Annual Report 2016-17

सत्यमेव जयते

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

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INTRODUCTION

1.1 Mandate of Department of Pharmaceuticals

CHAPTER – 1
INTRODUCTION

1.1 Mandate of Department of Pharmaceuticals

The Cabinet Secretariat notified creation of a new Department, namely the Department of Pharmaceuticals, under the Ministry of Chemicals & Fertilizers which came into being w.e.f. 1st July 2008 with the objective to give greater focus and thrust on the development of pharmaceutical 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 pharmaceutical sector which required integration of work with other ministries.

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 pharmaceutical sector.
4. Development of infrastructure, manpower and skills for the pharmaceutical 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 pharmaceutical research, including work related to international conferences in related areas in India and abroad.
8. Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
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 for Pharmacy Education and Research.

12. Planning, development and control of, and assistance to, all industries dealt 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 divided into three Divisions viz. Pharmaceuticals Industry Division, Public Sector Undertakings Division and R& D Division comprising of National Institute of Pharmaceutical Education & Research (NIPER) and Research & Development. The National Pharmaceuticals Pricing Authority, an attached office of this Department is entrusted with the work of fixation and revision of prices of pharmaceuticals products under Drug Price Control Order 2013.

Shri Jai Priye Prakash is the Secretary, who holds the charge of this Department w.e.f 01.07.2016.

Chapter 2

AN OVERVIEW OF PHARMACEUTICALS INDUSTRY

CHAPTER - 2
AN OVERVIEW OF THE PHARMACEUTICALS INDUSTRY

2.1 Financial Performance of the Drugs and Pharmaceuticals Industry

Financial Performance of the Drugs & pharmaceuticals industry. Pharma exports record CAGR of 11.9% for decade ending 2015-16. Expect to complete projects worth ₹ 105.7 billion during 2016-19.

The Annual turnover of the Indian Pharma Industry during 2015-16 was 1,85,388 crores during 2015-16. It represented a decline of 7.4% over the correspondence figure for 2014-15 i.e. 2,00,151 crores. The CAGR for last 5 financial years was 8.88%.

The domestic Pharma market witnessed a slowdown in the ongoing financial year owing to the Government's efforts to make medicines affordable. The impact of this can be seen in the industry's financials as well. The drugs & pharmaceuticals industry reported poor sales performance for two consecutive quarters ended September 2016. Sales grew by a mere 2.9 per cent in the September 2016 quarter, after a sluggish 2.5 per cent growth registered in the June 2016 quarter. The industry's operating expenses rose by 5.4 per cent during the September 2016 quarter, much faster than the growth in sales. As a result, the industry's operating profit declined by 5.4 per cent. Operating margin contracted by 185 basis points to 21.1 per cent. A 3.4 per cent decline in the industry's post-operating expenses restricted the decline in its net profit to 0.8 per cent. The industry's net profit margin contracted by 160 basis points to 13.7 per cent during the quarter.

The absolute figures available from the data provided by Centre for monitoring Indian Economy Private Limited (CMIE) for the last 5 years is as per the following table.

Income & Expenditure Summary : Drugs & Pharmaceuticals Industry

	Rs. Million: 2010-11 to 2015-16						
S. No.	**Particular**	**2010-11**	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**
1.	Total Income	14,09,099	15,10,061	16,48,757	19,18,723	20,01,508	18,53,879
2.	Total expenses	11,58,652	14,21,040	15,18,117	17,53,437	18,36,297	16,44,004
3.	Profit before tax	4,39,716	3.18,476	3,38,153	4,39,199	4,56,616	4,50,514
4.	Profit after tax	2,77,945	1,17,337	1,52,141	1,89,291	1,90,994	2,17,781

Source Centre for monitoring Indian Economy Pvt. Ltd. (CMIE) data as on 15/02/2017

Performance of Pharma Exports: - During the decade ending 2015-16, India's drug exports grew at a CAGR of 11.9 per cent. This growth was backed by large number of drugs going off patent, rise in the number of drug approvals and access to new markets. According to the CMIE data, the trend in drug exports reversed in the ongoing financial year. During April-November 2016, drug exports fell by one per cent. This is on account of tightening of regulatory mechanism by various countries, price erosion in the US market and economic crisis in the emerging markets. For the year 2016-17 as a whole, drug exports are expected to dip by 0.4 per cent. The Quarterly financial indicators of Indian Pharma Industry reflecting the figures of percentage change over previous corresponding quarter are presented in the following table.

Income & Expenditure Summary: Drugs & Pharmaceuticals Industry (Quarterly)					
Y-o-Y % change: Mar 2016 to Dec 2016					
S. No	**Particulars**	**Mar-16**	**Jun-16**	**Sep-16**	**Dec-16**
1.	Total Income	4.57	3.37	3.77	5.1
2.	Net sales	7.38	2.52	2.91	4.1
3.	Total expenses	1.43	3.55	14.65	5.42
4.	Operating expenses	3.17	3.64	5.15	4.8
5.	Raw materials, stores & spares	-8.91	-3.71	-1.66	-1.81
6.	Salaries and wages	8.89	10.7	15.11	12.92
7.	Power & fuel	-13.16	12.38	11.7	18.52
8.	Interest expenses	14.26	13.36	0.63	-1.25
9.	Depreciation	-11.41	13.5	9.75	9.73
10.	PBT	12.95	-7.67	-4.79	8.02
11.	Total tax provision	1.46	-10.13	-16.33	17.7
12.	Net profit (PAT)	17.41	-6.82	-0.96	5.11
13.	Total expenses net of P& E	42.96	-6.81	-0.99	2.35
14.	PBDIT net of P& E	2.6	3.56	4.05	5.6
15.	PBDIT net of P&E	16.28	-2.57	-2.03	5.66
16	PBDIT net of P&E & OI (Operating Profit)	18.47	-6.77	-5.45	2.93
17.	Count	151	151	149	128

Performance of Pharma Imports: - During April-November 2016, drug imports declined by 9.3 per cent. This was on account of withdrawal of customs duty exemption on a total of 71 drugs by the government. This move aimed at reducing the dependence on drug imports and encourage local production. For the year 2016-17, drug imports are likely to decline by 9.3 %.

