सत्यमेव जयते

Government of India

Ministry of Chemicals & Fertilizers

DEPARTMENT OF PHARMACEUTICALS

ANNUAL REPORT 2020-21

Annual Report 2020-21

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 Industry:

The Indian pharmaceutical industry is the world's 3rd largest by volume and 14th largest in terms of value. Total Annual Turnover of Pharmaceuticals was Rs. 2,89,998 crore for the year 2019-2020. Total pharmaceutical exports and import were to the tune of Rs. 1,46,260 crore and Rs. 42,943 crore respectively in the year 2019-20.

Major Segments of Pharmaceutical Industry are Generic drugs, OTC Medicines and API/Bulk Drugs, Vaccines, Contract Research & Manufacturing, Biosimilars & Biologics.

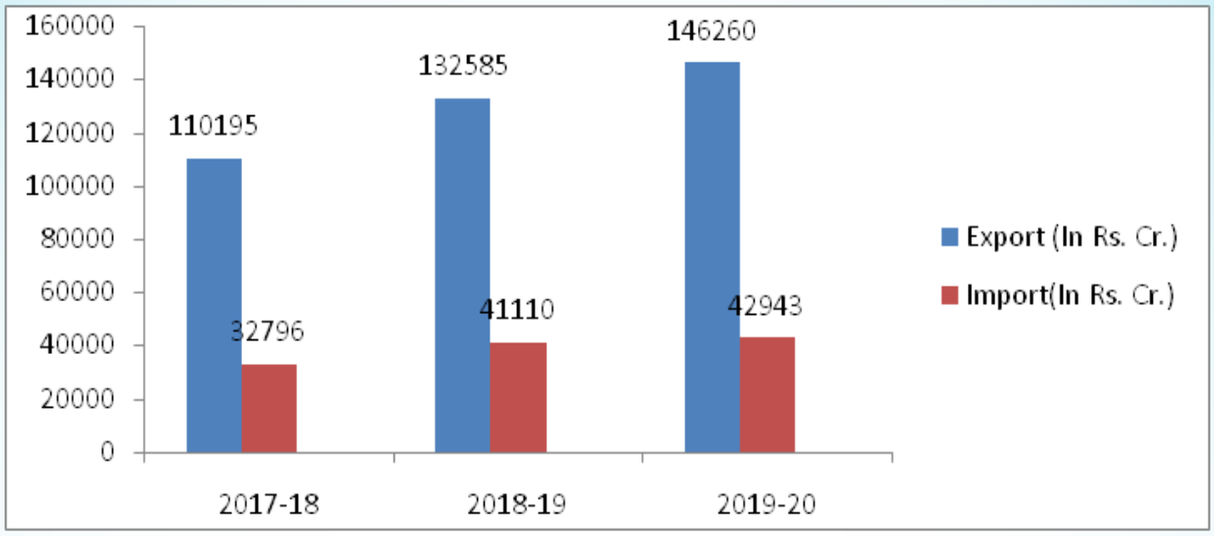
India has the second-highest number of US FDA approved plants outside the US. India is a global leader in the supply of DPT, BCG, and Measles vaccines. India accounts for 60 percent of global vaccine production, contributing 40 to 70 percent of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine.

India is the largest provider of generic drugs globally. 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". Pharma sector currently contributes to around 1.72% of the country's GDP.

India's pharmaceutical sector forms a major component of the country's foreign trade, with attractive avenues and opportunities for investors. India supplies affordable and low-cost generic drugs to millions of people across the globe and operates a significant number of United States Food and Drug Administration (USFDA) and World Health Organization (WHO) Good Manufacturing Practices (GMP)-compliant plants. India has occupied a premier position among pharmaceutical manufacturing countries of the world.

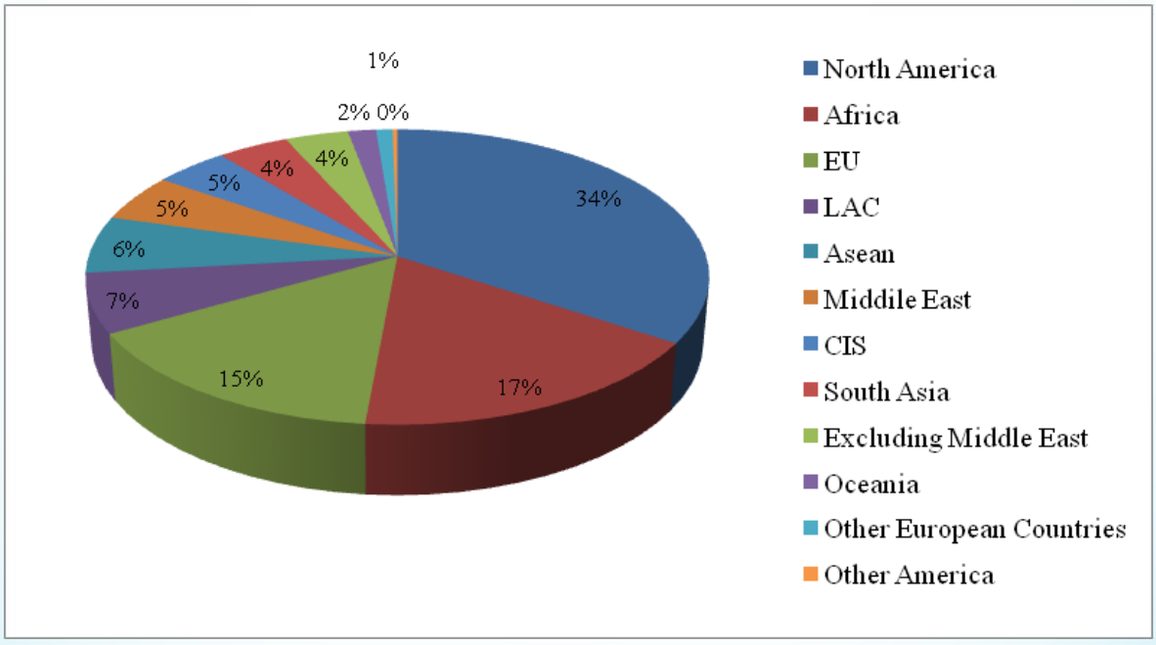
India is 3rd largest market for APIs globally, 8% share in Global API Industry, 500+ different APIs are manufactured in India and it contributes 57% of APIs to prequalified list of the WHO.

Graph-1A
(Trade in Pharmaceuticals)



(Source: DGCIS Kolkata)

Graph-1B
(Region wise India's Pharma exports FY 2019-20)



(Source: Pharmaceuticals Export Promotion Council of India)

1.2 Medical Devices

The Medical Device industry is highly capital intensive with a long gestation period and requires development/induction of new technologies. The major manufacturing of medical devices in the country is currently happening with respect to disposables such as catheter, perfusion sets, extension lines, cannula, feeding tubes, needles, syringes and implants such as cardiac stents, drug eluting stents, intra-ocular lenses and orthopaedic implants. Medical devices ranges from simple, low-risk devices such as medical thermometers, disposable gloves etc. to complex, high-risk devices like pacemakers, Implants, Ventilator, CT Scan and MRI etc.

Basic Medical Devices

High-end Medical Devices

1.3 Indian Medical Device Market

Medical device industry in India has the potential to reach $50 bn by 2025. India is the 4th largest Asian medical devices market after Japan, China, and South Korea and also ranks among the top 20 global medical device markets in the world. Currently, India is exporting ventilators, PPEs, diagnostic kits, sanitizers and surgical gloves (2/3 ply) in the ongoing COVID-19 pandemic. Exports and Imports of Medical Devices over past two financial years are as under:

Table-1A
(India's Medical Devices Trade) **(Values in USD million)**

Imports		Exports	
2018-19	**2019-20**	**2018-19**	**2019-20**
5700.44	5845.41	2138.14	2292.87

Source: Engineering Export Promotion Council of India (EEPC)

Graph-1C
(India's Medical Devices Trade)

Table-1B
(Classification of HS codes at 8-digit w.r.t. exports)

Range	Exports-E (Mn USD)	No. of Codes	Exports		%Share	
			2018-19	2019-20	2018-19	2019-20
1	E > 50	10	1066.02	1106.61	49.9	48.3
2	25 < E ≤ 50	18	576.64	653.45	27.0	28.5
3	10 < E ≤ 25	19	303.14	342.09	14.2	14.9
4	5 < E ≤ 10	14	86.58	97.83	4.0	4.3
5	1 < E ≤ 5	34	82.93	75.64	3.9	3.3
6	E ≤ 1	52	22.83	16.98	1.1	0.7
TOTAL		**147**	**2138.1**	**2292.6**	**100.0**	**100.0**

Table-1C
(Export Data For Medical Devices)

Range 1 - Exports to World(E) E > 50 mn USD			Exports Values in US $ million	
			WORLD	
S No.	HS Code	Commodity Description	2018-19	2019-20
1	30066010	CONTRACEPTIVE BASED ON HORMONES	138.16	144.19
2	63079090	OTHR MADE UP ARTCLSOTHRTHNCOTTION	200.45	145.7
3	90181990	Other- Electro - DiagnostcApprts	108.91	95.33
4	90183930	Cannulae	82.75	95.5
5	90183990	Others	174.6	189.23
6	90189019	Other Diagonostics Instruments	31.1	66.92
7	90189099	Other Surgical Instruments and Appliances (INCLVTRNRY)	78.2	102.01
8	90211000	Orthopaedic or fracture appliances	38.51	52.86
9	90223000	X-ray tubes **	125.91	133.52
10	90229090	Other	87.43	81.35
	Sub Total		1066.02	1106.61
	TOTAL		2138.14	2292.6
	% share in total exports		49.86	48.27

Table-1D
(Classification of HS codes at 8-digit w.r.t. imports)

Range	Imports- I (Mn USD)	No. of Codes	Imports		% Share	
			2018-19	2019-20	2018-19	2019-20
1	I > 75	24	4114	4166	72.2	71.3
2	50 < I ≤ 75	8	438	501	7.7	8.6
3	25 < I ≤ 50	17	590	622	10.3	10.6
4	10 < I ≤ 25	21	305	330	5.4	5.6
5	5 < I ≤ 10	17	124	117	2.2	2.0
6	1 < I ≤ 5	34	118	101	2.1	1.7
7	I ≤ 1	26	11	10	0.2	0.2
TOTAL		147	5700.4	5845.4	100.0	100.0

Source: EEPC

1.4 India Pharma 2020 and India Medical Device 2020

The 5th Edition of India Pharma 2020 and India Medical Device 2020 was organized in collabo-

ration with FICCI. It witnessed over 1200 delegates and visitors from all over India, meeting with buyers to provide an exclusive platform for various stakeholders to present their offerings through exhibition, international conference; B-2-B meetings; MSME vendor development program and the DPIIT investment lounge. DoP also announced the launch of Pharma Bureau, a Body of Technical Experts, which would act as a single-point interface for the pharmaceutical and medical device industry for issues relating to the Government of India and various State Governments. DoP had also conferred "5th India Pharma and India Medical Device Awards" for 6 categories. The three-day event including exhibition witnessed participation of over 200 exhibitors showcasing their products to delegates and business visitors from across the country.

The theme of this year's pharma conference was "Meeting Challenges for Affordable and Quality Healthcare". As part of Conference, various Plenary Sessions were organized on Ease of Doing Business; Ecosystem for R&D, Innovation & Start Ups in the Pharma Sector; State Drug Regulators Meet with Pharmaceutical & Medical device industry; Affordability, Accessibility and Availability of Quality Drugs & Medical Devices; Emerging trends in Healthcare. State drug regulators from 15 states participated in the regulators meet. FICCI-EY Report "Reshaping India into a Life Sciences Innovation Hub" was also released during the Event. The Pharma CEO Round Table was chaired by Hon'ble Union Minister. Over 50 CEOs had detailed discussions on Pharma Sectoral Issues relating to API Industry Revival; Drug Pricing; Ease of doing Business; Regulatory including Clinical Trials, recent Export Ban by DGFT due to COVID-19 and other forward-looking suggestions by the industry.

Medical Devices Conference was organized with focused theme "Promoting Affordable Quality Medical Devices for Universal Healthcare" witnessing deliberations on various key sessions such as Role of Regulations in Med-tech, Innovate to Make in India for the world; Affordability, Accessibility and Availability of Quality Drugs & Medical Devices; Emerging trends in Healthcare. The key highlight of this Event, CEOs Round Table was chaired by Hon'ble Minister and attended by over 40 CEOs and key issues like Medical Devices Regulations, Standards, Role of Innovations were discussed during the Conference. This year for the first time, a start-up Boot Camp was organized to promote new innovations in the sector and support their growth, in which 12 innovators presented their innovations in the presence of industry members and investors.

1.4.1 5th India Pharma and Medical Device Awards

5th India Pharma and Medical Device Awards were conferred on 5th March 2020 by Shri D.V. Sadananda Gowda, Hon'ble Minister (Chemicals & Fertilizers) to celebrate Innovation and Excellence in the Pharma and Med Tech Sectors. List of Winners of 5th India Pharma and India Medical Device Awards are as under:-

Table-1E
(Winner-awardees of 2020)

Category No.	Category Name	Name of Awardee
1	India Pharma Leader Award	Lupin Limited
2	India Pharma Bulk Drug Company of the Year Award	SMSLifesciences India Ltd.

3	India Pharma Innovation of Year Award	Laurus Labs Limited
4	India Pharma Corporate Social Responsibility (CSR) Programme of the Year Award	Sun Pharmaceutical Industries Ltd.
5	India Medical Device Company of Year Award	Innovation Imaging Technologies Pv Ltd
6	India Pharma Swachhta Champion Award	Karnataka Antibiotics and Pharmaceuticals Limited

Hon'ble Minister (C&F), Hon'ble MOS (C&F), Secretary (Pharma) and other dignitaries at the India Pharma 2020 & India Medical Device 2020 held on 5-7 March 2020 at Gandhinagar, Gujarat

Award distribution at the India Pharma 2020 & India Medical Device 2020

Lighting the lanp ceremony at the India Pharma 2020 & India Medical Device 2020

Press conference at the India Pharma 2020 & India Medical Device 2020

1.5 Foreign Direct Investment (FDI) in Pharmaceutical Sector

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 pharmaceutical greenfield projects are allowed upto 100% under the automatic route and for brownfield pharmaceutical projects, foreign investment beyond 74% to upto 100% Government approval is required.

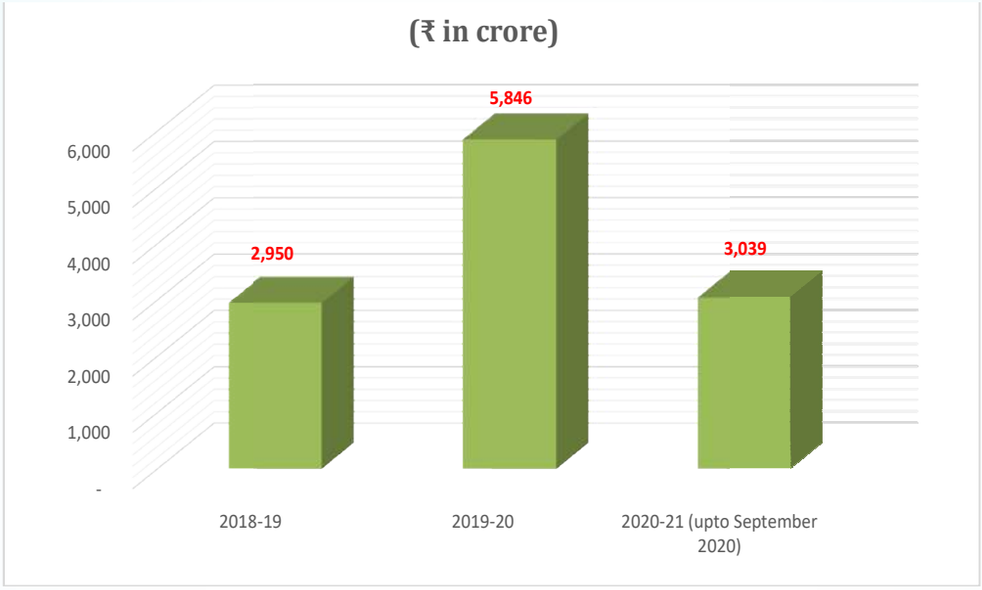
After abolition of Foreign Investment Promotion Board (FIPB) in May 2017, the Department of Pharmaceuticals has been assigned the role to consider the foreign investment proposals under the Gov-

ernment approval route. Apart from this, the Department considers all FDI proposals of pharmaceutical sector arising out of Press Note 3 of 2020 dated 17.04.2020 wherein investors/ultimate beneficiaries in the proposals are from the land sharing bordering countries of India.

The Department of Pharmaceuticals has approved 17 FDI proposals worth Rs. 1,512 crore under the brownfield pharmaceutical projects in the year 2020-21 (upto December 2020).

Graph-1D

(FDI inflows in Pharmaceutical sector, which includes both pharmaceuticals and medical devices)



Source: Compiled from DPIIT's website

1.6 Joint Working Group (JWG)/High Technology Cooperation Group (HTCG)

Department of Pharmaceuticals has the following Joint Working Groups/High Technology Coop eration Group:-

1. EU-India Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices
2. India-Tunisia Joint Working Group on Drugs and Pharmaceuticals
3. India-Ukraine Joint Working Group on Pharmaceuticals and Healthcare
4. India-Belarus Joint Working Group on Pharmaceuticals
5. India-Philippines Technical Working Group (TWG) for considering "Pharmazone" and "Registration and other Issues related to Pharmaceuticals"
6. India-Algeria Joint Working Group (JWG) on Pharmaceuticals
7. India-Egypt Joint Study Group (JSG) on Pharmaceuticals and Health
8. India-Uzbekistan Joint Working Group on Pharmaceuticals
9. India-Russia Joint Working Group on Pharmaceuticals to readdress the issues on India Pharma Industries
10. India-China Joint Working Group on Pharmaceuticals

1.7 International Participations

10th meeting of EU-India Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices was held on 15th October 2020 at New Delhi through Video Conferencing under the Co-Chairmanship of Shri Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals.

1.8 National Pharmaceutical Pricing Policy 2012

The Department of Pharmaceuticals notified the National Pharmaceutical Pricing Policy-2012 (NPPP-2012) on 07.12.2012 with the objective to put in place a regulatory framework for pricing of drugs to ensure availability of required medicines - "essential medicines" - at reasonable prices, while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well-being for all. The Government is now contemplating to introduce a new National Pharmaceutical Policy with the following objectives:

- Making essential drugs accessible at affordable prices to the common masses;
- Providing a longer-term stable policy environment for the pharmaceutical sector;
- Making India sufficiently self-reliant in end-to-end indigenous drug manufacturing;
- Ensuring world class quality of drugs for domestic consumption & exports;
- Creating an environment for R & D to produce innovator drugs;
- Ensuring growth and development of the Indian Pharma Industry.

