	"Excellent" as per Internal Assessment

Table 6G

(Marketing: Share of Institutions and retail)

Sl. No.	Div & Products	Market Profile/ Major Clients
1.	DIV I–FERRICALUM	SAIL(Durgapur, IISCO, Bokaro, Refractory Unit, IISCO Chasnala) BCCL(Bowra & Block II) IPCL(Farakka, Disergarh) PHE(Malda, Siliguri) Other Private Parties & Municipal Corporations
2.	DIV II – GENERIC TABLET, CAPSULE, OINTMENT, INJECTION, LIQUID, HAND SANITIZER	AFMSD, ESIC, RAILWAY, SAIL, DHS, APMSIDC, TSMSIDC, JMHIDPCL, Other State Governments. SECL & other PSUs
	DIV-II –BRAND AQUAPTYCHOTIS, EU-THERIA, KALMEGH	Sold through Retail Trade As OTC Medicines
3.	DIV-III–COSMETIC & HOME PRODUCTS	Mainly Trade Business (70-75%) & Bulk Government Institutions Business (25-30%)

6.3.11 Various events organised:

(i) International Women's Day was celebrated in BCPL on 8th March 2024 to celebrate the achievements of women.

Womens Day Celebration

(ii) Vigilance Awareness Week 2023 was observed with the theme **"Say no to corruption; commit to the Nation"** from 30th October, 2023 to 5th November, 2023 at Corporate Office, Panihati Factory, Maniktala Factory, Kanpur Factory and Mumbai Office of BCPL.

(iii) Hindi Pakhwada was celebrated at BCPL from 14th September to 29th September, 2023. Essay, Recitation, Extempore competition etc. were organized and prizes were distributed to the winners of the competition.

Price Distribution During Hindi Pakhwada

(iv) Swacchata Pakhwada was observed from 1st to 15th September, 2023. Employees of BCPL took part in cleaning the adjacent area of office premises/ factory premises, record room during Swachhta Abhiyan.

Cleaning Work During Swatchta Pakhwada

6.4 Hindustan Antibiotics Limited (HAL)

6.4.1 Background:

Hindustan Antibiotics Ltd (HAL) is a wholly owned Government of India Company engaged in the manufacturing & marketing of life saving drugs. HAL was established in 1954 with WHO/ UNICEF assistance. HAL is the first pharmacy CPSE to manufacture the antibiotics bulk drugs like Penicillin, Streptomycin and Gentamycin

HAL has the rare distinction of inventing two new molecules viz. Hamycin and Auerofungin.

HAL, at present, is focusing on manufacturing pharma formulation and promising agro- formulation to cater to wide range of pharma and agro market. HAL pharma products includes various dosage forms like Dry Powder Injectable products, Tablets, Capsules, Intra-Venous Fluid (IVF) products and Liquid Syrup

6.4.2 Brief of Facilities available:

HAL manufacturing facilities include the following:

a) Formulation facility:

HAL Pharma products includes various dosage forms like Dry Powder Injectable products, Tablets, Capsules, Intra-Venous Fluid (IVF) products and Liquid Syrup

At present, manufacturing formulation capacities including pharma & agro-chem, are shown in Table 6H.

Table 6H

(Details of manufacturing formulation capacities)

Sr.No.	Production facilities	Capacities (Existing) Lac Nos. / annum
A.	**Pharma Plants:**	
1	**Dry Powder Injectables:**	
a.	Cephalosporin	**600**
b.	Penicillin	**600**
2	**Tablets:**	
a.	Penicillin	**8600**
b.	Non-Penicillin	**8600**
3	**Penicillin Capsules:**	1400
4	**I.V.Fluids:**	120
5	**Liquid Syrup & External preparation:**	24
B	**Agro-Chem Plants:**	
1	Streptocycline	100
2	Humaur formulation	210 KL
C	***Alcoholic Hand Disinfectant (AHD)***	12
D	***HAL Cloud Clinic in nos.***	12000

6.4.3 Performance Highlights:

HAL manufacturing facilities are situated on approx. 86.5 acres of land at Pimpri and include the following:

a) Formulation facility: HAL Pharma products includes various dosage forms like Dry Powder Injectable products, Tablets, Capsules, Intra-Venous Fluid (IVF) products, Ointments and Liquid Syrup.

b) All Formulation Plants are being upgraded to WHO-GMP compliance.

c) HAL has re-started manufacturing and marketing of its IVF products, the facility for which was under upgradation since last couple of years. HAL is the only unit in the pharma public sector to have facility for manufacture of IVF Fluids.

d) Research and Development: HAL's R & D Department is engaged in manufacturing standard size Narcotic Drugs Detection Kits as per requirements of Narcotic Control Bureau, Department of Internal Security, Ministry of Home Affairs, Government of India, New Delhi. HAL is the only exclusive manufacturer of this product in the country.

e) HAL weathered a challenging period from 2013-14 to 2015-16, where employees endured a 28-month delay in salary payments. However, the Company has successfully steered to a steady growth, since then and consolidated its position in India as a leading Public Sector Pharmaceutical Company. During the year 2023-24, all the manufacturing units were operational and it has helped in enhancing the total turnover of the company to ₹.197.00 crore.

f) During the year 2023-24, HAL continued to operate the State-of-the-Art facility for manufacturing of Alcoholic Hand Disinfectant (brand name HALRUB) and is supplying to all Government Institutions, ESIs, GMSDs etc.

g) During the year 2023-24, HAL upgraded "Clinic on Cloud" - a Health Kiosk- which was earlier measuring 23 health parameters in 5 minutes, now it measures 51 health parameters. This is a sort of Health ATM which identifies different health parameters. This Health Kiosk stores data of the person on its cloud storage & can be very useful to Health Institutions, Govt. Hospitals, CPSEs etc.

h) All the systems including receipt in the Stores, issue for production, consumption of raw material as well as packaging material for the product, out-turn of production to marketing & distribution, personnel records including time-office has been computerized using ERP System.

i) After implementation of VRS, HAL has outsourced non-core services like transport to outside party for better economy.

j) The company has achieved "Excellent" rating in Corporate Governance consecutively for the last three years.

k) HAL has carried out R&D for manufacture of an agro product Trichoderma, a bio fungicide used for treatment of plants against fungal infections. HAL has applied for registration of the product with Central Insecticide Board (CIB) and commercial production shall commence once approval is received from CIB.

6.4.4 Details of Production, Sales Turnover and Net Profit / Loss

Table 6I

(Details of Production, Sales Turnover and Net Profit / Loss for the last four years)

(₹ in Crore)

Particular	2020-21	2021-22	2022-23	2023-24 (Provisional)
Value of Production	78.80	89.72	120.85	162.12
Sales Turnover	89.56	152.16	172.45	197.00
Net Profit (Loss)	(38.25)	(16.82)	(53.88)	(26.78)

During 2021-22, HAL achieved a Sales Turnover (total revenue) of ₹.152.16 crores against ₹.89.56 crores in 2020-21, a rise of 62%.

The sales turnover further increased to Rs.172.45 crore in 2022-23 registering a 14% increase over the turnover in 2021-22. As per provisional estimates for 2023-24, the sales turnover has again registered a 14% increase over 2023-23 to reach Rs.197.00 crore.

Graph 6A

(Performance of HAL)

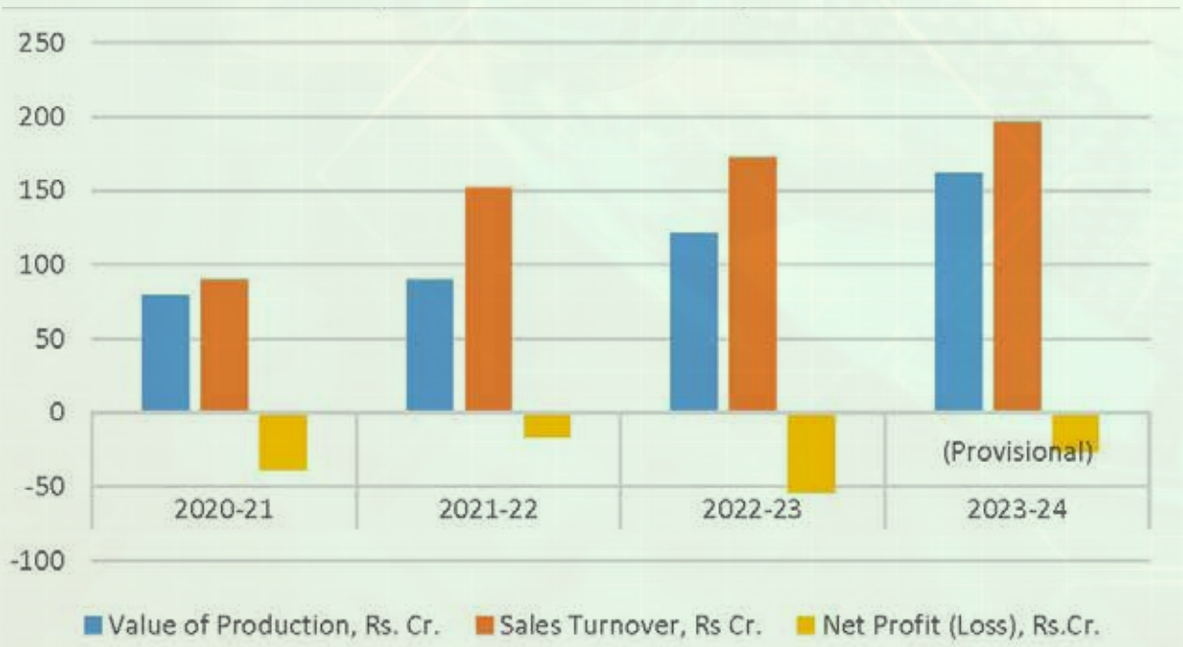


Table 6J

[Financial performance upto March 2024 (Estimates/Provisional)]

(₹. in Crores)

S.NO	Particulars	April 2023 to September 2023 (Provisional)	October 2023 to March 2024 (Estimates/Provisional)	Cumulative up to March 2024 (Estimates/ Provisional)
1.	Value of Production	65.73	96.39	162.12
2.	Total Turnover	88.18	108.82	197.00
3.	Profit/Loss +/-	(12.29)	(14.49)	(26.78)

6.4.5 Manpower:

As on 31.03.2024, manpower of HAL is 388 with 91 Officers and 297 non-Officers.

6.4.6 Strategy for Marketing:

HAL's strategy for marketing is to focus on the following aspects:

- Expanding its product range and customer base by introducing new drugs and formulations
- Enhancing its brand image and visibility by improving the quality of its products, adopting good manufacturing practices, and obtaining various certifications and accreditations.
- Strengthening its distribution network and sales force by entering into strategic alliances and partnerships with other public and private sector entities, such as HLL Lifecare Ltd. for marketing of HAL-Clinic on Cloud Medical Devices.
- Leveraging its R&D capabilities and infrastructure to develop innovative and cost-effective drugs and formulations, and to meet the emerging challenges and opportunities in the pharmaceutical sector.
- Reducing its operational costs and liabilities by introducing mechanized processes and automation in its manufacturing and functioning of other departments.

6.4.7 Various social activities/days/awards observed/received in Hindustan Antibiotics Ltd. during 2023-24:

(i) HAL participated in the G20-Exhibition on Research and Development of Therapeutics, Vaccines and Diagnostics on 5-6 June 2023 held at Hyderabad. HAL showcased its state-of-the-art medical device HAL Clinic -n-Cloud, which measures 51 health parameters in a short span of time. Also, new generation disinfectants were displayed by HAL on the show. Hon'ble Secretary Ms. S. Aparna visited HAL Stall on 6th June 2023.

(ii) Ministry of Chemicals and Fertilizers, Gov of India, awarded HAL Rajbhasha Shield for the year 2022-23 for commendable work in official language, Hindi.

MD, HAL receiving the Award from Hon'ble Union Minister of Chemicals and Fertilizers in May 2023

(iii) 26th January, the Republic Day was celebrated in Hindustan Antibiotics Ltd. Various programmes were held like felicitation of the employees completing 25 years of their service in the company. Awards were given to those employees who have made exemplary contribution to the company

(iv) 10th March – Foundation Day : HAL was founded on 10th March 1954. The Foundation Day was celebrated with great zeal and enthusiasm in the company.

(v) 19th February, 2023 was celebrated as Shri Chhatrapati Shivaji Maharaj Jayanti Day. A special grant is given to Shri Shiv Smarak Pratishthan, the association run by the employees of the company, for celebrating the day. During the function, a special lecture was organized by Shri Shiv Smarak Pratishthan.

(vi) 14th April,2023 Bharatratna Dr Babasaheb Ambedkar Jayanti celebrated in H.A Residential Colony by the H.A. Schedule Caste / Schedule Tribe Employees Association. The Association is given a grant for celebrating the function.

(vii) Boudha Jayanti is celebrated on 5, May 2023 by the Boudh Jan Mandal, functioning in H.A. Residential Colony which is the association of employees of the company.

(viii) Swach Bharat Abhiyaan was observed from 2nd October,2023 to 15th October,2023. All the employees in the company took part in the abhiyaan and cleaned the surroundings.

(ix) 26th November,2023 observed as Constitution Day to commemorate the adoption of the Constitution of India. On the day employees read the Preamble of India.

(x) Hindi Pakhwada was celebrated at HAL with great fervor and enthusiasm on 14th September, 2023. Essay, Slogan, Shudha Lekhan. Debate competition etc. were organized to commemorate the Hindi Pakhwada at HAL. Prizes were distributed to the winners of the competition

6.5 Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL)

6.5.1 Background:

Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) is a profit making Joint Sector Company incorporated in 1981 [with 59% share by Government of India and 41% share by Government of Karnataka through Karnataka State Industrial and Infrastructure Development Corporation (KSIIDC)].

The basic objective of the Company is to make available lifesaving drugs of good quality to Government Hospitals and other Institutions along with private medical practitioners.

The paid-up share capital of the Company as on date (31.03.2024) is ₹13.49 Crores.

6.5.2 Facilities:

- At Bangalore Plant, pharmaceutical products are being manufactured and the Company has WHO-GMP Certified manufacturing facilities for the following segments;
  - Dry Powder Injections - Cephalosporin
  - Dry Powder Injections - Penicillin
  - Dry Powder Injections - General
  - Liquid Injections
  - Non-Parenteral
  - Oral Solid Dosages

- At Kotur, Dharwad, Karnataka State, the following Ayurvedic Products are being manufactured.
  - Liquid Orals
  - Powders
  - Oils

- Government of India has accorded approval to KAPL under 'PLI Scheme' for Bulk Drug Project 7-ACA. The required construction activities are going on in full swing at DMIC Vikram Udyogpuri, Ujjain.