Change in Principal Commodities by DGCIS for better access to Foreign Trade data: It is important to point out that foreign trade data relevant for modern system of medicines (relevant for the DoP) was not available. It was mainly on account of non-availability of any clarity about the relevant HS Codes for Drug & Pharmaceuticals. The basket of commodities considered for compilation of data on exports was different from

the one considered for compilation of data for imports. In order to alleviate this problem after creation of separate Department of Pharmaceuticals, during 2008, the DoP constituted an inter-Departmental Committee to list out the HS Codes relevant for Bulk Drugs & Drug intermediates under chapter 29 and also list relevant HS Codes that are not under the domain of DoP even in chapter 30 for Pharmaceutical formulations.

Based on the report of the above referred committee the DGCIS has since revised Principal Commodity Groups and foreign trade data after March 2014 is now accessible for following 4 main Principal Commodities:

1. Bulk Drugs & Drugs intermediates,
2. Drug formulation and Biologicals,
3. Surgicals and
4. AYUSH and Herbal Products.

Details about relevant HS Codes are now available on the websites of DGCIS and DGFT.

The Future Prospects: - After completion of projects worth Rs.170.4 billion seen during 2010-13, investments in the drugs and pharmaceuticals industry slowed down to Rs.57.2 billion during 2013-16. We expect project completions to pick-up in the coming years. Apart from formulations, the industry is investing to expand its capacity to manufacture active pharmaceuticals ingredients (API) or bulk drugs manufacturing with an aim to become self-sufficient with respect to API requirements. The industry commissioned 11 projects during April-December 2016. Of these, cost details of eight projects are available. These projects involve an investment outlay of Rs.11.6 billion. Glaxosmithkline Pharmaceuticals, Shantha Biotechnics, Cipla Biotec and Aurobindo Pharma are some of the companies which completed their projects during the period.

It is expected that projects worth Rs.17.5 billion to be completed by March 2017. Going forward, projects worth Rs.45.1 billion are expected to be completed in 2017-18, followed by projects worth Rs.31.5 billion to come up in 2018-19.

2.2 Pharmaceuticals Pricing Policy

The Department of Pharmaceuticals had 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, even 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.

Subsequently, to implement the NPPP-2012, the new Drugs (Prices Control) Order, 2013 was notified on 15.05.2013 to control the prices of specified dosages and strengths as under National List of Essential Medicines-2011(NLEM-2011). This was modified to include medicines included in NLEM-2015 vide notification dated 10.03.2016 after the same was received from Ministry of Health & Family Welfare who had constituted an Expert Core Committee to review and recommend the revision of National List of Essential Medicines (NLEM-2011) in the context of contemporary knowledge of use of therapeutic products.

2.3 Foreign Direct Investment in Pharmaceuticals Sector

Department of Industrial Policy & Promotion has reviewed the Foreign Direct Investment (FDI) Policy and vide their Press Note No. 5 (2016 Series) dated 24/06/2016 has amended the FDI Policy whereby Pharmaceutical Companies for Greenfield Pharma Projects can invest 100% FDI through automatic route and for Brownfield Pharma Projects foreign investment upto 74% is allowed under automatic route and beyond that the companies have to come through government route.

2.4 Cluster Development Programme for Pharma Sector (CDP-PS)

With a vision to catalyze and encourage quality, productivity and innovation in pharmaceutical sector and to enable the Indian Pharmaceutical Industry especially SMEs to play a leading role in a competitive global market, Hon'ble Minister of Chemicals and Fertilizers approved the introduction of **Cluster Development Programme for Pharma Sector (CDP-PS)** on 27.10.2014. The said report was released by Hon'ble Minister of Chemicals and Fertilizers on 17.06.2015.

The CDP-PS is a Central Sector Scheme. The total size of the scheme is proposed as Rs.125 Crores for CDP-PS for 12th Five Year Plan.

Assistance under the Scheme will be Rs. 20.00 Crore per cluster or 70% of the cost of the project, whichever is less for creation of common facilities. Some of the indicative activities under the Common facilities are:

- Common Testing Facilities
- Training Centre

- Effluent Treatment Plant
- R&D Centres
- Common Logistics Centre

3. Projects and Development India Limited (PDIL) who were chosen as the Project Management Consulting (PMC) for implementing the scheme had called EOIs and after processing the same, Scheme Selection Committee (SSC) has selected the proposal of M/s Chennai Pharma Industrial Infrastructure Upgradation Company, Alathur., Chennai, Tamilnadu. Further, the proposal of M/s Andhra Pradesh Industrial Infrastructure Corporation (APIIC) Limited along with other proposals received is being examined by PDIL.

2.5 Scheme for Financing Common Facility Centers (CFCs) at Bulk Drug Park

The vision of the Department of Pharmaceutical (DoP), Ministry of Chemicals & Fertilizers is to catalyze and encourage quality, productivity and innovation in Bulk Drug Sector and to enable the Indian Bulk Drug Industry to reduce the dependency on import of Bulk Drugs. For this, world class quality manufacturing facilities with high level of productivity with innovative capabilities are required. However, these are on one hand very capital intensive and cannot be established and opened by Bulk Drug Manufacturing Units on their own due to financial constraints.

In this direction, the Department proposes in the first instance to start a scheme for Financing Common Facility Centres (CFCs) at 3 Bulk Drug/API Parks in the country at a total cost of Rs. 450 crores. Some of the indicative activities under this Common facilities are:

i. Effluent Treatment Plants
ii. Captive Power Plant
iii. Steam and Cooling and water systems
iv. Incubation facilities
v. Common logistic facilities
vi. Advance common testing centre
vii. Regulatory awareness facility centre

The objectives of this scheme are as under:-

(i) Increasing the competitiveness, easy access to standard testing and infrastructure facilities and value addition in the domestic Bulk Drug Industry through creation of common world class facilities.
(ii) Strengthening the existing infrastructure facilities in order to make Indian Bulk Drug Industry a global leader in Bulk Drug Exports.
(iii) Reducing the cost of production by 20-25% in the Bulk Drug Park leading to better availability and affordability of Bulk Drug in domestic market.
(iv) Exploiting the benefits arising due to optimization of resources and economies of scale.

Department of Expenditure's in-principle approval has been received for implementing the scheme.

