सत्यमेव जयते

Government of India
Ministry of Chemicals & Fertilizers
DEPARTMENT OF PHARMACEUTICALS

आज़ादी का अमृत महोत्सव

Annual Report 2021-22

Annual Report
2021-22

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

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CHAPTER 1

An Overview

CHAPTER 1

An Overview

1.1 Pharmaceutical Sector

Indian pharmaceutical industry is known for its generic medicines and low-cost vaccines globally. Transformed over the years as a vibrant sector, presently Indian Pharma ranks third in pharmaceutical production by volume. In the last nine years, Indian Pharma sector has grown steadily by CAGR of 9.43%. Pharma sector has been consistently earning trade surplus. During 2020-21, total pharma export was ₹180555 crore (USD 24.35 Bn) against the total pharma import of ₹49436 crore (USD 6.66 Bn), thereby generating trade surplus of USD 17.68 Bn. Till end September 2021, total pharma export has been ₹ 87864 crore (USD 11.88 Bn) as against total import of ₹ 33636 crore (USD 4.66 Bn), thereby generating a trade surplus of ₹ 54228 crore (USD 7.22 Bn). Major segments of Indian Pharmaceutical Industry include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics.

Indian pharmaceutical industry also plays significant role globally. India has the highest number of United States Food and Drug Administration (USFDA) compliant Pharma plants outside of USA. There are 500 API manufacturers contributing about 8% in the global API Industry. India is the largest supplier of generic medicines with 20% share in the global supply by manufacturing 60000 different generic brands across 60 therapeutic categories. Access to affordable HIV treatment from India is one of the greatest success stories in medicine.India is one of the biggest suppliers of low-cost vaccines in the world.Because of the low price and high quality, Indian medicines are preferred worldwide, thereby rightly making the country the “pharmacy of the world”.

The Indian pharma industry has also played an important role in meeting the challenges for mitigation of the infection in COVID pandemic. The industry worked in close collaboration with the government and academic institutes etc., to quickly develop and refine manufacturing processes which helped to ensure a consistent supply of medicines needed for the management of COVID-19 (*e.g.* Remdesivir, Ivermectin, Hydroxychloroquine, Dexamethasone, Tocilizumab, Favipiravir *etc.*). Indian drug supplies throughout the COVID-19 pandemic period have provided relief to over 120 countries for Hydroxychloroquine (HCQ), 20 countries for paracetamol and about 96 countries for vaccines across the world.

Table -1A

(Pharma Sector's Growth at Current Prices)

Item/Year	Output (₹ in Cr.)	Growth Rate
2015-16	3,03,352	16.56
2016-17	3,21,472	5.97
2017-18	3,28,677	2.24
2018-19	3,98,852	21.35
2019-20	3,89,094	-2.45
2020-21*	4,27,109	9.77

*Estimated based on trend growth rate (CAGR) of output at 9.77% achieved during 2013-14 to 2019-20.

Source: National Accounts Statistics-2021, Ministry of Statistics and Programme Implementation.

1.1.1 Major Credentials of Pharma Industry

- India provides generic medicines to more than 200 countries
- 8 out of 20 Global Generic companies are from India
- Over 55% Exports to Highly Regulated Markets
- 90% of WHO Pre-Qualified APIs are sourced from India
- 65-70% of WHO's vaccine requirements are sourced from India
- No. of USFDA approved sites: 741 (as of August 2021)
- No. of ANDA Market Authorizations secured by Indian companies: 4,346 (as on December 2020)

1.1.2 Foreign Direct Investment (FDI)

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

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

The Department of Pharmaceuticals has approved 10 FDI proposals worth ₹ 7,860 crore inflows under the brownfield pharmaceutical projects during the financial year 2021-22 (till December 2021). The FDI inflows in pharmaceutical sector (pharmaceuticals and medical devices activities) in the last three years under both the routes, government and automatic are as follows:

Graph -1A
(FDI inflows in Pharmaceutical Sector)

FDI inflows in Pharmaceutical Sector
(₹in crore)

Source: Compiled from data provided by DPIIT.

1.1.3 FDI linked Compliance Monitoring Portal

An online Portal, namely, "FDI linked Compliance Monitoring Portal" has been developed by the Department to monitor progress of FDI inflows received by the Indian Companies in the pharmaceutical sector and ensure compliances of FDI linked performance conditions as required under the extant FDI Policy. The web-link of the portal is: http://fdi.pharmaceuticals.gov.in/. The online portal will help in reporting by companies and tracking progress of FDI inflows apart from creating database of companies receiving FDI in the sector.

(Homepage of FDI linked Compliance Monitoring Portal)

1.2 Medical Device Industry

Medical Device industry is a sunrise sector and has the potential of growing highest among all the sectors in the healthcare system. Various categories of devices starting from consumables to implantable medical devices are being manufactured in India. Major manufacturing of medical devices in the country is happening with respect to disposables such as catheters, perfusion sets, extension lines, cannula, feeding tubes, needles, syringes, and implants such as cardiac stents, drug-eluting stents, intra-ocular lenses and orthopedic implants.

The Medical Device industry is highly capital intensive with a long gestation period and requires development/induction of new technologies. The sector also requires continuous training of healthcare system providers to adapt to new technologies. Most of the high technology and innovative products originate from a well-developed ecosystem and innovation cycle, which is yet to be fully developed in India. India depends on imports to an extent of 85% of its domestic requirements of medical devices.

India is one of the fastest growing markets in the global medical devices industry and is expected to grow at a CAGR of 15 per cent. Indian medical devices market stood at USD 11 billion in 2020**.** Indian Medical Device industry is expected to reach USD 50 Bn by 2030. 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 past two financial years are as under:

Table -1B
(Export and Import of Medical Devices)

(Values in USD million)

Imports		Exports	
2019-20	**2020-21**	**2019-20**	**2020-21**
5845.41	6240.55	2292.87	2531.62

Source: EEPC

A. Export Data

a) Category wise

Table -1C

(Category wise Export Data)

(USD Million)

S. No.	Segment	Exports 2019-20	Exports 2020-21	% Share (2019-20)	% Share (2020-21)
1	Consumables & Disposables	1082.53	1290.26	47.21	50.97
2	Surgical Instruments	49.77	53.64	2.17	2.12
3	Electronics Equipment	998.87	984.73	43.56	38.90
4	Implants	94.12	98.81	4.10	3.90
5	IVD Reagent	67.58	104.18	2.95	4.12
	TOTAL	**2292.87**	**2531.62**		

Source: EEPC

b) Top Export Destinations

Table -1D
(Top Export Destinations)

(USD Million)

S. NO.	Country	Exports 2020-21	% Share
	World	**2531.6**	**100.0**
1	USA	600.01	23.7
2	Germany	133.70	5.3
3	China	133.00	5.3
4	France	74.89	3.0
5	Singapore	74.80	3.0
	Sub Total	**1016.40**	**40.15**

Source: EEPC

B. Import Data

a) Category-wise

Table -1E
(Category wise Import Data)

(USD Million)

S. NO.	Segment	Imports 2019-20	Imports 2020-21	% share (2019-20)	% share (2020-21)
1	Electronics Equipment	3646.53	3568.64	62.38	57.18
2	Surgical Instruments	180.10	103.62	3.08	1.66
3	Consumables & Disposables	1076.23	1470.77	18.41	23.57
4	IVD Reagent	527.20	871.89	9.02	13.97
5	Implants	415.35	225.63	7.11	3.62
	TOTAL	**5845.41**	**6240.55**		

Source: EEPC

b) Top Import Destinations

Table -1F
(Top Import Destinations)

(USD Million)

S. NO.	Country	Imports 2020-21	% Share
	World	**6240.6**	**100.0**
1	China	1110.9	17.8
2	USA	984.1	15.8
3	Germany	668.5	10.7
4	Singapore	517.8	8.3
5	Japan	237.0	3.8
	Sub Total	**3518.26**	**56.38**

1.3 Investor Summit

The Department of Pharmaceuticals in collaboration with Invest India organized an Investors Summit on Opportunities and Partnerships in Pharmaceuticals and Medical Devices virtually on 27.10.2021 to uncover several exciting opportunities for growth and investment across the Pharmaceuticals and Medical Devices ecosystem. The Summit was graced by Dr. Mansukh Mandaviya, Hon'ble Minister for Chemicals and Fertilizers and Health & Family Welfare as the Guest of Honour. The Investors Summit conducted five detailed technical sessions with a laser-eyed focus on exploring opportunities for domestic R&D driven manufacturing in biopharmaceuticals, becoming the land of opportunities for medical devices with expansion of diagnostics and medical equipment, financing the growing startup ecosystem, and providing comprehensive facilitation and support to PLI applicants.

Address of Dr. Mansukh Mandaviya, Hon'ble Minister for Chemicals and Fertilizers and Health & Family Welfare during Investor Summit

1.4 India Pharma 2021 and India Medical Device 2021

Department of Pharmaceuticals organizes India Pharma & India Medical Device series of events as an annual activity. The 6th edition of India Pharma 2021 and India Medical Device 2021 was organized by the Department in collaboration with FICCI and Invest India from 25th February to 2nd March 2021 virtually. The special focus during the 6th edition of India Pharma & India Medical Device events was the Global Investors Meet.

The objectives of India Pharma & India Medical Device 2021 were to:

(i) Endeavor to address industry issues and to create a platform to recommend solutions

(ii) Facilitate sharing of knowledge and best practices

(iii) Promote India as a Manufacturing hub in the Pharmaceutical and Medical Devices Sector

(iv) Establish India as a premier global healthcare destination and attract investments

(v) Provide a platform to network and collaborate

(vi) Identify new priority areas and deliberate upon them

The theme for India Pharma 2021 was "Indian Pharma Industry: Future is Now" and for India Medical Device was "India MedTech Future: Innovate & Make in India through Global Alliance". Salient components of the event included showcasing of investment opportunities in India, panel discussions with industry leaders, International Drug Regulator Session, India Pharma & Medical Device Awards, and a discussion of sectoral startups.

1.4.1 6th India Pharma and India Medical Devices Awards

6th India Pharma and India Medical Device awards were conferred on 25.02.2021 by Shri D.V. Sadananda Gowda, the then Hon'ble Minister (Chemicals & Fertilizers) in recognition of innovation and excellence in Pharma and Med Tech sectors. List of Winners of 6th India Pharma and India Medical Device Awards is as under: -

Table -1G

(List of Winners of 6th India Pharma and India Medical Device Awards)

S. No.	Category of Awards	Winner
1.	India Pharma Leader Award	Laurus Labs Limited
2.	India Pharma Bulk Drug Company of the Year Award	Metrochem API Private Limited
3.	India Pharma Innovation of the Year Award	Glenmark Pharmaceuticals Limited
4	India Pharma Corporate Social Responsibility (CSR) Programme of the Year Award	Lupin Limted
5	India Medical Devices Company of the Year Award	Wrig Nanosystems Private Limited

Special award for excellent contribution towards meeting the challenges faced by Pharma and Medical Devices Industry during the Covid-19 pandemic was given to Dr. P.D. Vaghela, Ex-Secretary, Department of Pharmaceuticals.

Inaugural Session: India Pharma 2021 & India Medical Device 2021

Address of Secretary (Pharma) During Inaugural Session of India Pharma 2021 & India Medical Device 2021

1.5 International Cooperation

(A) Joint Working Group (JWG)

Department of Pharmaceuticals co-chairs the following Joint Working Groups/High Technology Cooperation Group:

(i) EU-India Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices

(ii) India-Tunisia Joint Working Group on Drugs and Pharmaceuticals

(iii) India-Ukraine Joint Working Group on Pharmaceuticals and Healthcare

(iv) India-Belarus Joint Working Group on Pharmaceuticals

(v) India-Philippines Technical Working Group (TWG) for considering "Pharmazone" and "Registration and other Issues related to Pharmaceuticals"

(vi) India-Algeria Joint Working Group (JWG) on Pharmaceuticals

(vii) India-Egypt Joint Study Group (JSG) on Pharmaceuticals and Health

(viii) India-Uzbekistan Joint Working Group on Pharmaceuticals

(ix) India-Russia Joint Working Group on Pharmaceuticals to readdress the issues on India Pharma Industries

(x) India-China Joint Working Group on Pharmaceuticals

(B) The Department participated in the 9th Session of India-Cyprus Joint Committee on Economic, Scientific, Technical and Industrial Cooperation (JCEC) held on 21.10.2021, 1st Joint Working Group (JWG) under the MoU between India and Italy on cooperation in the field of Health and Medical Sciences on 26.10.2021 and 1st Joint Working Group (JWG) meeting between India and Uzbekistan on cooperation in the field of Health on 01.11.2021 wherein areas of collaboration identified included investments in Pharma and medical device sector in India; partnerships between National Institutes of Pharmaceutical Education and Research (NIPERs) and foreign counterpart towards nurturing and promoting quality and excellence in pharmaceutical education

and research; Speedy WHO PQ approvals for drugs / vaccines manufactured in India and industry to industry collaboration to promote resilient and diversified supply chains.

(C) Meeting of the High-Level Delegation from Colombia led by their Hon'ble Health Minister was held with the Indian Delegation, led by Secretary, DoP and comprising of officials of the Department, CDSCO, Pharmexcil, Invest India and the Indian Pharmaceutical Alliance on 27.09.2021. The Colombian Delegation appreciated about the sound regulation and affordable prices of drugs manufactured in India and also expressed their intent w.r.t. decentralization of production in Colombia. Further, they also looked forward for strengthening their supply chain, transfer of Technology and Transfer of Knowledge. The Indian Delegation acknowledged that healthcare was an important priority and achieving health security and drug security was a process requiring patience and perseverance.

A Photograph taken during Meeting of the High-Level Delegation from Colombia led by their Hon'ble Health Minister with the Indian Delegation

Based on the deliberations of the meeting, a draft MoU is proposed to be signed with the Colombian side encompassing the following: -

(i) Collaboration on Pharmaceutical Education leveraging the expertise and experience of NIPERs
(ii) Collaboration on sharing best practices such as PMBJP
(iii) Industry to industry collaboration.
(iv) Participation in Trade Negotiations led by Department of Commerce

(D) The Department has been actively involved in representing the Pharma sector interests in Early Harvest Schemes, Preferential Trade Agreements, Free Trade Agreements and Comprehensive Economic Partnership Agreements being negotiated with countries including UAE, Israel, UK, Chile, Iran, South Korea, Australia, Canada, Switzerland, Saudi Arabia, Vietnam, Qatar and has also engaged in multilateral forum discussions viz., India-EU Connectivity Partnership, G20 Trade and Investment Working Group and the upcoming event in the World Expo at Dubai.

1.6 COVID-19 related actions taken by the Department

1.6.1 COVID Drugs Management Cell (CDMC)

A COVID Drugs Management Cell (CDMC) has been set up in the Department of Pharmaceuticals (DoP) to oversee the management of smooth supply of drugs used in COVID -19 management during the pandemic. Daily meetings of the CDMC were conducted to review and prioritize the actions required with respect to the issues surrounding drug production and availability. The CDMC has been able to respond to the COVID drug requirements of the country during the second wave with the collective support from the officials of the DoP, the NPPA and the CDSCO. Looking at the importance and the quantum of work, the DoPT also attached one Additional Secretary, one Joint Secretary and five Directors with DoP who were then assigned specific tasks in the Department.

1.6.2 Drugs Coordination Committee (DCC)

Looking at the inter-departmental nature of the issues with regard to COVID drug availability, a Drugs Coordination Committee (DCC) was constituted vide OM dated 20.05.2021 as an institutional mechanism with representation from the Department, the Ministry of Health & Family Welfare, the Directorate General of Health Services (DGHS), the Indian Council of Medical Research (ICMR), the Directorate General of Foreign Trade (DGFT), the Ministry of External Affairs (MEA), the CDSCO and the NPPA for efficient decision making on all the issues with respect to COVID-19 related drugs. Meetings of DCC were held from time to time under the chairpersonship of Secretary, DoP on the following issues:

(a) To ascertain the different drugs and their inputs, both in COVID-19 clinical management protocol or otherwise in demand where the pharmaceutical industry needs to be further sensitized to augment production on an urgent basis

(b) To ascertain the various alternatives of the listed drugs in case of the domestic industry to supplement the supply to meet the demand as projected by MoHFW

(c) To operationalize new drug permissions related to COVID -19 management given by DCGI for speedy manufacturing

(d) To facilitate equitable availability of the drugs across the country

(e) To assess the need to procure and / or import drugs

(f) To facilitate Indian pharmaceutical companies in obtaining raw material, equipment, etc. from foreign countries

1.6.3 Allocation of commercial shipments of Tocilizumab

This began on 30.04.2021 as a joint exercise between the Department of Pharmaceuticals and Ministry of Health and Family Welfare, Government of India to ensure equitable distribution of limited availability of this drug since it was not manufactured in the country and sourced through imports from M/s. Roche, Switzerland. Subsequently, efforts to develop the drug indigenously yielded results with M/s. Hetero Biopharma Limited, after due regulatory approvals, manufacturing the drug domestically. Accordingly, an allocation of the drug from the production plan of M/s. Hetero Biopharma Ltd. was made on 01.10.2021.

1.6.4 Export of Remdesivir and Amphotericin-B

On 01.06.2021 and 14.06.2021, export policy of remdesivir injection / API and Amphotericin-B injections, respectively, was amended from 'Prohibited' to 'Restricted'. Subsequently, DGFT has been referring applications for export in this regard to DoP and DoHFW for recommendations. Until the end of October 2021, about 2.4 crore vials of Remdesivir and about 10.7 lakh units of Amphotericin B were recommended for export to DGFT.

1.7 Special Campaign for disposal of pendency and Swachhata carried on from 2nd October to 31st October

As per the directions of the Hon'ble Prime Minister and as subsequently conveyed vide DO No.1/50/3/2021-Cab dated 09.09.2021 addressed to all Secretaries, the "**Special Campaign**" had been undertaken from 2nd - 31st October 2021. The objective was to timely and effectively dispose of pending references from Members of Parliament, references of State Governments, references from Inter-Ministerial Consultations (IMC), Parliamentary Assurances and Public Grievances. It was also emphasized to review, during the campaign, existing processes with a view to reducing compliance burden and to discard redundant scrap materials, obsolete items, unnecessary paper works including weeding out of files of temporary nature to improve cleanliness of workplace.

Department of Administrative Reforms & Public Grievances (DARPG) which is designated as Nodal Department, organized training for Nodal Officers of the campaign, elaborated the action plan to be carried out during the campaign and put a dedicated Dashboard portal "SCDPM" for effective monitoring of the Campaign. During the preparatory phase from 13th -29th September 2021, pending issues/references were identified to be uploaded in the Portal.

Hon'ble Minister of Health & Family Welfare and Chemicals & Fertilizers, Dr. Mansukh Mandaviya vide his Note dated 29.09.2021 directed all the three Departments of the Ministry of Chemicals & Fertilizers to conduct a Special Drive on Swachhta Abhiyan during the campaign period from 02.10.2021 to 31.10.2021. It was also directed to involve all the Attached Offices/Subordinated Offices/ Statutory Bodies/ Autonomous Bodies/ PSUs, etc. under the administrative control of the Ministry in the Special Drive on Swachhta Abhiyan. The activities like cleanliness of building/premises, disposal of wastes, garbage, condemned furniture; e-waste and cleaning/maintaining of sitting area, etc. were emphasized for the campaign.

1.7.1 Activities undertaken during the Special Campaign

Department of Pharmaceuticals chalked out its Action Plan for making the Special Campaign outcome oriented. All organizations under its administrative control were informed to join the campaign and undertake all the activities desired during the special campaign.

During the preparatory phase starting from 13th - 29th September 2021, the Department undertook the exercise of identifying pending issues involving all divisions/sections of the Department pertaining to

(a) references received from Members of Parliament, (b) references received from State Governments, (c) references received for Inter-Ministerial Consultation (IMC), (d) pending Parliamentary Assurances,

(e) pending Public Grievances and (f) any existing processes that could be amended for reducing compliance burden. This was followed by identification of physical files to be reviewed for digitization and weeding out. Action plan was also drawn for undertaking Special Drive on Swachhta Abhiyan during the campaign to include activities like discarding scrap materials, obsolete items, unnecessary paper works and cleaning the workplace (office rooms and their corridors) in all its three locations- Shastri Bhawan, Udyog Bhawan and at Janpath Bhawan. Finally, all the identified pending references/public grievance/ files to be reviewed etc. were uploaded in the DARPG portal as targets to be disposed of during the campaign period.

The Special Campaign on Disposal of Pending Matters was given special importance. Secretary (Pharma) took a special meeting with all senior officers of the Department and directed all sections/ divisions to clear all pending matters on priority and review physical files to be weeded out including cleaning of office rooms and corridors. While monitoring the progress of the different activities under the campaign on daily basis, Secretary also personally visited different office rooms, both at Shastri Bhawan and Janpath to see the work in progress and encourage the staff. The progress of works/activities being undertaken under the Special Campaign was also reviewed during the Weekly Senior Officers' Meetings.

All efforts were made to timely and effectively dispose of all the pending references of members of Parliament, State Governments, and IMC. Apart from the number of public grievances found pending as on 30th of September 2021, effort was being also made to clear all public grievances as and when they were received. Similarly, wherever possible, all divisions/sections were directed to fulfil the pending Parliamentary Assurances.

The summary of the targets as set, and their achievements are as under:

Table -1H
(summary of the targets and their achievements)

Sl. No.	Item	Target	Achievement	
			achieved	pending
1.	MP References	22	22	-
2.	Parliamentary Assurances	20	4 IR uploaded	16
3.	IMC References	2	2	-
4.	Public Grievances	46	46	-
5.	**File Management:**			
	a. Total No. of physical files for review	8020	8020	-
	b. Old Files weeded out	4900	4900	-
6.	Cleanliness Drives	12	12	-
7.	Rules for simplification	0	0	-
8.	PG Appeals	0	0	-

Some of the photographs showing the impact of the Special Campaign, particularly the cleanliness drive- "Swachhta Abhiyan" are shown in the following pages.

Room No.218A, Shastri Bhawan

Room No.G-25, Shastri Bhawan

1.8 Interactive Session 2021 for "Improving Efficiency in the functioning" of the Department of Pharmaceuticals

Interactive Session 2021 for "Improving Efficiency in the functioning" of the Department of Pharmaceuticals was organized on 30.10.2021 in Sushma Swaraj Bhawan, Dr. J.P. Rizal Marg, Chanakyapuri, New Delhi.

The Interactive Session included plenary session followed by motivational session, technical ses-

sion and personal interaction by Secretary with officers and staff. During the plenary session, secretary shared the experience of Chintan Shivirs being organized annually by the Government of Gujarat with participation of Chief Minister, Ministers and Senior officers to review the performance and potential of each sector, in a non-hierarchical, off-site environment; a practice followed by Corporates as part of their work culture for improvement of their functioning and monitoring Key Result Areas of individual employees. Underscoring the importance of capacity building of the staff, particularly for Young Professionals on Specific Modules, the Secretary also suggested to follow "EPM" for improving work culture where 'E' stands for Efficient, 'P' stands for Proactive, and 'M' stands for Meaningful. The need to have more of such interaction session was also expressed.

During the motivational session, Shri Arun Gaur, Resource Person spoke about motivational factors and how a person could get motivated. Motivation required high energy levels in a person through various means and when there were challenges, there should be reason for a person to get motivated. These were not mere economic considerations, social security, or warmth in relations but also the requirement of emotional fulfillment. A motivated person's mind would be ready for setting goals for him, despite various other challenges.

Thereafter two parallel sessions - one for ASO and above level officers on general office procedure and rules such as Conduct rules, Vigilance and RTI Matters and the other for PA/PS and support staff on office management by two resources persons viz. Shri Ravinder Kumar and Shri Arun Gaur respectively were conducted. The staff and officers of the Department had lively and elaborate interaction with the resource persons on various matters related to rules and office management.