Proposed Bulk Drug Manufacturing Unit at Ujjain

6.5.3 Production and Sales Performance:

Table 6K

(Details of year wise production and sales)

(₹. in Crore)

S. No.	Financial Year	Production	Sales
1.	2020-2021	434.64	426.16
2.	2021-2022	479.76	473.87
3.	2022-2023	528.65	527.57
4.	2023-2024 (Provisional)	464.70 (Provisional)	462.09 (Provisional)

6.5.4 Achievements/Major Accolades:

- WHO GMP accredited Company.
- Pan India presence.
- ISO 9001:2015 - Quality Management System (QMS)
- ISO 14001:2015 - Effective Environmental Management System (EMS)
- ISO 45001:2018 - Occupational Health and Safety Assessment Series (OH&SMS),
- ISO 50001:2018 - Energy Management System (EnMS).
- PIC/S Certification

6.5.5 Popular Brands:`

Pharma – Trade:

Table 6L

(Pharma - Trade)

Sl No	Products	Therapy Segments	Market Value (₹. in lakhs)
1	Grenil	Anti Migraine	1159.00
2	Kaptocin(Oxytocin)	Hormone	198.00
3	Cyfolac	Probiotics	555.00

4	Remcc	Cough & Cold	319.00
5	Verclav	Antibiotic	262.00
6	PoP E	Platelet Booster	180.00
7	Zinfe	Haematinic	232.00
8	Numol	Pain Medication	220.00
9	Kaplicon	Antifungal	33.00

Ayurvedic Products:

Table 6M
(Ayurvedic Products)

Sl. No.	Products	Therapy Segments	Market Value (₹. in lakhs)
1	PoP-E	Platelet Booster	180.00
2	Apifeast	Appetizer	102.00
3	Husky Powder	Bowel Regulator	86.00
4	Exol	Hepato-Biliary Stimulant	27.00
5	K-Thrin	Thrombocytopenia	55.00
6	Numol H	Pain Management	104.00
7	Antaf	Antacid-Antiflaltulant	56.00
8	Appikap	Appetizer	30.00

Veterinary Products:

Table 6N
(Veterinary Products)

Sl No	Products	Therapy Segments	Market Value (₹. in lakhs.)
1	Pensbiotic	Antibiotics	306.40
2	Gentabiotic	Antibiotics	261.74
3	Cetriax	Antibiotics	395.61
4	K-Flox	Antibiotics	164.58
5	Kalvimin Group	Feed Supplement	638.73
6	K- Live	Hepato-Protective	263.93
7	Cal-K	Ecto-Parasiticide	222.71

6.5.6 Distribution Network:

Pharma:

The company has been expanding its operations in retail trade sector with a planned effort so as to cater to the needs of the private medical practitioners. In this direction the company has been periodically launching new products in the various therapeutic segments. The domestic operations spans through the country manned by a highly dedicated professional field force and backed by a well-knit channel of distribution ensuring KAPL's presence at the metro as well as micro markets.

KAPL has its branches located in almost all the State Head Quarters. The Company also has an excellent distribution network at almost 18 branches at major cities catering to the respective State area through channel marketing. The supplies are made effective through approved Stockists to Retailers, Nursing Homes and Dispensing doctors in the Trade Segment and directly to Institutions in Rate Contract (RC) & Non-Rate Contract (NRC) Sectors.

6.5.7 Marketing:

Pharma:

The Company has been mainly focusing on prescription market where many of the MNCs and Private Pharma Players have a major share. The Company is also dependent on PP Policy (PPP) for Institutional Business, where concentration is on Central Govenment. Hospitals, State Government Hospitals, Corporates, PSU Hospitals, Defence and Insurance. It has potential to expand in Trade Segment and also to increase volumes by focusing on CPSE Hospitals and large Corporate Hospitals.

Veterinary:

Veterinary Products are being focused for Veterinary Practitioners, Farmers, Animal Husbandry Department of all States and Milk Unions for Veterinary Products and Feed Supplements.

New Products (Pharma & Veterinary)

Table 6O

(Details of New Products)

Sl. No.	Products	Therapeutic Category
Pharma		
a	Numol 650 Tab	Anti-pyretic
b	Numol 250mg Sups.	Anti-pyretic
c	Verclav Duo	Antibiotic
d	Kapitz 100mg / 200mg	Anti-fungal
Veterinary		
Sl. No.	**Products**	**Therapeutic Category**
a	KAP-3	Multi-vitamin
b	KAPTIK	Ectoparasiticide

Company is manufacturing and marketing Oxytocin Injection as per the decision of Government of India.

6.5.8 Exports:

KAPL products are currently exported to about 17 countries such as Malaysia, Thailand, Phillipines, Namibia, Uganda, Myanmar, Yemen, South Africa, Fiji, Botswana, Zimbabwe, Mozambique, Zambia, Bhutan, Sudan, Sri Lanka, and Uzbekistan. The Company plans to further export medicines to additional countries, such as Cambodia, Brazil, Peru and EU countries.

Visit of Dr.Madhuchanda Kar, Independent Director of KAPL to KAPL Peenya Plant on 17.07.2023

Members of the Parliamentary Standing Committee on Chemicals & Fertilizers, Govt. Of India, Study Tour Held at Vizag on 02.09.2023. Seen with Department of Pharmaceuticals Officials and Team KAPL

Visit of Parliament Standing Committee on 28.12.2023. Seen with Department of Pharmaceuticals Officials and Team KAPL

6.6 Rajasthan Drugs & Pharmaceuticals Limited (RDPL)

6.6.1 Background

Rajasthan Drugs & Pharmaceuticals Limited (RDPL) is a Central Public Sector Unit in Joint Sector with a total paid-up equity capital of Rs.4.98 Crores where Government of India (GoI) and Rajasthan State Industrial Development & Investment Corporation Limited (RIICO, Govt. of Rajasthan) hold 51% and 49% shares respectively. It was incorporated in 1978 and commercial production started in 1981. The Company has its manufacturing facilities & registered office at Jaipur. The production activities in the Company have stopped since October, 2016.

6.6.2 Performance

Table 6P

(Performance of RDPL)

(Rupees in Crore)

	2018-19	2019-20	2020-21	2021-22	2022-23
Net Worth	(-) 63.72	(-)89.93	(-) 99.27	(-) 101.40	(-) 103.20
Turnover	0.13	NIL	NIL	NIL	NIL
Earnings (Before Tax)	(-) 11.59	(-)26.21	(-)9.34	(-) 2.13	(-)1.80
Earnings (After Tax)	(-) 11.59	(-)26.21	(-)9.34	(-) 2.13	(-)1.80
Net Profit/Loss	(-) 11.59	(-)26.21	(-)9.34	(-) 2.13	(-)1.80

6.6.3 Present Status of RDPL

On 01.03.2023, Union Cabinet decided to transfer RDPL to State Government of Rajasthan. Accordingly, RDPL is under active process of transfer.

CHAPTER 7

National Pharmaceutical Pricing Authority (NPPA)

7.1 National Pharmaceutical Pricing Authority (NPPA)

7.2 Pricing

7.3 Trade Margin Rationalisation of Medical Devices

7.4 Review Order

7.5 Exemptions granted under Para 32 of DPCO, 2013

7.6 Price Revision of Anti-Cancer Drugs Based on Trade Margin Rationalization

7.7 Savings to the Consumers

7.8 Growth in Therapeutic Segments in 5 Years

7.9 Monitoring availability of drugs through weekly surveys

7.10 Price Monitoring & Enforcement Activities

7.11 Recovery of overcharged amount

7.12 E-initiatives

7.13 Implementation of Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme

7.14 Activities undertaken under 'Azadi ka Amrit Mahotsav'

7.15 Rajbhasha Implementation

7.16 Rajbhasa Prosthsahan Pakhwara 2023

7.17 Vigilance Awareness Week

7.18 Rashtriya Ekta Diwas

7.19 Swachhata Pakhwada, Swachhata Hi Seva and Special Campaign 3.0

7.20 eNewsletter of NPPA: Aushadh Sandesh

7.21 Workshop on Review of working of DPCO 2013 and NPPP 2012

Chapter 7

National Pharmaceutical Pricing Authority (NPPA)

7.1 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 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.

The Government notified the DPCO, 2013 on 15.05.2013 in supersession of DPCO, 1995.

7.1.1 Salient features of DPCO, 2013 are as follows:

- The National List of Essential Medicines (NLEM), notified by the Ministry of Health & Family Welfare is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of the DPCO, 2013 which constitutes the list of scheduled medicines for the purpose of price control.
- Ceiling prices of scheduled formulations are fixed based on 'market-based data'.
- Price control is applied to specific formulations with reference to the medicine (active pharmaceutical ingredient), route of administration, dosage form / strength as specified in the First Schedule.
- The National List of Essential Medicines, 2022 (NLEM 2022) was notified by the Ministry of Health and Family Welfare on 13.09.2022. NLEM, 2022 was thereafter notified as the First Schedule of DPCO, 2013 on 11.11.2022 by the Department of Pharmaceuticals.

7.1.2 Functions of the National Pharmaceutical Pricing Authority (NPPA) are:

- To implement and enforce the provisions of the extant DPCO in accordance with the powers delegated to it
- To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations
- To monitor the availability of medicines, identify shortages, if any, and to take remedial steps
- To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations
- To deal with all legal matters arising out of the decisions of the Authority
- To render advice to the Central Government on changes/revisions in pharmaceutical policy
- To render assistance to the Central Government in parliamentary matters relating to pharmaceutical pricing

7.2 Pricing

7.2.1 Price Fixation

A. Ceiling Price

NPPA fixes the ceiling price of formulation listed in Schedule I of DPCO, 2013. Under the market-based approach adopted in DPCO, 2013, the ceiling price of a scheduled formulation is determined by first working out the simple average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular formulation having a market share of one percent and above, and then adding a notional retailer margin of 16 percent to it. The maximum retail price (MRP) for that particular drug formulation must not exceed the notified ceiling price plus applicable taxes.

National List of Essential Medicines (NLEM) 2022 was issued on 13.09.2022 by Ministry of Health and Family Welfare. Further, Department of Pharmaceuticals through notification S.O. 5249 (E) dated 11.11.2022 has notified it as Schedule-I of DPCO, 2013. There is an addition of 34 drugs while 26 drugs from the previous list (NLEM, 2015) have been dropped. NPPA has fixed the ceiling prices of 923 formulations (733 formulations under NLEM 2022 & 190 formulations under earlier NLEMs) under DPCO, 2013 till 31.03.2024. The details of ceiling prices effective as on 31.03.2024 in various therapeutic categories is given in Table 7A.

Table 7A

(Categories of Medicines under which Ceiling Prices have been fixed under NLEM, 2022)

	Total Ceiling Prices Fixed		Ceiling Prices Fixed under NLEM, 2022	
Therapeutic Category	**Drugs**	**Formulations**	**Drugs**	**Formulations**
Anti-infective Medicines	71	191	62	165
Anticancer Medicines	62	131	59	118
Neurological Disorder Medicines	18	63	18	59
Psychiatric Disorder Medicines	14	42	14	41
Cardiovascular Medicines	26	65	25	59
HIV Management Medicines	21	29	20	23
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs)	12	35	11	24
Anti-Diabetic drugs	8	11	8	11
Hormones, other Endocrine Medicines and Contraceptives	18	37	16	33
Others	158	319	106	200
Unique Drugs / Formulations	**388***	**923**	**321***	**733**

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

The prices are notified through various Gazette Notifications which are also uploaded on NPPA's website at www.nppaindia.nic.in. The ceiling prices become operative and legally enforceable from the date on which the price is notified in the Gazette.

B. Retail Price

NPPA fixes the retail price of medicine based on the Form-I application received from the manufacturing/ marketing companies. The notified retail prices are applicable only to the applicant manufacturing/marketing companies. The retail prices of the medicine are also fixed by the same method as applicable for fixation of ceiling price. NPPA notified retail prices of around 2799 'new drugs' [those qualifying as 'new drugs' as per para 2(1)(u) of DPCO, 2013] till 31.03.2024 under DPCO, 2013. The details are as below:

Table 7B

(Retail Prices fixed by NPPA under DPCO 2013)

Therapeutic Group	No. of new drugs for which retail prices fixed
Non-Communicable disease	**1518**
Anti-Diabetic drugs	1003
Cardiovascular drugs	487
Anti-Cancer drugs	28
Others	**1281**
Total	**2799**

Also, exercising extraordinary powers under DPCO, 2013 in public interest, MRP of 106 non-scheduled drug formulations, including 22 diabetic and 84 cardiovascular drugs was capped in July, 2014. In addition, trade margin on selected 42 anti-cancer medicines was capped to up to 30% in February 2019 on pilot basis.

C. Pricing of Medical Devices:

- **Coronary Stents:**

  Coronary Stents were included in Schedule-I of DPCO, 2013 in December 2016. NPPA notified the ceiling prices for Coronary Stents under Para 19 of the DPCO, 2013 vide notification S.O. 412(E) dated 13.02.2017. The ceiling prices were subsequently revised from time to time considering annual Wholesale Price Index (WPI). Recently, NPPA vide notification S.O.1551 (E) dated 26.03.2024 has revised the ceiling prices considering WPI @0.00551 %.

- **Condoms:**

  The Government had fixed ceiling prices for Condoms vide Gazette Notification No. 1791 (E) dated 10.07.2014 under NLEM, 2011. The current ceiling prices of the Condoms were notified vide Notification No. S.O. 1549(E) dated 26.03.2024 under NLEM, 2022.

- **Intra Uterine Devices (IUD):**

  The Government had fixed ceiling prices for various categories of IUDs vide Gazette Notifications No.1334 (E) dated 27.04.2017 and 1668(E) dated 24.05.2017. The current ceiling prices of the IUDs were notified vide Notification No. S.O. 1547(E) dated 26.03.2024 under NLEM, 2022.

➢ **Orthopaedic Knee Implants for Knee Replacement System:**

NPPA fixed the ceiling price of the Orthopaedic Knee Implants, a non-scheduled medical device, for the first time on 16.08.2017 under Para 19 of the DPCO, 2013 vide notification S.O.2668(E). Subsequently, the validity of the ceiling prices was extended from time to time. Recently, NPPA vide notification S.O.4078 (E) dated 15.09.2023 has extended the applicability of ceiling prices on Orthopaedic Knee Implants to up to 15.09.2024.

7.3 Trade Margin Rationalisation of Medical Devices

With an aim to regulate the prices of medical devices, essential for diagnostic purposes, in general and specifically for COVID-19 management, NPPA on recommendation of Standing Committee on Affordable Medicines and Health Products (SCAMHP), NITI Aayog, vide Gazette Notification dated 03.06.2021 had capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level. Price reduction in 70 out of 252 products was observed and retail prices declined by up to 54% (up to Rs.54,337). NPPA vide notification S.O. 1519 (E) dated 29.03.2023 had extended the capping of trade margin for Oxygen Concentrator till 30.06.2023.

Similarly, Trade margin on Pulse Oximeter, Glucometer, Blood Pressure Monitor, Nebulizer and Digital Thermometer was also capped at 70% vide notification S.O.2808(E) dated 13.07.2021. NPPA vide notification S.O. 1518 (E) dated 29.03.2023 had extended the capping of trade margin for these five medical devices till 30.06.2023. Further, the capping of trade margin for aforementioned medical devices was not extended as the situation has gone back to the pre-pandemic level. However, the prices of the same are monitored under the extant provisions of DPCO, 2013.

7.4 Review Order

Any company aggrieved by the orders of NPPA, files review application to Department of Pharmaceuticals under Para 31 of the DPCO, 2013. DoP after physical hearing in the matter gives necessary review directions and NPPA implements the review directions on merit. During the year 2023-24 (up to 31.03.2024), one review order (Review Order No. 31015/75/2023-Pricing (E-24296) dated 05.03.2024) is pending for implementation with NPPA for which draft sheet has been uploaded on NPPA's website on 15.03.2024.