2.6 Ease of Doing Business

The Department of Pharmaceuticals has from time to time keeping with the need has been amending the provisions of Drug (Prices Control) Order-2013 (DPCO-2013) for doing ease of business. In this direction, on 22 March, 2016, the Department amended Para-11 of DPCO-2013 so as to facilitate IV Fluid Manufacturers which would also result in bringing in more foreign investment in the country and increasing employment opportunities for the countrymen.

2.7 International Cooperation / Export Promotion of Pharmaceuticals

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

Department of Pharmaceuticals has the following Joint Working Groups/High Technology Cooperation 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-US High Technology Cooperation Group (HTCG)
5. India-Belarus Joint Working Group on Pharmaceuticals
6. India-Philippines Technical Working Group (TWG) for considering "Pharmazone" and "Registration and other Issues related to Pharmaceuticals"
7. India-Algeria Joint Working Group (JWG) on Pharmaceuticals
8. India-Egypt Joint Study Group (JSG) on Pharmaceuticals and Health.

International Participations

1. 7th Meeting of EU-India was held on 5-6 July 2016 at Brussels under the Co-chairmanship of Shri Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals.
2. A delegation led by Dr. M.A. Ahammed, the then Joint Secretary, Department of Pharmaceuticals participated in 10th Annual Bio Pharma & Health Summit 2016 held on 02.06.2016 at Boston (USA)
3. 6th Meeting of India-Tunisia Joint Working Group on Drugs & Pharmaceuticals was held on 11-13 January, 2017 at Tunis under the Co-chairmanship of Shri Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals

2.8 Pharmaceuticals Promotion Development Scheme (PPDS):

The Objective of Pharmaceuticals Promotion Development Scheme(PPDS) is promotion, development and export 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. 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 206 of GFR 2005,

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) How to handle 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, Convention, Exhibitions, Pharmacy week, 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 any other activity not covered under above categories which may be decided by the Department of Pharmaceuticals from time to time.

Events organized/to be organized under Pharmaceuticals Promotion Development Scheme (PPDS) during 2016-17 -

1 Conference on “APIs: Reducing dependence on Imports” on 28 July 2016 at Baddi, Himachal Pradesh in association with the Associated Chambers of Commerce & Industry of India **(**Assocham)

2 Seminar on "Bio-Pharma: Biosimilars & Biogeneric; Emerging Investment Destination" on 6 October 2016 at Hyderabad in association with the Associated Chambers of Commerce & Industry of India **(**Assocham)

3 Workshop (Indian Drug Manufacturers Association) on "Technology Upgradation and Pharmaceutical Promotion" at National Institute of Pharmaceutical Education and Research (NIPER), Kolkata on 29-30 July 2016 in association with NIPER, Kolkata

4 National Conference on "Green Chemistry Challenges and Opportunities in India" on 9 September 2016 at Durgapur in association with Durgapur Viswagandha Science Society

5 World Congress on "Drug Discovery & Development-2016" on 23-25 November 2016 at Bangalore in association with Bio Genesis Health Cluster

6 National level Seminar "Global Perspective on Medical Devices" on 10 December 2016 at Rajkot in association with Saurahshtra University

7 National Symposium on (i) What do the fresher lacks for getting better jobs on 14-17 November 2016 and (ii) Job Fair for Student on 23-27 January 2017 at Ahmedabad in association with National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad

8 Seminar on "Meeting Quality and Achieving Global Compliance" on 29 July 2016 at Bangalore in association with *Indian Drug Manufacturers' Association (*IDMA)

9 Workshop on "Building Consumer Awareness on improving Accessibility to Medicine" on 26/27 October 2016 in association with Consumer Online Foundation

10 Seminar on "Meeting Quality and Achieving Global Compliance" on 26 August 2016 at Mumbai in association with *Indian Drug Manufacturers' Association (*IDMA)

11 Seminar on "Meeting Quality and Achieving Global Compliance" on 10 October 2016 at Nashik in association with *Indian Drug Manufacturers' Association (*IDMA)

12 National Seminar on Drug (Code for Marketing) Order UCPMP on 16 September 2016 at Bangalore in association with Karnataka Drugs & Pharmaceuticals Manufacturers Association (KDPMA)

13 Seminar/Workshop on "Awareness on Jan Aushadhi Scheme" at Amritsar in association with PHD Chamber of Commerce & Industry (PHDCCI)

14 Seminar/Workshop on “Awareness on Jan Aushadhi Scheme” at Bhopal on 30 September 2016 in association with PHD Chamber of Commerce & Industry (PHDCCI)

15 Eight Awareness programmes on “Jan Aushadhi Scheme” in AP and Telangana in association with National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad

16 National Conference on “Innovations in Novel Pharmaceutical Technology/Processes alongwith a Workshop on GLP/GMP Compliance” on 24-25 November 2016 at Hyderabad in association with National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad

17 National level Conference “Pharma Industry Meet on Cluster Development: Strengthening Indian Pharma Industry” on 19 October 2016 at Hyderabad in association with National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad

18 Seminar/Workshop on Awareness on Cluster Development Programme at Dehradun on 23 February 2017 in association with PHD Chamber of Commerce & Industry (PHDCCI)

19 Seminar/Workshop on Awareness on Cluster Development Programme on 16 March 2017 at Hyderabad in association with PHD Chamber of Commerce & Industry (PHDCCI)

20 2nd Exhibitor on “Pharmaceuticals & Medical Equipment” on 8 February 2017 at New Delhi in association with the Associated Chambers of Commerce & Industry of India (Assocham)

21 Bio-Asia 2017 on 6-8 February 2017 at Hyderabad in association with Federation of Asian Biotech Associations (FABA)

22 Conference on Drug Discovery and Development: Cancer and Lifestyle disease on 16-17 February 2017 at Hyderabad in association with National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad

23 Seminar on “IPC 68th Indian Congress Pharma visio 2020: Seminar on Noval Drug Delivery system at Vishakhapatnam in association with Indian Pharmaceutical Association (MP Branch), Indore

24 Seminar on “Expectation of Regulators from Industries regarding WHO-GMP on 15 July 2016 at Indore in association with Indian Pharmaceutical Association (MP Branch), Indore

25 Workshops on IPR for Pharma & Biotech Sector and Regulatory Perspectives at Hyderabad, Ahmedabad and Mumbai in association with Pharmaceuticals Export Promotion Council of India (Pharmexcil) at Ahmedabad, Mumbai and Hyderabad