A photograph taken during Interactive Session 2021

CHAPTER 2

FUNCTIONS AND ORGANISATIONAL SET-UP

2.1 Mandate of Department of Pharmaceuticals

2.2 Vision

2.3 Mission

2.4 Organizational set-up

2.5 Attached Office

2.6 Registered Society

2.7 Autonomous Institutes

2.8 Public Sector Undertakings

CHAPTER 2

Functions And Organisational Set-Up

2.1 Mandate of Department of Pharmaceuticals

The Department of Pharmaceuticals was created on 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 requires coordination 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-sectorial 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 & Medical Device Divisions. National Pharmaceuticals Pricing Authority (NPPA) is an attached office of the Department.

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

The Department has as many as 13 Divisions to carry out various mandated functions and responsibilities. The summary of the various Divisions is given below:

(a) 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 Department of Expenditure.

(b) 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.

(c) Policy Division- all policy matters other than Pricing Policy; processing of Foreign Direct Investment (FDI) proposals; Drug Coordination Committee, Project Development Cell, International Cooperation and any other matters related to WTO/ TRIPS / Patents, etc. and trade agreements; Joint working

groups of various countries, regional groups etc.; Matters related to Ministry of Commerce; New PLI Scheme under Atmanirbhar Bharat, implementation of scheme "Promotion of Bulk Drug Parks".

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

(e) NIPER Division - All matters related to National Institutes of Pharmaceutical Education & Research (NIPERs) under the administrative control of the Department of Pharmaceuticals.

(f) Scheme Division- Internal coordination of the schemes, implementation of the scheme "Pradhan Mantri Bhartiya Janaushadhi Pariyojana(PMBJP)"; Implementation of "Pharmaceuticals Promotion and development Scheme (PPDS)"; Implementation of PLI Scheme for Medical Devices, Implementation of PLI Scheme for Bulk Drug, implementation of Pharmaceutical Technology Upgradation Assistance Scheme(PTUAS), implementation of the scheme assistance for pharmaceuticals industry for common facilities.

(g) Medical Device Division- All matters related to Medical Devices & Medical Device Industry including promotion, production & manufacture; all issues related to investment in the medical device sector, implementation of the scheme "Assistance to Medical Device Parks, regulatory issues (other than Pricing) related to Medical Devices Section.

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

(i) Establishment & Administration Division- all matters related to Establishment, Information Technology (IT), Cash and Administration, dealing with provision of day to day articles needed for smooth running of office, housekeeping services, maintenance of office equipments including air conditioners, photocopiers etc., printing of annual report, hospitality services. Establishment deals with all service-related matters of officers/officials of Department of Pharmaceuticals.

(j) Parliament Division- all matters related to the Meetings of consultative committee, Standing Committee, Parliamentary Assurances etc. and also centralized handling of parliament questions like marking of questions, handling of questions once questions get approved by Joint Secretary/ Secretary, taking approval of Minister and submission of necessary copies to Lok Sabha / Rajya Sabha/ PIB etc.

(k) Coordination Division- all matters of coordination related to intra and inter-Department, RTI, preparation of Department's Annual Report.

(l) Vigilance Division-all matters related to vigilance, transparency and accountability.

2.5 Employment of Scheduled Castes / Scheduled Tribes / Physically Handicapped

The status of employment of Scheduled Castes / Scheduled Tribes / Other Backward Classes / Physically handicapped in the Department of Pharmaceuticals, as on 31.12.2021 is as under:

Table-2A

(Employment position of SC/ST in the Department)

Group	Total No. of Posts	In position	Scheduled Castes	Scheduled Tribes	Other Backward Classes	Physically Handicapped
A	26	21	4	2	1	-
B	48	26	3	3	7	-
C	18	16	5	-	5	-
Total	92	63	12	5	13	-

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 based on nominations made by the Department of Personnel & Training. (the organizational chart of the Department is given at Annexure 2A)

2.6 Attached Office

National Pharmaceutical Pricing Authority - an attached office of the Department and its 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.

2.7 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, Ministry of Chemicals & Fertilizers, Government of India, with the objective to have focused and empowered structure to implement the Jan Aushadhi Scheme launched by Department of Pharmaceuticals.

2.8 Autonomous Institutes

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 Raebareli with the help of Mentor Institutes during 2007-08.

2.9 Public Sector Undertakings

Central Public Sector Undertakings- the Department has 5 Central Public Sector Undertakings under its administrative control, they are

(a) Indian Drugs & Pharmaceuticals Limited (IDPL), Dundahera Industrial Complex, Dundahera, Gurgaon, Haryana

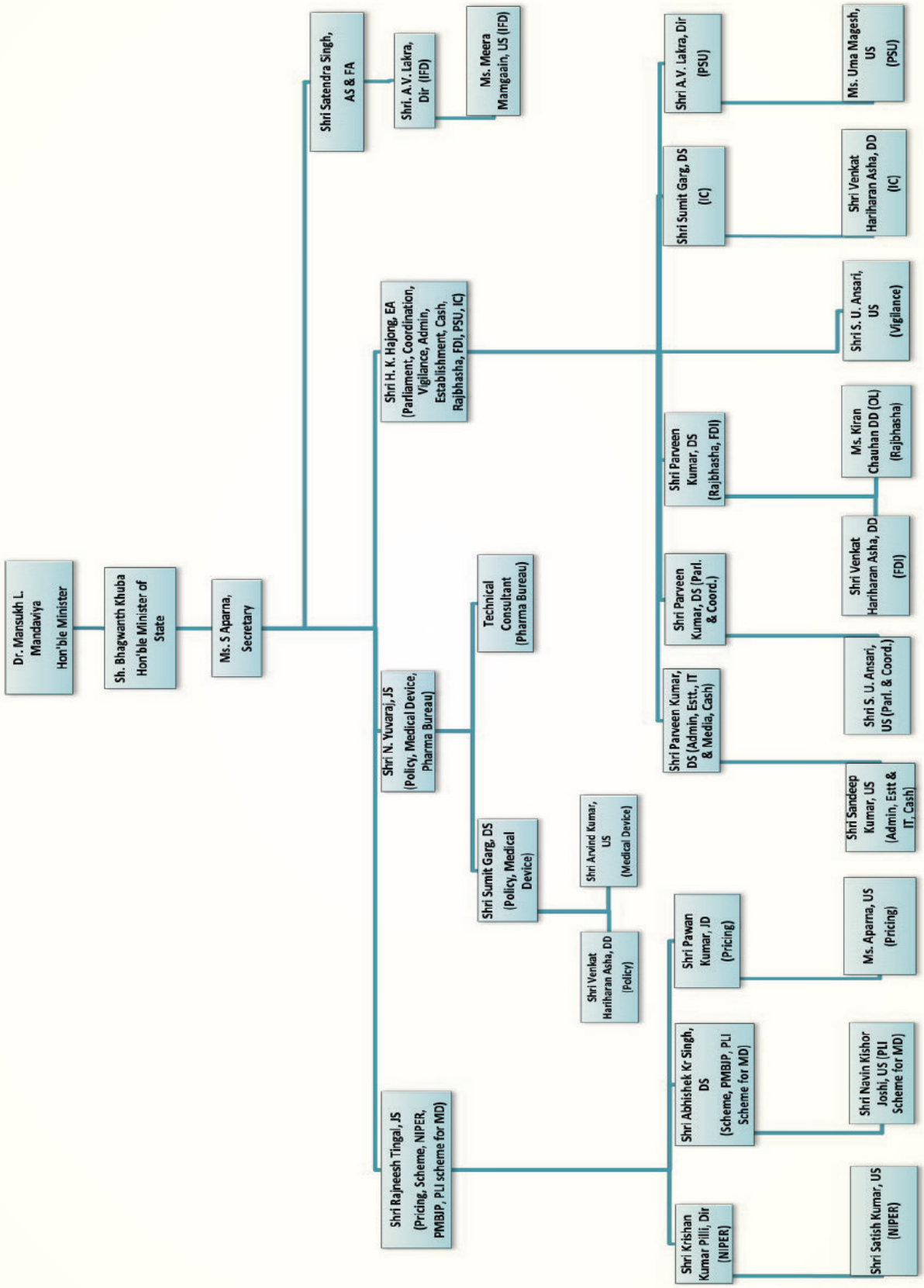
(b) Hindustan Antibiotics Limited (HAL), Pimpri, Pune, Maharahstra

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

(d) Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata, West Bengal

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

Annexure - 2A


Dr. Mansukh L. Mandaviya Hon'ble Minister
Sh. Bhagwanth Khuba Hon'ble Minister of State
Ms. S Aparna, Secretary
Shri Satendra Singh, AS & FA
Shri. A.V. Lakra, Dir (IFD)
Ms. Meera Mamgaain, US (IFD)
Shri H. K. Hajong, EA (Parliament, Coordination, Vigilance, Admin, Establishment, Cash, Rajbhasha, FDI, PSU, IC)
Shri A.V. Lakra, Dir (PSU)
Ms. Uma Magesh, US (PSU)
Shri Sumit Garg, DS (IC)
Shri Venkat Hariharan Asha, DD (IC)
Shri S. U. Ansari, US (Vigilance)
Shri Parveen Kumar, DS (Rajbhasha, FDI)
Ms. Kiran Chauhan DD (OL) (Rajbhasha)
Shri Parveen Kumar, DS (Parl. & Coord.)
Shri Venkat Hariharan Asha, DD (FDI)
Shri Parveen Kumar, DS (Admin, Estt., IT & Media, Cash)
Shri S. U. Ansari, US (Parl. & Coord.)
Shri Sandeep Kumar, US (Admin, Estt & IT, Cash)
Shri N. Yuvaraj, JS (Policy, Medical Device, Pharma Bureau)
Technical Consultant (Pharma Bureau)
Shri Sumit Garg, DS (Policy, Medical Device)
Shri Arvind Kumar, US (Medical Device)
Shri Venkat Hariharan Asha, DD (Policy)
Shri Rajneesh Tingal, JS (Pricing, Scheme, NIPER, PMBJP, PLI scheme for MD)
Shri Pawan Kumar, JD (Pricing)
Ms. Aparna, US (Pricing)
Shri Abhishek Kr Singh, DS (Scheme, PMBJP, PLI Scheme for MD)
Shri Navin Kishor Joshi, US (PLI Scheme for MD)
Shri Krishan Kumar Pilli, Dir (NIPER)
Shri Satish Kumar, US (NIPER)

CHAPTER 3

Programmatic Interventions

3.1 Central Sector Schemes

3.2 Umbrella Scheme for Development of Pharmaceutical Industry

3.3 Pharma Bureau and other initiatives taken by the Department for promotion of Pharmaceutical and Medical Device Industry

CHAPTER 3

Programmatic Interventions

3.1 Central Sector Schemes of the Department

The Department has four 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) and (d) Development of Pharmaceutical Industry, an Umbrella Scheme. 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 two schemes namely NIPER scheme and Development of Pharmaceutical Industry are operated by the Department directly. The details of each of the schemes are given as follows:

3.2 Umbrella Scheme for Development of Pharmaceutical Industry

The Department has an umbrella scheme namely 'Development of Pharmaceutical Industry'. Its objective is to increase efficiency and competitiveness of domestic pharmaceutical 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 for mass consumption. This Scheme is a Central Sector Scheme and comprises the following sub-schemes:

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

(b) Promotion of Bulk Drug Parks

(c) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices

(d) Promotion of Medical Device Parks

(e) Production Linked Incentive (PLI) Scheme for Pharmaceuticals

(f) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

(g) Assistance to Pharmaceutical Industry for Common Facilities (API-CF)

(h) Pharmaceutical Promotion and Development Scheme (PPDS)

The Guidelines for implementation of the sub-schemes are available on the Department's website at https://pharmaceuticals.gov.in/schemes. EFC has recommended to de-link sub-schemes (f) to (h) from the Umbrella scheme and implement them as a separate scheme.

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

With a view to attaining self-reliance and reduce import dependence in critical APIs, a sub-scheme called "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India" was approved by the Government of India on 20.03.2020. The scheme intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. The guidelines for 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 following four categories-

(i) Target Segment I – Key Fermentation Based KSMs/Drug Intermediates

(ii) Target Segment II - Key Fermentation Based Niche KSMs/Drug Intermediates

(iii) Target Segment III – Chemical Synthesis Based KSMs/Drug Intermediates

(iv) Target Segment IV – Other Chemical Synthesis Based KSMs/Drug Intermediates/APIs

The tenure of the scheme is from 2020-21 to 2029-30 with total financial outlay of ₹ 6,940 crore. The financial incentive under the scheme will be provided on sales of 41 identified products for six 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%.

A total of 239 applications were received, out of which 49 applicants were selected for 32 products.

The details regarding actual investment up to December 2021 are as follows:

Table - 3A
(Segment wise Details of Investment)

Sl. No.	Target Segment	Total Applicants approved	Total Committed Investment (₹ in crore)	Actual Investment upto December, 2021 (₹ in crore)
1	Key Fermentation based KSMs/ Drug Intermediates	3	2114.17	22.91
2	Fermentation based niche KSMs/ Drug Intermediates /APIs	6	357.27	35.31

3	Key Chemical Synthesis based KSMs/Drug Intermediates	5	334.34	165.19
4	Other Chemical Synthesis based KSMs/ Drug Intermediates/APIs	35	879.60	551.47
	Total	**49**	**3685.38**	**774.88**

Out of 49 applications approved in two rounds, three Projects have been commissioned as follows:

(i) Emmenar Pharma Pvt Ltd- (product- Cyclohexane Diacetic Acid) : Committed investment of ₹ 21.94 crore and Committed production capacity is 1500 MT.

(ii) Centrient Pharmaceuticals India Pvt Ltd (product- Atrovastatin) : Committed investment of ₹ 137.74 crore and Committed production capacity is 180 MT.

(iii) Meghmani LLP (product- Para Amino Phenol) : Committed investment of ₹ 55.06 crore and Committed production capacity is 13500 MT.

3.2.2 Scheme for Promotion of Bulk Drug Parks

To promote setting up of bulk drug parks in the country for providing easy access to world class common infrastructure facilities to bulk drug units located in the parks in order to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry, a scheme called "Promotion of Bulk Drug Parks" has been approved by the Government of India on 20.03.2020. The Scheme has been notified vide Gazette Notification No.-31026/16/2020-Policy dated 21.07.2020. The guidelines of the scheme were issued on 27.07.2020.

The total financial outlay of the scheme is ₹ 3000 crore. The tenure of the scheme is from FY 2020-21 to FY 2024-25. Financial assistance to a selected Bulk Drug Park would be 70% of the project cost of common infrastructure facilities. In case of Northeastern 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 ₹ 1000 crore.

The Scheme envisages creation of world class infrastructure facilities in order to make Indian bulk drug industry a global leader by easy access to world class common infrastructure facilities to bulk drug units located in the parks, meeting the standards of environment at a reduced cost through innovative methods of common waste management system and reaping the benefits arising due to optimization of resources and economies of scale. A total of 13 States have submitted proposals under this Scheme which are presently under evaluation by the Project Management Agency.

3.2.3 Production Linked Incentive (PLI) scheme for Pharmaceuticals

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, a scheme called "Production Linked Incentive Scheme for Pharmaceuticals" has been approved by the Government of India on 24.03.2021. The Scheme has been notified vide Gazette Notification No. - 31026/60/2020-Policy dated 03.03.2021. The guidelines of the scheme were issued on 01.06.2021. The scheme covers pharmaceutical goods under following three categories:

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

Category 2: Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates.

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 total financial outlay of the scheme is ₹ 15,000 crore and three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sale of 6 years. The tenure of the scheme is from FY 2020-21 to 2028-29.

The scheme will promote innovation for development of complex and high-tech products including products of emerging therapies and In-vitro Diagnostic Devices. It is expected to promote the production of high value pharmaceutical products in the country and higher value addition in exports. Further, it is also expected to improve accessibility and affordability of medical products including orphan drugs to the Indian population.

The operational guidelines of the Scheme were issued on 01.06.2021. Thereafter, multiple rounds of outreach sessions were held with the concerned stakeholders including States/UTs, industry associations as well as companies for wide dissemination as well as providing clarifications.

The last date of submitting applications was 31.08.2021. Total 278 applications were received, out of which 55 applicants have been selected.

3.2.4 Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

The sub-scheme is aimed at providing interest subvention to the eligible Micro, Small and Medium Pharma Enterprises (MSMEs) having GMP compliant manufacturing facilities (both for Bulk Drugs and Pharmaceutical Formulations) and a proven track record to migrate from Schedule-M to World Health Organization (WHO)/ Good Manufacturing Practices (GMP) standards to enable them to participate and compete in global markets and earn foreign exchange. This would be achieved by providing assistance as interest subvention against sanctioned loan by any scheduled commercial bank/ financial institution both in public and private sector. The eligible units intending to upgrade their manufacturing infrastructure to WHO-GMP standards have to secure a loan from a Financial Institu-

tion for upgrading their infrastructure and technology. The upper limit of interest subvention on loans for technology/infrastructure upgradation shall be restricted to 5% (6% in special cases) per annum for a period of three years on a reducing balance basis. The maximum loan eligible for this purpose is ₹ 10 crore per beneficiary. The acquisition of WHO-GMP certification will enable them to manufacture pharmaceutical products to the globally accepted standards of quality, safety and efficacy thereby increasing their global competitiveness and market share.

3.2.5 Assistance to Pharmaceutical Industry for Common Facilities (API-CF)

This sub-scheme is implemented in a Public Private Partnership (PPP) mode. Financial assistance under this scheme is provided for creation of Common Facilities, such as Common Testing Centre, Training Centre, R&D Centre, Central Effluent Treatment Plan (CETP), Common Logistic Centre, etc. to a Special Purpose Vehicles(SPVs) set up for the purpose. Maximum limit for the grant-in-aid under this scheme is ₹ 20.00 crore per cluster or 70% of the cost of the project, whichever is less. The Scheme Steering Committee (SSC) under the Chairmanship of Secretary (Pharma) is empowered to approve project components and funding of the proposal.

Objective of the scheme:

(i) Strengthening the existing infrastructure facilities in order to make Indian Pharma Industry a global leader in Pharma Sector.

(ii) Easy access to standard testing facilities and value addition in the domestic Pharma Industry especially to SMEs through creation of common world class facilities for increased competitiveness.

(iii) To help industry meet the requirements of standards of environment at a reduced cost through innovative methods of common Waste Management System.

(iv) Exploit the benefits arising due to optimization of resources and economies of scale.

A total of ₹ 18.00 crore has been sanctioned for the year 2021-22. One project of Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC), to set up CETP at Alathur, Tamil Nadu has been completed. The total cost of the project was ₹ 10.59 crore. The Plant has been commissioned.

Two new project proposals have been 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 project cost of ₹ 31.44 crore. An amount of ₹ 5.50 crore has been released as 1st installment.

(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, Distt Sirmaur, Himachal Pradesh of project cost of ₹ 7.20 crore. An amount of ₹ 3.02 crore has been released in two installments.

Three other proposals have been given 'in principle' approval, i.e.:

(i) Proposal of Jeedimetla Effluent Treatment Limited (JETL) for Common Effluent Treatment plant at project cost of ₹ 29.91 Cr.

(ii) Proposal of Bulk Drug Manufacturers Association (India) to set up "Advanced Analytical Testing Facility and Training Center" at Jeedimetla, Hyderabad.

(iii) Proposal of Sirmour Green Environ Ltd. (SGEL) to set up a Common Effluent Treatment Plant (CETP) at Industrial area Gondpur, Tehsil Paonta Sahib, Distt Sirmaur Himachal Pradesh.

Common Effluent Treatment Plant (CETP) at Alathur, Tamil Nadu run by M/s Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC)

Common Effluent Treatment Plant (CETP) run by M/s Kala Amb Infrastructure Development Company (KDIC), Sirmaur, Himachal Pradesh

Common Facility Centre of Inducare Pharmaceuticals and Research Foundation (IPRF), Pune, Maharashtra

3.2.6 Pharmaceutical Promotion & Development Scheme (PPDS)

The Scheme aims at the promotion, development and export promotion in Pharmaceutical sector by extending financial support for conducting 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 sector. Under PPDS the Department of Pharmaceuticals on its own or through financial support by way of Grant-in-aid to the Institutions, organizations, Voluntary organizations or Non-Government Organizations as mentioned in Rule 228 of GFR 2017.

(i) Conduct Training/knowledge improvement programs/activities on issues/subjects relevant to growth of pharmaceutical industry.

(ii) Organize Summits, Conventions, Exhibitions, Pharmacy weeks, meetings etc. in India and abroad and produce promotional materials like films, displays etc.

(iii) Conduct research studies, sector reports etc.

(iv) Purchase books, quality standards, pharmacopoeias, magazines, directories, software for developing information data banks, developing e-learning modules etc.

(v) Give awards to achievers in pharmaceutical industry.

(vi) For creating awareness and publicity of important activities related to Pharmaceutical/ Medical Device and related sector.

(vii) For any other activity not covered under above categories which may be decided by the Department of Pharmaceuticals from time to time.

During the last five years, 112 events have been organised under Pharmaceutical Promotion and Development Scheme (PPDS). Financial Details of last five years on the expenditure on account of Workshops/Conferences & webinars conducted are as follows:

Table - 3B

(Year wise Financial Details of Workshops/Conferences & webinars)

(₹ in crore)

Year	BE	RE	Actuals	workshops / conference/ webinars conducted
2016-17	2.00	1.25	1.14	32
2017-18	2.00	1.50	1.00	36
2018-19	2.00	1.00	0.55	12
2019-20	2.00	1.19	1.06	22
2020-21	1.00	0.50	0.50	10 webinars, 2 studies

A total of ₹ 2.00 crore has been sanctioned for the year 2021-22. During current Financial Year, the Department has identified 10 studies in the pharmaceutical and medical devices sector proposed to be conducted and has issued RFP for the same. Department also organizes yearly India Pharma and Medical Device event under PPDS scheme.

Expenditure Finance Committee (EFC) in its meeting on 24th September, 2021 has approved the three sub-schemes, viz., PTUAS, API-CF and PPDS as a separate scheme with an outlay of Rs. 500 crore for a five-year period, viz., 2021-22 to 2025-26.

A photo of the e-symposium

3.2.7 Scheme for Promotion of Medical Device Parks

The Scheme was earlier called as "Assitantce to Medical Device Industry for Common Facility Center" under which the Department had 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 superconducting magnetic coils testing & research facility. The Department has released a grant of ₹ 14.99 crore to AMTZ till December, 2021.

The scheme has now been revised to "Promotion of Medical Devices Parks. The objective of the scheme is to provide easy access to standard testing and laboratory facilities through creation of world class Common Infrastructure Facilities at medical device parks for increased competitiveness, reduction of the cost of production and enhancing better 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 27.07.2020. The scheme provides grant-in-aid to medical device parks with maximum limit of ₹ 100 Crore per park or 70% of the project cost of common infrastructure facilities, whichever is less. The Government vide letter dated 24.09.2021 has in-principal approved financial assistance for common infrastructure facilities for 4 medical device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh, with the scheme being implemented by a State Implementing Agency. Detailed Project Report provided by these States are under evaluation. The State Government will provide land and necessary infrastructure such as access road, power, water supply, etc. to the park.

3.2.8 Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices

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

The Scheme is applicable only to 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 2020-21 to 2027-28 with total financial outlay of ₹ 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 years. The products under the scheme have been categorized under following four categories:

(i) Cancer care / Radiotherapy medical devices

(ii) Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices

(iii) Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices

(iv) AII Implants including implantable electronic devices

In total 42 applications were received under the scheme in two rounds. Out of these, 21 applications have been approved with a total Committed Investment of ₹ 1059.33 Crore.

The details regarding actual investment up to December 2021 are as follows:

Table - 3C
(Segment wise Details of Investment)

Sl. No.	Target Segment	Total Applicants approved	Total Committed Investment (₹ in crore)	Actual Investment upto December 2021 (₹ in crore)
1	Cancer care /Radiotherapy medical/ devices	1	24.50	1.06
2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	7	372.14	7.81

3	Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices	7	354.50	121.68
4	All Implants including implantable electronic devices	6	308.19	36.72
	Total	**21**	**1059.33**	**167.27**

3.3 Pharma Bureau and other initiatives taken by the Department for promotion of Pharmaceutical and Medical Device Industry

3.3.1 Pharma Bureau

- Pharma Bureau provides facilitation to investors and resolution of their inter-departmental coordination issues in the Pharmaceutical and Medical Device sector.
- It consists of technical experts in the area of:
  - (i) Pharmaceuticals
  - (ii) Medical Devices
  - (iii) Project Management
  - (iv) Legal
  - (iv) 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 most critical roadblocks.
- It also works as Project Development Cell of the Department.