7.5 Exemptions granted under Para 32 of DPCO, 2013

During the FY 2023-24 till 31.03.2024, NPPA has granted exemption under Para 32 of DPCO 2013 to three companies as under:

i. Exemption granted under Para 32 (i) to M/s.Troikaa Pharmaceuticals Limited for the formulation Paracetamol Injection (Intramuscular) 250mg/ml, 2ml notified vide S.O. 3561 (E) dated 08.08.2023.

ii. Exemption under Para 32 (i) & (ii) of DPCO 2013 granted to M/s.Cadila Pharmaceuticals Limited for their product Cholecalciferol Aqueous Injection 6,00,000 IU/2ml (Vitamin D3 Injection) notified vide S.O. 4662(E) dated 25.10.2023

iii. Exemption granted under Para 32 (i) of DPCO 2013 to M/s. Panacea Biotec Limited for their product EasyfourPol (DTwP-Hib-IPV) Vaccine notified vide S.O. 4661 (E) dated 25.10.2023.

7.6 Price Revision of Anti-Cancer Drugs under NLEM, 2022

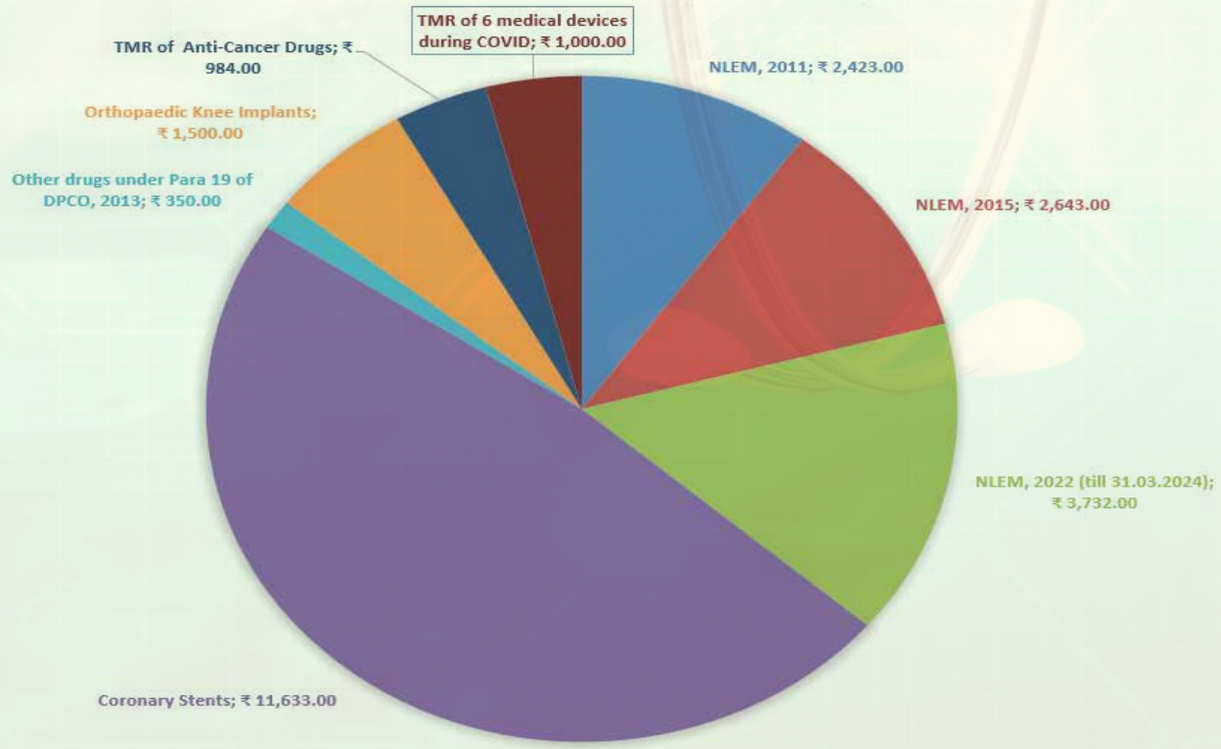
As on 31.03.2024, ceiling prices of 131 Anti-cancer formulations (including palliative care) are effective. The ceiling prices of 118 Anti-cancer formulations (including palliative care) have been fixed under NLEM, 2022. Further, ceiling prices of 13 formulations fixed under NLEM, 2015 are also effective. This has resulted in an estimated annual savings of around Rs. 294.24 crore on account of fixation of ceiling prices of Anti-cancer formulation under NLEM, 2022.

7.7 Savings to the Consumers

The fixation of ceiling prices of scheduled formulations listed in NLEM 2022 (revised Schedule-I) has enabled savings of Rs.3732 crore (till 31.03.2024) to the consumers in addition to the saving of Rs.11,633 crore annually to consumers on account of price fixation of coronary stents. The details of savings are shown in Graph 7A. However, the total savings calculated are in the nature of additional savings since prices of many scheduled drugs are historically under price control. The above estimated savings include savings only on account of Ceiling Price fixation under NLEM 2011, NLEM 2015, NLEM 2022 and other specific measures taken such as trade margin rationalization on Anti-Cancer drugs, price capping of Anti-diabetic/cardiovascular disease, ceiling price fixation of Stents and price capping of knee implants. Additionally, consumers are also benefited due to 10% cap on annual increase in MRP of non-scheduled drugs. Hence, absolute savings on account of price regulation under DPCO, 2013 are likely to be much more than the above estimate.

Graph 7A

{Estimated Annual Saving (Rs. In Crore)}



7.8 Growth in Therapeutic Segments in 5 Years

Major segments of Indian Pharmaceutical Industry include generic drugs, Over the Counter (OTC) medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics. During the past five years from 2019-20 to 2023-24, cardiac, gastro intestinal, anti-diabetic and anti-Infective therapeutic category of drugs have registered high sales with significant Compound Annual Growth Rate (CAGR) of 7.33%, 7.89%, 4.85% and 4.76% respectively (Table 7C). The sales data in absolute terms was not very high for the sex stimulants/rejuvenators and stomatologicals but this class of drugs showed the highest growth at 11.43% and 11.09% respectively.

Table 7C

(Growth in different therapeutic segments during past five years)

Class	Sales 2019-20 (In Cr.)	Sales 2023-24 (In Cr.)	CAGR %
ANTI DIABETIC	14137.90	17919.02	**4.85%**
ANTI MALARIALS	577.46	579.24	**0.06%**
ANTI-INFECTIVES	19788.13	24964.52	**4.76%**
ANTI-NEOPLASTICS	3013.28	4484.62	**8.28%**
BLOOD RELATED	4404.81	5932.81	**6.14%**
CARDIAC	18284.21	26041.80	**7.33%**
DERMA	9724.53	13082.04	**6.11%**
GASTRO INTESTINAL	15828.65	23142.83	**7.89%**
GYNAECOLOGICAL	4536.94	6502.38	**7.46%**
HORMONES	2549.69	3357.62	**5.66%**
NEURO / CNS	8778.67	12149.54	**6.72%**
OPHTHAL / OTOLOGICALS	2589.18	3539.05	**6.45%**
OTHERS	1153.93	1505.80	**5.47%**
PAIN / ANALGESICS	9621.29	14084.89	**7.92%**
RESPIRATORY	11132.77	16009.22	**7.54%**
SEX STIMULANTS / REJUVENATORS	794.14	1364.05	**11.43%**
STOMATOLOGICALS	782.30	1323.30	**11.09%**
UROLOGY	1944.00	2930.44	**8.55%**
VACCINES	2225.40	1733.60	**-4.87%**
VITAMINS / MINERALS / NUTRIENTS	12645.53	17329.46	**6.50%**
Grand Total	144512.80	197976.22	**6.50%**

Source: Pharmatrac Market Database (March 2024)

#Vaccines are mostly supplied to institutions and hence vaccines showing negative CAGR of 4.87% may not reflect the correct picture as Pharmatrac market database does not capture institutional sales.

Based on the sales data for the FY 2023-24, it is observed that the market share of large, medium and small companies across all categories was 79%, 18% and 3% respectively **(Table 7D**). In Anti-Infectives, Anti-Malaria, An-

ti-diabetic, Cardiac, Respiratory & Neuro categories, large companies have a high share (more than 85%) whereas in pain/analgesics, Gynaecological & Anti-Neoplastics etc. the share of large companies was around 65%.

Table 7D

(Group of drugs and company size wise market share during FY 2023-24)

Class	Sales 2023-24 (In Cr.)	Market Share in % of companies		
		Large	Medium	Small
ANTI DIABETIC	17919.02	85%	13%	2%
ANTI MALARIALS	579.24	88%	6%	6%
ANTI-INFECTIVES	24964.52	89%	9%	2%
ANTI-NEOPLASTICS	4484.62	69%	28%	2%
BLOOD RELATED	5932.81	73%	23%	4%
CARDIAC	26041.80	86%	13%	1%
DERMA	13082.04	74%	20%	6%
GASTRO INTESTINAL	23142.83	80%	16%	4%
GYNAECOLOGICAL	6502.38	67%	29%	3%
HORMONES	3357.62	87%	11%	2%
NEURO / CNS	12149.54	87%	9%	4%
OPHTHAL / OTOLOGICALS	3539.05	58%	34%	8%
OTHERS	1505.80	59%	32%	9%
PAIN / ANALGESICS	14084.89	68%	28%	4%
RESPIRATORY	16009.22	86%	11%	3%
SEX STIMULANTS / REJUVENATORS	1364.05	91%	7%	2%
STOMATOLOGICALS	1323.30	58%	35%	7%
UROLOGY	2930.44	85%	13%	2%
VACCINES	1733.60	59%	31%	9%
VITAMINS / MINERALS / NUTRIENTS	17329.46	61%	34%	5%
Grand Total	197976.22	79%	18%	3%

Source: Pharmatrac Market Database (March 2024)

Note: Companies have been classified as Large, Medium and Small based on the domestic turnover of ₹ 1,000 crore and above, between ₹ 100 crore to ₹ 1,000 crore and up to ₹ 100 crore respectively.

7.9 Monitoring availability of drugs through weekly surveys

The availability of key medicines 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.

7.10 Price Monitoring & Enforcement Activities

Monitoring Availability and Affordability of Medicines

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/ complaints received from various sources

Graph 7B

The monitoring of increases in the price of formulations beyond the permissible limit is also done on the basis of Pharmatrac data and individual complaints received.

Whenever companies are found selling scheduled formulations at prices higher than the price notified by NPPA, action is taken against such companies under the relevant provisions of DPCO 2013 and the overcharged amount, along with interest is levied on the company. Action is also taken whenever companies are found to have taken an increase in price which is more than permissible under the DPCO, 2013. Thus, companies selling non-scheduled formulations at a price which is higher by more than 10% of the MRP in the preceding twelve months for that drug and in case of scheduled formulations companies taking an increase more than that of Wholesale Price Index (WPI) are liable for action for overcharging under the relevant provisions of DPCO, 2013.

NPPA monitors the availability of drugs, identifies shortages, if any, and takes remedial steps to make the drugs available to consumers. As and when the reports for shortages of a particular drug(s), in any part of the country are received, the concerned company is asked to rush the stock to the affected areas and to make the drugs available.

To ensure that medicines are available to patients at the notified prices, NPPA works closely with State Drugs Controllers for enforcement activities. Samples of medicines are picked up from the open market regularly and analysed to monitor the price at which the medicines are sold to patients. Enforcement activities from 2014-15 to 2023-24 are given in Table 7E

Table 7E

(Number of Samples collected and violations)

Year	Number of Samples Collected	*Prima Facie* Violations detected
2014-2015	3898	1020
2015-2016	2534	613
2016-2017	1817	930
2017-2018	2418	1032
2018-2019	1391	324
2019-2020	938	350
2020-2021	1073#	537#
2021-2022	907#	391#
2022-2023	1081#	455#
2023-2024	2284#	888#

Note: # -Overcharging cases referred from State Drug Controllers and PMRUs are included under the 'Samples Collected'.

7.11 Recovery of overcharged amount

The overcharged amount is recovered from the pharmaceutical companies along with interest and penalty thereon as per the provisions of DPCO. Cases of companies not complying with the demand notices are referred to the District Collectors for recovery of overcharged amounts as arrears of land revenue and could also attract prosecution under the provisions of the Essential Commodities Act, 1955.

As on 30.9.23, NPPA has about 2433 overcharging cases and an amount of Rs.1371.9 crore (approx.) under DPCO 1979, DPCO 1987, DPCO 1995 & DPCO 2013 has been recovered from the pharmaceutical companies. Action for recovery of the overcharged amount along with interest thereon is a continuous process. NPPA takes action as per the provisions of DPCO, 1979, DPCO, 1987, DPCO 1995 & DPCO 2013 read with the Essential Commodities Act, 1955.

7.12 E-initiatives

NPPA has also undertaken following e-initiatives for better disposal of grievances of general public:

A. Pharma Sahi Daam and Pharma Jan Samadhan APP

Pharma Jan Samadhan (PJS) serves as a robust e-governance tool for protection of consumer interest through effective implementation of the Drugs (Prices Control) Order, 2013 with the objective to put in place a speedy and effective complaint redressal system with respect to availability of medicines, overpricing of medicines, sale of 'new drugs' without prior price approval (WPA) and refusal to supply or sell medicines. Complaints can be registered under PJS link available at the NPPAs website i.e.www.nppaindia.nic.in or on Pharma Sahi Daam App and also at the toll free number 1800111255 & Email – monitoring-nppa@gov.in.

Any individual or consumer organization or stockiest / distributor / dealer / retailer or State Drug Control-

ler can lodge complaints online to NPPA through PJS. Action on the complaint received through PJS with complete information is initiated within 48 hours by the NPPA.

The Pharma Sahi DaamApp 2.0 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).

B. Integrated Pharmaceutical Database Management System (IPDMS)

Integrated Pharmaceutical Database Management System was launched by NPPA in 2015 which was further upgraded to a more responsive, cloud-based version, IPDMS 2.0 and was launched on 29.08.2022. 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. Graph 7C shows the number of companies registered in IPDMS from March, 2017 to March 2024:

Graph 7C

(Number of Companies Registered in IPDMS)

7.13 Implementation of Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme

Consumer Awareness, Publicity and Price Monitoring (CAPPM), a Central Sector Scheme of NPPA has two components, viz. (i) Assistance to set-up Price Monitoring and Resource Units (PMRUs) in the States/ UTs, and (ii) Advertisement and Publicity for CAPPM. 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. Under this scheme 100% funds are provided to PMRUs for their recurring and non-recurring expenditure.

NPPA is in the process of establishing Price Monitoring and Resource Units (PMRUs) in all the 36 States/

UT. As on 31.03.2024, PMRUs have been set up in 31 States/ UTs viz. Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh, Himachal Pradesh, Bihar, Uttarakhand, Meghalaya, Arunachal Pradesh, Chandigarh Assam, Dadra & Nagar Haveli and Daman & Diu and Lakshadweep. Setting up of PMRUs in remaining States/ UTs is in different stages of progress.