26 National Conference: PharmaMEd 2016 in association with PHD Chamber of Commerce & Industry (PHDCCI)

27 Seminar/Workshop on Awareness on Cluster Development Programme at Ahmedabad on 29 January 2017 in association with PHD Chamber of Commerce & Industry (PHDCCI)

28 Seminar on Price Regulation impact on Accessibility and Industry Perspectives in association with PHD Chamber of Commerce & Industry (PHDCCI)

The Department of Pharmaceuticals provided financial assistances for the following activities/events for promotion and development of Pharma sector from Pharmaceuticals Promotion Development Scheme (PPDS) during Financial Year – 2016-17:-

S. No.	Financial assistances
1	Financial assistance to **Associated Chambers of Commerce & Industry of India (**Assocham) for organizing Conference on "APIs: Reducing dependence on Imports" at Baddi, Himachal Pradesh
2	Financial assistance to **Associated Chambers of Commerce & Industry of India (**Assocham) for organizing One day Seminar on "Bio-Pharma: Biosimilars & Biogeneric; Emerging Investment Destination" at Hyderabad
3	Financial assistance to National Institute of Pharmaceutical Education and Research (NIPER), Kolkata for organizing Workshop (Indian Drug Manufacturers Association) on "Technology Upgradation and Pharmaceutical Promotion" at NIPER, Kolkata on 29-30 July 2016
4	Financial assistance to Durgapur Viswagandha Science Society for organizing National Conference on "Green Chemistry Challenges and Opportunities in India" on 9 September 2016 at Durgapur
5	Financial assistance to Bio Genesis Health Cluster for organizing World Congress on "Drug Discovery & Development-2016" on 23-25 November 2016 at Bengaluru
6	Financial assistance to Saurahshtra University for organizing One day National level Seminar "Global Perspective on Medical Devices" on 10 December 2016 at Rajkot
7	Financial assistance to National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad for organizing National Symposium on (i) What do the fresher lacks for getting better jobs on 14-17 November 2016 and (ii) Job Fair for Student on 23-27 January 2017 at Ahmedabad
8	Financial assistance to *Indian Drug Manufacturers' Association (*IDMA) for organizing Seminar on "Meeting Quality and Achieving Global Compliance" to be held on 29 July 2016 at Bengaluru
9	Financial assistance to Consumer Online Foundation for organizing Workshop on "Building Consumer Awareness on improving Accessibility to Medicine" on 26/27 October 2016

10	Financial assistance to *Indian Drug Manufacturers' Association (*IDMA) for organizing Seminar on "Meeting Quality and Achieving Global Compliance" on 26 August 2016 at Mumbai
11	Financial assistance to *Indian Drug Manufacturers' Association (*IDMA) for organizing Seminar on "Meeting Quality and Achieving Global Compliance" on 10 October 2016 at Nashik
12	Financial assistance to Karnataka Drugs & Pharmaceuticals Manufacturers Association (KDPMA) for organizing One day National Seminar on Drug (Code for Marketing) Order UCPMP on 16 September 2016 at Bangalore
13	Financial assistance to Federation of Indian Chambers of Commerce & Industry (FICCI) for Hosting Dinner during India Pharma 2016 and India Medical Device 2016
14	Financial assistance to PHD Chamber of Commerce & Industry (PHDCCI) for organizing Seminar/Workshop on "Awareness on Jan Aushadhi Scheme" at Amritsar on 16 September 2016
15	Financial assistance to PHD Chamber of Commerce & Industry (PHDCCI) for organizing Seminar/Workshop on "Awareness on Jan Aushadhi Scheme" at Bhopal on 30 September 2016
16	Financial assistance to National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad for organizing 8 Awareness programme on "Jan Aushadhi Scheme" from 15 August 2016 to November 2016 in AP and Telangana
17	Financial assistance to National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad for organizing National Conference on "Innovations in Novel Pharmaceutical Technology/Processes alongwith a Workshop on GLP/GMP Compliance" on 24-25 November 2016 at Hyderabad
18	Financial assistance to National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad for organizing National level Conference "Pharma Industry Meet on Cluster Development: Strengthening Indian Pharma Industry" on 19 October 2016 at Hyderabad
19	Financial assistance to PHD Chamber of Commerce & Industry (PHDCCI) for organizing Seminar/Workshop on Awareness on Cluster Development Programme at Dehradun on 23 February 2017
20	Financial assistance to PHD Chamber of Commerce & Industry (PHDCCI) for organizing Seminar/Workshop on Awareness on Cluster Development Programme on 16 March 2017 at Hyderabad
21	Financial assistance to Associated Chambers of Commerce & Industry of India (Assocham) for organizing 2nd Exhibitor on "Pharmaceuticals & Medical Equipment" on 8 February 2017 at New Delhi
22	Financial assistance to Federation of Asian Biotech Associations (FABA) for organizing Bio-Asia 2017 on 6-8 February 2017 at Hyderabad
23	Financial assistance to National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad for organizing Conference on Drug Discovery and Development: Cancer and Lifestyle disease on 16-17 February 2017 at Hyderabad
24	Financial assistance to Federation of Indian Chambers of Commerce & Industry (FICCI) for Dinner during India Pharma 2017 and India Medical Device 2017
25	Financial assistance to Indian Pharmaceutical Association (IPA), Indore for organizing Seminar on "IPC 68th Indian Congress Pharma visio 2020: Seminar on Noval Drug Delivery system at Vishakhapatnam
26	Financial assistance to Indian Pharmaceutical Association (IPA), Indore for organizing Seminar on "Expectation of Regulators from Industries regarding WHO-GMP on 15 July 2016 at Indore
27	Financial assistance to Pharmaceuticals Export Promotion Council of India (Pharmexcil) for organizing Workshops on IPR for Pharma & Biotech Sector and Regulatory Perspectives at Hyderabad, Ahmedabad and Mumbai on 26.09.2016, 03.10.2016 and 04.01.2017 respectively