3.3.2 Preference to domestic manufacturers in Public Procurement Policy

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 had 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 available in the country, under Para 3(a) of PPO Order dated 16.09.2020. This will enable procurement of these notified medical devices only from the “Class-I local suppliers”.

3.3.3 Regulation of Medical Devices

The Medical Device Sector has largely been unregulated and the Government was constantly-endeavoring to bring all the medical devices under regulatory framework of MoHFW. Accordingly, the MoHFW issued the Medical Device Rules, 2017 under the Drugs and Cosmetic Act, 1945 to give effect to regulation of medical devices in a phased manner. Since the phased regulation has its initial challenges, the Department of Pharmaceuticals is working closely with MoHFW to resolve the issues faced by the medical device industry. Further, since the medical devices are also regulated for various other purposes by different departments, the Department keeps engaging with all such regulators in the spirit of ease of doing business and reduction in compliance burden for the sector.

Further, owing to the diversified nature of the industry which includes both the domestic manufacturers and international suppliers of medical devices, it is natural to have a diversity of views on issues concerning the sector. Accordingly, to follow a consensus approach on such issues for the larger benefit of the sector, the Department has constituted a "Standing Forum of Medical Associations" to deliberate upon different issues that are referred to it by the Department and arrive at a set of policy which, in turn, enables the Department to undertake consultation with the wider range of stakeholders including regulatory authorities.

3.3.4 Uniform Code for Medical Devices Marketing Practices

The industry has been constantly raising the demand for having a separate code for marketing practices of medical devices instead of Uniform Code for Pharmaceuticals Marketing Practices which primarily caters to pharmaceutical drugs. The Uniform Code for Medical Devices Marketing Practices (UCMDMP) is at advanced stage of consultation with stakeholders after which it shall be finalized for implementation.

3.3.5 National Medical Device Policy

The Medical Device Sector is a sunrise sector and is witnessing significant growth. A National Medical Device Policy (NMDP) would give a direction and certainty to the industry and acts as guidance to the sector. This will also enable the Department to have a focused approach for the sector. The draft NMDP is under active consultation with stakeholders and will be soon finalised. The policy would aim to facilitate an orderly growth of the medical device sector to meet the underlying objectives of accessibility, affordability, safety and quality, while ensuring focus on self-sustainability and innovation. The policy would act as an enabler for the sector to realize its full potential by covering the various aspects of the sectors.

CHAPTER 4

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

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 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. The first Jan Aushadhi Kendra was opened on 25.11.2008 at Amritsar, Punjab. The scheme didn't take off and by 31.03.2014, only 80 stores were functioning.

In 2015, Committee of Secretaries set up by Hon'ble Prime Minister to deliberate on health-related issues had recommended that "Jan Aushadhi Kendras" should be expanded.

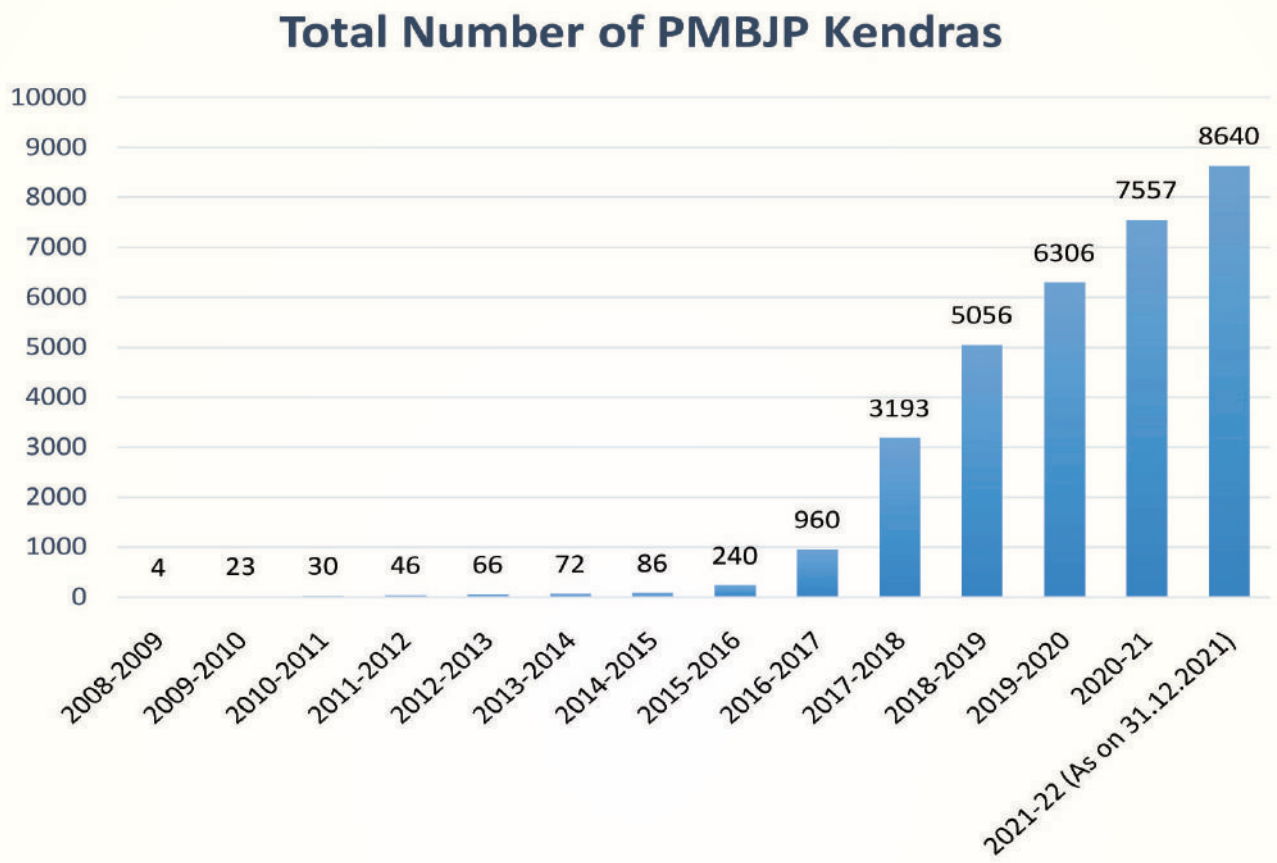
Accordingly, franchisee like model was adopted and an intensive media campaign in national and regional newspapers inviting individual entrepreneurs to apply for establishing and running PMBJP Kendra was undertaken. In response, the applications received were scrutinized and eligible applicants were assisted with drug license and other infrastructure facilities to open the Kendras. The gate was opened for private participation in procurement as well as sale of medicines.

The target of opening 3000 Kendras was achieved in December 2017. Further, revised target of total 6000 outlets was achieved in March, 2020. As on 31.12.2021, 8640 Janaushadhi Kendras are functional across the country. Product basket of PMBJP comprises 1451 drugs and 240 surgical equipment. PMBJP has decided to include AYUSH products, specifically 75 Ayurvedic drugs in the product basket of the Pariyojana. An e-tender has been prepared by PMBI for procurement of the same.

Journey so far

Graph-4A

(Year wise Progress in the total number of PMBJP Kendras)



4.1.1 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.

4.1.2 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 01.12.2008 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 approval of the Governing Council set up under the chairmanship of the Secretary of the Department.

4.1.3 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 and 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:

4.1.4 Normal Incentive

The incentive to Kendras run by entrepreneurs that are linked with PMBI through software has been enhanced upto ₹ 5 Lakh. The incentive is given @ 15% of monthly purchase 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.

4.1.5 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 of furniture and fixtures
ii. ₹ 0.50 lakh as reimbursement for computer, internet, printer, scanner etc.

4.1.6 Saving to a Common man

During the financial year 2019-20, PMBJP had achieved sales of ₹ 433.61 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 2020-21, sales of ₹ 665.83 Crore was achieved, which has led to savings of about ₹ 4000 Crore to the citizens as compared to the branded medicines. In the current financial year i.e. 2021-22 till 31.12.2021, PMBI has achieved sales of ₹ 652.67 Crore which led to savings of approximately ₹ 3,800 Cr. for the citizens.

4.1.7 Procurement of medicines

Product basket of PMBJP comprises of around 1,451 drugs and 240 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.

4.1.8 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 two regional warehouses at Chennai and Guwahati have been established. Another warehouse is planned to be opened during current financial year. In addition, appointment of Distributors in States/UTs is also being envisioned to strengthen the supply chain system. 39 distributors are functioning all across the country.

4.1.9 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.

4.1.10 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, analyze product comparison of Generic vs Branded medicine in the form of MRP saving etc.

4.1.11 Awareness about the Scheme

The awareness about the salient features of the Scheme is spread through various types of advertisements with like 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.

4.2 Progress Report during the last five financial years

Table-4A

(Year wise Progress of Number of PMBJP Kendras and Sales therein)

Financial Year	Number of PMBJP Kendras functional		Sales at MRP (Value in Crore)
	Yearly Addition	Cumulative	
2016-17	720	960	32.66

2017-18	2233	3193	140.84
2018-19	1863	5056	315.70
2019-20	1250	6306	433.61
2020-21	1251	7557	456.95
2021-22 (as on 31.12.2021)	1083	8640	652.67

4.3 Achievements during last one year

4.3.1 Coverage of the Scheme

As on 31.12.2021, 8640 PMBJP Kendras are functional across the country. The Pariyojana has marked its presence in every district of India by covering all the districts of the country.

4.3.2 Basket of medicines & Stock position

Product basket of PMBI comprises around 1451 drugs and 240 surgical instruments.

4.3.3 Introduction of New Incentive Plan

To make the scheme more attractive, the incentive provided to the Kendra owners has been enhanced from existing ₹ 2.50 lakh to ₹ 5.00 lakh, maximum @ ₹ 15,000 per month. Further, one time incentive of ₹ 2 lakh for computer and furniture has been approved for stores opened by women, SC and ST & any entrepreneur in aspirational districts or North-Eastern States.

4.3.4 Suvidha Sanitary Napkin

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 2018, which are now available for sale in all PMBJP Kendras across the country @ ₹ 1.00 per sanitary pad. Till now more than 19.00 crore pads have been sold through PMBJKs.

4.3.5 Inclusion of Ayush medicines in the product basket of PMBJP

Decision has been taken to include 75 AYUSH drugs especially Ayurvedic medicines in the product basket to expand the utility of *Kendras*. An e-tender has been prepared by PMBI for procuring the same.

4.3.6 Performance of PMBJP during outbreak of COVID 19

PMBI sold about 55 lacs Face Masks, 1.65 lacs units of sanitizers, 64 lacs tablets of Azithromycin and 387 lacs Paracetamol Tablets in the financial year 2021-22 till 31.12.2021 through more than 8600

Jan Aushadhi kendras functioning across the country. Under PMBJP, best quality N-95 facemask is being made available at only Rs. 25/- per unit at all PMBJKs. PMBI has also supplied drugs worth Rs. 30 crore to Ministry of External Affairs (MEA) for distribution to friendly countries.

There are many medicines and OTC items, being used during the treatment of COVID-19, available in PMBJP basket. As mentioned above, various items have been made available through PMBJPKs for citizens in their respective areas.

4.3.7 Launch of new range of Nutraceutical Products

To benefit public health, Pradhan Mantri Bhartiya Janaushadhi Pariyojana has recently launched several Nutraceutical products to help boost the immunity of all (including women and children). PMBJP prices of all these products are 50%-90% lesser than the one offered in the market.

4.3.8 Steps taken for increasing viability of kendras

Number of Kendras increased to 8640 from 7557 in the last financial year. Average monthly sales turnover per store has also increased from ₹ 51,000/- to ₹ 66,000/-. Further, kendras have been permitted to sell OTC & allied cosmetic products.

As per survey conducted by PMBI, total average sales per kendra is coming up to ₹ 1.50 lacs p.m. (including Jan Aushadhi medicines of ₹ 66,000/- and rest from OTC products, nutraceuticals and cosmetics).

(i) New medicines and nutraceuticals product like glucometer, protein powder, malt-based food supplements have been launched where per unit margin is more.

(ii) New norms introduced to maintain distance between two kendras in order to avoid un-healthy competition.

(iii) Department has taken various steps to ensure market expansion. State Health departments and associated government authorities have been requested to open Jan Aushadhi Stores in various government hospitals by providing rent free spaces to private individuals. Stores have also been categorized and more focus given on A and B category stores.

(iv) To ensure awareness among masses, various media platforms like print, outdoor, TV & social media, etc. are being used regularly. Government is also adopting an integrated approach for spreading awareness about PMBJP with State Governments. Promotion workshops are also being organized across India with store owners, doctors and various important dignitaries.

(v) Product basket has also been expanded to provide complete range of medicines for increasing footfall to the kendras. At present 1451 drugs and & 240 surgical equipment are available in the product basket of PMBJP.

4.4 Jan Aushadhi Diwas Celeberation

All PMBJP Kendra owners celebrated 7th March 2021 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.

Hon'ble Prime Minister himself spoke to the beneficiaries of the scheme through video conferencing on the occasion of Jan Aushadhi Diwas on 7th March 2021.

Celebration of Janaushadhi Diwas 2021

Union Ministers of India at celebration of Janaushadhi Diwas 2021

Shri Trivendra Singh Rawat,
Hon'ble Chief Minister, Uttarakhand

Shri Piyush Goyal
Hon'ble Minister for Ministry of Railways
& Minister of Commerce and Industry

Shri Mansukh Mandaviya,
Minister of State for Chemicals &
Fertilizers and Shipping

Shri Rattan Lal Kataria,
Hon'ble Minister of Jal Shakti and
Ministry of Social Justice and Empowerment

Shri Pralhad Joshi,
Hon'ble Minister for Ministry of
Parliamentary Affairs, Coal and Mines

4.5 Azadi Ka Amrit Mahotsav

Azadi Ka Amrit Mahotsav is an initiative of the Government of India to celebrate and commemorate 75 years of progressive India and the glorious history of its people, culture, and achievements. In this connection, PMBI organized various activities/events on 10.10.2021 at 750 locations covering all states and UTs of the country. These activities were dedicated to the Senior Citizens of India who have not only been instrumental in bringing India thus far in its evolutionary journey but also hold within them the power and potential to enable Prime Minister's vision of activating India 2.0, fueled by the spirit of Aatma Nirbhar Bharat.

A full day event was organized at 34 supreme locations and 2 iconic locations where Health Check-up Camps, Jan Aushadhi Paricharcha and free distribution of First Aid Kits to 75 and above aged senior citizens were organized by PMBI.

Similarly, at 714 different locations, events were organized where 75 "First Aid Kits" at each location have been distributed to 75 and above aged senior citizens. 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 50,000 beneficiaries provided this "First Aid Kits" of PMBJP products. A brochure/e-brochure containing message of the Hon'ble Prime Minister was also distributed during these events, as a part of the First Aid Kit. Approximately, 1 Lakh citizens attended Health Check-up Camp, across the country.

One iconic event organized at Bangalore, Karnataka in the presence of Dr. Mansukh Mandaviya, Hon'ble Minister of Health & Family Welfare and Chemicals & Fertilizers, Shri Basavaraj Bommai, Hon'ble Chief Minister of Karnataka, Shri Tejasvi Surya, Hon'ble Member of Parliament Bangalore South along with other dignitaries. Around 1,000 citizens attended this iconic event.

Another iconic event organized at Bidar, Karnataka, was attended by Shri Bhagwanth Khuba, Hon'ble Minister of State for Chemicals & Fertilizers and New & Renewable Energy, Shri Prabhu Chauhan, Minister of State for Animal Husbandry, Department of Karnataka, Shri Ishwar Khandre, Hon'ble MLA Bhalki, Shri Bandeppa Khashempur, Hon'ble MLA, Bidar (South), Shri Sharnu Salgar, Hon'ble MLA, Humnabad, along with other dignitaries. The event was attended by about 1000 participants.

Distribution of Certificate by Dr. Mansukh Mandaviya, Hon'ble Minister of Health & Family Welfare and Chemicals & Fertilizers in presence of Shri Basavaraj Bommai, CM Karnataka and Shri Tejasvi Surya, MP Bangalore South

Certificate distribution during iconic activity organised during Azadi ka Amrit Mahotsav

4.6 Unity Day Week - 2021

National Unity Day week or Rashtriya Ekta Diwas is celebrated on October 31 every year to mark the birth anniversary of Sardar Vallabhbhai Patel. This year PMBJP celebrated "National Unity Day" week and organized "Jan Aushadhi Mitra Sammelan" at 75 locations across the country on 29.10.2021 covering all State/UTs.

Events were organized at 75 locations including one iconic location where Jan Aushadhi Mitra Sammelan were organized by PMBI. In this Sammelan's, interactive sessions were held in the presence of State/UT officials, Public Representatives, Doctors, Health Workers, Nurses, Pharmacists, Jan Aushadhi Mitra's and other stakeholders to discuss about the PMBJP and its salient features and achievements. More than 10,000 Jan Aushadhi Mitras and Jan Aushadhi Prabuddh's participated in these events, across the country.

National Unity Day celebration through PMBJP

CHAPTER 5

National Institutes Of Pharmaceutical Education & Research (NIPERs)

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National Institutes of Pharmaceutical Education & Research (NIPERs)

5.1 Background

Indian Pharma Industry has been a global leader in Generic drugs. In order to acquire leadership position in drug discovery and development and to continue to excel in the formulations, the Government recognized that 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, NIPER Act, 1998 and was declared as an Institute of National Importance.

During 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institutes. Subsequently, NIPER at Madurai was approved in 2012. During 2015-16, Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh, Maharashtra and Rajasthan. Another NIPER is proposed to be set up at Bengaluru, Karnataka.

The present status of seven existing NIPERs is as under:

Table-5A
(Present Status of NIPERs)

NIPER	Academic session started in	Status of land/construction
Mohali	1998	NIPER, Mohali has its own campus in 129.25 Acres of land.
Ahmedabad	2007	60 acres land in Gandhinagar, Gujarat has been allocated and Hindustan Steelworks Corporation Limited (HSCL) has been selected as Project Management Consultant (PMC). The tender for construction of campus has been finalized. Construction has begun.
Guwahati	2008	51.42 acres land at Village Sila, Changsari Dist, Kamrup has been allocated and Engineering Projects India Limited (EPIL) has been selected as Project Management Consultant (PMC). Construction was started in June 2015. More than 95% construction work of the campus has been completed.
Hajipur	2007	12.5 acres of land at EPIP Campus, Industrial Area, Hajipur has been allocated by Govt. of Bihar.
Hyderabad	2007	Government of Telangana has allocated 50 acres of land for construction of NIPER-Hyderabad campus. The Department has proposed to allot 50 acres of IDPL land to NIPER-Hyderabad for construction of its permanent campus.
Kolkata	2007	10 acres of land at Mouza-Gopalpur, P.S. Kalyani, Dist Nadia has been allocated by Govt. of West Bengal. The Department has allotted 20.55 acres of land of BCPL, Panihati, Kolkata for construction of its permanent campus.
Raebareli	2008	49 acres land at Village Vinayakpur, Pargana Bachrawan, Tehsil Maharajganj, Raebareli has been allocated.

5.1.1 Aims and Objectives

The 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 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 the developing countries,

(xiv) To act as nucleus for interaction between academic and industry by encouraging 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.

5.1.2 Administrative structure of NIPERs

NIPER Act was notified in the year 1998 (amended in 2007), NIPER Statutes were notified in 2003 (amended in 2014), NIPER Ordinances were notified in 2005 (amended in 2014). Parliament has passed NIPER (Amendment) Bill 2021 in the winter session for making certain amendments in NIPER Act, 1998, which includes rationalizing the composition of the Boards of Governors, setting up of a NIPER Council under the chairmanship of Hon'ble Minister of Chemicals & Fertilizers and enabling these Institutes to start undergraduate, integrated and other short term and online courses.

5.1.3 Board of Governors, Directors and other Committees

Board of Governors (BoG) of the respective Institute is responsible for general superintendence, direction and control of its affairs. Chairman, BoG is appointed by the Visitor. Director of the Institute is appointed by the BoG with prior approval of Visitor. The last BoG of NIPER Mohali was constituted on 03.10.2016 for a term of three years, which expired on 02.10.2019. The First BoGs of other six NIPERs were constituted for a period of three years on 09.03.2019.

Table-5B

(List of Chairpersons-BOG/Directors of NIPERs)

NIPER	Chairman: BoG NIPERs	Director -NIPERs
NIPER-Ahmedabad	**Dr. Ketan R. Patel** Chairman-cum Managing Director, Troikaa Pharmaceuticals Ltd., Gujarat	Vacant
NIPER-Guwahati	**Dr. S Chandra Shekhar** Director, CSIR-IICT, Hyderabad	Dr. USN Murty
NIPER-Hajipur	**Prof. Sanjay Singh** Vice Chancellor, Babasaheb Bhimrao Ambedkar University, Lucknow	Dr. Gayathri V. Patil (Suspended) Dr. V. Ravichandiran (Additional Charge)
NIPER-Hyderabad	**Dr. Satish Reddy** Chairman, Dr. Reddy's Laboratory Ltd., Hyderabad	Dr. Shashi Bala Singh
NIPER-Kolkata	**Prof. (Dr.) Bhabatosh Biswas** Former Vice Chancellor West Bengal University of Health Sciences, Kolkata	Dr. V. Ravichandiran
NIPER-Raebareli	**Prof. Rakesh Kapoor** Director, Sanjay Gandhi PGIMS, Lucknow	Vacant Dr. USN Murty (Additional charge)
NIPER-Mohali	Yet to be constituted	Prof. Dulal Panda

5.1.4 National Institutional Ranking Framework (NIRF)

As per National Institutional Ranking Framework of the Ministry of Education, under the 'Pharmacy' category, six NIPERs are amongst the top thirty-three pharmacy Institute in the country, as under:

Table-5C
(Year wise NIRF ranking of NIPERs)

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

5.1.5 Funds released during last 5 years

Table-5D
(Year wise Release of Fund to NIPERs)

Year/ NIPERs	Moh	Ahm	Guw	Haj	Hyd	Kol	Rae	Total
2017-18	44.81	27.96	52.00	5.00	30.00	11.50	9.50	**180.77**
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*	37.00	25.00	38.70	21.00	38.00	27.64	17.00	**204.34**
Total	**201.96**	**143.96**	**247.55**	**66.50**	**163.50**	**103.96**	**86.51**	**1013.94**

* Till 31.12.2021.

5.1.6 Admission process

Admissions are made through a common Joint Entrance Examination (JEE) held every year in the month of June/July for admission in various branches in MS/Ph.D. The applicants, who have qualified Graduate Pharmacy Aptitude Test (GPAT), are eligible to appear in 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

5.1.7 New Initiatives

As part of recent initiatives, NIPERs have been associated for providing technical assistance, testing facilities, etc. under recently launched PLI, Parks Schemes. M.Tech (Medical Devices) courses have

been started in four NIPERs. Medical Device Testing Facilities are being started in NIPERs. A detailed report in this regard has been prepared and accepted at the level of Hon'ble Minister for Chemicals & Fertilizers and steps initiated for obtaining NABL accreditation for testing labs. Steps have been taken for enhanced Academia Industry Linkage, enhanced collaboration amongst NIPERs and with Research Institutions of other Departments.

5.1.8 Recent Research Initiatives

Drug Development for Affordable Healthcare: One of the recommendations of the Budget webinars organized by Ministry of Education was to implement a Programme on "Drug Development for Affordable Health care" in mission mode. NIPERs have taken the lead, prepared draft proposal & after detailed inter departmental consultations identified areas for Drug Discovery and Development (four diseases where already reached proof of concept stage - Antimicrobial Resistance, Oral Cancer, Chronic obstructive pulmonary disease and Breast Cancer) and Drug Discovery (based on ICMR 2019 report on top ten diseases in India). The Report was considered in the meeting of Inter-departmental committee on Pharma Research chaired by Secretary Pharmaceuticals and has since been submitted to the National Research Foundation (NRF) for funding.

