Annual Report
2022-23

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

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BRIEF CONTENTS

CHAPTER 1

An Overview

CHAPTER 1

An Overview

1.1 Pharmaceutical Industry

The Indian pharmaceutical industry ranks third globally in pharmaceutical production by volume and is known for its generic medicines and low-cost vaccines. The sector contributed to around 1.32% of the Gross Value Added (at 2011-12 constant prices) of the Indian Economy in 2020-21. The total annual turnover of Pharmaceuticals in the fiscal year 2021-22 was Rs. 3,44,125 crore (USD 42.34 Bn). Major segments of Indian Pharmaceutical Industry include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics. India is a global leader in the supply of DPT, BCG, and Measles vaccines. India is one of the biggest suppliers of low-cost vaccines in the world. India accounts for 60 percent of global vaccine production, 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. There are 500 API manufacturers contributing about 8% in the global API Industry. India is the largest supplier of generic medicines. It manufactures about 60,000 different generic brands across 60 therapeutic categories and accounts for 20% of the global supply of generics. Access to affordable HIV treatment from India is one of the greatest success stories in medicine. Because of the low price and high quality, Indian medicines are preferred worldwide, making it "pharmacy of the world". The sector has been growing at a healthy rate. The trend in annual turnover in the sector over the last five years may be seen in the Table- 1A

Table -1A

(Pharma Sector's Growth at Current Prices)

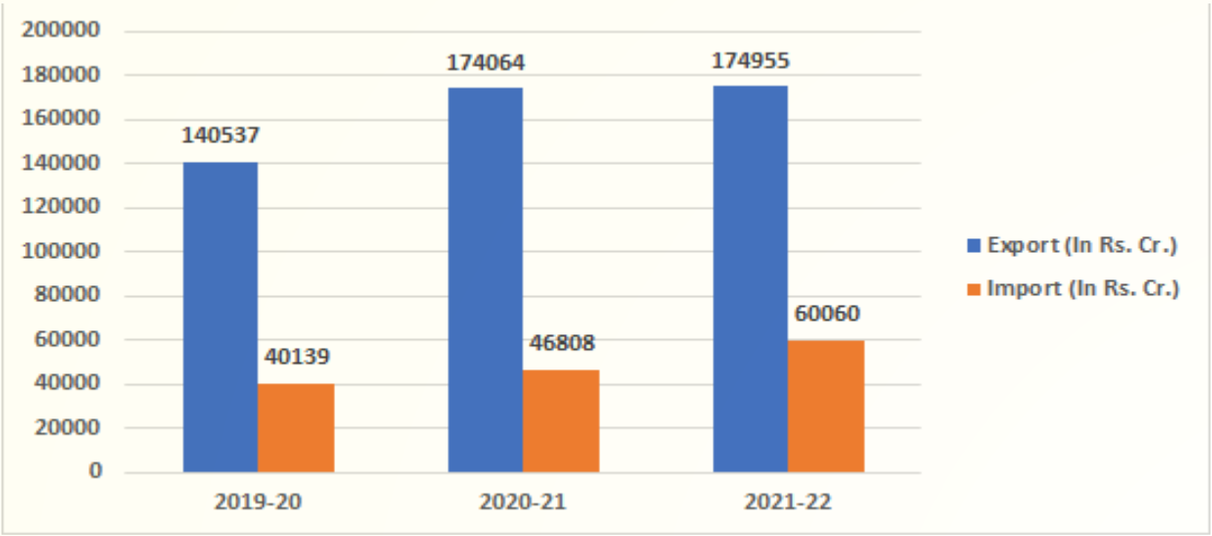
Financial Year	Turnover (Rs. in Crore)	Growth Rate
2017-2018	2,26,423	3.03
2018-2019	2,58,534	14.18
2019-2020	2,89,998	12.17
2020-2021	3,28,054	13.12
2021-2022	3,44,125	4.89

Source: Pharmatrac/NPPA/DGCIS, Kolkata

Indian pharmaceutical industry plays significant role globally, supplying affordable and low-cost generic drugs to millions of people across the globe. The sector offers lower cost without compromising on quality as is reflected by the fact India has the highest number of United States Food and Drug Administration (USFDA) approved pharmaceutical plants outside the US and also a significant number of World Health Organization (WHO) Good Manufacturing Practices (GMP)-compliant plants as well as plants approved by regulatory authority of other countries. India's pharmaceutical sector forms a major component of the country's foreign trade and has been consistently making trade surplus as may be seen from the Graph 1A. During 2021-22, total exports of pharmaceuticals stood at Rs. 1,74,955 crore (USD 23.5 Bn) while total imports were to the tune of Rs. 60,060 crore (USD 8.06 Bn) resulting in a trade surplus of Rs. 1,14,895 crore (USD 15.44 Bn).

Graph 1A

(Import-Export of Pharmaceuticals)



Source: DGCI&S, Ministry of Commerce and Industry

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

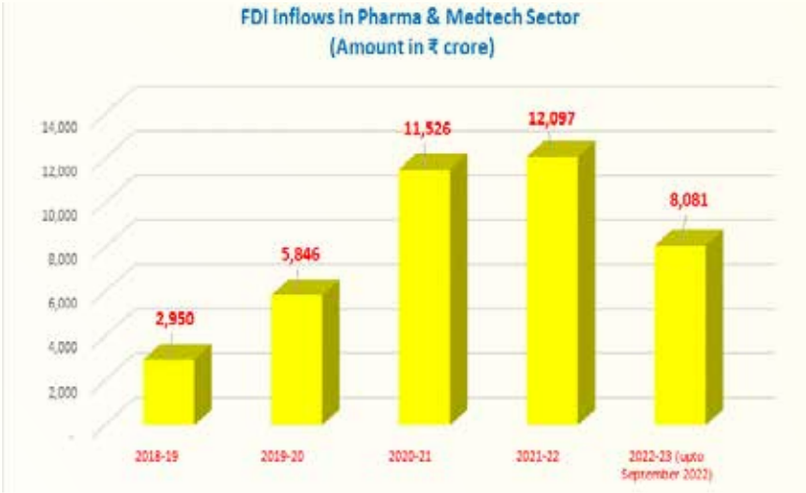
1.1.1 Foreign Direct Investment

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 3.71% of total FDI inflows in the country across various sectors. Total FDI inflows in Pharma and Medtech Sectors have been ₹ 1,32,568 crore from April 2000 to September 2022. During the financial year 2022-23 (till December 2022), Department of Pharmaceuticals approved 13 FDI proposals that would result in foreign investment inflow of ₹ 2,814 crore in the brownfield projects of pharmaceutical sector. The FDI inflows in the pharmaceutical sector (pharmaceuticals and medtech activities) in the last four years under both the routes, government and automatic, is depicted in Graph 1B below:

Graph 1B

(FDI inflows in Pharmaceutical Sector)



Source: Compiled from data provided by DPIIT.

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 medtech activities, separately may be seen in the table 1B below:

Table 1B

(FDI inflows in Drugs & Pharmaceuticals Activities)

Financial Year	FDI Inflows Drugs & Pharmaceuticals	FDI Inflows Medtech Activities
2018-19	1,842	1,108
2019-20	3,650	2,196
2020-21	11,015	511
2021-22	10,552	1,545
2022-23 (upto September 2022)	5,453	2,628

1.2 Medical Device Industry

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. The medical devices are 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 Reagents.

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.

1.2.1 Indian Medical Device Market

Medical devices are a sunrise sector of the Indian economy. The size of the Indian medical devices market is estimated at USD 11 Billion (Rs.90,000 Cr) in 2022[1], is expected to grow to USD 50 Billion by 2030 with CAGR of 16.4 % . The export of medical devices sector has been growing at a CAGR of 9.37 % over the last 5 years[2]. The Indian medical device market share in the global market is estimated to be 1.65%[3] . 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. Currently, India is exporting ventilators, PPEs, diagnostic kits, sanitizers and surgical gloves (2/3 ply) etc. Export and Import of Medical Devices over the past two financial years are as under:

Table 1C

(Export and Import of Medical Devices over past two financial years)

(USD million)

Imports		Exports	
2020-21	**2021-22**	**2020-21**	**2021-22**
6240.55	8539.50	2531.62	2923.16

Source: EEPC

A. Category-Wise Export and Import Data

Table 1D

(Category wise Export Data)

(USD Million)

S. No.	Segment	Exports F.Y. 2020-21	% Share F.Y. 2020-21	Exports F.Y. 2021-22	% Share F.Y. 2021-22
1	Consumables & Disposables	1290	51%	1378	47%
2	Surgical Instruments	54	2%	71	2%
3	Electronics Equipment	985	39%	1163	40%
4	Implants	99	4%	135	5%
5	IVD Reagent	104	4%	176	6%
	Total	2532		2923	

Source: EEPC India, Ministry of Commerce

[1] Report published by NITI Aayog in 2021 on "Investment Opportunities in India's Healthcare Sector"
[2] Source – EEPC, Ministry of Commerce
[3] Report published by KIHT on "GLOBEXIM -2021"

Table 1E

(Export data- Top Export Destinations)

(USD Million)

S. NO.	Country	Exports F.Y. 2021-22	% share F.Y. 2021-22
	World	2923.16	100.0
1	USA	631.48	21.60
2	China	146.94	5.03
3	Germany	127.29	4.35
4	France	89.36	3.06
5	Singapore	82.73	2.83
6	UAE	79.01	2.70
	Sub Total	1156.81	40.15

Source: EEPC India, Ministry of Commerce

Table 1F

(Category wise Import Data)

(USD Million)

S. NO.	Segment	Imports F.Y. 2020-21	% share F.Y. 2020-21	Imports F.Y. 2021-22	% share F.Y. 2021-22
1	Consumables & Disposables	1471	24%	1624	19%
2	Surgical Instruments	104	2%	169	2%
3	Electronics Equipment	3569	57%	5441	64%
4	Implants	226	4%	423	5%
5	IVD Reagents	872	14%	883	10%
	Total	6242		8540	

Source: EEPC India, Ministry of Commerce

Table 1G

Import data- Top Import Destinations

(USD Million)

S. NO.	COUNTRY	Imports F.Y. 2021-22	% share F.Y. 2021-22
	World	8539.50	100.0
1	UAE	1657.67	19.41
2	USA	1464.73	17.15
3	China	782.35	9.16
4	Germany	729.21	8.54

5	Singapore	343.08	4.02
6	France	341.99	4.00
	Sub Total	**5319.03**	**62.29**

Source: EEPC India, Ministry of Commerce

1.3 India Pharma 2022 and India Medical Device 2022

Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, in association with Federation of Indian Chambers of Commerce & Industry (FICCI) organized the 7th edition of the International Conference on Pharmaceuticals & Medical Devices Industry i.e. – India Pharma 2022 & India Medical Device 2022 from 25th -27th April, 2022 at Dr. Ambedkar International Centre, New Delhi.

India Pharma 2022 and India Medical Device 2022 featured a well-crafted thematic Conference with Sector-specific roundtables, Drug Regulators meet and theme sessions for Pharma and Medical Devices Sector. The inaugural session was held on 25th April 2022 in the presence of Dr Mansukh Mandaviya, Hon'ble Minister for Chemical and Fertilizers, Dr Bhagwanth Khuba, Hon'ble Minister of State for Chemicals and Fertilizers along with other Government officials and Industry officials followed by CEO roundtable for Pharma and Medical Devices Sector and International and State Drug Regulators Meet. FICCI collaborated with Invest India to organize the Investors Forum to give a boost to investment in the country in the Pharmaceuticals & Medical Device sector

7th India Pharma and India Medical Devices Awards

7th India Pharma and India Medical Device awards were conferred on 27.04.2022 by Dr. Mansukh Mandaviya, the Hon'ble Minister for Chemical and Fertilizers in recognition of innovation and excellence in Pharma and Med Tech sectors. List of Winners of 7th India Pharma and India Medical Device Awards is as under:

Table 1H

(List of Winners of 7th India Pharma and India Medical Device Awards)

Category of Award	Rank	Company Name
India Pharma Leader of the Year	Winner	Cipla Limited
India Medical Devices Leader of the Year	Winner	Poly Medicure Limited
	Runner-up	Healthium Medtech Limited
	2nd Runner-up	Transasia Bio-Medicals Limited
India Pharma (Formulation) Company of the Year	Winner	Micro Labs Limited
India Medical Device Company of the Year	Winner	Trivitron Healthcare
	Runner-up	Nice Neotech Medical Systems Private Limited
	2nd Runner-up	Kanam Latex Industries Privet Limited
India Medical Devices MSME of the Year	Winner	Nice Neotech Medical Systems Private Limited
	Runner-up	Premium Healthcare Disposables Privet Limited
	2nd Runner-up	AVI Healthcare Private Limited

India Medical Devices Start-up of the Year	Winner	Vanguard Diagnostics (P) Limited
India Pharma Innovation of the Year	Winner	Glenmark Pharmaceuticals Limited
India Medical Devices Innovation of the Year	Winner	Meril Life Sciences Private Limited
India Pharma CSR of the Year	Winner	Zydus Lifesciences Limited
	Runner-up	Glenmark Pharmaceuticals Limited
	2nd Runner-up	Lupin Limited

Inaugural Session: India Pharma 2022 and India Medical Device 2022

1.4 International Cooperation

1.4.1 Joint Working Group (JWG) Meetings:

(i) India-Tunisia Joint Working Group on Drugs and Pharmaceuticals: The 7th Meeting of India-Tunisia Joint Working Group on Pharmaceuticals was held on 14.01.2022 through virtual mode hosted by New Delhi. In the meeting, both sides discussed issues including increasing market access of Indian exports of pharma products to Tunisia, greater cooperation / Joint Ventures, cooperation in the field of pharmaceu-

tical education and research and cooperation in AYUSH.

(ii) India – Egypt Joint Working Group on Pharmaceuticals: The first meeting of JWG on Drugs and Pharmaceuticals was held on 14.03.2022 through virtual mode hosted by New Delhi. Both sides agreed to take forward the areas of cooperation in pharmaceutical trade, regulatory cooperation, AYUSH and Pharmaceutical education and research by identifying focal points from both sides.

(iii) A New Joint Working Group on Pharmaceuticals with Kazakhstan was constituted on 15.03.2022 : Drawing from the discussions held in the 7th Session of India-Kazakhstan Joint Working Group on Trade & Economic Cooperation led by Department of Commerce.

(iv) India - Russia Joint Working Group on Pharmaceuticals: The 2nd meeting of the India-Russia JWG on Pharmaceuticals was held on 21.12.2022. Deliberations were held to improve market access of Drugs and Ayurveda. Further, it was also agreed to promote cooperation in the capacity building between the two countries.

1.4.2 Participation by Delegation of Department of Pharmaceuticals in the international events / meetings:

(i) Africa Health ExCon from 5th to 7th June 2022: The Department participated in the first edition of the Africa Health ExCon (Exhibition and Conference) at Egypt International Exhibition Centre (EIEC) Cairo, Egypt organized by the Unified Procurement Authority for Medical Supply and the Management of Medical Technology of Egypt. The Egyptian Government laid strong emphasis to boost domestic manufacturing of APIs, biosimilars and drugs in new therapeutic areas and evinced keen interest to strengthen collaboration with India. It was felt that it is the right time to connect the Pharmaceutical industry in India with the Egyptian counterparts to leverage synergies, diversify the global supply chain and further strengthen Indian health efforts in the continent of Africa.

Dr. Vinod Kotwal, Member Secretary, NPPA and Shri. Venkat Hariharan Asha, Deputy Director, Department of Pharmaceuticals with officials of Embassy of India, Cairo in their meeting with Egyptian Authorities.

(ii) Health Forum in Cartagena, Columbia from 8th to 10th June, 2022: During the visit, it was learnt that the Colombian Government is laying strong emphasis to boost the domestic manufacturing of drugs & vaccines in Colombia. The expectation of the Colombian Government is to take the learning and indus-

try's expertise to develop their own industry since Colombia is heavily import-dependent for drugs and vaccines. Further, the demand for veterinary vaccines is also very high in Colombia.

Shri. Rajneesh Tingal, Joint Secretary and Dr. Sumit Garg, Deputy Secretary, Department of Pharmaceuticals making a presentation at the Health Forum, Cartagena.

(iii) Make in India related trade and investment events/ seminars in Poland from 22nd – 26th June, 2022, in partnership with the Polish Chambers of Commerce and Industry: The objectives of the visit included inviting investments from Poland to promote 'Make in India'; focus on overall investment opportunities in India with a special focus on opportunities in pharmaceuticals, auto components and chemicals; and promote joint ventures between Poland and Indian entrepreneurs.

(iv) 3rd Health Working Group Meeting in Bali under Indonesian G20 Presidency during 22-24 August, 2022: The Agenda of the 3rd Health Working Group meeting under the presidency of Indonesia was "Expanding Manufacturing and Research Hubs for Pandemic Prevention, Preparedness and Response(P-PR)". It included sessions on Establishing the G20 Network of Researchers and Manufacturers related to Public Health Emergencies; Strengthening the Network of Researchers and Manufacturers related to Public Health Emergencies; the Role of Public Private Partnerships to support Research and Manufacturing Hubs; and the G20 Initiative to strengthen Research and Manufacturing Ecosystem to achieve equitable VTD access and Development Capacity. Further, a side event was also arranged on Anti-Microbial Resistance (AMR) wherein the G20 acknowledged the seriousness of AMR and stressed upon strengthening the AMR surveillance and to improve data quality and incentivizing the development of new drugs. G20 also acknowledged the need of strengthening the existing structure and the importance of Quadripartite co-operation on AMR and integration with One Health Approach.

Dr. Richa Pandey, Deputy Secretary, Department of Pharmaceuticals participating in the 3rd HWG meeting at Bali under the Indonesian G20 Presidency.

(v) Visit of Hon'ble Union Minister for Chemicals & Fertilizers to Saudi Arabia: Dr. Mansukh Mandaviya, Hon'ble Union Minister for Chemicals & Fertilizers visited Saudi Arabia on 25th August, 2022. During his visit Hon'ble Minister had a bilateral discussion with the Saudi Minister of Industry and Mineral Resources Mr. Bandar bin Ibrahim Alkhorayef regarding the pharmaceutical sector. Both sides agreed to strengthen cooperation in vaccine manufacturing.

Dr. Mansukh Mandaviya, Hon'ble Minister, Chemicals and Fertilizers interacting with Saudi Delegation during his visit.

(vi) India-Russia Intergovernmental Commission-Trade, Economic, Scientific, technological and Cultural Cooperation (IRIGC-TEC) on 8 November 2022 in Moscow: Hon'ble External Affairs Minister (EAM) was the Co-chair from the Indian side and Deputy Prime Minister and Industry of Russia Mr. Denis Manturov was the Co-Chair from the Russian side. The IRIGC-TEC, inter-alia, discussed areas of cooperation in pharmaceuticals also.

Dr. N. Yuvaraj, Joint Secretary, Department of Pharmaceuticals, part of EAM delegation for the IRIGC-TEC

(vii) Medica trade fair 14th – 17th November, 2022 in Dusseldorf, Germany: The Department gained understanding on global ecosystem of medical devices including major base of foreign companies; their product and markets; their production facilities outside their own countries; their keenness to invest in India for manufacturing and trend in visibility of Indian manufacturing companies over time.

Shri. Abhishek Kumar Singh, Deputy Secretary, Department of Pharmaceuticals, participating in Medica 2022.

(viii) Trade and Public Health Workshop by WTO in Geneva, Switzerland from 28.11.2022 to 02.12.2022: Done in close collaboration with the WHO and WIPO, it is a unique workshop that blends the social elements of public health with the commercial elements of trade and intellectual property with the

objective to achieve the larger health outcomes.

Dr. Sumit Garg, Deputy Secretary, Department of Pharmaceuticals participated in the WTO workshop from Department of Pharmaceuticals

1.4.3 Visit of foreign delegations to India hosted by the Department:

(i) Mexican Delegation on 30th March 2022: Discussions were held to explore areas of joint research, joint production and expansion in bilateral trade.

(ii) Uzbekistan delegation visit to India: A delegation from Uzbekistan visited India during July 26-28, 2022 under the aegis of the India-Uzbekistan Inter-Governmental Commission (IGC) led by Department of Commerce from the Indian side. During their visit, the Dy PM of Uzbekistan had a meeting with Hon'ble Minister for Chemicals & Fertilizers as well as officials from the Department on 28.7.2022 at Nirman Bhavan, New Delhi. Various areas of cooperation were discussed including the status of two MoUs in pharmaceutical cooperation signed between the two countries.

1.4.4 Participation in negotiations of Trade Agreements led by the Department of Commerce:

(i) Agreements concluded in the year:

a) India-Australia Economic Cooperation and Trade Agreement (ECTA): Annex 7A on pharmaceuticals inter-alia provides that, 'each Party's Therapeutic Goods Regulator may utilise, as appropriate, Good Manufacturing Practice (GMP) inspection reports from regulatory authorities recognised by that Party's Therapeutic Goods Regulator as a comparable regulator in relation to the quality assessment of manufacturing facilities in the territory of the other Party, subject to its laws and regulations, as amended from time to time. This may reduce the requirement for, or duration of, in-country inspections in the territory of the other Party'.

b) India-UAE Comprehensive Economic Partnership Agreement (CEPA): Annex 5A provides for Bilat-

eral Cooperation on Pharmaceutical Products and includes consideration of establishing 'fast-track' procedures for pharmaceutical products from at least one of the regulatory authorities / reference countries viz., Australia, Canada, EU, Japan, USA or UK.

(ii) Ongoing negotiations to expand scope of existing agreements: India-Korea CEPA

(iii) Ongoing negotiations on fresh agreements with Gulf Cooperation Council (GCC comprising Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE) FTA negotiations; UK, Canada, Israel and EU.

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

- India-Taiwan Economic Consultation (ITEC): The 15th Deputy Minister/Secretary-Level Economic Consultations between India and Taiwan were held on 4th November 2022.
- 8th Session of India-Greece Joint Economic Committee held on 15th April, 2022
- 2nd Session of India-Croatia Joint Economic Commission held on 13th October, 2022.
- 10th session of India-Oman Joint Commission Meeting (JCM) on 11th May, 2022.
- First Session of India-Mauritius High Powered Joint Trade Committee (HPJTC) from 1-3 August, 2022.
- 11th Session of Indian-Belarusian Intergovernmental Commission on Trade, Economic, Scientific, Technological & Cultural Cooperation held on 10th November 2022 in New Delhi
- 10th India-Kyrgyzstan IGC on Trade, Economic, Scientific and Technological Cooperation held on 3rd November 2022.
- 12th India-Sweden Joint Working Group on Health meeting held on 2nd December, 2022.

DoP officials with Ambassador of Sweden to India post the 12th India-Sweden Joint Working Group on Health

- 20th Session of Indo-Swedish Joint Commission for Economic, Industrial and Scientific Cooperation

(JCEISC) Technical /Expert Group meeting on 7th December 2022.

1.4.6 Participation of the Department in multilateral events / fora led by Ministry of External Affairs / Department of Commerce / Department of Health and Family Welfare to take forward areas of pharmaceutical cooperation:

- G20 Indonesian Presidency
- WTO negotiations on TRIPS waiver
- Meetings of BRICS and IBSA
- World Economic Forum
- Dubai World Expo
- US: Global Action Plan
- Indo-Pacific Economic Framework
- Foreign Office Consultations led by MEA / various embassies of India across the world.

1.5 Covid -19 related actions taken by the Department

A COVID Drugs Management Cell (CDMC) was set up in the Department of Pharmaceuticals (DoP) in the month of April 2021 to oversee the management of smooth supply of drugs used in COVID-19 management during the pandemic. The CDMC has representatives from National Pharmaceuticals Pricing Authority (NPPA) and the Central Drugs Standards Control Organization (CDSCO) as well. The Group initially met on daily basis to review and prioritize actions required with respect to issues surrounding drug production and availability. With the easing of the Pandemic situation, meetings of CDMC are now held on a periodic basis under the chairpersonship of the Secretary, DoP.

The Committee reviews the position of production and supply of drugs identified under Buffer Stock Management of COVID- 19 drugs and also takes stock of the availability and production of different protocol drugs and their APIs. The manufacturers-wise production and stock position of all drugs are monitored and their APIs are also being tracked by CDSCO through a newly designed CDMS portal and reviewed by CDMC. The status of preparedness of the API and formulation manufacturers of Paxlovid with regard to drug approval, expected date of production and the related aspects are also being reviewed from time to time. Surveys of different drugs and medical devices are also being regularly conducted, both by NPPA through its PMRUs and CDSCO, to keep an eye on their availability.

1.6 Special Campaign on Disposal of Pending Matters (SCDPM) and Swachhata

1.6.1 Special Campaign on Disposal of Pending Matters (SCDPM)

The Government of India announced Special Campaign 2.0 from 2nd October to 31st October, 2022 with a focus on Swachhata and Reducing Pendency in Government. The Special Campaign 2.0 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 during the current year is on:

A.- Disposal of identified Pending references

1. References from MPs
2. Parliamentary Assurance

3. IMC Reference (Cabinet Proposals)
4. State Government References
5. Public Grievances
6. PMO References

B – Record Management

C – Cleanliness & Office Scrap Disposal

D – Easing of Rules/Processes

E – Public Grievance Appeals.

SCDPM 2.0 was held from 2nd October to 31st October, 2022 and in keeping with the focus of the campaign, all field/outstation offices attached/subordinate offices autonomous bodies and Public Sector Undertakings of the Department participated in the drive. Accordingly, besides the department's offices in Shastri Bhawan, Janpath Bhawan and Udyog Bhawan; National Pharmaceutical Pricing Authority (NPPA), National Institutes of Pharmaceutical Education and Research (NIPERs) at Ahmedabad, Guwahati, Hyderabad, Mohali and Raebareli, 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 Drive on Disposal of Pending Matters 2.0.