28	Financial assistance to Directorate of Advertising and Visual Publicity (DAVP) for organizing DAVP advertisements in connection with India Pharma 2017 and India Medical Device 2017
29	Financial assistance to PHD Chamber of Commerce & Industry (PHDCCI) for organizing National Conference: PharmaMEd 2016 on 9 December 2016
30	Financial assistance to PHD Chamber of Commerce & Industry (PHDCCI) for organizing Seminar/Workshop on Awareness on Cluster Development Programme at Ahmedabad on 29 January 2017
31	Financial assistance to PHD Chamber of Commerce & Industry (PHDCCI) for organizing Seminar on Price Regulation impact on Accessbility and Industry Perspectives
32	Financial assistance to Green Chemistry for organizing Industrial Conference on 20-21 February 2017

2.9 India Pharma 2017 and India Medical Device 2017

India Pharma 2017 and India Medical Device 2017, International Exhibitions & Conferences on Pharmaceuticals and Medical Devices sector at Bangalore International Exhibition Centre, Bengaluru, Karnataka was held on 11-13 February 2017. Both the events consisted of International Exhibitions & Conferences along with a series of concurrent events, such as CEOs' Forum, Buyer-Seller Meet, International Drug Regulators Meet etc. These events provided a platform to global investment community to connect with stakeholders in the Pharma & Medical Devices sectors in India, Central and State Governments, leading business leaders and top executives from the industry, academics and experts from the world. These events had participation from Pharma Formulation, Bulk Drugs, Machinery and Technology segment of the Pharmaceutical and Medical Electronics Industry and Medical Electronic & Devices The CEO's Roundtables provided ample opportunities for discussing the major policies and trends in the growth of the industry in the Indian Pharmaceutical & Medical Device Industry with the Hon'ble Minister and top discussion makers in the Government.

2.10 India Pharma Awards

Shri Ananth Kumar, Hon'ble Minister of Chemicals and Fertilizers and Parliamentary Affairs gave away the 2nd India Pharma and Medical Devices Award 2017 at Bengaluru on 11th February, 2017. The list of awardees is given below:-

Sl. No.	CAT No.	Category of Award	Name of the Company
i)	1	Overall India Pharma Excellence Award	Lupin Limited
ii)	2	India Pharma Leader Award	Shri Dilip Surana, CMD, Micro Labs Limited
iii)	3	India Pharma Company of the Year Award	Glenmark Pharmaceuticals Ltd.
iv)	4	India Pharma Bulk Drug Company of the Year Award	Lupin Limited
v)	7	India Pharma Innovation of the Year Award	Dr. Reddy's Laboratories Ltd.
vi)	8	India Pharma Research & Development Achievement Award	Sun Pharmaceutical Industries Limited
vii)	9	India Pharma Corporate Social Responsibility (CSR) Programme of the Year Award	Lupin Limited
viii)	10	India Medical Devices Company of the Year Award	Meril Life Sciences Private Limited
ix)	11	India Pharma Export Company of the Year Award	Camus Pharma Pvt. Ltd.
x)	12	India Pharma Bulk Drugs Export Company of the Year Award	Camus Pharma Pvt. Ltd.
xi)	14	India Medical Devices Export Company of the Year Award	Meril Life Sciences Private Limited
xii)	15	India Pharma PSU of the Year Award	Karnataka Antibiotics & Pharmaceuticals Limited

Chapter 3

AN OVERVIEW OF MEDICAL DEVICE INDUSTRY

CHAPTER – 3
AN OVERVIEW OF MEDICAL DEVICE INDUSTRY

3.1 Indian Medical Device Industry:

Medical device industry is a multi-product industry, producing wide range of products. India is growing as a key market for Medical Devices and Diagnostics. Indian Medical Device industry depends on imports up to an extent of almost 70%. Most hi-tech innovative products and technology originate from a well-developed eco-system and innovation cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports. Department of Pharmaceuticals has a mandate to boost the medical device manufacturing sector in India.

In September 2014, the Indian Government launched the "Make in India" campaign, with the objective of making India a global manufacturing hub; thus, bringing foreign technology and capital into the country. Accordingly, a Task Force was formed under the Chairmanship of Secretary, Department of Pharmaceuticals (DoP), to address issues relating to the promotion of domestic production of high end medical device in the country. The Task Force in its report released on 8th April 2015 had made a set of recommendations for the promotion of medical device industry in the country.

3.2 Medical Device Market Size – Global

- The global medical device market was estimated at USD 228 bn in 2015 (INR 14.82 lakh crores).
- Industry estimates suggest that the global medical device market will grow at a CAGR of 7.8% from 2010 to 2020.
- The market is expected to reach USD 332 bn (INR 21.58 lakh crores) by 2020.

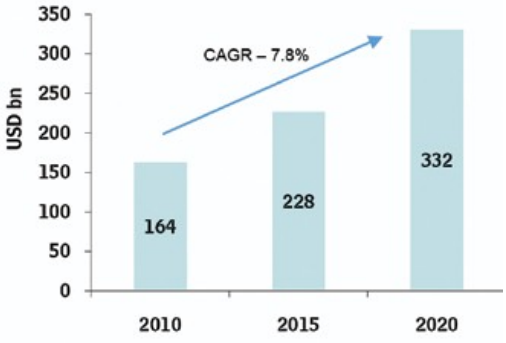


Figure: Global Medical Device Market Size

3.3. Medical Device Market Size- India

- The Indian medical device market has grown from USD 2.02 bn (INR 13,130 Crores) in 2009 to USD 3.9 bn (INR 25,259 Crores) in 2015 at CAGR of 15.8%.

This accounts for approximately 1.7% of the global medical device market in 2015.

- The Indian Medical Device market contributes to 4% of the Indian healthcare market which is pegged at USD 96.7 bn (INR 6.29 Lakh Crores), in 2015.
- The industry estimate suggests that the Indian medical device market will grow to USD 8.16 bn (INR 53,053 crore) in 2020 at CAGR of 16%.
- India is one of the top 20 global medical device markets and the 4th largest medical device market in Asia.