Common Research program: In order to align Research as per needs of country, all NIPERs have come together with a Common Research Programme by sharing their expertise and Resources to develop cost-effective, sustainable & affordable process for synthesis of 16 API & 2 KSM materials and each NIPER to take up a molecule as per their expertise and work in areas relating to Process technology, Product development / Novel drug delivery, Biosimilars, Off patented Drugs, Biologicals / Pharmacology and toxicology and Drugs repurposing for new indications.

5.1.9 Financial Resilience

The financial pressure on higher educational institutes continues to raise as expenses are growing while financial support from government will continue to decline in future. The current imbalanced expense and revenue structure demand for aggressive pursuit of alternative revenues. NIPERs too, in the quest of achieving self-reliance, are searching for alternative revenue sources. In this context, a roadmap has been prepared for NIPERs for next 15 years suggesting alternative revenue sources, achievable & measurable targets and recommendations for policy level changes, if required.

5.2 NIPER S.A.S Nagar (Mohali)

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

NIPER S.A.S. Nagar has a campus that caters for research facilities, three boy's hostels with intake capacity of 472 and a girl's hostel with intake capacity of 220, 18 married hostels, 133 quarters (Type–II –

12, Type-III – 36, Type-IV – 30, Type-V – 42, Type-VI – 12, Director Bungalow – 1) for the NIPER staff. Board of Governors has been constituted to oversee its functioning. NIPER offers Masters' and Ph.D. degrees in 16 streams and caters to the various needs of pharmaceutical industry.

5.2.1 Achievements

In 2021-22, the Institute has published 76 articles in journals of repute (till 31.10.2021). Institute has filed 198 patents applications and out of which 109 patents are granted/issued till date. Since the inception of academic programme (till 08.11.2021), 4004 students have passed out (Masters 2968, MBA 689 & Ph.D. 347).

5.2.2 Research areas in NIPER SAS Nagar

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

B. **Other diseases -** Metabolic pathways in diseases like inflammation, infection, cancer, diabetes, obesity, Parkinson's disease, neurodegeneration 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 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
(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
(Status of Academic and Non –Academic Staff)

Man-Power	In-Position
Academic	25+1(Director)
Non-Academic	120

5.2.4 Total fund allocated by the Government during the last 4 years

Table-5F
(Year wise allocation of fund)

(₹ In crore)

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	37.00	37.00*

*Fund released till 31.12.2021.

5.2.5 Students

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

Table-5G
(Status of Admissions in various Desciplines)

Level Masters/ Doctoral	Degree MS/MBA/M.Tech/ Ph. D	Discipline	Year wise Admission	
Years			2020-21	2021-22
Masters'	M.S.(Pharm.)	Medicinal Chemistry	26	28
Doctoral	PhD			6
Masters'	M.S.(Pharm.)	Pharmaco-informatics	17	20
Doctoral	PhD		1	6
Masters'	M.S.(Pharm.)	Natural Products	13	14
Doctoral	PhD			7
Masters'	M.S.(Pharm.)	Traditional Medicine	5	5

Masters'	M.S.(Pharm.)	Pharmaceutical Analysis	9	9
Doctoral	PhD			
Masters'	M.S.(Pharm.)	Pharmacology & Toxicology	18	20
Doctoral	PhD		1	7
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)	17	17
Doctoral	PhD		1	4
Masters'	M.Tech.(Pharm.)	Pharmaceutical Technology (Biotechnology)	11	11
Doctoral	PhD			
Masters'	M.S.(Pharm.)	Pharmaceutics	20	22
Doctoral	PhD		1	7
Masters'	M.S.(Pharm.)	Biotechnology	35	38
Doctoral	PhD		3	8
Masters'	M.Pharm.	Pharmacy Practice	9	9
		Clinical Research	9	9
Doctoral	PhD	Pharmacy Practice	1	5
Masters	M. Tech	Medical Devices	11	11
Doctoral	PhD			
Masters'	MBA	Pharm. Management	46	47
Doctoral	PhD		1	2

5.2.6 Teacher-Student ratio

Table-5H

(Teacher-Student Ratio in 2021-22)

Course	Ratio (Student / Faculty)
Ph.D.	52/25= 2.08:1
Masters' (Science)	229/22 = 10.41 : 1
MBA (Pharm.)	47/3 = 15.67 : 1

5.2.7 Placement

Table-5I
(In campus/off campus Placements status)

Academic Year	Total Students	No. of students Interested	No. of students placed
2017-19	242	232	155
2018-20	224	188	153
2019-21	248	218	158
2020-22	254	243	-

Most of the students, who are interested get placements. Though number seems low as large number of Master's students prefer to get admission in PhD within the country or outside the country. Few other students are interested in setting up their own businesses.

5.2.8 Innovation/knowledge transfer

Patents and Commercialization: 198 (filed)/109 (granted)/07 (licensed) since inception

Total revenue generated FY 2020-21: ₹ 8.57 crore and FY 2021-22: ₹ 4.84 crore (till 28-10-2021)

H Index – NIPER S.A.S. Nagar – H index- 120 (till 30-09-2021 Scopus)

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, S.A.S. Nagar has encouraged the GoI to set up more NIPERs across the country to meet the growing demands of the pharmaceutical sector. In addition, NIPER has carried out training programmes for personnel from India and abroad under ITEC-SCAAP, capacity building programmes (World Bank-sponsored) and SMPIC. There also has been participation of the institute in rebuilding of public sector enterprises like IDPL, BCPL, HAL, etc.

Skill development trainings under skill vigyan program were sanctioned by PSCST & DBT program for different roles in pharmaceutical industry.

- Training and analytical services provided to small and medium-scale enterprises (SMEs): Setting up of a centre for SMEs
- Member of committee evaluating 'Investigational New Drugs' (IND) applications, PLI scheme
- 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 MoH&FW (GOI)

5.2.10 MoUs/Agreements signed recently

Table-5J
(Status of MoUs/Agreements signed)

Sl. No	Party to the MOU	Date of Execution
1	Zeon Lifesciences Limited, Paonta Sahib, (HP)	22-10-2021
2	Bristol-Myers Squibb Company, New Jersey, USA	30-09-2021

Flag Hosting on Independence Day-2021

Swachhta Pakhwada, September 1-15, 2021

Programs organised during NIPERs Week, Azadi ka Amrit Mahotsav, October 4-9, 2021

4.10.2021 : Hon'ble Minister (Chemicals & Fertilizers) inaugurated NIPER Week long programme for all seven NIPERs from 4th -9th October, 2021, followed by lecture on Story of Pharma @ 75 : Future opportunities

5.10.2021 : Industrial leadership conclave: The role of pharmaceutical industry in development of India since Independence

6.10.2021 : Popular Science Lectures (Academic): Drug Discovery @ 75

7.10.2021 : Alumni Interaction/Presentation: Experience at NIPER and in real world

8.10.2021 : Exhibition at Pharmaceutical Heritage Centre and Medical Plant Garden

9.10.2021 : Popular Science Lectures : Drug Discovery @ 75

Rashtriya Ekta Diwas- Weeklong Celebrations, October 24-31, 2021

24.10.2021 : Lecture on "Scientific Development of India in the last 75 years with reference to Pharma.

25.10.2021 : Unity March at NIPER, Mohali

26.10.2021 : Poster making competition on Ideas @ 75 National Security, Ideas @ Innovation, Peace and Unity, Ideas @ 75 Sustainability.

27.10.2021 : Essay Writing Competition

28.10.2021 : Patriotic Play was organized at NIPER Convention Centre, Mohali.

29.10.2021 : Unity Rally organized in city around NIPER, Mohali.

30.10.2021 : A cultural programme depicting the vivid Indian culture organized by NIPER students.

31.10.2021 : Lectures on "Post – independence development in Indian Pharmaceutical Industry.

5.3 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 princi-

pal 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 the state-of-the-art facilities for carrying out advanced research in the areas of pharmaceutical importance.

5.3.1 Achievements

Table-5K
(Achievements of NIPER Hyderabad)

Sl.No.	Particular	Achievement
1	Master Students Passed Out	1205
2	Master Students pursuing course	340
3	Students pursuing Ph.D course	120
4	Doctoral degree awarded	78
5	Patents (filed)	20
6	Research Publications	783
7	Sanctioned extramural research projects	44

5.3.2 Details of Faculty & Staff

(i)	Regular Faculty	: 20
(ii)	Regular Staff	: 12
(iii)	Contractual Faculty	: 06
(iv)	Contractual Administrative and Technical Staff	: 02

5.3.3 Total Allocation by the Government during the last 4 years

Table-5L
(Year wise Allocation of fund)
(₹ In crore)

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	38.00	38.00*

*Fund released till 31.12.2021.

5.3.4 Teacher-Student ratio

Presently 1:12

5.3.5 Employability/ Placements Status

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-5M
(Status of in-campus/off campus placements)

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

5.3.6 Teachers

NIPER 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 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.

5.3.7 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

5.3.8 Innovation / knowledge transfer

- Patents and commercialization- 15 patents filed in areas of Cancer Drug Discovery, Formulation Development and Analytical Method Development
- Internal Revenue Generation: 10.52 Crore (FY 2020-21)

5.3.9 Impact of NIPER

Creation of human resources by imparting high quality education and training in pharmaceutical sciences helped the pharmaceutical industry.Serve 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 Pharmaceutical Industry in the country.

5.3.10 Innovation / knowledge transfer 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
- Sarvotham Care Limited
- Babasaheb 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
- Lifeactivus 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, Andhra 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

5.3.11 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.

Address of Secretary (Pharma) in 9th Convocation organized by NIPER-Hyderabad

9th Convocation organized by NIPER-Hyderabad on 24th July, 2021

Hindi Diwas celebrated at NIPER-Hyderabad on 14th September 2021

NIPER-Hyderabad conducted 2 days workshop on 3D Printing & 3D Bioprinting on 23-24 September 2021

NIPER Hyderabad organized Industry Connect on 18th October 2021

NIPER Hyderabad Members taking Integrity Pledge as part of Vigilance Awareness Week on 26th October 2021

5.4 NIPER- Ahmedabad

NIPER-Ahmedabad was set up in 2007 is currently functioning from a transient, temporary building on a 60-acre landsite 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) and from academic year 2020 NIPER-A has started Master's Program in MBA (Pharm.). The interdisciplinary courses and cultural diversity at NIPER Ahmedabad sparks 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 the pharmaceutical education and research and to initiate the new era of Pharmaceutical and biomedical sciences.

Construction of campus: Construction of Campus of NIPER Ahmedabad has been started from FY 2020-21 by HSCL, PMC appointed for the same. Around 10% of work has been completed.

5.4.1 Achievements

National Institute Ranking Framework-2021 (NIRF): The Institute has been Ranked All India Ranking of #10th among all Pharmacy Educational and Research Institutions in India as per NIRF 2021 released by Ministry of Education, Government of India.

Atal Ranking of Institutions on Innovation Achievements-2020 (ARIIA): The Institute has been placed in Band A (Rank Between-11th– 25th) Under the category of Publicly Funded Institutions.

Publications: The Institute has published 636 articles in peer reviewed journals of repute with total citations of 8094.

Patents: Institute has filed up till now 14 patents wherein faculty or students of NIPER-Ahmedabad are inventors.

MoU Signed: Institute has 25 MoUs signed till now for different academic institutes and industry.

CAS Registry Number: 15 Novel compounds synthesized at NIPER Ahmedabad received CAS Registry Number.

5.4.2 Students in MS Programme

(i) 714 M.S Pharm. students have already graduated from NIPER- Ahmedabad and are well placed in various Pharma industries in India and abroad.

(ii) Presently, 297 students are pursuing their M.S. (Pharm) and MBA (Pharm) course in 8 disciplines.

5.4.3 Students in PhD Programme

(i) 16 students have been awarded Ph.D. Degree till date.

(ii) 85 students are continuing for their Ph.D. studies.

5.4.4 Placement of Students

100% placement of willing students has been achieved

5.4.5 Details of Faculty & Staff

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

Table-5N
(Status of Regular and Contractual Staff)

Position	Regular	Contractual
Faculty Position	20	1
Non-Faculty Position	17	7

5.4.6 Total Allocation by the Government during the last 4 years

Table-5O
(Year wise Allocation of Fund)

(₹ In crore)

Year	Allocation BE	Allocation RE	Total Release
2018-19	12.00	12.00	12.00
2019-20	15.00	18.50	18.50
2020-21	36.50	60.50	60.50
2021-22	40.00	25.00	25.00*

* Fund released till 31.12.2021

5.4.7 Students

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

Table-5P

(Status of Admissions in various disciplines)

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

*PhD Project Seats

Table-5Q

(Year wise Status of Admissions in various disciplines)

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

*PhD Project Seats

5.4.8 Teacher-Student ratio

Presently 1: 18.1 (21 Faculty: 382 students)

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

Table-5R
(Year wise Status of Placement)

Batch	Total no of student	Not placed	Total no of student placed	Going for higher studies
2017-19	72	1	46	25
2018-20	96	13	65	18
2019-21	107	2	83	22

5.4.10 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.

5.4.11 MoUs signed During 2020-21

Table-5S
(Status of MoUs signed)

Sl. No	MOU Details	MOU Date
1	Novartis Healthcare Pvt. Ltd., Switzerland	11-06-2020
2	Novugen Pharma (Malaysia) SDN BHD 3, Jalan Jururancang U1/21, Hicom-glenmarie Industrial Park, 40150 Shah Alam, Selangor, Malaysia	31-08-2020
3	All India Institute of Medical Sciences, Jodhpur	04-09-2020
4	State Implementing Agency (SIA) Gujarat Industrial Development Corporation (GIDC) Block 3,4,5 Udhyog Bhavan sector -11 Gandhinagar 382011	22-09-2020

5	IIT Gandhinagar, Gujarat 382355	12-10-2020
6	Intas Pharmaceuticals Ltd., 2nd Floor, Chinubhai Center, Ashram Rd, Ahmedabad, Gujarat 380009	09-11-2020
7	AIIMS, Bhopal	18-2-2021
8	Nestle food safety Institute, Manesar Gurugram, Haryana	13-7-2021

5.4.12 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

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

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

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 Ayurvedic polyherbal formulations

Department of Pharmaceutical Analysis:

- Drug-excipient compatibility studies
- Forced degradation studies of APIs and NCEs using HPLC, LC-MS/MS and qNMR

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
- 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
- Parkinson's Disease

5.4.13 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 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.

5.4.14 Awards/Achievement

(i) **National Institute Ranking Framework-2021 (NIRF):** The Institute has been Ranked All India Ranking of #10th among all Pharmacy Educational and Research Institutions in India as per NIRF 2021 released by Ministry of Education, Government of India.

(ii) **Atal Ranking of Institutions on Innovation Achievements-2020 (ARIIA):** The Institute has been placed in Band A (Rank Between 11th – 25th) Under the category of Publicly Funded Institutions.

(iii) **CAS Registry Number:** 15 Novel compounds synthesized at NIPER Ahmedabad received CAS Registry Number.

5.4.15 Patents

The Institute filed 6 patents during the financial year 2020-21

5.4.16 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:

JanAndolan Campaign organised on 14-10-2021

A Workshop on Career in Medical Writing and Project Management: From an Expert's Perspective (27-10-2021)

Vigilance Awareness Week (27-10-2020 to 2-11-2020)

Celebrating Constitution Day (26-11-2021)

5.5 NIPER-Guwahati

NIPER Guwahati started functioning from 2008 under the Mentor Institute, Guwahati Medical College, Guwahati up to July 2017. Dr. USN Murty took over the charge of the Director of the Institute from 03.11.2016. NIPER-Guwahati is now functioning from its own permanent campus at Changsari, Kamrup (Rural), North Guwahati, Assam from January 2020.

This institute owns Eight (08) 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 Min. of Electronics & IT, and
(viii) Pharmacovigilance Centre from Indian Pharmacopoeia Commission (IPC) Ghaziabad, Min. of Health & Family Welfare.

5.5.1 Achievements

(i) Ph.D. – 60 (enrolled), Degrees Awarded – 13 (since inception),
(ii) Total M.S. (Pharm.) (since inception),
Students enrolled – 563
Graduated – 389 (170 students are currently pursuing their PG Courses)
(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, 303 articles have been published since inception in peer-reviewed International journal out of which 78 articles have been published in 2020-21 in various National and International Journals.
(v) Institute has total 13 patents including 02 design patent and 2 copyrights. 06 Patent got published in 2020-21 by Indian Patent Office.

5.5.2 Details of faculty & staff

Administrative Staff : 20
Multi-Task Staff : 13

Academic Staff:
Associate Professors : 06
Assistant Professors : 10 +2*
Research Associate : 04
Technical Staff : 06
*Ramalingaswami Fellow

5.5.3 Total Allocation by the Government during the last 4 years

Table-5T
(Year wise Allocation of fund)

(₹ In crore)

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	38.70	*38.70

* Fund released till 31st December 2021

5.5.4 Students

Degrees/programmes and Subjects offered (with year)

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

*Ph.D. Project Seats

5.5.5 Teacher-Student ratio

Teacher: Student Ratio: 1:11.8

5.5.6 Employability/ Placements Status

All Students of the institute were successfully placed in different premium industries/companies during on campus placement in the year of 2020-21. 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.

5.5.7 Research

Biotechnology:

Development of Biopharmaceuticals using Biomolecular Engineering/Synthetic Biology approaches –

(i) Oncogenic mRNA cleaving Deoxyribozymes
(ii) Development of new approaches of Immune rerouting for targeting cancer cells
(iii) Riboswitch mediated gene regulation of oncogenes
(iv) Generation of random Protein coding sequences & Aptamer based therapeutics and diagnostic-tools

Pharmacology and Toxicology:

(i) Molecular Pharmacology
(ii) Development of Cancer targeted drug delivery systems
(iii) Screening Indian biodiversity and Indian Systems of Medicine in search of newer compounds in the area of inflammation, arthritis, diabetes, cancer and hepatoprotective activities
(iv) Targeting RANKL for the treatment of inflammation and cancer induced bone disorders
(v) Screening of NCE's & North-East plant products for anti-Parkinson's and antidepressant effects
(vi) Studies on the mitigation of drug induced toxicities through natural products derived from North-east India

Pharmacy Practice:

(i) Study of drug utilization pattern for antiepileptic and antipsychotic drugs
(ii) Impact of Lipodystrophy on Quality of Life, Social and Psychological Aspects in PLHIV on First line and Second line Anti Retroviral regimen
(iii) Haemovigilance: An important tool for improving safe blood transfusion practices

Pharmaceutics:

(i) Dosage form design, development, optimization and evaluations for BCS-II-IV drugs
(ii) Micro-and nanotheragnosis concepts for the early detection and treatment of malignant diseases and other life-threatening diseases
(iii) Eradication of biofilm-producing microorganisms from the surfaces of implanted or inserted medical devices into human body
(iv) Ligand anchored lipid/polymer-mediated nanoarchitectonics
(v) Pharmacoengineered delivery devices to fight against neglected diseases
(vi) Pharmaceutical 3D & 4D Printing Technology
(vii) Extrusion based biofilaments processing for fused-filaments applications
(viii) Translational cutting-edge pharmaceutical research & development

Pharmaceutical Analysis:

(i) Bioavailability, IVIVC and IVIVE analysis

(ii) Analytical (ICH Guidelines) & Bio-analytical (FDA-Industry Guidance) method development & validation using HPLC, UPLC, LC- MS/MS

(iii) Short-term/accelerated, mid-term and long-term stability testing of formulations and degradation studies.

(iv) Pharmacokinetic, Toxicokinetic, Metabolic and Impurity profiling

5.5.8 Student's enrolment

Current strength of Ph.D. students: 46
(Pharmacology & Toxicology-13; Biotechnology-07; Pharmacy Practice-07; Pharmaceutics-11; Pharmaceutical Analysis-06 and Medicinal Chemistry-2)

Current strength of Master's Students: 170
(Pharmacology & Toxicology-30; Biotechnology-18; Pharmacy Practice-18; Pharmaceutics-36; Pharmaceutical Analysis-37; Medicinal Chemistry-11; Pharmaceutical Technology (Formulation-11 and Medical Devices-09)

5.5.9 Patents and Commercialization

Institute has in total 13 patents and 2 copyright, of which 02 is design patent, where 02 patents & 01 design patent got granted by Indian Patent Office.

5.5.10 Collaboration

NIPER-G entered into 36 active MoUs. During the financial year 2020-21, NIPER-Guwahati has exchanged MoUs with the many pioneer institutes like CSIR-CDRI, Lucknow, AIIMS-Bibinagar, Telengana, AIIMS-Jodhpur, ISBD-Manipur, AMTZ-Vizag, A.P, etc.

5.5.11 Impact of NIPER

The establishment of NIPER-Guwahati has given a strong boost to the promotion of Pharmaceutical Education & Research in the North Eastern region of India. Research efforts of NIPER Guwahati have revived the studies on medicinal value of local herbs of North Eastern Region against various diseases. NIPER-Guwahati has organized several virtual/physical conferences, meeting, workshop, skill development programme, etc. to promote & foster entrepreneurship culture in NER. This institute is supporting traditional healers & 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.

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

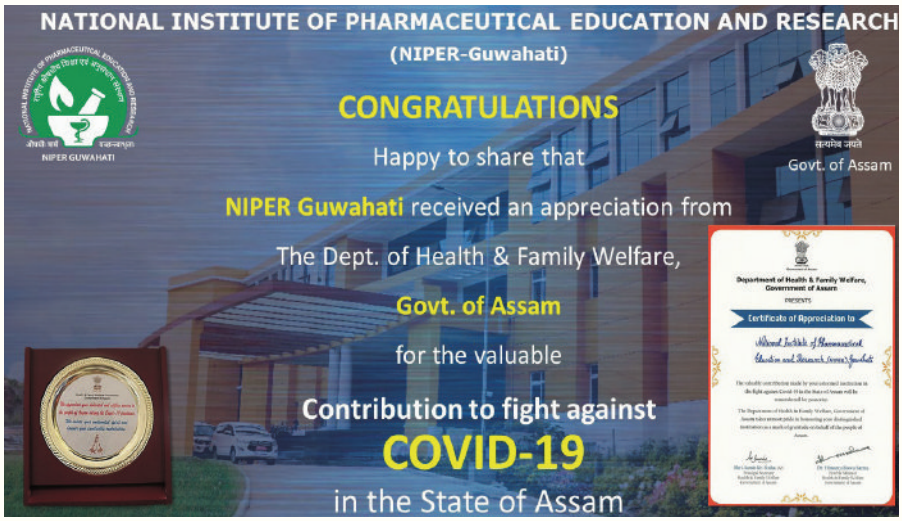
Table-5V

(Year wise status of students received M.S./M. Pharm. Degree)

Sl. No.	Batch	Number of students enrolled	Number of students received degree
1	2015-17	26	26
2	2016-18	35	35
3	2017-19	39	39
4	2018-20	65	65
5	2019-21	70	70
Total		**170**	**170**

Some Photographs

NIPER-Guwahati handed over their synthesized & validated first reference standard material to National Dope Testing Laboratory (NDTL). New Delhi, India.



NIPER-Guwahati did immense contribution to the state of Assam during COVID outbreak

Design granted & patented "A face protecting device" signed for the mutual non-disclosure agreement, & technology is transferred to Hindustan Antibiotics Limited (HAL, a *Govt. of India Enterprise under Ministry of Chemicals and Fertilizers, Govt. of India), Pimpri, Pune, Maharashtra.*

NIPER-G entered MoU with 04 potential innovators from NER for rollout of their BIG-NER projects on their innovations

5.6 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 with 150 enrolled students. It is currently running from its transit campus in Lucknow with a world class central Instrumentation facility within its premises and an animal house to perform pre-clinical studies.