1.9 COVID-19 Response

The Department of Pharmaceuticals actively led the fight against the COVID-19 pandemic, not only nationally but also internationally. Since the onset of the COVID-19 crisis and the resultant lockdown, DoP worked on a mission mode basis to address the challenges arising out of the same. The challenges included co-ordination with various Ministries/Departments and State Governments to resolve the issues associated with availability of Drugs for COVID-19 and other Essential Drugs including HCQ, Paracetamol, Vaccines, TB, Insulin and cardiac drugs, issues relating to sub optimal production, logistics, shortages and exports of pharmaceuticals and medical devices. There was continuous and round-the-clock activity including work on weekends & Gazette holidays. DoP had to face issues with a range of activities and multifaceted challenges which the Department had never dealt earlier. The details are outlined below:

A. Assessing the Availability and Ensuring Adequate Stock of Essential Items.

- India, one of the largest manufacturers of drug formulations/medicines is heavily dependent on China for import of critical bulk drugs. India imports around 70% of total imports of bulk drugs from China. The outbreak of the deadly Novel Corona Virus (COVID-19) in China in December 2019 brought out the risk of disruption of supply chain which could jeopardize the Indian pharma sector and could have adverse impact on the drug security in India. DoP regularly monitored the availability of medicines to avoid any potential shortage in the country.
- Immediately after the first case of the COVID-19 pandemic in India was reported on 30 January 2020, DoP assessed the situation and fast-tracked actions as a measure of public healt paredness.The Department held a series of meetings on 31st January; 2nd, 3rd and 6th February 2020 with all the stakeholders to assess the domestic availability of (i) Drug Lopinavir+Ritionavir fixed

drug combination which was included in the initial protocol of ICMR for treating the COVID-19 disease (ii) Active Pharmaceutical Ingredients (API), intermediates and Key Starting Materials (KSM) for which India is critically dependent on China.

- DoP assisted Ministry of Health and Family Welfare and Ministry of External Affairs to procure various medical supplies required in India and other countries.
- Regular meetings were held under the chairmanship of Secretary (Pharmaceuticals) to review the status of availability of ventilators, thermometers, PCR machines, diagnostics kits and related logistics issues and to explore manufacturing of ventilators by automobile companies.
- DoP conducted series of meetings through Video conferencing with the officers/officials of Central Government Ministries/Departments/Organisations, DCGI/State Drug Controers/ Pharma and Medical Device Associations, Pharma/ Medical Device Manufacturers and Air Cargo Units for ensuring availability/stock of medicines and medical devices (PPE kit, Gloves, Masks, Hand Sanitizers, Face Shield, other essential medicines and logistics issues.
- An inter-ministerial Committee was constituted by DoP on 06.02.2020 under the chairmanship of Dr. Eswara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to address the issue of drug security in the country. The committee submitted its report on 27.02.2020. The Committee reviewed the situation regarding impact on import of APIs and KSMs due to outbreak of Corona virus and identified four core issues viz. (1) Disruption of manufacturing activity in China due to holidays (2) Logistics issues (3) Restriction on movement of personnel and (4) Availability of raw materials for manufacturing of APIs/KSMs. The committee observed that there could be major impact on import of certain APIs and KSMs which are manufactured in Hubei province in China. Based on the recommendations of the Committee:
  - DoP issued necessary instructions to National Pharmaceutical Pricing Authority (NPPA), Drugs Controller General of India (DCGI) and State Governments to ensure adequate supply of APIs and formulations at affordable prices in the market and to prevent black-marketing, illegal hoarding, creating artificial shortages in the country.
  - DoP made recommendations to DGFT to restrict exports of 13 APIs and formulations made using these APIs. (On 03.03.2020 DGFT notified restriction on exports of 13 APIs and their corresponding formulations as a measure against the implications of COVID-19 outbreak in China.). Subsequently, after a short period the export restrictions were removed when the domestic availability became adequate.

B. Measures to ensure domestic manufacturing of critical bulk drugs.

The outbreak of the COVID-19 in China brought out the risk of disruption of supply chain of critical bulk drugs for the Indian pharmaceutical sector, highlighting the need for India to attain a sufficient degree of self-reliance in bulk drugs. In this regard, a Technical Committee was constituted by DoP on 02.03.2020 under the chairmanship of Dr. Eswara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to make recommendations for the revival of fermentation industry, new technologies for manufacturing of APIs including its backward integration, costing of the projects and identification of strategic business models. On the basis of the recommendations of the committee, the Department prepared the following two schemes for promoting domestic manufacturing of critical KSMs/ Drug Intermediates and APIs by attracting investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs:

(a) 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: Under the scheme, financial incentive is proposed for manufacturing of 41 eligible products under the four Target Segments viz.:

i. Fermentation based KSMs/Drug Intermediates.
ii. Fermentation based niche KSMs/Drug Intermediates /APIs.
iii. Key Chemical Synthesis based KSMs/Drug Intermediates.
iv. Other Chemical Synthesis based KSMs/Drug Intermediates/APIs.

Incentives for incremental sales will be given to selected participants for a period of 6 years. The total outlay of the scheme is Rs. 6,940 crore and the scheme is under implementation after receiving good response from the participants.

(b) Scheme for Promotion of Bulk Drug Parks: To provide grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total size of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25).

The detailed guidelines of the above-mentioned schemes are available on the website (http://pharmaceuticals.gov.in) of the Department of Pharmaceuticals.

C. Support to Industry during lockdown

The lockdown across the country in the wake of the COVID 19 pandemic had resulted in supply disruptions even though pharma and medical devices industry was exempted by the government from the lockdown as they are essential services. The major challenge was with respect to transportation, especially inter-state movement of medicines and medical products and movement of labourers. In addition, there were other challenges in terms of non-availability of ancillary services such as availability of Packing Materials, courier services etc. The issues are given in detail below:

(a) Challenges in transportation.

Connectivity between company to warehouse and warehouse to stockists was disrupted. The various problems faced included:

i. Non availability of trucks due to unwillingness/ reluctance of transporters.
ii. Shortage of willing truck drivers as they were facing issues of manhandling by police, unavailability of food and diesel on the way.
iii. Principally, unorganized labour is employed for loading/unloading and operating trucks. Most of this labour force had returned to their hometowns as they had assurance of being paid even when not working.
iv. Trucks were frequently held up at borders of states/districts due to restrictions imposed by local administration. Lock down strictness/understanding was not uniform across the country. Strictness

also varied according to the status of new Covid-19 cases found in a particular area.

v. Secondary transportation from CFA (drug forwarding agencies) to stockists (medical stores) was also badly hampered.

vi. Air transport – severe reduction of cargo movement from key international hubs.

- Stopping of passenger flights also impacted movement of cargo that used to come in on these flights.
- Dedicated cargo freighters are quite few.
- Essential and life-saving drugs are getting piled-up at hub locations, but movement to India is slow.

(b) Reduced availability of workers.

i. Movement of labour to-from plants was restricted. Some of these workers travel across state boundaries and were being stopped at borders.

ii. Contractual workers deployed in packing, material movement, loading & unloading were mainly from states like UP, Bihar & Odisha. Many of whom had left for their home states. Apart from factors like fear of contracting disease, pressure from the family not to go to work, the announcement by Government of India that they would get their wages/salary irrespective of the fact that they worked or not was also one of the reasons of their not reporting for work. The Pharma workers needed to be exhorted/ motivated to continue coming to work. There was a need to make them realize that similar to medical professionals their role is also very important and the country was looking towards them in this challenging situation.

iii. Housing societies in which the employees of pharma units resided, pressurized them not to go to work due to their fear that their daily movement could bring infection in their society.

(c) Dependence on mandatory items which were generally not considered essential by states/local administration but were actually essential for manufacturing of medicines.

Ancillary suppliers of inputs including packaging material, excipients (required for tablets and capsules manufacturing), utility consumables like briquettes/gases (required to run boilers) and spare parts were not able to operate/supply as they were not recognized by Police/local administration to be essential commodities and services.

(d) Restriction in Inter-state movement of workers in plants situated at border of two states.

Inter-state and inter-district daily movement of workers was not being allowed from Vapi (Gujarat) to plants in Daman & Silvasa. Major Pharma companies such as Sun Pharma (3 plants), IPCA, Alchem, USV, Macleod etc. have plants there. Apart from these plants, there are more than 30 plants of Small & Medium size Companies. Similarly, in Baddi & Paonta Sahib (Himachal Pradesh), a large number of Pharma units were facing this problem as many of their workers lived in Punjab & Haryana. Apart from the above-mentioned examples there were other such instances e.g. workforce in Sarigam plant of Mylan company in Gujarat were not allowed from UT of Silvasa & Daman.

(e) Disruption in operations of Courier services.

Operation of courier services is a very important factor in the supply chain of medicines. Pharma Industry has informed that the courier services were largely not operational. In some metro cities,

the courier services had started operating, however it remained non-operational for most Tier1 and Tier2 cities. The dispatches from Carrying & Forwarding agents to stockiest had become a big challenge.

D. Actions initiated in the Department to address Logistics related issues

- Regular meetings were held with State Drug Controllers, Drug and medical devices manufacturer Associations and Chemists and Pharmacist Associations and the situations were assessed and resolutions given on real time basis. Cases brought out by Industry Associations & general public continuously were taken up with the States/UTs over phone calls and e-mails.

- Various WhatsApp groups which formed to tackle issues arising out of lockdown e.g group of association of pharmaceutical and medical devices manufacturers, group of distributors of AIOCD, group of Drug Controller General of India with the state drug controllers, group of automobile companies interested in making ventilators, group of glove manufacturers, group of masks, overall IMC group on exports of medicines, group of officers from railways and postal services etc. Many issues brought to the knowledge of department through these WhatsApp groups were flagged to concerned states/ departments.

- A Control Room (with Phone No. 011-23389840 and email: helpdeskpharma@gov.in) was set up on 28.03.2020 in Department of Pharmaceuticals for handling transport and logistics services related issues of industry engaged in providing essential services following the lockdown across the country. A total of 277 cases were handled from 29.03.2020 to 20.05.2020. The cases received related to the following issues viz. Transportation of goods/medicines/ medical equipments; Cargo/ custom related issues; Regulatory issues; Pharma companies HRD matters like shortage of workers, issue of e-pass to employees/workers etc.; availability of Essential medicines; Inter-state transport issues; Medical equipment manufacturing and Manufacturing restricted /barred in some states; permission to function printing and packaging units required by drug manufacturers. The issues raised were addressed and resolved; required information provided; some issues were forwarded to concerned authorities for redressal, as the case may be.

- DoP requested Ministry of Home Affairs (MHA) to issue necessary instructions to State Authorities for effective resolution of issues faced in production, distribution and management of critical, lifesaving essential medicines and medical devices including non-operational courier services and ancillary suppliers of inputs including packaging materials, excipients, utility consumables and spare parts not recognized as essential services in the wake of lockdown for COVID-19. MHA was further requested to take suitable effective measures to prevent any shortage of medicines and medical devices in future and DoP made certain suggestions for tackling the situation including ferrying back contractual labourers from their native places; treating commercial driving license as a pass during the lock down; sensitizing local authorities of the need to restore production of medicines and medical devices, restoration of courier services etc.

- DoP was in constant touch with Key Ministries/Depts. including Civil Aviation, Posts, Air Force, Railways, Customs for effective resolution of transport and logistics services related issues in ensuring availability of medicines across the country.

- DoP conducted various meeting through video conferencing with representatives of major pharma and medical devices associations to discuss latest issues/ challenges faced by them following lock-down for COVID-19, to obtain the status update from the industry regarding their working and to take suggestions from them on tackling the situation.
- DoP requested all Chief Secretaries of States/UTs to ensure that all district authorities and field agencies are informed that no separate passes are required for through traffic of trucks and goods carriers including empty trucks etc., so that there is no ambiguity at the ground level and movement of through traffic of trucks and goods carriers including empty trucks is allowed without hindrance.
- Further, DoP along with NPPA and CDSCO regularly monitored the working status of pharmaceutical and medical device manufacturing units and assess the situation, pre COVID and post COVID.

E. Letters written to Ministries/Departments/States etc. by Secretary DoP

Secretary wrote to all the Chief Secretaries of States and UTs on 23.03.2020 to direct the authorities concerned to make necessary arrangements for issuance of IDs/Entry Pass so as to facilitate movement of the workers engaged in these essential activities.

On 02.04.2020 Secretary also wrote to Secretary, Ministry of Home Affairs to issue necessary instructions to State authorities in order to ensure availability of life saving essential medicines during this critical time. Further, Secretary on 03.04.2020 wrote to Secretary, Ministry of Home Affairs requesting him for issuing appropriate instructions for urgent intervention of the State authorities in the issues related to the supplies of ancillary goods and operation of courier services.

On 09.04.2020, Secretary wrote to Secretary, Ministry of Home Affairs suggesting measures to prevent shortage of medicines in the domestic market, which included allowing pharma and medical device industry to ferry back their contractual labourers from their native places, allowing drivers in possession with driving license of a commercial vehicle to move with or without their vehicle, addressing the apprehensions of drivers regarding ill treatment by the police and to motivate/incentivize (Insurance etc.) them, sensitizing State and District Authorities to the need of bringing back the production of pharma and medical device industry to its pre-lockdown level and need to make courier services fully functional for ensuring movement of medicines and medical devices.

On 24.04.2020, Secretary wrote to Secretary, Ministry of Home Affairs for issuing instructions to State authorities to take effective measures for enabling pharma units to work in full capacity and raise the production to reach the pre-lockdown level and avoid future shortages of medicines and medical devices in the country. List of ancillary service relating to pharma and medical device industry was also provided for circulation to State Authorities for their clarity.

The interventions by the Department resulted in timely issuance of instructions/advisories to State/local authorities ensuring that the production process in the pharmaceutical industry is not hampered and supply of essential medicines in the country is not adversely affected. As per the information provided by CDSCO, of the 5891 manufacturing units operational in the country in the pre Covid-19 situation only 3222 manufacturing units (55.1%) were operational with 39.5% employees working and average daily production of 34.4% during mid-April 2020. However, the situation improved after that and as on 01.07.2020, 4797 manufacturing units (81.4%) were operational with 53.49% employees working and having an average daily production of 50.00%.

CHAPTER-2

Functions and Organizational 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 to give 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 require coordination with other Ministries.

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

1. Drugs and Pharmaceuticals, excluding those specifically allotted to other Departments.
2. Medical Devices- Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.
3. Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceuticals sector.
4. Development of infrastructure, manpower and skills for the pharmaceuticals sector and management of related information.
5. 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.
6. Promotion of public- private-partnership in pharmaceutical related areas.
7. International Co-operation in pharmaceuticals research, including work related to international conferences in related areas in India and abroad.
8. 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.
9. Technical support for dealing with national hazards in pharmaceutical sector.
10. All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.
11. All matters relating to National Institutes of Pharmaceuticals Education and Research.
12. Planning, development and control of, and assistance to all, industries deal with by the Department.
13. Bengal Chemicals and Pharmaceuticals Limited.
14. Hindustan Antibiotics Limited.
15. Indian Drugs and Pharmaceuticals Limited.
16. Karnataka Antibiotics and Pharmaceuticals Limited.
17. Rajasthan Drugs and Pharmaceuticals 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.
(Ms. S. Aparna is holding the charge of Secretary of the Department w.e.f. 01.10.2020)

2.2 Vision:

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

2.3 Mission:

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

2.4 Organizational Set-up:

The 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 the 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; 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 and implementation of the 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 "Pharmaceutical 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), and 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 and implementation of the scheme "Assistance to Medical Device Parks"

(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 also 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.

(h) Coordination Division- all matters of coordination related to intra and inter-Department, RTI, preparation of Annual report, submission of monthly summary report to cabinet etc.

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

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 31.12.2020 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	27	21	5	2	1	-
B	48	23	3	3	7	-
C	18	16	5	-	5	-
Total	93	60	13	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)

2.5 Attached Office

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

2.6 Registered Society

Bureau of Pharma PSUs of India (BPPI) - set up on 1st December, 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

2.7 Autonomous Institutes

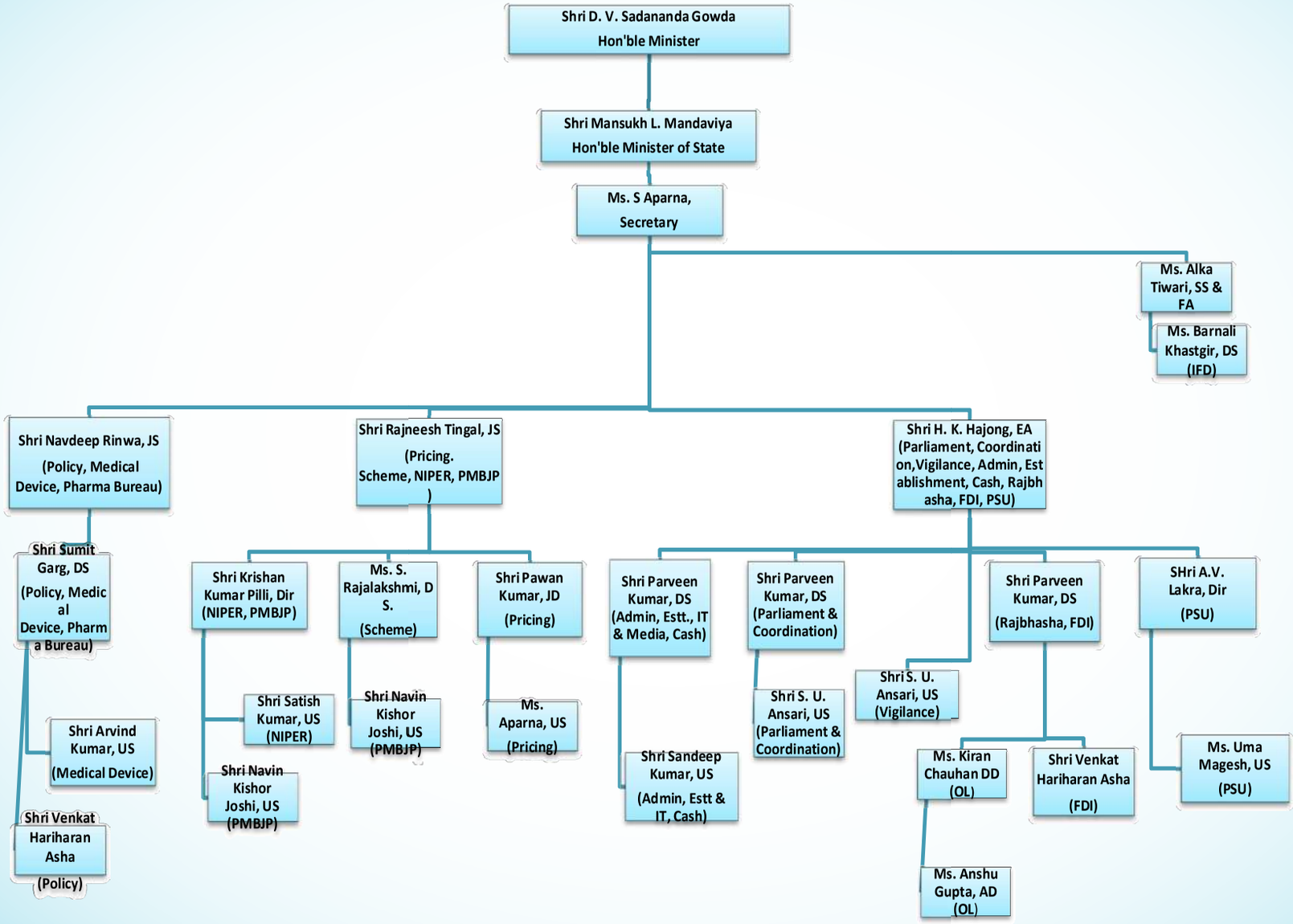
National Institute of Pharmaceutical Education & Research (NIPER)- NIPER at SAS Nagar (Mohali) was set up as a registered society under the Societies Registration Act 1860, Subsequently the Institute was given statutory recognition by an act of Parliament, NIPER Act, 1998 and was declared as an Institute 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.

2.8 Public Sector Undertakings

Central Public Section undertakings- the Department has 5 Central Public Section undertakings under its Administrative control, they are

(a) Indian Drugs & Pharmaceuticals Ltd. (IDPL), Dundahera Industrial Complex, Dundahera, Gurgaon, Haryana,
(b) Hindustan Antibiotics Ltd, Pimpri, Pune, Maharashtra,
(c) Karnataka Antibiotics & Pharmaceuticals Limited, Bangalore-560010,
(d) Bengal Chemicals & Pharmaceuticals Ltd, Kolkata, West Bengal and
(e) Rajasthan Drugs and Pharmaceuticals Limited, Road NO.12, V.K.I. Area, Jaipur-302013.