Some of the important achievement of the campaign in the department were carrying out cleaning operations at record number of Campaign Sites for cleaning drive (7021 sites), weeding out of 6453 physical files which was 158% of the initial target, establishing two best practices viz., (i) disposal of expired medicines, (ii) cleaning of 7000 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) throughout the country, disposal of scrap and earning of revenue and maintaining zero appeals against Public Grievances resolution. Department of Pharmaceuticals was on fourth position in terms of identification of maximum number of cleanliness sites in the country among all Ministries/Departments of Government of India.

Details of the Campaign Sites and photographs of the Cleaning Drive conducted in the Department of Pharmaceuticals are given below:

Table 1I

(List of Swachhata Campaign Sites of Department of Pharmaceuticals)

S.No.	Name of Organization/Institution	No. of Swachhata Campaign Sites
1.	Department of Pharmaceuticals	3
2.	National Institute of Pharmaceutical Education & Research (NIPER)	5
3.	Public Sector Undertakings	4
4.	National Pharmaceutical Pricing Authority (NPPA) & their Price Monitoring & Research Units	8
5.	Pharmaceuticals & Medical Devices Bureau of India (PMBI) and their 7000 PMBJP Kendras	7001
	Total:	**7021**

Cleaning Drive in Department of Pharmaceuticals – Shastri Bhawan, Janpath Bhawan and Udyog Bhawan

Before **After**


Room No. 347, Shastri Bhawan


Room No.348, Shastri Bhawan


Room No.25, Shastri Bhawan (Inspection by Senior officials of Admn. Division)

Weeding out of old files/records in PSU Division, Udyog Bhawan

Cleaning Drive at Janpath Bhawan

ii. Swachhata Pakhwada from 1st to 15th September, 2022:

DoP observed Swachhata Pakhwada from 1-15 September, 2022 in all Sections of the Department, its attached office (NPPA), Society (PMBI), autonomous bodies – all NIPERs and PSUs. Awards were conferred on National Institute of Pharmaceutical Education & Research (NIPER), Hyderabad, Pharmaceutical & Medical Devices Bureau of India (PMBI), Hindustan Antibiotics Limited (HAL), Pune for their achievements during the drive.

1.7 Azadi Ka Amrit Mahotsav (AKAM)

i. Har Ghar Tiranga Programme:

As part of the commemoration of Azadi Ka Amrit Mahotsav (AKAM), Department celebrated "Har Ghar Tiranga" Programme from 13th to 15th August, 2022. Provision of National Flag in Khadi, along with the salient features of Flag Code was made for all Officers and staff in the department for ensuring full participation in the programme.

ii. International Yoga Day Celebration:

International Day of Yoga (IDY 2022) was celebrated by DoP on 21st June, 2022 to raise awareness 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 to mark the Azadi Ka Amrit Mahotsav.

iii. COVID Vaccination Amrit Mahotsav:

DoP organized a Covid Vaccination Campaign on 24th August, 2022 as part of celebration of Azadi Ka Amrit Mahotsav. The Vaccination Campaign was a big success in terms of participation by employees and their dependents, as a total 120 persons taken booster dose vaccination during the day.

1.8 National Cyber Security Awareness Initiatives in DoP:

During the last one year, Department took various efforts to sensitize officials, not only of the department but also of its attached office, autonomous bodies and PSUs. In this connection, a webinar on Cyber Jagrookta Diwas was organised on 4th May, 2022 and the following four topics were covered:

a. Cyber Crimes and Safety
b. Concept and use of Cyber Hygiene in daily life
c. Introduction to Social Networks
d. Electronic Payments and Safeguard therein.

The department had carried out a survey through NIC Internal Team and completed installation of antivirus software in all the Computers. Also Do's and Don'ts of Cyber Hygiene (in Hindi and English) and Cyber Security Guidelines for Govt. Employees as forwarded by MeitY were distributed to all NIPERs and these have been uploaded on the Website of the Department for awareness creation.

1.9 Gender Sensitization and women empowerment:

During the year 2022-23, Webinar on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013 was organised for the officers and staff of the Department to sensitize them on the issue. Also, a week long Self-Defense Training Programme for Women Employees, from 2nd August to 5th August, 2022, was organised by the Department in collaboration with Ministry of Skill Development & Entrepreneurship which saw enthusiastic participation of all women employees of the Department. Participants found the programme very encouraging and useful in their daily life.

CHAPTER 2

Functions and Organisational Set-Up

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Introduction

2.1 Mandate of the Department of Pharmaceuticals

The Department of Pharmaceuticals was created on the 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 organizations 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 dealing with by the Department.

xiii. Bengal Chemicals and Pharmaceuticals Limited.

xiv. Hindustan Antibiotic Limited.

xv. Indian Drugs and Pharmaceuticals Limited.

xvi. Karnataka Antibiotics and Pharmaceuticals Limited.

xvii. Rajasthan Drugs and Pharmaceutics Limited.

The work of the Department has been mainly divided into Pricing, Policy, Scheme, NIPER, PSU, FDI, IC & Medical Device Divisions. National Pharmaceuticals Pricing Authority (NPPA) is an attached office of the Department.

(Ms. S. Aparna is holding the charge of Secretary of the Department w.e.f. 01.10.2020)

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 Janaushadhi scheme

2.4 Organizational Set-Up

The main activities of the Department are policy-making, sectorial planning, promotion and Development of Pharmaceutical industries. The administrative and managerial control of the public sector undertakings engaged in the manufacturing of various pharmaceutical items and some other organizations are major functions of the Department.

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

The Department has 14 Divisions to carry out various mandated functions and responsibilities. The summary of the main functions of the 14 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, etc.; Review cases against NPPA's orders; Administration of DPEA funds; Administration of 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; all Policy matters related to International Trade, WTO/FTAs/WHO/WIPO etc.; Project Development Cell; Matters related to Pharma Bureau; Implementation of Scheme for Promotion of Bulk Drug Parks; all matters related to 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 PLI Scheme for Pharmaceuticals; Implementation of Strengthening of Pharmaceutical Industry scheme; Implementation of Pharmaceutical and Medical Devices Promotion and Development (PMPDS) scheme; Implementation of PMBJP scheme.

(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 UCMDMP.

(viii) International Cooperation -

All matters related to International Co-operation 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 & Administration Division -

All matters related to Establishment, Information Technology (IT), Cash and Administration, dealing with procurement and distribution of day-to-day articles needed for smooth running of the office, housekeeping services, maintenance of office equipment including air conditioners, photocopiers, etc., printing of annual report and other event-specific banners, posters, standees, hospitality services, etc.

Establishment deals with all service-related matters of officers/officials of the Department of Pharmaceuticals.

(xii) Parliament & Coordination -

All matters related to Parliament and Coordination of all intra and inter-ministerial work.

(xiii) Vigilance Division -

All matters related to Vigilance including interaction with Central Vigilance Commission (CVC).

2.4.2 Organisation Set-up of the Department

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. Appointment to posts in Group B and C is mostly done on the basis of nominations made by the Department of Personnel & Training.

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 30.11.2022 is as under:

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
A	26	23	3	3	1	-
B	48	24	4	0	7	-
C	18	15	5	0	4	-
Total	92	62	12	3	12	-

2.4.3. 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 (the organizational chart of the Department is given at Annexure 2A).

2.5 Attached Office

National Pharmaceutical Pricing Authority

An attached office of the Department and it's 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) 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)

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 Central 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,

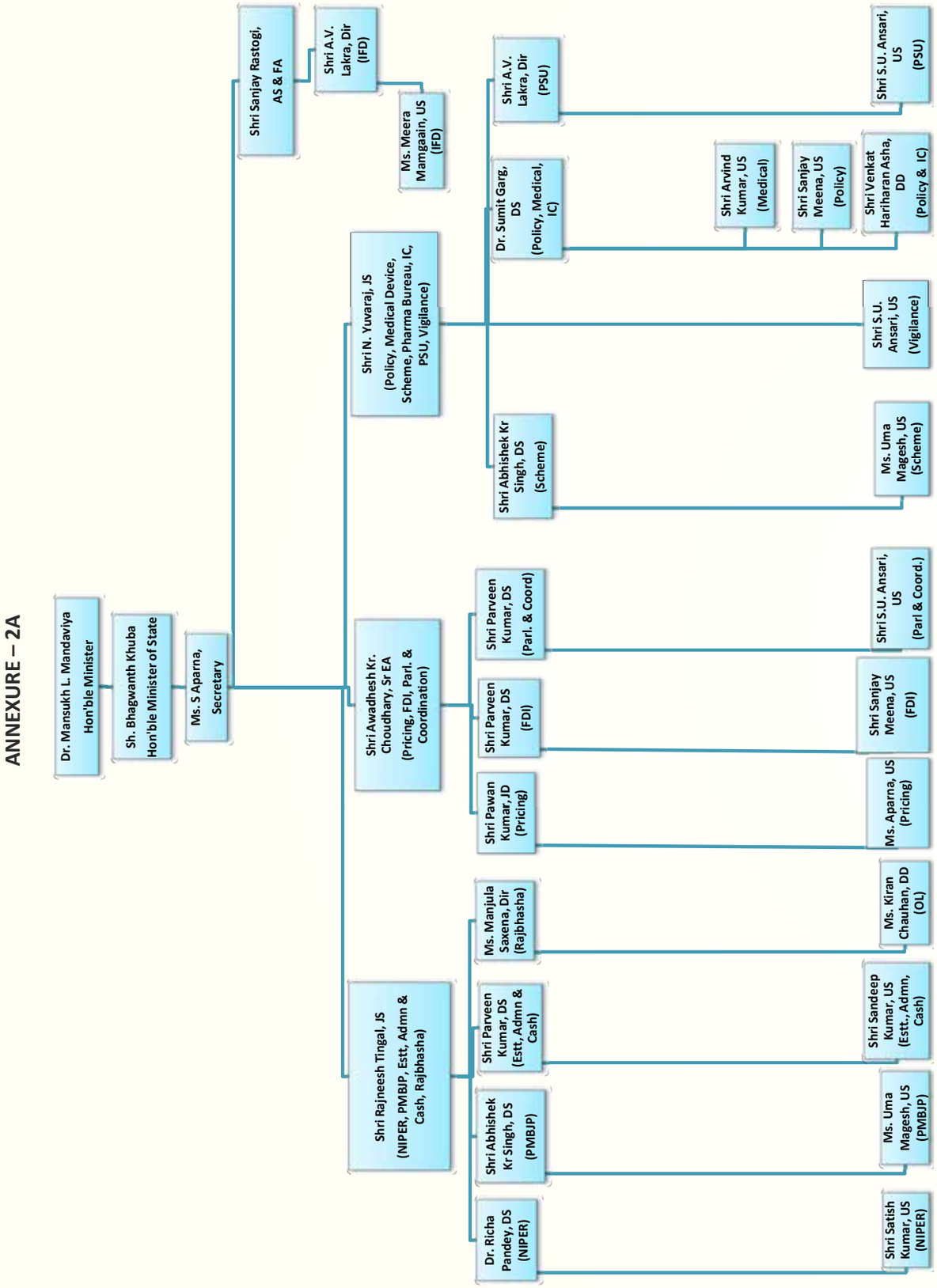
(b) Hindustan Antibiotics Ltd. (HAL), Pimpri, Pune, Maharashtra,

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

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

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

ANNEXURE – 2A


Dr. Mansukh L. Mandaviya
Hon'ble Minister
Sh. Bhagwanth Khuba
Hon'ble Minister of State
Ms. S Aparna,
Secretary
Shri Sanjay Rastogi,
AS & FA
Shri A.V.
Lakra, Dir
(IFD)
Ms. Meera
Mamgaain, US
(IFD)
Shri N. Yuvaraj, JS
(Policy, Medical Device,
Scheme, Pharma Bureau, IC,
PSU, Vigilance)
Dr. Sumit Garg,
DS
(Policy, Medical,
IC)
Shri Arvind
Kumar, US
(Medical)
Shri Sanjay
Meena, US
(Policy)
Shri Venkat
Hariharan Asha,
DD
(Policy & IC)
Shri A.V.
Lakra, Dir
(PSU)
Shri S.U. Ansari,
US
(PSU)
Shri S.U.
Ansari, US
(Vigilance)
Shri Abhishek Kr
Singh, DS
(Scheme)
Ms. Uma
Magesh, US
(Scheme)
Shri Awadhesh Kr.
Choudhary, Sr EA
(Pricing, FDI, Parl. &
Coordination)
Shri Parveen
Kumar, DS
(Parl. & Coord)
Shri Parveen
Kumar, DS
(FDI)
Shri Pawan
Kumar, JD
(Pricing)
Shri S.U. Ansari,
US
(Parl & Coord.)
Shri Sanjay
Meena, US
(FDI)
Ms. Aparna, US
(Pricing)
Shri Rajneesh Tingal, JS
(NIPER, PMBJP, Estt, Admn &
Cash, Rajbhasha)
Ms. Manjula
Saxena, Dir
(Rajbhasha)
Shri Parveen
Kumar, DS
(Estt, Admn &
Cash)
Shri Abhishek
Kr Singh, DS
(PMBJP)
Dr. Richa
Pandey, DS
(NIPER)
Ms. Kiran
Chauhan, DD
(OL)
Shri Sandeep
Kumar, US
(Estt., Admn,
Cash)
Ms. Uma
Magesh, US
(PMBJP)
Shri Satish
Kumar, US
(NIPER)

CHAPTER 3

Programmatic Interventions

CHAPTER 3

Programmatic Interventions

- **Central Sector Schemes**

The Department has five Central Sector Schemes, namely (a) Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), (b) Consumer Awareness, Publicity and Price Monitoring (CAPPM), (c) National Institute of Pharmaceutical Education & Research (NIPER), (d) Development of Pharmaceutical Industry, an Umbrella Scheme and (e) Production Linked Incentive (PLI) Schemes. The PMBJP scheme is being implemented through Pharmaceuticals and Medical Devices Bureau of India (PMBI) which is an autonomous society registered under Societies Registration Act, 1860. CAPPM is implemented through National Pharmaceutical Pricing Authority (NPPA) which is an attached office of the Department. The remaining schemes namely NIPER scheme, PLI schemes and Development of Pharmaceutical Industry are operated by the Department directly. The details of each of the schemes are given as follows:

3.1 Production Linked Incentive (PLI) Schemes

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

- PLI Scheme for promotion of domestic manufacturing of critical key Starting materials (KSMs)/ Drug Intermediates (Dis)/ Active Pharmaceutical Ingredients (APIs) in India
- PLI Scheme for Promoting Domestic Manufacturing of Medical Devices
- 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 PLI Scheme for promotion of domestic manufacturing of critical KSMs /DIs / APIs in India

The "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 20th March, 2020 to promote self-reliance and reduce import dependence in critical APIs. The scheme intends to boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. The guidelines for the implementation of the scheme were initially issued on 27.07.2020. However, based on the feedback received from the investors, the guidelines were revised on 29.10.2020.

The scheme covers 41 products under the following four categories-

i. Target Segment I – Key Fermentation Based KSMs/DIs

ii. Target Segment II - Key Fermentation Based Niche KSMs/DIs

iii. Target Segment III – Chemical Synthesis Based KSMs/DIs

iv. Target Segment IV – Other Chemical Synthesis Based KSMs/DIs/APIs

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

i. For fermentation based products, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%.

ii. For chemical synthesis based products, incentive for FY 2022-23 to FY 2027-28 would be 10%.

The Government has received a good response to the scheme. A total number of 249 applications were received under the scheme for the 41 products spread across the four Target Segments for the scheme from all over the country. Out of 249, 51 applications have been approved with a total committed investment of Rs. 4,138.41 crore and expected employment generation of around 10,598 persons. The status of Projects / Plants with respect to the investment as per the Quarterly Review Report (QRR) of September 2022 may be seen from Table-3A.

Table 3A
(Status of Projects / Plants: Investment as per QRR of September 2022)

Sl. No.	Target Segment	Total Applicants approved	Total Committed Investment (₹ in crore)	Actual Investment up to Sep 2022# (₹ in crore)	Actual Employment up to Sep 2022# (No. of persons)
1	A. Key Fermentation based KSMs/Drug Intermediates	4	2299.17	502.29	420
2	B. Fermentation based niche KSMs/Drug Intermediates /APIs	6	500.27	50.45	113
3	C. Key Chemical Synthesis based KSMs/Drug Intermediates	6	459.37	218.37	192
4	D. Other Chemical Synthesis based KSMs/ DIs	35	879.60	936.26	1182
Total		**51**	**4,138.41**	**1,707.37**	**1,907**

Actual Investment is not updated for 2 projects as applicants are in process of submitting Bank Guarantee and 1 applicant has withdrawn from the scheme

3.1.2 PLI Scheme for Promoting Domestic Manufacturing of Medical devices

The domestic medical devices industry faces several challenges including lack of adequate infrastructure, constraints in domestic supply chain and logistics, high cost of finance, inadequate availability of quality power, limited design capabilities and low investments on R&D and skill development. With a view

to address some of these challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies, the 'PLI Scheme for Promoting Domestic Manufacturing of Medical Devices' was approved by the Government of India on 20th March, 2020. The guidelines for implementation of the scheme were issued on 29.10.2020.

The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of Rs. 3,420 crore. Under the Scheme, financial incentive will be 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 (5) years. The details of Incentive under the scheme are as follows:

Table 3B

(Details of Incentive under the scheme)

Category of applicant	Rate of Incentive on Incremental Sales of Manufactured Goods for respective FY	Incentive rate
Category A	FY 2022-23 to FY 2026-27	5% limited to Rs. 121 cr per applicant
Category B	FY 2022-23 to FY 2026-27	5% limited to Rs. 40 cr per applicant

The products under the scheme has been categorized under the following four Target Segments -

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

In total 42 applications were received under the scheme. Out of these 21 applications have been approved with a total committed investment of Rs. 1,058.97 crore and expected employment generation of around 6,411 persons. The status of Projects/ Plants with respect to investment as per the Quarterly Review Report (QRR) of September 2022 may be seen from the Table-3C below:

Table-3C

(Investment as per QRR of September 2022)

Sl. No	Target Segment	Total Applicants Approved	Total Committed Investment (₹ in crore)	Actual Investment up to Sep 2022# (₹ in crore)	Actual Employment up to Sep 2022# (No. of persons)
1	Key Fermentation based KSMs/Drug Intermediates	4	2299.17	502.29	420

2	Fermentation based niche KSMs/Drug Intermediates /APIs	6	500.27	50.45	113
3	Key Chemical Synthesis based KSMs/Drug Intermediates	6	459.37	218.37	192
4	Other Chemical Synthesis based KSMs/ DIs	35	879.60	936.26	1182
	Total		**4,138.41**	**1,707.37**	**1,907**

 # Round-III application filing window for category B medical devices is closed on 21st November 2022

3.1.2 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 Operational Guidelines have been issued on 01.06.2021.

The scheme covers pharmaceutical goods under the 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 / Key Starting Materials / Drug Intermediates (except for the 41 eligible products already covered under the "PLI Scheme for promotion of domestic manufacturing of critical KSMs / DIs / APIs").
- **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 devices; Other drugs as approved; Other drugs not manufactured in India.

The tenure 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 FY 2022-23 to FY 2025-26, 8% for FY 2026-27 and 6% for FY 2027-28. The incentives for the three groups i.e., Group A (with global manufacturing revenue of Rs. 5000 crore or more), Group B (with global manufacturing revenue of Rs. 500 crore or more) and Group C (with global manufacturing revenue of less than Rs. 500 crore) may be seen from the following table:

Table 3D

(Ceiling of Incentive)

Group	Incentive ceiling per applicant	Ceiling of additional incentive per applicant, if any	Total Incentive Ceiling for the group
A	1000 cr	200 cr	11000 cr

B	250 cr	50 cr	2250 cr
C	50 cr	10 cr	1750 cr

Table 3E

(Category-wise incentive rate and period)

Product category	Incentive rate	Incentive period
1 & 2: Biopharma, Phyto-pharmaceuticals, Complex Generic Drugs, Patented drugs, Cell-based or Gene therapy drugs, complex excipients, Orphan drugs, APIs/KSMs/DIs, Spl Capsules like HPMC, etc.	10% (first 4 years), 8% (5th year) & 6% (6th year)	2022-23 to 2027-28
3: Repurposed drugs, Auto-immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs, IVD Devices, etc.	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 and the tenure of the scheme is from FY 2020-21 to 2028-29. Applications were called from the industry under the scheme till 31.08.2021. In total 271 applications have been received and Fifty-five (55) applicants have been selected under the scheme including 20 MSMEs. The scheme is also expected to bring in investment of more than 17,000 crore in the pharmaceutical sector.

The support to pharma industry, spans a breadth of product categories from *cell and gene therapy to phyto-pharmaceuticals.* The support under PLI schemes is expected to promote the production of high-value products in the country and increase the value addition in exports as well as generate employment for both skilled and unskilled personnel, estimated at 20,000 direct and 80,000 indirect jobs as a result of growth in the sector. Total incremental sales of Rs.2,94,000 crore are estimated during six years from FY 2022-23 to 2027-28. The status of investment in Projects/ Plants as per the Quarterly Review Report (QRR) of September 2022 may be seen from the following table:

Table 3F

(Investment as per QRR of September 2022)

Sl. No.	Category of Applicants	Total Applicants approved	Total Committed Investment (₹ in crore)	Actual Investment up to Sept 2022 (₹ in crore)*	No. of mfg. locations proposed	No. of mfg. locations commissioned	No. of R&D locations
1	**Group A (Pharmaceuticals)**	11	11000	9014	152	126	14
2	**Group B (Pharmaceuticals)**	9	2250	3450	63	58	9
3	**Group C (Non-MSME)**	14	700	1215	37	31	5
4	**Group C (MSME)**	16	3311	1385	44	36	1
5	**Group C - IVD**	5	164	100	13	10	2
Total		**55**	**17,425**	**15,164**	**309**	**261**	**31**

*** Investments are based on the figures provided by the applicants. Out of 55 applicants 45 applicants have submitted the QRR report.**

3.2 Umbrella Scheme for Development of Pharmaceutical Industry

Under the umbrella scheme for Development of Pharmaceutical Industry (DPI), the Department implements a Central Sector Scheme namely 'Strengthening of Pharmaceuticals Industry' with three sub-schemes (Rs.500 Cr) and Two Park Schemes {one for Bulk Drugs (Rs.3000 Cr) and another for Medical Devices (Rs.400 Cr)}. Its objective is to increase efficiency and competitiveness of domestic pharmaceutical and MedTech 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.

3.2.1 Scheme for Promotion of Bulk Drug Parks

The scheme to promote setting up of bulk drug parks in the country was approved by the Government on 20th March, 2020. The Scheme envisages creation of world class common infrastructure facilities to bulk drug units located in the parks. The easy access to such facilities to bulk drug units located in the parks would bring down their manufacturing cost and increase competitiveness of the domestic bulk drug industry. The scheme would help minimize country's dependence on imports by providing fillip to indigenous manufacturing and facilitate Indian bulk drug industry becoming global leaders.

- Under the scheme, financial assistance would be provided for the creation of Common Infrastructure Facilities (CIF) like (i) Central Effluent Treatment Plant(s) (CETP) (ii) Solid waste management (iii) Storm water drains network (iv) Common Solvent Storage System, Solvent recovery and distillation plant (v) Common Warehouse (vi) Dedicated power sub-station and distribution system with the necessary transformers at factory gate (vii) Raw, Potable and Demineralized Water (viii) Steam generation and distribution system (ix) Common cooling system and distribution network (x) Common logistics (xi) Advanced laboratory testing Centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers (xii) Emergency Response Centre (xiii) Safety/ Hazardous operations audits centre and (xiv) Centre of Excellence etc. in any upcoming Bulk Drug Park promoted by State Government/State Corporation.
- The total financial outlay of the scheme is Rs. 3000 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025. Financial assistance to a selected Bulk Drug Park would be 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 would be 90% of the project cost. Maximum assistance under the scheme for one Bulk Drug Park would be limited to Rs. 1000 crore.
- Gujarat, Himachal Pradesh and Andhra Pradesh were selected under the scheme for providing grant-in-aid for creation of common infrastructure facilities in their proposed Bulk Drug Parks.

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

- Total Project Cost-Rs. 1635.98 crore
- Area: *2000.46* acres
- Major Common Infrastructure facilities being developed under the scheme include Roads, drainage, Boundary, green area, water supply, Waste Water Conveyance Network System –HTDIS and LTDIS (CETP) and treatment system, marine outfall, Power Supply, Steam Co-generation plant including distribution, Common Solvent recovery system, Solid Waste Management, Common Solvent Recovery system, Warehousing and common logistics, Analytical Testing labs, Centre of Excellence, etc.

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, Infrastructure of Roads and internal drains, common Infrastructure of Marine Discharge and 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 5 MLD, 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 etc.

3.2.2 Promotion of Medical Devices Parks

The Department has approved financial assistance of ₹ 25 crore to the project of Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh under the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre". The financial assistance is being given for development of Common Facility Centre for superconducting magnetic coils testing & research facility. The Department has released of ₹ 22.49 crore to AMTZ. This scheme aimed at providing financial assistance to States/UTs for creation of Common Facility Centre in the medical devices parks being developed by them. The scheme has now been revised to "Promotion of Medical Devices Parks".

The objective of the Promotion of Medical Devices Parks scheme is to provide easy access to standard testing and laboratory facilities through the creation of world-class Common Infrastructure Facilities at medical device parks. This would help reduce the cost of production and increase competitiveness and improve availability and affordability of medical devices thereby creating a robust ecosystem for domestic manufacturing of medical devices. The guidelines of the scheme were issued on 27th July 2020.

The scheme provides grant-in-aid to medical device parks with a maximum limit of ₹ 100 Crore per park or 70% of the project cost of common infrastructure facilities, whichever is less. The Government approved financial assistance for common infrastructure facilities for four medical device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh. The expected date of completion of the Parks is June, 2024. As per scheme guidelines, first tranche of grant-in-aid of Rs. 30 crore each has been released to the four States.