5.6.1 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 16 patents and one copyright till 2020-21.
- The Institute received nearly ₹ 1.50 Cr. as extramural research grant for research in the thematic areas of the Institute.
- More than 150 publications in last 3 years (74 publications in the current year) in the journals of international repute.
- Central Instrumentation Facility was created housing sophisticated instruments such as Nuclear Magnetic Resonance (NMR), LC-MS (QTOF-HRMS), HPLC, FT-IR, Flow-cytometry, Animal imaging system, DSC, and Confocal system etc.

5.6.2 Academic/Non-Academic staff

Administrative Staff : 05
Multi-Task Staff : 13

Academic Staff:

Associate Professors : 05
Assistant Professors : 11
Research Associate : 01
Staff: Technical : 03

Second Phase recruitment for regular staff is under process and the posts are likely to be filled shortly.

5.6.3 Total fund allocation by the Government during the last 4 years

Table-5W
(Year wise Allocation of fund)

(₹ 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	26.00	26.00	*17.00

*Fund released till 31.12.2021

5.6.4 Students

Table-5X
(Year-wise status of Degrees/programs and subjects offered with admission)

Year	M.S. (Pharm) Admission	M.S. (Pharm) Completion	PhD Admission	PhD Completion
2017-19	36	36	05	02
2018-20	56	56	06	Pursuing
2019-21	62	60	06	Pursuing
2020-22	74	Pursuing	06	Pursuing
2021-23	90	Pursuing	18	Pursuing

5.6.5 Teacher: Student Ratio

Presently - 1:13

5.6.6 Employability/ Placements Status

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Table-5Y
(Year-wise status of placement)

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	75

5.6.7 Awards/ Teachers

Table-5Z
(Award received by Teachers)

Name	Discipline	Recognition
Dr. Gopal Khatik	Assistant Professor Medicinal Chemistry	Selected as an expert "Drug Discovery Challenge/ Hackathon for development of anti-Covid-19 molecules" organized by AICTE, CSIR and supported by Office of Principal Scientific Advisor, Govt. of India.
Dr Rakesh K. Singh	Associate Professor Pharmacology and Toxicology	Selected as an expert "Drug Discovery Challenge/ Hackathon for development of anti-Covid-19 molecules" organized by AICTE, CSIR and supported by Office of Principal Scientific Advisor, Govt. of India.
Dr Anoop Kumar	Assistant Professor (Contract) Pharmacology and Toxicology	Selected as an expert "Drug Discovery Challenge/ Hackathon for development of anti-Covid-19 molecules" organized by AICTE, CSIR and supported by Office of Principal Scientific Advisor, Govt. of India.
Dr. Kirti Jain	Assistant Professor Pharmaceutics	Awarded with prestigious "ICMR – Shakuntala Amir Chand Award" for the year 2019. [Vide Notification No. 3/1/3/ICMR awards(3)/2019-HRD; Dated 29.12.2020]
Ashima Thakur	PhD student Medicinal Chemistry	**Best Oral presentation (1st place) award** in 12th NIPER–R E-Symposium on Translational Research & Drug Delivery System, February 15-16, 2021

Sumadhura Bomaraju	PhD student	**Best poster presentation (2nd place) award** in 12th NIPER–R symposium on Translational Research & Drug Delivery System, February 15-16, 2021
Shriyansh Srivastava	M.S. (Pharm). Student	**Best Poster presentation (1st place) award** in 12th NIPER–R E-Symposium on Translational Research & Drug Delivery System, February 15-16, 2021

5.6.8 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: 09 worth ₹ 2.40 Crore

5.6.9 Impact of NIPER

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 number of milestones and Pharma industries have shown interest in collaborating with it 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 such as *Japanese Encephalitis*, Tuberculosis and Neurodegenerative diseases. An online portal has been created to facilitate seamless sample analysis for drug discovery. The Institute is also providing highly skilled human resources for the Indian Pharmaceutical Industry.

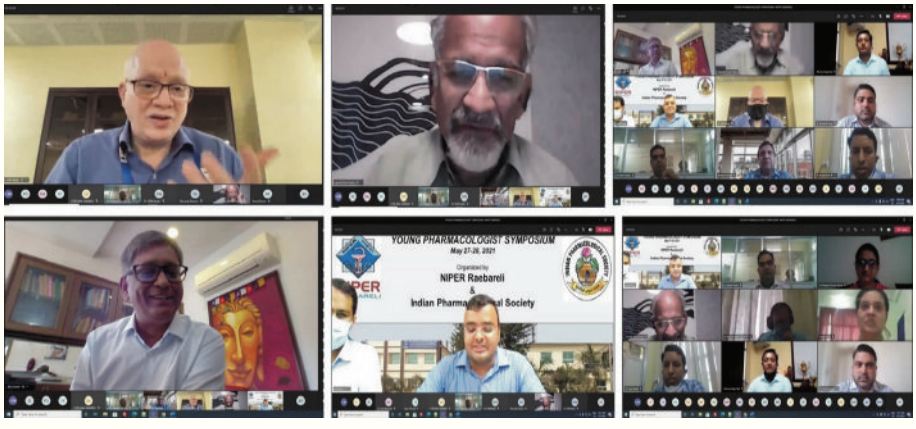
5.6.10 Various events/workshops carried out by the institute


Covid-19 Pandemic awareness Drive

World Environment Day (5th June 2021)

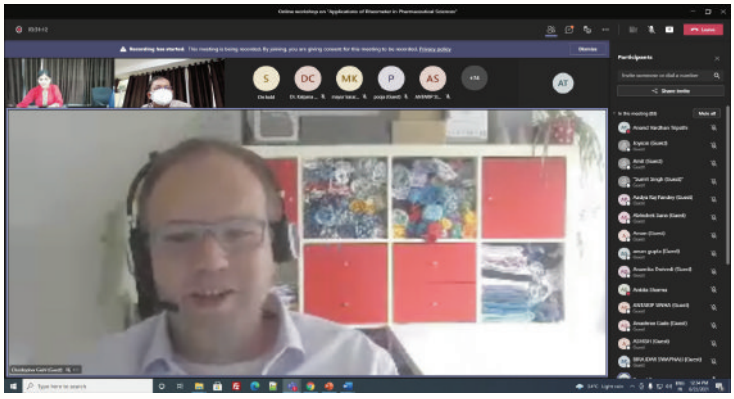
Constitution Day Activities

Dr USN Murty welcomed the torch bearer of pharmacology field, young pharmacologists and delegates to the young Pharmacologist Symposium organized at NIPER-R from 27-28 May, 2021 in association with indian pharmacological Society. He also highlighted the importance of community pharmacy, social pharmacology, and role of animal studies in vaccine research.

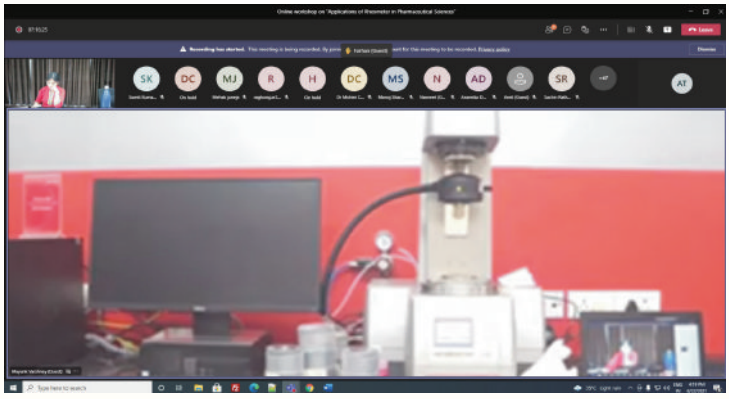


Young Pharmacologists Symposium organized in collaboration with Indian Pharmacological Society

Applications of Rheometer in Pharmaceutical Sciences" June 22, 2021



Dr. Christopher Giehl from Germany delivering lecture on Basics of Rheology and Pharmaceutical Applications



Training and live demonstration of sample analysis on Rheometer

5.7 NIPER-Kolkata

National Institute of Pharmaceutical Education & Research Kolkata (NIPER-Kolkata) was established in 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. Now, teaching and research remains central function and overriding goal.

5.7.1 Achievements

In 2020-21, 31 research papers published, 1 MoU signed. Since inception, 508 highly skilled M.S. (Pharm.) students have graduated and 4 students have been awarded Ph.D. degree.

5.7.2 Academic and Non-Academic staff

NIPER Kolkata has 12 Teaching and 13 Non-Teaching regular employees. Two teaching faculties are in contractual positions. In addition, there are 19 outsourced/contractual non-teaching employees.

5.7.3 Total allocation by the Government during the last 4 years

Table-5AA
(Year wise Allocation of fund)

(₹ In Crore)

Year	BE	RE	Total Released
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	27.64	27.64*

*Fund released till 31.12.2021.

5.7.4 Students

Degrees/Programs and Discipline offered with admission status:

Table-5AB
(Year wise status of Admission in various discipline)

Level	Degree	Discipline	No. of students admitted			
			2018-19	2019-20	2020-21	2021-22
Masters	M.S. (Pharm.)	Medicinal Chemistry	08	08	15	16
		Natural Products	08	06	06	09
		Pharmacoinformatics	03	04	03	07
		Pharmacology & Toxicology	08	13	13	17
		Rare disease	-	-	-	
		Pharmaceutics	-	-	13	18
		Medical Devices				11

Doctoral	Ph.D.	Medicinal Chemistry	-	-	03	04
		Natural Products	01	-	-	02
		Pharmacoinformatics	-		-	-
		Pharmacology & Toxicology	-	01	03	03
		Pharmaceutics	-	-	02	03

5.7.5 Teacher-Student ratio

Presently - 1:10

Academic and research activities of the institute are strengthened by Regular faculty and guest faculty.

5.7.6 Employability/ Placements Status

Most of the students have been absorbed in the industries, colleges and research institutes. A number of students are pursuing higher studies within the country as well as abroad. Placement was achieved for these students according to their options for employment in companies as well as in Institute for teaching and higher studies.

Table-5AC
(Employability/Placements Status)

Masters: M.S. (Pharm.)		
Year (Batch)	**Total No. of students**	**No. of students placed**
2016-2018	42	36
2017-2019	44	32
2018-2020	27	19
2019-2021	31	24
Total	**144**	**111**
Doctorate: Ph.D.		
2018-2022	01	01 Pursuing
2019-2023	01	01 Pursuing
2020-2024	08	08Pursuing
2021-2025	12	12 Pursuing
Total	**22**	**22 pursuing; 4 placed**

5.7.7 Recognition to Faculty

Faculty at NIPER Kolkata includes regular faculty, DST inspire faculty and other guest faculty are also involved from Calcutta University, Jadavpur University, Indian Association for the Cultivation of Science, Kolkata, Bose Institute, Kolkata, Saha Institute of Nuclear Science, CSIR-CGCRI, NICED, AIIH & PH and SSKM Hospital, TCG Life Sciences and they are well recognized in their own areas to handle academic activities of the institute which is further strengthen by having research funds from various funding agencies including

Research grants from DBT, New Delhi, WB State DBT, Kolkata, SERB, New Delhi, CCRH, New Delhi, CMERI, New Delhi. They all are involved in publishing their research work in high impact journals.

For rare diseases, there are 16 guest faculties from AIIHPH, Kolkata Medical College, Kolkata Apollo Hospital, Medica super specialty hospital, Tata Medical centre Kolkata, Drugs controller, Kolkata, CSIR-IICB etc.

5.7.8 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

Establishing Drug Testing Lab (DTL) facility for surgical dressings and drug eluting implants under process.

5.7.9 Innovation/ Knowledge transfer/ MoUs signed

NIPER-Kolkata is closely working with many regional pharmaceutical and biotechnological companies supporting their product development. NIPER-Kolkata has developed product/provided scientific data for BIOWIN products of M/s. Bio Green Remedies Pvt. Ltd. Hyderabad by computational machine, and evaluation of chlorine dioxide Gaseous Disinfection product by M/s. Inventz Life Science Pvt. Ltd. Chennai and it's currently marketed in the trade name of ORNISTOP which is widely used for eradication of bacteria, fungiand spores.

NIPER-K has extended consultancy service to M/s. Natreon INC USA Kolkata for Withaferin deriv-

atives. Indigenous ventilator has been developed by M/s. Broadline Technologies Pvt. Ltd. and CSIR-Central Electrochemical Research Institute, Karaikudi in collaboration with NIPER-Kolkata, is under clinical trials study at Government Rajaji Hospital, Madurai (Hospital affiliated to Madurai Medical College, Madurai and Tamil Nadu) and Woodlands Hospital, Kolkata.

Memorandum of Understanding with various Institutes/organizations executed to promote academic and research co-operation for fostering research work. The Institute has signed total 18 MoUs. This year the Institute has signed one MoU with Taylor & Francis.

5.7.10 Impact of NIPER

(i) A total of 508 highly skilled students have graduated
(ii) 4 scholars have been awarded with the Ph.D. degree
(iii) 339 students are engaged to work in companies/institutions
(iv) 235 high quality research papers have been published
(v) In vivo animal imaging, confocal microscopy, 3D printing and flow reactor, BSL-2 facility has been established to promote research activities at NIPER Kolkata
(vi) Currently the institute is funded by research projects to the tune of ₹ 3.9 crore from various national funding agencies
(vii) NIPER-Kolkata has developed product/provided scientific data for BIOWIN products of M/s. Bio Green Remedies Pvt. Ltd. Hyderabad by computational machine
(viii) Scientist Chair in the name of Acharya Prafulla Chandra Roy funded by M/s. Bio Green Remedies Pvt. Ltd is has been created by NIPER Kolkata
(ix) NIPER-Kolkata 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 ₹ 1 Lakh for outstanding contribution in the concept of flow reaction application in API
(x) Evaluation of chlorine dioxide Gaseous Disinfection product by M/s. Inventz Life Science Pvt. Ltd. Chennai and its currently marketed in the trade name of ORNISTOP has been conducted by NIPER Kolkata
(xi) Number of patents: One

5.7.11 Institution Leadership Impact of NIPER

NIPER Kolkata is being reaching out to various undergraduate and post-graduate institutions helping them with various research projects. Currently it has 26 outreach partners

NIPER Kolkata was involved in providing oxygen concentrator to the needy during covid crisis in collaboration with AMTZ-Visakhapatnam.

NIPER Kolkata has taken a major research drive towards developing newer strategies to tackle infectious disease, metabolic disorders and neurodegenerative disorders

The institute has conducted twelve events by virtual mode during March – October 2021. Some of the photographs of the events are given below.

5.7.12 Events organized at NIPER Kolkata

Azadi Ka Amrit Mahotsav: Pharma @75 Opportunities

Inauguration of Drugs & Medical Device Testing Facility by Chairperson, Smt. Kanimozhi Karunanidhi, MP of Loksabha

The 9th Convocation of NIPER Kolkata

Visit of the Parliamentary Standing Committee to NIPER Kolkata

5.8 NIPER-Hajipur

NIPER-Hajipur started functioning in 2007 under the mentorship of Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna till 31.10.2018. Its own first Director assumed charge 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.S. 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) with an annual intake in Biotechnology 18, Pharmacy Practice 16, Pharmacology & Toxicology 17, Pharmaceutical Analysis 10 and Pharmaceutics 11 for each course

5.8.1 Achievements

Since its inception, a total of 440 students have been passed out (M. Pharm- 424 and PhD- 16), 83 research papers have been published and 9 MoUs have been signed so far, out of those, 5 MoUs signed during this academic year (2021-22) alone. One Indian Patent was filed in November 2020.

5.8.2 Faculty & Staff

Details of faculty & staff are appended below:

Academic : Director & 09 (regular)
Non-Academic : 06 (regular), 03 (on contract)

5.8.3 Fund allocation by the Government during the last 4 years

Table-5AD
(Year wise Allocation of fund)

(₹ in Crore)

Year	Budget Estimated	Revised Estimated	Total Release
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	21.00	21.00*

*Fund released till 31.12.2021.

5.8.4 Students

Students are admitted through a common Joint Entrance Examination (JEE) of all NIPERs. The PG

sanctioned seat intake in Biotechnology 18, Pharmacy Practice 16, Pharmacology & Toxicology 16, Pharmaceutical Analysis 10 and Pharmaceutics 11. And for PhD in Biotechnology 04, Pharmacy Practice 04, Pharmacology & Toxicology 04, Pharmaceutical Analysis 02 and Pharmaceutics 01.

Table-5AE
(Status of Student intake)

Students	Male	Female	General	OBC	SC	ST	EWS +PH	Total
PG-II (current) (Batch 2020-22)	29	22	21	14	7	3	5+1	51
PG-I (current) (Batch 2021-23)	40	31	15	28	12	04	08+04	71
Ph.D. (on roll)	15	10	11	05	06	2	00+01	25

5.8.5 Teacher-Student ratio

Presently 1:10

5.8.6 Employability/ Placements Status

Table-5AF
(Placement details of NIPER-Hajipur MS Students)

Batch Year	Total No of Students	Placement		% Placement (Total)
		Industry	Higher Studies	
2017-19	32	21	04	78%
2018-20	36	05	07	33%
2019-21	42	11	17	67%

Table-5AG
(Placement details of NIPER-Hajipur PhD Students)

Batch Year	Total No of Students	Placement		% Placement (Total)
		Industry	Higher Studies	
2013-18	2	0	2	100%
2014-19	1	0	1	100%
2015-20	3	2	--	67%

5.8.7 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

- Medication safety studies such as DUE/DUR, Drug interactions/Pharmacoeconomics studies in clinical facilities
- Clinical efficacy and safety studies along with pharmacovigilance and materiovigilance activity pertaining to infectious diseases such as HIV, tuberculosis and Cancer. Further to extrapolate the molecular findings

Departmental Research Activities: Dept. of Pharmacology & 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.

5.8.8 Impact and achievements

The Institute has successfully produced 424 PG and 16 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

Some photographs

Azadi ka Amrit Mahotsav (AKAM)
Ideas@75
Innovation peace and Unity

Economy@75

Programs organised during Swachhata Pakhwara

A photograph taken during programs organised on World Pharmacists Day

Observance of Vigilance Awareness Week 2021

CHAPTER 6

PUBLIC SECTOR UNDERTAKINGS (PSUs)

CHAPTER 6

Central Public Sector Undertakings (CPSUs)

6.1 Background

There are five Public Sector Undertakings (PSUs) under the aegis of the Department, namely, Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL), Indian Drugs & Pharmaceutical Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL).

The Cabinet in April 2016, while considering a proposal for sale of part of surplus and vacant land of Hindustan Antibiotics Limited (HAL) for meeting its liabilities directed that the Minister of Finance, Minister of Road Transport, Highways & Shipping and Minister of Chemicals & Fertilizers might comprehensively examine the status of all pharmaceutical companies in the public sector and suggest the future course of action. After detailed deliberations, the Ministers recommended in December 2016 that:

i. Only that much of surplus land of Hindustan Antibiotics Limited (HAL), Indian Drugs & Pharmaceuticals Limited (IDPL), Rajasthan Drugs & Pharmaceuticals (RDPL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL) as would be required to meet the liabilities be sold through open competitive bidding to Government agencies and the outstanding liabilities be cleared from the sale proceeds. Voluntary Separation Scheme/Voluntary Retirement Scheme also be implemented in these PSUs to pave way for their closure. Remaining part of the land should be managed in accordance with guidelines of Department of Investment and Public Asset Management (DIPAM) and Department of Public Enterprises (DPE) in this regard and if need be, vested in a SPV created for this purpose.

ii. After liabilities have been met, balance sheet cleansed and the Voluntary Separation Scheme/ Voluntary Retirement Scheme effected, the IDPL & RDPL be closed and HAL & BCPL be put up for strategic sale.

iii. While taking a decision to close the PSUs, the Department may also explore the possibility of hiving off the subsidiary companies of HAL and IDPL for private participation, wherever found viable.

The Cabinet considered the recommendations of the Ministers and approved the same in its meeting held on 28.12.2016.

The Department/ PSUs had the tenders issued for sale of surplus land of the PSUs, but no bids were received, the bidding being restricted to the government agencies as per the Cabinet's decision. As the land could not be sold, the liabilities of the PSUs could not be met and no progress made in respect of their closure/ strategic sale. The matter was again placed before the Cabinet, which in its meeting held on 17.07.2019 decided:

(i) Modifying the earlier decision dated 28.12.2016 of sale of land of PSUs to government agencies and instead permitting the sale of land as per revised DPE guidelines dated 14.06.2018;

(ii) Constitution of a Committee of Ministers for taking all decisions pertaining to closure/ strategic sale of the four Public Sector Undertakings, including the sale of assets and clearance of outstanding liabilities.

Committee of Ministers held a meeting on 27.05.2021 to consider the liabilities and sale of assets of the pharma PSUs, under the chairmanship of Union Home Minister. In view of pending dues of the retirees of HAL and RDPL and the proposals of sale/transfer of land which only involved transfer to Government entities, the committee approved the following:

(a) Budgetary support of ₹ 139 crore- ₹118.00 crore for HAL and ₹ 21.00 crore for RDPL, as loan at supplementary budget of 2021-22 to clear pending employees' dues.

(b) Return of 833.38 acres of leasehold land of IDPL at Rishikesh including 1.01 acres of freehold land, to the Government of Uttarakhand and to pay the agreed electricity dues of ₹ 46.39 crore to UPCL from sale proceeds of assets at other locations.

(c) Transfer of 50 acres of land out of IDPL plant site-I, Hyderabad to NIPER, making book adjustment against Government of India Loan to IDPL/ notional grant to NIPER, Hyderabad.

(d) Transfer of 20.55 acres of land of BCPL at Panihati, Kolkata to NIPER Kolkata for setting up regular campus at Reserve price of ₹ 345.24 crore and waiver of all Government of India Loan to BCPL of ₹ 193.71 crore along with accrued interest.

(e) Sale of 3.5 acres of land of HAL at Pune to EPFO at negotiated price of ₹ 42.00 crore.

Separately, the Cabinet Committee on Economic Affairs (CCEA) in its meeting held on 01.11.2017 'in principle' approved strategic disinvestment of 100% Government of India equity in KAPL.

Providing budgetary support to PSUs, detailed as below:

RDPL- Release of ₹ 21.00 crore (Rupees Twenty-one crore only) to RDPL during 2021-22 for payment of Leave Encashment, Gratuity and other perk & allowances of RDPL retired employees

HAL - Release of ₹ 76.00 crore (Rupees Seventy-Six crore only) to HAL during 2021-22 for payment to be released to EPFO (interest amount)

HAL - Release of ₹ 42.00 crore (Rupees Forty-Two crore only) to HAL during 2021-22 for payment of Medical claims, Gratuity, Leave encashment, LTC claim of HAL retired employees/VR employees.

IDPL - Release of ₹ 70 lakh (Rupees Seventy lakh only) to IDPL, as a loan during 2021-22 for ODCL, a joint venture of IDPL against VRS of regular employees.

Basic Information of all the PSUs:

Table-6A

(Basic Information of all the PSUs)

(As on Dec' 2021)

	HAL	IDPL	RDPL	BCPL	KAPL
Established in	1954	1961	1978	1981	1981
Classification/ Status	Sick, under strategic dis-investment	Under Closure	Under Closure	Profit earning, under strategic disinvestment	Miniratna Category – I, under strategic disin-vestment
Net worth (₹ in crore)	-626.55	-8076	-63.72	-40.24	236.17
Total Turnover (₹ in crore)	73.63	-	NIL	54.45	364.96
Operating profit/loss (₹ in crore)	-5.25	-28	-12.60	12.58	25.46
Liabilities (₹ in crore)	920.71	-7873.96	114.16	225.85	84.34
Total land (in acre)	263.57	1816.13	9.35	71.57	39.48
Leasehold (in acre)	-	833.38	-	1.10	-
Freehold (in acre)	263.57	982.75	9.35	70.47	39.48

The information relating to IDPL and RDPL are as on Oct, 2021.

6.2 Indian Drugs and Pharmaceuticals Ltd. (IDPL)

6.2.1 Background

IDPL was incorporated as a public limited company on 5th April, 1961 under the Companies Act, 1956. 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). Two 100% wholly owned subsidiaries, namely, IDPL (Tamil Nadu) Limited, Chennai (Tamil Nadu) and Bihar Drugs & Organic Chemicals Limited (BDOCL) at Muzaffarpur (Bihar), where there is no production activity since October 2018 and November 1996 respectively. The production activities at Joint Venture, Orrisa Drugs and Chemicals Limited (ODCL) have also been stopped.