ORGANIZATIONAL CHART – DEPARTMENT OF PHARMACEUTICALS



CHAPTER-3

Programmatic Interventions

3.1 Scheme for Development of Pharmaceutical Industry

3.2 Medical Device Schemes

3.3 Pharma Bureau

CHAPTER 3

Programmatic Intervention

3.1 Scheme for Development of Pharmaceutical Industry

3.1.1 Umbrella Scheme - Development of Pharmaceutical Industry

The Department has an Umbrella Scheme namely 'Scheme for 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 and availability of quality pharmaceuticals for mass consumption. This Scheme is a Central Sector Scheme and comprises the following seven 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. Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices
c. Promotion of Bulk Drug Parks
d. Promotion of Medical Device Parks
e. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
f. Assistance to Pharmaceutical Industry for Common Facilities (API-CF)
g. 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.

New PLI Scheme for Pharmaceuticals

The Union Cabinet in its meeting on 11.11.2020 approved yet another Production Linked Incentive scheme for Pharmaceuticals with the objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains.

The outlay of the scheme is Rs 15,000 crore and three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme is proposed to be from 2021-22 to 2028-29.

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

With a view to attain self-reliance and reduce import dependence in critical APIs, a scheme called "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key

Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India" has been approved by the Government of India on 20th March, 2020. The Scheme intends to boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. The guidelines for 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. Financial incentives under the scheme shall be provided on sales of 41 identified products for six (06) years at the rates given below:

(i) For Fermentation Based Products, Incentive for FY 2023-24 to FY 2026-27 would be 20%, for 2027-28 - 15% and for 2028-29 - 5%.

(ii) For Chemical Synthesis Based Products, Incentive for FY 2022-23 to FY 2027-28 would be 10%.

The tenure of the Scheme is from FY 2020-21 to FY 2029-30. The total financial outlay of the Scheme is Rs. 6,940 crore.

The scheme has received good response from the industry. A total of 215 applications have been received under the Scheme.

b) Promotion of Bulk Drug Parks

The outbreak of the COVID-19 in China has brought out the risk of disruption of supply chain of critical bulk drugs for the Indian pharmaceutical sector, highlighting the need for India to attain a sufficient degree of self-reliance in bulk drugs. In this regard, a Technical Committee was constituted by DoP on 02.03.2020 under the chairmanship of Dr. Eswara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to make recommendations for the revival of fermentation industry, new technologies for manufacturing of APIs including its backward integration, costing of the projects and identification of strategic business models. On the basis of the recommendations of the committee, Department had prepared the scheme for promoting domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs.

This sub-scheme aims to provide grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total size of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25). The application window of the scheme got closed on 15.10.2020. A total number of 13 States have submitted their proposals under the scheme.

c) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

The objective of the sub-scheme is to facilitate Small and Medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to World Health Organization (WHO)/Good Manufacturing Practices

(GMP) standards so as to enable them to participate and compete in global markets. Assistance in the form of interest subvention against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private sector will be provided to 900 Pharma SMEs of proven track record. The Scheme will be implemented through a Public Sector Financial Institution (PSFI) to be identified by the Government by inviting Expression of Interest. A total of Rs. 144 Crore has been earmarked for the scheme. The upper limit of interest subvention on loans for technology/infrastructure upgradation shall be restricted to 6% per annum for a period of three years on reducing balance basis. The maximum loan eligible for this purpose will be Rs. 4 Crore, availed by the concerned SME.

d) 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 Rs 20.00 crore per cluster or 70% of the cost of project whichever is less. A total of Rs 12.00 crores has been sanctioned for the year 2020-21.

At present one project of Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC) to set up Common Effluent Treatment Plan (CETP) at Alathur, Tamil Nadu is under process. The total cost of the project is Rs 10,59,90,000/-. The project is expected to be completed by January, 2021. Four other proposals have been given 'in principle approval'.

e) Pharmaceutical Promotion & Development Scheme (PPDS)

The Scheme aims at 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. An indicative list of subject is as under: - a. Quality Management System/Quality Improvement Program b. Handling USFDA notice c. Success Story Presentation-Pharmaceutical Entrepreneur d. Government regulations/guidelines for clinical trials in India versus USA, EU etc. e. Waste Management.
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.

3.2 Medical Device Schemes

a) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices

The domestic medical devices industry faces challenges related to considerable cost of manufacturing disability, among other things, on account of lack of adequate infrastructure, domestic supply chain and logistics, high cost of finance, 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" has been approved by the Government of India on 20th March, 2020. 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 is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% on incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The tenure of the scheme is from FY 2020-21 to FY 2027-28. The total financial outlay of the Scheme is Rs 3,420 crore. The four Target Segments of medical devices are :-

- Cancer care/ Radiotherapy medical devices
- Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nu clear Imaging devices
- Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Cate gory
- Renal Care medical devices and all Implants including implantable electronic devices.

The scheme has received good response from the industry. A total number of 28 applications have been received under the scheme.

Guidelines for implementing the provisions of Public Procurement (Preference to Make in India) Order for Medical Devices Sector

The policy of the Government of India is to encourage 'Make in India' and promote manufacturing and production of goods and services in India with a view to enhancing income and employment. In this direction, DPIIT has issued revised Public Procurement (Preference to Make in India) Order, 2017 dated 16.09.2020 and accordingly, Department of Pharmaceuticals has issued the revised guidelines dated 09.11.2020 for implementing the provisions of the public procurement order relating to goods & services related to Medical Device Sector.

b) Promotion of Medical Devices Parks

Recognizing the need for creation of medical technology parks and creation of testing and labo-

ratory facilities, a scheme called "Promotion of Medical Device Parks" has been approved by the Government of India on 20th March 2020. Under this scheme, the central government will finance the creation of common infrastructure facilities with a grant-in-aid of Rs. 100 crore each to 4 medical device parks which will come up in 4 different States. Such financing of the common infrastructure facilities will reduce the burden of capital expenditure on the manufacturers who will develop their units in these parks. Therefore, by providing support to the capital expenditure of the manufacturers, the Government aims to attract investment in the medical device sector. The total financial outlay of the scheme is Rs. 400 crore and the tenure of the scheme is from FY 2020-2021 to FY 2024-2025.

Financial assistance to a selected Medical Device Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Medical Device Park would be limited to Rs 100 crore.

A Medical Device Park project selected under the Scheme will be implemented by a State Implementing Agency (SIA). The proposals under the scheme will be approved by the Scheme Steering Committee (SSC) constituted by Department of Pharmaceuticals. A Technical Committee, constituted by the DoP will assist the SSC in discharging its functions by providing advice on technical matters. A Project Management Agency (PMA) will assist DoP for effective implementation of the Scheme.

The application window of the scheme got closed on 15.10.2020. A total number of 16 States have submitted their proposals under the scheme.

3.3 Pharma Bureau

- Pharma Bureau provides facilitation to investors and resolution of their inter-departmental coordination issues in the Pharmaceuticals and Medical Devices sector.
- It consists of technical experts in the area of :-
  1. Pharmaceuticals
  2. Medical Devices
  3. Project Management
  4. Legal
  5. 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.

CHAPTER-4

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP)

4.1 Background of the Scheme

4.2 Progress made during the last five financial years

4.3 Achievements during last one year

4.4 Jan Aushadhi Diwas Celebration

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 are identical in the therapeutic value.

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

Objectives

- To make available quality medicines consumables and surgical items at affordable prices for all and reduce out of pocket expenditure of consumers/patients.
- To popularize generic medicines among the masses and dispel the prevalent notion that low priced generic medicines are of inferior quality or are less effective.
- To ensure easy availability of the menstrual health services to all women across India.
- Generate employment by engaging individual entrepreneurs in the opening of PMBJP Kendras.

Implementing Agency

Bureau of Pharma Public Sector Undertakings of India (BPPI) was set up on 1st December, 2008 by the Department with a major objective to have focused and empowered structure to implement the Jan Aushadhi Campaign.

The Governing Council of the Bureau in its 34th meeting held on 26.02.2020 decided to change its name from 'Bureau of Pharma PSUs of India (BPPI)' to 'Pharmaceuticals & Medical Devices Bureau of India (PMBI)' and also to constitute a Pharma Bureau within. It also decided to revise/ expand its Memorandum of Association. Subsequently, the SFC of the PMBJP Scheme has been approved with provision of including establishment expanses of the Pharma Bureau.

Salient features of the Scheme

The Scheme has been approved for continuation with the financial outlay of Rs. 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 surgical 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:

Normal Incentive: The incentive to Kendras run by entrepreneurs that are linked with BPPI through soft-

ware has been enhanced up to Rs. 5 Lakh. The incentive is given @ 15% of monthly purchase made from BPPI by these Kendra subject to a ceiling of Rs. 15,000/- per month. This also applies to existing Kendras whose existing limit of incentives of Rs. 2.50 lakh has been fully disbursed.

Additional Incentive

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

i. Rs. 1.50 lakh reimbursement of furniture and fixtures
ii. Rs. 0.50 lakh as reimbursement for computer, internet, printer, scanner etc.

Procurement of medicines

Product basket of PMBJP comprises of around 1,450 drugs and 204 surgical instruments. The medicines are procured only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers for ensuring the quality of the products. Apart from this, each batch of drug is tested at laboratories accredited by 'National Accreditation Board for Testing and Calibration Laboratories' (NABL). Only after passing the quality tests, the medicines are dispatched to PMBJP Kendras

Implementation of IT Enabled Warehousing/Supply Chain System

To overcome the problem of making the range of products available, IT-enabled End-to-End Supply Chain system has been implemented and one central warehouse at Gurugram and three regional warehouses at Chennai, Bengaluru & Guwahati. Further, it has been planned to open two more warehouses in Western and Central India. In addition, appointment of Distributors in States/UTs is also being envisioned to strengthen the supply chain system.

Implementation of SAP and POS System

A single IT enabled system (SAP) introduced in 2017 ensure monitoring of every process from placing the order of medicines to manufactures till the supply of drugs to Store's doorstep.

Saving to a Common man

A medicine under PMBJP is priced on the principle of a maximum of 50% of the average price of the top three branded medicines. Therefore, the price of Jan Aushadhi Medicines is cheaper at least by 50% and in some cases, by 80% to 90% of the market price of branded medicines. In the financial year 2019-20, PMBJP achieved sales of Rs. 433.61 crores (at MRP). This has led to savings of approximately Rs. 3,000 crores of the common citizens of the country. The number of Kendras increased to 6871 from 6306 in the financial year 2019-20. The average monthly sales turnover per store also increased from Rs. 45,000/- to Rs. 51,000/-.

Suvidha Sanitary Napkins

To ensure easy availability of the menstrual health services to all women across the country, "Janaushadhi Suvidha Oxy-Biodegradable Sanitary Napkin" was launched by the Department in the year 2018, which are now available for sale in all PMBJP Kendras across the country @ Rs. 1.00 per sanitary pad. The Jan Aushadhi Suvidha napkins come with a special additive, which makes it bio-degradable when it comes

in contact with oxygen after being discarded. This step has ensured 'Swachhta, Swasthya and Suvidha' for the women in the country.

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.

Awareness about the Scheme

The awareness about the salient features of the Scheme is spread through various types of advertisements through Print Media, Radio, TV & Cinema Advertisements and Outdoor publicity like Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping. In addition, the public are educated about the usages of Jan Aushadhi generic medicines through social media platforms like Facebook, twitter, Instagram, YouTube, etc. It has also been planned to start a comprehensive media campaign in FM Radio & TV in coming festival season.

4.2 Progress made during the last five financial years:

Table-4A

Financial Year	Number of PMBJPKendras functional		Sales at MRP Value in Cr.
	Yearly Addition	Cumulative	
2014-15	14	86	7.29
2015-16	154	240	12.16
2016-17	720	960	32.66
2017-18	2233	3193	140.84
2018-19	1863	5056	315.70
2019-20	1250	6306	433.60
2020-21 (As on 05.01.2021)	712	7018	473.70

4.3 Achievements during last one year

Coverage of the Scheme

As on 05.01.2021, 7018 PMBJP Kendras are functional across the country. The Pariyojana has marked its presence in every district of India by covering all the 734 districts of the country.

Basket of medicines & Stock position

Product basket of BPPI comprises of around 1450 drugs and 204 surgical instruments.

Introduction of New Incentive Plan

To make the scheme more attractive, the incentive provided to the Kendra owners has been en-

hanced from existing Rs. 2.50 lakh to Rs. 5.00 lakh, maximum @ Rs. 15,000 per month. Further, one time incentive of Rs. 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.

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 the year 2018, which are now available for sale in all PMBJP Kendras across the country @ Rs. 1.00 per sanitary pad. Till now more than 9 cr. pads have been sold through PMBJKs.

In his address to the nation from the ramparts of the Red Fort on the Independence Day, 2020, the Hon'ble Prime Minister referred about the issue of mensuration hygiene and subsidized sanitary pads being provided by PMBJKs all across the country. Pursuant thereto, efforts are on for upscaling of scheme of distribution of Suvidha Sanitary Napkins.

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.

Role of PMBJP during Covid-19

In the wake of COVID 19 crisis, BPPI has sold about 15 lacs Face masks, 80 lacs tablets of Hydroxychloroquine and 100 lacs Paracetamol Tablets, which saved around Rs. 1,260 crore of the citizens and also maintaining adequate stock of the medicines which are currently under demand viz. Face Masks, Hand Sanitizers, Hydroxychloroquine, Paracetamol and Azithromycin. Recently, BPPI has launched N95 masks @ Rs 25 per piece.

BPPI is maintaining adequate stock of the medicines which are currently under demand viz. Face Masks, Hand Sanitizers, Hydroxychloroquine, Paracetamol and Azithromycin. 60% growth in Sales has been achieved in the 1st half of the Financial Year 2020-2021 as compared to same period of the previous Financial Year. Envisioning current market demand, BPPI has also placed purchase orders for procurement of these medicines to have enough stock for the next six months.

4.4 Jan Aushadhi Diwas Celebration

All PMBJP Kendra owners celebrated 7th March 2020 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 announced for instituting awards in various categories for those who have contributed for successful implementation of the scheme. On Jan Aushadhi Diwas 2020, Hon'ble Prime Minister of India, Shri Narendra Modi interacted with people from various PMBJKs through video conferencing. The Prime Minister interacted with stores owners and beneficiaries at selected stores across the country, including Guwahati, Dehradun, Coimbatore, Varanasi and Pune.

Celebration of Jan Aushadhi Diwas on 7th March 2020

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

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

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

Shri D. V. Sadananda Gowda,
Hon'ble Minister for Chemicals & Fertilizers

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

CHAPTER-5

NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPERs)

CHAPTER 5

National Institutes of Pharmaceutical Education & Research

5.1 Background

1. 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, 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.

2. 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 the year 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.

3. 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 85% 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. Department has proposed to allot 20 acres of surplus land of BCPL to NIPER-Kolkata for construction of its permanent campus.
Raebareli	2008	49 acres land at Village Vinayakpur, Pargana Bachrawan, Tehsil Maharajganj, Raebareli has been allocated.

4. The aims and objectives of NIPER 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 researches 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 organise national or international symposia, seminars and conferences in selected areas of phar-

maceutical 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. 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).

6. Board of Governors 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 has expired on 02.10.2019. It is yet to be re-constituted. The First BoGs of other six NIPERs were constituted for a period of three years on 09.03.2019.

Table-5B

(Board of Governors of NIPERs)

NIPER	**Chairman: BoG NIPERs**
NIPER-Ahmedabad	**Dr. Ketan R. Patel** Chairman-cum Managing Director, Troikaa Pharmaceuticals Ltd. Gujarat
NIPER-Guwahati	**Dr. S. Chandra Shekhar** Director, CSIR-IICT, Hyderabad
NIPER-Hajipur	**Dr. Sanjay Singh** Vice Chancellor, Babasaheb Bhimrao Ambedkar University, Lucknow
NIPER-Hyderabad	**Dr. Satish Reddy** Chairman, Dr. Reddy's Laboratory Ltd., Hyderabad
NIPER-Kolkata	**Prof. (Dr.) Bhabatosh Biswas** Former Vice Chancellor, Bengal University of Health Sciences, Kolkata
NIPER-Raebareli	**Prof. Rakesh Kapoor** Director, Sanjay Gandhi PGIMS, Lucknow

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 pharmacy Institute in the country, as under:

Table-5C
(NIPERs in NIRF Ranking)

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

5.2 NIPER Mohali

NIPER S.A.S. Nagar has been declared as an "Institute of National Importance" through an Act of Parliament. 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 for ten different fields, 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. NIPER offers Masters' and Ph.D. degrees in 15 streams and caters to the various needs of pharmaceutical industry.

1. Achievements –

Academic excellence : In 2020-21, the Institute has published 79 articles in journals of repute (till 25th November 2020). Institute has filed 192 patents applications and out of which 104 patents are granted/ issued till date. Since the inception of academic programme (till 20th November 2020), 3746 students have passed out (Masters 2764, MBA 643 & Ph.D. 335).

2. Research –

A. Neglected diseases - Research is carried out in the areas of tuberculosis, leishmaniasis 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. Standardization of Herbal drugs and formulations

iv. Toxicological studies

D. Other areas

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

3. Students

Table-5D

(Degrees/programmes/ subject offered year-wise with admission status)

Level Masters/ Doctoral	Degree MS/MBA/MTech/ Ph. D	Discipline	No. of students admitted	
Years			**2019-20**	**2020-21**
Masters'	M.S.(Pharm.)	Medicinal Chemistry	28	26
Doctoral	PhD		2	
Masters'	M.S.(Pharm.)	Pharmacoinformatics	17	17
Doctoral	PhD		0	1
Masters'	M.S.(Pharm.)	Natural Products	13	13
Doctoral	PhD		4	
Masters'	M.S.(Pharm.)	Traditional Medicine	5	5
Masters'	M.S.(Pharm.)	Pharmaceutical Analysis	9	9
Doctoral	PhD		0	
Masters'	M.S.(Pharm.)	Pharmacology & Toxicology	18	18
Doctoral	PhD		4	1
Masters'	M.S.(Pharm.)	Regulatory Toxicology	9	9
Masters'	M.Tech.(Pharm.)	Pharmaceutical Technology (Formulations)	7	7
Doctoral	PhD		0	

4. Academic and Non – academic Staff

Table-5E

(Academic and non-academic staff position)

Man-Power	Sanctioned	In-Position	Vacancy
Academic	62	26	36
Non-Academic	223	127	96

5. Total fund allocated by the Government during the last 4 years

Table-5F

(Allocation of fund by the Government during last 4 years)(In Rs.)

Year	Allocation BE (Crores)	Allocation RE (Crores)	Total Release (Crores)
2017-18	27.74	42.32	42.31
2018-19	32.00	29.00	29.00
2019-20	30.60	30.60	30.60
2020-21*	41.00	45.77	45.77

*Fund released till December 2020.

5.3 NIPER- Hyderabad

NIPER-Hyderabad started functioning in September 2007 in the premises of IDPL, R&D centre, Balanagar, Hyderabad. The Institute has been functioning with the mission of developing human resource with excellence through conducting Postgraduate 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 and Pharmaceutical Management.