3.2.3 Strengthening of Pharmaceutical Industry (SPI)

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers has released the guidelines for the scheme "Strengthening of Pharmaceutical Industry" (SPI), with a total financial outlay of Rs. 500 Cr for the period from FY 2021-22 to FY 2025-26 on 11.3.2022. The scheme will address the rising demand for support to the 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:

- Assistance to Pharmaceutical Industry for Common Facilities (API-CF)
- Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
- Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

i. **Assistance to Pharmaceutical Industry for Common Facilities (API-CF)** is provided to strengthen the existing pharmaceutical clusters' capacity for creating common facilities. This will not only improve the quality but also promote competitiveness and sustainable growth of the units in the clusters.

ii. **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)** aims 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). Under the scheme, interest subvention or capital subsidy on loans of such enterprises are provided, which further facilitates the growth in volumes as well as in quality of these units; 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. SIDBI has been appointed as the Project Management Consultant (PMC) for the SPI scheme.

It is expected that the units supported under this scheme will act as Demonstration Firms for the pharma clusters and MSMEs Pharma Industries, encouraging them to improve quality and undertake technological upgradation of the units.

In the earlier scheme known as Cluster Development Programme for Pharma Sector (CDP-PS) which is now renamed as Assistance to Pharmaceutical Industry for Common Facilities (API-CF), one project of Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC) viz., setting up Common Effluent Treatment Plant (CETP) at Alathur, Tamil Nadu has been completed. The total cost of the project was Rs. 11.02 crore (revised from Rs.10.59 crore due to GST implementation). Further, two more project proposals were given final approval on 31.3.2021 viz.:

i. Proposal of Inducare Pharmaceuticals and Research Foundation (IPRF) for creation of Common Facility Centre at Pune, Maharashtra at approved project cost of Rs. 31.44 crore. Three instalments have been released to the SPV of project (IPRF).

ii. Proposal of Kala Amb Infrastructure Development Company (KIDC) to set up a Common Effluent Treatment Plant (CETP) at Industrial area Kala Amb Tehsil Nahan, District Sirmaur, Himachal Pradesh with project cost of Rs. 7.20 crore. Three instalments has been released to the SPV of project (IPRF).

The status of Projects as captured through pictures/images on site are as follows:

a. Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC)

b. Kala Amb Infrastructure Development Company (KIDC)

4C- Equalisation Tank

9E- PH- Neutralization Tank

5C- Anoxic Chamber

Laboratory/ Office Room

2C-Bar Screen Chamber

3C- Grit Chamber Mechanical

0.15 MLD
4E- Flash Mixer
5E- Reaction Chamber
6E- Primary Setting Tank

c. Inducare Pharmaceuticals and Research Foundation (IPRF)

Under the new sub-scheme Assistance to Pharmaceutical Industry for Common Facilities (API-CF) of Strengthening of Pharmaceutical Industry (SPI) Scheme, application window was opened for inviting applications for project proposals. A total of 20 applications/project proposals were received from Seven States and Union Territories. The first Scheme Steering Committee (SSC) meeting to consider these proposals was held in the month of October 2022. The SSC found that of 20 applications/project proposals, 17 applications / project proposals were eligible for being considered under the scheme. Of these 17 applications/project proposals, 7 applications/project proposals were shortlisted and they have been requested to submit the Detailed Project Report (DRP) by 15.12.2022. Further examination and finalization of projects for approval is under process.

Under Sub-Scheme Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) more than 60 applications have been registered. The promotional outreach events were held at various States and UTs, the details are as follows:

Table 3G
(promotional outreach events held at various States and UT)

S. No.	Date	Venue	Partnering Organizations	Subject of the event
1.	21/07/22	Delhi	CII	Launch of the scheme by the Hon'ble Union Minister and national level outreach programme on the various sub-schemes of Strengthening of Pharmaceuticals Industry (SPI) Scheme.
2.	5/08/22	Ahmedabad	IDMA	State level outreach programme for the State of Gujarat
3.	6/08/22	Bengaluru	Karnataka Drugs & Pharmaceuticals Manufacturers Association	State level outreach programme for the State of Karnataka
4.	10/08/22	Jaipur	PHDCCI	State level outreach programme for the State of Rajasthan

5.	12/08/22	Mumbai	IDMA	State level outreach programme for the State of Maharashtra
6.	12/08/22	Chandigarh	PHDCCI	State level outreach programme for the States of Punjab, Haryana and UT – Chandigarh
7.	20/08/22	Hyderabad	BDMA	State level outreach programme for the State of Telangana
8.	27/08/22	Visakhapatnam	BDMA	State level outreach programme for the State of Andhra Pradesh
9.	27/08/22	Haridwar	CII	State level outreach programme for the State of Uttarakhand
10.	30/08/22	Baddi, H.P.	Laghu Udyog Bharti	State level outreach programme for the State of Himachal Pradesh. This outreach programme was graced by the presence of Hon'ble MoS.
11.	13/09/22	Chennai	FICCI	State level outreach programme for the State of Tamil Nadu
12.	17/10/22	Video Conference	SIDBI	Virtual Outreach programme for the Sub-Scheme PTUAS of SPI scheme, convened by the Secretary, DoP, involving State Drugs Controllers & Industry Departments , State level Pharma Manufacturing Associations & CDSCO, including their regional offices of Northern States / UTs viz Uttarakhand, Rajasthan, Haryana, Himachal Pradesh, Punjab, Chandigarh and Jammu and Kashmir
13.	15/11/2022	Video Conference	SIDBI	Virtual Outreach programme for the Sub-Scheme PTUAS of SPI scheme, convened by the Secretary, DoP, involving State Drugs Controllers& Industry Departments , State level Pharma Manufacturing Associations & CDSCO, including their regional offices of Western States/ UTs viz Maharashtra, Gujarat, Daman and Diu, Goa and Dadra and Nagar Haveli
14.	25/11/2022	Video Conference	SIDBI	Virtual Outreach programme for the Sub-Scheme PTUAS of SPI scheme, convened by the Secretary, DoP, involving State Drugs Controllers& Industry Departments , State level Pharma Manufacturing Associations & CDSCO, including their regional offices of Southern States / UTs viz Andhra Pradesh, Karnataka, Kerala, Puducherry, Tamil Nadu, Telangana, Lakshadweep and Andaman and Nikobar Strengthening of Pharmaceuticals Industry (SPI)

The Photos of the events are as follows:

1. Baddi Event

2. Mumbai Event

3. **Haridwar Event**

4. **Chennai Event**

5. Jaipur Event

iii. Assistance to Medical Device Industry for Common Facility Centre

The Department has approved financial assistance of ₹ 25 crore to the project of Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh under the sub-scheme termed as "Assistance to Medical Device Industry for Common Facility Centre". The financial assistance is being given for development of Common Facility Centre for superconducting magnetic coils testing & research facility. The Department has released three grant-in-aid instalments of ₹ 22.49 crore to AMTZ. This scheme aimed at providing financial assistance to States/UTs for creation of Common Facility Centre in the medical devices parks being developed by them. The scheme has now been revised to "Promotion of Medical Devices Parks".

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

In addition to the programmatic interventions such as PLI scheme for Medical Devices and Medical Devices Park Schemes etc., as explained above Department of Pharmaceuticals is also engaged with various other schematic and non-schematic interventions for promotion of Medical Devices Sector as delineated below:

A. 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. In the same line, the Department has also issued revised guidelines for implementation of the Order for **Pharmaceuticals** Sector on 30.12.2020.

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 within 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".

Further, various central procurement agencies are also finding it difficult to find local suppliers of medical devices for which there are no local manufacturers. Accordingly, with the help of MoHFW, the Department has facilitated one-time exemption under the provisions of the PPO-MII Order so that the procuring entities are able to procure the required medical devices.

B. 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. To drive the growth of the sector, a draft National Medical Device Policy, 2023 has been prepared in consultation with the medical device industry. The draft is under consideration for finalization of the Policy.

C. Other Initiatives for the Medical Device Industry

- **Regulatory Streamlining:** The Medical Device Sector has largely been unregulated and the Government was constantly endeavouring to regulate all the devices. In the year 2020, the Ministry of Health & Family Welfare notified all the medical devices as drugs and proposed their phased regulation plan. The Department of Pharmaceuticals is working closely with MoHFW and the industry for resolving issues related to phase-wise implementation of MDR, 2017. Medical Devices are being regulated by a number of regulators and to discuss the issues of the industry with different regulators, the Department organized a regulatory round table wherein representatives of industry associations and regulators discussed various issues to find mutually agreeable solutions of the issues.
- **Constitution of Standing Forum of Medical Devices:** The Medical Device Sector has seen significant activity in recent years with an increase in demand, roll out of the regulatory timeline, the introduction of Production Linked Incentive Schemes etc., all of which have contributed to a need to take on board a range of views on important policy issues. The Department has been consulting the Industry on many of these issues from time to time. 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 the 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 D/o Pharmaceuticals has the mandate for the promotion of the Medical Device industry, the NMDPC has been reconstituted under the chairpersonship of Secretary, D/o Pharmaceuticals with the concurrence of DPIIT on 5th August 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. The first meeting of the reconstituted NMDPC was held on 14th September 2022 wherein issues of the Industry were taken up.

- **Setting up of the Export Promotion Council for Medical Devices:** Department of Commerce has approved the creation of a separate Export Promotion Council for Medical Devices under the administrative control of DoP. The proposed EPC may be located in NCR, preferably YEIDA, in UP where a Medical Device Park is coming up with the assistance from Government of India under the clusters development scheme. The creation of the Export Promotion Council is under progress.

- **India Pharma and Medical Devices Event:** Annually, the Department organizes the event, with Industry partners, to deliberate the important issues of the Industry. The CEOs Round Table, during the Event, involves meeting of top CEOs of the MedTech Industry with the Hon'ble Union Minister to brain-storm on the important issues and arrive at the way forward. The India Pharma and Medical Devices 2022 was conducted during 25-27th April 2022.

- **MedTech Expo (IMTE) 2023:** Department of Pharmaceuticals is organising the first edition of India MedTech Expo (IMTE) 2023, in association with FICCI and other MedTech Industry Associations. This will be a unique, all-encompassing platform to showcase the strength and potential of the Indian medical devices ecosystem. India MedTech Expo 2023 will create opportunities to network and explore collaborations, by bringing together all the stakeholders such as PLI participants, start-ups, MSMEs, R&D facilities, innovative entrepreneurs, incubators, public and private hospitals, academia, research institutions, investors, state governments etc.

- The scheme ***"Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana (PMBJP)"*** are making available close to 250 types of surgical supplies in over 8800 Jan Aushadhi Kendras at highly affordable prices.

- The **National Pharmaceutical Pricing Authority (NPPA)** monitors the prices of Non-Scheduled Medical Devices and fixes the ceiling prices for Scheduled Medical devices. In view of the extraordinary circumstances due to COVID pandemic and with the aim of making medical devices affordable, the prices of (i) Pulse Oximeters, (ii) Blood Pressure Monitoring Machines, (iii) Nebulizers, (iv) Digital Thermometers, (v) Glucometers and (vi) Oxygen Concentrators were brought under price cap using Trade Margin Rationalization.

D. Interventions by other Departments for promotion of Medical Devices Industry

- To foster Make-in-India product development and nurture the clinical validation ecosystem in the MedTech sector, the Indian Council of Medical Research (ICMR) has established the ***"Medical Device and Diagnostics Mission Secretariat (MDMS)"***. This program aims to support and catalyze research, development and indigenous manufacturing of cost-effective medical devices to strengthen the healthcare sector in India and reduce import dependence through a mission-mode consortia approach.

- ***"Health Technology Assessment in India (HTAIn)"*** scheme of the Department of Health Research conducts studies that provide evidences related to cost-effectiveness, clinical- effectiveness and safety of medicines, devices and health programs to support evidence-based decision-making in healthcare services for the development of quality and affordable medical devices in the country.
- Health and Wellness Centers across the country are being equipped with medical devices required for primary diagnostic services under ***"Ayushman Bharat program".***
- **New Drugs, Medical Devices and Cosmetics Bill, 2022, proposed by MoHFW:** The Drugs and Cosmetics Act, 1940 is a pre-independence legislation enacted by the Central Legislative Assembly. Review of obsolete laws and updating of the existing laws is a continuing process to accommodate changed requirements and adaptation of new technology. The Government has time and again emphasized the need to review obsolete laws and to periodically repeal and amend laws, for which Bill are being brought before the Parliament. In light of recommendations of the Central Government and the need to have comprehensive legislation, a committee was constituted for framing the **New Drugs, Cosmetics and Medical Devices Bill**. As per recommendations of the Committee, the Ministry of Health and Family Welfare, proposed a draft New Drugs, Medical Devices and Cosmetics Bill, 2022 in order to keep pace with changing needs, times, and technology. The draft bill is under stakeholder consultation**.**

3.4 Pharma Bureau

Pharma Bureau provides facilitation to investors and resolution of their inter-departmental co-ordination 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

- Pharma Bureau also provides policy support to DoP for framing incentive schemes for the industry.
- Pharma Bureau is committed to its goal to increase engagement, productivity and satisfaction of entrepreneurs of pharmaceutical and medical devices sector by addressing the most critical roadblocks.
- It also works as the Project Development Cell of the Department.

CHAPTER 4

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMB-JP)

CHAPTER 4

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

4.1 Background

Despite the country being one of the leading exporters of generic medicines to the world, the majority of Indians lack sufficient access to affordable medicines. The branded (Generic) medicines are sold at significantly higher prices than their un-branded generic equivalents, though they are identical in their therapeutic value.

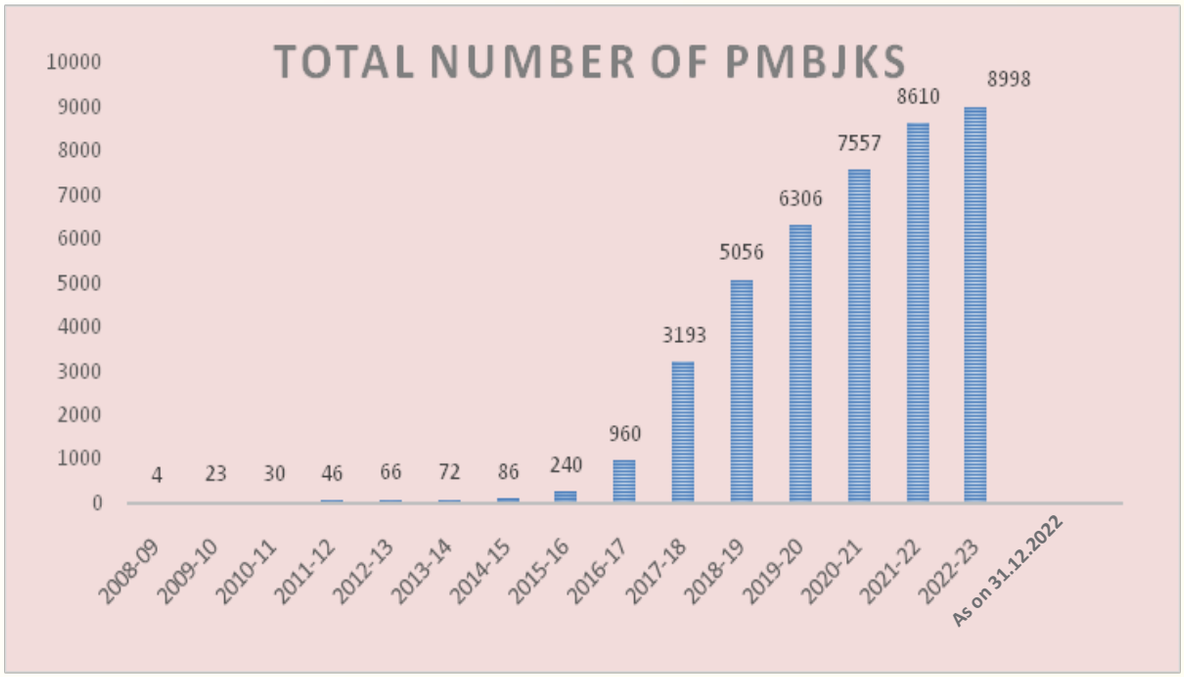
With an objective of making quality generic medicines available at affordable prices to all especially for the poor and the deprived ones, *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) was launched by the Department in the year 2008. Under this scheme, dedicated outlets known as *Pradhan Mantri Bhartiya Janaushadhi Kendras* (PMBJK) are opened all over the country to provide generic medicines to the masses.

As on 31.12.2022, 8,998 Janaushadhi Kendras are functional across the country. Product basket of PMBJP comprises 1759 drugs and 280 surgical equipment.

Journey so far

Graph-4A

(Year-wise progress in the total number of PMBJP Kendras)



Objectives

- To make available quality medicines, consumables and surgical items at affordable prices for all and reduce out of pocket expenditure of consumers/patients.

- To popularize generic medicines among the masses and dispel the prevalent notion that low priced generic medicines are of inferior quality or are less effective.
- To ensure easy availability of the menstrual health services to all women across India.
- Generate employment by engaging individual entrepreneurs in the opening of PMBJP Kendras.

Implementing Agency

Pharmaceuticals & Medical Devices Bureau of India (PMBI) [erstwhile known as Bureau of Pharma Public Sector Undertakings of India (BPPI)] was set up on 1st December, 2008 by the Department with a major objective to have focused and empowered structure to implement the *Jan Aushadhi Campaign*. It is a society registered under the Societies Registration Act, 1860. The Bureau is headed by Chief Executive Officer (CEO). The policy decisions are taken with the approval of the Governing Council set up under the chairmanship of the Secretary of the Department. Further, the performance of the PMBI is regularly reviewed by the Executive Council (EC) which is headed by the Joint Secretary, Department of Pharmaceuticals.

Salient features of the Scheme

The Scheme has been approved for continuation with the financial outlay of ₹ 490 crore for the period from 2020-2021 to 2024-2025. The target is to open 10,500 PMBJP *Kendras* in all over the country by March, 2025. It has also been decided to enhance the product basket of PMBJP up to 2,000 medicines and 300 surgicals by March 2025.

In order to popularize the Scheme amongst individual entrepreneurs, the incentive has been doubled. In case of women, Divyang, SC, ST entrepreneurs and entrepreneurs opening stores in aspirational districts, Himalayan, Island territories and the North-Eastern States, new incentive plan has been launched with following details:

Normal Incentive

The incentive to Kendras run by entrepreneurs that are linked with PMBI through software has been enhanced up to ₹ 5 Lakh from ₹ 2.50 lakh earlier. The incentive is given @ 15% of monthly purchases made from PMBI by these Kendra subject to a ceiling of ₹ 15,000/- per month. This also applies to existing Kendras whose existing limit of incentives of ₹ 2.50 lakh has been fully disbursed.

Additional Incentive

In order to popularize the Scheme amongst women, Divyang, SC & ST entrepreneurs and entrepreneurs opening stores in aspirational districts, Himalayan, Island territories and North-Eastern States, a new incentive plan has been launched. Such Kendras now get an amount of ₹ 2 lakh in addition to normal incentives, as under:

i. ₹ 1.50 lakh reimbursement for furniture and fixtures.

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

Saving to a Common Man

During the financial year 2019-20, PMBJP has achieved sales of ₹ 433.63 crore (at MRP). This has led to savings of approximately ₹ 2500 crore of the common citizens of the country as these medicines are cheaper by 50% to 90% of average market price. In the financial year 2020-21, sales of ₹ 665.83 Crore were achieved, which has led to savings of about ₹ 4000 Crore to the citizens as compared to the branded medicines. In the financial year 2021-22, PMBI achieved sales of ₹ 893.57 Crore which led to savings of

approximately ₹ 5,400 Cr. for the citizens. In the current financial year i.e., 2022-23 till 31.12.2022, PMBI has achieved sales of ₹ 853.55 Crore which led to savings of approximately ₹ 5000 Cr. for the citizens. In all these years, the scheme has led to estimated savings of Rs. 18000 crore for citizens.

Procurement of medicines

Product basket of PMBJP comprises of 1759 drugs and 280 surgical instruments. 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

To overcome the problem of making the range of products available, IT-enabled End to End Supply Chain system has been implemented and one central warehouse at Gurugram and three regional warehouses at Chennai, Guwahati & Surat have been established. Further, it has been planned to open two more warehouses in Western and Central India.

Implementation of SAP and POS System

A single IT enabled system (SAP) was introduced in 2017 to ensure monitoring at every step in the process i.e., from placing the order of medicines to manufacturers till the supply of drugs reaches the Store's doorstep.

Suvidha Sanitary Napkins

To ensure easy availability of the menstrual health services to all women across the country, "*Janaushadhi Suvidha* Oxy-Biodegradable Sanitary Napkin" was launched by the Department in the year 2018, which are now available for sale in all PMBJP Kendras across the country @ ₹ 1.00 per sanitary pad. The *Jan Aushadhi Suvidha* napkins come with a special additive, which makes it bio-degradable when it comes in contact with oxygen after being discarded. This step has ensured 'Swachhta, Swasthya and Suvidha' for the women in the country. As on 31.12.2022 more than 32.49 Crore pads have been sold through PMBJKs.

Jan Aushadhi SUGAM

A mobile application "Janaushadhi Sugam" is an important facility for the general public by providing a digital platform at the tip of their fingers, by the virtue of which they can avail a host of user-friendly options like - locate nearby PMBJK (direction guided through Google Maps), search janaushadhi medicines, analyse product comparison of Generic Vs Branded medicine in the form of MRP saving etc.

Awareness about the Scheme

The awareness about the salient features of the Scheme is spread through various types of advertisements through Print Media, Radio, TV & Cinema Advertisements and Outdoor publicity like Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping. In addition, the public are educated about the usages of *Jan Aushadhi* generic medicines through social media platforms like Facebook, twitter, Instagram, YouTube, etc. Department on its behalf, regularly request Stat/UT Government to create awareness about the Scheme.

4.2 Progress Report during the last five financial years

Table 4A
(Year wise Progress of Number of PMBJP Kendras and Sale therein)

Financial Year	Number of PMBJP Kendras functional		Sales at MRP (Value in Cr.)
	Net Yearly Addition	Cumulative	
2017-18	2226	3306	140.84
2018-19	1834	5140	315.28
2019-20	1166	6306	433.63
2020-21	1251	7557	665.83
2021-22	1053	8610	893.57
2022-23 (As on 31.12.2022)	388	8998	853.55

4.3 Achievements of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) during last one year

Table 4B
(Achievements of PMBJP in last financial year i.e. during 2021-2022)

Sl. No.	Particular	Status as on 31.03.2021	Status as on 31.03.2022	Achievemnts during 2021-22
1.	Pradhan Mantri Bhartiya Janaushadhi Kendra functional, across the country	7557	8610	1053 new PMBJKs opened
2.	Product Basket	Drugs – 1449 Surgical - 204	Drugs – 1616 Surgical - 250	167 new drugs added 46 new surgicals added
5.	Sales at MRP	Rs. 665.83 Cr.	Rs. 893.56 Cr.	Rs. 227.73 Crore increased in sale
6.	Mobile App for General Public	10.23 lakh downloads	14.64 lakh downloads	4.21 lakh download
7.	Jan Aushadhi Suvidha Sanitary Napkin	12.37 Crore Pads sold	23.65 Crore Pads sold	11.28 Crore pads sold during 2021-22
8.	Warehouses for supply of medicines	3	4	1 new warehouse was established at Surat
9.	Social Media - Followers on Facebook page	10.36 lakh	10.83 lakh	0.50 Lakhs followers increased on Facebook page

4.4 Jan Aushadhi Diwas Celeberation

All PMBJP Kendra owners celebrated 7th March 2022 as "Janaushadhi Diwas" across the country. In the celebration, a wide range of activities were carried out to propagate the achievements of the scheme and create awareness about its benefits. All activities were organized in close co-ordination with Kendra owners, beneficiaries, students, media, doctors, pharmacists, NGOs, social workers and people's representative like Hon'ble MPs, MLAs & local body members. Each day was celebrated with a special theme dedicated to Women, Children, Students, NGO's, Health & Heritage etc.

Hon'ble Prime Minister spoke to the beneficiaries of the scheme through video conferencing on the occasion of Jan Aushadhi Diwas on 7th March 2022.

Celebration of Janaushadhi Diwas 2022

4.5 Azadi Ka Amrit Mahotsav

Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), under the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers organized various activities / events on 10th October 2022 at 35 different locations, across the country to celebrate the Azadi Ka Amrit Mahotsav. A full day event was organized at 35 locations where Health Check-up Camps, Jan Aushadhi Paricharcha and free distribution of First Aid Kits of Jan Aushadhi medicines were organized by PMBI. Officials of PMBI conveyed the salient features of PMBJP to General Public, Doctors, Health Workers, Nurses, Pharmacists, Jan Aushadhi Mitra's, stakeholders, etc. More than 875 beneficiaries have been provided "First Aid Kits" of PMBJP products. Approximately, 5000 citizens attended Health Check-up Camp, across the country.

AzadiKaAmritMahotsav

4.6 Celebration of Swachhata Special Campaign 2.0

PMBI celebrated Swachhata Special Campaign 2.0 by undertaking a number of activities. The special campaign kick started with the Swachhata Special Campaign 2.0 on 01.10.2022 under the Chairmanship of Chief Executive Officer, PMBI. More than 7,000 centers collaborated with this campaign to achieve its defined target. The Swachhata pledge was conducted virtually to include all concerned stakeholders of PMBI. All employees of PMBI head office along with distributors, Jan Aushadhi Kendra Owners, and other stakeholders weeded out old documents and bills from the office to make workstation spaces clean and clutter-free.