Under Advertisement and Publicity for CAPPM- both NPPA and PMRUs conduct IEC activities like training, seminars, webinars, campaigns with different stakeholders regarding consumer awareness.

During the F.Y. 2023-24, NPPA has organized eleven online webinars and four awareness campaigns. The main aim of these webinars/ campaigns was to create awareness and provide 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.

7.14 Activities undertaken by NPPA under 'Azadi ka Amrit Mahotsav'

(i) India MedTech Expo 2023 event on Medical Devices sector from 17th - 19th August 2023 at Helipad Exhibition Centre, Gandhinagar, Gujarat

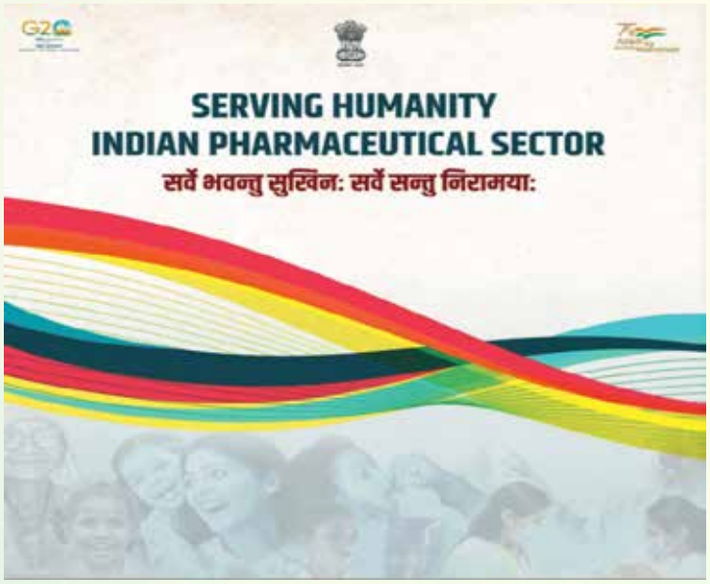
Department of Pharmaceuticals, Government of India organized '**India MedTech Expo 2023'** a large-scale event on medical devices sector from 17th – 19th August 2023 at Helipad Exhibition Centre, Gandhinagar, Gujarat to showcase India's journey and opportunities in the sector. The main objective of the event was to bring together industry, academia, research institutions, investors, State Governments, MedTech parks and the Government officials for taking the Pharma sector on a higher growth trajectory.

The inaugural event, held on 17th August 2023, was graced by Hon'ble Union Minister of Health & Family Welfare and Chemicals & Fertilizers, Dr. Mansukh Mandaviya along with Chief Minister of Gujarat Shri Bhupendrabhai Patel. Dr. V.K. Paul, Member, NITI Aayog; Ms. S. Aparna, Secretary Pharma; Shri K.K. Pant,Chairman NPPA, along with other dignitaries. The dignitaries also unveiled the Coffee Table Book titled:

Serving Humanity: The Indian Pharmaceutical Sector

"जन औषधि - सस्ती भी अच्छी भी"

Counsling of Coffee Table Book



The Coffee Table Book showcases the inspiring story of India becoming "Pharmacy of the world". It throws light on the visionaries from the past whose collective efforts have transformed the generic drug industry into a vital cornerstone of modern healthcare. The book serves as a testament to the tireless efforts and unwavering dedication of countless individuals who have contributed to the development, accessibility and success of the sector.

Awareness Campaign by NPPA at India Medtech Expo 2023

A three day Awareness Campaign at 'India Medtech Expo 2023' in Gandhi Nagar, Gujarat was organised by NPPA along with the Officials of PMRU Gujarat from 17.08.2023 to 19.08.2023. During the campaign activities like displaying creatives, running TVCs on LED screen, distributing brochures and providing information through interaction/ discussion with people were undertaken. Through these activities, visitors including Doctors, Government Officials, Pharmaceutical/ Medical Device manufacturer/ Marketers, Pharma Students, Start-ups and others were made aware about Pharmaceutical Pricing, Functions of NPPA, Pharma Sahi Daam Mobile App and IPDMS 2.0. More than 250 people were covered during the campaign.

Address Compaign at India Medtech Expo

(ii) Webinar on Management of expiry/ near expiry medicines

In the Run-up of India @ 75, 'Azadi ka Amrit Mahotsava', NPPA organized a webinar with PMRUs on 'How to handle medicines nearing expiry date or already expired' on 14.08.2023. The main aim of webinar was providing guidance and sharing of knowledge with PMRUs for ensuring the safe and responsible disposal of expiry/ near expiry medicines. In the webinar, Dr.H.S. Rehan, Director, Professor and Head, Department of Pharmacology, Lady Hardinge Medical College and Associated Hospital, apprised about:

- Factors contributing to high prevalence of expired drugs
- Types of Pharmaceutical waste
- Hazards of unused/ expired medicines
- Challenges in handling expiry/ near expiry medicines
- Strategies to reduce wastage of medicines
- Methods for safe disposal of medicines

The PMRUs in the State/ UTs have actively participated in the webinar.

(iii) State Level Events/ Seminars organised by PMRUs

In the Run up of India @75 'Azadi ka Amrit Mahotsava', till 31.03.2024, 64 State level events were organized by PMRUs in their respective States/ UTs viz. Tripura, Jammu & Kashmir, Uttar Pradesh, Madhya Pradesh, Andhra Pradesh, Kerala, Mizoram, Punjab, Ladakh, Karnataka, Jharkhand, Nagaland, Haryana, Goa,Meghalaya, Puducherry and Uttarakhand on various topics. These events were aimed at spreading awareness among people about fixation of Ceiling Prices under NLEM 2022 and its significance in Healthcare, Drug Price Regulations under the provisions of DPCO, 2013, role of NPPA in making the drugs affordable and available for all, Functions of PMRUs, Pharma Sahi Daam Mobile App and IPDMS 2.0.




Events Organised under Azadi ka Amrit Mahotsava

7.15 Rajbhasha Implementation

In NPPA, Official Language Implementation Committee (OLIC) works under the Chairmanship of Chairman, NPPA and all other officers of NPPA are members of this Committee. The Committee reviews the progressive use of Hindi in day-to-day official work in its quarterly meetings held in the office of NPPA. Members of the Committee discuss about progress in their respective divisions and also give suggestions to improve the use of Hindi in official work.

NPPA received shield for remarkable progress in Raj Bhasha Hindi in the Hindi Salahkar Samiti meeting of Ministry of Chemicals and Fertilizers held on 30.05.2023.

HMCF Giving the Shield to Chairman NPPA for Remarkable Progress in RajBhasha

7.16 Rajbhasa Protsaahan Pakhwara 2023

Hindi Protsaahan Pakhwara 2023 was organised in NPPA from 18.09.2023 to 29.09.2023 with an objective to encourage officers and employees to progressively increase the use of Hindi in their day-to-day official work and to help the Department create an atmosphere conducive to use of Hindi. During this period, various competitions were organized in which regular as well as contractual and outsourced staff participated enthusiastically. Winners of different competitions were awarded with cash prizes and certificate by Chairman, NPPA on 19.10.2023. In the same program, awards were also given to the winners of Hindi Incentive Scheme and Swachhta Pakhwada competitions.

Program Undertaken During Hindi Pakhwara

7.17 Vigilance Awareness Week

Vigilance awareness week was observed in NPPA from 30.10.2023 to 05.11.2023. The direction of CVC was circulated among the officials of NPPA urging them to take integrity pledge.

7.18 Rashtriya Ekta Diwas

Rashtriya Ekta Diwas was observed in the office of NPPA on 31.10.2023.

7.19 Swachhata Pakhwada, Swachhata Hi Seva and Special Campaign 3.0

(i) Swachhata Pakhwada:

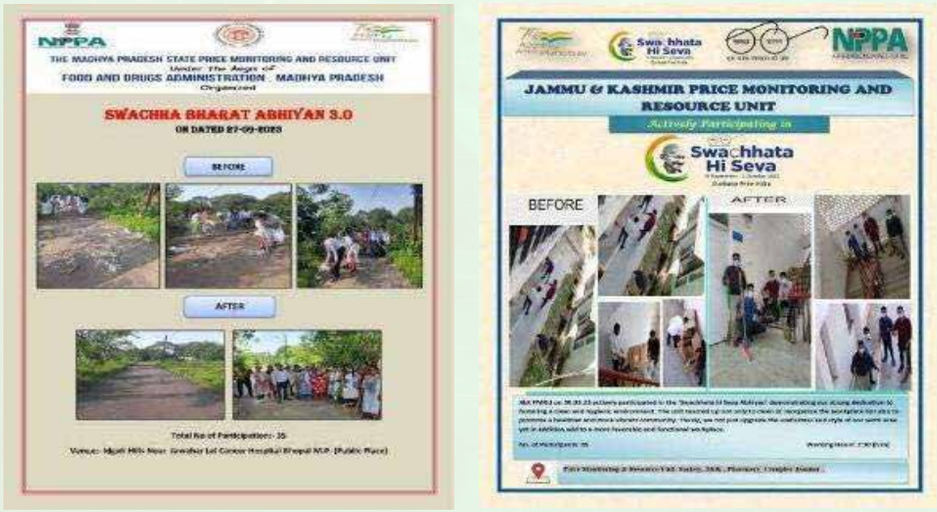
NPPA observed Swachhata Pakhwada from 01.09.2023 to 15.09.2023. The message of Hon'ble Minister on the occasion of Swachhata Pakhwada 2023 was disseminated among the officers and staff of NPPA to encourage them to contribute more to the success of Swachhata Pakhwada-2023.

During this period the staff and officers were sensitised about the Swachhata Phakhwada 2023 to maintain cleanliness of the office premises including the individual sitting area and the surrounding. During the Pakhwada, old and unusable furniture, scrap items and e-waste were identified for disposal as per the procedure. One thousand files were identified and reviewed.

To inculcate the habit of swachhata and to inspire officials of NPPA, competitions on Swarachit Kavita Path and Debate/ Discussion on 'Swachhata' were organised and the best three in each category were awarded. The competitions were held on 11th and 12th September 2023.

(ii) Swachhata Hi Seva campaign:

In response to the Government of India's 'Swachhata Hi Seva' (SHS) campaign, NPPA in co-ordination with PMRUs in the States/ UTs conducted 'Swachhata Hi Seva' (SHS) i.e. preparatory phase campaign from 15th September – 1st October 2023 to raise awareness about cleanliness and sanitation. Massive cleanliness drives were undertaken by PMRUs in the States/ UTs at Office premises as well as public places as was envisaged by SHS. The details of swachhata activities along with photos of prior to the activity/post the activity, number of people who participated and location (the building/ premises name) were uploaded on the SHS Portal at https://swachhbharatmission.gov.in/. PMRUs devoted 373 hours of shramdan for carrying out the Swachhata activities at Offices, Government Colleges, Places near Hospitals, nearby Gardens, Housing Complexes etc.



Program Undertaken By PMRUS during Swatchhta Hi Sewa Compaign

(iii) Special Campaign 3.0:

(a) Under Special Campaign 3.0 during October 2023, NPPA in co-ordination with PMRUs in the States/ UTs conducted '**Swachhata Special Campaign 3.0**' from 02.10.2023 to 31.10.2023. The focus areas

of the Campaign included space management, disposal of scrap /waste materials, cleanliness drives, plantation, disinfection, beautification of public places.

During the campaign period from 02nd – 31st October 2023, 68 different activities were carried out i.e. cleanliness drives, plantation of trees, beautification and other innovative activities to exemplify the importance of team efforts with emphasis on Jan Bhagidari (803 Persons), Swachhata and Shramdaan (1341 devoted man hours) at different public places like colleges/schools, parks, water tanks, roads, Drug Control offices, Testing & Research Laboratories etc.

Cleaning activities undertaken During special compaign 3.0

Initiative taken to install a box for unused Disposing expired/unused medicines

(b) During this period, under the Special Campaign 3.0, NPPA adopted following two best practices:

(i) To ensure the safe and proper disposal of leftover/expired/near expiry medicines and to protect our environment, "**Guidelines on Storage and Disposal of Drugs"** was framed by NPPA in consultation with Lady Hardinge Medical College/Hospital and circulated to SDCs and PMRUs for use. These guidelines will help the PMRUs to ensure the safe and responsible disposal of expired/ near expiry medicines and to protect the environment.

(ii) With the objective of ensuring proper disposal of expired/unused medicines, National Pharmaceutical Pricing Authority (NPPA) in association with Lady Hardinge Medical College (LHMC) / Hospital, Delhi and Mediflo undertook an initiative to keep a box in the office premises of NPPA at the YMCA, Cultural Centre Building for collection of expired/unused medicines and their subsequent proper disposal. An event in this regard was organized by NPPA on 18.10.2023, which was attended by Shri Kamlesh Kumar Pant, Chairman, NPPA, Dr. Vinod Kotwal, Member Secretary, NPPA, Shri Sanjay Kumar, Adviser, NPPA, Ms. Gayatri Nair, Economic Adviser, DoP, Shri G.L. Gupta, Director (Admin & M&E), NPPA, Prof H.S. Rehan, Professor and Head of Pharmacology, LHMC, Delhi and other officials of NPPA, and representative from YMCA.

Chairman, NPPA encouraged the employees of NPPA and others visiting the building to rise to the occasion and to make best use of the box for dropping the expired/unused medicines. Prof. Rehan further informed that the collected medicines will be taken away from time to time and segregated by Lady Hardinge Medical College and Mediflo for further disposal after assessing their utility. He also explained as to why proper disposal of ex-

pired / unused medicines is important for various reasons including prevention of misuse and abuse of especially controlled substances and reduction of harm to environment and ecosystem from biodegradable antibiotics, anti-neoplastics (anti-cancer), etc.

7.20 e-Newsletter of NPPA: Aushadh Sandesh

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

Table 7F

Month	Topic of Article
April, 2023	Health technology assessment in India: implications for value-based pricing for drugs and devices
June, 2023	Biosimilars – the emerging wave for the Indian Pharma Sector
August, 2023	MSME and innovation
October, 2023	Changes in Disease Profile – Patient awareness and Action
December, 2023	Pradhan Mantri Bhartiya Janaushadhi Pariyojana– India's Initiative for affordable medicines
February, 2024	An analysis of Antibiotics use as per WHO AWaRe classification

7.21 Workshop on Review of working of DPCO, 2013 and NPPP, 2012

NPPA in coordination with Department of Pharmaceuticals organized an interactive workshop under the chairmanship of Dr V.K. Paul, Member(Health), NITI Aayog on 16.05.2023 with the representatives of Pharmaceutical and Medical Device Associations on "Review of working of DPCO, 2013 and NPPP, 2012. " About 100 industry stakeholders participated in this workshop. The workshop aimed at getting the industry feedback regarding amendments in DPCO 2013, wherever necessary.