6.2.2 Present Status

The Union Cabinet decided on 28.12.2016 for closure of the company. All units are now closed in view of closure decision of the Union Cabinet. Committee of Ministers held a meeting on 27.05.2021 to consider the liabilities and sale of assets of the pharma PSUs, and approved as under:

(a) Return of 833.38 acres of leasehold land of IDPL at Rishikesh including 1.01 acres of freehold land, to the Government of Uttarakhand and to pay the agreed electricity dues of ₹ 46.39 crore to UPCL from sale proceeds of assets at other locations.

(b) Transfer of 50 acres of land out of IDPL plant site-I, Hyderabad to NIPER, making book adjustment against Government of India Loan to IDPL/ notional grant to NIPER, Hyderabad.

(c) The committee further observed that apart from the valuation of assets done by M/s. NBCC as per DPE guidelines and as followed by DIPAM as well, separate valuation by Independent Assest Valuers should be done to arrive at realistic floor prices. This process should be adhered to for opening competitive bidding to Govt. entities and private entities alike.

Presently, the company has no regular employees as all the regular employees have been given VRS as per DPE Guidelines dated 14.06.2018. There are 76 contractual employees in the Company including its two Subsidiaries.

6.3 HINDUSTAN ANTIBIOTICS LIMITED (HAL)

6.3.1 Background

HAL is wholly owned Government of India Company engaged in the manufacturing & marketing of life saving drugs. HAL was established in 1954 with WHO/ UNICEF assistance. HAL was the first company in India to manufacture the Antibiotics Bulk drugs like Penicillin, Streptomycin and Gentamycin etc.

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

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

6.3.2 Performance Rating Under MoU

HAL has entered into MOU for the year 2020-21 with the Ministry of Chemicals & Fertilizers, Deptt. of Pharmaceuticals, based on the Audited Results of the Company, HAL has received “GOOD” MOU Rating for the year 2020-21. HAL had also been rated “GOOD” for MOU 2019-20 by Department of Public Enterprises (DPE).

6.3.3 Corporate Governance

HAL is committed to follow Good Corporate Governance Practices in conducting business in legal, ethical & transparent manner. During the Year 2020-21, HAL got the “EXCELLENT” rating for compliance of Guidelines on Corporate Governance issued by DPE for CPSEs. During 2019-20 also, HAL got “EXCELLENT” rating.

6.3.4 Brief of Facilities available

HAL manufacturing facilities include the following:

a) **Bulk Plant:** HAL is having fermentation-based manufacturing facilities including 19X92M3 fermenter along with its downstream processing, solvent recovery and associated utilities like steam, chilled water, cooling tower water, compressed air etc. These facilities were earlier used for manufacturing fermentation-based bulks like Penicillin-G, Streptomycin Sulphate.

b) **Formulation facility:** HAL is focusing at present on manufacturing Pharma formulation and promising Agro- formulation to cater to wide range of Pharma and Agro market. HAL Pharma products includes various dosage forms like Injectable products, Tablets, Capsules, Intra-Venous products, Liquid Syrup etc.

At present, manufacturing formulation capacities including Pharma & Agro-Chem, are as follows:

Table-6B
(Status of Manufacturing Capacity)

Sl.No.	Production facilities	Capacities (Existing) Lac Nos. / annum
A.	**Pharma Plants**	
1	**Powder Injectable**	
	(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 tones
4	Azotomeal	50 KL*
5	Phosphmeal	50 KL*
C	**Alcoholic Hand Disinfectant (AHD)**	12

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

During the year 2020-21, HAL has consolidated manufacturing of following Agro Products which were closed for the last 8 to 10 years:

- Aureofungin
- Humaur
- Phosphomeal
- Azetomeal

6.3.5 Research and Development

HAL's R & D Department is engaged in manufacturing standard size Narcotic Drugs Detection Kits, Precursor Chemicals Detection Kits and Ketamine Detection Kits as per requirements of 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.

6.3.6 Present Status of the Company

At the Cabinet meeting held on 28.12.2016, it was decided to sell surplus land of Hindustan Antibiotics Limited (HAL) through open competitive bidding to Government agencies and clear the outstanding liabilities from the sale proceeds.

It was decided that after meeting the liabilities, HAL would be put up for Strategic Sale. HAL made earnest efforts for sale of surplus land through Govt. Agency M/s MSTC, but could not find buyers, despite issuing tenders several times. Meanwhile, the Department of Public Enterprises (DPE) has issued revised guidelines on 14.06.2018 in respect of disposal of land of the PSUs.

As funds could not be generated through sale of surplus land, the employees of HAL could not be paid salaries since May 2017 and VRS scheme could not be floated till June 2019.

Subsequently, the Union Cabinet at its meeting held on 17.07.2019, has approved the following:

(i) Modifying the earlier decision dated 28.12.2016 of sale of land of PSUs to government agencies and instead permitting the sale of land as per revised DPE's guidelines dated 14.06.2018; and

(ii) Providing budgetary support as loan to the tune of ₹ 280.15 crore for meeting the liabilities of outstanding salaries upto June 2019 and granting VRS to 500 employees.

(iii) Constitution of a Committee of Ministers for taking all decisions pertaining to closure/ strategic sale of the Pharma Public Sector Undertakings, including the sale of assets and clearance of outstanding liabilities.

6.3.7 Sale of Land Assets of the Company

HAL is having 263 acres of land, out of which Cabinet has sanctioned sale of 87.7 acres of land to meet up its liabilities. The Company has signed an MOU with NBCC on 26.10.2019 as Land Management Agency for sale of land. The Company has submitted details of surplus land of HAL and all properties of its two Subsidiary Companies namely, MAPL, Nagpur and MSDPL, Manipur to NBCC. NBCC has submitted the valuation report.

Details of Production, Sales Turnover and Net Profit / Loss for the last three years are as below:

Table-6C

(Year wise Financial Status of HAL)

(₹ in Crore)

Particulars	2016-17	2017-18	20118-19	2019-20	2020-21	2021-22 As on 31.12.2021 (Provisional)
Production	11.36	37.44	54.51	43.05	78.80	57.80
Turnover	14.78	35.57	63.17	58.56	89.56	73.63
Net Profit (Loss)	(78.24)	208.32*	(71.10)	(138.30)**	(38.26)	-5.25 (Operating profit/ loss) before interest & interest & depreciation

* Due to waiver of GOI loan and interest thereon

** During the year 2019-20, the loss is Rs. 72.42 crore which has increased due to employee separation cost (VRS) impact of Rs. 65.88 crore, hence the total net loss is arrived Rs. 138.30 crore.

Expected Financial Results for the period Apr'21 to Mar'22

Table-6D
(Expected Financial Results)

(₹ In crore)

Particulars	Apr'-Sept'21 (Provisional)	Apr'21 to Mar'22 (Provisional/Estimates)
VOP (value of Production)	48.70	101.15
Sales (Net)	53.01	110.00
Profit/Loss +/(-)	(11.31)	(23.27)

Agrovet is continuing to contribute in a major way to the overall turnover of the company. This has been possible due to restarting of production activities of various plants including Pilot Plant (for manufacture of Aureofungin & Humaur) & IVF Plant (for manufacture of large volume parenteral). IVF Plant was restarted after almost four & half years

6.3.8 Awards received by HAL during 2021-22

During the year, HAL has received following awards:

(i) Pune Best Employer Brand Awards 2021 (July 2021)

(ii) National Awards CEO of the Year 2021 (August 2021)

Pune Best Employer Brand Awards 2021 were hosted by Employer Branding Institute, World HRD Congress and Stars of the Industry Group. HAL received the award for orienting itself to productive and efficient work culture and taking all steps to achieve the enhanced turnover and profitability for the company.

The National Awards for CEO of the Year was awarded to Ms. Nirja Saraf, Managing Director, Hindustan Antibiotics Ltd. for yeoman service to the Hindustan Antibiotics Ltd. for enhancing its sales turnover from a paltry ₹ 10.73 crore in 2016-17 to a respectable ₹ 89.58 crore in 2020-21. The event was organized and endorsed by World Federation of Human Resources Professionals, World CSR Day, World Federation of Marketing Professionals and others

6.3.9 Projects implemented so far

HAL has completed setting-up of new Cephalosporin power injectable facilities. This facility was accredited with WHO-GMP certification in July 2010. The upgradation of Betalactam & Quality Control

Lab is complete and ready for WHO-GMP inspection. Non-Parental facility is also being planned to be upgraded to WHO-GMP compliance in near future.

Planned New Projects:

HAL is planning upgradation of following facilities to generate more funds for the company:

- Facility for bulk Amoxicillin Trihydrate IP with initial capacity of around 50 to 60 Tons per month.
- Facility for APIs Meropenem & Telmisartan.
- Upgradation of facility for Alcoholic Hand Disinfectant (AHD), the only CPSU to have such facility.
- Rooftop Solar Panels for generation of power equivalent to 1 MW.

As on 1st November 2021, HAL has employee strength of 436. HAL has relieved 385 nos. of employees through VRS and is in the process to relieve another 150 to 200 employees, which shall reduce the salary burden and help to enhance productivity.

The manufacturing of these bulk APIs shall also compliment the Hon'ble Prime Minister's 'Make in India' initiative for bulk drugs / APIs.

6.3.10 Strategy for Marketing

HAL's sales are at present largely dependent on institutional sale with PPP model. For reducing the dependence on PPP business following strategy would be adopted:-

- Enhancing the Trade Sale through well established distribution network of distributors, C & F agents and branches to support product supply chain.
- Inducting new products having high value & high margin & phasing out products which are at the end of their life cycle.
- Increasing the sales of existing high margin products.
- To be competitive in Institutional business with cost reduction.
- To expand Agro-vet business having high potential & better margin.
- To capture growing export markets since the manufacturing facilities would be WHO-GMP compliant.

6.3.11 Rationalization of Manpower

The Company had 918 employees on 31st March, 2019. As on 1st November 2021, the total number of employees is 436.

Various social security schemes like Provident Fund, Gratuity & Medical schemes are also in place in the Company.

During the year 2020-21-22, several training programees / seminars were arranged on topics like cGMP, Project Management, Tendering Procurement and Contract Management etc. About 63 employees attended these in-house training programmes.

6.3.12 Outsourcing of operations of Non-core area

HAL at present is operating non-core areas like canteen and hospital on its own. It is planned to outsource these operations for better economy.

Commercial exploitation of Company's colony and factory infrastructure Colony

a. Colony area is around 100 acres and there are around 900 Quarters Present occupancy is around 30 to 40%. Considering required manpower strength, occupancy of quarters will be reduced further.
b. Idle quarters and unoccupied land in the colony can be developed for commercial use and this may fetch recurring revenue for the company for self-sustenance in future.

Factory

a. All the bulk plants and utility plants are idle, necessary approval is required to monetize the idle assets.

6.3.13 ERP system for efficient functioning

(a) All the systems including receipt in the Stores, issue for production, consumption of raw material as well as packaging material for the product, out-turn of production to marketing & distribution, Personnel including time-office is being computerized using ERP System.
(b) This system will enable to have updated information instantly and thereby can have efficient monitoring of inventory, consumption and reduce manpower.

6.3.14 Cost cutting measures

(a) System of regular monitoring of 'A' category raw material and packaging material with respect to the standard consumption norms is being introduced.
(b) Utilization of funds to reduce interest burden and controls on fund management.
(c) Cost cutting measures in all the areas of operation is strictly enforced.
(d) Optimum utilization of available manpower is enforced.

6.3.15 Various Social activities/days observed in Hindustan Antibiotics Ltd. during the year 2020-21 and 2021-22.

26th January, the Republic Day is celebrated in Hindustan Antibiotics Ltd. Various programmes like felicitation of the employees completing 25 years of their service in the Company, Exemplary Awards are given to those employees those who have achieved something special during their service etc.

19th February is celebrated as the birthday of Shri Chhatrapati Shivaji Maharaj. During the function the speech of the knowledgeable orator is organized by Shri Shiv Smarak Pratishthan.

National Safety Week is observed in the Company from 4th March to 10th March. The safety bills are showcased all over the premises of the company and various safety devices are kept for exhibition.

14th April, Bharatratna Dr Babasaheb Ambedkar Jayanti is celebrated in H.A. Residential Colony by the H.A. Schedule Caste / Schedule Tribe Employees Association.

Boudha Jayanti is celebrated by the Boudh Jan Mandal, functioning in H.A. Residential Colony which is the association of employees of the company.

21st May is celebrated as Anti-Terrorism Day in the Company. The oath taking function is arranged by the management and the oath is taken by all the employees of the company.

15th August, the Independence Day is celebrated in Hindustan Antibiotics Ltd. Various programmes like felicitation of the employees completing 25 years of their service in the Company,

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.

The Vigilance Week is observed from 26th October to 1st November. Various programmes like Debate Competition, Essay Competition, and Slogan Competition etc are held.

25th November is observed for 'Communal Harmony' and voluntary funds are raised from the employees of the company and are sent to the appropriate government body as a donation to take care of the terrorism affected children of the nation.

26th November is observed as Constitution Day to commemorate the adoption of the Constitution of India. On the day the collective reading of Preamble of India is done by the employees.

HAL - Building Front View Of Cephalosporin Plant

Awards received by HAL

Celebration of as the birthday of Shri Chhatrapati Shivaji Maharaj

Celebration of Bharatratna Dr. Babasaheb Ambedkar's Jayanti

Celebration of Independence Day in Hindustan Antibiotics Ltd

Program organised during Swacchata Pakhwada

Observation of Vigilance Week

6.4 Karnataka Antibiotics & Pharmaceuticals Limited, Bengaluru (KAPL)

6.4.1 Background

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 lifesaving 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 ₹ 13.49 crore. 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-6E
(Year wise Details of Production and Sales)

(₹ in Crore)

Years	Production	Sales
2016-2017	405.51	386.27
2017-2018	366.82	353.83
2018-2019	388.63	360.36
2019-2020	489.57	437.08
2020-21	319.90	328.67
2021-22 (upto 31st Dec' 2021)	355.68	363.16

6.4.3 Past Achievements

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

Popular Brands:

Pharma – Trade

Table-6F
(Product wise Market Value of Pharma Trade)

(₹ in Crore)

No	Products	Therapy Segments	NLEM	Monopoly	Market Value
1	Grenil	Anti-Migraine	No	No	6.58
3	Cyfolac	Pre & Probiotics	No	No	2.64

4	Remcc Group	Cough & Cold	No	No	1.42
5	Zinfe Group	Hematinic	Yes	No	1.07
6	Verclav Group	Antibiotic	No	No	1.18
7	PoP-e	Platelet Booster	No	No	1.34

Agrovet:

Table-6G
(Product wise Market Value of Agrovet)

(₹ in Crore)

No	Products	Therapy Segments	NLEM	Monopoly	Market Value
1	K—Cyline	Insecticide	No	No	4.67
3	Kalvimin Group	Feed Supplement	No	No	4.78
4	K- Live	Hepato-Protective	No	No	3.01
5	K—Cythrin	Ecto- Parasiticide	No	No	2.71
6	Pensbiotic MD/DS ,Gentabiotics, K-Flox	Antibiotics	No	No	8.05
7	Fluvet	Ecto- Parasiticide	No	No	1.55

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

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 our 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-6H
(Catagory wise List of Products)

Sl.No	Products	Therapeutic Category
PHARMA		
a	K- PUREB HAND SANITIZER & HAND GEL	Hand Sanitizer
b	D3 LX CHEWABLE TAB	Vitamin & Nutrient Supplement
c	ANTAF TAB & SYRUP	Antacid
d	DYCON TAB & SYRUP	Anti-Diarrheal
e	EXOL TAB & SYRUP	Hepatoprotective
f	VAST SYRUP	Anti-Cough
g	SIP N FIT GRANULES	Immunomodulator
AGROVET		
a	FENZOLE – 3.1 gm bolus	Anthelmintic Oral
b	CAL K gel 300 mL	Animal Feed Supplement
c	IVERMEC INJ 100 mL	Endecticide Parentral

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

6.4.5 Exports

KAPL products are currently exported to about 16 countries such as Malaysia, Thailand, Philippines, Botswana, Bhutan, Kenya, Namibia, Myanmar, Mozambique, Sudan, Srilanka, Uganda, Uzbekistan, Yemen, Zambia & Zimbabwe etc. to name a few. Its Penicillin and Cephalosporin Dry Powder Parenteral facilities and also Liquid Injection manufacturing facilities are compliant to International GMP norms and approved by PICs (Malaysia), MCAZ (Zimbabwe), NDA (Uganda).

Current Status on manufacture of Oxytocin

Karnataka Antibiotics and Pharmaceuticals Limited is manufacturing and supplying Oxytocin, to various State Governments and other Government institutions as per their order.

6.4.6 Visit Of Hon'ble Minister Shri Bhagwanth Khuba

Shri Sunil Kumar Kaimal, Managing Director, welcoming Shri Bhagwanth Khuba, Hon'ble Minister of State, Ministry of Chemicals & Fertilizers, New and Renewable Energy, during his visit to KAPL Plant on 14.08.2021

A Photograph taken during the visit of Shri Bhagwanth Khuba, Hon'ble Minister of State, Ministry of Chemicals & Fertilizers, New and Renewable Energy

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 scheme for revival in 1995 by the erstwhile Board for Industrial & Financial Reconstruction (BIFR).

6.5.2 Business Operations

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

Manufacturing Locations: At present BCPL has four factories; 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, which is essential to prevent the spread of Coronavirus Disease (COVID-19) in present Pandemic scenario.

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

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

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

Past Achievements: The Company has retained its brand position in Home products / Disinfectants even during the crisis period and 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 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 and a Gross Margin of ₹24.05 Crore.

In the consecutive 2nd financial year also i.e., in 2017-18, BCPL reported a Net Profit of ₹10.06 Crore. In the year 2018-19, BCPL again reported a Net Profit of ₹25.26 Crore, ₹13.07 Crore in 2019-20 and during the year 2020-21, BCPL has reported a Net Profit of ₹6.08 Crore. Further, BCPL has repaid the entire Bank Loan of ₹28 Crore to United Bank of India which was taken in 1983 by mortgaging Registered Office building and now BCPL is a debt free company. BCPL has also paid ₹23.73 Crore to Government of India till date, towards repayment of loans taken in the year 2005 and 2006.

6.5.4 Product profile and range

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

Table-6I
(Product Profile)

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

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

6.5.5 Manpower

Table-6J
(Catagory wise Manpower)

Particulars	Manpower (As on 31.10.2021)
Executives	47
Supervisors	9
Workers	76
Grand Total	**132**

6.5.6 Distribution network

The company has a strong distribution network pan India with 9 Depots and 7 C&F Agencies. BCPL has also opened 3 Exclusive Retail Stores in Kolkata and 1 in Mumbai.

6.5.7 Performance

Details of Production, Turnover and Financial Performance of BCPL from 2016-17 onwards are as under:

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

(₹ in Crore)

Particulars	2021-22 upto 31.12.2021 (Prov.)	2020-21	2019-20	2018-19	2017-18	2016-17
Production	55.59	90.39	84.19	123.45	98.18	102.69
Income	54.45	73.86	85.63	119.67	94.80	110.24
Gross Margin	12.58	13.75	20.26	32.83	24.23	24.05
Interest Expenses (Finance cost)	0.02	0.09	0.68	2.45	9.05	15.07
Depreciation	4.61	5.92	5.12	5.12	5.12	4.47
Net Profit(Loss)	7.39	6.08	13.07	25.26	10.06	4.51
Net Worth	(40.24)	(47.63)	(53.71)	(66.78)	(92.04)	(102.10)

DPE rating:

Table-6L
(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"

Marketing : Share of Institutions and retail

Table-6M
(Share of Institutions and retail)

Sl. No.	Div & Products	Market Profile/Major Clients
1.	DIV I – 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
	DIV II – BRAND AQUAPTYCHOTIS, EU-THERIA, KALMEGH	Sold Through Retail Trade As Otc Medicines
3.	DIV III – COSMETIC & HOME PRODUCTS	Mainly Trade Business (70-75%) & Bulk Government Institutions Business (25-30%)

6.5.8 Future projects

(i) **ASVS Project:**

BCPL is planning to start ASVS Project as the product is not available in the country at the moment in required quantity. BCPL has stopped production of ASVS for the last 12 years due to non-availability of fund and also due to project cost escalation the project could not be started. The total project cost for ASVS block as on date is ₹ 31.00 Cr. Further, BCPL is under strategic sale so the project could not be taken up.

(ii) **HDPE Jars Production Unit:**

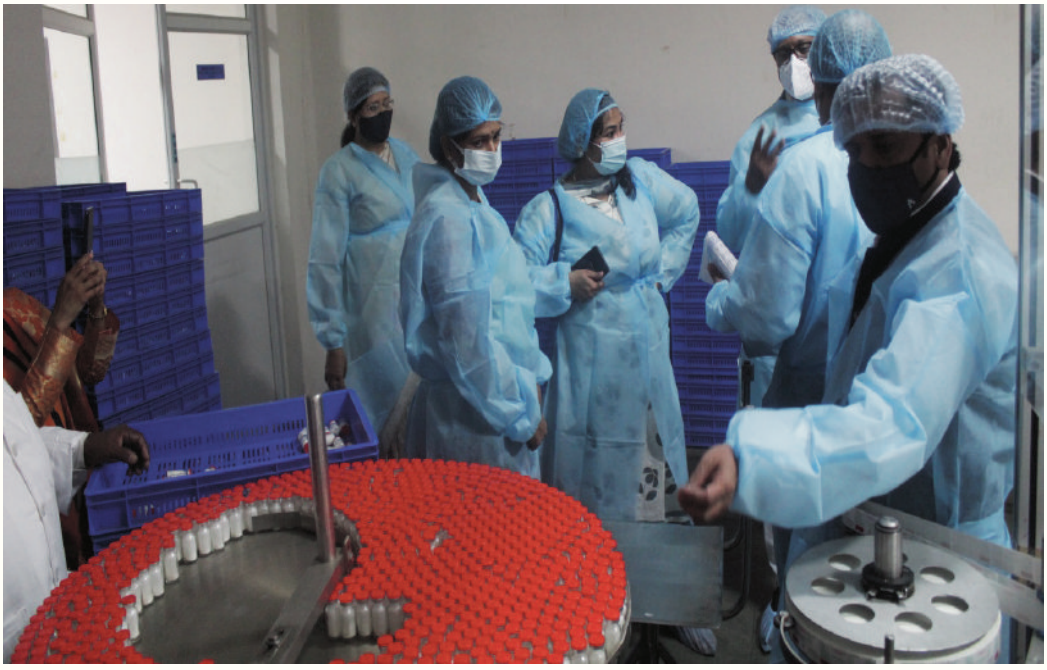
BCPL is planning to establish a production facility at Panihati for manufacturing of HDPE Jars for production of Pheneol etc, for which Board has given in-principle approval. Approximate Project Cost would be ₹12.00 Crore and expected savings in Procurement Costs - ₹3.00 Crore (approx.) per year and thereby, Company can earn a Profit of ₹ 2 to ₹3 crore per year.

(iii) **Manufacturing facilities of Bulk Drugs/Active Pharmaceutical Ingredients:**

In order to become self-sufficient in manufacturing of bulk drugs, BCPL has applied for Production Linked Incentive(PLI) scheme for promotion of domestic manufacturing of Critical Key Starting Material (KSMs)/Drug Intermediates(DIs)/Active Pharmaceutical Ingredients (APIs) in India for API/Bulk Drugs like Norfloxacin, Ciprofolxanin, Ofloxacin, Levofloxacin, Vitamin B1 and Vitamin B6.

Cabinet has decided on 28th December 2016 for strategic sale of the company after meeting all its liabilities from sale of surplus land through open competitive bidding to Government Agencies. But no bidder submitted an offer. Further, Bengal Chemicals Sramik Karmachari Union filed a Writ Petition before the Hon'ble High Court of Calcutta on 20/06/2017 against the decision of the Union Cabinet of Strategic Sale of BCPL and the hearing concluded on February 6, 2018. On February 13, 2018, order passed by Hon'ble High Court of Calcutta in respect of the aforesaid Writ Petition which set aside the decision of the Union Cabinet regarding strategic sale of BCPL. Subsequently, the Administrative Ministry has preferred an Appeal before the Hon'ble Divisional Bench of the High Court of Calcutta, which is pending before the Hon'ble High Court.