Celebration of Swachhata Special Campaign 2.0

CHAPTER 5

National Institutes of Pharmaceutical Education & Research (NIPERs)

CHAPTER 5

National Institutes of Pharmaceutical Education & Research (NIPERs)

5.1 Background

Indian Pharma Industry is a global leader in Generic drugs. In order to acquire a leadership position in drug discovery and development and to continue to excel in the formulations, the Government recognized that the human resources/talent pool is very critical. 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 the year 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 seven existing NIPERs is as under:

Table 5A
(The status of allotment of land and construction of campuses of the NIPERs)

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). About 54% of construction of the campus has been completed. The construction is likely to be completed by March, 2023.
Guwahati	2008	About 51.42 acres land at Village Sila, Changsari Dist, Kamrup was allocated for NIPER, Guwahati and M/s Engineering Projects India Limited (EPIL) has been selected as Project Management Consultant (PMC). Construction of NIPER-Guwahati campus has been completed and the institute has started functioning from its new campus.
Hajipur	2007	About 12.5 acres of land at EPIP Campus, Industrial Area at Hajipur has been allocated by Govt. of Bihar for NIPER, Hajipur. MoU has been signed with CPWD for construction of campus. Tender has already been issued.
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. Tender is under issue.
Kolkata	2007	About 10 acres of land at Mouza-Gopalpur, P.S. Kalyani, Dist Nadia has been allocated by Govt. 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. Tender is under issue.
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. Tender has already been issued.

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. (Ms.) Madhu Dikshit, Former Director, CSIR-CDRI	Dr. Gayathri V. Patil (under suspension) Dr. V. Ravichandiran (Additional Charge)
Raebareli	Prof. Samit Chattopadhyay, Former Director CSIR-IICB	Dr. Shubhini Saraf
Kolkata	Prof. P Balaram, Former Director, IISc, Bengaluru	Dr. V. Ravichandiran
Hyderabad	Dr. Satyanarayana Chava, CEO, Laurus Labs, Hyderabad	Dr. Shashi Bala Singh
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 conductive 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, taking into account 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, three of the six NIPERs have remained amongst the top ten pharmacy Institute in the country since 2019. 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
Mohali	2nd	1st	3rd	3rd	4th	4th
Hyderabad	5th	6th	6th	5th	6th	2nd
Ahmedabad	-	14th	9th	8th	10th	10th
Guwahati	-	-	-	11th	19th	13th
Raebareli	-	-	-	18th	13th	27th
Kolkata	-	-	-	27th	33rd	-

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)

Year/NIPER	Moh	Ahm	Guw	Haj	Hyd	Kol	Rae	Total
2018-19	29.00	12.00	33.50	9.50	24.00	12.00	15.00	**135.00**
2019-20	30.60	18.50	43.90	5.00	27.00	18.00	17.01	**160.01**
2020-21	60.55	60.50	79.45	26.00	44.50	34.82	28.00	**333.82**
2021-22	51.00	54.00	59.45	41.00	72.91	47.64	46.00	**372.00**

2022-23*	43.05	28.00	32.00	15.00	29.00	15.75	14.50	**177.30**
Total	**214.20**	**173.00**	**248.30**	**96.50**	**197.41**	**128.21**	**120.51**	**1178.13**

*Till December, 2022

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: ₹ 31,000- 35,000/ - 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.

5.2 NIPER SAS Nagar (Mohali)

NIPER SAS Nagar 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 work.

NIPER SAS Nagar has a campus that caters for research facilities, three boys' hostels with intake capacity of 472 and a girls' hostel with an intake capacity of 220, a married hostel with an 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. It offers Masters, Integrated (Master-PhD) and PhD degrees in 16 streams and caters to the various needs of pharmaceutical industry.

5.2.1 Achievements

Academic excellence

During 2022-23, the Institute has published 85 articles in journals of repute (till 17th October, 2022). Institute has filed 205 patent applications and out of which 116 patents are granted/issued till date. Since the inception of the academic programme, 4282 students have passed out (Masters 3175, MBA 733 & Ph.D. 374).

5.2.2 Research areas in NIPER SAS Nagar

A. Neglected diseases

Research is carried out in the areas of Leishmaniosis, 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 are being worked out.

C. Drug development and formulation

i. Improvement of oral bioavailability, synergistic anticancer efficacy and reduced toxicity of drugs has been attempted
ii. New formulations and NDDS are being developed.
iii. Green sustainable synthesis of APIs, KSMs and intermediates
iv. Standardization of Herbal drugs and formulations
v. Toxicological studies

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 RNA 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 study of food effects on drug PK
x. HEOR and pharmacovigilance

5.2.3 Academic and Non –academic Staff

Table 5E

Details of Academic and Non-academic Staff

Man-Power	In-Position
Academic	24+1(Director)
Non-Academic	118

5.2.4 Funds allocated during the last 5 years (Rs. In crores)

Table 5F
(Details of Funds allocated during the last 5 years)

Year	Allocation BE	Allocation RE	Total Release
2018-19	32.00	29.00	29.00
2019-20	30.60	30.60	30.60
2020-21	41.00	60.55	60.55
2021-22	43.00	51.00	51.00
2022-23	74.05	74.05	43.05 (Till Dec, 22)

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
Masters'	M.S.(Pharm.)	Medicinal Chemistry	-	-	-	-	-	28	27
Masters + Ph.D	Integrated PhD		-	-	-	-	-	-	1
Doctoral	PhD		1	3	2	2	-	6	13
Masters'	M.S.(Pharm.)	Pharmaco- informatics	-	-	-	-	-	18	20
Doctoral	PhD		-	1	2		1	5	4
Masters'	M.S.(Pharm.)	Naural Proucts	-	-	-	-	-	13	15
Doctoral	PhD		-	1	-	4	-	7	6
Masters'	M.S.(Pharm.)	TraditionalMedicine	-	-	-	-		5	5
Masters'	M.S.(Pharm.)	Pharmaceutical Analysis	-	-	-	-	-	9	9
Masters + Ph.D	Integrated PhD		-	-	-	-	-	-	1
Doctoral	PhD		-	-	-	-	-	-	4
Masters'	M.S.(Pharm.)	Pharmacology & Toxicology	-	-	-	-	-	20	22
Masters + Ph.D	Integrated PhD		-	-	-	-	-	-	1
Doctoral	PhD		-	3	3	3	1	5	9

Masters'	M.S.(Pharm.)	Regulatory Toxicology	-	-	-	-	-	9	9
Masters'	M.Tech. (Pharm.)	Pharmaceutical Technology (Formulations)	-	-	-	-	-	7	7
Doctoral	PhD		-	-	-	-	-	-	-
Masters'	M.Tech. (Pharm.)	Pharmaceutical Technology (Process Chemistry)	-	-	-	-	-	16	18
Doctoral	PhD		-	1	4	1	1	4	4
Masters'	M.Tech. (Pharm.)	Pharmaceutical Technology (Biotechnology)	-	-	-	-	-	10	11
Doctoral	PhD		-	-	2	-	-	-	-
Masters'	M.S.(Pharm.)	Pharmaceutics	-	-	-	-	-	22	24
Doctoral	PhD		1	4	1	3	1	7	8
Masters'	M.S.(Pharm.)	Biotechnology	-	-	-	-	-	37	38
Doctoral	PhD		-	3	4		2	8	9
Masters'	M.Pharm.	Pharmacy Practice	-	-	-	-	-	9	9
		Clinical Research	-	-	-	-	-	9	9
Doctoral	PhD	Pharmacy Practice	-	-	1	1	1	5	4
Masters	M. Tech	Medical Devices	-	-	-	-	-	11	10
Doctoral	PhD		-	-	-	-	-	-	-
Masters'	MBA	Pharm. Management	-	-	-	-	-	45	48
Doctoral	PhD		-	-	-	1	1	2	-
Total Currently Enrolled			**2**	**16**	**19**	**15**	**8**	**317**	**345**

5.2.6 Teacher-Student ratio

Table 5H
(Teacher-Student ratio)

Course/Ratio	Total Ratio (S: F)
Ph.D.	170/24 = 7.08:1
Masters'(Science)	459/21 = 21.85:1
MBA (Pharm.)	93/3=31:1
Total	**722/24=30.08**

5.2.7 Placement

Table 5I

(The placements status - in campus/off campus)

Academic Year	Total Students	No. of students Interested	No. of students placed	% of Student placed	Average Package (In lakhs)
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%	5.65
2020-22	252	243	200	82.30%	7.26
2021-23	**268**	265	-	-	-

Most of the students, who are interested get placements. Large number of 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: 205(filed)/116(granted)/07(licensed) since inception.

ii. Total revenue generated FY 2020-21: Rs. 8.57 crore and FY 2021- 22: Rs. 10.024 crore FY 2022-23 (till 14.10.2022) 6.82 crore.

iii. H Index - NIPER SAS Nagar - H index- 127 (till 14-10-2022 Scopus).

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

5.2.9 Impact of NIPER

The success of NIPER, SAS Nagar has encouraged the Government to set up more NIPERs across the country to meet the growing demands of the pharmaceutical sector. In addition, NIPER has carried out training programmes for personnel from India and abroad under ITEC, capacity building programmes (World Bank- sponsored) and SMPIC.

Skill development trainings under skill Vigyan program were sanctioned by PSCST & DBT program for different roles in the 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 'Investigational New Drugs' (IND) applications, PLI scheme etc.
- 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).

5.2.10 NIPER-PHARMACON 2022

NIPER Mohali, in collaboration with other NIPERs, organized the first International Conference on "Recent Trends and Future Opportunities in Pharmaceuticals (NIPER-PHARMACON 2022)" from 10th – 12th November, 2022. It brought together leaders in diverse fields of pharmaceutical fields like - Drug discovery, drug delivery systems, active pharmaceutical ingredients, precision medicines, phytopharmaceuticals and medical devices. Dedicated start-up and industry sessions were also organized. More than 900 participants from international and national academia and industry attended the conference. International and National speakers gave presentations on the theme of the conference in technical sessions to provide advance learning and research experience in pharmaceuticals to the delegates. Industry-NIPERs interaction at conference help to address R&D challenges related to specific stages of the innovation value chain in pharmaceutical sciences and secondly, to undertake joint/collaborative activities leading to human resource development, R&D, institutional capacity building, and entrepreneurship development. Further, the conference helped in networking and enhancing the brand NIPER.

Photographs of Events (seminar / webinar / other Events) conducted at NIPER, SAS Nagar

Seminar by Prof. Sankar K. Guchhait on Natural product-inspired scaffold hopping and strategic synthesis: Discovery of target-specific anticancer agents

One Week training programme on High performance liquid chromatography (HPLC) organized by SMPIC


One Day Institutional Visit under Scientific Social Responsibility (SSR) Policy of SERB (Science and Engineering Research Board)

Brainstorming session on resource mapping within CRIKC in LeaP (Life Sciences & Pharmacy)


Two-week intensive ITEC training programme on "Recent Trends and Challenges in Regulation and Standardization of Herbal Drugs and Formulations


Pharmaceutical Industrial training being conducted at Technology Development Centre-Dosage Formulation


Educational visit by students from Dept. of Bioengineering, Integral University, Lucknow on 26.07.2022

NIPER Students Research Symposium-2022 (NSRS-2022)


Swachhata Pledge (01.09.2022)


One day symposium was organized on "Integration of AYUSH Medicines and Ethnopharmacology

One day Symposium on "Theoretical Chemistry and Biology (TCB)

5.3 NIPER Kolkata

National Institute of Pharmaceutical Education & Research Kolkata (NIPER-Kolkata) was established in the year 2007 and is presently functioning at 'Chunilal Bhawan, Maniktala, 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. Teaching and research remain the central function and overriding goal of the Institute.

5.3.1 Achievements

In 2022-23, 53 research papers were published and 2 MoUs signed. About 49 highly skilled M.S. (Pharm.) students have graduated in July, 2022.

5.3.2 Academic and Non-Academic staff

NIPER Kolkata has 14 teaching and 14 non-Teaching regular employees. In addition, 16 non-teaching employees are in outsourced/contractual engagement for the office.

5.3.3 Total fund allocated by the Government during the last 5 years

Table 5J

(Year-wise Allocated of Fund to NIPER Kolkata)

(Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2018-19	12.00	12.00	12.00
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	-	15.75 (Till Dec' 22)

5.3.4 Teacher-student ratio: 1:15

Academic and research activities of the institute are strengthened by regular & contractual faculty.

5.3.5 Awards received by Faculty

Dr. Pallab Datta, Department of Pharmaceutics is recognized as the Top 2% scientist according to the list by Stanford University.

5.3.6 Students

Table 5K

(Degrees/Programs and Disciplines offered year-wise with admission status)

Level	Degree	Discipline	No. of students admitted
			2022-23
Masters	**M.S.(Pharm.)/ MTech**	Medicinal Chemistry	16
		Natural Products	09
		Pharmacoinformatics	07
		Pharmacology & Toxicology	17
		Pharmaceutics	19
		Medical Devices	10
		Pharmaceutical Analysis	10
		Total	**88**
Doctoral	**Ph.D.**	Medicinal Chemistry	08
		Natural Products	05
		Pharmacoinformatics	02
		Pharmacology & Toxicology	05
		Pharmaceutics	06
		Pharmaceutical Analysis	-
		Total	**26**
Doctoral	**I-PhD**	Pharmacology & Toxicology	**02**
Total			**116**

5.3.7 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 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.

5.3.8 Innovation/ Knowledge transfer/ MoUs signed

1. Memorandum of Understanding made on **30.05.2022** between NIPER-Kolkata and **Netaji Subhas Chandra Bose Cancer Hospital, Kolkata**. Purpose of the MoU is to promote co-operation in academic education and research.

2. Memorandum of Understanding made on **12.06.2022** between NIPER-Kolkata and **National Institute of Technology, Sikkim.** Purpose of the MoU is to encourage the faculty members and students of both organizations.

5.3.9 Impact of NIPER, Kolkata

a. A total of 49 highly skilled students have graduated.

b. 50 high-quality research papers have been published.

c. Differential Scanning calorimetry, Thermogravimetric Analyzer and Particle Size Analyzer facility has been established to promote research activities.

d. Currently the institute is funded by research projects in the tune of Rs.3.9 crore from various national funding agencies.

e. Scientist Chair in the name of Acharya Prafulla Chandra Roy funded by M/S Bio Green Remedies Pvt. Ltd has been created by NIPER Kolkata.

f. The Institute has introduced a yearly award in the name of Shri. Acharya Prafulla Chandra Ray Flow Chemistry Technology Award" with a citation and cash award of Rupees One Lakh for outstanding contribution in the concept of flow reaction application in API.

g. Number of patents: One submitted.

Patent Details

Table 5L

(Patent Details)

Application No.	Dated	CBR No.	Title
202231022417	15.04.2022	4879	Novel Synthesis of 2- cyano-4'- methylbipheny1 for the preparation of Sartans

5.3.10 Institution Leadership Impact of NIPER

NIPER Kolkata is reaching out to various undergraduate and post-graduate institutions helping them with various research projects. Currently, the institute has 26 outreach partners. The Institute was involved in providing oxygen concentrator to the needy during COVID crisis in collaboration with AMTZ-Visakhapatnam. The Institute has undertaken a major research drive towards developing newer strategies to tackle the infectious disease, metabolic disorders and neurodegenerative disorders.

Glimpses of the Events organized at NIPER Kolkata

Celebrated fit India freedom Run 3.0 at NIPER Kolkata

8th International Yoga Day Celebrations

Organization of Hindi Pakhwada

Meeting of Research Advisory Committee

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. Currently 265 students are enrolled at NIPER, Raebareli and is at present running from its transit campus in Lucknow. The campus has 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 has filed 20 patents and one copyright till 2021-22.
- The Institute received nearly 1.76 Cr. Rupees as extramural research grant for research in the thematic areas of the Institute.
- More than 179 publications in last 3 years with 29 publications in journals of international repute and 23 Books and Chapter contribution in reputed publications in current year.
- 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 houses 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	:	10

Academic Staff:

Associate Professors	:	05
Assistant Professors	:	11
Research Associate	:	02
Staff: Technical	:	07
Multi-Task Staff	:	00

5.4.3 Total fund allocation by the Government during the last 5 years

Table 5M

(Year-wise Fund allocated to NIPER, Raebareli)

(Rs. in Crore)

Year	Allocation BE	Allocation RE	Total Release
2018-19	12.00	15.00	15.00
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	14.50 (Till Dec' 22)

5.4.4 Students

Table 5N

(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 -02=**03**	Pursuing	**02**	-	-
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	Pursuing	19-1=18	Pursuing		-	-
2022-24	110	Pursuing	28	Pursuing		03	Pursuing
Current Status	197	Pursuing	65	Pursuing		03	Pursuing

5.4.5 Teacher: Student Ratio - 1:16

5.4.6 Employability/ Placements Status

Table 5O

(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

5.4.7 Awards/ Teachers

Table 5P

(Details of Awards received by Teachers)

S.No.	Name	Discipline	Recognition
1	Dr. Ashok K. Datusalia	Assistant Professor, Department of Pharmacology and Toxicology/Regulatory Toxicology	Member, International Society for Neurochemistry (ISN)-School Initiative
2	Dr Sapana Kushwaha	Assistant Professor, Department of Pharmacology and Toxicology	Associate Topic Editor for Frontiers in Toxicology "Rising Stars" in Developmental and Reproductive Toxicology
3	Dr Sapana Kushwaha	Assistant Professor, Department of Pharmacology and Toxicology	International Union of Toxicology (IUTOX) Travel Award, 2022 by the IUTOX Education Committee, USA
4	Dr. Keerti Jain	Associate Professor, Pharmaceutics	Enlisted among World's Top 2% Scientists, consecutively for year 2020 and 2021 in the field of Pharmacology & Pharmacy, a list created by Stanford University, USA.
5	Mr. Vishwas P. Pardhi	PhD Scholar -Pharmaceutics [Supervisor: Dr. Keerti Jain]	Won second prize in poster presentation at international symposium on the topic "Development and Evaluation of Binary/Ternary Solid Dispersions of Bedaquiline Fumarate to Improve its Pharmaceutical Attributes" held at NIPER-Kolkata on 15th February 2022.
6	Mr. Smith Patel	MS student- Medicinal Chemistry	Got full Ph.D. fellowship $ 29,730 and fee waiver at the University of Pittsburgh (USA)
7	Ms. Girija Pawge	MS student- Medicinal Chemistry	Got full Ph.D. fellowship of $ 65,600 at the University of Connecticut (USA)

5.4.8 Research

a. Active Research Areas:

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

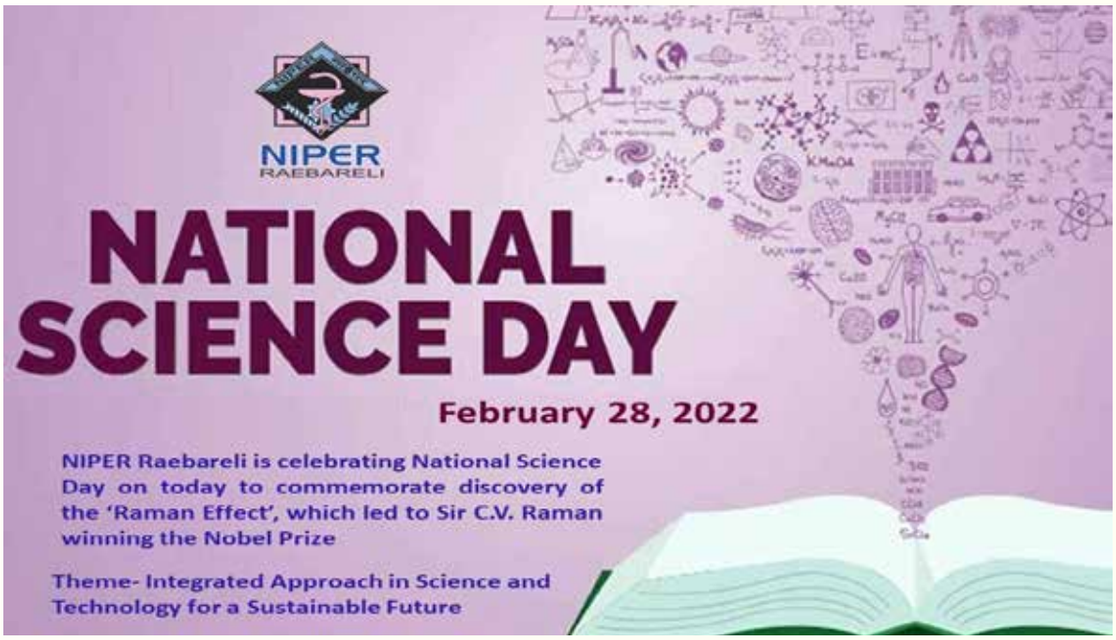
b. Development of green and eco-friendly synthetic methods

c. Projects: Ongoing: 11 worth Rs. 1.76 Cr. Approx.

5.4.9 Impact of NIPER, Raebareli

NIPER-Raebareli has emerged as an Institution of significance both in academics and research particularly in Central India with modern laboratories, highly sophisticated instrument. It has achieved a number of milestones and Pharma industries have shown interest in collaborating with the institutes, besides training its students for 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 like such as Japanese Encephalitis, Tuberculosis and Neurodegenerative diseases. An online portal has been created to facilitate seamless sample analysis for drug discovery. It is also providing highly skilled human resources for the Indian Pharmaceutical Industry.

Various events/workshops carried out by the institute



A Glimpse of NIPER- Raebareli celebrating Science Day, 2022

7th Convocation Ceremony of NIPER Raebareli

Swachhta Pakhwada (1-15 September 2022)

Celebration of National Unity Day

International Symposium on Toxicology and Applied Pharmacology on 29.09.2022 and 30.09.2022

5.5 NIPER- Hyderabad

NIPER-Hyderabad started functioning in September, 2007 in the premises of IDPL, R&D Centre, Balanagar, Hyderabad. The Institution's vision is to serve as a leading global institution in higher learning and research in Pharmaceutical Sciences and Management. Its mission is to be one of the principal sources of professional manpower in the field and strengthen the Indian Pharmaceutical industry through conducting Post Graduate and PhD courses. NIPER-Hyderabad has M.S. (Pharm), M. Tech. and MBA courses in different disciplines i.e., Medicinal Chemistry, Pharmaceutical Analysis, Pharmacology & Toxicology, Pharmaceutics, Process Chemistry, Regulatory Toxicology, Natural Products, Pharmacoinformatics, Regulatory Affairs, Medical Devices and Pharmaceutical Management. The institute is well equipped with state-of-the-art facilities for carrying out advanced research in the areas of pharmaceutical importance.

5.5.1 Achievements

Table 5Q

(Details of Achievements)

Sl. No.	Particular	Achievement
1	Master Students Passed Out	1366
2	Master Students pursuing course	365
3	Students pursuing Ph.D course	131
4	Doctoral degree awarded	91
5	Patents (filed)	23
6	Research Publications	879
7	Sanctioned extramural research projects	55

5.5.2 Details of Faculty & Staff

i. Regular Faculty : 20
ii. Regular Staff : 29
iii. Contractual Faculty : 05
iv. Contractual Administrative and Technical Staff : 23

5.5.3 Total Allocation by the Government during the last 5 years

Table 5R

(Allocation of funds to NIPER, Hyderabad)

(Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2018-19	24.00	24.00	24.00
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	29.00 (Till Dec'22)

5.5.4 Teacher-Student ratio

Presently 1:20

5.5.5 Employability/ Placements Status

A. Year wise Companies participated in campus selection/placement

Every year students were placed in reputed companies like Johnson & Johnson, Novartis, Dr Reddy's Laboratories Ltd., Genpact, Hetero, Tech Mahindra, Granules India, Syngene, Springers Nature Publishing, Eli Lilly, Cipla, Sai life Sciences, AMRI, ViVo Biotech, Credo Life Sciences, Cognizant Healthcare, Mylan, Gentech, Shasun, Lupin, Aurobindo, Biological E, Aizant, Cognizant Health care, Core Diagnostics, Aurobindo, Macleods Pharmaceuticals, Roche etc.

Table 5S
(Placements status of last few years)

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

5.5.6 Teachers

The Institute has some of the talented and dedicated faculty who came from the best institutions and having good training abroad as post-doctoral fellows in their area of 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

A. Patents and commercialization: 18 patents filed in areas of Cancer Drug Discovery, Formulation Development and Analytical Method Development

B. Internal Revenue Generation: 6.73 Crores (FY 2021-22)

5.5.9 Impact of NIPER

Creation of human resources by imparting high-quality education and training in pharmaceutical sciences helped the pharmaceutical industry. Serving as a research institute and focusing on thrust areas of national and international relevance. Institute helped in fostering academic and industrial collaborations to address some of the key issues in the pharma sector and the needs of the pharmaceutical industry in the country. Research at NIPER Hyderabad is nurtured through various academic programmes run by its departments and various sponsored programmes funded by industry and national organizations.

5.5.10 Collaborations / MoUs

NIPER-Hyderabad signed 43 MoUs with national and international bodies to enhanced research areas and multidimensional research. The principal collaborators are:

- Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru
- AMTZ, Vizag
- Momentous Molecules Private Ltd., Banjara Hills, Hyderabad
- PS3 Laboratories LLP, Kukatpally, Hyderabad
- Innatura Scientific Pvt. Ltd., Uppal, Hyderabad-
- CSIR-IITR
- Sarvothamcare limited
- Babasheb Bhimrao Ambedkar University, Lucknow
- NBI Bioscience Private Limited, New Delhi
- Phaeno Biotech, Inc, USA
- University of Bialystok, Poland,
- Lifeactivus, Tenchi KSM and NIPER Hyderabad
- ESIC Medical College Sanathanagar, Hyderabad
- Lifeactivns Private Limited, Medchal, Hyderabad
- Apollo Hospitals Educational & Research Foundation (AHERF)
- National Institute for Micro, Small and Medium Enterprises (ni-msme)
- Vline Pharmachem Private Ltd
- Lorven Biologics Private Limited, Andra Pradesh
- Zystus Nutraceuticals Private Limited
- Almelo Private Limited, Hyderabad
- National Research Development Corporation, New Delhi
- IIT Hyderabad
- Dr Reddy's Laboratories Ltd, Hyderabad
- Central Council for Research Institute of Unani Medicine (CCRUM)
- BOGAR Laboratories
- Novartis Healthcare Pvt. Ltd
- Extrovis Pvt. Ltd.
- Biological E. Ltd.
- United States Pharmacopeia (USP, India), Hyderabad
- National University of Singapore
- Department of Health Sciences of University "Magna Graecia" of Catanzaro
- Dr Reddy's Laboratories Ltd, Hyderabad
- Bharat Biotech International Ltd

- Indian Pharmacopoea Commission
- LV Prasad Eye Research Foundation
- Sambalpur University, Odhisha
- Global Woman Association of Science and Entrepreneurship, Vizag
- Icozen Therapeutics Private Limited
- Avay Lifescience, Bangalore, Karnataka
- Crescent Formulation Pvt Ltd
- Sigachi Industries Limited
- IKP Knowledge Park
- Ferring Pharmaceuticals
- Jodas Expoim Pvt. Ltd.
- NIF
- Pleadis Therapeutics
- IGNTU, Amarkantak

Various events/ Workshops carried out by the Institute: -NIPER Hyderabad conducted various scientific events, workshops training for students. Following are some photographs of the various events in NIPER-Hyderabad.