Review of working of DPCO, 2013 and NPPP, 2012

CHAPTER 8

Fostering International Cooperation

8.1 Joint Working Group (JWG) Meetings

8.2 Workshops / conferences/ roundtable on international collaboration organized by DoP

8.3 Participation by delegation of Department of Pharmaceuticals in international events /meetings

8.4 Visit of foreign delegations to India hosted by DoP / international meetings facilitated by DoP

8.5 Participation in negotiations of Trade Agreements led by the Department of Commerce

8.6 Participation in negotiations of WHO led by the Department of Health and Family Welfare

8.7 Participation of the Department in meetings of Joint Working Group / Trade Committees led by Department of Commerce /Department for Promotion of Industry and Internal Trade/ Department of Health and Family Welfare to take forward areas of pharmaceutical cooperation

8.8 G20 Events of the Department

8.9 Bilateral meetings by Department of Pharmaceuticals in the G-20 Presidency 2023 events /meetings

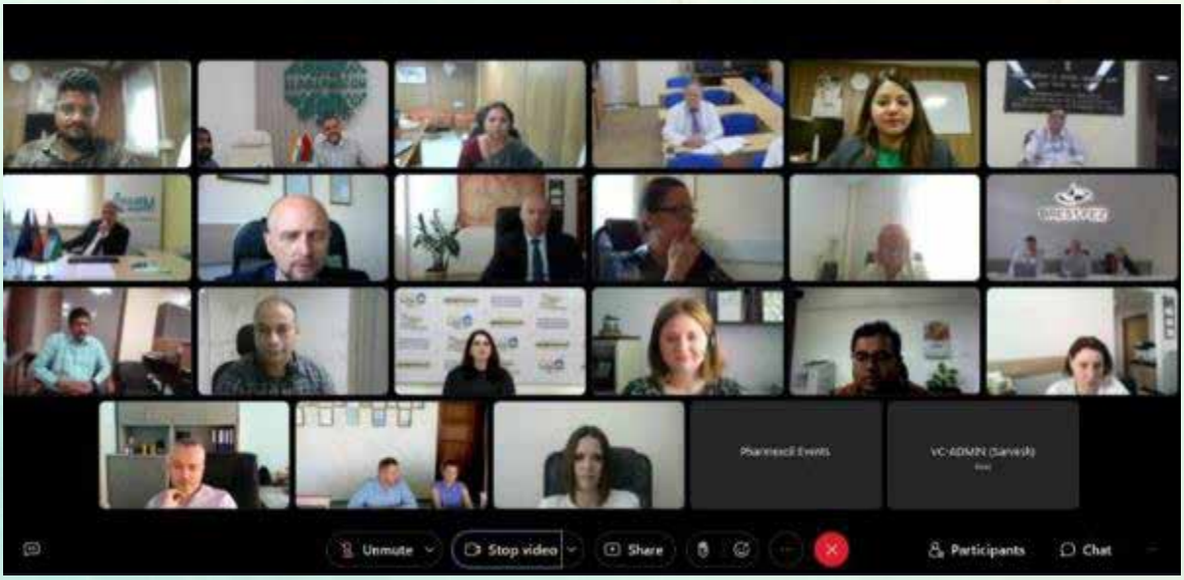
Chapter 8

Fostering International Cooperation

The International Cooperation Division of the Department of Pharmaceuticals (DoP) deals with matters related to bilateral as well as multilateral cooperation in the areas of pharmaceuticals and medical devices. Bilateral cooperation primarily entails facilitation of institutional collaboration through NIPERs, seeking resolution of market access issues and webinars for bilateral investments. These are taken up in Joint Working Groups (JWGs) on Pharmaceuticals led by DoP as well as other bilateral meetings held independent of JWGs; and inter-ministerial bilaterals viz., JWG led by Department of Health and Family Welfare, Joint Trade Committees / Working Groups led by Department of Commerce (DoC), Investment Committees led by Department for Promotion of Industry and Internal Trade and meetings facilitated by Ministry of External Affairs. Matters related to G20, BRICS, QUAD, World Economic Forum as well as WHO and WTO are also dealt with by the Division. In 2023-24, the following activities were undertaken by the Division to take forward the areas of cooperation in pharmaceuticals and medical devices.

8.1 Joint Working Group (JWG) Meetings:

India-Belarus Joint Working Group (JWG) on Pharmaceuticals: The 2nd meeting of the India-Belarus Joint Working Group on Pharmaceuticals was held on 4th August 2023 through virtual mode hosted by New Delhi. The Belarus delegation was led by Mr. Androsyuk B.N., Deputy Minister of Health from the Republic of Belarus, and the Indian delegation was led by Ms. Gayatri Nair, Economic Adviser, Department of Pharmaceuticals. In the meeting, both sides reviewed bilateral trade, discussed aspects of regulation and possible collaboration in capacity building & research, Ayurveda pharmacopeia and investments.



Officials of Indian side and Belarus side along with Indian and Belarus stakeholders in 2nd Meeting of the India-Belarus JWG on Pharmaceuticals

8.2 Workshops / conferences / roundtable on international collaboration organized by DoP

i. A workshop was organized by Department of Pharmaceuticals and Ministry of External Affairs on 24.02.2023 with select resident Missions of Asia, Africa and Latin America , to showcase Pradhan Mantri Bhartiya Jan Aushadhi Pariyojna (PMBJP) model as a best practice which can be emulated by other governments to

provide quality medicines to their citizens while saving substantial amount to the public exchequer**.** The workshop was co-chaired by Hon'ble Minister of Chemicals and Fertilizers and Health and Family Welfare Dr. Mansukh Mandaviya and Hon'ble Minister for External Affairs Dr. S. Jaishankar.

Hon'ble Minister for Chemicals and Fertilizers, Dr. Mansukh Mndaviya addressing the Conference on Pradhan Mantri Bharatiya Janaushadhi Pariyojana with Heads of Missions in Delhi

ii. The Department of Pharmaceuticals conducted a virtual conference with the member states, observers, and dialogue partners of the Shanghai Cooperation Organization (SCO) on 2nd May 2023 on the topic "***Collaborations in developing and manufacturing cost effective diagnostics and therapeutics***". The conference deliberated about leveraging the works undertaken in India on cost-effective diagnostics and therapeutics by SCO members as well as emphasizing the importance of ensuring affordable medical countermeasures to promote effective access and availability. The conference was chaired by Shri. Awadhesh Kumar Choudhary, Senior Economic Advisor, Department of Pharmaceuticals. During the conference detailed presentations were made by experts from various organisations like National Institute for Pharmaceutical Education and Research (NIPER)-Kolkata, Indian Pharmaceutical Alliance (IPA), Indian Council for Medical Research (ICMR), World Health Organization (WHO), Department of Biotechnology (DBT), Foundation for Innovative New Diagnostics (FIND), Association of Diagnostic Manufacturers of India (ADMI), Global Antibiotic Research & Development Partnership (GARDP), and Biotechnology Industry Research Assistance Council (BIRAC).

Opening remarks by Shri. Awadhesh Kumar Choudhary, Senior Economic Advisor, Department of Pharmaceuticals in the SCO meeting.

iii. DoP chaired the "India-Sweden Ease of Doing Business Roundtable" on 27th February 2024 in collaboration with Invest India in which the Embassy of Sweden in India, Swedish Chamber of Commerce India, Business Sweden along with Sweden Industry representatives also participated. Opportunities for collaboration in Promotion of Research and Innovation in the Pharmaceutical and Medical Technology Sector (PRIP) Scheme, in bulk drug parks and medical devices parks were showcased followed by interactive session.

Officials of DoP, Embassy of Sweden in India, Swedish Chamber of Commerce India, Business Sweden along with Sweden Industry representatives at "India-Sweden Ease of Doing Business Roundtable"

8.3 Participation by delegation of Department of Pharmaceuticals in international events /meetings

i. Shri. Awadhesh Kumar Choudhary, Senior Economic Advisor, DoP participated in the investment roadshow in Tokyo and Osaka, Japan led by Secretary, DPIIT during 27 February to 1 March 2023. Senior Economic Advisor also participated in the Make in India Seminar showcasing opportunities in the Indian Pharmaceutical and Medical Devices Sector. Further, a dedicated Round Table meeting in Medical Devices was held with Japanese Companies to portray investment prospects in India and elicit information on any plans of Japanese companies w.r.t. expansion in India.

ii. Shri. Venkat Hariharan Asha, Deputy Director, DoP participated in the 4th Meeting of India-US Counter Narcotic Working Group (CNWG) on 19-20 July, 2023 at Washington D.C. U.S.A wherein Memorandum of Understanding between The United States of America and The Republic of India concerning bilateral Drug Policy Framework was discussed.

Indian Delegation for the 4th Meeting of the India-US Counter Narcotic Working Group (CNWG) at Washington D.C. U.S.A

iii. Dr. Richa Pandey, Deputy Secretary, DoP participated in the 5th Indo-US Health Dialogue at Washington DC, USA between 10th-13th October 2023 and made a presentation related to Pandemic Preparedness and Response (Resilient Supply Chain and Access to Medical Products) as well as Health Safety & Security & Strengthening and Harmonization of Regulatory System at the meeting.

Indian Delegation at the 5th Indo-US Health Dialogue at Washington DC, USA

iv. Shri Awadhesh Kumar Choudhary, Senior Economic Advisor, DoP, participated in the 6th Meeting of the Intergovernmental Commission (IGC) for Commercial, Economic, Scientific and Technological Cooperation between the Republic of Azerbaijan and the Republic of India 25th-26th October, 2023 in Baku, Azerbaijan The Azerbaijan-India IGC was co-chaired by Mr. Mukhtar Babayev, Minister of Ecology and Natural Resources, on behalf of the Government of the Republic of Azerbaijan and Smt. Anupriya Patel, Minister of State for Commerce and Industry, on behalf of the Government of India wherein cooperation in the pharmaceutical sector through National Institutes of Pharmaceutical Education and Research (NIPERs) was discussed.

v. Ms. Gayatri Nair, Economic Advisor, DoP participated in the second World Local Production Forum (WLPF) organized by the World Health Organisation at The Hague, The Netherlands from November 6 to 8, 2023 as a panellist in the session titled "Tackling bottlenecks of Regional Production". Her presentation highlighted the essential ingredients required for a successful regional production initiative and the major interventions by Government of India, especially Department of Pharmaceuticals in supporting all stages of product development from ideation to commercialization.

Participation in the second World Local Production Forum (WLPF) at The Hague, Netherlands.

vi. Ms Divya Kadyan, Section Officer (IC section), DoP participated in the Inter - Government Sub-Committee (IGSC) meeting on Trade, Transit and Cooperation to Control Unauthorized Trade between India and Nepal on 12th -13th January, 2024 at Kathmandu, Nepal wherein market access issues of pharmaceuticals were discussed.

Meeting of the IGSC at Kathmandu, Nepal.

8.4 Visit of foreign delegations to India hosted by DoP / international meetings facilitated by DoP

i. A meeting was chaired by Secretary, Pharmaceuticals with H.E. Dr. Amin Al Amiri, Assistant Under Secretary in Ministry of Health, UAE along with UAE delegation on 13th February 2023 wherein investment opportunities in bulk drug parks and medical devices parks, challenges of Indian companies exporting to UAE in obtaining time-bound marketing authorisation under India-UAE CEPA, possible collaboration with NIPERs and investment opportunities in Pharma and Medical Devices sector in UAE were discussed.

Meeting with H.E. Dr Amin Al Amiri, Assistant Under Secretary in Ministry of Health, UAE

ii. Meeting with Mr. Teodoro Maldonado, Ambassador of Ecuador was held on 20th March 2023 through virtual mode hosted by New Delhi to further explore possibilities w.r.t. sourcing more medicines by Ecuador from India. In the meeting discussions were held about adoption of Pradhan Mantri Jan Aushadhi Pariyojana in Ecuador.

iii. Meeting with Mr. Lama A. Alabduiwahab, Organizations and International Cooperation, Ministry of Industry and Mineral Resources, Kingdom of Saudi Arabia was organized on 22nd March 2023 through virtual mode hosted by New Delhi under chairmanship of Joint Secretary, DoP from the Indian side wherein possible cooperation in bilateral investments between the two sides was explored.

iv. Meeting with Prof. Padmashree Gelh Sampath, Senior Advisor to the President of the African Development Bank (AfDB) was held on 13th June 2023 wherein collaboration with AfDB, with participation of African Pharmaceutical Technology Foundation (APTF), Africa Centre for Disease Control and Prevention (CDC) and Partnership for African Vaccine Manufacturing (PAVM) to brainstorm to identify potential investment opportunities in Africa was discussed.

v. Meeting with Department of Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport, Netherlands was organized on 21st June 2023 under chairmanship of Joint Secretary, DoP wherein collaboration between India – Netherlands to promote equity and affordability of pharmaceutical products in Netherlands, cross border investment and partnership to strengthen resilience in global supply chains, collaboration of NIPERs including development of Centre of Excellence (CoE) between NIPERs and concerned counterpart institutions in Netherlands was discussed.

vi. Meeting of Secretary, Pharmaceuticals with H.E. Mr. Didier Vanderhasselt, Ambassador of Belgium to India was held on 10.07.2023 to further explore possibilities w.r.t. sourcing more medicines by Belgium from India, and discussions about technology transfer on specific products.

vii. Secretary, DoP held a meeting with Seychelles High Commissioner on 07.08.2023 to discuss pharma cooperation between the two countries and greater sourcing of medicines from India by Seychelles.

viii. Ambassador of the Republic of Cuba, H.E Mr. Alejandro Simancas Mann met Secretary, DoP on 28.08.2023 and discussed areas of cooperation in pharma including recognition of Indian Pharmacopoeia, bilateral exchange between regulators and sourcing greater medical supplies from India.

ix. Meeting with the Eurasian Economic Commission facilitated by Embassy of India, Moscow was held on 04.09.2023 wherein issues pertaining to Good Manufacturing Practices (GMP) certification and clinical trials in member countries of Eurasian Economic Union were discussed to explore possibilities to boost export of pharmaceuticals from India to the Eurasian Economic Union and promote access of affordable medical countermeasures therein.

x. Ms. Louise Sevel, Counsellor for Health, Embassy of Denmark in Delhi met Economic Advisor, DoP on 14th September 2023 and shared insights & information about the pharmaceutical industry in India and Denmark. Also potential areas of collaboration, including possibility of co-development of Center for Excellence with NIPERs, was discussed.

Meeting with Ms. Louise Sevel, Counsellor for Health, Embassy of Denmark in Delhi

xi. DoP participated in the meeting between Hon'ble Minister, Health & Family Welfare and Chemicals & Fertilizers with Mrs. Hélène Budliger Swiss State Secretary of Economic Affairs and Dr. Severin Schwan, Chairman of the Board of Directors of Roche Holding Ltd. on 20th September, 2023 wherein issues pertaining to pharmaceutical patents were discussed.

xii. Dr. Robert Califf, Commissioner of the U.S. Food and Drug Administration met Secretary, DoP on 22.09.2023. Issues pertaining to supply chain resilience; monitoring of drug shortages and assurance of continuity of supply chain; nurturing quality ecosystem; and potential of India as a future hub of clinical trials were discussed.

Meeting with Dr. Robert Califf, Commissioner of the U.S. Food and Drug Administration

xiii. A Meeting was convened under chair of Secretary, Department of Pharmaceuticals with Mr Selby Pillay, Ambassador, Seychelles Foreign Affairs Department; CEO, Health Care Agency; Chief Pharmacist and Procurement Officer for Pharmaceutical Supplies from Seychelles; Director General, Pharmexcil and officers from Ministry of External Affairs (MEA) and Seychelles High Commission on 11th October 2023 wherein the possibility of greater sourcing of medicines by Seychelles from India was discussed.