1. Achievements:

Table-5G

(Achievements of NIPER Hyderabad)

1	Master Students Passed Out	1060
2	Master Students pursuing course	303
3	Students pursuing Ph.D course	97
4	Doctoral degree awarded	53
5	Patents (filed)	15
6	Research Publications	715
7	Sanctioned extramural research projects	34

2. Details of Faculty & Staff:

i.	Regular Faculty	: 14
ii.	Regular Staff	: 06
iii.	Contractual Faculty	: 02
iv.	Contractual Administrative and Technical Staff	: NIL

3. Total Allocation by the Government during the last 4 years

Table-5H

(Allocation of fund by the Government during last 4 years) (Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2017-18	20.00	30.00	30.00
2018-19	24.00	24.00	24.00
2019-20	25.00	27.00	27.00
2020-21	30.50	30.50	30.50

***Fund released till December 2020.**

4. Teacher-Student ratio:

Presently 1:8

5. Employability/ Placements Status:-

A. Year wise Companies participated in campus selection / placement

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

B. Last few years placements status: in campus/off campus

Table-5I

(Placement Status : in Campus / off Campus)

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

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.

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

8. Innovation / knowledge transfer

a) Patents and commercialization- 15 patents filed in areas of Cancer Drug Discovery, Formulation Development and Analytical Method Development

b) Revenue Generation: 1.20 Crores (FY 2020-21) till Nov-2020

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.

10. Collaborations / MoUs

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

- Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru
- AMTZ, Vizag
- Momentous Molecules Private Ltd., Banjara Hills, Hyderabad
- PS3 Laboratories LLP, Kukatpally, Hyderabad
- Innatura Scientific Pvt. Ltd., Uppal, Hyderabad
- CSIR-IITR
- Sarvotham care limited
- Babasheb Bhimrao Ambedkar University, Lucknow
- NBI Bioscience Private Limited, New Delhi
- Phaeno Biotech, Inc, USA
- University of Bialystok, Poland,
- Lifeactivus, TenchiKSM and NIPER Hyderabad
- ESIC Medical College Sanathanagar, Hyderabad
- Lifeactivns Private Limited, Medchal, Hyderabad
- Apollo Hospitals Educational & Research Foundation (AHERF)
- National Institute for Micro, Small and Medium Enterprises (ni-msme)
- Vline Pharmachem Private Ltd

- Lorven Biologics Private Limited, Andra Pradesh
- Zystus Nutraceuticals Private Limited
- Almelo Private Limited, Hyderabad
- National Research Development Corporation, New Delhi
- IIT Hyderabad
- Dr Reddy's Laboratories Ltd, Hyderabad
- Central Council for Research Institute of Unani Medicine (CCRUM)
- BOGAR Laboratories
- Novartis Healthcare Pvt. Ltd
- Extrovis Pvt. Ltd.
- Biological E. Ltd.
- United States Pharmacopeia (USP, India), Hyderabad
- National University of Singapore
- Department of Health Sciences of University "Magna Graecia" of Catanzaro
- Dr Reddy's Laboratories Ltd, Hyderabad
- Bharat Biotech International Ltd
- NATCO Pharma Ltd, Hyderabad
- Natural & Essential Oils Pvt. Ltd.
- Natco Research Center
- Clearsynth Labs Ltd Research Center
- DAEWOONG Pharmaceutical Co. Ltd.
- Dr. Reddy's Institute of Life Sciences
- Calyx Chemicals and Pharmaceuticals Ltd.
- College of Pharmacy, University of Minnesota
- Central Research Institute of Unani Medicine (CRIUM), Hyderabad
- Jubilant Biosys Ltd., Bangalore

11. Various events/ Workshops carried out by the institute

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

Some Photographs

NIPER-Hyderabad conducted its 8th e-Convocation on July 24th, 2020

NIPER Hyderabad celebrated 14th Foundation Day on 10th November, 2020

5.4 NIPER- AHMEDABAD

NIPER-Ahmedabad was set up in 2007 and 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 Masters 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.

1. Achievements:

National Institute Ranking Framework-2020 (NIRF)

The Institute has been Ranked # 2nd in Teaching and Learning Resources (TLR) and All India

Ranking of #8th among all Pharmacy Educational and Research Institutions in India as per NIRF 2020 released by Ministry for Human Resource Development, Government of India.

Atal Ranking of Institutions on Innovation Achievements-2020 (ARIIA)

The Institute has been placed in Band A (Rank Between11th– 25th) under the category of Publicly Funded Institutions

Publications - The Institute has published 530 articles in peer reviewed journals of repute.

Students in MS Programme

i. 607 M.S Pharm. students have already graduated from NIPER-Ahmedabad and are well placed in various Pharma industries in India and abroad.

ii. Presently, 252 students are pursuing their M.S. (Pharm) and MBA (Pharm) course in 8 disciplines.

Students in PhD Programme

i. 10 students have been awarded Ph.D. Degree till date.

ii. 65 students are continuing for their Ph.D. studies.

Patents - Institute has filed up till now 12 patents wherein faculty or students of NIPER-Ahmedabad are inventors.

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

2. Details of Faculty & Staff

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

Table-5J
(Details of Faculty & Staff)

Faculty	Regular	Contractual
Associate Professor	6	0
Assistant Professor	12	1
Admin Staff	10	04
Technical Staff	03	05

3. Total Allocation by the Government during the last 4 years (Rs. in crores)

Table-5K
(Total Allocation by the Government during the last 4 years)

Year	Allocation BE	Allocation RE	Total Release
2017-18	22.96	27.96	27.96
2018-19	12.00	12.00	12.00
2019-20	15.00	18.50	18.50
2020-21*	36.50	36.50	36.50

*** Fund released till December 2020**

4. Students

Table-5L

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

Masters/ Doctoral	MS /PhD	Discipline	No. of students admitted		
			2018-19	2019-20	2020-21
Masters	M.S.(Pharm.)	Biotechnology	10	10	13
Doctoral	PhD		01	1	4
Masters	M.S.(Pharm.)	Medicinal Chemistry	16	17	22
Doctoral	PhD		01	3	4 +2*
Masters	M.S.(Pharm.)	Medical Devices	10	11	14
Doctoral	PhD		01	0	1
Masters	M.S.(Pharm.)	Natural Products	10	10	10
Doctoral	PhD		01	1	1
Masters	M.S.(Pharm.)	Pharmaceutical Analysis	18	21	22
Doctoral	PhD		01	2	3
Masters	M.S.(Pharm.)	Pharmacology & Toxicology	15	17	22
Doctoral	PhD		01	3	3 + 2*
Masters	M.S.(Pharm.)	Pharmaceutics	17	21	22
Doctoral	PhD		01	2	3 + 1*
MBA (Pharm)	MBA (Pharm)		-	-	20
			103	**119**	**169**

***PhD Project Seats**

Table-5M

Degree/MS/MBA/ M.Tech/Ph.D	Discipline	No. of students admitted			
		2017-19	2018-20	2019-20	2020-21
MS	7 Disciplines	72	96	107	125
Ph.D	7 Disciplines	11	7	12	19 +5*
MBA (Pharm)		-	-	-	20

*PhD Project Seats

5. Teacher-Student ratio:

Presently 1: 16.6 (19 Faculty: 317 students)

Table-5N
(Teacher-Student ratio)

Course	Ratio
Ph.D.	(S-65:F19) /3.4:1
Masters' (Science)	(S-252 :F19) /13.2 :1

* Guest faculty members are also taking classes

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

Table-5O
(Employablity/Placements Status)

Batch	Total no of student	Not placed	Total no of student placed	Going for higher studies
2016-18	69	6	54	9
2017-19	72	1	46	25
2018-20	96	13	65	18

7. Teachers: International Research Collaboration

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

8. MoUs signed during 2019-20

Table-5P
(MoUs signed during 2019-20)

MoUs	Date
University of Prince Edward Island, Canada	21-03-2019
Sai Life Sciences Limited, Hyderabad	01-04-2019
Université Paris-EstCréteil (UPEC) CréteilCedex, France	01-04-2019
Ophthalmic Marketing & Services Pvt. Ltd., Ahmedabad	03-09-2019
Novartis Healthcare Pvt. Lt., Switzerland	11-06-2020

Novartis Healthcare Pvt. Lt., Switzerland	11-06-2020
NovugenPharma, Shah Alam, Selangor, Malaysia	31-08-2020
All India Institute of Medical Sciences, Jodhpur	04-09-2020
IITGandhinagar, Gujarat	12-10-2020
State Implementing Agency (SIA), Gujarat Industrial Development Corporation (GIDC), Gandhinagar	22-10-2020
Intas Pharmaceuticals Ltd.Ahmedabad, Gujarat	09-11-2020

9. Research: Active Research Areas:

Department of Biotechnology

Genetic profile and biomarker identification of OSCC patients through transcriptome analysis

- Dissecting the molecular mechanisms by which healthy cells become cancerous and metastasize
- Epigenetic modulation in diabetic nephropathy through 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
- Differential regulation of L-type calcium channels in ischemic brain injury
- Development of targeted therapeutics for acute myeloid leukemias (AMLs)
- Establishment of Patient-derived organoids (PDO) from head and neck cancer patient's samples

Department of Medicinal Chemistry

- Multi target-directed ligands for Alzheimer's proteopathy
- Ultrashort-peptides and peptidomimetics as smart-bioinspired material
- Reversible anticancer covalent inhibitors
- Construction of drug candidate(s) through C–H bond activation
- Sustainable synthesis and functionalization of carbo/heterocycles employing water as reaction me-dium
- Green chemical process toward the synthesis of pharmaceuticals (drugs)

Department of Medical Devices

- Biomaterial Platforms
- 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
- Development of osteoconductive and high strength bone cements for joint arthoplasties

- Advanced strategies for cancer theranostics
- Paper microfluidics for diagnostic applications
- Micro/nanodevices for life-sciences and biomedical applications
- Development of bioengineered 3D disease models with a focus on cancer
- Fabrication of in vitro biophysical micro environment to understand disease biology
- Non-invasive screening platforms for early detection of cancer

Department of Natural Product

- LC-MS based dereplication strategy for isolation of novel bioactive natural products from plant sources
- Establishment of Q-Marker system for standardization of traditional Ayurvedic polyherbal formulations
- Finger printing herbal extracts by LC-UV-MS for chemical marker identification and extraction efficiency
- Bio-prospecting of endolichenic fungi to discover novel bioactive scaffolds
- Identification of a Natural Products possessing GLP-1R agonist activity from the plants recognized to have anti-diabetic potential;

Department of Pharmaceutical Analysis

- Drug-excipient compatibility studies
- Forced degradation studies of APIs and NCEs using HPLC, LC-MS/MS and qNMR
- Drug-Device compatibility and drug release study
- Bioanalysis, drug metabolism and pharmacokinetics
- Analytical Approaches for Polymer Characterization
- Biosimilars characterization

Department of Pharmacology and Toxicology

- Mitochondrial protection in ischemic stroke using intra-arterial mesenchymal stem cell treatment
- Stem Cell Therapy to Counteract Endoplasmic Reticulum Stress in Ischemic stroke
- Therapeutic strategy based on targeting growth hormone releasing hormone (GRH) receptors for mitochondrial protection in ischemic stroke
- Investigating the role of inosine on inflammasome signaling in animal model of ischemic stroke
- Exploring the effect of endoplasmic reticulum stress in exacerbation of stroke pathology in chronic kidney disease
- Deciphering the role of statin in neurogenesis after focal cerebral ischemia
- Exacerbation of ischemic stroke pathology in CKD: Involvement of mitochondrial dysfunction
- Probable mechanism of exacerbation of Ischemic stroke pathology in CKD
- Investigating the role of inosine in cerebral ischemia via pi3k/akt pathway
- Neuroprotective role of apelin-13 in post stroke depression
- Exploring neuroprotective effect of Phyllanthusemblica in animal model of ischemic stroke
- Exploring DAP-kinase pathway in Ischemic stroke by Intra-Arterial Mesenchymal Stem Cells (MSCs) intervention

- Targeting interplay of lectin–like ER chaperone with calcineurin by stem cells therapy in ischemic stroke
- Intra Arterial delivery of mesenchymal stem cells to target "ER-UPR mediated neuronal cell death" in ischemic stroke
- Inhibition of Caspase 1 via Stem Cell Therapy to prevent Mitophagy and neuronal cell death in cerebral ischemia.
- Investigating the role of enteric neuronal inflammation in the pathogenesis of Parkinson's disease
- Targeting alpha synuclein accumulation and transmission: Role of AMPK activator
- Exploring the role of miRNAs in the breast cancer metastasis by regulating PKM2 and CD98 expression
- Effect of Boronic acid derivative on chemically induced oral carcinoma in mice via activation of Pyruvate kinase M2

Department of Pharmaceutics

- Development of novel polymeric nanomaterial for effective cytosolic delivery of anticancer bioactive
- Formulation Development of Injectable RNA interfering nanoparticle for targeted therapy of diabetic nephropathy
- Tripartite approach for the treatment of triple-negative breast cancer (TNBC) using graphene oxide wrapped polymeric nanoparticles
- NIR laser activatable Nanoplates for the treatment of resistant tumors
- NIR laser activatable Nanoseeds for the prevention of post-surgical relapse of the resectable tumor
- Electrospraying Vs Lyophilization: Impact of on Solid-state properties of drug Nanosuspension
- Formulating the poorly soluble drugs in conventional dosage forms for bioenhancement
- Exploiting the oral route for delivery of macromolecular therapeutics using penetration enhancer(s)

10. 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.

11. Awards

1. The faculty got various multilateral Research Grants, Start-up Research Grants, IBRO Regions Connecting Grant and various awards.

2. The student got various fellowships including ICMR-Senior Research Fellowship, DST Travel Grant, Khorana Program for Scholars 2020, Japan-Asia Youth exchange program in science, Copenhagen Travel Grant Award and won various awards including Best Posters Award, PharmInnova Award, got selected in MHRD Innovation Cell, Japan-Asia Youth exchange program in science, selected in IBRO-APRC, Nestle powder challenge award, Paul Dudley White International Scholar Award, etc.

12. Patents

The Institute filed 12 patents during the year.

13. 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:

7th Convocation of NIPER-A (18-01-2020)

A workshop on Mammalian cell culture, cell-based staining, imaging & molecular expression techniques (16-20 September- 2019)

Dr. A P J Abdul Kalam innovation week (7th Oct. to 11th Oct. 2019)

International Conference On Neurological Disorders & Therapeutics (ICNDT) 2019 (24th to 26th Oct-2019)

National Unity Day (31-10-2019)

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 3rd November 2016. NIPER-Guwahati is now functioning from its own permanent campus at Changsari, Kamrup (Rural), North Guwahati, Assam from January 2020.

This institute owns six National Centers identified by different 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 Affairs ; 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.

1. Achievements: -

i. Ph.D. - 44 (enrolled), Degrees awarded – 09 (since inception),

ii. Total M.S. (Pharm.) (since inception),
Students enrolled – 460
Graduated - 324 (135 students are currently pursuing their P.G. courses)

iii. 95% of students in each department got placed in various reputed Industries like Novartis, SPARC, Sun Pharma, Lupin, etc. through on/off campus placement modes.

iv. Publications: In total, 268 articles have been published since inception in peer-reviewed International journal out of which 51 articles have been published in 2019-20 in various National and International Journals.

v. Institute has total 08 patents including 1 design patent and 2 copyrights.

2. Details of faculty & staff

Administrative Staff	:	11
Academic Staff		
Associate Professors	:	04
Assistant Professors	:	06
Research Associate	:	04
Staff: Technical	:	05
Multi-Task Staff	:	12

3. Total Allocation by the Government during the last 4 years.

Table-5Q
(Allocation by the Government during the last 4 years.) **(Rs. in crores)**

Year	Allocation BE	Allocation RE	Total Release
2017-18	31.50	52.00	52.00
2018-19	33.50	33.50	33.50
2019-20	36.90	43.90	43.90
2020-21	34.45*	34.45	34.45

*Fund released till December 2020

4. Students:-

Degrees/programmes offered and subjects offered (with year)

Table-5R
(Degrees/programmes and subjects offered year-wise with admission status)

Level	Degree	Discipline	Year		
Masters/ Doctoral	MS/ MBA/ M.Tech/ Ph.D		2017-18	2018-19	2019-20
Masters	MS (Pharm)	Pharmacology and Toxicology	20	15	15
Masters	MS (Pharm)	Biotechnology	9	10	10
Masters	M. Pharm.	Pharmacy Practice	10	10	9
Masters	M. Pharm.	Pharmaceutics	Not started	15	18
Masters	M. Pharm.	Pharmaceutical Analysis	Not started	15	18
Doctoral	Ph.D.	Pharmacology and Toxicology	2	2	1+2*
Doctoral	Ph.D.	Biotechnology	1	1	0
Doctoral	Ph.D.	Pharmacy Practice	1	1	1
Doctoral	Ph.D.	Pharmaceutics	Not started	2	1+2*
Doctoral	Ph.D.	Pharmaceutical Analysis	Not started	1	1+1*

5. Teacher-Studentratio:

Biotechnology	:	1:5
Pharmacology and Toxicology	:	1:5
Pharmacy Practice	:	1:5
Pharmaceutics	:	1:6
Pharmaceutical Analysis	:	1:8

6. Employability/ Placements Status :

In the acedemic session 2019-20, 6 students have been placed in Novartis, Hyderabad. Many other companies are in pipeline for placements.

7. Research

Biotechnology:

Development of Biopharmaceuticals using Biomolecular Engineering/Synthetic Biology approaches -

- Oncogenic mRNA cleaving Deoxyribozymes

- Development of new approaches of Immune rerouting for targeting cancer cells
- Riboswitch mediated gene regulation of oncogenes
- Generation of random Protein coding sequences & Aptamer based therapeutics and diagnostic tools

Pharmacology And Toxicology

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

Pharmacy Practice

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

Pharmaceutics

- Lipid nanoarchitectionics against dreadful diseases
- Pharmacoengineering & Molecular Pharmaceutics
- Ligand anchored targeted drug delivery systems
- Drugs in-adhesive (DIA) matrix patch design
- Pathogen mimetic delivery devices
- Nanomedicines & Nanobiotechnology
- Translationalcutting edge pharmaceutical & biomedical research
- Pre-formulation studies of active pharmaceutical ingredients
- Dosage form development and optimization for poorly water-soluble drug molecules
- Drug targeting using lipid-and polymer-based nanoparticulate systems
- Micro-and nano-theragnosis concepts for the early detection and treatment of malignant diseases and other life-threatening diseases
- Eradication of biofilm-producing microorganisms from the surfaces of implanted or inserted medical devices into human body

Pharmaceutical Analysis:

- Bioavailability, IVIVC and IVIVE analysis
- Analytical (ICH Guidelines) & Bio-analytical (FDA-Industry Guidance) method development & validation using HPLC, UPLC, LC- MS/MS

- Short-term/accelerated, mid-term and long-term stability testing of formulations and degradation studies
- Pharmacokinetic, Toxicokinetic, Metabolic and Impurity profiling

8. Students' enrolment:

Current strength of Ph.D. students: 31
(Pharmacology & Toxicology-13; Biotechnology-06; Pharmacy Practice-04; Pharmaceutics-06 and Pharmaceutical Analysis-03)

Current strength of Masters Students: 135
(Pharmacology & Toxicology-30; Biotechnology-20; Pharmacy Practice-19; Pharmaceutics-33 and Pharmaceutical Analysis-33)

9. Patents and Commercialization:

Institute has total 08 patents and 2 copyright, of which 1 is design patent.

10. Collaboration:

NIPER-G entered into 26 active MoUs. During the financial year, NIPER-Guwahati has exchanged MoUs with the many Institutes like IIT-Bombay, ILBS-New Delhi, CSIR-CCMB, etc.