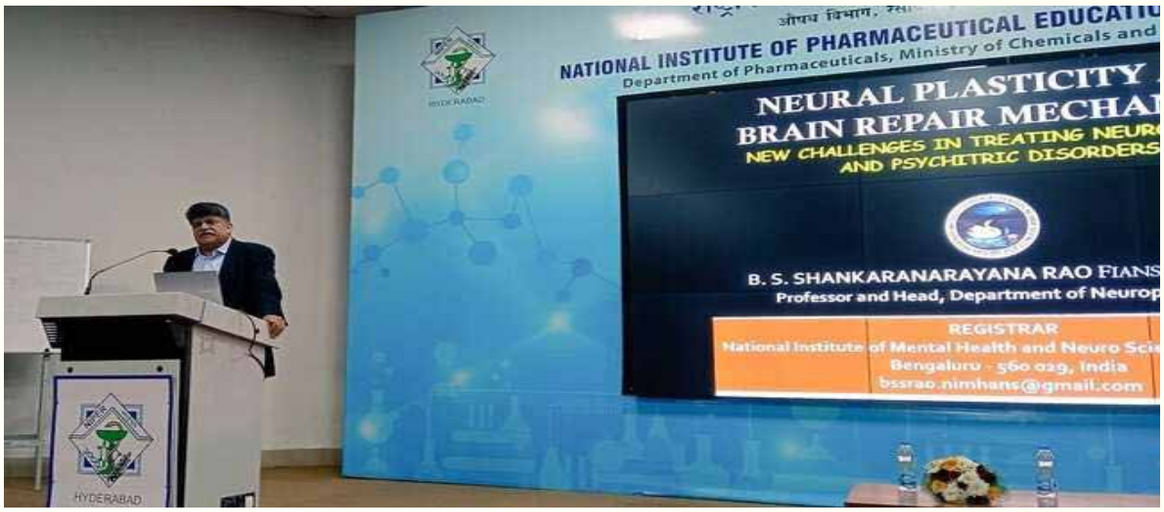
International Conference on Nextgen Therapeutics & Diagnostics organized by NIPER-Hyderabad on 20th April, 2022 to 22nd April, 2022

First CEOs/ MDs Roundtable Meet at NIPER-Hyderabad on 29th April, 2022

FDP Workshop on Animal Cell Culture Techniques organized by NIPER-Hyderabad on 23rd May, 2022 to 3rd June, 2022

Inauguration of 6 Month Student Training Program Quality Assurance & Quality Control in the Pharma Industry organized by NIPER Hyderabad on 5th July, 2022

One Month Summer Research Internship Programme for Students from Gujarat State Biotechnology Mission by NIPER Hyderabad from 4th July, 2022 to 3rd August, 2022



High-End Workshop Karyashala on Preclinical and Molecular Neuropharmacology Training at NIPER-Hyderabad from 12th September, 2022 to 19th September, 2022

5.6 NIPER Hajipur

NIPER Hajipur started functioning in 2007 under the mentorship of ICMR-Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna till 31.10.2018. Its own first Director assumed charges with effect from 01.11.2018. It imparts postgraduate (MS) pharmacy education and doctoral degree (PhD) in Five (05) 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) and
v. M.S. and PhD in Pharmaceutics (From 2021-22)
vi. M.S. and PhD in Regulatory Toxicology (From 2022-23)

The annual intake in PG programmes are: Biotechnology-19, Pharmacy Practice-18, Pharmacology & Toxicology-18, Pharmaceutical Analysis-13, Pharmaceutics-13 and Regulatory Toxicology-10 for each course.

5.6.1 Achievements

Since its inception, a total of 492 students have passed out (M. Pharm- 475 and PhD- 17), 175 research papers have been published and 11 MoUs have been signed so far, out of these, two MoUs were signed during this academic year (2022-23). One Indian Patent was filed in December 2021.

5.6.2 Details of faculty & staff are appended below

Academic : Director & 10 (regular)
Non-Academic : 10 (regular), 03 (on contract)

5.6.3 Fund allocation by the Government during the last 4 years and the Current year

Table 5T

(Year-wise fund allocation to NIPER, Hajipur)

Year	Budget Estimated	Revised Estimated	Total Release (Rs. in Crores)
2018-19	9.50	9.50	9.50
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	15.00 (Till Dec' 22)

5.6.4 Students

Students were admitted through a common Joint Entrance Examination (JEE) of all NIPERs. The status of student intake are as under:

Table 5U

(Status of Student intake)

Students	Male	Female	General	OBC	SC	ST	EWS +PH	Total
PG-II (current) (Batch 2021-23)	40	31	21	28	12	4	6	71
PG-I (current) (Batch 2022-24)	49	42	29	38	17	06	01	91
Ph.D. (on roll)	28	18	22	10	06	2	00	40

5.6.5 Teacher-Student ratio : 1:16

5.6.6 Employability/ Placements Status

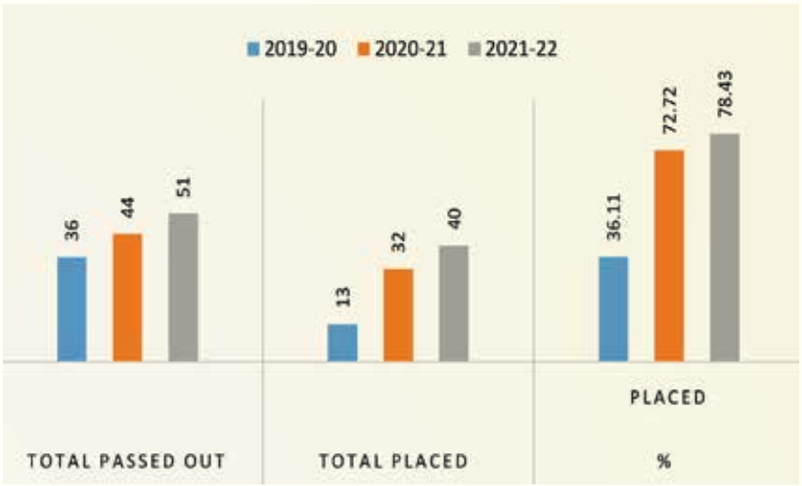
Training and Placement Cell is responsible for continuous improvement in quality system through maintaining the database of students/scholars and feedback mechanism from time to time. The details of the campus placement at graduate exit (As on 25th Oct 2022) is as follows:

Table 5V

(Details of campus placement)

ACY	Total passed out	Total Placed	% Placed	Placed in Industry, JRF/project fellow	Opted Higher studies
2018-19	32	26	81.26 %	21	4
2019-20	36	13	36.11 %	9	4
2020-21	44	32	72.72 %	18	18
2021-22	51	40	78.43%	25	15

Graph 5A
(Details of campus placement)



Recruiter includes 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, Parexel, etc.

5.6.7 Research

Departmental Research Activities: Dept. of Biotechnology

- Application of Nanotechnology as a biosensor for detection and diagnosis of diseases.
- Creating solutions that utilize micro-and nanoscale technologies for the treatment of neurological diseases.

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 & 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-K)
- 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

5.6.8 Impact and achievements

The Institute has successfully produced 475 PG and 17 PhD students in three disciplines who are either employed in different pharmaceutical industries or pursuing their higher education in different institutes or universities across the globe. Many of NIPER Hajipur ex-students are engaged as faculty at different institutions. Pharmacology and Toxicology laboratory was established in October 2020. During the year, the animal house has received CPCSEA approval. Apart from that in the academic year 2021, Pharmaceutical Analysis and Pharmaceutics branches were introduced with Masters and Ph.D. In the academic year 2022, Regulatory Toxicology with Masters and Ph.D course introduced.

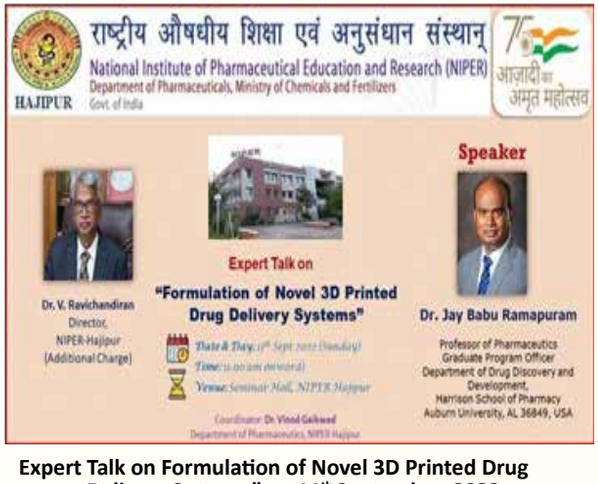
Some photographs

Visit of Hon'ble Minister Dr. Mansukh Mandaviya, Ministry of Chemicals and Fertilizers & Health and Family Welfare, Govt. of India on 4th June, 2022

Entrepreneurship Impact Lecture Series 2022 conducted on 15th June, 2022

Dr. Arun Bandyopadhyay, Director, CSIR–IICB, Kolkata and Dr. Krishna Pandey, Director, ICMR-RMRIMS, Patna interacted with faculty members and research scholars for collaborative research, dt. 09/07/2022

Two days National Symposium on Proteomics in Drug Discovery- 25-26th August 2022.



Expert Talk on Formulation of Novel 3D Printed Drug Delivery Systems" on 11th September, 2022.

Celebration of International Day of Yoga (IDY-2022) on 21st June 2022.


4th Convocation of NIPER Hajipur conducted on 23rd July, 2022.


Glimpses of Flag Rally on the eve of #AzadiKaAmritMahotsav on 13th August, 2022

Celebration of Nation's 76th Independence on 15th August, 2022.

5.7 NIPER Guwahati

NIPER Guwahati started functioning in 2008 under the Mentor Institute, Guwahati Medical College, Guwahati up to July 2017. The first regular Director took over the charge of the Director of the Institute on 3rd November 2016. NIPER Guwahati has been functioning from its permanent campus at Changsari, Kamrup (Rural), North Guwahati, Assam, since January 2020.

This institute owns nine (09) National Centers identified by premium funding agencies of Govt. 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, Min. of Commerce
vi. GLP accredited animal house facility from Min. of DoNER

vii. Advanced Centre for Drug Design from MeiTY, Min. of Electronics & IT, and

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

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

5.7.1 Achievements

i. Ph.D. – 119 (enrolled), Degrees Awarded – 28 (since inception),

ii. Total M.S. (Pharm.) /M.Pharm/M.Tech (since inception),
Students enrolled : 837
Graduated : 559
Students are currently pursuing their P.G Programmes: 264

iii. Almost 100% of NIPER-G students in each department got successfully placed in various reputed Industries like Dr. Reddy's, Gland Pharma, MacLeod's, GVK-Bioscience, Syngene etc. through on/off campus placement modes.

iv. Publications: In total, 411 articles have been published in peer-reviewed National and International journals out of which 108 articles have been published in 2021-22 & additional 124 articles also have been published till December 2022.

v. Institute has total 15 patents including 03 design patents and 2 copyrights.

5.7.2 Details of faculty & staff

Administrative Staff : 19+2 (Contractual)
Academic Staff : 21
Professors : 02
Associate Professors : 4
Assistant Professors : 15+1 (1 ad hoc)
Research Associate : 09
Technical Staff : 15
Multi-Task Staff : 20
Ramalingaswami Fellow : 01

5.7.3 Total Allocation by the Government during the last 5 years. (Rs. in crores)

Table 5W
(Allocation of fund to NIPER, Guwahati)

(Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2018-19	33.50	33.50	33.50
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	35.00	32.00 (Till Dec'22)

5.7.4 Students

Degrees/programmes offered and Subjects offered (with year)

Table 5X
(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
Masters	M.S. (Pharm.)	Pharmacology and Toxicology	15	15	15	18	19
Masters	M.S. (Pharm.)	Biotechnology	10	10	10	10	15
Masters	M. Pharm.	Pharmacy Practice	10	9	10	12	14
Masters	M.S. (Pharm.)	Pharmaceutics	15	18	18	20	24
Masters	M.S. (Pharm.)	Pharmaceutical Analysis	15	18	19	25	27
Masters	M. Pharm.	Pharmaceutical Technology (Formulations)	Not started	Not started	11	12	14
Masters	M.S. (Pharm.)	Medicinal Chemistry	Not started	Not started	11	12	15
Masters	M. Tech.	Medical Devices	Not started	Not started	10	16	16
Integrated PG-PhD	Integrated PG-PhD	Pharmacology and Toxicology	Not started	Not started	Not started	Not started	1
Integrated PG-PhD	Integrated PG-PhD	Pharmaceutics	Not started	Not started	Not started	Not started	1
Integrated PG-PhD	Integrated PG-PhD	Pharmaceutical Technology (Formulations)	Not started	Not started	Not started	Not started	1
Doctoral	Ph.D.	Pharmacology and Toxicology	2+2*	1+2*	2	3	7
Doctoral	Ph.D.	Biotechnology	1	0	2	3	6+1*
Doctoral	Ph.D.	Pharmacy Practice	1	1	1+1*	3	1+1#
Doctoral	Ph.D.	Pharmaceutics	2*	1+3*	4+1*	7	8
Doctoral	Ph.D.	Pharmaceutical Analysis	1*	1+1*	2+1*	5	6
Doctoral	Ph.D.	Medicinal Chemistry	Not started	Not started	2	4	4

***Ph.D. Project Seats**

#Ph.D. DST Inspire Fellow

5.7.5 Teacher-Student ratio

Pharmacy Practice	:	1:6
Pharmacology and Toxicology	:	1:10
Biotechnology	:	1:6
Pharmaceutics	:	1:12
Pharmaceutical Analysis	:	1:9
Pharmaceutical Technology (Formulations)	:	1:5
Medicinal Chemistry	:	1:5
Medical Devices	:	1:9

5.7.6 Employability/ Placements Status

Out of 100 students in the year of 2021-22, 70 students got placed in reputed pharmaceutical industries during on/off campus placements. Few companies to mention are Dr. Reddy's, Gland Pharma, MacLeod's, GVK-Bioscience, Syngene. Remaining 30 students opted for higher education and joined for PhD 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:

The Department of Pharmacology and Toxicology teach and research the physiological, pharmacological, toxicological, and nutritional basis of disease and therapeutics. Our diverse faculty's cutting-edge research spans the following areas:

- 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, etc.
- 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 z 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 disease), 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

- Cold plasmas (CP) technology
- Nanoscaffold for the multicellular spheroid and organotypic 3D culture
- Biosensors
- Ultrathin sensors z Paper based Diagnostics
- Nanobiotechnology
- Microfluidics devices
- Multiplexed detection of cancer biomarker
- Mechanical characterization of hypodermic needles, Single use syringes, catheters and Class A, & B Medical Devices

5.7.8 Student's enrolment

Current strength of Ph.D. students : 80

(Pharmacology & Toxicology-14; Biotechnology-12; Pharmacy Practice-07; Pharmaceutics-22; Pharmaceutical Analysis-15 and Medicinal Chemistry-10)

Current strength of Masters Students : 264

(Pharmacology & Toxicology-36; Biotechnology-24; Pharmacy Practice-26; Pharmaceutics-43; Pharmaceutical Analysis-51; Medicinal Chemistry-26; Pharmaceutical Technology (Formulations)-27 and Medical Devices-31)

5.7.9 Patents and Commercialization

Institute has in total 15 patents, 2 copyrights and 03 design patents.

5.7.10 Collaboration

NIPER-G entered into 49 active MoUs. Till date, NIPER-Guwahati has exchanged MoUs with pioneer institutes like CIPET-Guwahati, NPL-New Delhi, CSIR-CDRI, Lucknow, CSIR-National Physics Laboratory (NPL), Sankardev Netralaya, Guwahati, Assam, Rajiv Gandhi University, Itanagar, Arunachal Pradesh, AIIMS-Bibinagar, Telengana, Institute of Bioresources and Sustainable Development (IBSD), Imphal, Manipur etc.

5.7.11 Impact of NIPER

The establishment of NIPER-Guwahati has given a strong boost to the promotion of Pharmaceutical Education & Research in the North East region of India. Research efforts of NIPER Guwahati have revived the studies on the medicinal value of local herbs of North East Region (NER) against various diseases. NIPER-Guwahati has organized several virtual/physical conferences, meeting, workshop, skill development programme, etc. to promote and foster entrepreneurship culture in NER. This institute is supporting traditional healers and potential entrepreneurs from different states of NER like Assam, Mizoram, Meghalaya, Sikkim, Tripura, etc. to promote them from regional to global level.

The newly joined faculty members of NIPER-Guwahati have been awarded several Extramural funded projects in the year 2020-21 from different funding agencies like ICMR, SERB, DST, BIRAC-NER scheme, etc.

Number of students received M.S./M. Pharm/M.Tech. Degree

Table 5Y

(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	٦٥
5	2019-21	70	70
6	2020-22	103	100
Total		**338**	**335**

Some Photographs

Visit of the parliamentary standing committee on Chemicals and Fertilizers

5.8 NIPER Ahmedabad

NIPER Ahmedabad was set up in 2007 and is currently functioning from a transient, temporary building on a 60-acre land site at Gandhinagar since August 2016. The institute is presently offering MS and Ph.D. programs in 07 streams (Pharmaceutics, Pharmaceutical Analysis, Pharmacology & Toxicology, Biotechnology, Natural Products, Medicinal Chemistry, and Medical Devices). From academic year 2020 NIPER-A has also started Master's program in MBA (Pharm.). The interdisciplinary courses and cultural diversity at NIPER Ahmedabad spark the spirit of innovative research and all-round development of its students. The location of the Institute ensures a symbiotic association with Pharmaceutical Industries, Medical centers, and technological universities. The Institute aspires to serve as a good launching platform to revamp pharmaceutical education and research and to initiate a new era of Pharmaceutical and bio-medical sciences.

Construction of campus: Construction of Campus of NIPER Ahmedabad has been started from FY 2020-21 by HSCL, which is the PMC appointed for the same. About 56% of work has been completed.

5.8.1 Achievements

Publications: The Institute has published 886 articles in peer reviewed journals of repute with total citations of 12692.

Patents: Till now, Institute has filed 15 patents wherein faculty or students of NIPER-Ahmedabad are inventors.

MoU Signed: Institute has signed 27 MoU till now with different academic institutes and industry.

Students in MS Programme

i. 856 M.S Pharm. students have already graduated from NIPER Ahmedabad and are well placed in various Pharma industries in India and abroad.

ii. Presently, 316 students are pursuing their M.S. (Pharm) and MBA (Pharm) course in 8 disciplines.

Students in PhD Programme

i. 24 students have been awarded Ph.D. Degree till date.

ii. 116 students are continuing for their PhD studies.

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

5.8.2 Details of Faculty & Staff

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

Table 5Z
(Details of Faculty & Staff)

Position	Regular	Contractual
Faculty Position	18	1
Non-Faculty Position	17	3

5.8.3 Total Allocation by the Government during the last 4 years

Table 5AA
(Year-wise allocation of fund to NIPER, Ahmedabad)

(Rs. in crores)

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	107.00	28.00 (Till Dec'22)

5.8.4 Students

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

Table 5AB

(Year wise status of Admission in various disciplines)

Masters/ Doctoral	MS /PhD	Discipline	No. of students admitted			
			2019-20	2020-21	2021-22	2022-23
Masters	M.S.(Pharm.)	Biotechnology	13	15	15	15
Doctoral	PhD		4	4	4	2+1*
Masters	M.S.(Pharm.)	Medicinal Chemistry	22	22	22	21
Doctoral	PhD		4 +2*	5	5	10
Integrated PhD			-	-	-	1
Masters	M.S.(Pharm.)	Medical Devices	14	15	15	15
Doctoral	PhD		1	3	3	3
Masters	M.S.(Pharm.)	Natural Products	10	12	12	16
Doctoral	PhD		1	3	3	1
Masters	M.S.(Pharm.)	Pharmaceutical Analysis	22	22	22	23
Doctoral	PhD		3	5*1	5	8
Integrated PhD						1
Masters	M.S.(Pharm.)	Pharmacology & Toxicology	22	22	22	22
Doctoral	PhD		3 + 2*	5	5	9
Masters	M.S.(Pharm.)	Pharmaceutics	32	22	22	24
Doctoral	PhD		3+1*	5	5	7
Integrated PhD			-	-	-	1
MBA (Pharm)	MBA (Pharm)		20	25	25	26
			169	**186**	**185**	**206**

***PhD** Project Seats

Degree/MS/MBA/ M.Tech/Ph.D	Discipline	No. of students admitted				
		2018-20	2019-20	2020-21	2021-22	2022-23
MS	7 Disciplines	96	107	125	125	162
Integrated PhD	3 Disciplines	-	-	-	-	03
Ph.D	7 Disciplines	7	12	19 +5*	30+1*	40+1*
MBA (Pharm)		-	-	20	25	26

***PhD** Project Seats

5.8.5 Teacher-Student ratio

Presently 1: 22.73 (19 Faculty: 432 students)

5.8.6 Employability/ Placements Status

Table 5AC

(Placements status of last 3 years - in Campus/off campus)

Batch	Total no of student	Not placed	Total no of student placed	Going for higher studies
2018-20	96	13	65	18
2019-21	107	2	83	22
2020-22	142	2	115	25

5.8.7 Teachers: International Research Collaboration

NIPER Ahmedabad has established an International Research Collaboration with faculties from Harvard Medical School, Boston, USA, Johns Hopkins University School of Medicine, Baltimore, MD, USA, Massachusetts Institute of Technology, USA; 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. The MoUs signed during 2021-22 & 22-23 are listed in the following table:

Table 5AD

(MoUs signed during 2021-22 & 22-23)

Sl. No	MOU Details	MOU Date
1	AIIMS, Bhopal	18-02-2021
2	Nestle food safety Institute, Manesar Gurugram, Haryana	13-07-2021
3	Manipal Academy of Higher Education, Tiger Circle Road, Madhav Nagar, Manipal, Karnataka 576104	13-09-2021
4	GCS Hospital, Medical College & Research Centre Opp. D. R.M. Office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad-380 025, Gujarat, India	17-08-2022

5.8.8 Research: Active Research Areas

Department of Biotechnology:

- Genetic profile and biomarker identification of OSCC patients through transcriptomeanalysis
- Dissecting the molecular mechanisms by which healthy cells become cancerous and metastasize
- Epigenetic modulation in diabetic nephropathy through miRNA
- 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:

- Peptides and peptidomimetics based soft material for biomedical applications
- Construction of drug candidate(s) through C–H bond activation
- Development of reversible anticancer covalent inhibitors
- Targeted therapy for CNS related disorder and Injury
- Borrowing Carbonate-Enabled AllylicAmination Reactions under Additive- and Reductant-Free Nickel Catalysis Employing Allylic Alcohols
- Green chemical process toward the synthesis of pharmaceuticals (drugs).

Depatment of Medical Devices:

- Biomaterial Platformsin 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
- Osteoconductive and high strength bone cements for joint arthroplasties
- Advanced strategies for cancer theranostics
- Paper-based microfluidics for diagnostic applications
- Micro/nanodevices for life sciences and biomedical applications
- 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
- C-H activation strategy for the total synthesis and/or semi-synthesis of Natural Products
- Establishment of Q-Marker system for standardization of traditional Ayurvedicpolyherbal formulations
- Bio-prospecting of endolichenic fungi to discover novel bioactive scaffolds
- Endophytic fungi as a source of sustainable and novel bioactive molecules
- Microbial biotransformation of andrographolide to generate chemically diverse bioactive scaffolds with antidiabetic activity
- Establishing the targeted and untargeted metabolomic technology pipeline for natural product and cancer metabolomics
- Identification of plant-derived Natural Products possessing GLP-1R agonist activity.

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
- 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 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 activatable Nanoplates for the treatment of resistant tumors
- NIR laser activatable Nanoseeds for the prevention of post-surgical relapse of the respectable tumor
- Electro spraying Vs Lyophilization: Impact of 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 a 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 in 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. The discussions are scientifically stimulating and have led to healthy cross talks and collaborations.

5.8.10 Awards/Achievements

1. National Institute Ranking Framework-2022 (NIRF): NIPER – A has been Ranked 10th among all Pharmacy Educational and Research Institutions in India as per NIRF 2022 released by Ministry Education , Government of India.
2. Top 2% World Scientist: Dr.Rakesh K. Tekade was listed in Top 2% World Scientist by a recent list published by ELSEVIER.
3. Selected for Oral Presentation at 14th World Stroke Congress: Ms. Aishika Datta NIPER-A PhD Stu-

dent (Department of Pharmacology and Toxicology) has been selected for Oral Presentation at 14th World Stroke Congress, Singapore to present her PhD research work

4. 1st position in West Zone and participating: Ms. Srushti Shah M.S. student NIPER-A achieved 1st position in West Zone and is participating as a finalist in Disso Research Presentations India (DRPI) 2022 - online under M. Pharm category

5. 3rd prize in Research Paper Contest: Mr. Shyam Kumar Lokhande, PhD scholar under the supervision of Dr. Dinesh Kumar (Department of Medicinal Chemistry) received the 3rd prize in the Student Research Paper Contest held at NIPER Research Symposium, Organized by NIPER Kolkata.