Meeting with Mr Selby Pillay, Ambassador, Seychelles Foreign Affairs Department

xiv. A Meeting was chaired by Secretary, Department of Pharmaceuticals with H.E. Ana Taban, Ambassador of the Republic of Moldova to the Republic of India on 27.10.2023 wherein various aspects of bilateral cooperation between Moldova and India were discussed.

xv. Dr. Rahul Gupta, Director, US Office of National Drug Control Policy (ONDCP); Mr. John Unger Special Advisor; and Mr. Gary Applegarth, First Secretary, US Embassy, and official from MEA met Secretary, Pharmaceuticals on 20th November 2023, wherein ongoing work undertaken to mitigate drug abuse and diversion of illicit chemicals/drugs were discussed.

xvi. Mr. Bart Ooijen, Counsellor of Health, Welfare, and Sport and Ms Ravleen Pal, Deputy Head of Economic Section, Embassy of Netherlands met Economic Advisor, DoP on 28th November 2023 wherein possible cooperation in bilateral investments, capacity building with NIPERs and strengthening of pharmaceutical supply chains between India and Netherlands were discussed.

xvii. Dr. Mohamad Peykanpur, Hon'ble Director General, Ministry of Health of Islamic Republic of Iran, Mr. Mohammadreza Abedi, Deputy Director General, Ministry of Health of I.R of Iran along with a delegation of officers from Ministry and Embassy of Islamic Republic of Iran met Economic Advisor, DoP on 30th November, 2023**,** wherein possible collaboration with NIPERs and investment opportunities in Pharma and Medical Devices sector were discussed.

Meeting with Dr. Mohamad Peykanpur, Hon'ble Director General, Ministry of Health of I.R of Iran, MR Mohammadreza Abedi- Deputy Director General, Ministry of Health of I.R of Iran and officials of Embassy of Iran.

xviii. Mr. Yuta Yamashita, First Secretary, Embassy of Japan in India and representatives from Japan Medical Device Association in India (JMDAI) and Japanese Pharmaceutical Association of India (JPAI) met Economic Advisor, DoP on 8th December 2023 wherein possible cooperation in bilateral investments, regulatory issues and issues related to medical devices sector were discussed.

Meeting with Mr. Yuta Yamashita,First Secretary, Embassy of Japan in India and representatives from Japan Medical Device Association in India (JMDAI) and Japanese Pharmaceutical Association of India (JPAI)

xix. Secretary, Department of Pharmaceuticals met Dr. Manoj Kumar Mohapatra, Ambassador of India to Guatemala on 21st December 2023 wherein bilateral ties in pharmaceuticals were discussed.

xx. Economic Advisor, DoP met Ms. Ravleen Pal, Deputy Head of Economic Section, Embassy of The Netherlands on 11th March 2024 wherein a draft concept of a MoU between Department of Pharmaceuticals & the Dutch Ministry on Pharmaceuticals and Medical Devices was discussed**.**

8.5 Participation in negotiations of Trade Agreements led by the Department of Commerce

(i) DoP participated in the 4th and 5th round of India-Australia CECA negotiations on Rules of Origin on 11th August 2023 and 29th August, 2023, respectively, in Vanijya Bhawan, New Delhi.

(ii) DoP participated in the 13th round of India-UK FTA negotiations on 10th October 2023 wherein Goods Market Access between India and UK was discussed. DoP also participated in the negotiations on the Pharma Annex under the proposed FTA on 6th and 14th March, 2024.

(iii) The India-EFTA Trade and Economic Partnership Agreement was signed on 10th March 2024 wherein Switzerland, Norway and Iceland shall upon entry into force of the Agreement, eliminate all import duties and charges having equivalent effect to import duties, for pharmaceuticals and medical devices imported by these countries from India. It also consists of an Annex on Protection of Intellectual Property which includes protection of undisclosed information in lines with the TRIPS agreement. DoP participated in the internal discussions held by Department of Commerce on aspects related to pharmaceuticals and medical devices in the Agreement.

8.6 Participation in negotiations of WHO led by the Department of Health and Family Welfare

Officials of DoP participated virtually in the ninth meeting of Intergovernmental Negotiation Body (INB9) organized by WHO held from 18th March - 28th March 2024, wherein intense negotiations was convened on the negotiating text of Pandemic Instrument/Agreement/Accord.

8.7 Participation of the Department in meetings of Joint Working Group / Trade Committees led by Department of Commerce /Department for Promotion of Industry and Internal Trade/ Department of Health and Family Welfare to take forward areas of pharmaceutical cooperation:

i. DoP participated in the 2nd Meeting of the Joint Working Group on Medical Cooperation between Kingdom of Morocco and Republic of India held on 12.01.2023 virtually, wherein inter alia, potential areas to strengthen bilateral cooperation in pharmaceuticals was discussed.

ii. DoP participated in the Quad Health Security Partnership meeting between Republic of India, Australia, Japan and USA on Vaccine and Health Security held on 16.02.2023 through virtual mode.

iii. DoP participated in the 1st Joint Working Group (JWG) meeting between Republic of India and Oman on cooperation in the field of Health held on 24.02.2023 at New Delhi, wherein potential areas to strengthen bilateral cooperation in pharmaceuticals was discussed.

iv. DoP participated in the 18th India - Australia Joint Ministerial Commission (JMC) meeting on 11.03.2023 chaired by Hon'ble Minister, Commerce and Industry.

v. DoP participated in the India-Russia Inter-Governmental Commission on Trade & Economic Cooperation (IRIGC-TEC) review meeting co-chaired by EAM from Indian side on 6th March 2023. Subsequently, DoP also participated in the meeting of 24th India-Russia Working Group on Trade & Economic Cooperation (WG-TEC) held on 24th March, 2023 led by Commerce Secretary wherein both sides acknowledged discussions held in the 2nd JWG on Pharmaceuticals meeting on 21.12.2022 and agreed to take further steps in this regard.

vi. DoP participated in the 12th session of India-Spain Joint Commission for Economic Cooperation (JCEC) meeting on 13th April 2023 at New Delhi co-chaired by the Commerce Secretary from the Indian side. Both sides discussed potential areas for mutual collaboration, including strengthening API supply chains.

vii. DoP participated in the 24th Session of the India-Russia Inter-Governmental Commission on Trade, Economic, Scientific, Technical and Cultural Cooperation on 18 April 2023 led by H.E Dr. S. Jaishankar, the Minister of External Affairs from the Indian side. Both sides acknowledged discussions held in the 2nd JWG on Pharmaceuticals meeting on 21.12.2022 and agreed to take further steps in this regard.

viii. DoP participated in the 16th Session of India- Austria Joint Economic Commission (JEC) on 12th June, 2023 Vienna through virtual mode and the 11th Session of India-Slovak Joint Economic Committee (JEC) on 14th June, 2023 through virtual mode. The meeting was co-chaired by Ms. Nidhi Mani Tripathi, Joint Secretary, DoC for both the JEC sessions from the Indian side.

ix. DoP participated in the 1st Joint Working Group meeting between India and Kyrgyzstan on 12th June 2023 through virtual mode. The meeting was chaired by Mr. Lav Agarwal, Additional Secretary, Ministry of Health and Family Welfare from Indian side.

x. DoP participated in the Bilateral meetings of Industrial Collaboration Working Group (ICWG) and Joint Working Group (JWG) with Taiwan on 15th June, 2023 through virtual mode. The meeting was co-chaired by Ms. Manmeet K. Nanda, Joint Secretary, DPIIT from the Indian side. Both sides discussed the potential areas to strengthen bilateral cooperation in pharmaceuticals.

xi. DoP participated in the 3rd Joint Working Group (JWG) meeting between India and Denmark on 28th June 2023 at New Delhi co-chaired by Mr. Lav Agarwal, Additional Secretary, Ministry of Health and Family Welfare from Indian side and Ms. Dorte Bech Vizard, Deputy Permanent Secretary, Patient Safety, Medicines and Global Health, Ministry of Interior and Health Pharmaceutical Cooperation, Medical Devices

and Diagnostics from the Denmark side. Both sides discussed potential areas to strengthen cooperation in pharmaceuticals, medical devices and diagnostics.

xii. DoP participated in the 2nd Joint Working Group meeting between India and Maldives on health cooperation held on 5th July 2023 co-chaired by Mr. Lav Agarwal, Additional Secretary, Ministry of Health and Family Welfare from the Indian side. A presentation was made on "Pharmaceutical and Medical Device Sector in India."

xiii. DoP participated in the bilateral meeting between the Hon'ble Minister of Health and Family Welfare of India and the Hon'ble Minister of Health of the United Republic of Tanzania on 25th July 2023 wherein the potential areas to strengthen bilateral cooperation in pharmaceuticals and explore potential collaborations in the pharmaceuticals sector was discussed.

xiv. DoP participated in the 19th Session of India- Switzerland Joint Economic Commission (JEC) on 24th November 2023, Geneva through virtual mode wherein possible collaboration with NIPERs and investment opportunities in Pharma and Medical Devices sector was discussed.

xv. DoP participated in the 1st Joint Working Group meeting in the field of Health and Medicine between India and Cambodia held on 17th January, 2024 co-chaired by Dr Manashvi Kumar, Joint Secretary, Ministry of Health and Family Welfare from the Indian side. A presentation was made on "Pharmaceutical and Medical Device Sector in India."

xvi. DoP participated in the 2nd Joint Working Group meeting on health cooperation between India and Germany held on 13th February, 2024 co-chaired by the Ministry of Health and Family Welfare from the Indian side wherein areas of collaboration in Pharmaceuticals and Medical Devices were discussed.

xvii. DoP participated in the 5th Joint Working Group meeting on health cooperation between India and Netherlands held on 15th February, 2024 co-chaired by the Ministry of Health and Family Welfare from the Indian side wherein, possible collaboration with NIPERs and investment opportunities in Pharma and Medical Devices sector in Netherlands were discussed.

xviii. DoP addressed the participants in the buyer-seller meet for pharma companies of India and Ireland on 20th March 2024 through virtual mode organized by Embassy of India, Dublin and made a presentation on the overview, strengths, Government initiatives and possible areas of collaboration with the Indian Pharma and medical devices sector.

xix. Economic Advisor, DoP was part of delegation led by EAM with his Ukrainian counterpart for reviewing the activities of the India-Ukraine Inter Governmental Commission on 29th March 2024 and made an intervention regarding updates and potential collaboration in the pharma sector.

Training and Capacity Building

i. Officials of Department of Pharmaceuticals participated in the three-day National Workshop on TBT Agreement for enhancing capacity of Indian Officials to implement the WTO TBT Agreement on 13-15 March 2023 at Vanijya Bhawan, New Delhi organised by Department of Commerce in association with World Trade Organisation and Centre for WTO Studies (CWTOS) and Centre for Trade and Investment Law (CTIL).

ii. DoP participated in the stakeholder workshop jointly organized by the EU Delegation to India and the Embassy of Sweden on 'One Health Approach to Antimicrobial Resistance: Environment and Manufacturing Industry' at the Embassy of Sweden on 24 April 2023. The goal of the workshop was to review the state-of-play, initiate a productive discussion and identify areas for further collaboration, to pave the way for a sustainable and effective solution to this emerging problem, with the goal of reducing the impact of antibiotics in the environment and curbing the spread of AMR.

iii. Officials of the Department of Pharmaceuticals participated in a two-day National Workshop on "Investment Commitments in International Treaties" on 21st and 22nd September 2023, at Vanijya Bhawan, New Delhi organized by Department for Promotion of Industry and Internal Trade.

iv. Officials of the Department of Pharmaceuticals participated in the seminar on the theme of "Unlocking Trade for Growth", "Preparing for the Future of Work" and "Advancing Financial Inclusion" on 6th November 2023 organized by the Department of Commerce.

8.8 G20 Events of Department

During the G20 Indian Presidency's Health Track, the Department of Pharmaceuticals (DoP) took charge of organizing and spearheading a series of impactful events, held both in physical and virtual formats. On March 24, 2023, department organized a webinar on theme "Collaborative Research on Therapeutics," as part of Business-20 (B-20), followed by organizing a co-branded Event with FIND-UNITAID on theme - "Expanding Regional Manufacturing Capacity for Diagnostics" on 16th April in Goa as part of 2nd HWG (Health Working Group). Furthermore, a virtual webinar on the Science-20 (S20) was also organised in collaboration with INSA on April 18, 2023.

Additionally, in 3rd HWG Department organized a series of event including a co-branded event with PATH with Theme "Building consensus for future health emergencies prevention, preparedness, and response" on 3rd June, and a side event on "Strengthening Global Collaboration on Research and Development in MCMs (Diagnostics, Vaccines, and Therapeutics)" on 5th June, which saw a participation 19 G20 member countries, 10 invited states, and 22 international organisation among others. A series of field visits were planned for G20 delegates to ICMR-NARFBR & Bharat Biotech in Genome Valley in Hyderabad to exemplify the innovative strength and resilient manufacturing capacities of the Indian pharmaceutical industry along with organizing an Industrial exhibition jointly with MoHFW & CII which featured over 40 exhibitors with representations from both industry and academia.

In 4th HWG Deputies and Ministers Meeting, Department engaged in bilateral meetings with 14 nations and organization during the ministers' meeting in Gujarat and Delhi in addition to strategic field visits to Zydus SEZ and Torrent R&D Center in Ahmedabad and inauguration of PMBJK centre by Hon'ble HMCF. Additionally, DoP with FICCI organized a cobranded event- Med-Tech Expo, showcasing evolving medical technologies in India with a central theme 'India: The Next MedTech Global Hub – Future of Devices, Diagnostics, and Digital which was inaugurated by Hon'ble HMCF and saw visits from G20 delegates including Health Minister's from Australia, Japan, Mauritius in addition to hosting Industry Interaction with Indonesian Delegation. The success of these events was underscored both in New Delhi Leader's Declaration and Modi-Biden Joint Statement where opportunities for deeper collaboration to secure, de-risk, and strengthen pharmaceutical supply was acknowledged.

Officials of DoP PATH and CEPI at G20 co-branded event on 3rd June 2023

Officials of DoP, ICMR & M/o Ayush at 3rd Health Working Group from 4th to 6th June 2023, in Hyderabad

8.9 Bilateral meetings by Department of Pharmaceuticals in the G-20 Presidency 2023 events

i. Secretary, Department of Pharmaceuticals led discussions related to pharmaceutical cooperation in dedicated bilateral meetings chaired by Dr. Mansukh Mandaviya, Hon'ble Minister for Health & Family Welfare and Chemicals & Fertilizers, with Netherlands, UK, Germany, Japan, WHO, Indonesia, Egypt, EU, Saudi Arabia, Sri Lanka, USA, Singapore, Australia and Nepal, on the sidelines of the 4th Health Working Group meeting under Indian G20 Presidency during 15th August 2023 to 21st August 2023 in Delhi and Gandhinagar. The key areas of pharma cooperation that were discussed included strengthening supply chain & boosting investments; manufacturing in India for the globe; R&D, skilling and capacity building; boosting

global affordable healthcare across pharmaceuticals, vaccines and medical devices.