Figure: Medical Device Market Size- India

3.4 Medical Device Segments – India

- Diagnostic imaging is the largest segment within Indian medical device market in 2015. It constitutes USD 1.18 bn (INR 7,650 crores) in 2015 and will grow to USD 2.47 bn (INR 15,561 Crores) in 2020.
- Others and IV diagnostics comprise largely of electrical and electronic devices. The others category (patient monitors, ECG machine, Defib, etc) is estimated at USD 0.94 Bn (INR 5,922 Crores) in 2015 and will grow to USD 1.98 Bn (12,880 Crores) in 2020. Similarly, the IV diagnostics market constituted of USD 0.39 bn (INR 2,550 crores) in 2015 and will reach USD 0.82 bn (INR 5,356 Crores) in 2020.
- Similarly, Orthopedics & Prosthetics and Consumables will grow from a cumulative USD 0.90 bn (INR 5,850 crores) in 2015 to USD 1.88 bn (INR 12,220 crores) in 2020.
- Dental products and Patient Aids will grow from a cumulative USD 0.47 bn (INR 2,961 Crores) in 2015 to USD 1.1 bn (INR 6,930 Crores) in 2020

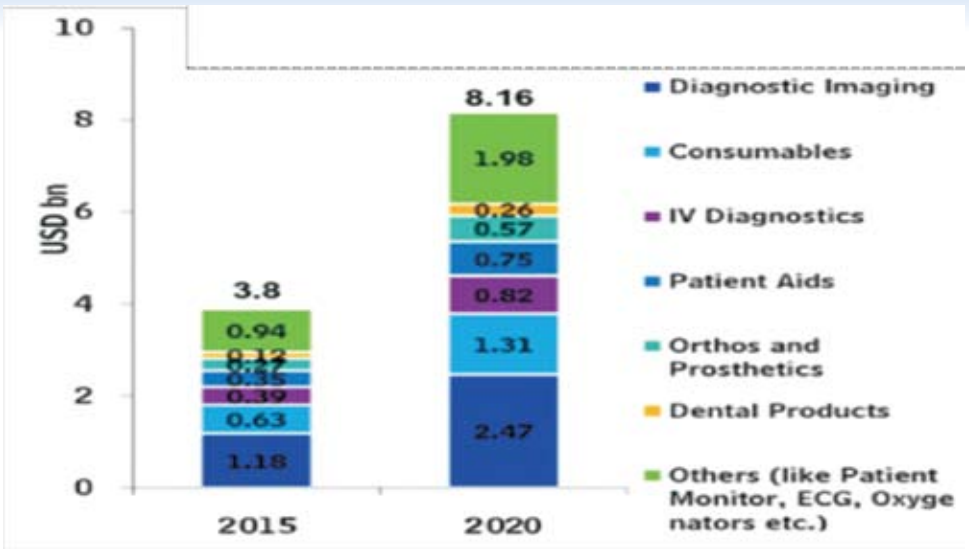


Figure: Growth Factors Driving the Medical Device Demand in India

The various factors driving the demand of medical device in India are as under:

(i) Growing Population

(ii) Ageing Population

(iii) Increasing Disease Burden of Chronic Diseases

(iv) Increasing Health Insurance Penetration

(v) Growing Medical Tourism

(vi) Demand for Healthcare Infrastructure

a. Emerging Healthcare Service Formats

b. Quality and Accreditation of Hospitals as par with International Standards.

3.5 Medical Device Rules, 2016

The mandate for regulation of Medical Device Industry from safety and standards point of view is with Ministry of Health & Family Welfare, which has notified Medical Devices Rules, 2017 on 31.01.2017. The new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and conform to best international practices. The new Rules seek to remove regulatory bottlenecks to make in India, facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety. The salient features of these Rules are:

i. Medical devices will, under the new Rules, be classified as per GHTF practice, based on associated risks, into Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk). The manufacturers of medical devices will be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.

ii. Through these Rules, a system of 'Third Party Conformity Assessment and Certification' through Notified Bodies is envisaged. The Notified Bodies will be accredited by the National Accreditation Board for Certification Bodies (NABCB). The NABCB will, before accrediting Notified Bodies, assess their competence in terms of required human resources and other requirements.

iii. The Rules also seek to evolve a culture of self-compliance by manufacturers of medical devices and, accordingly, the manufacturing licences for Class A medical devices will be granted without prior audit of manufacturing site. Manufacture of Class A and Class B medical devices will be licenced by State Licensing Authorities concerned after Quality Management System audit by an accredited Notified Body. For all manufacturing sites, Quality Management System will need to be aligned with ISO 13485. Manufacture of Class C and Class D medical devices will be regulated by the Central Licensing Authority and, where required, assistance of experts or notified bodies will be taken. Import of all medical devices will continue to be regulated by CDSCO.

iv. Separate provisions for regulation of Clinical Investigation (clinical trials) of investigational medical devices (i.e. new devices) have also been made at par with international practices and, like clinical trials, these will be regulated by CDSCO.

v. There will be no requirement of periodic renewal of licences. Accordingly, manufacturing and import licences will remain valid till these are suspended or cancelled or surrendered. Further, the entire process starting from submission of application to grant of permission/licence will be processed through online electronic platform. Timelines have been defined for most activities at the regulators end.

vi. These Rules envisage creation of a robust eco-system for all stakeholders including innovators, manufacturers, providers, consumers, buyers and regulators.

vii. The Rules will provide a conducive environment for fostering India specific innovation and improving accessibility and affordability of medical devices across the globe by leveraging comparative cost advantage of manufacturing in India. The objective, transparent and predictable regulatory framework will boost the confidence of investors and, as a consequence, the quality and range of products and services will improve and business burdens will be reduced.

3.6 Initiatives for Promotion of Medical Device Industry:

The vision of the Department of Pharmaceutical (DoP), Ministry of Chemicals & Fertilizers is to catalyze and encourage quality, productivity and innovation in Medical Device Sector and to enable the Indian Medical Device Industry to reduce the dependency on import of Medical Devices. For this, world class quality manufacturing facilities with high level of productivity with innovative capabilities are required. However, these are very capital intensive and cannot be established and opened by Medical Device Manufacturing Units on their own due to financial constraints.