6. FENS-IBRO/PERC Travel Grant: Ms. Aishika Datta NIPER-A Ph.D. student (Department of Pharmacology and Toxicology) awarded with FENS-IBRO/PERC Travel Grant to present her research work at 13th FENS Forum of Neuroscience, Paris, France (July 9-13, 2022).

7. First place in the Women's Healthcare Challenge competition: PhD students Mr. Gourang Hari Gupta, Ms. Vaidehi Bhavsar and Mr. Ashish Sahu won First Prize in the Women's Healthcare Challenge competition at the P&G Health Women in Healthcare Summit.

8. Second place in the Women's Healthcare Challenge competition: M.S. students Mr. Anand More and Ms. Pratiksha Jadhav won second Prize in the Women's Healthcare Challenge competition at the P&G Health Women in Healthcare Summit.

9. Best Poster Award: Ms. Anuradha Gadeval PhD Scholar under the Supervision of Dr. Rakesh K. Tekade in Department of Pharmaceutics received Best Poster Award for her Masters Research entitled as "Green Graphenenanoplates for combined photo-chemo-thermal therapy of triple-negative Breast Cancer" in AICTE Sponsored International Conference held at Modern Institute of Pharmaceutical Sciences, Indore. M.P.

5.8.11 Patents

The Institute has filed 1 patent and 1 patent was grated in 2021-22.

1. Patent filed

Patent Title: PLGA-Dipeptide complex as biocompatible pharmaceutical excipient composition for control drug release, Indian Patent Application No. 202221006145 (Date: 04/02/2022) **Name of Inventor**: Bichismita Sahu, Ravi Shah, Shubham Patil, Habeeb Saleha, Prerana, Neeraj Kulkarni, Prajakta Gajanan TialaRao, Feniben Chetanbhai Kapadiya.

2. Patent Granted

Patent Title: Carbonate Browsing Technology Enabled Allylic Amination Using Allyl Alcohols under Nickel Catalysis, Indian Patent Application No. 202021016956 (**Date of Granted**: 29/07/2022) **Name of Inventor**: Dinesh Kumar, Gargi Nikhil Vaidya.

5.8.12 Events/ Workshops carried out by the institute

NIPER Ahmedabad conducted various events, conference workshops/seminar/webinar/ training for students. Some of the photographs of the various events in NIPER-Ahmedabad are as under:

The Parliamentary Standing Committee study tour at NIPER-Ahmedabad held on 15th June 2022

Hands-on workshop on GC-MS/MS Analysis of Volatile Organic Compounds and Pharmaceutical Impurities

Celebration of International Yoga Day

Van Mahotsav

Swachhta Pakhwada 2022

CHAPTER 6

Public Sector Undertakings (PSUs)

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 these five CPSEs

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

Table 6A

(Basic information of Pharma CPSEs)

(As on 31st December, 2022)

	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 (in Cr.)	-658.25	-8147.67	-91.58	160.98	258.11
Turnover (in Cr.)	106.91	NIL*	Nil	76.17	395.21
Operating profit/loss (in Cr.)	15.43	-33	-27.86	8.15	23.71
Liabilities (in Cr.)	1274.64	-6142.63	142.03	216.85	125
Referred to BIFR	1997	1992	No	1992	NA

* Rs 27.50 cr (from rental and ETP)

6.1.1 Decisions on Pharma PSUs

The main decisions related to the pharma CPSEs by the cabinet and CoM are given below;

i. **Cabinet decision on 28.12.2016,** wherein it was recommended that only that much of the surplus land of HAL, IDPL, RDPL & BCPL as would be required to meet the liabilities be sold through open competitive bidding to Government agencies and clear outstanding liabilities from the sale proceeds. After liabilities have been met, the balance sheet cleansed and VSS/VRS effected; IDPL and RDPL to be closed and HAL and BCPL to put for strategic sale. Possibilities of hiving off subsidiary companies of IDPL and HAL for private participation to be explored. The decision on strategic disinvestment of 100% Government of India equity in KAPL was taken by CCEA on 1.11.2017 in a note

moved by DIPAM.

ii. Cabinet further reviewed the matter on 17.07.2019 and recommended for sale of land as per revised DPE's guidelines dated 14.06.2018; budgetary support as loan of Rs 330.35 crore for meeting the employees' liabilities including unpaid salary and VSS/VRS of three PSUs- IDPL, HAL & RDPL; constitution of Committee of Ministers for taking all decisions pertaining to closure/ strategic sale including sale of assets and clearance of outstanding liabilities.

iii. As per the recommendation of the Cabinet, Committee of Ministers (CoM) was constituted in September 2019. The first meeting of the Committee of Ministers (CoM) was held on 27.05.2021 in which following recommendations were made:

- Budgetary support of Rs. 139 crore (Rs. 118 crore for HAL and Rs. 21 crore for RDPL) to clear pending employees' dues.
- Return of 833.38 acres of leasehold land of IDPL at Rishikesh including 1.01 acres of freehold land to Govt. of Uttarakhand and to pay the agreed electricity dues of Rs.46.39 crores to UPCL from sale proceeds of assets at other locations.
- Sale of 3.5 acres of land of HAL at Pune to EPFO at negotiated price of Rs. 42 cr.
- Transfer of 50 acres of land out of IDPL plant site-I, Hyderabad to NIPER, Hyderabad for setting up regular campus at Reserve price of Rs. 889.50 crore making book adjustment against Govt. of India loan to IDPL/notional grant to NIPER, Hyderabad.
- Transfer of 20.55 acres of land of BCPL at Panihati, Kolkata to NIPER Kolkata for setting up regular campus at Reserve Price of Rs. 345.24 crore and waiver of the entire GoI loan to BCPL of Rs. 193.71 crore along with accrued interest.

iv. Decisions of 2nd Meeting of Committee of Ministers (CoM) held on 22.06.2022:

- The Committee approved, in principle, transfer of RDPL to Govt of Rajasthan and waiver of GOI's loan of Rs. 60.29 crore and advised the DoP to move a Cabinet Note. Cabinet Note is under active consideration.
- The Committee recommended to refer the freehold land of IDPL's plants at Gurugram and Hyderabad to DPE (except the buildings required for administrative purposes and to extract the rental income to meet its day-to-day expenses) for monetization of IDPL's assets through SPV being set up by DPE. Department may seek budgetary support for expediting closure of the company.
- The Committee approved to refer BCPL to DIPAM for strategic disinvestment.
- The Committee approved to refer HAL to DIPAM for strategic disinvestment, including the sale of its surplus land to meet its liabilities.

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 millions at affordable prices. IDPL was basically conceived and established as a part of Healthcare Infrastructure 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), Hyderabad (Telangana) and two 100% wholly owned subsidiaries, namely, IDPL (Tamil Nadu) Limited, Chennai (Tamil Nadu) and Bihar Drugs & Organic Chemicals Limited (BDOCL) at Muzaffarpur (Bihar). In addition, IDPL has one Joint Venture, promoted in collaboration with Industrial Promotion & Investment Corporation of Orissa Limited (IPI-

COL), Government of Odisha, namely Odisha Drugs & Chemicals Ltd. (ODCL) Bhubaneswar having shares of 51% and 49% respectively.

The Union Cabinet decided on 28.12.2016 for the closure of the company. In view of the Cabinet decision, the company is in the process of closure. The company signed an MoU with M/s NBCC to act as Land Management Agency (LMA) in October'2019 for disposal of its land /immovable properties and with M/s MSTC Limited to function as Auctioning Agency (AA) for the sale of its moveable and immovable properties by e-auctioning. 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 back to the Government of Uttarakhand.

The valuation of Movable Assets (plants & machinery) of all plants and subsidiaries have been done. The company is in process of disposal of the same through approved Auctioning Agency, viz., M/s MSTC Limited.

All units are now closed 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.

6.2.2 100% IDPL Wholly Owned Subsidiaries

A. IDPL (Tamil Nadu) Ltd, Chennai

IDPL (TN) Ltd. Chennai was incorporated in September, 1965, initially it was a Surgical Instruments Plant and later diverted to formulations. In terms of revival package approved by BIFR in 1994 this Plant was converted into a wholly owned subsidiary in the name and style of IDPL (Tamil Nadu) Limited, Chennai with effect from 01.04.1994. IDPL (Tamil Nadu) is a Schedule-M compliant plant and was engaged in manufacture of pharmaceuticals formulations up to September'2018. There is no production activity in this unit since October' 2018.

B. Bihar Drugs & Organic Chemicals Ltd. (BDOCL), Muzaffarpur

Bihar Drugs & Organic Chemicals Ltd., (BDOCL) Muzaffarpur was incorporated in 1979, converted into a wholly owned subsidiary with effect from 01.04.1994. IDPL holds the entire equity capital of this Unit. Since November 1996 there is no production activity in BDOCL Plant.

C. Joint Venture - Orissa Drugs and Chemicals Ltd (ODCL), Bhubaneshwar

Orissa Drugs & Chemicals Limited (ODCL) was incorporated in 1979 and commissioned fully for production from September, 1983. ODCL is a Joint Venture promoted by Indian Drugs & Pharmaceuticals Ltd. (IDPL) and Industrial Promotion & Investment Corporation of Orissa (IPICOL). IDPL holds 51% of the equity shares and 49% is with IPICOL. The erstwhile BIFR passed orders for winding it up in April, 2003 under the provisions of SICA Act, 1985. High Court of Orissa had appointed a provisional Liquidator, which was subsequently stayed. There has been no production activity since January, 2021. With consent of all shareholders, an application has since been filed at the High Court for vacation of stay.

6.3 Hindustan Antibiotics Limited (HAL)

Introduction:

Hindustan Antibiotics Ltd (HAL) is a wholly owned Government of India Company engaged in the

manufacturing and 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 etc.

HAL has the rare distinction of inventing two new molecules viz. Hamycin and Aureofungin. HAL, at present, is focusing on manufacturing pharma formulations and promising agro formulations to cater to wide range of pharma and agro market. HAL pharma products include various dosage forms like Dry Powder Injectable products, Tablets, Capsules, Intra-Venous Fluid (IVF) products, Liquid Syrup etc.

HAL is bouncing back to productive and efficient work culture and taking all the steps to achieve the enhanced turnover and profitability for the company.

6.2.3 Present Status of the Company

Brief of Facilities available:

HAL manufacturing facilities include the following:

(a) Bulk Plant:

HAL is having fermentation-based manufacturing facilities including 19x92 M^3 fermenters along with its associated utilities like steam, chilled water, cooling tower water, compressed air etc. These facilities were earlier used for manufacturing fermentation based bulk drugs like Penicillin-G, Streptomycin Sulphate, Gentamycin etc. These facilities are idle at present.

(b) Formulation facility:

HAL Pharma products include various dosage forms like Dry Powder Injectable products, Tablets, Capsules, Intra-Venous Fluid (IVF) products, Liquid Syrup etc. At present, manufacturing formulation capacities including Pharma and Agro-Chem, are as follows:

Table 6B

(Manufacturing formulation capacities including Pharma & Agro-Chem)

Sr.No.	Production facilities	Capacities (Existing) Lac Nos. / annum
A.	**Pharma Plants:**	
1	Dry Powder Injectables:	
a.	Cephalosporin	450
b.	Penicillin	450
2	Tablets:	
a.	Penicillin	1200
b.	Non-Penicillin	2400
3	Penicillin Capsules:	2500
4	I.V.Fluids:	120
5	Liquid Syrup & External preparation:	24
B	**Agro-Chem Plants:**	
1	Agro- Chem (Streptocycline)	100

2	Humaur formulation	210 KL*
3	Aureofungin Bulk	0.810 tonnes
4	Azotomeal	50 KL*
5	Phosphmeal	50 KL*
C	**Alcoholic Hand Disinfectant (AHD)**	**30**
D	**HAL Cloud Clinic**	**12000**

* Capacity of these products can be increased depending upon requirement since HAL is having sizable idle fermentation facilities

HAL has re-started manufacturing and marketing its IVF products. HAL is the only Pharma CPSE to have facility for the manufacture of IVF Fluids.

(c) Research and Development:

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

(d) Other Highlights:

- The Company has successfully steered to a steady growth and consolidated its position in India as a leading Public Sector Pharmaceutical Company. During the year 2021-22, all the Plants of HAL were operational. This helped in enhancing the turnover of HAL to Rs.152.16 crores.
- During the year 2021-22, HAL continued to operate the State-of-the-Art facility for manufacturing of Alcoholic Hand Disinfectant (brand name HALRUB) and is supplying to all Govt. Institutions, ESIs, GMSDs etc.
- During the year 2021-22, HAL upgraded *"Clinic on Cloud"* - a Health Kiosk- which was earlier measuring 23 health parameters in 5 minutes, now it measures 45 health parameters. This is a sort of Health ATM which identifies different health parameters, from which one can identify their physical fitness & take corrective action accordingly. This Health Kiosk stores data of the person on its cloud storage and can be very useful to Health Institutions, Govt. Hospitals, CPSEs etc.
- The Govt. of India has approved the sale of 87.70 acres of HAL land and modified its earlier decision and allowed HAL to sell its land by following revised DPE guidelines dtd.14.6.2018. The Cabinet in its meeting held on 17.7.2019, approved support as a loan to the tune of Rs.280.15 crores for meeting the employee's liabilities (unpaid salary and VRS). HAL introduced and implemented VRS during 2019-20 and 20-21. A total of 385 employees were given VRS. HAL is having 417 employees as on 31.12.2022.
- The Cabinet also approved constitution of the Committee of Ministers for taking all decision pertaining to the strategic sale of HAL including the sale of assets and clearance of outstanding liabilities.
- HAL has completed sale of its 3.5 acres of land to EPFO.
- 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 and distribution, Personnel records including time-office has been computerized using ERP System.
- After implementation of VRS, HAL has outsourced non-core area like transport to outside party for better economy.
- The company has achieved "Excellent" rating in Corporate Governance for the year 2021-22.

- HAL has carried out R&D for manufacture of an agro product Trichoderma, a biofungicide 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 be started once the approval is received from CIB.

6.2.4 Details of Production, Sales Turnover and Net Profit / Loss for the last three years

Table 6C
(Production, Sales Turnover and Net Profit / Loss of HAL)

(Rs in Crores)

	2020-21	2021-22	2022-23 Up to Dec. 22 (Provisional)
Value of Production	78.80	89.72	81.50
Sales Turnover	89.56	152.16	119.57
Net Profit (Loss)	(38.25)	(16.82)	(4.48)

6.2.5 Financial performance Up to March-2023 (Estimates/Provisional)

Table 6D
(Financial performance up to March-2023)

(Rs. In Crores)

Particulars	Apr 22 to Dec 22	Jan 22 to Mar 23	Cumm. upto March 23
	(Provisional 2022-23)	(Estimates/Provisional)	(Estimates/Provisional)
Value of Production	81.50	39.65	121.15
Total Turnover	119.57	37.68	157.26
Profit/ (Loss) Before exceptional and extra ordinary items.	(4.48)	(0.77)	(5.25)

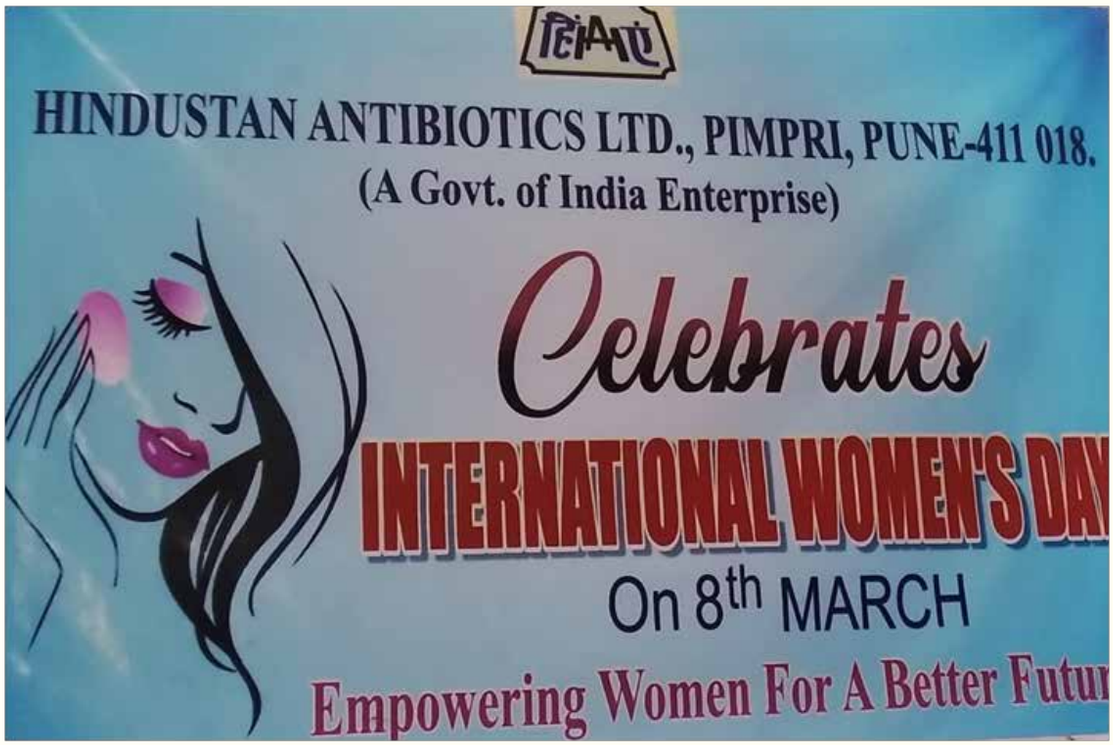
6.2.6 Subsidiaries

Table 6E
(Details of Subsidiaries)

Sl. No.	Name of the Subsidiary	Year of incorporation
1	Maharashtra Antibiotics and Pharmaceuticals Limited (MAPL)	1979
2	Manipur State Drugs & Pharmaceuticals Limited (MSDPL)	1989

Various Social activities/days observed in Hindustan Antibiotics Ltd. during the year 2021-22 and 2022-23

30th January is observed as Martyr's Day in the company and the 2 Minutes silence is observed by all the employees of the company on the day at 11.00 am to pay tribute to those who have given their lives for the nation.



International Women's Day - International Women's Day was celebrated in HAL on 8th March 2022 to commemorate the cultural, political and socioeconomic achievements of woman. It is also a focal point in the women's rights movement, bringing attention to issues such as gender equality, reproductive rights and violence & abuse against women.

10th March – Foundation Day: HAL was founded on 10th March 1954. The Foundation Day was celebrated with great zeal and enthusiasm in the company. A Pooja ceremony was organized on this auspicious occasion. Gifts were distributed to all the employees of the company as a token of appreciation for their services to the company.

19th February is 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 the speech of the knowledgeable orator is organized by Shri Shiv Smarak Pratishthan.

Swaccha Bharat Abhiyaan i.e. Swacchata Pakhwada is observed from 2nd October the Birthday of Mahatma Gandhi to 15th October.

Swaccha Bharat Abhiyaan i.e. Swacchata Pakhwada is observed from 2nd October the Birthday of Mahatma Gandhi to 15th October. All the employees in the company take part in the abhiyaan and clean the surroundings.

Hon'ble Minister of Health and Family Welfare and Minister of Chemicals and Fertilizers, Dr. Mansukh L. Mandaviya Ji visited HAL on 2nd July 2022 and inaugurated the State Art Facility for manufacture of Alcoholic Hand Disinfectant. The Hon'ble Minister also visited other Plants of HAL. Hon'ble Minister interacted with the employees of HAL .

Azadi Ka Amrit Mahotsav – Har Ghar Tiranga **was celebrated in HAL with the right spirit and enthusiasm. Flags were distributed to the Employees of HAL who hoisted the same at their respective residence.**

6.4 Karnataka Antibiotics & Pharmaceuticals Limited, Bengaluru (KAPL)

6.4.1 Background

Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) is a Profit making Joint Sector Company incorporated in the year 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 life saving drugs of good quality to Government Hospitals and other Institutions along with Private Medical Practitioners. The Company has WHO-GMP Certified manufacturing facilities for Dry Powder Injectables, Liquid Injectables, Tablets, Capsules, Dry Syrups and Suspensions. The paid-up share capital of the Company as on date is Rs. 13.49 crores. At Bangalore Plant, Pharmaceutical Products are being manufactured and at Kotur, Dharwad, Karnataka State, Ayurvedic Products are being manufactured.

6.4.2 Production and Sales Performance

Table 6F

(Production and Sales Performance of KAPL)

(Rs. in Crores as on 31.12.2022)

YEARS	PRODUCTION	SALES
2019-2020	489.57	432.15
2020-2021	434.64	426.16
2021-2022	479.76	473.87

6.4.3 Past Achievements

- Mini Ratna CPSE
- ISO 9001:2015 (QMS), ISO 14001:2015 (EMS) and ISO 45001:2018 (OSHAS)
- PIC/S Certification

Pharma – Trade:

Table 6G
(Pharma – Trade)

No	Products	Therapy Segments	NLEM	Monopoly	Market Value (Rs. in lakhs)
1	Grenil	Anti Migraine	No	No	1256.14
2	Oxytocin	Hormone	Yes	No	304.73
3	Cyfolac	Probiotics	No	No	474.24
4	Remcc	Cough & Cold	No	No	301.21
5	Verclav	Antibiotic	Yes	No	242.24
6	PoP E	Platelet Booster	No	No	222.51
7	Zinfe	Haematinic	No	No	208.74
8	Numol	Pain Medication	No	No	164.02

Ayurvedic Products:

Table 6H
(Ayurvedic Products)

No	Products	Therapy Segments	NLEM	Monopoly	Market Value (Rs. in lakhs)
1	PoP-E	Thrombocytopenia	No	No	79.00
2	Apifeast	Appetizer	No	No	62.61
3	Husky Powder	Bowl Regulator	No	No	38.80
4	Exol	Hepato-Biliary Stimulant	No	No	12.78
5	K-Thrin	Thrombocytopenia	No	No	15.52
6	Numol H	Pain Management	No	No	14.37
7	Antaf	Antacid-Antiflaltulant	No	No	11.21
8	Appikap	Appetizer	No	No	9.82

Agrovet:

Table 6I
(Agrovet)

No	Products	Therapy Segments	NLEM	Monopoly	Market Value (Rs. in lakhs.)
1	Kalvimin Group	Feed Suppliment	No	No	400.00

2	K- Live	Hepato-Protective	No	No	260.00
3	Cal-K	Ecto-Parasiticide	No	No	150.00

6.4.4 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 20 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.

6.4.5 Marketing

Pharma:

The Company has been mainly focusing on Prescription Market as Medical Professional as our Customers, where many of the MNCs and Private Pharma Players have a major share. The Company is also dependent on PPP Policy for Institutional Business, where the concentration is on Govt. 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.

Agrovet:

The Company is focusing on Agro Dealers, Department of Agriculture / Horticulture for Agro Products. Veterinary Products are being focused on Veterinary Practitioners, Farmers, Animal Husbandry Department of all States and Milk Unions for Veterinary Products and Feed Supplements.

New Products (Pharma & Agrovet)

Table 6J

(New Products - Pharma and Agrovet)

Sl.No	Products	Therapeutic Category
Pharma		
a	REMCC LM SYRUP	Cold & cough syrup
b	CAPLICON CREAM	Anti fungal

Agrovet		
Sl No	**Products**	**Therapeutic Category**
a	Taspin SP	Analgesic

b	K Live Pet	Liver Tonic – Pet
c	Kapoxure pet Shampoo	Medicated Shampoo for pet
d	Mite-Out Pet Shampoo	Medicated Shampoo for pet
e	Fensole Pet (wormer Tablets)	De-wormer
Ayurveda		
Sl No	**Products**	**Therapeutic Category**
a	Gomilk Plus 100's tab	For milk let down
b	Ekbolic Plus 500ml and 1000ml	Uterine cleanser
c	Bloatguard Plus 100ml	Anti Bloat
d	Suruchi Plus Bolus	Rumenotoric
e	Suruchi Plus 100 gm and 500 gm powder	Rumenotoric

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

Exports

KAPL products are currently exported to about 16 countries such as Malaysia, Thailand, Philippines, Namibia, Uganda, Myanmar, Costa Rica, Zimbabwe, Hong Kong, Zambia, Bhutan, Sudan and Company plans to export the medicines to additional Countries, such as Brazil, Peru, Slovakia and South Africa.

Ms. S. Aparna, IAS, Secretary, Department of Pharmaceuticals is seen with Managing Director Shri Sunil Kumar Kaimal and other Senior Officers during her visit to KAPL Plant on 11.02.2022

Shri Sunil Kumar Kaimal welcoming Ms. S. Aparna, IAS, Secretary, Department of Pharmaceuticals at Corporate Office, KAPL on 12.07.2022

6.5 Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)

6.5.1 Background

BCPL was founded in 1901 by Acharya Prafulla Chandra Roy, 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 a scheme for revival in 1995 by the erstwhile Board for Industrial & Financial Reconstruction (BIFR).

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.

Manufacturing Locations:

At present, BCPL has four factories one each at Maniktala (Kolkata) and Panihati in West Bengal, Mumbai and Kanpur.

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 in Tablet, Capsule, Ointment and Cosmetics Sections is going on full-fledged. Maniktala Unit of BCPL also produces Cantharidine Hair

Oil. Bengal Chemicals has launched its Hand Sanitizer "BENSANI+" on 2nd August, 2020, during COVID-19 pandemic.

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, BCPL touches an all-time record of manufacturing 60,680 bottles of Phenol 450ml. in a single day (26th September, 2020) as against an average daily production of 30,000 bottles.

Mumbai Unit:

Mumbai unit was set up in 1938 and further the commercial space developed has been leased out to third parties for the generation of additional sources of revenue.

Kanpur Unit:

Kanpur Unit was set up in 1949, primarily produces tablets for acute disorders.

6.5.2 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 now.