11. Impact of NIPER:

The establishment of NIPER-Guwahati has given a strong boost to the promotion of Pharmaceutical Education & Research in the North East region of India. Research efforts of NIPER Guwahati have revived the studies on medicinal value of local herbs of North East Region against various diseases. NIPER-Guwahati has organized a National conference entitled "Ethno-medicine and Traditional Health Practices in Northeast region of India" in collaboration with the Society for Ethnopharmacology (SFE), India, on 25th August 2018. Around 76 traditional healers from Assam, Mizoram, Meghalaya, Sikkim and Tripura attended this meet and showcased their plant-derived medicinal products in individual stalls.

The faculty members of NIPER-Guwahati have been awarded 06 Extramural projects in the year 2018 from different funding agencies like DBT, DST, DRDO, Ministry of Environment, Forest and Climate Change, etc.

NIPER-Guwahati is the only NIPER to have a Synthetic Biology Laboratory, which has been awarded 'Genome Editing Task Force' project by DBT, Govt. of India. The Institute has entered into several MoUs with leading Research institutes, Hospitals and Pharmaceutical Industries to give students and faculty the best of the academic and research support to eventually come up with technologies and products for the benefit of the society.

12. Number of students received M.S./M. Pharm. degree

Table-5S
(Number of students received M.S./M. Pharm. degree)

Sl. No.	Batch	Number of student 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	
Total		100	100

Some Photographs

Felicitation of Chief Guest, Prof. Anil D. Sahasrabudhe, Chairman, AICTE

NIPER-Guwahati conducted One-day Workshop on "Good Pharmacy Practice (GPP) Training for Community Pharmacists" on 28 September 2019.

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.

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 12 patents and one copyright till 2019-20.
- The Institute received nearly one crore rupees as extramural research grant for research in the thematic areas of the Institute.
- More than 100 publications in last 3 years (52 publications in the current year) in the journals of International repute.
- One book entitled "Handbook on the Preparedness on Chemical Warfare Agents" published by Elsevier/ Academic Press (USA).
- Central Instrumentation Facility was created housing sophisticated instruments such as Nuclear Magnetic Resonance (NMR), LC-MS (QTOF-HRMS), HPLC, FT-IR, Flow-cytometry etc.

2. Academic/Non-Academic staff

Academic	01	Director Regular
	10	Associate Professor/ Assistant Professor (7 Regular, 3 Contract)
Non-Academic	19	Administrative/Technical Staff (7 Regular, 12 Contractual/Outsourced)

Total 19 posts of regular faculty and 25 posts of regular Non-faculty have been created in February, 2019. Second Phase recruitment for regular staff is under process and the posts are likely to be filled shortly.

3. Total fund allocation by the Government during the last 4 years:-

Table-5T
(Total fund allocation by the Government during the last 4 years)

(Rs. in Crore)

Year	Allocation BE	Allocation RE	Total Release
2017-18	8.50	9.50	9.45
2018-19	12.00	15.00	15.00
2019-20	16.00	17.01	17.01
2020-21*	22.00	22.00	22.00

*Fund released till December 2020.

4. Students

Degrees/programmes offered and subjects offered (with year) with admission status:

Table-5U

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

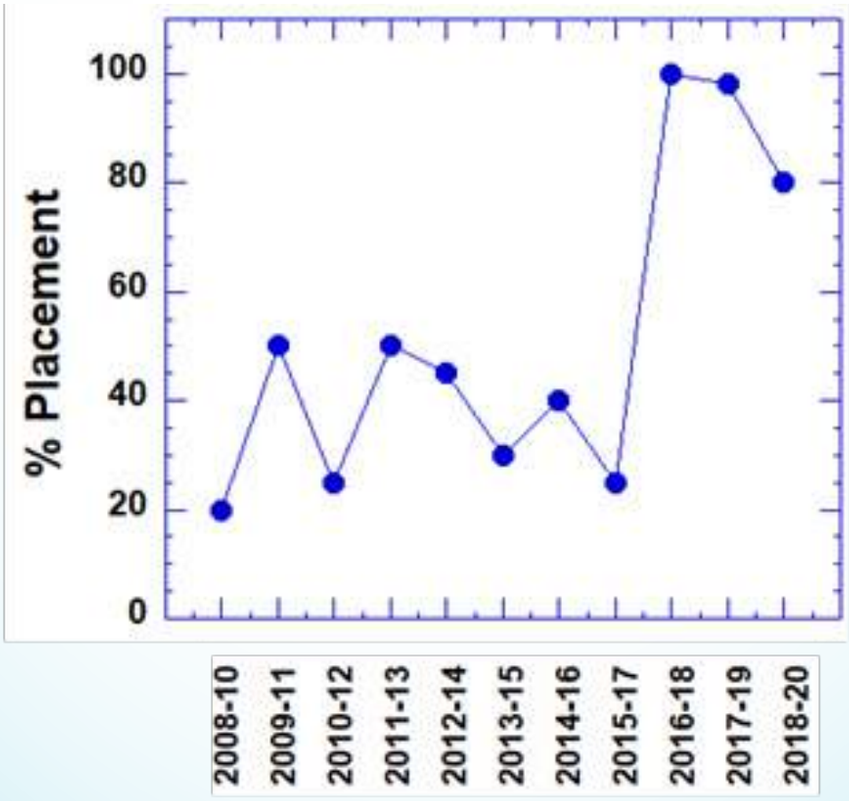
Subject	Degree	Sanctioned seats	Admission Status
Medicinal Chemistry	M.S. (Pharm)	22	20
Pharmaceutics	M.S. (Pharm)	17	15
Pharmacology & Toxicology	M.S. (Pharm)	16	15
Regulatory Toxicology	M.S. (Pharm)	11	11
Medicinal Chemistry	Ph.D	02	02
Pharmaceutics	Ph.D	02	02
Pharmacology & Toxicology	Ph.D	02	02

5. Teacher Student Ratio - 1:14

6. Employability / Placements Status, A graph showing the year-wise placement status of NIPER-Raebareli.

Graph-5A

(Year-wise placement status of NIPER-Raebareli)



List of some of the companies participated in 2020

7. Awards/ Teachers:

Dr. S.J.S Flora was Ranked as No.1 Toxicologist in India

In a subject-wise analysis conducted by the team of scientists at Stanford University, ten scientists from different NIPERs spread across the country have found place in the world ranking of top 2% scientists in India. Dr. S.J.S Flora, Director was ranked No. 1 in the list of Indian toxicologists and globally he was ranked 44th.

8. Research

a. Active Research Areas:

- Neurodegenerative diseases
- Heavy Metal Toxicity
- Japanese Encephalitis
- Tuberculosis
- Development and evaluation of drugs using Nano formulations.
- Development of green and eco-friendly synthetic methods

b. Projects: Ongoing : 03

c. Publications and Patents : 50

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 milestiones and Pharma industries have shown interest in collaborating with us besides training our students for short term and long term basis.

The Institute initiated collaborative projects/ work with national and international academic and research institutes in the area of immediate importance like such as Japanese Encephalitis, Tuberculosis and Neurodegenerative diseases. An online portal has been created to facilitate seamless sample analysis for drug discovery. NIPER Raebareli is also providing highly skilled human resources for the Indian Pharmaceutical Industry.

10. Various events/workshops carried out by the institute

i. Distinguished Lecture Series

The Institute started the "Distinguished Lecture Series" to bring the subject experts in the field of Pharmaceutical Sciences on a regular basis with a purpose to bring eminent researchers to talk about their research and also to acquaint young students with the emerging trends in this field. To state in this series, various eminent academic & Industry experts were invited who visited and interacted with faculty & students of NIPER-R for possible research collaboration.

ii. Rajbhasha Workshop

Hindi workshop was organized on 14th June to promote progressive use of Hindi as an official language and in accordance with Official Language Act, rules and orders.

iii. Workshop on "Scientific Writing and Research Ethics" (October 31, 2019)

The Institute conducted one day workshop on "Scientific Writing and Research Ethics" which focused on creativity in writings and scientific research in all its conceptual, methodological, disciplinary and professional aspects.

iv. Constitution Day Activities

The Institute organized various programs/ activities on the theme throughout the year.

Dr. P.D. Vaghela, Secretary Department of Pharmaceuticals was the Chief Guest of 5th Convocation of NIPER-Raebareli

5.7 NIPER Kolkata

The National Institute of Pharmaceutical Education & Research, Kolkata (NIPER-Kolkata) was established in the year 2007 and is presently functioning from its rented campus at Chunilal Bhawan, Maniktala, Kolkata. It is striving to achieve academic excellence through teaching, research and scholarship. At the moment teaching remains central function and overriding goal.

1. Achievements

In 2020-21(till November 2020) 24 research papers published, 4 MoU signed. Since inception, 479 students have been graduated, Master- 477 students and PhD- 2 students.

2. Academic and Non-Academic staff:

Total 19 posts of faculty and 25 posts of Non-faculty have been approved by Department of Expenditure in January 2019.

3. Total allocation by the Government during the last 4 years

Table-5V
(Allocation of fund by the Government during the last 4 years)

(Rupees in Crore)

Year	BE	RE	Total Release
2017-18	9.00	11.50	11.50
2018-19	12.00	12.00	12.00
2019-20	16.00	18.00	18.00
2020-21*	23.00	23.00	23.00

*Fund released till December, 2020.

4. Students

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

Table-5W
(Degrees/programs and Subjects offered year-wise with admission status)

Level	Degree	Discipline	No. of students admitted					
			2015-16	2016-17	2017-18	2018-19	2019-20	2020-21
Masters	M.S. (Pharm.)	Medicinal Chemistry	17	14	16	08	08	14
		Natural Products	13	14	14	08	06	07
		Pharmacoinformatics	09	14	14	03	04	05
		Pharmacology	-	-	-	08	13	14

		& Toxicology						
		Rare disease	-	-	-	-	-	-
		Pharmaceutics	-	-	-	-	-	14
Doctoral	Ph.D.	Medicinal Chemistry	-	04	04	-	-	03
		Natural Products	-	04	04	01	-	-
		Pharmacoinformatics	-	02	04	-		-
		Pharmacology & Toxicology	-	-	-	-	01	03
		Pharmaceutics	-	-	-	-	-	02

5. Teacher-Student ratio: 1:6

Classes are managed by NIPER faculty and visiting faculty /guest faculty.

6. Employability/ Placements Status

Since inception, large number of Pharma Companies came to NIPER-Kolkata to recruit students. 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-5X
(Employability/Placements Status)

Masters : M.S. (Pharm.)		
Year (Batch)	Total No. of students	No. of students placed (*as per available records with us)
2007-2009	29	24
2008-2010	32	26
2009-2011	40	29
2010-2012	49	33
2011-2013	47	30
2012-2014	37	29
2013-2015	49	20
2014-2016	42	29
2015-2017	39	32
2016-2018	42	36
2017-2019	44	32
2018-2020	27	19
Total	***477***	***339***

‘

Doctorate: Ph.D.		
2013-2017	02	02 Placed
2016-2020	10	09 Pursuing
2017-2021	12	10 Pursuing
2018-2022	01	01 Pursuing
2019-2023	01	01 Pursuing
2020-2024	08	08 Pursuing
Total	**34**	**32 Pursuing and 2 placed**

7. Recognition to Faculty:

Faculty of NIPER-Kolkata includes DST awarded/funded faculty and other guest faculty are also involved from the Mentor Institute and other Institutes of Kolkata, such as 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. For rare diseases 16 guest faculty from AIIHPH, Kolkata Medical College, Kolkata Apollo Hospital, Medica super specialty hospital, Tata Medical centre all from Kolkata, Drugs controller Kolkata, CSIR-IICB etc. Five adjunct faculties (2 from Sanofi India Ltd., 1 from Biological E and 2 from CSIR-CGCRI) are also part of the faculty.

8. Research

- Structural bioinformatics; New drug discovery/repurposing for Infectious Diseases and Metabolic disorders.
- Structural bioinformatics; New drug discovery/repurposing for Infectious Diseases and Metabolic disorders.
- Metabolic bio-engineering for production of small molecules
- Immunology, Leishmaniabiology, Vaccines.
- Diabetes mediated Non-alcoholic steatohepatitis and Hepatocellular carcinoma: Pharmacological and biochemical characterization.
- Phytochemistry; Chemicals transformation; Herbal products analysis
- Network Pharmacology of herbal medicines in Respiratory diseases
- Biopharmaceuticals

9. Innovation/ Knowledge transfer/ MoUs signed

Memorandum of Understanding various Institutes/organizations executed to promote academic

and research co-operation for fostering research worksigned between the following:

1. M/s. Broadline Technologies Private Limited, Chennai and NIPER Kolkata;
2. Innvocept Global Solution Pvt. Ltd., Thane and NIPER Kolkata.
3. Sikkim University, Gangtok and NIPER Kolkata.
4. Vishwa-Syntharo PharmaChem Private Limited Pvt. Ltd., Chennai and NIPER Kolkata

10. Impact of NIPER:

a. A total of 477 highly skilled students have been graduated.
b. 2 scholars have been awarded with the Ph.D. degree.
c. 339 students are engaged to work in companies/institutions.
d. 113 Research papers have been published.
e. M.S. (Pharm.) students of NIPER-Kolkata stood 1st and 2nd position in the National Eligibility Test for Ph.D. course admission conducted by NIPER-Hyderabad, Mohali and Ahmedabad continuously three years 2016-17, 2017-18 and 2018-19 respectively.

11. Institution Leadership Impact of NIPER

Institutions are important for the development and success of a society. Institutions serve as a place for the evolution of ideas. An institute must labor to meet the requirement of social circumstances. NIPER-K has taken a major research drive towards developing newer strategies to tackle two important infectious diseases like tuberculosis and Leishmaniasis.

NIPER Kolkata Webinar on COVID-19 on 30-April-2020

The 8th Convocation of NIPER Kolkata held on 30.09.2020 at 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. It imparts education in three specializations, namely (i) M.S. in Biotechnology, (ii) M. Pharm. in Pharmacy Practice, and (iii) M. S. in Pharmacology & Toxicology with an intake of 19 in each course.

1. Achievements

Since inception, total 393 students have been passed out (M. pharm- 382 and Ph.D- 11), 83 research papers have been published and 5 MoUs have been signed so far. NIPER-Hajipur has signed 4 MoUs in this academic year. 1 Patent was filed in November 2020.

2. Details of faculty & staff are appended below

Academic : Director, 05 (regular) and 03 (on Contract)

Non-Academic : 01 (regular) and 03 (on contract)

3. Fund allocation by the Government during the last 4 years:

Table-5Y
(Fund allocation by the Government during the last 4 years)

Year	Budget Estimated	Revised Estimated	Total Release (Rs. in Crores)
2017-18	6.00	5.00	5.00
2018-19	9.50	9.50	9.50
2019-20	10.50	10.50	5.00
2020-21*	15.00	15.00	15.00

4. Students

Students are admitted through a common Joint Entrance Examination (JEE) of all NIPERs. The PG sanctioned seat intake in each of the 03 (three) existing departments is 19 (nineteen) and 02 (two) for Ph.D. in each Department.

Table-5Z
(Capacity intake for PG and Ph.D degrees)

Students	Male	Female	General	OBC	SC	ST	EWS +PH	Total
PG-II (passed out) (Batch 2018-20)	23	13	17	10	07	02	0	36
PG-II (current)	27	15	08	20	10	04	0	42
(Batch 2019-21)								
PG-I (current) (Batch 2020-22)	29	23	22	14	7	3	5+1	52
Ph.D. (on roll)	14	06	13	04	03	0	0	20

5. Teacher-Student ratio 1:10

6. Employability/ Placements Status

Table-5AA
(Placement details of NIPER-Hajipur MS Students for last 3 years)

Batch Year	Total No of Students	Placement		% Placement (Total)
		Industry	Higher Studies	
2016-18	28	16	09	89%
2017-19	32	21	04	78%
2018-20	36	05	07	33%

Table-5AB
(Placements details of NIPER-Hajipur PhD Students for last 3 years)

Batch Year	Total No of Students	Placement		% Placement (Total)
		Industry	Higher Studies	
2012-17	3	1	2	100%
2013-18	2	0	2	100%
2014-19	1	0	1	100%

7. Research

7.1 Departmental Research Activities: Deptt. of Biotechnology

- Chromosome organization and regulation of transcription in pathogenic organisms
- mechanism of drug resistance and development of effective drugs against resistant microbes
- Structure guided discovery of small molecule/peptide-based inhibitors as drug candidates.
- Application of Nanotechnology as a biosensor for detection and diagnosis of diseases.
- Application of functionalized and conjugated gold Nanoparticles for improved antimicrobial efficacy.
- Ubiquitin conjugating enzymes as drug targets in Leishmaniadonovani.
- Green synthesized gold nanoparticles as antifungal and antiparasitic agents.

7.2 Departmental Research Activities: Dept. of Pharmacy Practice

- Exploration of nutritional and immunological factors along with quality of life in patients of visceral leishmaniasis.
- Exploration of cardiovascular risk along with quality of life and KAP study in patients with HIV/VL co-infection in Bihar
- Evaluation of Efficacy and Toxicity of Concurrent Capacitabine with Radiation in Locally Advanced Rectal Cancer Patients of Bihar.
- Knowledge, Attitude and Practices study regarding awareness on cervical cancer screening and HPV Vaccination in Bihar, India.
- Evaluation of Adverse Drug Reaction of Imatinib with reference to P110 & p190 fusion Transcripts in Chronic Myloid Leukemia Patients and its exploration in Indian Populations.
- Assessment of Risk Factors and Management of Post Kala Azar Dermal Leishmaniasis, Project.
- HPV and its Associated Clinical Outcomes in Cervical Cancer.

7.3 Departmental Research Activities: Deptt. of Pharmacology & Toxicology

- Cognito-behavioural studies including Fluorosis-induced neuro-developmental disorders.
- Anticancer research with electrochemical therapy, immunotherapy and chemotherapy approaches
- Role of extracellular vesicles (Exosomes) in drug-tolerant persister cells and its contribution to cancer-initiating cells in breast cancer.
- To study the molecular reprogramming landscape of pre and post neoadjuvant chemotherapy in Gastric Cancer and its therapeutic implications in Humanized mice for the 3Dorganoid model.
- Establishing the cross-talk between RNA methylation and tumor-initiating cells with respect to Autophagy /EMT /Metabolism Extracellular vesicles
- Evaluation of investigational drugs on different disease model (wound healing, Diabetes, Hypertension, Cancer)

7.4 Funded Projects

- Modulation of fluoride-induced histopathological, cognitive-behavioural alteration in adult and developing rodents by naringin (Rs ~ 96 Lakhs, Funding agency ICMR)

8. Special Lectures/Webinars conducted

The Institute organized special lectures on 'Visceral Leishmaniasis and Kala-azar – current status

and future implications', 'Role of actin and cytoskeletion proteins in survival and infection of parasite L. donovani', special webinar on the topic "COVID-19 outbreak – the significance of virus and its urgent awareness". In collaboration with NIPER-Kolkata, NIPER-Hajipur organized Webinar on the theme "COVID-19: from a challenge to an opportunity for Indian pharmaceutical companies to be self-reliant" Foundation day was celebrated on 26th and 27th November through online mode with Dr. YK Gupta as the chief guest.

9. Impact and achievements

The Institute has successfully produced 382 PG and 11 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 established in October 2020. During the year, animal house has received CPCSEA approval.

10. Future plan of NIPER-Hajipur

NIPER-Hajipur is in process of expanding its academic infrastructure by incorporating 2 new departments –Pharmaceutics and Pharmaceutical Analysis from next session. A central instrumentation facility is under development. Recruitment in regular positions in the 1st phase for teaching/non-teaching position has been completed. Infrastructure development of campus with hostels, boundary walls, and new buildings for academic activities is under process.