Meeting with US Secretary of Health & Human Services, H.E. Xavier Becerra

Meeting with H.E. Steve Barclay, Secretary of State for Health & Social Care of the UK.

Meeting with Dr. Tedros Adhanom Ghebreyesus, Director General, WHO

Meeting with the Health Minister of Saudi Arabia, H.E. Fahad bin Abdurrahman Al-Jalajel

Meeting with H.E. Ernst Kuipers , Minister of Health, Welfare & Sport of the Netherlands.

Meeting with H.E. Karl Lauterbach , Federal Minister of Health of Germany.

Meeting with Ms. SandraGallina , Directorate-General for Health and Food Safety, European Commission

Meeting with Mr. Keheliya Rambukwella, Hon'ble Minister of Health of Sri Lanka

Meeting with H.E. Khaled Abdel Ghaffar, Acting Minister of Health and Population of Egypt

Meeting with H.E. Katsunobu Kato, Minister of Health, Labour, & Welfare of Japan.

Meeting with the Health Minister of Singapore, H.E. Ong Ye Kung

Meeting with Health Minister of Indonesia , H.E. Budi G. Sadikin

Meeting with H.E. Mohan Bahadur Basnet, Minister for Health and Population, Nepal.

Officials of IC Division at the G20 4th Health Working Group Meeting

ii.. DoP in collaboration with the Indian Pharmaceutical Association (IPA), organized a dedicated industry interaction event on 20th August 2023 in Gandhinagar on the sidelines of the 4th Health Working Group meeting. This event was graced by the presence of esteemed individuals, including Dr. Mansukh Mandaviya, the Honorable Union Minister of Health and Family Welfare; Mr. Budi Gunadi Sadikin, the Indonesian Minister of Health; Dr. Ernst Kuipers, the Minister of Health, Welfare, and Sport of the Netherlands; Ms. S Aparna, Secretary, DoP; Sudarshan Jain, the Secretary General of IPA; and Dr. Viranchi Shah, President IDMA. Furthermore, the event witnessed the participation of Indonesian delegates, numerous Indian pharmaceutical companies, various associations, as well as officials from the Department, IPA and Indian Drug Manufacturers Association (IDMA).

HMCF Inaugural address at the Indian Industry Interaction with G20 Health Working Group Delegates.

Participants in the Industry Interaction Session

iii. The Department organized a series of field visits and guided tours for G20 delegates, including Health Ministers from G20 nations aimed to highlight India's thriving pharmaceutical sector and R&D and manufacturing facilities of leading pharmaceutical firms. These guided tours saw keen participation from Senior Industry leaders from leading pharmaceutical companies of Indonesia, International Organizations (World Bank, Wellcome Trust, Global Fund etc.), Ministry of Health Officials from Oman, Mauritius, Indonesia including Honorable Health Minister Mauritius and Indonesia respectively among others and paved the way for advanced and direct discussions on joint collaborations and investment opportunities to fuel growth and innovation in both countries.

CHAPTER 9

Implementation of Rajbhasha

9.1 Use of Hindi in official work

9.2 Official Language Implementation Committee

9.3 Hindi Prayog Protsahan Pakhwara, 2023

9.4 Review of use of Hindi in the offices under the Department

9.5 Hindi Advisory Committee

CHAPTER 9

Implementation of Rajbhasha

9.1 Use of Hindi in official work

Every possible effort was made for implementation of the various provisions of the Official Language Policy of the Union of India including those of Official Languages Act, 1963 as well as Official Languages (Use for Official Purposes of the Union) Rules, 1976 and orders issued thereunder. All the documents mentioned in Sub Section (3) of Section 3 of the Official Languages Act, 1963 were issued bilingually i.e. in Hindi as well as in English. Letters received in Hindi and representations etc. signed in Hindi were replied to in Hindi as per provisions of the Rule 5 and Rule 7(2) of the Official Languages (Use for Official Purposes of the Union) Rules, 1976 (as amended in 1987).

9.2 Official Language Implementation Committee

Official Language Implementation Committee of the Department under the Chairmanship of the Joint Secretary periodically reviews the progressive use of Hindi in the official work and suggests suitable measures to increase the use of Hindi in the official work. Its meetings were held on regular intervals and implementation status of the various targets set in the Annual Programme for transaction of the official work of the Union in Hindi for the year 2023-24 issued by the Department of Official Language, Ministry of Home Affairs was reviewed.

9.3 Hindi Prayog Protsahan Pakhwara, 2023

Hindi Prayog Protsahan Pakhwara was observed in the Department from 14th to 29th September, 2023 with the objective to encourage the officers and employees of the Department to progressively increase the use of Hindi in their official work and also to help the Department create an atmosphere conducive to use of Hindi.

In addition to the message issued by Secretary (Pharmaceuticals) requesting all the officers/employees to make a commitment to use Hindi in official work, various Hindi competitions were held during the Pakhwara in which officers/officials of the Department participated. Winners were awarded cash prizes.

9.4 Review of use of Hindi in the offices under the Department

Periodical review of the use of Hindi in the offices under the Department was made through the quarterly reports submitted by them in compliance with the targets set in the Annual Programme for use of Hindi for the year 2023-24. During this year, to achieve the prescribed target (inspection of at least 25% offices) stated in the Annual Official Language Programme 2023-24, inspection of three subordinate offices of Department of Pharmaceuticals was carried out.

9.5 Hindi Advisory Committee

The meeting of Hindi Advisory Committee of the Ministry of Chemicals and Fertilizers under the Chairmanship of Honourable Minister, Chemicals and Fertilizers was held on 30.05.2023 at New Delhi.

CHAPTER 10

10.1 Right to Information Act 2005

CHAPTER 10

10.1 Right to Information Act 2005

As per the provisions of the Right to Information (RTI) Act, 2005, a RTI cell has been established in the Co-ordination Division of the Department which acts as the Nodal Cell for all RTI related matters of the Department. RTI applications/appeals are transferred to the Central Public Information Officers (CPIOs) concerned by the RTI cell. The cell also coordinates follow-up action on the appeals/orders received from the Central Information Commission (CIC) and submits returns. The list of Central Public Information Officers (CPIOs) and Appellate Authorities in the Department are updated regularly on the website of the Department i.e. http://pharmaceuticals.gov.in. Proactive action for transparency is taken under Section 4 of the RTI Act for suo-moto disclosures on the website of the Department. The audit report of the proactive disclosure under the RTI act is also uploaded on the website of the Department.

The Department has taken the following measures in compliance of the RTI Act.

a) Under Secretary/ Section Officer level officers have been designated as Central Public Information Officers (CPIOs) under section 5(1) of the RTI Act, according to the subjects being handled by them.

b) Director /Deputy Secretary level officers have been designated as Appellate Authorities in terms of section 19(1) of the RTI Act, in respect of Under Secretaries/Section Officers working as CPIOs under them.

c) To facilitate the receipt of applications under the RTI Act, 2005, a provision has been made to receive the applications at the Central Registry Cell of the Department. The applications so received are further forwarded by the RTI cell to the CPIOs/Public Authorities concerned.

d) The Department has started receiving registration of application and appeals under the RTI Act on the Management Information System (RTI MIS) software available on the website of CIC (http://rti.gov.in).

During the financial year 2023-24 i.e. from 01.04.2023 to 31.03.2024, a total of 355 RTI applications and 10 RTI First Appeals were received in this Department. These were promptly transferred / forwarded to the concerned public authorities/CPIOs for providing information to the applicants.

CHAPTER 11

Information and Communication Technology

11.1 Local Area Network (LAN)

11.2 Website and Social Media

11.3 Video Conferencing

11.4 Virtual Private Network (VPN) Facility

11.5 Workflow Automation

11.6 E- Governance

11.7 National Cyber Security Awareness Initiatives in the Department

CHAPTER 11

Information and Communication Technology

Under the Digital India programme, Department of Pharmaceuticals has taken various initiatives toward the adoption of e-Governance for delivering information and services online. This has led to benefits in terms of transparency, easy accessibility of services, improvement in internal processes and decision-making support system.

An IT-based Computer Centre, set up by National Informatics Centre (NIC) is operational in the Department and is equipped with the latest Client machines for providing various IT-related services to the Department. NIC is delivering valuable services like technical consultancy, networking, application development and implementation, internet & email, database management and training. With NIC's presence and expertise, Department had been able to steer the following IT/e-governance initiatives. Also to enhance delivery and security, web applications have been migrated to cloud environment.

11.1 Local Area Network (LAN)

All work places in the Department are connected on Local Area Network (LAN) which is already IPv6 compliant and is managed by the National Informatics Centre (NIC) to provide round the clock facilities for email, intranet / internet and database access operations. The IPv6 compliant ICT hardware is available to all officers/ divisions/ sections for use at their desktop. WAN to Shastri Bhawan has two links viz. PGCIL of 10 G and another link from MTNL of 1G.

11.2 Website and Social Media

The bilingual website of the Department, http://pharmaceuticals.gov.in, is hosted on NIC cloud to ensure security and maximum reach of information to the citizens. The website is developed by NIC using content management framework and is compliant with the Guidelines for Indian Government Websites (GIGW). It provides details of the organizational set up of the Department, its functions, subordinate offices, policies, publications, and statistical data/information on functional parameters. Standardization Testing and Quality Certificate (STQC) certification has been completed.

In order to comply with the directions of Ministry of Electronics & Information Technology (MeitY) that the website should be GIGW 3.0 compliant, which is further advanced in terms of cyber security and accessible to differently abled persons, the Department of Pharmaceuticals has taken steps to engage a professional agency to upgrade the Website.

Social media has enormous potential to reach out to people. Department has opened Facebook and Twitter (now 'X') to create awareness. Posts to create awareness regarding activities and decisions taken by the Department are posted on Facebook and Twitter('X') pages of the Department.

11.3 Video Conferencing

Video conferencing facility has been provided to all the officers of the Department. PSUs and NIPERs have also installed video conferencing facilities in their respective offices. This facility has helped in conducting seminars

and interactions as part of various government programmes, apart from remote reviews and meetings. Meeting of *Pragati,* the monitoring tool of PM office, is conducted every month and Hon'ble PM interacts with all Secretaries and State Chief Secretaries to address issues which are long pending through video conferencing.

Department has procured Webex video conferencing software for conducting conferences and VCs with industry associations and organisations not having NIC network/facilities.

11.4 Virtual Private Network (VPN) Facility

The Virtual Private Network (VPN) facility, provided to officials during Covid pandemic to facilitate them to work from home and undertake official work smoothly, has been continued, to facilitate disposal of urgent official matters outside office. During the last three years, the Department has extended this facility to 104 accounts, out of which 38 were provided in the current financial year.

11.5 Work Flow Automation

Another initiative taken by the Department towards the promotion of Digital India is the implementation of automation of work flow inside the Department. E-office is a standard product that presently consists of e-File, e-Tour, Knowledge Management System (KMS), Personnel Information Management System (PIMS), Collaboration & Messaging Service (CAMS) and is aimed at increasing the usage of work flow and rule based file routing, quick search and retrieval of files and office orders, digital signatures for authentication, forms and reporting components. E-Office has been implemented to reduce duplicity of work, increase transparency and efficiency. Substantial work has been done during the Special Drive on Swachhata Abhiyan by focusing on digitization of physical files, as File Management System was a thrust area of the Special Drive for converting them to e-files. The e-Office system in the Department has been upgraded to e-file Version 7.2.5 in November, 2022. The Department is working on increasing the number of e-office users' account (e-Office Lite) from 93 to 175 (further extendable up to 250 numbers); both for the Department and its attached office, NPPA. This is at an advanced stage of implementation.

11.6 e- GOVERNANCE:

Taking advantage of the latest ICT enabled tools, Department of Pharmaceuticals with the support of NIC has taken initiatives toward the adoption of best practices. Various applications have been developed and implemented though NIC to strengthen, monitor and speed up decision making by ensuring availability of easy and faster access to information.

- **SPARROW**- Smart Performance Appraisal Report Recording Online Window application, which allows online submission of APAR of IAS, other central services, and CSS/CSSS cadre officers, has been implemented successfully.
- **Visitor Management System** – e-Visitor System is a web based solution for Visitor Management. This facilitates citizens for online registration of requests for their visit, approval to authenticated visitors and issue of gate pass.
- **Legal Information Management & Briefing System (LIMBS)** – LIMBS is a web based portal developed by the Department of Legal Affairs, Ministry of Law & Justice for monitoring and handling of various court cases of the Government. Cases pertaining to High Court and Tribunals are being uploaded by the concerned departments. It facilitates officials to generate useful reports.
- **Online RTI-MIS** – To dispose of and monitor RTI applications efficiently, the Department has taken initia-

tives for using Online RTI-MIS. Necessary training was imparted to concerned officials/staff for implementing RTI-MIS successfully.

- **Centralized Public Grievance Redress Monitoring System (CPGRAMS)**: CPGRAMS is implemented in the Department and all the attached offices to address public grievances received online in a time bound manner.
- **E-publishing of Tenders** – E-publishing of tenders is implemented by uploading tenders on Central Public Procurement Portal/Government e Marketplace (GeM). It has improved the accessibility of tenders.
- **Electronic-Human Resource Management System (e-HRMS)** is a web based Human Resource Management System (https://ehrms.gov.in/) implemented in the Department of Pharmaceuticals. Personnel Data of all the employees are uploaded. Module Service Book Detail, Leave and LTC are operational. The Department has successfully implemented and moved to e-HRMS 2.0.
- **https://supremo.nic.in/** is a web portal being maintained by the Department of Personnel and Training (DOPT), Government of India. This is single user platform related to employees of the Government of India. Information of the personnel under the Appointment Committee of the Cabinet (ACC) is being uploaded onto the website.
- **e-Samiksha -** eSamikSha is a Digital Governance Platform for Easy, Instant and Secure Exchange of Information. It is an online monitoring and compliance mechanism developed to fast track the compliance of pending action-points/proposals /issues/projects/schemes/targets, of various implementing agencies such as Ministries/Departments/Organizations of Government of India, State Governments, Autonomous Bodies and PSUs

To enhance e-Governance in the Department the following initiatives have been taken up:

(i) Development of software for grant – in - aid under Plan Scheme "Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)." The objective of PMPDS is promotion and development the pharmaceutical and medical device sector by extending financial support for conduct of seminars, conferences, exhibitions, sending delegations from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports and addressing critical issues of the sector. PPDS Portal http://ngogrant.pharmaceuticals.gov.in has been developed and implemented.

(ii) An MIS for monitoring different activity of National Institutes of Pharmaceutical Education & Research has been developed and hosted on NIC cloud (http://nipermis.pharmaceuticals.gov.in/).

(iii) Research Portal (https://research.pharmaceuticals.gov.in/) has been developed and is implemented by NIC. This portal is under the process of transfer to NIPER Hyderabad for further development and maintenance of the application. The portal provides a link between academia and industry to benefit from the research done by NIPERS in the field of pharmaceuticals and medical device.

(iv) Foreign Direct Investment (http://fdi.pharmaceuticals.gov.in/) portal has been made live and user assistance is under process. Companies under FDI may register in the portal. Equity transfer, production, export, research and development are being monitored.