6.5.3 Sickness and Revival

The Company was referred to erstwhile BIFR in 1992. The revival package for BCPL was approved by the Government in December 2006. The package of ₹440.60 Cr. was approved which comprised of restructuring of existing debts on the books of BCPL, capital investments, support for the 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 the Company in 2006, it was running in losses and its operational performance had come down drastically to ₹17 Crore turnover in 2013-14, which was the lowest ever turnover since its inception as Government of India Company, and reported a Net Loss of ₹36.55 Crore in 2013-14.

However, from the financial year 2016-17 onwards, the company turned around and reported a Net Profit of ₹4.51 Crore during the year and years following thereafter. Thus, BCPL reported a Net Profit of ₹10.06 Crore in 2017-18, ₹25.26 Crore in 2018-19, ₹13.07 Crore in 2019-20, ₹6.08 Crore in 2020-21 and ₹7.47 Crores in 2021-22. Further, BCPL repaid the entire Bank Loan of ₹28 Crore to United Bank of India which was taken in 1983 by mortgaging the Registered Office building and now BCPL is a debt free company. After repayment of Government of India Loans of Rs.23.73 Crores as on 31.03.2021, there was a balance in Plan Loan and Non-Plan Loan including Accrued Interest amounting to Rs.193.71 Crores. Government of India vide Order under file No.53017/08/2017-PSU(Part) dated 09/09/2021 has given a waiver of Government of India Loans along with Accrued Interest amounting to Rs.193.71 Crores against the 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 31.03.2022.

Product profile and range

The products manufactured under each of these business segments are mentioned below:

Table 6K
(Details of products manufactured under each of these business segments)

Division-I	Division–II		Division-III		
Industrial-Chemicals	Pharma Generics	Pharma Brand-ed	Disinfectants	Hair Oil	Other Prod-ucts
Alum, Bleaching Powder	Tablets, Capsules, Injectables, Oint-ments, Liquids, Ex-ternal-Liquids,ASVS, BENSANI+	Aqua Pty-chotis, Kal-megh, Euthe-ria, Benflam Gel	Pheneol, White Tiger, Klin Toilet, Lysol	Cantha-ri-dine Hair Oil	Naphthal-en-eBalls Liquid Soap Aguru Essence

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

6.5.4 Manpower (Category- wise- Manpower)

Table 6L
(Category wise Manpower details)

Particulars	Manpower (As on 31.12.2022)
Executives	47
Supervisors	17
Workers	62
Grand Total	**126**

6.5.5 Distribution network

The company has a strong distribution network pan India with 6 Depots and 6 C&F Agencies. BCPL has also opened 3 Exclusive Retail Stores in Kolkata and 1 in Mumbai.

6.5.6 Performance

Details of production, Turn over and Financial Performance of BCPL from 2016-17 onwards are as under

Year - wise Financial- Status of BCPL

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

(₹ in Crore)

Particulars	2022-23 (Upto 31st December, 2022 Prov.)	2021-22	2020-21
Production	108.03	84.73	90.39
Income	76.17	72.05	73.86
Gross Margin	22.96	15.23	13.75

Interest Expenses(Finance cost)	0.57	0.03	0.09
Depreciation	4.51	6.15	5.92
Net Profit(Loss)	8.15	7.47	6.08
Net Worth	160.98	153.55	(47.63)

DPE Rating:

Table 6N
(Year wise DPE rating)

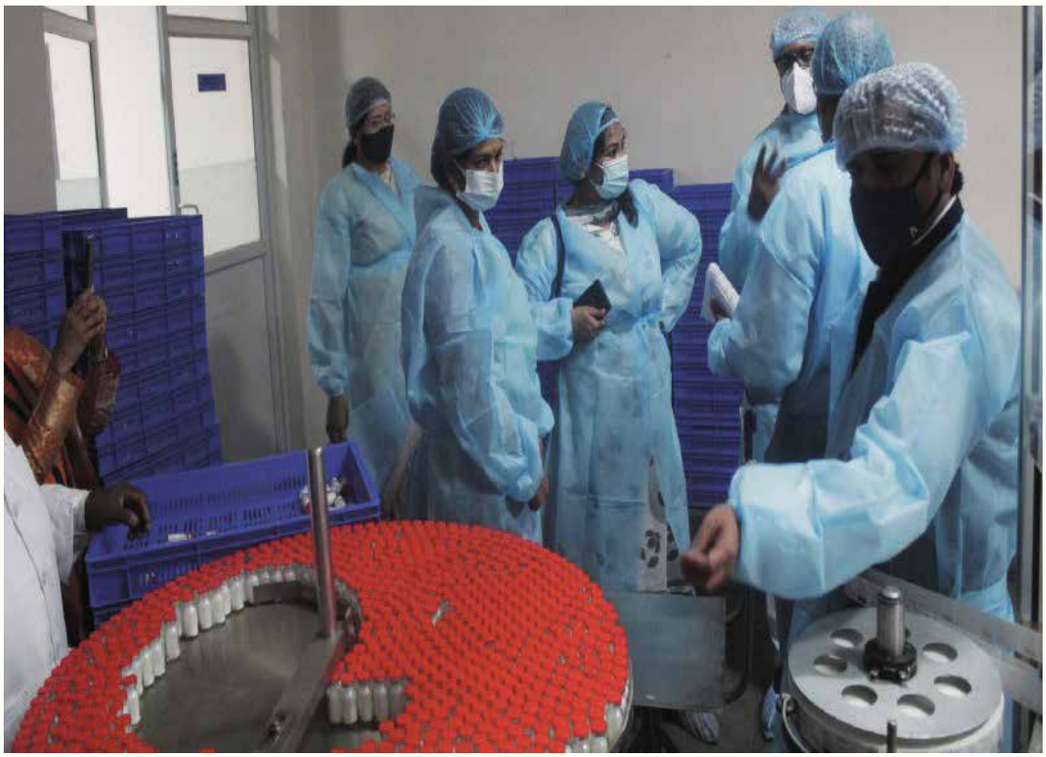
Year	MOU Assessment	Corporate Governance
2016-17	"Very Good"	"Excellent"
2017-18	"Not applicable"	"Excellent"
2018-19	"Not applicable"	"Excellent"
2019-20	"Not applicable"	"Excellent"
2020-21	"Not applicable"	"Excellent"
2021-22	"Not applicable"	"Excellent" as per Internal Assessment

6.5.7 Marketing

Share of Institutions and retail (Share of Institutions and retail)

Table 6O
(Share of Institutions and retail)

Sl. No.	Div & Products	Market Profile/ Major Clients
1.	DIV–Ferric Alum	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
3.	DIV-II –Brand Aquaptychotis, Eu-Theria, Kalmegh	Sold Through Retail Trade As OTC Medicines
4.	DIVIII–Cosmetic & Home Products	Mainly Trade Business (70-75%) & Bulk Government Institutions Business (25-30%)



Plant of BCPL

Some Products of BCPL

6.6 Rajasthan Drugs & Pharmaceuticals Ltd.(RDPL)

Rajasthan Drugs & Pharmaceuticals Limited (RDPL) is a Central Public Sector Unit in the Joint Sector with a total paid-up equity capital of ₹4.98 crore 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 and registered office at Road no. 12, VKI Industrial Area, Jaipur (Rajasthan). The production activities in the Company have stopped since October, 2016.

6.6.1 Performance

Table 6P
(Financial Parameters)

(Rs.in Crores)

	2017-18	**2018-19**	**2019-20**
Net Worth	(-) 54.78	(-)69.88	-91.58
Turnover	0.40	0.14	NIL
Earnings (Before Tax)	(-)15.25	(-)15.10	-27.86
Earnings (After Tax)	(-)15.25	(-)15.10	-27.86
Net Profit/Loss	(-)15.25	(-)15.10	-27.86

Pursuant to the recommendation of Committee of Ministers (CoM) on 27.05.2021, a provision of 21.00 crores was made as loan in the supplementary budget of 2021-22 to RDPL for clearing pending employees' and was released. Most employees submitted their full and final settlement affidavit and accordingly settled their dues. Subsequently, the CoM in its meeting of June 2022 recommended transfer the shares of RDPL to the State Government of Rajasthan. The draft cabinet note for transfer the shares is under Inter-Ministerial consultation stage.

CHAPTER 7

National Pharmaceutical Pricing Authority (NPPA)

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*, include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to the affordability, availability, and accessibility of medicines.

The Government notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995.

7.1.1 Salient features of DPCO, 2013

- The National List of Essential Medicines (NLEM), as notified by the Ministry of Health & Family Welfare, from time to time, is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of 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 13th September 2022, replacing the NLEM 2015. Accordingly, NLEM 2022 was notified as the First Schedule of DPCO 2013, on 11th November 2022, by the Department of Pharmaceuticals.

7.1.2 The functions of the National Pharmaceutical Pricing Authority (NPPA)

- 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 the pricing of drugs/formulations.
- To monitor the availability of medicines, identify shortages, if any, and take remedial steps.
- To collect/maintain data on production, exports and imports, market share of individual companies, the 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) 2015 contained 966 scheduled drug formulations (including formulations as per explanation 1 to Schedule – I of DPCO 2013) spread across 31 therapeutic groups and NPPA has fixed the ceiling prices of 890 formulations under DPCO, 2013 till 31st December, 2022 as follows:

Table 7A
(Categories of Medicines under which Ceiling Prices have been fixed under NLEM, 2015)

Category	Number of Medicines	Number of Formulations
Anti-Cancer	44	86
Anti-TB	14	35
Anti-HIV	11	39
Anti-Diabetics	5	12
Cardiovascular	30	74
Other	254	644
Total	**358**	**890**

The prices are notified through 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.

National List of Essential Medicines (NLEM) 2022 was issued on 13th September 2022 by the Ministry of Health and Family Welfare. Further, DoP through notification S.O. 5249 (E) dated 11th November 2022 has notified it as Schedule-I and medicines have been categorized into 29 therapeutic categories covering 384 drugs. There is an addition of 34 drugs, while 26 from the previous list (NLEM, 2015) have been dropped. As per the provisions of Para 17 of DPCO, 2013, NPPA is required to fix the ceiling price within 60 days of notification by DoP. The Ceiling price of 119 formulations were notified on 19.12.2022 and of 97 formulations are approved in 106th Authority meeting held on 30.12.2022.

Table 7B
(Categories of Medicines under which Ceiling Prices have been fixed under NLEM, 2022)

Drugs Category	Formulations
Anti-bacterial Medicines	45
Medicines used in for HIV	14
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs)	12

Anti-cancer medicines	29
Cardiovascular Medicines	22
Hormones, Endocrine Medicines and Contra-ceptives	15
Medicines used in Neurological Disorders	26
Medicines used in treatment of Psychiatric Disorders	22
Others	31
Grand Total	**216**

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 on the same method as applicable for fixation of ceiling price. NPPA notified retail prices of 2196 'new drugs' [those qualifying as 'new drugs' as per para 2(u) of DPCO, 2013] till 31st December, 2022 under DPCO, 2013.

NPPA also fixed the retail prices of Fixed Dose Combinations (FDCs) of various anti-diabetic drugs that have become off-patent/on verge of becoming off-patent (included in 2196 new drugs) to ensure that the benefit of drug becoming off-patent is passed on to the consumer. The price fixation has been done in respect of FDCs of various strengths of Vildagliptin + Metformin, Dapagliflozin + Metformin, Sitagliptin + Metformin and Linagliptin + Metformin.

Table 7C
(Reduction in prices of off-patent/on verge of becoming off-patent FDCs)

S. No.	FDC	% Reduction as compared to prices in Patented period
1	Vildagliptin + Metformin	66% (approx.)
2	Dapagliflozin+Metformin	73% to 81 %(approx.)
3	Saxagliptin+Metformin	58% (approx.)
3	Sitagliptin+Metformin	32% to 56% (approx.)
4	Linagliptin + Metformin	38% to 67% (approx.)

Also, during recent years exercising extraordinary powers under DPCO, 2013 in the public interest, MRP of 106 non-scheduled drug formulations, including 22 diabetic and 84 cardiovascular drugs was capped. Also, a cap of up to 30% on Trade margin of selected 42 anti-cancer medicines was imposed on a pilot basis in February, 2019.

C. Pricing of Medical Devices:

- **Coronary Stents:**

Coronary Stents were included in Schedule-I of DPCO, 2013 in December 2016 and NPPA had notified the ceiling prices for Coronary Stents under Para 19 of the DPCO, 2013 vide notification S.O.412(E) dated 13th February 2017. The ceiling prices were subsequently revised from time to time considering the annual Wholesale Price Index. Recently, NPPA vide notification S.O.1502 (E) dated 30.03.2022 has revised the ceiling prices considering WPI @ 10.76607%. Coronary stents have been included in the recently noti-

fied Schedule-I too (S.O. 5249 (E) dated 11th November 2022).

- **Orthopedic Knee Implants for Knee Replacement System:**

NPPA fixed the ceiling price of the Orthopedic Knee Implants, a non-scheduled medical device, for the first time on 16th August 2017 under Para 19 of the DPCO, 2013 vide notification S.O.2668(E) and subsequently, the validity of the ceiling prices was extended from time to time. Recently, NPPA vide notification S.O.4343 (E) dated 15th September, 2022 has extended the applicability of ceiling prices up to 15th September, 2023.

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 the recommendation of Standing Committee on Affordable Medicines and Health Products (SCAMHP), NITI Aayog, capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level, vide Gazette Notification dated 03rd June, 2021. Price reduction in 70 out of 252 products was observed and retail Prices were reduced by up to 54% (up to ₹54,337). NPPA vide notification S.O. 6177(E) dated 30th December, 2022 has extended the capping of trade margin for Oxygen Concentrator till 31st March, 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.6176(E) dated 30th December, 2022 has extended the capping of trade margin for these five medical devices till 31st March, 2023.

7.4 Review Order

Any company aggrieved by the orders of NPPA, files a review application to the Department of Pharmaceuticals under para 31 of the DPCO, 2013. Department of Pharmaceuticals after the physical hearing in the matter gives necessary review directions. NPPA implements the review directions of DoP on merit.

During the year 2022-23 (up to 31.12.2022), two review orders are pending for implementation as the matter are under further examination and reconsideration by expert committee/NPPA.

7.5 Exemptions granted under Para 32 of DPCO, 2013

During the FY 2022-23, NPPA has granted an exemption under Para 32(i) of DPCO 2013 to M/s Serum Institute of India Pvt. Ltd for the Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V) in (i) single dose (0.5 ml) vial, (ii) multi-dose (5 dose-2.5 ml) vial), and (iii) single dose (0.5ml) pre-filled syringes vide SO No. 1783 (E) dated 12th April 2022.

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

NPPA capped the Trade Margin of select 42 Anti-Cancer non-scheduled formulations vide order S.O. 1041(E) dated 27.02.2019. The Pilot has been taken up as Proof of Concept, invoking the provision of paragraph 19 of DPCO, 2013, under extraordinary circumstances in the public interest. As per data submitted by manufacturers, the MRP for 526 brands have shown a reduction of up to 91%. Percentage wise

reduction in prices of brands is as follows:

Graph – 7A
(Percentage-wise reduction in prices of bands)

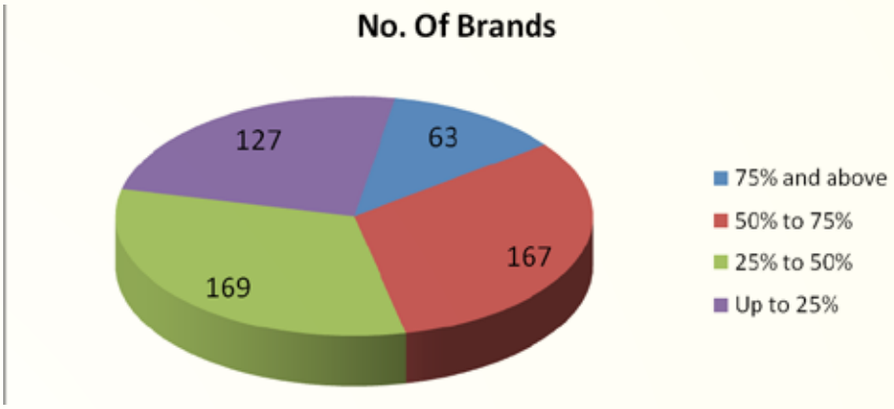


Table 7D
(Percentage-wise reduction in prices of bands)

S.No.	Slab-percentage reduction in prices	Number of Brands
1	75% and above	63
2	60% to 75%	167
3	25% to 50%	169
4	Up to 25%	127
	Total	**526**

For example, the price of BIRLOTIB brand tablets (10's pack) of Erlotinib 150mg medicine which was earlier ₹ 9,999/- per 10 tablets pack has been reduced to ₹ 892/- per 10 tablet pack (reduction of 91%) and similarly price of PEMESTAR 500 brand injection of Pemetrexed medicine which was earlier ₹ 25400 per injection has reduced to ₹ 2509 per injection (reduction of 90%) after rationalisation of trade margin.

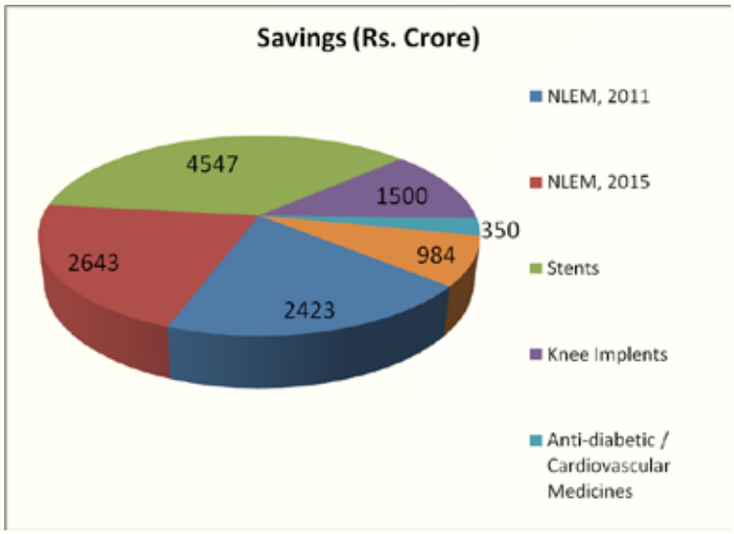
This has resulted in notional annual savings of ₹984 crore per annum to cancer patients. NPPA has issued necessary directions to State Drug Controllers and Superintendents of Hospitals / Medical Institutions to ensure compliance of the order issued so that the benefits under this measure be available to the patients.

7.7 Savings to the Consumers

The fixation of ceiling prices of scheduled formulations listed in NLEM 2015 (revised Schedule-I) has enabled savings of ₹2643 crore to the consumers in addition to the saving of ₹4,547 crores annually to consumers on account of price fixation of coronary stents. Fixation of ceiling prices of scheduled formulations under Schedule-I of NLEM 2011 enabled savings of ₹2423 crore to the consumers. The para 19 price notifications resulted in savings of approximately ₹350 crore to the consumers. Fixation of the ceiling price of the Orthopaedic Knee Implants, a Non-Scheduled medical device, has enabled notional savings of ₹1500 crore annually to the consumers. A savings of ₹984 crore to the consumers is estimated through the trade margin rationalization of anti-cancer drugs. Thus, the regulation of prices of medicines under DPCO 2013 by NPPA has resulted in net savings of approximately ₹12447 crore per annum to the consumers. 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 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- 7B
(Savings to the consumers)



7.8 Initiatives taken to address the exigencies arising out of Covid-19 pandemic

7.8.1 Availability of Essential Drugs

During the COVID-19 pandemic, NPPA played an active role in addressing the exigencies arising out of the pandemic and undertaking necessary measures to ensure continued availability of life-saving essential medicines throughout the country. In 2020, prices were revised for Heparin and capped of Liquid Medical Oxygen (LMO) and the Oxygen Inhalation (Medicinal gas) to ensure their continued availability at reasonable price. The prices of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer were also regulated under 'Trade Margin Rationalisation' Approach to improve their accessibility and affordability during this period.

NPPA interacted closely with the pharma industry, manufacturers; All India retail Associations of Chemists and Druggists (AIOCD); State Drug Controllers (SDCs); etc., to ensure that supply chains were not disrupted. Also, Pharmatrac weekly data on sales, inventory days, etc. were analysed. NPPA in close coordination with CDSCO held meetings with the manufacturers as well as the retail association to monitor production at the manufacturer(s) level and the supply of the drugs in the trade.

7.8.2 Monitoring through availability surveys

The availability of key medicines is being monitored through regular surveys conducted by Drug Controller General (I) officials at chemist shops at various locations across the country from time to time. The same is also being supplemented w.e.f. May 2021 through weekly availability surveys of COVID management drugs conducted by the Price Monitoring and Resource Units (PMRUs) of NPPA. Five medical

devices were also included in the weekly survey w.e.f. July 2021.

7.9 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 and manufacturing, biosimilars and biologics. During the past five years from 2017-18 to 2021-22 **(Table 7E)**, the highest growth has been seen in the Urology therapeutic segment at 9.78% though the sales data in absolute terms was not very high. However, Cardiac and Respiratory therapeutic categories of drugs have high sales and also had a Compound Annual Growth Rate (CAGR) between 8.29%- 8.50%. This was followed by CAGR between 7.44%-7.47% in the anti-diabetic, hormones and vitamins/minerals categories. Vaccines are mostly supplied to institutions and hence vaccines showing negative CAGR of 3.70% may not reflect the correct picture as Pharmatrac market database does not capture institutional sales.

Table 7E
(Growth in different Therapeutic segments during past five years)

Class	Sales 2017-18 (in Rs. Crore)	Sales 2021- 22 (in Rs Crore)	CAGR (%)
Anti-Infectives	16,850	23,807	7.16%
Cardiac	14,591	21,915	**8.47%**
Gastro Intestinal	13,756	19,622	7.36%
Anti-Diabetic	11,075	15,879	7.47%
Vitamins / Minerals / Nutrients	10,437	14,945	7.44%
Respiratory	9,111	13,569	**8.29%**
Pain / Analgesics	8,303	11,740	7.17%
Derma	8,155	10,642	5.47%
Neuro / CNS	7,348	9,898	6.14%
Gynecological	6,200	8,015	5.27%
Anti-Neoplastics	2,546	3,063	3.77%
Ophthalmic / Otologicals	2,259	2,669	3.39%
Hormones	2,143	3,072	7.47%
Vaccines	2,133	1,767	-3.70%
Urology	1,510	2,408	**9.78%**
Blood Related	1,450	1,800	4.42%
Others	1,149	1,450	4.76%
Sex Stimulants / Rejuvenators	690	956	6.74%
Stomatologicals	584	1,015	11.69%
Anti-Malarial	524	559	1.29%
Grand Total	1,20,815	1,68,791	6.92%

Source: Pharmatrac Market Database

Based on the sales data for the FY 2021-22, it is observed that the market share of large, medium and small companies across all categories was 77%, 20% and 4% respectively **(Table 7F**). In Anti-Infectives,

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

Table 7F
(Group of drugs and company size wise market share during FY 2021-22)

Group of Drugs	Sales (₹ in Crore)	Market Share in % of companies		
		Large	Medium	Small
Anti-Infectives	23,807	89%	9%	2%
Cardiac	21,915	85%	14%	1%
Gastro Intestinal	19,622	76%	20%	4%
Anti-Diabetic	15,879	79%	19%	2%
Vitamins / Minerals / Nutrients	14,945	59%	36%	6%
Respiratory	13,569	82%	15%	3%
Pain / Analgesics	11,740	68%	26%	6%
Derma	10,642	66%	29%	5%
Neuro / CNS	9,898	88%	7%	5%
Gynecological	8,015	67%	29%	4%
Hormones	3,072	85%	13%	2%
Anti-Neoplastics	3,063	61%	36%	3%
Ophthalmic / Otologicals	2,669	65%	24%	11%
Urology	2,408	81%	17%	2%
Blood Related	1,800	62%	31%	7%
Vaccines	1,767	63%	30%	7%
Others	1,450	52%	37%	12%
Stomatologicals	1,015	54%	34%	11%
Sex Stimulants / Rejuvenators	956	88%	10%	2%
Anti-Malarial	559	89%	5%	6%
Grand Total	1,68,791	77%	20%	4%

Source: Pharmatrac Market Database

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.

7.10 Price Monitoring & Enforcement Activities

The Government is effectively monitoring the prices of scheduled as well as non-scheduled medicines under DPCO, 2013 and takes action against companies found overcharging the consumers based on the references received from the State Drugs Controllers; individuals; samples purchased from the open market; reports from market based data; and complaints reported through the grievance redressal websites, 'Pharma Jan Samadhan' and 'Centralized Public Grievance Redress and Monitoring System (CPGRAMS)'. 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. Similar action is taken whenever companies are found selling non-scheduled formulations at a price which is 10% higher than the MRP of the preceding twelve months and Wholesale Price Index (WPI) violation for scheduled formulations. Non-compliance with the notified ceiling prices in case of scheduled drug formulations or, in other words, the MRP breaching ceiling price plus applicable local taxes tantamount to overcharging the consumer. Such overcharged amounts are recovered from the pharmaceutical company along with interest thereon from the date of overcharging.

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 analyzed to monitor the price at which the medicines are sold to patients. Enforcement activities from 2010-11 to 2022-23 (up to 31.12.2022) are given in the table-7G below:

Table – 7G

(Details of enforcement activities)

Year	No. of Samples Collected	Prima Facie Violations detected (cases in number)
2010-2011	553	225
2011-2012	559	156
2012-2013	626	165
2013-2014	993	389
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
2021-22	907#	391
2022-23 (up to 31.12.2022)	605#	281

#Cases of Overcharging 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.