Some photographs

Republic Day and Independence Day Celebrations

CHAPTER-6

PUBLIC SECTOR UNDERTAKINGS (PSUs)

CHAPTER 6

CENTRAL PUBLIC SECTOR ENTERPRISES

Background

1. 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 & Pharmaceuticals Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL).

2. 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 may 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.

3. 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 to:

(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.

(ii) Providing budgetary support as loan to the tune of Rs 330.35 cr. for meeting the employees' liabilities (Unpaid salary – Rs. 158.35 cr. + VRS Rs.172.00 cr.) as per following break-up:

a. IDPL – Rs. 6.50 cr.
b. RDPL – Rs. 43.70 cr.
c. HAL – Rs. 280.15 cr.

(iii) 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.

4. Separately, the Cabinet Committee on Economic Affairs (CCEA) in its meeting held on 1.11.2017 has 'in principle' approved strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru.

Table-6A

(Summary of CPSUs of the Department)

(As on December 2020)

	HAL	IDPL	RDPL	BCPL	KAPL
Established in	1954	05/04/1961	02-11-1978	1981	1981
Classification	Sick	Schedule-B, Sick PSU	CPSE-UNDER CLOSURE	Sick (now Profit Making)	Miniratna "C"
Net worth (in cr.)	-606.20	-7785.84 cr	21.32Cr.	-53.68	216.53
Turnover (in cr.)	63.97	0.15 cr	NIL	55.50	366.67
Operating profit/loss (in cr.)	-19.47 (loss before Interest,Depreciation)	-160 cr	-12.60CR	22.30	27.50
Liabilities (in cr.)	1053.08	7860.65 cr.	75.29Cr	208.92	95.37
Referred to BIFR	1997	Referred to BIFR on 25.05.1992 BIFR declared IDPL Sick on 12.08.1992	NO	1992	No
Total land	263.57 acres	Gurgaon: 89.79 acres (Freehold) Hyderabad: 891.95 acres (Freehold) Rishikesh: 833.878 acres (Leasehold) **Total: 1815.618 acres** **(**Excluding Subsidiary Unit**)**	37856 SQ.MTR	72.89 acre	40 Acres & 8 Guntas
Leasehold	NIL	833.878 acres	NIL	1.10 acre	-
Freehold	263.57 acres	981.74 acres	37856 Sq.Mtr.	71.79 acre	40 Acres & 8 Guntas

6.2 Indian Drugs and Pharmaceuticals Ltd. (IDPL)

Background:

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

The Registered Office of the Company is located at IDPL Complex, Dundahera, Gurgaon. The company has three main Plants at Rishikesh (Uttarakhand), Gurugram (Haryana), Hyderabad (Telangana) and two 100% wholly owned subsidiaries, namely, IDPL (Tamil Nadu) Limited, Chennai (Tamil Nadu) and Bihar Drugs & Organic Chemicals Limited (BDOCL) at Muzaffarpur (Bihar). In addition, IDPL has one Joint Venture, promoted in collaboration with Industrial Promotion & Investment Corporation of Orissa Limited (IPICOL), Government of Odisha, namely Odisha Drugs & Chemicals Ltd. (ODCL) Bhubaneswar having share of 51% and 49% respectively.

IDPL played a major role in the strategic National Health Programmes like Family Welfare Programme & Populations Control (Mala-D & Mala-N), anti-malarial (Chloroquine) and prevention of dehydration (ORS) by providing quality medicines. IDPL has encourage indigenous production and supporting Government in meeting emergent situations in Cyclone, Flood and Earthquake in Odisha, Uttrakhand and J&K providing lifesaving medicines on time. IDPL has always supplied quality medicines and its presence has played a price balancing role in the competitive and business environment.

The main objectives of setting up IDPL were not to earn profits but to encourage indigenous production of pharmaceuticals and to support various health programmes of the Central Government. IDPL earned Profit before Depreciation, Interest & Tax (PBDIT) from 1965 to 1968 and again from 1971 to 1974. It earned net profit from five years continuously from 1974 to 1979; the Company lost its profitability primarily due to change in Government policy about import of bulk drugs from supply to pharmaceuticals Industry. The imports, which were canalized through IDPL till 1979, were entrusted to State Trading Corporation (STC). IDPL was thus divested of a profit-making segment. The erstwhile Board for Industrial & Financial Reconstruction (BIFR) declared IDPL as a sick industrial Company in August. 1992. In February 1994, BIFR approved the Rehabilitation Scheme under Section 17(2) of SICA. The package, however, failed to turnaround the company. In January 1996, BIFR appointed Industrial Development Bank of India (IDBI) as Operating Agency (OA) for Techno-Economic Analysis and preparation of Revival Package. The issue of revival of the company remained pending in BIFR as well as with the Govt. while attempts were made in 2001-02 to privatize the Company. OA (IDBI) however, did not find any proposal worthy of recommendations to BIFR.

Based on a Draft Rehabilitation Scheme (DRS) prepared by IDPL, a Note for Cabinet Committee on Economic Affairs (CCEA) was prepared and submitted for approval on 11.5.2007. The Note was considered by CCEA in its meeting held on 17.5.2007 and it referred the matter to Group of Ministers (GoM). The GoM in its meeting held on 11.10.2007 advised that IDPL's revival plan should be based on public

interest goals and ensuring the viability of the Company. The Union Cabinet decided on 28.12.2016 for closure of the company.

In view of Cabinet decision, the company is in the process of closure. The company has signed an MoU with M/s NBCC to act as Land Management (LMA) in October' 2019 for disposal of its land / immovable properties and with M/s MSTC Limited to function as Auctioning Agency (AA) for sale of its moveable and immovable properties by e-auctioning. The valuation of Land of IDPL Gurugram Plant and Hyderabad Plant (including building) has been done by Land Management Agency (LMA) –NBCC and approved by the Board.

A valuer has also been appointed to assess the moveable and immoveable properties of IDPL. The valuation of Movable Assets and Immovable Assets (Building only) of Rishikesh (Main Plant) and Subsidiaries Units – BDOCL Muzaffarpur & IDPL (TN) Ltd., Chennai has been done by a Govt. approved valuer and approved by the respective Board. The valuations of Movable Assets and Immovable Assets of IDPL Gurugram (excluding land) and Hyderabad (excluding Land & building) are under process by the valuer.

All units are now closed in view of closure decision of the Union Cabinet taken on 28.12.2016. Presently, the company has no regular employees as all the regular employees of IDPL have been given VRS as per DPE Guidelines dated 14.06.2018. There are only 76 contractual employees in the Company including 100% Subsidiaries.

100% IDPL Wholly Owned Subsidiaries:

IDPL (Tamil Nadu) Ltd, Chennai

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

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

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

Joint Venture

Orissa Drugs and Chemicals Ltd (ODCL), Bhubaneshwar

Orissa Drugs & Chemicals Limited (ODCL) was incorporated in 1979 and commissioned fully for production from September 1983. ODCL is a Joint Venture promoted by Indian Drugs & Pharmaceuticals Ltd. (IDPL) and Industrial Promotion & Investment Corporation of Orissa (IPICOL). IDPL holds 51% of

the equity shares and 49% is with IPICOL. The erstwhile BIFR passed orders for winding up in April 2003 under the provisions of SICA Act, 1985. High Court of Orissa had appointed a provisional Liquidator. This has since been stayed by a larger Bench of the Odisha High Court.

Presently Company is engaged in manufacture of pharmaceuticals formulations in the form of Tablets, Capsules, Powder, ORS and Injectables etc. ODCL Plant is Schedule-M compliant.

Injectible Section-ODCL

Tablet & Oitment Sections of Hyderabad Unit

RMG
Ointment Mfg.Tube filling

FBD
Purified water

Blister Packg.
HPLC

Prod. Facility
Generation System

Finished Products

Blister Packing Machine (Gurgaon Plant)

Planetary Mixer (Gurgaon plant)

Blister Packing Machine -Rishikesh

Tablet Section- ODCL

6.3 Hindustan Antibiotics Limited (HAL)

Background

Hindustan Antibiotics Limited (HAL) is a wholly owned Government Company engaged in the manufacturing & marketing of life saving drugs. It was established in 1954 with WHO/ UNICEF assistance and the first to manufacture the Antibiotics like Bulk drugs, Streptomycin and Gentamycin. 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.

Performance Rating Under MoU

HAL has entered into MOU for the year 2019-20 with the Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals. Based on the audited results of the Company, HAL is likely to receive "EXCELLENT" MOU rating for the year 2019-20. The company has also been rated "GOOD" in the MOU 2017-18 and 2016-17 by the Department of Public Enterprises (DPE).

Corporate Governance

HAL is committed to follow good Corporate Governance Practices in conducting its business in legal, ethical & transparent manner. During the year 2019-20, HAL has got "EXCELLENT" rating in Self Evaluation for compliance of Guidelines on Corporate Governance issued by DPE for CPSEs. During previous years also HAL has got "Excellent" rating in this category.

Joint Ventures and Subsidiaries

The company has two subsidiaries, namely, Maharashtra Antibiotics and Pharmaceuticals Limited (MAPL) and Manipur State Drugs & Pharmaceuticals Limited (MSDPL)

Brief of Facilities available

The company's manufacturing facilities include the following: -

a. Bulk Plant:

HAL is having fermentation-based manufacturing facilities including 19X92M3 fermentors 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, Gentamycin etc. These facilities are idle at present.

b. Formulation facility:

The company is focusing at present on manufacturing Pharma formulation and promising Agro-formulation to cater to wide range of Pharma and Agro market. Its pharma products include various dosage forms like Dry Powder Injectable products, Tablets, Capsules, Intra-Venous Fluid (IVF) products, Liquid Syrup etc.

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

Table-6B

(Manufacturing formulation capacities including Pharma & Agro-Chem)

Sr.No.	Production facilities	Capacities (Existing) Lac Nos. / annum
A.	**Pharma Plants:**	
1	**Dry Powder Injectables:**	
a.	Cephalosporin	450
b.	Penicillin	450
2	**Tablets:**	
a.	Penicillin	1200
b.	Non-Penicillin	2400
3	**Penicillin Capsules:**	**2500**
4	**I.V.Fluids:**	**120**
5	**Liquid Syrup & External preparation:**	**24**
B	**Agro-Chem Plants:**	
1	Agro- Chem (Streptocycline)	180
2	Humaur formulation	210 KL*
3	Aureofungin Bulk	0.810 tionnes
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

c. During the year 2019-20, HAL has consolidated manufacturing of following Agro Products:

i. Aureofungin
ii. Humaur
iii. Phosphomeal
iv. Azetomeal

d. During the year 2019-20, the company has re-started manufacturing and marketing of its IVF products, which was under upgradation. The company is proud to state that it is the only unit in the pharma PSUs to have facility for manufacture of IVF Fluids.

e. 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. HAL is the only exclusive manufacturer of the product in the country.

Present Status of the Company

The Company has successfully steered to a steady growth and consolidated its position in the country as a leading Public Sector Pharmaceutical Company. During the year 2019-20, all its Plants were operational, which helped in enhancing the turnover of the company.

The Cabinet in its meeting held on 17.7.2019 approved loan to the tune of Rs. 280.15 crores for meeting the employee's liabilities (unpaid salary and VRS). The company introduced and implemented VRS during 2019-20 and a total of 380 employees were given VRS. The company is having 460 employees as on 01.12.2020. The company appointed M/s NBCC as the Land Management Agency (LMA) for its main plant as well as subsidiaries. The process of hiving off of MAPL and MSDPL is in process and is expected to be completed early. After valuation of its surplus 87.70 acres of land by M/s NBCC, the company is expected to dispose of its land subject to approval of the Government.

The company proposes to manufacture APIs, for which a proposal for in-principle approval has been submitted. The company is also exploring the possibility of exporting its quality products to African countries. During the year 2019-20, HAL has contributed a sum of Rs.25.50 crores to the exchequer of Central and State Govt. by way of Income Tax, Customs, GST, Service Tax etc.

Details of Production, Sales Turnover and Net Profit / Loss

Table-6C
(In-house production figures for the last five years)

(Rs in Crores)

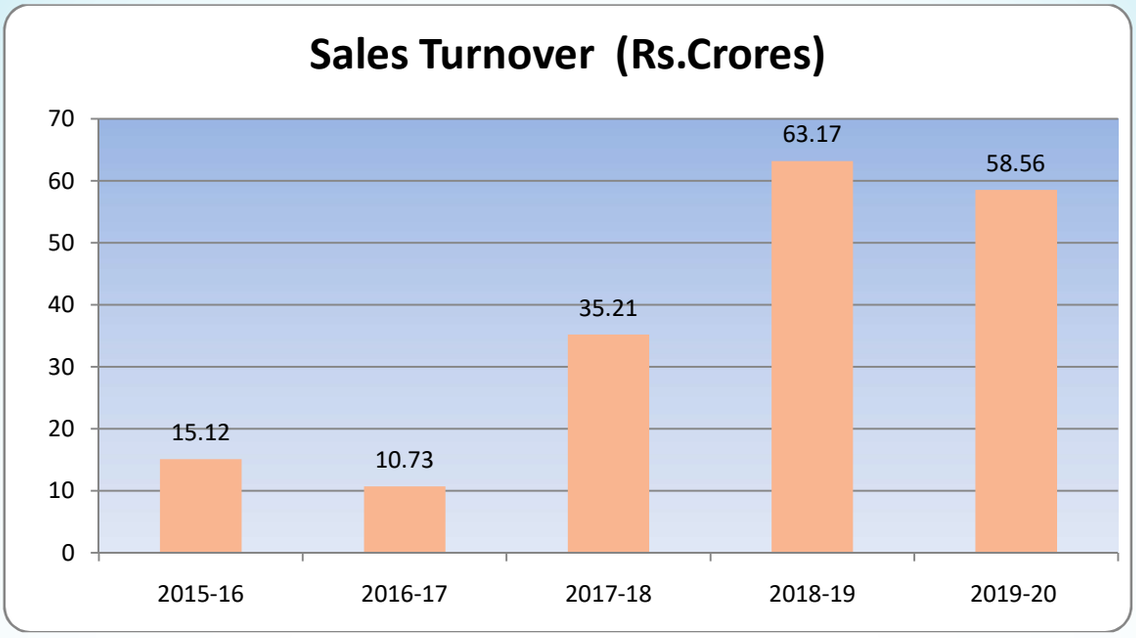
	2015-16	**2016-17**	**2017-18**	**2018-19**	**2019-20**	**2020-21 (till 15.12.20)**
Production	14.45	11.36	37.44	54.51	43.05	42.28
Sales Turnover	15.12	10.73	35.21	63.17	58.56	59.97
Net Profit (Loss)	(74.68)	78.24	208.32*	(71.10)	(138.30)**	(36.19)

* The said Net Profit is the result of an extraordinary item of income viz. waiver by Govt. of India of its Plan and Non-Plan loan of Rs.186.96 crores and the interest there on of Rs.89.94 crores. Total Rs.276.90 crores.

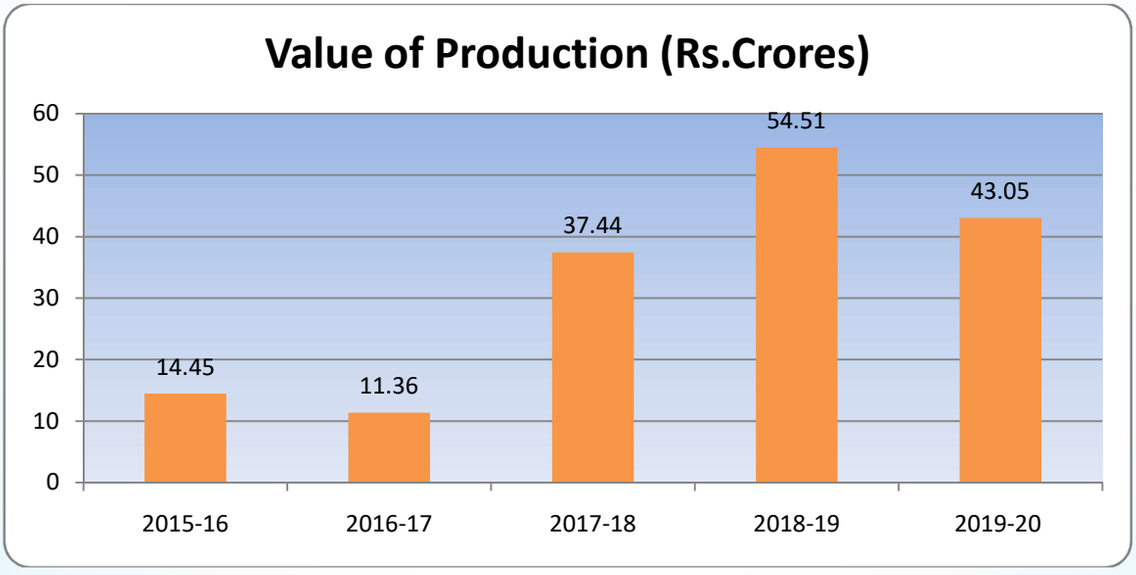
** The above loss is the result of the exceptional expenses such as relieving of employees on VRS. The actual operational loss is Rs. 66.10 crores as against Rs. 71.10 crores during the previous year.

During 2019-20, HAL has achieved production of Rs.43.05 crores against Rs.54.51crores in 2018-19 and achieved a sales turnover (total revenue) of Rs.58.56 crores in 2019-20 against Rs.63.17 crores in 2018-19. The operational loss in 2018-19 was Rs.71.10 crores, which was reduced to Rs. 66.10 crores for the year 2019-20.

Graph-6A
(Sales Turnover of HAL since 2015-16)



Graph-6B
(Value of Production in HAL since 2015-16)



Projects implemented so far:

HAL has completed setting-up of new Cephalosporin power injectable facilities. This facility was accredited with WHO-GMP certification. The upgradation of IVF, 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, during 2020-21. The setting-up of facility for Alcoholic Handrub Disinfectant, the only central PSU to have such facility, was also completed.

Planned Projects:

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

- Facility for bulk drugs like Meropenem, Telmisartan and Gabapentin. The funding for the above projects is proposed to be done through internal resources. The manufacturing of these bulk API's shall also compliment the Hon'ble Prime Minister's 'Make in India' initiative for bulk drugs / APIs.

- HAL is in the process of setting-up facility for HAL Cloud Clinic- a Health Kiosk- which measures 23 health parameters in 5 minutes. This is a sort of Health ATM which identifies different health parameters, from which one can identify their physical fitness & take corrective action accordingly. This Health Kiosk stores data of the person on its cloud storage & can be very useful to Health Institutions, Govt. Hospitals, CPSEs etc.

Strategy for Marketing:

HAL's sales are at present largely dependent on institutional sale with PPP model. In order to reduce the dependence on PPP business, the company intends to adopt the following strategies:

- 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.

Human Resource and Industrial Relations:

The Company had 918 employees on 31st March 2019, which were reduced to 460 as on 1st December 2020. The employees are getting salaries in 1997 pay scales. Various social security schemes like Provident Fund, Gratuity & Medical schemes are in place in the Company. During the year 2019-20, five training programmes / seminars were arranged on topic like cGMP, Good Documentation Practices & Data Integrity, Financial Empowerment of Women, International Yoga Day, Integrity – A way of life etc. About 124 officers and 95 workers attended these in-house training programmes.

The training centre, in coordination with the Monitoring Committee of 'Swachh Bharat Abhiyan', played major role in implementing 'Swachh Bharat Abhiyan' in the organization. Swachhata Pakawada was observed during 16th to 31st August, 2019 as per the directives from DPE (Min. of HI & PE). Cleanliness drives were carried out with enthusiasm and zeal by the employees, colony residents and also by H.A. School students.

Activities like Hindi Day / Pakhawada, International Yoga day, International Women's Day, Vigi-

lance Awareness Week and pledge taking on the occasions of Constitution Day & Anti-Terrorism Day were organized at Training centre.