3.6.1 Scheme for Financing Common Facility Centres (CFCs) at Medical Device Parks:

The Department has a proposal for scheme for "Development of Common Facilitation Centres for Medical Devices" in medical device parks under the Umbrella scheme for "Development of Pharmaceuticals Industry". This sub-scheme proposes for Financing Common Facility Centres (CFCs) at Medical Device Parks in the country at a total cost of Rs.250 crores. The manufacturing parks would include following facilities:

i. Component Testing centre,
ii. Electro-magnetic interference laboratory,
iii. Biomaterial/Biocompatibility testing centre,
iv. Medical grade low vacuum molding,
v. Cabinet molding, injection molding centres,
vi. 3 D designing and printing for medical grade products,
vii. Sterilization & Toxicity testing centre,
viii. Radiation testing centre,
ix. Warehousing,

x. Regulator's office,
xi. Other facilities commonly required in manufacturing of medical devices

Focus will be on creating an Eco System for High End Medical Device Manufacturing and Import Substitution with an eye for Export Market and states have selected separate verticals within medical devices segment suiting their regional capacities, availability of natural resources and expertise.

3.6.2. Corrections in the Inverted Duty Structure:

a. The customs department has raised import duty on 67 ITC Categories of Medical Devices from the current 5 per cent to 7.5 per cent to help companies manufacture these products in India itself.

b. Simultaneously, the exemption from special additional duty (SAD) on these medical devices has also been withdrawn, and they now attract 4 per cent SAD.

c. Further, to give fillip to domestic manufacturing, basic customs duty is being reduced from 7.5 per cent to 2.5 per cent along with full exemption from SAD on raw materials, parts and accessories for manufacture of medical devices falling under headings 9018 to 902230.

These changes will aid in removing the existing hurdles in domestic manufacturing of medical devices and encourage companies to produce these devices in India, rather than importing them.

3.6.3. Medical Device Promotion Council:

The Department is also considering a proposal for establishment of a Medical Device Promotion Council in co-operation with Andhra Pradesh MedTech Zone Ltd. (AMTZ) at Vishakhapatnam which will act as a facilitating and promotional body for domestic Medical Device Industry.

3.6.4. Preferential Market Access:

To promote domestic manufacturing of medical devices and to reduce the import dependency, the Department is considering a proposal for giving preference to domestic industry in purchase of medical devices by all government agencies.

3.6.5. Uniform Code For Medical Device Marketing Practices (UCMDMP):

Uniform Code for Pharmaceuticals Marketing Practices (UCPMP) for pharmaceutical as well as Medical Device Industry was announced to be implemented voluntarily for a period of six months w.e.f. 1.1.2015. This has further been extended up to 31.12.2015. In the meantime, the need for a separate code for Medical Device

Industry was felt and a draft Uniform Code for Medical Device Marketing Practices (UCMDMP) was prepared. Further, it was decided to consult UCMDMP with the stakeholders. Two meetings in this regard were held with the stakeholders for incorporating their suggestions and further course of action in the matter.

[Source: Para 1.1, 1.2, 1.3 & 2 (Medical Device Manufacturing in India: A Sunrise report by AMTZ)]

Chapter 4

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA.

CHAPTER 4
PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA.

Introduction:

The Jan Aushadhi Scheme was launched in the year 2008 with the aim of selling affordable generic medicines through dedicated sales outlets i.e. Jan Aushadhi Stores in various districts across the country. Some of the objectives of the scheme are as follows:-

- Ensure access to quality medicines
- Extend coverage of quality generic medicines so as to reduce and thereby redefine the unit cost of treatment per person
- Create awareness about generic medicines through education and publicity so that quality is not synonymous with only high price
- Be a public programme involving Government, PSUs, Private Sector, NGO, Societies, Co-operative Bodies and other Institutions
- Create demand for generic medicines by improving access to batter healthcare through low treatment cost and easy availability wherever needed in all therapeutic categories.

The first Jan Aushadhi Store was opened at Amritsar in Punjab in November 2008.

The original target of the campaign was to establish Jan Aushadhi Stores in every district of our country. Recently, “Pradhan Mantri Jan Aushadhi Yojana” (PMJAY) has been renamed as “Pradhan Mantri Bhartiya Janaushadhi Pariyojana” (PMBJP) and “Pradhan Mantri Jan Aushadhi Kendra” (PMJAK) as “Pradhan Mantri Bhartiya Janaushadhi Kendra” (PMBJK).

Bureau of Pharma PSUs of India (BPPI):

BPPI is an independent society set up by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers in December, 2008. BPPI’s mission “Is to make generic medicines available for all”. BPPI is responsible for proper monitoring and functioning of Pradhan Mantri Bhartiya Janaushadhi Kendras.

Progress during 12th Five-year Plan period:

As on end March 2012, only 112 Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) could be opened. To have an accelerated growth of the campaign, a New Business Plan was released during August 2013 with an ambitious target of opening 3000 PMBJK by the end of 2016-17. The plan also contained certain changes in the

scheme. Still by the end of previous financial year 2015-16, the number of PMBJK could reach a level of 269 functional PMBJK only.

Revamped Jan Aushadhi Scheme 2015:

Effective implementation of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) has been analyzed through organizing brain storming sessions and discussions with various stake holders and BPPI submitted their Strategic Action Plan (SAP 2015) to achieve the objectives set by the Government. Key areas of significance identified are Availability, Acceptability, Accessibility, Affordability, Awareness and Effective Implementation of the Scheme. Accordingly, a new Strategic Action Plan was prepared and the same was approved during September, 2015.

Major changes in Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) Action Plan:

BPPI have simplified the application format so that a common man can easily fill up the same. Besides above, the application fee of Rs. 2000/- which was charged earlier have been waived of to make the scheme popular.

Financial support to Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK):

An amount of Rs. 2.5 lakhs shall be extended to NGOs/agencies/individuals establishing PMBJK in government premises like hospitals/ medical colleges/Railways/Sate Transport/ Co-operation/ Municipalities/ Post offices etc. where space is provided free of cost by Government to operating agency:

Rs. 1 lakh reimbursement of furniture and fixtures

Rs. 1 lakh by way of free medicines in the beginning

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

PMBJK run by private entrepreneurs/pharmacists/NGOs/charitable organizations that are linked with BPPI headquarters through internet shall be extended an incentive up to Rs. 2.5 lakhs. This will be given @ 15% of monthly sales subject to a ceiling of Rs. 10,000/- per month up to a limit of Rs. 2.5 lakhs. In North Eastern States i.e. Naxal affected areas and Tribal areas, the rate of incentive will be 15% and subject to monthly ceiling of Rs. 15,000 and total limit of Rs. 2.5 lakhs. The Applicant belonging to weaker section like SC/ST/Differently-abled may be provided medicines worth Rs. 50,000/- in advance within the incentive of Rs. 2.5 lakhs which will be provided in the form of 15% of monthly sales subject to a ceiling of Rs. 10,000/- per month up to a total limit of Rs. 2.5 lakh.