NPPA has about 2295 overcharging cases as on 30-12-2022. As on 30-12-2022, an amount of ₹1321.15 crore (approx.) under DPCO 1979, DPCO 1995 & 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 undertaken following e-initiatives for better disposal of grievances of general public:

A. Pharma Sahi Daam and Pharma Jan Samadhan APP

The Pharma Sahi Daam (PSD) mobile APP and Pharma Jan Samadhan (PJS) applications were launched for the first time on 29th Aug 2016 and 12th March, 2015 respectively. PJS and PSD were revamped with additional features and version 2 was launched on 29th August 2022. The PJS is a web enabled system developed by the NPPA. PJS serves as a robust e-governance tool for the protection of consumer interest through the effective implementation of the Drugs (Prices Control) Order, 2013. The primary objective of PJS is to put in place a speedy and effective complaint redressal system with respect to the 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 Controller 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 additional features for the benefit of the common person. The App is available in Hindi and English and can be downloaded from Google play store free of cost for Android based mobile phones and from App store for iOS based mobile phones. It can be used for searching of prices for medicines (brand wise or formulation-wise), as well as the latest ceiling prices of scheduled drugs. Users can register a complaint or view the status of the complaint, which was raised earlier (OTP authentication). 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 will facilitate 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. 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)

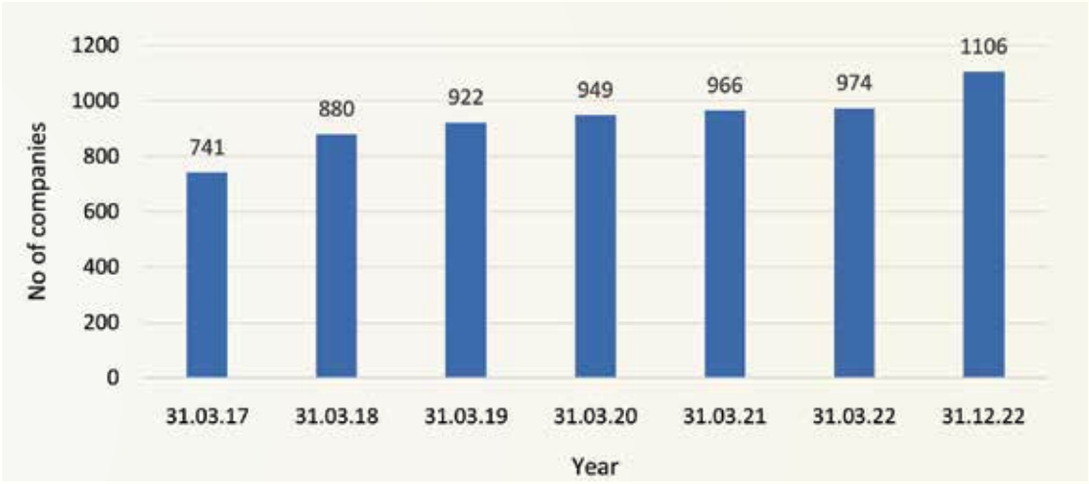
IPDMS version 1 was launched on 25th June, 2015. The version 2 of the IPDMS developed by NPPA in collaboration with the Centre for Development of Advanced Computing (CDAC) was launched on 29th August 2022.

The IPDMS 2.0 was developed in consultation with the stakeholders-both internal as well as external. This comprehensive online system provides a platform to the pharmaceutical manufacturer/ marketing/ importer/ distributor companies to file mandatory returns prescribed in Form I - VI, of DPCO, 2013. The Application for price approval of 'new drug' in Form-I can also be filed through this portal. The key features in the IPDMS 2.0 include:

- Real Time Dashboards
- Single Window Ecosystem
- Dynamic Reporting and Data Analysis
- Working Virtual Desks for Different Divisions
- Desktop Alert Management System
- Email, Mobile SMS Alerts
- Linkage of Pharma SahiDaam App with IPDMS Ver1
- Cloud enabled integrated Application for easy access

The number of companies registered in IPDMS as on 31.12.2022 is shown in Graph -7C:

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 thirty-six (36) States/ UT. As on 10.01.2023, PMRUs have been set up in twenty-five (25) 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 and Uttarakhand. 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 with different stakeholders regarding consumer awareness.

During the F.Y. 2022-23 till 31.12.2022, NPPA has organized 7 online webinars and a two days training programme for PMRUs in New Delhi. The main aim of these webinars was to provide guidance to PMRU Officials and staff on various activities to be performed by PMRUs.

7.14 Activities undertaken under 'Azadi ka Amrit Mahotsav'

(i) Celebration of Silver Jubilee of NPPA 29th Aug 2022

The 25 years of service to the nation of NPPA was celebrated on 29th August 2022, at Dr. Ambedkar International Centre, New Delhi. Union Minister of Chemical and Fertilizers, Dr. Mansukh Mandaviya addressed the audience on the occasion and Shri Bhagwanth Khuba, Minister of State for Chemicals & Fertilizers and New & Renewable Energy graced the function as guest of honour. Shri Kamlesh Pant, Chairman, NPPA delivered the welcome address. Ms. S. Aparna, Secretary, DoP was present on the occasion. Stakeholders from the pharmaceutical and MedTech devices industry, Central and State Governments, Price Monitoring and Resource Units, Civil Society, patient advocacy groups, Pharmaceutical Research and Academic Institutions, Think-Tanks and media representatives were present on the occasion.

Celebration of Silver Jubilee of NPPA 29th Aug 2022

At the inaugural session of the celebration, Integrated Pharmaceutical Database Management System 2.0 (IPDMS 2.0) and Pharma Sahi Daam 2.0 App were launched. A publication titled 'An overview of Drug Pricing @ NPPA 25 year Odyssey' was also launched at the inaugural session. The publication chronicles not only the 25 year journey of NPPA but also highlights the evolution of the drug regulatory system in the country with special emphasis on pricing regulation.

A group photograph of NPPA Staff with Hon'ble Minister (C&F), Hon'ble MoS (C&F) and Secretary (Pharmaceuticals) taken during Silver Jubilee of NPPA 29th Aug 2022

The inaugural session was followed by a panel discussion on the topic "Robust Data collection for policy making in Pharmaceutical and Medtech sector" chaired by Dr. V. K. Paul, Member Health, NITI Aayog. The panel discussion was moderated by Shri Satya S. Sundaram, E&Y. The expert panellists drawn from different areas having linkages with the topic under the discussion spoke. The expert panellists in the discussion were: Dr. Viranchi Shah, National President, IDMA; Shri Rajiv Mishra, Adviser, Department of Economic Affairs; Dr. V. G. Somani, Drug Controller General of India; Shri Ganesh P. Sabat, CEO, Sahajanand Medical Technologies Ltd; Shri Ashish Bhatnagar, Vice President, National Institute of Smart Government; Ms. Deepti Srivastav, Deputy Director General, Ministry of Statistics and Programme Implementation; and Shri Saurabh Thukral, Senior Specialist, NITI Aayog.

Guests present during celebration of Silver Jubilee of NPPA 29th Aug 2022

(ii) PMRU training programme

As part of activities to commemorate the occasion of 75th anniversary of Indian independence during the year long 'Azadi Ka Amrit Mahotsav', NPPA organized a two (2) days training programme in New

Delhi for the officials of PMRUs for bringing effectiveness and efficiency in their working and to increase the coordination between NPPA and PMRUs. The PMRU training programme was inaugurated by Ms. S. Aparna, Secretary, DoP on 29th August 2022 in the presence of Shri Kamlesh Pant, Chairman, NPPA, Shri Rajneesh Tingal, Joint Secretary, DoP and Dr. Vinod Kotwal, Member Secretary, NPPA. A PMRU Training Manual was also launched at the inaugural session.

Launch of PMRU Training Manual during the inaugural session

A group Photograph of NPPA staff

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 objective of this Committee is to review the progressive use of Hindi in day-to-day official work and the same is reviewed quarterly in the OLIC meetings held in the office of NPPA. Members of the Committee discuss about use of Hindi in their respective divisions and also give suggestions to improve the use of Rajbhasha in official work.

7.16 Rajbhasa Prosthsahan Pakhwara 2022

Rajbhasa Prosthsahan Pakhwara 2022 was organised in office of NPPA on 19.09.2022 to 30.09.2022

with the objective to encourage officers and employees to progressively increase the use of Hindi in their day-to-day official work and also to help the Department create an atmosphere conducive to use of Hindi. Hindi Pakhwara programme was successfully organised in 2022 and pledge was administered by Chairman, NPPA to all officers and staff of NPPA. Winners' of different competitions held during the Hindi Pakhwada were awarded with cash prizes and certificates by Chairman, NPPA on 19.10.2022.

Celebration of Rajbhasa Prosthsahan Pakhwara 2022

7.17 Vigilance Awareness Week

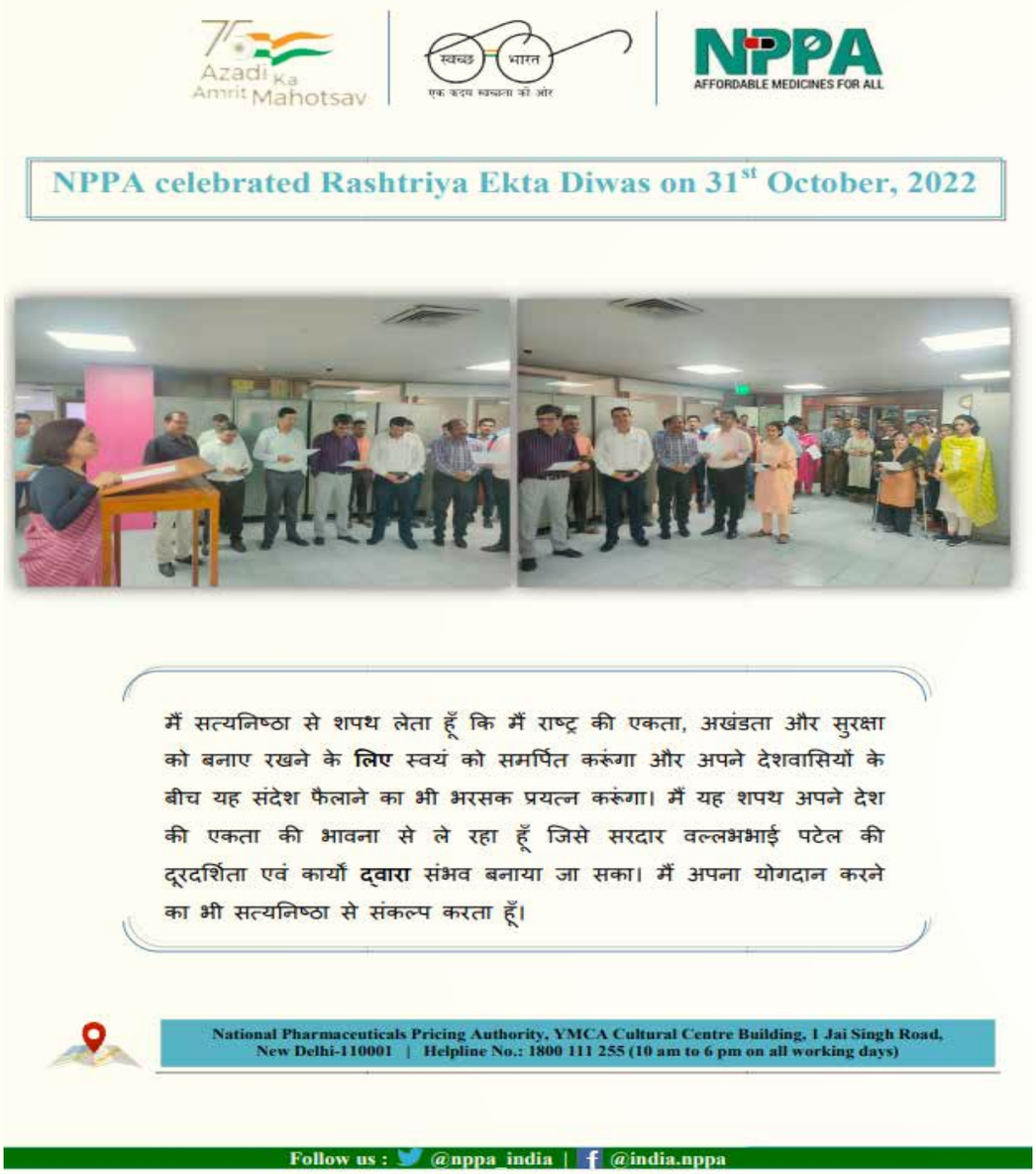
Vigilance awareness week was observed in NPPA from 30th October 2022 to 6th November 2022. Chairman, NPPA administered integrity pledge to all the officers.

Oath Taking Ceremony During Vigilance awareness week

7.18 Rashtriya Ekta Diwas

Rashtriya Ekta Diwas was observed in the office of NPPA on 31.10.2022. Dr. Vinod Kotwal, Member

Secretary, NPPA administered a pledge to all the officers and staff of NPPA.



Celebration of Rashtriya Ekta Diwas

7.19 Swachhata Campaign 2.0

National Pharmaceutical Pricing Authority conducted Swachhata Abhiyan during the period of September-October 2022. Under this Abhiyan various activities were carried out in compliance with Govt. instruction in this regard. Bio-medical items available in the form of tablets, capsule, strips, injection etc. in NPPA were reviewed, examined, identified and disposed off with due procedure in coordination with Pharmacology Department of Lady Harding Medical College. Old unused material/ furniture and 2284 files / records which are no longer necessary as per the record retention schedule were disposed of during this period. PMRUs also actively participated in the Swachhata Abhiyan and conducted cleanliness activities in their respective PMRU state Office.

Chairman, NPPA reviewed the activities relating to Swatchhata Campaign 2.0 in SOM on 14.10.2022

Photographs of the NPPA Office Premises on Completion of "Swachhata campaign 2.0"

7.20 e-Newsletter of NPPA: Aushadh Sandesh

During the year, five issues of e-Newsletter were released. It contained information on the latest development in the pharmaceutical sector in India as well as globally. In addition, an article by a pharma expert has also been included in these issues.

Table 7H
(release of e-Newsletter**)**

Month	Topic of Article
April, 2022	Coverage, Utilization and Impact of Ayushman Bharat Scheme on Access to Medicines in India
June, 2022	Need for India to be at the International HTA Platform
August, 2022	Judicious use of Medicines
October, 2022	Drug Price Control Orders: Over the Years
December, 2022	Improper Disposal of Expired Pharmaceuticals may Pose a Serious Threat to the Environment

7.21 Webinar on "Tracking the drugs: Ensuring last mile availability"

A webinar on the topic "**Tracking the drugs: Ensuring last mile availability**" was organised in hybrid mode on 30.11.2022, under the Chairmanship of Dr. V. K. Paul, Member (Health), NITI Aayog. The Guest of Honour of the webinar was Ms. S. Aparna Secretary, Department of Pharmaceuticals. About 340 participants attended the webinar from Pharma Association, Industry Representatives, Consumer Groups, Students, related departments and Price Monitoring Resource Units of States/ UTs etc.

The panel discussion was moderated by Shri Himanshu Agrawal, AVP, Invest India and had experts drawn from various fields i.e., Dr. Somani, Drug Controller General of India (DCGI); Shri Sudarshan Jain, Secretary General, IPA; Shri Amit Backliwal, CMD, Pharmasoftech AWACS; and Shri Swaminathan, CEO GS1, India.

Photographs taken during meeting

CHAPTER 8

IMPLEMENTATION OF RAJBHASHA

CHAPTER 8

Implementation of Rajbhasha

8.1 Use of Hindi in official work

Every possible effort was made for the implementation of the various provisions of the Official Language Policy of the Union of India including those of the 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).

8.2 Official Language Implementation Committee

Official Language Implementation Committee in the Department, under the Chairmanship of the Joint Secretary, periodically reviews the progressive use of Hindi in the official work and suggest suitable measures to increase the use of Hindi in the official work. Its meetings were held at regular intervals which reviewed the status of implementation of the various targets set in the Annual Programme for the transaction of the official work of the Union in Hindi for the year 2022-23, issued by the Department of Official Language, Ministry of Home Affairs.

8.3 Hindi Prayog Protsahan Pakhwara, 2022

Hindi Prayog Protsahan Pakhwara was observed in the Department from 14th to 29th September, 2022 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 to create an atmosphere conducive to use of Hindi.

In addition to the message issued by the Secretary (Pharma) requesting, inter-alia, all the officers/employees to make a commitment to the use of Hindi, various Hindi competitions were held during the Pakhwara in which officers/officials participated and made this programme successful. Winners were awarded with cash prizes.

8.4 Review of the status 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 on the progressive use of Hindi received from them in compliance with the targets set in the Annual Programme for use of Hindi for the year 2022-23. During this year, to achieve the prescribed target (inspection of at least 25% offices) in the Annual Official Language Programme 2022-23, inspection of two subordinate offices of the Department of Pharmaceuticals was carried out and two subordinate offices are proposed to be inspected in January, 2023.

8.5 Hindi Advisory Committee

The meeting of the Hindi Advisory Committee of the Ministry of Chemical and Fertilizers under the Chairmanship of Honourable Minister, Chemical and Fertilizers was held on 23.06.2022 at New Delhi.

CHAPTER 9

Citizen Centric Governance

CHAPTER 9

Citizen Centric Governance

9.1 Our Vision

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

9.2 Our Mission

- Investment for Make in India in the 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 the Janaushadhi scheme

9.3 Our Clients

- Citizens of India
- Pharmaceutical Industry including Micro, Small and Medium Enterprises
- Pharmaceutical companies seeking relief under DPCOs
- NPPA/CPSUs/NIPERs

9.4 Our Commitment

We are committed to provide impartial, sympathetic and prompt services to the public in matters relating to the pharmaceutical industry.

Our commitment is to take prompt steps to provide quick redressal of the grievances of our personnel and public at large.

Our commitment is to formulate policies and initiate consultations with all Industry Associations/ stakeholders and to amend them whenever so required.

9.5 Our Services

We formulate and implement policies relating to drugs and pharmaceuticals, drug intermediates and medical devices.

9.6 Our Activities

The key activities of the Department:

(i) To Promote the Pharmaceutical & Medical Device Industry through Policy support, scheme and incentivisation

(ii) Ensure availability of drugs at reasonable prices as per provisions of the Drugs (Prices Control) Order, 2013

(iii) Ensure proper functioning of the Central Pharma Undertakings in control of the Department

(iv) Project Based Support and Revival Schemes for CPSUs

(v) Ensure proper management of M. Pharma and Ph.D. programs in NIPERs

(vi) Develop Human Resources, Infrastructure for Pharma R&D and Industry including Public-Private-Partnerships (PPP)

(vii) Formulate Scheme/ Project for promoting Pharma Brand India

(viii) Formulate Scheme/ Project for promoting environmentally sustainable development of the Pharmaceutical Industry

(ix) Formulation of Annual Plan, Budget and Monitoring of Budget Expenditure. The Citizen Charter of the Department has been placed on the website of the Department.

9.7 Right to Information Act 2005

As per the provisions of the RTI Act, 2005, the RTI cell in Coordination Division has been established which acts as Nodal Cell for RTI matters. RTI applications are transferred to the CPIOs concerned. RTI cell also coordinates follow-up action on the appeals/orders received from Central Information Commission and submits returns etc. The list of Central Public Information Officers (CPIOs) and Appellate Authorities are updated regularly on the Department's website. Proactive action is taken under Section 4 of the RTI Act for suo-moto disclosures on the website in pursuance of transparency.

9.8 CPGRAMS (Centralized Public Grievances Redress and Monitoring System)

Public Grievances received through CPGRAMS are monitored and disposed of on regular basis.

CHAPTER 10

Information and Communication Technology

CHAPTER 10

Information and Communication Technology

Under Digital India program, 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 key services like Technical consultancy, Networking, application development and implementation, Internet & E-Mail, database management and Training. With NIC's presence and expertise, Department had been instrumental in steering following IT/E-governance initiatives. Also to enhance delivery and security, web applications are migrated to cloud environment.

10.1 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 E-mail, intranet / internet and database access operations. The IPv6 compliant ICT hardware is available to all officers/ divisions/ sections for use at their desktop.

10.2 Website and Social Media

The bilingual Web Site of 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 GIGW compliant. 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 is completed.

Social media has enormous potential to reach out to people. To improve the quality of Government decisions, policy making and create awareness, the department has opened accounts in Facebook and Twitter. Information regarding the conferences, Seminars, launches by Minister, Minister of State, Secretary and other officers of the Department is posted on it promptly. Various posts to create awareness regarding activities and decisions taken by the Department are posted on Facebook and Twitter pages of the Department.

10.3 Video Conferencing

Video Conferencing facility had been provided to all the officers of the Department ever since the breakout of COVID Pandemic. Of late, this facility has helped for conducting Seminars and Interactions as part of various Government Programmes, in compliance of requests made by different nodal departments. This has helped them to discuss all the important issues through VC while maintaining social distancing and other safety standards. Even otherwise, the non-availability of Conference Rooms does not affect conducting events through video conferencing. PSUs and Educational Institutions (NIPERs) had also

installed Video Conferencing facilities in their respective offices. VC facility enables the Department to interact with PSUs and NIPERs frequently for monitoring their performance and communicate decisions. Pragati meeting, 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. Video Conferencing facility is also utilized for interacting with foreign delegates.

Cloud based video conferencing facility is provided to the Secretary and Joint Secretary of the Department. Desktop video conferencing facility is available to each and every official of the Department. Department has also procured Webex video conferencing software for conducting conferences.

10.4 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 dispose of official work smoothly, have been continuing, as this facility is very useful to dispose of urgent official works even after office hours and on holidays/weekends. During the last three years, this department has extended this facility to 104 accounts, out of which 38 are in the current financial year.

10.5 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 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 during November, 2022. The work on increasing the number of e-office users' account (e-Office Lite) from 93 to 175, which can be extended up to 250 Numbers, both for the Department and its attached office, NPPA, is at an advanced stage of implementation.

10.6 e- GOVERNANCE

Taking advantage of latest ICT enabled tools; Department of Pharmaceuticals with the support of NIC has taken sincere initiatives toward the adoption of best practices. Various applications have been developed and implemented by NIC to strengthen, monitor and decision making and high availability of the right information at right time.

- **SPARROW**- Smart Performance Appraisal Report Recording Online Window application, which allows online submission of APAR of IAS and CSS 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 and approval is given to authenticated visitors and gate pass is issued.
- **Legal Information Management & Briefing System (LIMBS)** – LIMBS is a web based portal devel-

oped 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 initiatives 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 with minimum delay.
- **E-publishing of Tenders** – E-publishing of tenders is implemented by uploading tenders on Central Public Procurement Portal. It has improved the accessibility of tenders.
- **Electronic-Human Resource Management System (e-HRMS)** is a web based Human Resource Management System with portal 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.
- **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.

To enhance e-Governance further following initiatives has been taken up:

(i) Development of software for grant-in-aid under Plan Scheme "Pharmaceuticals and Medical Devices Promotion and Development Scheme (PMPDS)". The objective of PMPDS is promotion, development and promotion in Pharmaceutical and Medical Devices sector by extending financial support for conduct of seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting Pharma and Medical Devices Sector. PMPDS Portal http://ngogrant.pharmaceuticals.gov.in/ is developed and implemented.

(ii) National Institutes of Pharmaceutical Education & Research (NIPERs) are situated at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata, Raebareli and Mohali. NIPER MIS http://nipermis.pharmaceuticals.gov.in/ has been developed and hosted on NIC cloud to monitor different activities of the institutes. Next Version of the MIS is developed and is in the process of implementation.

(iii) Dashboard of the Department is developed and under implementation.

(iv) Stationery MIS (http://10.21.81.76/store) is the MIS of the Stationery item for the Department of Pharmaceuticals. Here employees can request for the stationery items. Dealing hand accepts the request and after approval of the Admin, employee can receive the item. Stock of the stationery items are being maintained and issued through this portal dynamically. The next Version of this software for constant improvisation is under development.

(v) Two new programs on Assistance to Pharmaceutical Industry for Common Facilities (APICF) and Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) are under process for active implementation.

(vi) Foreign Direct Investment (FDI) 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 and equity transfer are being monitored.

(vii) Award portal: this portal is developed and is under implementation phase. Aspirant companies get registered on the portal and can apply for the award and get entered their achievement under various categories. Winners are decided on the basis of the data availability.

(viii) CDMS Portal: This portal is developed and under implementation phase. This portal is designed to monitor the COVID related drug availability in the country during COVID period.

CHAPTER 11

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 11

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-560010.

(iv) Bengal Chemicals & Pharmaceuticals Ltd (BCPL), Kolkata, West Bengal.

(v) Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Road No.12, V.K.I. Area, Jaipur-302013

Annexure-II [B]

Address and Names of Head in PSUs under Department of Pharmaceuticals

Table-11A

(Address and Names of Head in PSUs under Department of Pharmaceuticals)

S.No.	Address and Organisation	Name	Designation
1	Indian Drugs & Pharmaceuticals Limited (IDPL), Dundahera, Gurugram, Haryana	Shri Rajneesh Tingal	Chairman & Managing Director(CMD) (Additional Charge)
2	Hindustan Antibiotics Limited (HAL), Pimpri, Pune, Maharashtra	Ms. Nirja Saraf	Managing Director
3	Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Jaipur, Rajasthan	Ms. Nirja Saraf	Managing Director (Additional Charge)
4	Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata, West Bengal	Ms. Nirja Saraf	Managing Director (Additional Charge)
5	Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru, Karnataka	Shri Sunil Kumar Kaimal	Managing Director

Annexure - II [C]

List of Responsibility Centers and Subordinate Organizations

Table-11B

(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, Gandhi-nagar-382355, Gujarat.
2	Dr. USN Murty- NIPER Guwahati	0361-2132751	murtyusn@gmail.com murty_usn@yahoo.com director@niperguwahati.ac.in	9127060998	Sila Katamur (Halugurisuk) P.O.: Changsari, Dist: Kamrup, Assam, Pin: 781101, Assam, India
3	Dr. Gayathri V. Patil (under suspension) 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@gmail.com director@niperkolkata.edu.in	9443963481	Chunilal Bhawan, 168, Maniktala main road, Kolkata-700054, West Bangal
6	Dr. Shashi Bala Singh-NIPER Hyderabad	040-23073741	director.niperhyd@gov.in director@niperhyd.ac.in	9999297992	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