Cost cutting measures

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

HAL- Building front view of Cephalosporin Plant

Celebration of Vigilance Awareness Week at H.A. Board Room

Participant receiving Award as a part of Hindi Pakhwada

Republic Day Celebrations at H.A. Company

Managing Director inspecting parade at H.A. School as a part of Independence Day Celebrations

Independence Day Celebrations at H.A. Company

6.4 Karnataka Antibiotics & Pharmaceuticals Limited, Bengaluru (KAPL)

Background:

Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) is a Profit-making Joint Sector Company incorporated in the year 1981 [with 59% share by Government of India and 41% share by Government of Karnataka through Karnataka State Industrial and Infrastructure Development Corporation (KSIIDC)]. The basic objective of the Company is to make available life-saving drugs of good quality to Government Hospitals and other Institutions along with Private Medical Practitioners. The Company has WHO-GMP Certified manufacturing facilities for Dry Powder Injectables, Liquid Injectables, Tablets, Capsules, Dry Syrups and Suspensions. The paid-up share capital of the Company as on date is Rs. 13.49 crores. At Bangalore Plant, Pharmaceutical Products are being manufactured and at plant at Kotur, Dharwad, Karnataka, Ayurvedic Products are being manufactured.

Production And Sales Performance:

Table-6D

(Production & Sales Perfromance of HAL) **(Rs. in Crores)**

YEARS	PRODUCTION	SALES
2017-2018	366.82	353.83
2018-2019	388.63	360.36
2019-2020	489.57	437.08
2020-21(UptoNov.2020)	319.90	328.67

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-6E
(Pharma Trade)

No	Products	Therapy Segments	NLEM	Monopoly	Market Value
1	Grenil	Anti Migraine	No	No	Rs. 13.00 Cr
3	Cyfolac	Pre & Probiotics	No	No	Rs. 5.00 Cr
4	Remcc Group	Cough & Cold	No	No	Rs. 3.00 Cr
5	Zinfe Group	Haematinic	Yes	No	Rs. 2.00 Cr
6	Verclav Group	Antibiotic	No	No	Rs. 2.00 Cr
7	PoP-e	Platelet Booster	No	No	Rs. 2.00 Cr

Pensbiotic MD/ DS, Gentabiotic, K-Flox

Agrovet:

Table-6F
(Agrovet)

No	Products	Therapy Segments	NLEM	Monopoly	Market Value
1	K- Cyline	Insecticide	No	No	3.5 Cr
3	Kalvimin Group	Feed Supplement	No	No	3 Cr
4	K- Live	Hepato-Protective	No	No	2.5Cr
5	K- Cythrin	Mineral Mixture	No	No	3 Cr
6	Pensbiotic MD/DS Gentabiotics, K-Flox	Antibiotics	No	No	6.5 Cr
7	Fluvet	Ecto-Parasiticide	No	No	1.5 Cr

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 Headquarters. 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 Cus-

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

Agrovet:

The Company is focusing on Agro Dealers, Department of Agriculture/ Horticulture for Agro Products. 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) For 2019-20

Table-6G

(New products-pharma & agrovat - for 2019-20)

Sl.No	Products	Therapeutic Category
PHARMA		
a)	Kapitra	Antifungal
b)	Kaplicon	Antifungal
AGROVET		
a)	Vet CPM (Chlorpheniramine Maleate) Inj	Anti Allergic
b)	K-Live Gold	Liver Tionic

Exports

KAPL products are currently exported to about 17 different countries including Russia, Malaysia, Philippines, Sri Lanka, South Africa, Zimbabwe, Yemen, Uganda, South Africa 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).

KAPL - Sole manufacturer of Oxytocin in the country

The High Court of Himachal Pradesh, Shimla has in its judgement dated 15.03.2016 in PIL No. 16 of 2014 noted that there is large scale clandestine manufacture and sale of drug Oxytocin leading to its grave misuse, which is harmful to animals and humans. The Government entrusted to KAPL the responsibility of being sole domestic manufacturer and distributor in the country. Further, manufacturing by private manufacturers was restricted vide Gazette Notification dated 27.04.2018 issued by the Ministry of Health & Family Welfare. Some private parties approached Hon'ble High Court of Delhi challenging the said notification and the High Court of Delhi vide its order dated 15.12.2018 quashed the said notification. Special Leave Petition has been filed by the Ministry of Health & Family welfare at the Hon'ble Supreme Court of India and the matter is presently sub judice.

The Oxytocin formulations manufactured by the KAPL are supplied only to the registered hospitals and clinics in Public and Private Sector directly, or to the Pradhan Mantri Bhartiya JanAushadhi Pariyojna (PMBJP) and AMRIT outlets in the country, which in turn supply the drug for its therapeutic usage to the registered hospitals and clinics in public and private sector.

Shri Sunil Kumar Kaimal, Managing Director receiving Award from Shri D.V. Sadananada Gowda, Hon'ble Minister for Chemicals & Fertilizers on 05.03.2020 during India Pharma Exhibition. Dr. P. D. Vaghela, IAS, Secretary, DOP (second from right), Shri Mansukh Mandaviya, Hon'ble Minister of State for Shipping (Independent Charge) and Chemicals and Fertilizers, Shri Vijay Rupani, Hon'ble Chief Minister, Gujarat. (second from left) are also seen.

6.5 Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)

Background

Bengal Chemicals and Pharmaceuticals Limited (BCPL) was founded in 1901 by Acharya Prafulla Chandra Roy, a renowned Scientist and Academician. The Government of India took over its management in 1977. The company was subsequently 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).

Business Operations

BCPL is engaged in the business of Industrial Chemicals (Ferric Alum), Generic Medicines and Home Products like Phenol, Naphthalene balls, Bleaching powder, Toilet cleaners, Floor cleaners and Hair oil.

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 Pharmaceuticals Formulations which include branded as well as unbranded generic medicines. Commercial production in Tablet, Capsule, Ointment and Cosmetics Sections is going on full-fledged. It also produces Cantharidine Hair Oil. In August 2020, the company launched its Hand Sanitizer "BENSANI+", which is essential to prevent the spread of Coronavirus Disease (COVID-19) in present pandemic scenario.

Panihati Unit: This unit set up in 1920 primarily produces Industrial Chemicals and Home Products which includes Pheneol, Naphthalene Balls as well as other Disinfectants and Chemicals. During the present pandemic situation, BCPL touched an all-time record of manufacturing 60,680 bottles of Pheneol 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. Presently, the commercial space developed has been leased out to third parties for generation of additional sources of revenue for the company.

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

Past Achievements

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

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 Rs 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 Rs.17 Crore turnover in 2013-14, which was the lowest ever turnover since its inception as Government Company and reported a Net Loss of Rs.36.55 Crore in 2013-14. However, from the financial year 2016-17 onwards, the company became a Turnaround Company and reported a Net Profit of Rs.4.51Crore and a Gross Margin of Rs.24.05Crore. In the consecutive 2nd financial year also i.e., in 2017-18, BCPL reported a Net Profit of Rs.10.06Crore. In the year 2018-19, BCPL again reported a Net Profit of Rs.25.26Crore and Rs.13.07Crore in 2019-20. Further, BCPL has repaid the entire Bank Loan of Rs.28Crore to United Bank of India which was taken in 1983 by mortgaging Registered Office building and now BCPL is a debt free company (except Govt. of India Loans). BCPL has also paid Rs.23.73 Crore to Government of India till date, towards repayment of loans taken in the year 2005 and 2006.

Product profile and range

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

Table-6H
(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	Cantharidine 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.

Manpower

Table-6I
(Manpower)

Particulars	Manpower (As on 30.11.2020)
Executives	48
Supervisors	13
Workers	84
Grand Total	145

Distribution network

The company has a strong distribution network pan India with 6 Depots and 6 C&F Agencies. BCPL has also opened 4 Exclusive Retail Stores in Kolkata and 1 in Mumbai.

Performance

The details of Production, Turnover and Financial Performance of BCPL from 2017-18 onwards are as under:

Table-6J
(Financial Performance of BCPL for last three years) **(Rs. in Crores)**

Particulars	2019-20	2018-19	2017-18
Production	84.19	123.45	98.18
Income	85.64	119.67	94.80
Gross Margin	20.26	32.83	24.23
Interest Expenses (Finance cost)	0.68	2.45	9.05
Depreciation	5.12	5.12	5.12
Net Profit(Loss)	13.07	25.26	10.06

DPE rating

Table-6K
(DPE rating)

Year	MOU Assessment	Corporate Governance
2017-18	"Not applicable"	"Excellent"
2018-19	"Not applicable"	"Excellent"
2019-20	"Not applicable"	"Excellent"

Marketing: Share of Institutions and retail

Table-6L
(Marketing: Share of Institutions and retail)

Sl. No.	DIV & Products	Market Profile/Major clients
1.	DIV I – Ferric Alum	SAIL (Durgapur, IISCO, Bokaro, Refractory Unit, IISCOCHASNALA) 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, Eutheria, 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%)

Future projects:

ASVS Project: BCPL was 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 Rs 31.00 Cr. Further, BCPL is under strategic sale so the project could not be taken up.

The Cabinet decision dated 28th December 2016 for strategic sale of the company after meeting all its liabilities from sale of surplus land was challenged by the Bengal Chemicals Sramik Karmachari Union filed a Writ Petition before the Hon'ble High Court of Calcutta, which vide its order dated 13.02.2018 set aside the decision of the Union Cabinet regarding strategic sale of the company. An appeal has been filed against the order and judgement for early listing and hearing.

Managing Director of BCPL administered the pledge to the Officers & Employees of BCPL, Corporate Office, on 21st October, 2020, to join the Jan Andolan launched by Hon'ble Prime Minister to fight against COVID-19

The Employees of Corporate Office of BCPL, Kolkata are taking integrity pledge on the occasion of Vigilance Awareness Week (27.10.2020- 02.11.2020)

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 Rs. 4.98 crores where Government of India (GoI) and Rajasthan State Industrial Development & Investment Corporation Limited (RIICO, Govt. of Rajasthan) hold 51% and 49% shares respectively. It was incorporated in 1978 and commercial production started in 1981. The Company has its manufacturing facilities & registered office at Road no. 12, VKI Industrial Area, Jaipur (Rajasthan). The production activities in the Company have stopped since October 2016.

Past Performance:

Table-6M
(Past Performance of RDPL)

(Rs. in Crores)

	2016-17	2017-18	2018-19
Net Worth	(-) 39.53	(-) 54.78	(-) 69.88
Turnover	7.66	0.40	0.14
Earnings (Before Tax)	(-) 14.88	(-) 15.25	(-) 15.10
Earnings (After Tax)	(-) 14.88	(-) 15.25	(-) 15.10
Net Profit/Loss	(-) 14.88	(-) 15.25	(-) 15.10

Union Cabinet has decided on 28.12.2016 for closure of RDPL, after selling its surplus land as would be required to meet the liabilities. M/s MSTC Limited was appointed as auctioning agency for e-auction

of RDPL on 19.04.2017. Central Government/State Government/leading PSUs/Financial Institutions were invited to bid for the land, but no response was received. The Union Cabinet has on 17.07.2019 modified its earlier decision and permitted sale of surplus land to any entity. Further, it has sanctioned Rs.43.70crore for meeting employees' liabilities. The Company has given VRS to 99 employees. Subsequently, the company has appointed M/s NBCC as Land Management Agency (LMA), which has done valuation of the land. The disposal of the land will be done on approval of the Government.

CHAPTER-7

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

CHAPTER 7

7.1 National Pharmaceutical Pricing Authority (NPPA)

7.1.1 The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals was constituted by the Government of India vide resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia, includes fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

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

7.1.3 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. It was, thereafter, notified as the First Schedule of DPCO 2013, in March 2016, by the Department of Pharmaceuticals.

7.1.4 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 the 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 881 formulations under DPCO, 2013 till 31st December 2020.

Statement showing range of reduction in ceiling price of scheduled formulation with respect to the highest price on the basis of data furnished by Pharmatrac/pharmaceutical companies is as given below:

Table-7A
(Statement showing % range of reduction in ceiling price)

% reduction with respect to Maximum Price	No. of formulations
0<= 5%*	242
5<=10%	140
10<=15%	104
15<=20%	101
20<=25%	93
25<=30%	69
30<=35%	46
35<=40%	26
Above 40%	60
Total formulations in NLEM 2015	**881**

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.

NPPA also capped the maximum retail price of 106 formulations (anti-diabetic and cardiovascular) under para 19 of DPCO 2013 in July 2014.

B. Retail Price

NPPA fixes the retail price of medicine based on the Form-I application received from the man-

ufacturing/ 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 1462 'new drugs' [those qualifying as 'new drugs' as per para 2(u) of DPCO, 2013] till 31st December 2020 under DPCO, 2013.

NPPA has taken special efforts for fixing retail price fixation of new drug cases and all the pending cases have been cleared. As on 31st December 2020 only current cases are pending for price fixation.

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 hearing gives necessary review directions. NPPA implements the review directions of the Department on merit.

NPPA has taken special efforts for implementation of review orders in time and implemented 47 review orders comprising 68 formulations during 2018-19, 10 review orders in 2019-20 and 2 review orders in 2020-21 (Till 31st December, 2020). As on 31st December 2020, one review order is pending for implementation.

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

National Pharmaceutical Pricing Authority capped the Trade Margin of all the non-scheduled formulations of select 42 Anti-Cancer drugs, recommended by Expert Committee of Ministry of Health & Family Welfare, under the 'Trade margin Rationalization Approach' vide order SO 1041(E) dated 27th February 2019. The Pilot has been taken up as Proof of Concept, invoking provision of para 19 of DPCO, 2013, under extra-ordinary circumstances in public interest.

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

Table – 7B
(Percentage wise reduction in prices of brands)

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

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

7.2.4 Savings to the Consumers

The fixation of ceiling prices of scheduled formulations listed in NLEM 2015 (revised Schedule-I)

has enabled savings of Rs. 2,643 crore to the consumers in addition to the saving of Rs. 4,547 crores 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 Rs.2,422.24 crore to the consumers. The para 19 price notifications resulted in savings of approximately Rs. 350 crore to the consumers. NPPA has also fixed the ceiling price of the Non-Scheduled Orthopaedic Knee Implants has enabled savings of Rs. 1,500 crore to the consumers. A savings of Rs. 984 crores 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 Rs. 12,447 crores per annum to the consumers.

7.2.5 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 with 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 are 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 life-saving essential drugs must remain available to the general public at all times.

Based on the recommendations of the Standing Committee on Affordable Medicines and Health Products (SCAMHP), ceiling price of shortlisted 21 scheduled formulations of 12 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
(Revision of Ceiling Retail Price under Para 19 of DPCO, 2013)

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	BCG vaccine		Each Dose	8.75
2.	Benzathine benzylpenicillin	Powder for Injection 12 lac units	Each Pack	17.84
3.	Benzathine benzylpenicillin	Powder for Injection 6 lac units	Each Pack	11.81
4.	Benzyl penicillin	Powder for Injection 10 Lac Units	Each Pack	7.64
5.	Chloroquine	Tablet 150mg	1 Tablet	1.16
6.	Dapsone	Tablet 100 mg	1 Tablet	0.35
7.	Furosemide	Tablet 40 mg	1 Tablet	0.74
8.	Furosemide	Injection 10mg/ml	1 ml	2.43
9.	Metronidazole	Oral Liquid 200 mg/5ml	1 ml	0.44
10.	Metronidazole	Tablet 200 mg	1 Tablet	0.68

11.	Metronidazole	Tablet 400 mg	1 Tablet	1.25
12.	Metronidazole	Injection 500mg/100ml	1 ml	0.20
13.	Ascorbic Acid (Vitamin C)	Tablet 500 mg	1 Tablet	1.34
14.	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	Tablet 400 mg(A)+80 mg(B)	1 Tablet	0.77
15.	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	Tablet 800 mg(A)+160 mg(B)	1 Tablet	1.98
16.	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	Oral Liquid 200mg(A)+40mg(B)/5ml	1 ml	0.32
17.	Pheniramine	Injection 22.75 mg/ml(10ml pack)	1 ml	1.67
18.	Pheniramine	Injection 22.75 mg/ml (2ml pack)	1 ml	2.24
19.	Prednisolone	Drops 1%	1 ml	4.92
20.	Clofazimine	Capsule 50 mg	1 Capsule	2.13
21.	Clofazimine	Capsule 100 mg	1 Capsule	3.63

7.2.6 Price Fixation Of Medical Devices:

A. Coronary Stents:

The Government had notified Coronary Stents as scheduled Medical Devices under DPCO, 2013 in December 2016. Aftermath, Government had notified the ceiling prices for Coronary Stents vide notification dated 13th February 2017. The current Ceiling Prices (excluding GST) for Coronary Stents for the year 2020-21 is as under:

i. Bare Metal Stents: Rs. 8,417/-

ii. Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents: Rs. 30,647/-

` The price reduction for Coronary Stents worked out up to 85% for Bare Metal Stents and 74% for Drug Eluting Stents in the year 2017. The Ceiling Prices fixation of Coronary Stents resulted in notional saving of Rs. 4,547 crores annually to the consumers/patients.

B. Orthopedic Knee Implants For Knee Replacement System:

NPPA has also fixed the ceiling price of the Non-scheduled Orthopaedic Knee Implants for the first time on 16th August 2017 under Para 19 of the DPCO, 2013 in the extraordinary circumstances in the larger public interest. The above ceiling price was to be maintained for one year i.e. up to 15th August 2018. Subsequently, NPPA vide Order dated 13th August 2018, extended the applicability of above ceiling prices for another one year (i.e. up to 15th August 2019).

In the year 2019, after revisiting the ceiling prices of the orthopaedic Knee Implants, the Authority allowed an increase in Maximum Retail Prices (MRPs) of orthopaedic Knee Implants up to 10% of the previous MRP vide Notification dated 13th August 2019. Further, in the year 2020, the Authority did not allow any increase in the ceiling prices of Knee Implants for the year 2020-21 and extended the same for the another one year up to 15th September 2021 vide Notification dated 15th September 2020. A summary of price revision for orthopaedic Knee Implants is as under:

Table -7D
(Price Revision of Orthopedic Knee Implants)

Type of Knee Implant	**Ceiling Price fixed w.e.f. 16/08/2017 to 15/08/2019 (Rs.)**	**Ceiling Price fixed w.e.f. 16/08/2019 to 15/09/2021 (Rs.)**
Primary Knee Implants		
Cobalt Chromium (widely used)	54,720	60,192
Special Metal like Titanium & Oxidized Zirconium	76,600	84,260
High Flex Implant	56,490	62,139
Revision Knee Implants		
Revision Implants	1,13,950	1,25,345

The aforesaid ***price reduction for orthopaedic Knee Implants worked out up to be 69%.*** The ceiling price fixation of orthopaedic Knee Implants resulted in notional saving of Rs. 1,500 crore annually to the consumers/patients.

7.3 Initiatives taken to address the exigencies of COVID-19

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. In times of the pandemic, the NPPA 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.

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 about upward increase in prices of API of the 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 got the issue examined through Export-Import Monitoring Committee constitut-

ed by NPPA to inform impact on API pricing. The Committee reported 200% increase in landing cost of Heparin API and on its recommendation, NPPA revised the ceiling price of Heparin upward for a period of six month to ensure its continued availability during the pandemic.