(v) Stationery MIS (http://10.21.81.76/store) is the MIS for request from Officers/Sections obviating the need for physical papers. Stock of the stationery items is maintained and issue of items reflected dynamically through this portal.

(vi) National Medical Devices Policy Strategies Monitoring Portal (https://nmdp.pharmaceuticals.gov.in) has been developed and is under implementation. This portal helps in monitoring of implementation schedule of strategies for projects under National Medical Devices Policy 2023.

11.7 National Cyber Security Awareness Initiatives in DoP

Department of Pharmaceuticals continued its efforts on national cyber security through sharing of webinar links of awareness programmes conducted by MHA (I4C), MeitY and other agencies to all employees, including employees of its attached office, autonomous bodies and PSUs for sensitizing officers on the latest developments in this field. As part of efforts towards cyber security audit, the NIC internal team of Department further reviewed the computer infrastructure on the efficacy of antivirus software installed in all computers.

CHAPTER 12

Other Activities of the Department

12.1 Special Campaign on Disposal of Pending Matters (SCDPM) and Swachhata Pakhwada

12.2 Culmination of Azadi Ka Amrit Mahotsav (AKAM)

12.3 International Yoga Day Celebration

12.4 Capacity Building through iGOT Karmayogi Platform

12.5 Rashtriya Ekta Diwas Celebration

12.6 Constitution Day Celebrations

Chapter 12

Other Activities of the Department

12.1 Special Campaign on Disposal of Pending Matters (SCDPM) and Swachhata Pakhwada

12.1.1 Special Campaign on Disposal of Pending Matters (SCDPM) 3.0

The Government of India announced Special Campaign 3.0 from 2nd October to 31st October, 2023 with a focus on Swachhata and Reducing Pendency in Government. The Special Campaign 3.0 was focused more on field/ outstation offices in addition to the Ministries/ Departments and their attached/subordinate offices. It aimed at reducing pendency in Ministries / Departments and increasing efficiency in decision making. The emphasis of the Campaign was on the following areas.

1. Disposal of identified pending references such as (i) References from MPs (ii) Parliamentary Assurance (iii) IMC Reference (Cabinet Proposals) (iv)State Government References (v) Public Grievances (vi) Public Grievance Appeals and (viii) PMO References
2. Record Management, which included, (i) physical files (reviewed/transferred to NAI/Identified for weeding/weeded out during the campaign period) and (ii) E-Files put up for review/closure
3. Cleanliness Campaigns
4. Space Freed
5. Office Scrap Disposal and Revenue earned thereof
6. Easing of Rules/Processes
7. Public Grievance Appeals.
8. Best Practices Reported.
9. Social Media Campaign
10. PIB Statements issued.

The focus of the Special Campaign 3.0 was on field/outstation offices such as attached/subordinate offices, autonomous bodies and Public Sector Undertakings to achieve saturation in weeding out old records/files, scraps and unserviceable equipment/machineries, plastic and other wastes, cleaning of public places to create awareness among general public towards the need to keep their neighbourhood clean and green. Accordingly, besides the department offices in Shastri Bhawan, Janpath Bhawan and Udyog Bhawan; National Pharmaceutical Pricing Authority (NPPA), National Institute of Pharmaceutical Education and Research (NIPERs) in Ahmedabad, Guwahati, Hyderabad, Mohali, Hajipur, Kolkata and Rae Bareli; Hindustan Antibiotics Ltd., Pune, Karnataka Antibiotics & Pharmaceuticals Ltd, Bengaluru, Bengal Chemicals & Pharmaceuticals Ltd, Kolkata and Pharmaceuticals & Medical Devices Bureau of India (PMBI) participated in the Special Campaign.

The Department was able to achieve major milestones during the campaign viz. (a) record number of campaign sites cleaned (9648 sites), (b) review of 5823 physical files and weeding out 1400 physical files, (c) eight Best Practices implemented/initiated during the campaign, (d) disposal of scrap and earning of revenue to the tune of Rs.3,41,387/-, (e) addressing 62 Public Grievances and maintaining zero Public Grievances appeals.

Details of the Campaign Sites and photographs of the Cleaning Drive conducted in the Department of Pharmaceuticals are given below:

Table 12A

(List of Swachhata Campaign Sites of Department of Pharmaceuticals during Special Campaign 3.0)

S. No.	Name of Organization/Institution	No. of Swachhata Campaign Sites
1.	National Institute of Pharmaceutical Education & Research (NIPER)	16
2.	Public Sector Undertakings	07
3.	National Pharmaceutical Pricing Authority (NPPA) & their Price Monitoring & Research Units	25
4.	Pharmaceuticals & Medical Devices Bureau of India (PMBI) in association with their 9600 PMBJP Kendras	9600
	Total:	**9648**

12.1.2 Special Campaign 3.0 Activities

Inspection of redundant materials for disposal held on 22/09/2023 by Nodal of the Department.

Scheme Section, Shastri Bhawan 2nd Floor

Administration Section, Room No.218A, Shastri Bhawan

Store Room, Janpath Bhawan (earlier)

Converted to Officer's cabin (after)


Cleaning Drive in NIPER HYDERABAD.

Cleaning Drive in NIPER KOLKATA

Cleaning Drive in NIPER GUWAHATI

Cleaning Drive by HAL, PUNE

12.1.3 Swachhata Pakhwada from 1st to 15th September, 2023:

Department of Pharmaceuticals observed Swachhata Pakhwada from 1-15 September, 2023 in all sections of the Department, its attached office (NPPA), Society (PMBI), autonomous bodies – all NIPERs and PSUs. Subsequently, the campaign was extended from 15th September to 30th September, 2023 under `Swachhata Hi Sewa' and on 1st October, 2023, all offices observed `Swachhata Hi Sewa Day' by conducting one-hour cleaning activities.

Secretary administered oath on Swachhata Pakhwada

12.2 Culmination of Azadi Ka Amrit Mahotsav (AKAM)

Har Ghar Tiranga Programme:

As part of the culmination of Azadi Ka Amrit Mahotsav (AKAM), Department of Pharmaceuticals celebrated "Har Ghar Tiranga" Programme from 13th to 15th August, 2023. National Flag in Khadi, along with the salient features of Flag Code were made available to all Officers and staff in the Department, on returnable basis, for ensuring full participation in the programme. Employees took selfies and posted it on `www.harghartiranga.com'.

12.3 International Yoga Day Celebration:

International Day of Yoga (IDY 2023) was celebrated by Department of Pharmaceuticals on 21st June, 2023 along with other Ministries/Departments, to increase awareness about benefits of Yoga and to encourage people to practice Yoga in their daily life. The attached Office (NPPA), autonomous bodies (NIPERs), PSUs (HAL, KAPL, BCPL) and PMBI actively participated in the programme.

12.4 Capacity Building through iGOT Karmayogi Platform:

Department of Pharmaceuticals has taken various measures to build capacity of its officials in various skills, policies, programmes and rules for effective and efficient public service delivery. Towards this, the Department has set up an internal Capacity Building Unit (CBU), finalized a Capacity Building Plan and 81 users have enrolled on iGOT Platform. Total course enrolment by the listed users is 144 and 65 courses have been completed by the users so far.

12.5 Rashtriya Ekta Diwas Celebration:

The Department had observed Rashtriya Ekta Diwas on 30th October, 2023 and all officers/officials took pledge under the leadership of Secretary.

12.6 Constitution Day Celebrations:

Department of Pharmaceuticals celebrated the 73rd Constitution Day on 24th November, 2023. All officers of the Department read the Preamble to the Constitution. Officers/officials also participated in online reading of the Preamble on the **MyGov.in** portal.

CHAPTER 13

Annexures

Annexure - I C&AG's audit observations

Annexure- II [A] List of PSUs

Annexure - II [B] Address and Name of Head of PSUs

Annexure - II [C] List of Responsibility Centers and Subordinate Organizations

Annexure - III Organizational Chart of NPPA

Chapter 13

Annexures

Annexure - I

C&AG's audit observations

There is no pending CAG Para pertaining to Department of Pharmaceuticals.

Annexure-II [A]

List of Public Sector Undertakings

(i) Indian Drugs & Pharmaceuticals Ltd (IDPL), Dundahera Industrial Complex, Dundahera, Gurgaon, Haryana.

(ii) Hindustan Antibiotics Ltd (HAL), Pimpri, Pune, Maharashtra.

(iii) Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bangalore.

(iv) Bengal Chemicals & Pharmaceuticals Ltd (BCPL), Kolkata, West Bengal.

(v) Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Road No.12, V.K.I. Area, Jaipur.

Annexure-II [B]

Address and Names of Head in PSUs under Department of Pharmaceuticals

Table-13A

(Address and Names of Head in PSUs under Department of Pharmaceuticals)

S.No	Address and Organization	Name	Designation
1	Indian Drugs & Pharmaceuticals Ltd. (IDPL), Gurgaon – 122016	Ms. Vinod Kotwal	Chairman & Managing Director (Additional Charge)
2	Hindustan Antibiotics Ltd.(HAL), Pimpri, Pune, Maharastra – 411018	Ms. Nirja Saraf	Managing Director
3	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL), Jaipur, Rajasthan - 302013	Ms. Nirja Saraf	Managing Director (Additional Charge)
4	Bengal Chemicals & Pharmaceuticals Ltd.(BCPL), Kolkata, West Bengal–700013	Ms. Nirja Saraf	Managing Director (Additional Charge)
5	Karnataka Antibiotics & Pharmaceuticals Ltd.(KAPL), Bangalore, Karnataka – 560010	Ms. Nirja Saraf	Managing Director (Additional Charge)

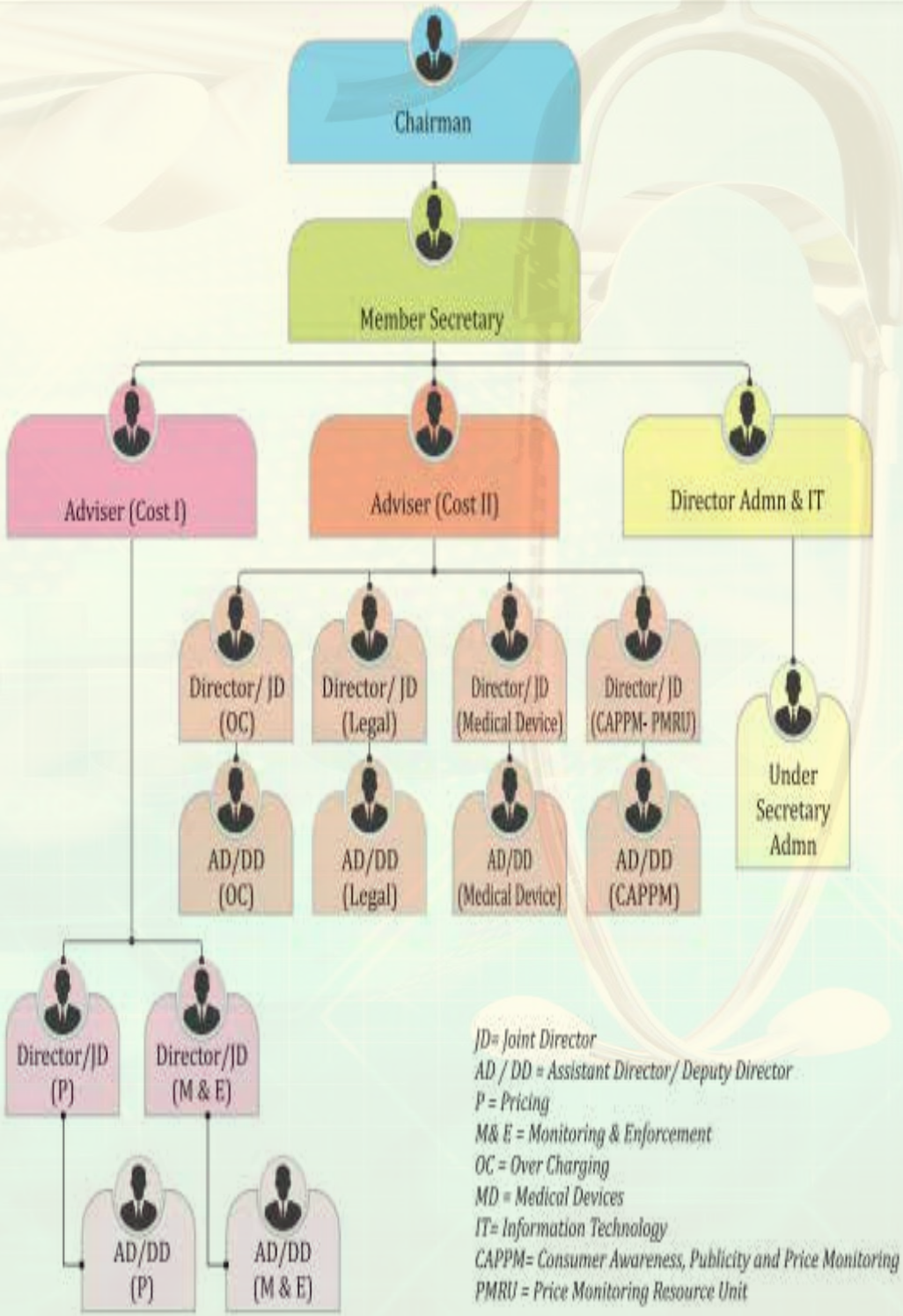
Annexure - II [C]

Table-13B

(List of Responsibility Centers and Subordinate Organizations)

Sl. No.	Directors of NIPER	Landline Number	Email	Mobile Number	Address
1	Dr. Shailendra Saraf, NIPER-Ahmedabad	079-66745555	director@niperahm.ac.in	9826150327	Palaj Opp. Air Force Station Head Quarter, Gandhinagar-382355, Gujarat.
2	Dr. USN Murty, NIPER Guwahati	0361-2132751	director@niperguwahati.ac.in	9127060998	Sila Katamur (Halugurisuk) P.O.: Changsari, Dist: Kamrup, Assam, Pin: 781101, Assam, India
3	Dr. V. Ravichandiran (Additional Charge), NIPER Hajipur	0612-2631565	director@niperhajipur.ac.in	9443963481	E.P.I.P. Campus, Industrial Area, Hajipur-844102, Bihar
4	Dr. Shubhini Saraf, NIPER- Raebareli	0535-2700851	director@niperraebareli.edu.in	9628176500	Bijnor-Sisendi Road, Sarojini Nagar, Near CRPF Base Camp, Lucknow (UP) - 226002
5	Dr. V. Ravichandiran, NIPER Kolkata	033-24995803 033-23200086	director@niperkolkata.edu.in	9443963481	Chunilal Bhawan, 168, Maniktala main road, Kolkata-700054, West Bangal
6	Dr. Shailendra Saraf, (Additional Charge) - NIPER Hyderabad	040-23073741	director.niperhyd@gov.in	9826150327	NIPER, Hyderabad IDPL Township, Balangar, Hyderabad-500007
7	Prof. Dulal Panda, NIPER Mohali	0172-2214690 0172-2214697	director@niper.ac.in	9820391591	SAS Nagar, NIPER Mohali, Punjab - 160062

Annexure – III Organizational Chart of NPPA



सत्यमेव जयते

Government of India

Ministry of Chemicals & Fertilizers

DEPARTMENT OF PHARMACEUTICALS