Liquid Products of BCPL



The Liquid Section of Maniktala factory of Bengal Chemicals & Pharmaceuticals Ltd.(BCPL) has been visited by the Hon'ble Members of Parliamentary Standing Committee on Chemicals and Fertilizers on 27th August, 2021.

Visit to Panihati factory of Shri H.K. Hajong, Economic Advisor, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, on 28th August, 2021.

During the Meeting of Hon'ble Members of Parliamentary Standing Committee on Chemicals and Fertilizers with Bengal Chemicals & Pharmaceuticals Ltd.(BCPL), on 27th August, 2021.

6.6 Rajasthan Drugs & Pharmaceuticals Limited (RDPL)

Rajasthan Drugs & Pharmaceuticals Limited (RDPL) is a Central Public Sector Unit in 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 & registered office at Road no. 12, VKI Industrial Area, Jaipur (Rajasthan). The production activities in the Company have stopped since October 2016.

Union Cabinet had decided on 28.12.2016 for closure of RDPL, after selling its surplus land, which would be required to meet the liabilities. Central Government/State Government/leading PSUs/Financial Institutions were invited to bid for the land, but no response was received. The Union Cabinet had on 17.07.2019 modified its earlier decision and permitted sale of land to any entity.

Committee of Ministers held a meeting on 27.05.2021 to consider the liabilities and sale of assets of the pharma PSUs, in view of pending dues of the retirees of RDPL and approved budgetary support of ₹ 21.00 crore for RDPL, as loan in the supplementary budget of 2021-22 to clear pending employees dues, which has since then been released.

6.7 Closure and strategic sale of Pharma PSUs

As per decision of the Union Cabinet on 28.12.2016, two PSUs, namely, Indian Drugs & Pharmaceuticals Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL)are to be closed and two other PSUs Hindustan Antibiotics Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are to be disinvested strategically. Before strategic disinvestment/closure of the PSUs, it was also recommended to clear all pending liabilities to sale of surplus land to the extent required.

The Union Cabinet in its meeting held on 17.07.2019 recommended sale of lands as per revised DPE guidelines dated 14.06.2018, approved budgetary support of Rs. 330.35 crore for meeting employees' liability (for both pending salary and VRS) of IDPL, RDPL and HAL and also recommended constitution of a Committee of Ministers for taking all decisions pertaining to closure/strategic sale of the PSUs including the sale of assets and clearance of outstanding liabilities.

Pursuant to the Cabinet decision dated 17.07.2019, the Committee of Ministers under the chairmanship of Hon'ble Home Minister was constituted which met on 27.05.2021 and approved, among other recommendations, to do third party valuation of the land by independent asset valuer to discover realistic floor price.

Present Status:

(a) The leasehold land of IDPL of 833.3 acres at Rishikesh including 1.101 acre of freehold land being returned to Government of Uttarakhand

(b) Transfer of 50 acres of land of IDPL plant at Hyderabad to NIPER Hyderabad against loan waiver of 889.5 crore and transfer of 20.5 acre land of BCPL at Panihati to NIPER Kolkata against loan waiver

of 193.71 crore are under progress

(c) 3.5 acres land of HAL has already been sold to EPFO at Rs. 42 crore

(d) RFP being floated for engaging independent asset valuer for valuation of assets of HAL and IDPL

CHAPTER 7

National Pharmaceutical Pricing Authority (NPPA)

CHAPTER 7

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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 29.08.1997. The functions of NPPA, inter-alia, includes fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

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

7.1.1 Salient features of DPCO, 2013 are as follows:

- The National List of Essential Medicines (NLEM), notified by the Ministry of Health & Family Welfare is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of 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 2015 (NLEM 2015) was notified by the Ministry of Health and Family Welfare in December 2015. NLEM 2015 was thereafter notified as the First Schedule of DPCO 2013, in March 2016, by the Department of Pharmaceuticals.

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

- To implement and enforce the provisions of the DPCO, 1995 / 2013 in accordance with powers delegated to it.
- To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
- To monitor the availability of medicines, identify shortages, if any, and to take remedial steps.
- To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.
- To deal with all legal matters arising out of the decisions of the Authority.
- To render advice to the Central Government on changes/revisions in Pharmaceutical policy.
- To render assistance to the Central Government in parliamentary matters relating to Pharmaceutical pricing.

7.2 Pricing

7.2.1 Price Fixation

A. Ceiling Price

NPPA fixes the ceiling price of formulation listed in Schedule I of DPCO, 2013. Under the market-based approach adopted in DPCO, 2013, the ceiling price of a scheduled formulation is determined by first working out the simple average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular formulation having a market share of one percent and above, and then adding a notional retailer margin of 16 percent to it. The maximum retail price (MRP) for that particular drug formulation must not exceed the notified ceiling price plus applicable taxes. NLEM 2015 contains 966 scheduled drug formulations (including formulations as per explanation 1 to Schedule – I of DPCO 2013) spread across 31 therapeutic groups. NPPA also fixes the ceiling prices of formulations listed under Explanation-I to Schedule – I of DPCO 2013. NPPA has fixed the ceiling prices of 886 formulations under DPCO, 2013 till 31.12.2021 as follows:

Table-7A
(Categories of Medicines under which Ceiling Prices have been fixed)

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	253	640
Total	**357**	**886**

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.

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 1798 'new drugs' [those qualifying as 'new drugs' as per para 2(u) of DPCO, 2013] till 31.12.2021 under DPCO, 2013.

7.2.2 Review Order

Any company aggrieved by the orders of NPPA files review application to Department of Pharmaceuticals under para 31 of DPCO, 2013. Department of Pharmaceuticals after physical hearing gives

necessary review directions. NPPA implements the review directions of Department of Pharmaceuticals on merit.

During the year 2021-22 (upto 31.12.2021), one review order issued by Department of Pharmaceuticals. The implementation was pending due to certain clarification being sought from Department of Pharmaceuticals.

7.2.3 Exemptions granted under Para 32 of DPCO, 2013

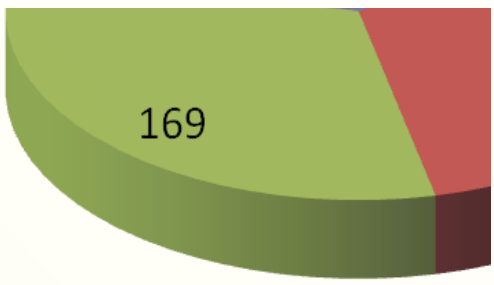
During 2020-21, NPPA has granted exemption under Para 32(i) of DPCO 2013 to M/s. Sun Pharmaceutical Industries Ltd. for the Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream' and M/s. Torrent Pharmaceuticals Ltd. .for Tapentadol Nasal Spray 225mg/ml in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative).

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

National Pharmaceutical Pricing Authority capped the Trade Margin of select 42 Anti-Cancer non-scheduled formulations, recommended by Expert Committee of Ministry of Health & Family Welfare, under the 'Trade margin Rationalization Approach' vide order SO 1041(E) dated 27.02.2019. The Pilot has been taken up as Proof of Concept, invoking provision of paragraph 19 of DPCO, 2013, under extra-ordinary circumstances in public interest.

As per data submitted by manufacturers, the MRP for 526 brands have been shown reduction up to 91%. Percentage wise reduction in prices of brands is as follows:

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



As per data submitted by manufacturers, the MRP for 526 brands have been shown reduction up to 91%. Percentage wise reduction in prices of brands is as follows: -

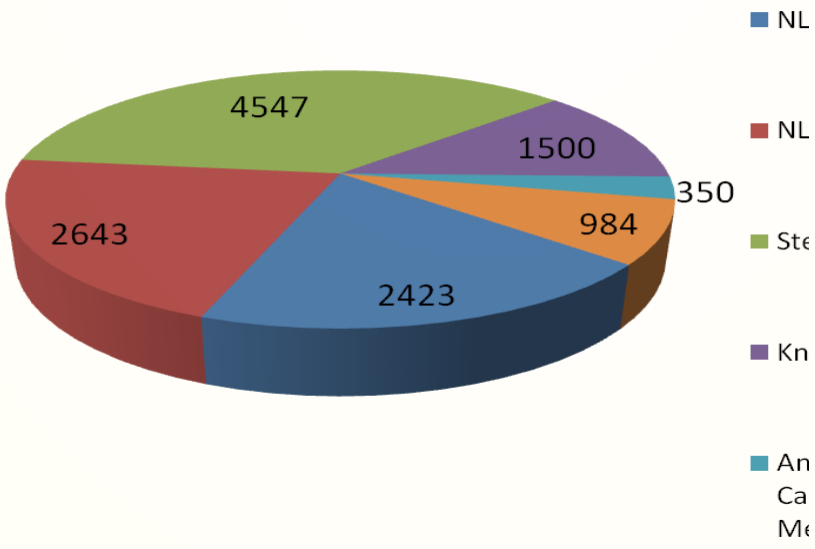
For example, the price of BIRLOTIB brand tablets (10's pack) of Erlotinib 150mg medicine which earlier was ₹ 9,999/- per 10 tablets pack has reduced to ₹ 892/- per 10 tablet pack (reduction of 91%) and similarly price PEMESTAR 500 brand injection of Pemetrexed medicine which was earlier ₹ 25400 per injection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

7.2.5 Savings to the Consumers

The fixation of ceiling prices of scheduled formulations listed in NLEM 2015 (revised Schedule-I) has enabled savings of ₹ 2643.00 crore to the consumers in addition to the saving of ₹ 4,547 crore 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 ₹ 2422.24 crore to the consumers. The para 19 price notifications resulted in savings of approximately ₹ 350 crore to the consumers. NPPA has also fixed the ceiling price of the Non Scheduled Orthopaedic Knee Implants, which has enabled savings of ₹ 1500 crore to the consumers. A savings of ₹ 984 crore to the consumers is estimated through the trade margin rationalization of anti-cancer drugs. Thus regulation of prices of medicines under DPCO 2013 by NPPA has resulted in net savings of approximately ₹ 12447 crore per annum to the consumers.

Graph-7B
(Savings to the Consumers)



7.2.6 Revision of Ceiling Retail Price Under Para 19 Of DPCO, 2013

Para 19 of DPCO, 2013 empowers the Government to revise the ceiling price of medicines under extra ordinary circumstances as it deems fit. Presently, the powers under para 19 of DPCO 2013 is entrusted to NPPA. NPPA received applications for upward price revision under para 19 of DPCO, 2013 citing various reasons like repeated price control, increase in API cost, increase in cost of production exchange rates etc. resulting in unviability in sustainable production and marketing of the drugs. Most of these drugs were used as first line of treatment and were crucial to the public health program of the country. The mandate of NPPA is to ensure availability of drugs at affordable prices and it was noted that while ensuring affordability, access cannot be jeopardized and the lifesaving essential drugs must remain available to the general public at all times.

Ceiling price of 9 scheduled formulations of 3 medicines were revised by allowing one-time price increase of 50% from the present ceiling price in public interest as an exceptional measure by invoking para 19 of DPCO-2013. The details of medicines are as follows:

Table-7C
(Scheduled Formulations where Ceiling Prices were revised)

S. No	Name of the Scheduled Formulation	Dosage Form & Strength	Unit	Ceiling Price (₹)	Existing S.O. No. & Date	
(1)	(2)	(3)	(4)	(5)	6(a)	6(b)
1	Carbamazepine	Oral Liquid 100 mg/5 ml	1 ml	0.29	1330 (E) Sl. No. 139	25.03.2021
2	Carbamazepine	CR Tablet 200 mg	1 Tablet	2.34	1330 (E) Sl. No. 140	25.03.2021
3	Carbamazepine	CR Tablet 400 mg	1 Tablet	4.61	1330 (E) Sl. No. 141	25.03.2021
4	Carbamazepine	Tablet 100 mg	1 Tablet	1.02	1330 (E) Sl. No. 142	25.03.2021
5	Ranitidine	Oral Liquid 75 mg/5ml	1 ml	1.08	1330 (E) Sl. No. 722	25.03.2021
6	Ranitidine	Tablet 150 mg	1 Tablet	1.10	1330 (E) Sl. No. 723	25.03.2021
7	Ranitidine	Injection 25 mg/1ml	1 ml	2.43	1330 (E) Sl. No. 724	25.03.2021
8	Ibuprofen	Tablet 200 mg	1 Tablet	0.59	1330 (E) Sl. No. 431	25.03.2021
9	Ibuprofen	Tablet 400 mg	1 Tablet	1.04	1330 (E) Sl. No. 432	25.03.2021

7.3 Initiatives Taken to Address the Exigencies Arising Out of Covid-19 Pandemic

During the COVID-19 pandemic in the country, NPPA played an active role in addressing the exigencies arising out of COVID-19 pandemic and undertook necessary measures to ensure continued availability of life saving essential medicines throughout the country.

7.3.1 Pricing of Drugs

Pricing is an instrument to ensure continued availability and affordability of essential life saving drugs with improved access to consumers. The list of drugs required for the management of the COVID-19 emanates from the Clinical Treatment Protocols issued from time to time by the AIIMS/ ICMR-COVID-19 National Task Force or the Joint Monitoring Group of the Minstry of Health and Family Welfare set up under the Directorate General of Health Services. The protocols keep getting updated based on the evidence of the effectiveness of the said drugs.

Most of drugs used for COVID management are scheduled drugs for which ceiling price has been given by NPPA. The details of the ceiling prices fixed are given in Table below:

Table-7D
(Ceiling Price of the scheduled drugs of COVID management protocol)

S.No.	Drugs	Ceiling Price (Notification dated 25.03.2021)
1.	Paracetamol – Tab of 650 mg	Rs. 1.84 per Tablet
2.	Dexamethasone Injection 4 mg/ml	Rs. 9.34 for 2ml pack; Rs. 13.80 for 10ml pack; Rs. 26.46 for 20ml pack; Rs. 35.36 for 30ml pack;
3.	Methyl Prednisolone Injection 40 mg/ml	Rs. 54.10 for 1ml pack
4.	Methyl Prednisolone Tablet	Rs. 5.11 per tablet of 8mg; Rs. 8.94 per tablet of 16mg
5.	Prednisolone Tablet	Rs. 0.56 per tablet of 5mg; Rs. 0.98 per tablet of 10mg Rs. 1.96 per tablet of 20mg; Rs. 2.82 per tablet of 40mg
6.	Enoxaparin Injection 40mg	Rs. 101.89 for 0.1ml pack
7.	Amphotericin Liposomal	Rs. 7484.24 for each pack of 50gm
8.	Amphoterecin B Deoxycholate Injection 50 mg per vial	Rs. 310.48 for each pack of 50gm
9.	Budesonide - Respiratory Solution	Rs. 10.74 for 0.5mg/ml and Rs. 12.95 for 1mg/ml for pack size of 1ml
10.	Heparin injection	Rs. 16.35 for 1000IU and Rs. 40.58 for 5000IU of 1ml pack (The ceiling prices of Heparin Injection extended till 31.03.2022)

The drugs that are part of COVID management protocol but non-scheduled as per DPCO, 2013 are Remdesivir, Posaconazole Injection, Tocilizumab and Infliximab injection. Further, for Lyophilised Remdesivir injections, MRPs of various brands earlier varied up to ₹ 5400/- per vial. However, on the intervention of the government, the major manufacturers/marketers of the Remdesivir Injection (a non-scheduled Drug) voluntary reduced retail prices, and agreed to revise these to less than ₹ 3500/- Accordingly, NPPA issued an Office Memorandum No. 37008/2021/Div.VI/NPPA dated 17.04.2021.

In times of the pandemic, the NPPA also invoked extraordinary powers in public interest to ensure that pricing issues do not impede the access to life saving drugs like Heparin and Medical Oxygen.

A. **HEPARIN:** Heparin is used as blood thinner and Heparin Injection 5000IU/ ml has been considered as an essential COVID plus medicine and widely used for COVID-19 treatment. The Active pharmaceutical Ingredient (API) of this drug is imported from China. For this drug, NPPA received representations from several manufacturers mentioning that there is an upward increase in prices of API of this drug. Heparin Injection 5000IU/ ml, being under ceiling price, the increase in API prices posed a challenge for continued availability of this important drug. NPPA revised the ceiling price of Heparin 1000IU Injection from ₹ 16.26 per ml (excluding GST) to ₹ 24.39 per ml (excluding GST) and 5000IU injection from ₹ 40.36 per ml (excluding GST) to ₹ 60.54 per ml (excluding GST) to ensure its continued availability during the pandemic. The revised ceiling prices have been extended upto 31.03.2022.

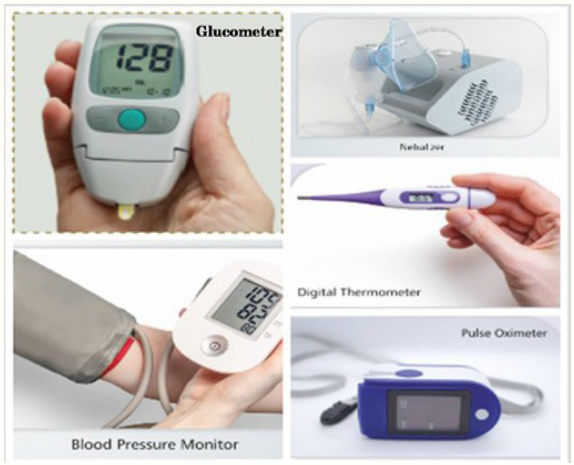
B. **MEDICAL OXYGEN**: The situation of COVID-19 resulted in increased demand of Medical Oxygen (MO) in the country. NPPA had repeated stakeholder consultations with Industry, Central Drugs Standard Control Organisation, PESO, Tariff Commission, Department for Promotion of Industry and Internal Trade and EG2 to understand the situation comprehensively. Medical Oxygen is not only an essential lifesaving drug but critical for COVID management. Due to increase in price of LMO being supplied to filler, the margins for them was squeezed which was impacting their operational viability. It was therefore, imperative to cap price of LMO to ensure uninterrupted availability of Medical Oxygen though cylinders to the hospitals and consumers

After extensive deliberation, NPPA, in exercise of extra ordinary powers, conferred by paragraph 19 of the Drug, (Prices Control) Order, 2013 and powers conferred under section 10(2)(l) of Disaster Management Act, 2005, in public interest, capped the price (ex-factory) of Liquid Medical Oxygen (LMO) to ₹ 15.22 per cubic meter (excluding GST) and the price (ex-factory) of Oxygen Inhalation (Medicinal gas) to ₹ 25.71 per cubic meter (excluding GST) for six months. The prices have been further extended upto 31.03.2022. Timely intervention by NPPA eased the situation of Medical Oxygen availability throughout the country, especially in distant and far flung areas.

7.3.2 Trade Margin Rationalisation of Medical Devices

With an aim to regulate the prices of medical devices, essential for diagnostic purposes, in general and specifically for COVID-19 management, NPPA on recommendation of Standing Committee on Affordable Medicines and Health Products (SCAMHP), NITI Aayog, vide Gazette Notification dated 03.06.2021 capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level. Price reduction in 70/252 products was and observed retail Prices reduced up to 54% (up to ₹ 54,337). In continuation of notification dated 03.06.2021, NPPA Gazette Notification dated 30.11.2021 extended the TMR notification up to 31.05.2022.

Similarly, vide notification dated 13.07.2021, trade margin on Pulse Oximeter, Glucometer, Blood Pressure Monitor, Nebulizer and Digital Thermometer was capped at 70%. The notification mandates to fix the Maximum Retail Price (MRP) as per the specified formula: Maximum Retail Price = Price to Distributor (PTD) + (PTD x TM) + Applicable GST, Where TM = Trade Margin not exceeding 70%.



Trade Margin Rationalisation of various Medical Devices

Based on the data provided by the companies, subsequent to the implementation of the notification dated 13th July 2021, the downward revision of MRP has been reported by imported and domestic brands across all the categories. The details are given below:

Table-7E
(Impact of TMR on Five Medical Devices)

S. No	Classification Wise	No of Product Reported after the Notification	No of Brands reported Downward revision of MRP	Decrease in MRP	
				(Rs)	(%)
(1)	(2)	(3)	(4)	(5)	(6)
1	Pulse Oximeter	277	137 (90%)	12 - 295375	1% 89%
2	Blood Pressure Monitoring Machine	329	306 (93%)	20 - 38776	1% 83%
3	Glucometer	105	84 (80%)	30 - 2250	1% 98%
4	Digital Thermometer	164	148 (90%)	8 - 44775	1% 89%
5	Nebulizer	257	244 (95%)	56 - 6165	1% 83%
	Total	1132	1033 (91%)		

7.3.3 Enhanced Production Capacity

On the intervention of government, during April-May, 2021 period the numbers of manufacturing units of Remdesivir increased from 20 to 57 and the country's production capacity of Remdesivir increased three times i.e. from 37 Lakh (approx.) vials per month to 1.05 Crore (approx.) vials per month.

7.3.4 Availability of Essential Drugs

NPPA has taken a number of steps to ensure the availability of medicines throughout the country. NPPA had greater interaction with Industry, manufacturers; All India Organisation of Chemists and Druggists (AIOCD); State Drug Controllers (SDCs); District Magistrates (DM) etc., to ensure that supply chains were not compromised. Such steps taken by NPPA are mentioned below:

A. Monitoring of COVID drugs as per allocation by Government of India:

Based on the allocation made by DoP and MoHFW for Remdesivir, Tocilizumab and Amphotericin, NPPA is following a multi-pronged approach to monitor and coordinate equitable distribution between States/UTs through close coordination with the Nodal Officers of the States/UTs and Liaison officers of the manufacturers to address supply issues, if any.

B. Coordination with the manufacturers of Buffer drugs and Nodal Officers of State/UT governments:

As a part of the measures being taken to strengthen the preparedness to meet any future surge, D/o Health and Family Welfare, GoI has vide communication dated 13.07.2021, shared the guidelines for Buffer Stock Management of drugs used for COVID-19 with the States/UTs, wherein it was emphasized that the States must initiate procurement on priority for building up buffer stocks. Department of Pharmaceuticals (DoP) has assigned NPPA to actively coordinate with States/ UTs and the manufacturers, if any facilitation is required to monitor supplies once the purchase orders are placed. Accordingly, regular meetings are being held with manufacturers in close collaboration with CDSCO and Nodal Officers of States/UTs to ensure un-interrupted supply and also to resolve any issues/challenges faced by manufacturers/States/UTs.

C. Control Room, Helpline and COVID-19 Dashboard:

NPPA has set up a Control Room (Helpline No.-1800111255/ Email: monitoring-nppa@gov.in) to receive complaints on availability of medicines and is making all out efforts to address the issues promptly by coordinating with the State authorities, manufacturers, marketers and their associations. During the second wave of COVID 19, out of 1139 complaints received on the helpline, 1011 were on shortages of COVID drugs and 128 on over-pricing and other issues. Necessary actions were taken to address these in coordination with the SDCs.

D. Monitoring through weekly surveys:

The availability of key medicines is being monitored through regular surveys being 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). Five medical devices were also included in the weekly survey w.e.f. July 2021. PMRUs undertake activities related to market based data collection, monitoring of the notified prices of medicines and detection of violation of the provisions of DPCO.

E. Black Marketing:

In the context of the rising cases of Corona Virus (COVID-19) in the country and as a measure of

public health preparedness in respect of COVID-19 drugs NPPA has directed all State Drug Controllers to closely monitor the production and availability of COVID-19 drugs to prevent black marketing and hoarding.

7.4 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 and 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 increase in the price of formulations beyond the permissible limit is also done on the basis of data submitted by AIOCD (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 formulation 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. 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 (EC Act), 1955.