Medical Oxygen:

The situation of COVID-19 resulted in increased demand of Medical Oxygen (MO) in the country. Medical Oxygen is not only an essential life-saving 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. Due to excess demand, delivery through cylinders had increased from 11% pre-COVID to 50% of current oxygen supply. 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 deliberations, NPPA, in exercise of extraordinary powers conferred by para 19 of the Drug (Prices Control) Order, 2013 and powers conferred under section 10(2)(l) of the Disaster Management Act, 2005, in public interest, capped the price of Liquid Medical Oxygen (LMO) and the Oxygen Inhalation (Medicinal gas) for six months. Timely intervention by NPPA eased the situation of Medical Oxygen availability throughout the country, especially in distant and far flung areas.

N95 Mask:

NPPA took cognizance of reports of differential pricing in government/institutional procurement and non-government procurement. In order to ensure availability of N95 mask at affordable prices in the country, NPPA directed Manufacturers/ Importers/Suppliers of N95 Mask to maintain parity in prices for non-government procurements and to make available the same at reasonable prices. After issuing such an Advisory, major manufacturers/importers of N-95 Masks reduced their prices significantly up to 67%.

NPPA fine tuned its interventions during the COVID pandemic to strike at profiteering tendencies by manufacturers/marketers in public interest. However, the strategy also ensured enabling ecosystem for the industry to increase production of quality benchmarked medical devices for domestic use and exports.

7.3.2 Medical Diplomacy:

During this period, Government had constituted an Inter-ministerial Empowered Committee to make recommendation for the export of drugs/items requested by foreign governments especially drugs like Hydroxychloroquine and Paracetamol. NPPA coordinated with drug manufacturers of these medicines and created a reporting framework for production and supply of these medicines. This facilitated the Empowered Committee to make recommendations for release of surplus drugs produced to foreign countries after ensuring the sufficient domestic availability.

Based on recommendations of Empowered Committee, DoP/NPPA issued recommendation/orders which enabled the MEA/DGFT to fulfill various export commitments towards 114 Countries, including SAARC Nations, in respect of HCQ and 24 Countries in respect of Paracetamol. This exercise was undertaken on humanitarian grounds as well as on Commercial terms.

7.3.3 Enhanced Production Capacity:

On the intervention of Empowered Committee, during March-May 2020 period the numbers of manufacturing units of Hydroxychloroquine increased from 2 to 12 and the country's production capacity of Hydroxychloroquine has increased three times i.e. from 10 Crore (Approx) tablets per month to 30 Crore (Approx) tablets per month. Currently, India is having surplus of Hydroxychloroquine tablets over and above its domestic requirements.

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 (DMs) etc. to ensure that supply chains were not compromised during lockdown and Unlock phases. Such steps taken by NPPA are mentioned below:

Monitoring Export/ Import Trends to ensure domestic availability of key drugs and Medical Devices: In order to monitor trends of export and import of APIs/Formulations and Medical Devices as well as to ensure timely availability of drugs mentioned by MoHFW, NPPA constituted an inter-ministerial Committee to develop a mechanism to assess bottlenecks and impediments in imports of APIs and to suggest possible alternative sources & export trend analysis to ensure domestic availability of key drugs and Medical Devices during the pandemic.

COVID-19 Treatment Protocol Drug Availability: NPPA undertook various steps to ensure the availability of life saving essential drugs like Hydroxychloroquine, Paracetamol, Methylprednisolone, Enoxaparin, Dexamethasone, Remdesivir etc. NPPA also ensured the availability of Vaccines, Anti-Tuberculosis drugs, Anti-diabetic drugs, Cardiac drugs, imported Anti- epileptic drugs and drugs like FDC Lopinovir&Ritionavir, Favipiravir, Zinc Sulphate, etc.

COVID and COVID plus Drugs Database: NPPA, in coordination with CDSCO, developed a comprehensive database for COVID & COVID plus (55+97) drugs as a measure of preventive preparedness for fighting COVID-19. This has been immensely useful in current scenario as well as future needs of the organization. A State wide mechanism was created to obtain timely alerts (ring the bell) in case of shortages to take immediate remedial action.

7.4 Monitoring & Enforcement

7.4.1 Monitoring Availability Of Medicines

The Government is effectively monitoring the prices of scheduled as well as non-scheduled medicines under DPCO, 2013 and takes action against companies found overcharging the consumers based on the references 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.

7.4.2 Monitoring Of Price Movement Of Medical Devices:

Para 20 of the DPCO, 2013 empowers the Government to monitor the Maximum Retail Price (MRP) of all the drugs including the non-scheduled formulations & notified medical devices as drugs and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months. The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

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.

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.

As per Ministry of Health & Family Welfare's Notification dated 11th February, 2020, all Medical Devices have been notified as 'Drugs' w.e.f. 1st April 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.

7.4.3 Price Monitoring and Resource Units (PMRUs)

NPPA is in the process of establishing Price Monitoring and Resource Units (PMRUs) at State level under the scheme of 'Consumer Awareness, Publicity and Price Monitoring'. PMRUs are societies registered under the Societies Registration Act having its own Memorandum of Association/Bye laws. PMRUs constituted at the State/Union Territories function under the direct supervision of the concerned State Drug Controllers for increasing outreach of NPPA. As on 31st December 2020, 17 PMRUs in the States of Kerala, Odisha, Gujarat, Rajasthan, Punjab, Haryana, Nagaland, Tripura, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh and Uttar Pradesh have been set up.

7.4.4 Enforcement Activities

To ensure that medicines are available to patients at the notified prices, NPPA works closely with State Drugs Controllers for enforcement activities. Samples of medicines are picked up from open market regularly and analyzed to monitor the price at which the medicines are sold to patients. Enforcement activities from 2010-11 to 2020-21(up to 30.11.2020) are given as under:

Table - 7E
(Enforcement Activities From 2010-11 To 2020-21)

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 (up to 30.11.2020)	1018#	522

Cases of Overcharging referred from State Drug Controllers are included under the 'Samples Collected'.

7.5 E-Initiatives:

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

7.5.1 Eco-System For Online Applications:

NPPA has implemented single window online Eco-system for timely disposal and monitoring of various applications filed by the pharmaceuticals companies under DPCO, 2013 to promote the Ease of Doing Business for 'Atmanirbhar Bharat'. Under the Eco-system, various applications such as retail price

approval, discontinuation approval etc. from pharmaceutical companies are received through on-line mode and duly acknowledged. Timelines for disposing off various applications has also been fixed and a tracking system is also in force by way of uploading the present status of applications received.

Through this reform, simplification in applying for various approvals has been ensured and burden to submit various documents with offline applications has been reduced for ease of doing business for Pharmaceuticals industry.

7.5.2 Pharma Jan Samadhan (PJS)

The PJS was launched on 12th March, 2015. PJS is a web enabled system developed by the NPPA with 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 redressal system with respect to availability of medicines, overpricing of medicines, sale of 'new drugs' without prior price approval (WPA) and refusal to supply or sell medicines. Complaints can be registered under PJS link available at the NPPAs website i.e. www.nppaindia.nic.in 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.

7.5.3 Pharma Data Bank (PDB) - Integrated Pharmaceutical Database Management System (IPDMS)

IPDMS was launched on 25th June 2015. IPDMS was developed by the NPPA in collaboration with 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. Application for price approval of 'new drug' in Form-I can also be filed through this portal.

IPDMS provides industry with a user-friendly mechanism to comply with the mandatory requirement of filing returns; it also helps NPPA to monitor price compliance. 966 Pharma companies have registered themselves under IPDMS and 81901 Product registered till 31st December, 2020.

7.5.4 Mobile Application 'Pharma Sahi Daam' And 'Search Medicine Price' Utility

NPPA launched its mobile app on 29.08.2016 named as "Pharma Sahi Daam" 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 facilitates consumers to verify whether medicines are being sold within the approved price range and also to detect any case of overpricing by pharmaceutical company/chemist. If there is any ceiling price violation, the buyer is able to lodge a complaint against company/ chemist through Pharma Jan Samadhan (http://www.nppaindia .nic.in/redressal.html).

7.6 Recovery Of Overcharged Amount:

NPPA has initiated about 2116 cases of overcharging as on 31st December 2020. Amount of Rs. 978.82 Crore (Rs. 557.74 Crore under DPCO 1995 and Rs. 421.08 Crore under DPCO 2013) has been recovered as on 31st December 2020, 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' 1995 / DPCO' 2013 read with Essential Commodities Act, 1955.

7.7 Rajbhasha Implementation:

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 to periodically review in 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. Official language Implementation Committee meetings were held on 25th September 2020 and 19th October 2020.

7.7.1 Rajbhasha Prayog Protsahan Pakhwara, 2020

Rajbhasha Prayog Protsahan Pakhwara, 2020 was organised in the NPPA from l6th to 30th September 2020 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. Because of COVID-19 five competitions were held by video conferencing and making PDF by scanning all the written paper. Officers and staff enjoyed competitions with video conferencing. Hindi Pakhwara programme was successful in 2020. Winners were awarded with cash prizes.

7.7.2 Review Of The Status Of Use Of Rajbhasha Under The Department:

Inspection of NPPA scheduled on l4th October 2020 by Parliamentary Official Language Committee was deferred.

7.8 Vigilance Awareness Week:

Vigilance awareness week was observed in NPPA from 27th October 2020 to 2nd November 2020. A pledge was administered by the Chairman to all the officers and staff of NPPA on 27th October 2020.

7.9 Constitution Day:

Constitution day was observed on 26th November 2020 in the office of NPPA. The Chairman NPPA read out the Preamble of the Constitution in the gathering of Senior Officers and staff of NPPA by maintaining 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, 2020

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

8.5 Conduct of Hindi Workshop

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 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 were held on regular intervals and implementation status of the various targets set in the Annual Programme for transaction of the official work of the Union in Hindi for the year 2020-21 issued by the Department of Official Language, Ministry of Home Affairs was reviewed.

8.3 Hindi Prayog Protsahan Pakhwara, 2020

Hindi Prayog Protsahan Pakhwara was observed in the Department from 14th to 28th September 2020 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 2020-21. During this year, to achieve the prescribed target (inspection of at least 25% offices) in the Annual Official Language Programme 2020-21, the successful inspection of subordinate offices of Department of Pharmaceuticals was not carried out due to pandemic.

8.5 Conduct of Hindi Workshop

To help the officers/employees of the Department of Pharmaceutical to work in official language in official work and to encourage to use official language Hindi, a Hindi workshop on the subject 'Official Language Rules and Hindi Quarterly Progress Report' was organised on 23.12.2020.

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, dye stuff and dye intermediates.

9.6 Our Activities

The key activities of the Department:

1. Ensure availability of drugs at reasonable prices as per provisions of the Drugs

(Prices Control) Order, 2013

2. Ensure proper functioning of the Central Pharma Undertakings in control of the Department.

3. Project Based Support and Revival Schemes for CPSUs

4. Ensure proper management of M Pharma and Ph.D. programs in NIPERs

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

6. Formulate Scheme/ Project for promoting Pharma Brand India

7. Formulate Scheme/Project for promoting environmentally sustainable development of Pharmaceutical Industry

8. 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 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 sincere initiatives towards adoption of E-Governance to deliver information and services online. This has led to benefits in terms of transparency, easy accessibility of services, improvement of internal processes and decision 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, Dept. has created Facebook and Twitter accounts. Information regarding the conferences, Seminars, launches by Minister, MoS, Secretary and other officers of Dept. 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 is provided to all the officers of the Department so as to discuss all the important issues through VC. PSUs and Educational Institutes (NIPERs) have also installed the Video Conferencing facility. VC facility enables Department to interact with PSUs and NIPER frequently to monitor their performance and communicate the decisions. Pragati meeting, monitoring tool of PM office, is conducted every month and Hon'ble PM interacts with all Secretaries and State CS 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, aVirtual Private Network (VPN) Facility was provided to them so that they can 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 implemented to reduce duplicity of work, increases transparency and efficiency.

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 (SPARROW) application which allows online submission of APAR of IAS and CSS cadre officers is 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 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, Deptt. has taken initiative to use Online RTI-MIS. Necessary training was imparted to concerned officials/staff to implement 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 is a web portal https://ehrms.gov.in/implemented in the Department of Pharmaceuticals. Employee Data of all the employees are uploaded. Module Service book Detail, Leave and LTC are operational.

- **https://supremo.nic.in/** is web portal being maintained by 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) are being uploaded onto the website.

To enhance e-Governance further following initiatives has 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, development and promotion 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 development phase.

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

- **Stationery MIS** (http://10.21.81.76/store) is the MIS of the Stationery item for the Department of Pharmaceuticals. Here employee can request for the stationery items. Dealing hand accepts the request and after approval of the Admin employee can receive the item. Stock of the stationery items are being maintained and issue through this portal dynamically. Next Version of this software is proposed.

- **E-registry of all Dak:** The Department has functioning module of e-diarising of all dak/receipts in the Department for the purpose of database and e-monitoring. All papers received in the Department including all official e-mails are diarised electronically in the Central Registryof the Department. Periodical reports of pending papers are generated and monitored.

- **NIPER MIS:** An information management portal for all the NIPERS which implement direct benefit transfer to students/PhD scholars has been prepared. Live data is shared from NIPER MIS with DBT UMANG Portal and the PRAYAS Portal.

- **The Department is in the process of preparing MIS** for monitoring and evaluation of the Foreign Direct Investment (FDI) in pharma sector and the sector specific conditions.

CHAPTER-11

ANNEXURES

Annexure - I [A]	List of PSUs and Other Organizations
Annexure - I [B]	Address and Name of various Organizations & PSUs
Annexure - I [C]	List of Responsibility Centers and Subordinate Organizations
Annexure – II	Organizational Chart of NPPA
Annexure – III	C&AG's audit observations

CHAPTER 11

ANNEXURES

ANNEXURE I [A]

List of Public Sector Undertakings

1 Indian Drugs & Pharmaceuticals Ltd, Dundahera Industrial Complex, Dundahera, Gurgaon, Haryana.
2 Hindustan Antibiotics Ltd, Pimpri, Pune, Maharashtra.
3 Karnataka Antibiotics & Pharmaceuticals Limited, Bangalore-560010.
4 Bengal Chemicals & Pharmaceuticals Ltd, Kolkata, West Bengal.
5 Rajasthan Drugs and Pharmaceuticals Limited. Road No.12, V.K.I. Area, Jaipur-302013.

OTHER ORGANISATIONS

1. Bengal Immunity Limited, Kolkata, West Bengal.
2. Smith Stanistreet Pharmaceuticals Ltd. Kolkata, West Bengal.

ANNEXURE I [B]

Address and Names of Head of various Organization & PSUs under the Department of Pharmaceuticals: -

Table-11 A
(Contact address of 5 PSUs)

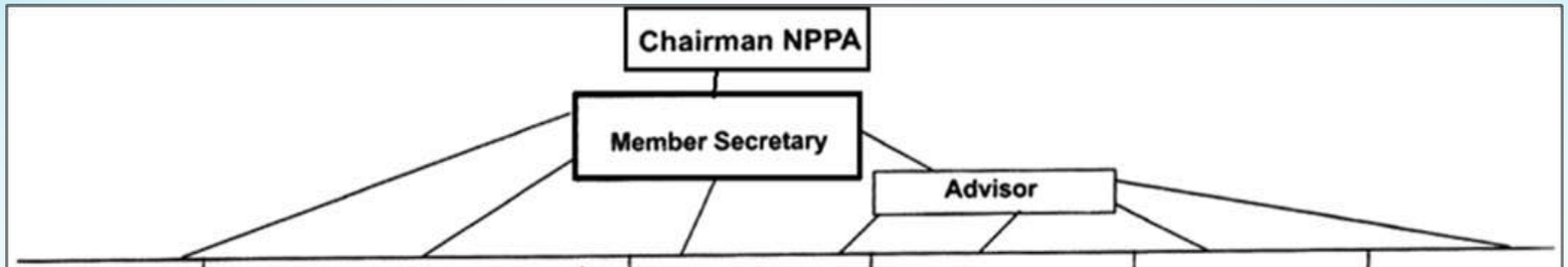
Sl. No.	Address and Organization	Name	Designation
1.	Indian Drugs & Pharmaceuticals Limited, (IDPL), Gurgaon	Shri Rajneesh Tingal	Chairperson & Managing Director
2.	Hindustan Antibiotics Limited (HAL), Pune-411010	Ms. Nirja Saraf	Managing Director
3.	Karnataka Antibiotics &Pharmaceuticals Limited (KAPL), Banglore-700013	Mr. Sunil Kumar Kaimal	Managing Director
4.	Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata-700013	Ms. Nirja Saraf	Managing Director (Additional Charge)
5.	Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Road No. 12 V.K.I Area Jaipur-302013	Ms. Nirja Saraf	Managing Director (Additional Charge)

ANNEXURE I [C]

List of Responsibility Centers and Subordinate Organizations

S. No.	Directors of NIPER	Landline Number	Email	Mobile butcher	Address
1	Dr. SJS Flora NIPER-Mohali (Additional Charge)	0172-2214690 0172-2214697	director@niper.ac.in sjsflora@niper.ac.in	9425482305	SAS Nagar, NIPER Mohali, Punjab - 160062
2	Dr. Kiran Kalia, NIPER-Ahmedabad	079-66745555	kirankalia@gmail.comdirector@niperahm.ac.in	9714618573	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	9999297992	NIPER, Hyderabad IDPL Township, Balangar, Hyderabad-500007
4	Dr.V. Ravichandiran, NIPER-Hajipur (Additional Charge)	0012-2631565	directorniperkolkata@gmail.comdirector@niperkolkata.edu.indirector@niperhajipur.ac.in	944396348 1	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	944396348 1	Chunilal Bhawan, 168, Maniktala main road, Kolkata-700054, West Bangal
6	Dr. USN Murty NIPER-Guwahati	0361-2132751	rnurtyusn@gmail.com murty_usn@yahoo.com director@niperguwahati.ac.in	9127060998	C/ o NITA-Mirza Santipur, Parlli Part, NH-37 Mirza, Kamrup, Assam – 781125
7	Dr. SJS Flora NIPER-Raebareli	0535-2700851	sjsflora@hotmail.com director@niperraebareli.edu.in	9425482305	Bijnor-Sisendi Road, Sarojini Nagar, Near CRPF Base Camp, Lucknow (UP) 226002

Organizational Chart of NPPA



Admn. Division	Mon.& Enf. Division-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 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 formulations and other DPCO related matters. 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. 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 Divsions 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	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 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.	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. 7. Notification of prices in the official Gazatte 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 Meetings - 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.	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 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 order whenever needed. 6. Examination of other issues related to overcharging under DPCO, 1995 for recovery of the overcharged 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.	1. Court cases under DPCO, 1987 and 1995 2. Court cases under DPCO, 2013 3. Advice to other Divisions of NPPA related to interpretation and applications of various provisions of DPCO. 4. Legal matters related to establishment matters / NPPA's accomodation 5. NPPA's working guidelines/ procedures etc. 6. Launching prosecution against the defaulting companies for violation of the provisions of DPCO. 7. Related Parliament Questions/ matters.

Annexure-III

Report No. 3 of 2020 of Comptroller and Auditor General of India (CAG) on Union Government (Economic & Service Ministries) - Compliance Audit Observations

Board of Governors (BoG) were not constituted in the six new NIPERs till March 2019 and the Steering Committee was discharging the functions of the BoG. The BoG at NIPER, Mohali was reconstituted after a delay of two years. In the absence of a dedicated governing body, permanent academic staff and adequate infrastructure facilities, the Institutes have been unable to achieve their objective to further pharmaceutical education in the country in a significant way. This adversely impacted performance in terms of research papers published and patents awarded and poor placement of students. The Institutes were largely financed by grants from Ministry and only a very small portion of the expenditure was met through their own revenue.

(Para 2.1)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Ministry of Chemicals & Fertilizers
DEPARTMENT OF PHARMACEUTICALS
अब दवाइयाँ हुई सस्ती ।
Pradhan Mantri Bhartiya Janaushadhi Pariyojna