NPPA monitors the availability of drugs, identify shortages, if any, and take remedial steps to make the drugs available to consumers. NPPA is carrying out this responsibility mainly through the State Drugs Controllers, NGOs and individuals. As and when the reports for shortages of 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. NPPA also monitors that companies do not discontinue the manufacturing of scheduled drugs, without prior intimation to NPPA. In cases where shortages are apprehended, NPPA also directs the companies to continue or increase the production.

To ensure that medicines are available to patients at the notified prices, NPPA works closely with SDCs for enforcement activities. Samples of medicines are picked up from open market regularly and analyzed to monitor the price at which the medicines are sold to patients. Enforcement activities from 2010-11 to 2021-22 (up to 31.12.2021) are given as under:

Table-7F
(Details of Enforcement Activities)

Year	No. of Samples Collected	Prima facie Violations detected
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(upto 31.12.2021	706 #	295

#Cases of Overcharging referred from State Drug Controllers and PMRUs are included under of Samples Collected'.

7.5 Recovery of Overcharged Amount

The overcharged amounts are recovered from the pharmaceutical company along with interest and penalty thereon from the date of overcharging. 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 initiated about 2209 cases of overcharging as on 30.09.2021. Amount of ₹1312.26/- Crore under DPCO 1979, DPCO 1995 & 2013 has been recovered as on 30.09.2021., from 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 Essential Commodities Act, 1955.

7.6 Monitoring of Price Movement of Medical Devices

NPPA by exercising the power under Para 20 of the DPCO, 2013, monitors the MRPs of all the non-scheduled Medical Devices to ensure that no manufactures/importers can increase the MRP more than 10% in preceding twelve months. Upon violation of the above provision, NPPA issues overcharging notices to the defaulting companies.

There are twenty-four (24) medical devices which have been notified/regulated as Drugs by Ministry of Health & Family Welfare, Government of India. Out of the above, four (4) medical devices namely (i) Cardiac Stents (ii) Drug Eluting Stents (iii) Intra Uterine Devices (Cu-T) and (iv) Condoms are scheduled medical devices which have been included in the Schedule-I of the DPCO, 2013. Hence, these four medical devices are under price control.

As per Ministry of Health & Family Welfare Notification dated 11.02.2020; all Medical Devices have been notified as 'Drugs' w.e.f. 01.04.2020. By virtue of the above, all the medical Devices have come under regulation of Drugs & Cosmetics Act, 1940, Medical Devices Rules, 2020 and Drugs (prices Control) Order, 2013 under Essential Commodities Act, 1955. This would enable the Government to regulate the Quality, Efficacy and Prices of Medical Devices in the country.

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

Consumer Awareness and Publicity and Price Monitoring (CAPPM), a Central Sector Scheme of National Pharmaceutical Pricing Authority (NPPA) has two components, viz. Assistance to set-up Price Monitoring and Resource Units (PMRUs), and Advertisement and Publicity for CAPPM.

NPPA is in the process of establishing Price Monitoring and Resource Units (PMRUs) at State/UT level. 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 the scheme assistance is extended to State/UTs to set-up Price Monitoring and Resource Units (PMRUs).

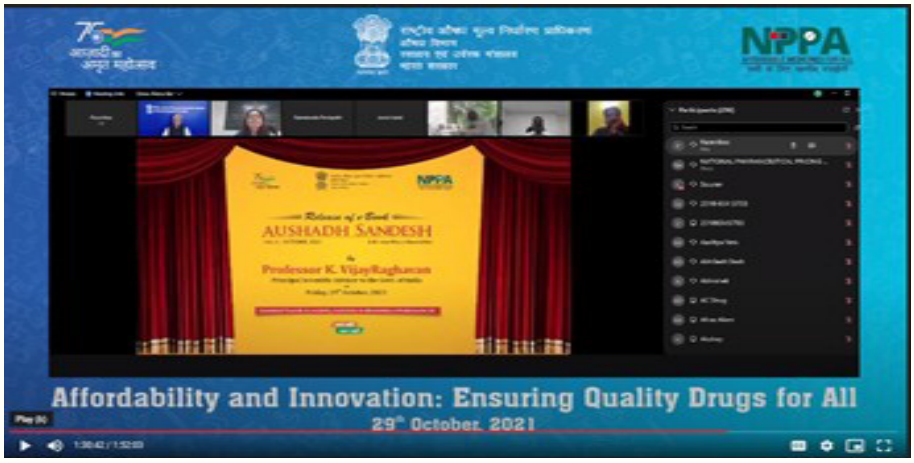
So far, PMRUs have been set up in twenty one (21) States/UT viz. Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry and West Bengal.

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. 2021-22, 6 webinars were organized by NPPA till 22.11.2021.

7.8 Activities undertaken under "Azadi Ka Amrit Mahotsav"

The Information shared on Twitter using hashtag #AzadiKaAmritMahotsav

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 webinar on ***"Affordability and Innovation: Ensuring Quality Drugs for All"*** on 29.10.2021 through video conferencing. The webinar was chaired by Prof. K. Vijay Raghavan, Principal Scientific Adviser to the Government of India and was graced by Ms. S. Aparna, Secretary, Department of Pharmaceuticals. Around 350 Participants from industry, academia, Central and State governments, Price Monitoring Resource Units (PMRUs), civil society, patient advocacy groups from all over the country joined the Webinar.



Webinar organised on the subject-Affordability and Innovation: Ensuring Quality Drugs for All

During the Webinar inaugural issue of bi-monthly E-Newsletter "Aushadh Sandesh" of NPPA was also launched by Prof. K. Vijay Raghavan, Principal Scientific Adviser to the Government of India. The E-Newsletter has been conceptualized with the intent of informing and disseminating information amongst the stakeholders about the latest regulatory initiatives of NPPA, government policies and initiatives in simple format which is easy to understand.

During the week-long special campaign (24.10.2021 to 31.10.2021), NPPA ran an awareness campaign on social media platforms on the theme of 'Affordability of Essential Drugs".

Some of the creatives run on the social media platforms

7.8.1 Activities undertaken by PMRUs

As part of activities to commemorate the occasion of 75th anniversary of Indian Independence during the year long 'Azadi ka Amrit Mahotsav' PMRUs also undertook special campaign from 24.10.2021 to 31.10.2021. They undertook the overall campaign with the theme of "'Affordability and Availability of Essential Drugs". During this special campaign PMRUs conducted Paricharcha on the topic, reached out to various stakeholders through electronic/print media, conducted awareness campaign in pharmacy colleges, panchayats etc.

Programs conducted by PMRUs during special campaign for Azadi Ka Amrit Mahotsav

All these events organized by the PMRUs had active participation from the various stakeholders i.e., manufacturers, chemists, industry associations, patient advocacy groups, etc. Some of the State Drug Controllers also reached out to a larger audience by giving interviews on television and radio. Some PMRUs also organised outdoor campaigns and publicity material in the form of brochures was also circulated by some PMRUs. The week long special campaign will prove to be a useful exercise in reaching out to various stakeholders and most importantly the consumers to make them aware about the various activities being undertaken by NPPA, and provisions of DPCO.

Some pictures of activities undertaken by PMRUs

7.9 E-Initiatives

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

7.9.1 Pharma Jan Samadhan (PJS)

PJS is a web enabled system developed by the NPPA with the assistance of National Informatics Centre (NIC). PJS serves as a robust e-governance tool for protection of consumer interest through effective implementation of the Drugs (Prices Control) Order, 2013. The primary objective of PJS is to

put in place a speedy and effective complaint redress system with respect to availability of medicines, overpricing of medicines, sale of 'new drugs' without prior price approval (WPA) and refusal to supply or sell medicines. Complaints can be registered under PJS link available at the NPPAs website i.e. www.nppaindia.nic.in 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.

7.9.2 Integrated Pharmaceutical Database Management System (IPDMS)

IPDMS was launched on 25.06.2015. IPDMS was developed by the NPPA in collaboration with the National Informatics Centre (NIC). This comprehensive online system provides a platform to the pharmaceutical manufacturer/ marketing/ importer/ distributor companies to file mandatory returns prescribed in Form II, Form III and Form V of DPCO, 2013. 975 Pharma companies have registered themselves under IPDMS and 87106 products registered till 31.12.2021.

NPPA is also undertaking up gradation of the IPDMS to make it web-enabled through CDAC.

7.9.3 Mobile Application 'Pharma SahiDaam' and 'Search Medicine Price' Utility

NPPA launched its mobile app on 29.08.2016 named as "Pharma SAHI DAM" for the benefit of the common people of India through which anybody can easily search the brand name, composition, ceiling price and MRP of the formulation. This app can be downloaded from Google play store free of cost for Android based mobile phones and from App store for IOS based mobile Phone (iPhone). Ceiling Price of scheduled formulations may also be obtained by using the tool 'Search Medicine Price' available in the website of NPPA. 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 (http://www.nppaindia .nic.in/redressal.html).

7.10 Rajbhasha Implementation

In NPPA Official language Implementation Committee has been working under the Chairmanship of the Chairman and others are the members of this Committee which includes joint Secretary and others Gazetted officers The objective of this Committee is periodically reviewing in each three months the progressive use in the Official work. All the members discuss and suggest the suitable measures to increase the use of Hindi in the Official work. Its meetings were held on regular intervals.

7.10.1 Rajbhasha Prayog Protsahan Pakhwara, 2021

Rajbhasha Prayog Protsahan Pakhwara, 2021 was organised in the NPPA from 16.09.2021 to 30.09.2021 with the objective to encourage the Officers and employees so that 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. Hindi Pakhwaraprogramme was successful in 2021 and a pledge was also administered by Director (Admn) to all the officers and staff of NPPA on 27.10.2021. Winners were awarded with cash prizes.

7.11 Vigilance Awareness Week

Vigilance awareness week was observed in NPPA from 26.10.2021 to 01.11.2021. A pledge was administered by the Member Secretary, NPPA to all the officers and staff on 26.10.2021.

7.12 Rashtriya Ekta Diwas

Rashtriya Ekta Diwas was also observed in the office of NPPA. A pledge was administered by Member Secretary, NPPA to all the officers and staff on 29.10.2021 following the COVID-19 norms.

CHAPTER 8

Implementation Of Rajbhasha

8.1 Use of Hindi in official work

8.2 Official Language Implementation Committee

8.3 Hindi Prayog Protsahan Pakhwara, 2021

8.4 Review of the status of use of Hindi in the offices under the Department

CHAPTER 8

Implementation Of Rajbhasha

8.1 Use of Hindi in official work

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

8.2 Official Language Implementation Committee

Department is having Official Language Implementation Committee working under the Chairmanship of the Joint Secretary/Economic Adviser to periodically review the progressive use of Hindi in the official work and suggest the suitable measures to increase the use of Hindi in the official work. Its meetings are being held on regular intervals and implementation status of the various targets set in the Annual Programme for transaction of the official work of the Union in Hindi for the year 2021-22 issued by the Department of Official Language, Ministry of Home Affairs reviewed regularly.

8.3 Hindi Prayog Protsahan Pakhwara, 2021

Hindi Prayog Protsahan Pakhwara was observed in the Department from 14th to 28th September, 2021 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 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 progressive use of Hindi received from them in compliance with the targets set in the Annual Programme for use of Hindi for the year 2021-22. During this year, to achieve the prescribed target (inspection of at least 25% offices) in the Annual Official Language Programme 2021-22, inspection of two subordinate offices of Department of Pharmaceuticals was carried out.

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 availability, accessibility and affordability of drugs and medical devices in the country.

9.2 Our 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

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, dyestuff and dye intermediates.

9.6 Our Activities

The key activities of the Department:

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

(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 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 offline and through CPGRAMS are monitored and disposed of on regular basis.

CHAPTER 10

Information And Communication Technology

10.1 Local Area Network (LAN)

10.2 Website and Social Media

10.3 Video Conferencing

10.4 Virtual Private Network (VPN) Facility

10.5 Workflow Automation

10.6 E- Governance

CHAPTER 10

Information and Communication Technology

Under Digital India program, Department of Pharmaceuticals has taken various initiatives towards adoption of E-Governance for delivering information and services online. This has led to benefits in terms of transparency, easy accessibility of services, improvement of 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 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 the delivery and security, web applications are migrated to cloud environment.

10.1 Local Area Network (LAN)

All workplaces 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 the use at their desktop.

10.2 Website and Social Media

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 organizational set up of the department, its functions, subordinate offices, policies, publications, statistical data/information on functional parameters Standardization testing and Quality Certificate (STQC) certification is completed.

Social media has enormous potential to reach people. To improve the quality of Government decisions, policy making and create awareness, Department has created Facebook and Twitter accounts. 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 various activities and decisions taken by the Department are posted on Facebook and twitter pages of the Department.

10.3 Video Conferencing

During the Corona Pandemic, to avoid person to person meetings, Video Conferencing facility has been provided to all the officers of the Department to discuss all the important issues through VC. PSUs and Educational Institutes (NIPERs) had also installed the Video Conferencing facility. VC facility enables Department to interact with PSUs and NIPER frequently for monitoring their performance and to

communicate the 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.

10.4 Virtual Private Network (VPN) Facility

During Corona Pandemic, when it was not possible for all the officials to attend the office, a Virtual Private Network (VPN) Facility was provided to them so that they could work from home and dispose of the official work smoothly.

10.5 Workflow Automation

Another initiative taken by Department towards Digital India is to implement automation of workflow 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 workflow 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 (2nd October to 31st October, 2021) on File Management System through digitization of physical files and converting them to e-files.

10.6 E-Governance

Taking advantage of latest ICT enabled tools; Department of Pharmaceuticals with the support of NIC has taken sincere initiatives towards adoption of best practices. Various applications have been developed and implemented by NIC to strengthen, monitoring and decision making and high availability of 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 developed by 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 Government of India. Information of the personnel under Appointment Committee of the Cabinet (ACC) is being uploaded onto the website.

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

- Development of software for grant-in-aid under Plan Scheme "Pharmaceuticals Promotion and Development Scheme (PPDS)". The objective of PPDS is promotion and development in Pharmaceutical 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 Sector. The software is under improvement phase.

- National Institutes of Pharmaceutical Education & Research (NIPERs) are situated at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata, Rae Bareli 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 has also been developed and is under the process of implementation.

- DBT MIS portal http://dbt.pharmaceuticals.gov.in is hosted on the NIC cloud for two schemes of Department of Pharmaceuticals, viz. Scholarship to NIPER students and Pardhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP). This portal disseminates the information about beneficiaries and transactions. This portal validates the beneficiary's details from Aadhar and transaction details from DBT Bharat.

- Dashboard of the Department has been developed and is under implementation.

- Stationery MIS (http://10.21.81.76/store) is the MIS of the Stationery item for the Department of Pharmaceuticals. By using this site, employees can request for the stationery items required by them. Based on the approval of Admin, employee can get the item. Stock of the stationery items are being maintained and issued through this portal dynamically. Next Version of this software is proposed.

- FDI linked Compliance Monitoring Portal has been made live and user assistance is under process.

- A Webinar on Cyber Security was conducted as part of the National Cyber Security Awareness Campaign during October, 2021 with Shri Karthikeyan Krishnamoorthy, IPS from Intelligence Bureau as the subject expert, for the benefit of regular employees of the Department.

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, Kolkata (BCPL), 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 of PSUs under the Department of Pharmaceuticals:

Table-11A
(Contact address of 5 PSUs)

Sl. No.	Address and Organization	Name	Designation
1	Indian Drugs & Pharmaceuticals Limited, (IDPL), Gurgaon	Shri Rajneesh Tingal	Chairman & Managing Director
2	Hindustan Antibiotics Limited (HAL), Pune-411010	Ms. Nirja Saraf	Managing Director
3	Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bangalore	Mr. Sunil Kumar Kaimal	Managing Director
4	Bengal Chemicals & Pharmaceuticals Ltd (BCPL), Kolkata, West Bengal.	Ms. Nirja Saraf	Managing Director (Additional Charge)
5	Rajasthan Drugs and Pharmaceuticals Limited (RDPL). Road No.12, V.K.I. Area, Jaipur-302013	Ms. Nirja Saraf	Managing Director (Additional Charge)

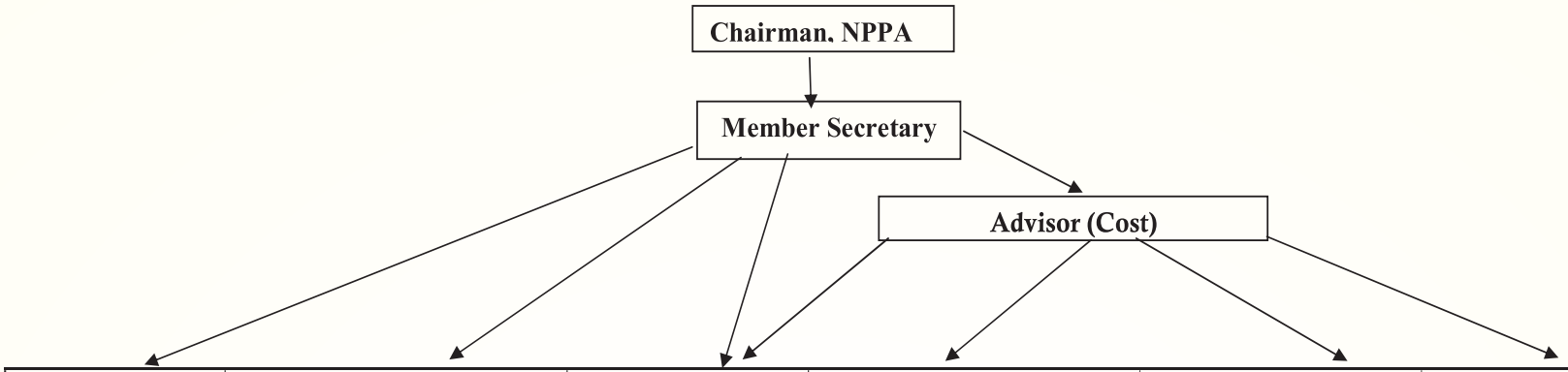
Annexure - II [C]

List of Responsibility Centers and Subordinate Organizations

Table-11B
(List of Responsibility Centers and Subordinate Organizations)

S. no.	Directors of NIPER	Landline Number	Email	Mobile Number	Address
1	Prof. Dulal Panda NIPER-Mohali	0172-2214690 0172-2214697	director@niper.ac.in	98203 91591	SAS Nagar, NIPER Mohali, Punjab - 160062
2	Dr. Kiran Kalia, NIPER-Ahmedabad	079-66745555	kirankalia@gmail.com director@niperahm.ac.in	97146 18573	Palaj Opp. Air Force Station Head Quarter, Gandhinagar-382355, Gujarat.
3	Dr. Shashi Bala Singh NIPER-Hyderabad	040-23073741	director.niperhyd@gov.in director@niperhyd.ac.in	99992 97992	NIPER, Hyderabad IDPL Township, Balangar, Hyderabad-500007
4	Dr.V. Ravichandiran, NIPER-Hajipur (Additional Charge)	0612-2631565	directorniperkolkata@gmail.com director@niperkolkata.edu.in director@niperhajipur.ac.in	94439 63481	E.P.I.P. Campus, Industrial Area, Hajipur-844102, Bihar
5	Dr.V. Ravichandiran, NIPER-Kolkata	033-24995803 033-23200086	directorniperkolkata@gmail.com director@niperkolkata.edu.in	94439 63481	Chunilal Bhawan, 168, Maniktala main road, Kolkata-700054, West Bangal
6	Dr. USN Murty NIPER-Guwahati	0361-2132751	murtyusn@gmail.com murty_usn@yahoo.com director@niperguwahati.ac.in	91270 60998	Sila Katamur (Halugurisuk) P.O.: Changsari, Dist: Kamrup, Assam, Pin: 781101, Assam, India
7	Dr. USN Murty NIPER-Raebareli (additional charge)	0535-2700851	director@niperraebareli.edu.in	91270 60998	Bijnor-Sisendi Road, Sarojini Nagar, Near CRPF Base Camp, Lucknow (UP) - 226002

Annexure – III Organizational Chart of NPPA



Admin Division	Mon. & Enf. Div-III	Overcharging - I	Pricing	Overcharging - II	Legal
1. Establishment matters 2. General Admn. 3. Cash/Budget 4. Coordination 5. R & I Section 6. Vigilance 7. Work related to Parliament Committees Matter 8. Consolidation and Compilation of Parliament Questions/ reply/ matters 9. ISO Audit 10. Any other subjects not listed elsewhere 11. All MP/VIP references and their coordination 12. Updation of NPPA's website	1. Enforcing and implementation of the prices of NLEM formulations fixed by NPPA 2. Monitoring of the price movement of non-NLEM formulations based on monthly reports of IMS and action thereof, if found more than 10% 3. Processing of SDCs reports received in respect of non-implementation of the prices of NLEM formulation and other DPCO related matter 4. Complaints received from individuals, NGOs, institutes related to pricing/ marketing at prices higher than the price fixed by NPPA or Price increase more than 10% 5. Sending reports to Overcharging Division for recovery of overcharged amount	1. All overcharging cases/files w.e.f. 01.01.2008 onwards under DPCO 1995, and related work. 2. Issue notice to the companies for overcharging and subsequent follow up. 3. Issue show cause notice, working out the overcharged amount and raise demand for recovery of the overcharged amount. 4. Recovery of overcharged amount under DPCO, 1995 5. Grant personal hearing and pass speaking/ reasoned	1. Fixation/Revision of prices of NLEM formulations. 2. Working out factors/ norms related to pricing formula given in DPCO, 2013 and its revision from time to time. 3. Collection of market based data for fixation of prices of NLEM formulations for which IMS data is not available. 4. Annual revision of prices of NLEM formulations based on WPI on or after 1st April, every year. 5. Annual revision of prices whenever there is a change in market structure in respect of NLEM formulations 6. Price fixation/ revision of non-NLEM formulations wherever considered necessary	1. All overcharging cases/files for the period from 2005 to 2007 under DPCO 1995, DPCO 2013 and related work. 2. Issue notice to the companies for overcharging and subsequent follow up. 3. Issue show cause notice working out the over-charged amount and raise demand for recovery of the overcharged amount 4. Recovery of overcharged amount under DPCO, 1995 5. Grant personal hearing and pass speaking/reasoned order whenever needed. 6. Examination of other issues related to overcharging under	1. Court cases under DPCO, 1987 and 1995 2. Court cases under DPCO, 2013 3. Advice to other Division of NPPA related to interpretation and applications of various provisions of DPCO 4. Legal matters related to establishment matters/NPPA's accommodation 5. NPPA's working guidelines/procedures etc. 6. Launching prosecution against the defaulting companies for

	6. Sending reports to Pricing Division to fix the prices in respect of NLEM formulations, if price is not fixed 7. Interaction/ correspondence with State Drugs Controllers in the matter related to enforcement of DPCO provisions 8. Shortage and availability of NLEM and non-NLEM formulations 9. Policy matter related to new DPCO. 10. Generation of Monthly Report based on IMS Data. 11. Price List collection & examination 12. Storage & Preservance of IMS Data and providing inputs to the concerned Divisions of NPPA 13. Old cases relating to Bulk Drugs 14. Production & Import Data of Bulk Drugs & Formulations 15. Related Parliament Questions/matters 16. RTI work 17. Work relating to RFD	order whenever needed. 6. Examination of other issues related to overcharging under DPCO, 1995 for recovery of the overcharged amount 7. Providing input to Legal Division for court cases. 8. Related Parliament Questions/matters	7. Notification of prices in the official Gazette and maintaining the price data of NLEM formulations 8. Annual exercise in respect of market structure/number of NLEM manufacturers for each NLEM formulations 9. Coordination work related to Authority Meeting – Agenda/Minutes 10. All overcharging cases/files for the period upto 31.12.2004 under DPCO 1995 & 1987 and related work. 11. Related Parliament Questions/matters	DPCO, 1995 for recovery of the over-charged amount. 7. Examination of other issues related to overcharging under DPCO 1995 and 2013 for recovery of the overcharged amount 8. Providing input to Legal Division for court cases. 9. All Plan Schemes of NPPA. 10. Related Parliament Questions/matters	violation of the provisions of DPCO 7. Related Parliament Questions/matters

सत्यमेव जयते

Government of India

Ministry of Chemicals & Fertilizers

DEPARTMENT OF PHARMACEUTICALS