Trade margin to retailers and distributors: Trade margins have been revised from 16% to 20% for Retailers and from 8% to 10% for Distributors.

Progress achieved during 2016-17 as on 16th February, 2016:

Availability:

Our basket of products and services is now augmented by adding more medicines reaching a level of 600+ medicines and 165 surgicals and consumables. Apart from procurement of medicines from CPSUs, BPPI is supplementing supply by direct purchase of medicines from private sector companies through open tendering process so as ensure availability of adequate medicines and to avoid any stock-out situation. BPPI has initiated the required action to take this figure to 1000 by the end of March 2017.

Supply Chain:

From Suppliers →CWH →C&F Agents →Distributors → JAK

BPPI has established a central warehouse at IDPL Complex, Gurugram to store adequate stock of medicines and also appointed C&F agents in 3 States and 40 Distributors spread over different states through an open tendering process. BPPI is going to appoint more C&F agents and distributors shortly considering the requirement to cover all the States/UTs.

Acceptability:

To ensure the quality of medicines procured from the CPSUs and private manufacturers for supplying to PMBJK, each batch of drugs is tested at BPPI's empaneled NABL accredited laboratories thereby ensuring quality, safety and efficacy of medicines and conformance with required standards. Only after being certified by these laboratories, medicines are dispatched to C&F agents, Distributors and PMBJKs.

Accessibility:

Number of PMBJK functioning as on 16.02.2017 has reached 794 (spread over 26 States/UTs), out of which 525 stores have been opened during the current financial year 2016-17.

By the end of this financial year, BPPI is putting all out efforts to have its presence in all the States in our country. BPPI strive to achieve the figure of 3000 PMBJK by the end of March 2017.

Awareness:

The awareness among common people regarding the PMBJK is poor. Media campaigns would play an important role in educating people about use of generic medicines. In this context, BPPI has initiated various steps, especially in those States where the PMBJK are now functioning so that people take full advantage of the

availability of generic medicines at affordable prices at the PMBJK. There are 794 PMBJK functional at present (as on 16.02.2017), few of which were established earlier. These PMBJKs need to be promoted in an organized way as the awareness is very less. Limited and non-availability of the medicines was another challenge. It is most important to create awareness among all stakeholders about the scheme, the business opportunity, the store locations and the medicines available with PMBJK.

BPPI intends to create awareness about PMBJP and its PMBJK in the towns where PMBJKs are already established using integrated media platform. Facelift of the PMBJK is required with standardized branding across all old stores as well as in the new PMBJK.

Various publicity channels like print media, visual media, SMS and other direct communication methods will be taken up. BPPI has already taken part in many exhibitions/workshops, seminars, etc.

BPPI participated in India Pharma, 2017 at Bangalore to contact many large scale manufacturers for PMJAY under one roof.

MoUs signed with Different State Governments for opening PMBJK:


Inauguration of Various PMBJK:


Youth education about PMBJP:

Other factors in ensuring success of the scheme:

The success of this initiative is dependent on other agencies too, such as Ministry of Health & Family Welfare, different State Governments, active co-operation of Hon. Members of Parliament, Hon. Members of different Legislative Assemblies, IMA, Hospitals run by Private Groups and Charitable Institutions, NGOs, Practicing Doctors, etc. State Governments are having their own schemes like free distribution of medicines. Non-prescription of Generic Medicines by the doctors is another critical factor. BPPI is continuing its efforts to persuade Doctors to prescribe only generic medicines. For this BPPI is working in close association with other Organizations and Government Departments. Seminars/Workshops inviting Doctors, Scientists, Government Officials and other Stakeholders will be also organized.

Budgeted Sales:

In the financial year 2015-16, BPPI has done Rs. 11.25 Crores sale and in the current financial year 2016-17, the projected sales shall be more than Rs. 20.00 Crores.

Jan Aushadhi scheme ahead:

The endeavor of BPPI is to make available at PMBJK all the commonly used generic drugs covering all the therapeutic groups. In the coming years, PMBJP shall provide the complete spectrum of Health care products and services, starting from making available all the generic drugs covering all the therapeutic groups.

In order to attract the citizen to get engaged with the PMBJP, paper advertisements were released inviting them to open PMBJK. In order to attract ST/SC and specially disabled citizens, the Government support scheme has been modified to give medicines worth Rs. 50,000/- in advance within the support of Rs. 2.50 lakhs to start the store.

Chapter 5

NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPERs)

CHAPTER - 5
NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPERs)

5.1 Background

Indian Pharma Industry has been a global leader in Generic drugs. In order to acquire leadership position in drug discovery and development and to continue to excel in the formulations, Government has recognized that human resources/talent pool is very critical. A National Institute of Pharmaceutical Education & Research (NIPER) was set up at Mohali, Punjab 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 it was declared as an Institute of National Importance.

During 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institutes. Subsequently, NIPER at Madurai was approved in 2012. During 2015-16, the Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh, Maharashtra and Rajasthan. The details are as under:

NIPER	Mentor Institute	Academic Session Started
Mohali	-	1992
Ahmedabad	-	2007
Guwahati	Guwahati Medical College, Guwahati	2008
Hajipur	Rajendra Memorial Research Institute of Medical Science (RMRIMS-Patna) under ICMR	2007
Hyderabad	CSIR-Indian Institute of Chemical Technology, Hyderabad	2007
Kolkata	CSIR-Indian Institute of Chemical Biology, Kolkata	2007
Raebareli	CSIR-Central Drug Research Institute, Lucknow	2008
Madurai	Under Process	-
Chhattisgarh	Under Process	-
Maharashtra	Under Process	-
Rajasthan	Under Process	-

Objectives of NIPERs:

1. to nurture and promote quality and excellence in pharmaceutical education and research;
2. to concentrate on courses leading to master's degree, doctoral and post-doctoral courses and research in pharmaceutical education;
3. to hold examinations and grant degrees;

4. to confer honorary awards or other distinctions;
5. 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;
6. to conduct courses for teachers, pharmaceutical technologies, community and hospital pharmacists and other professionals;
7. 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;
8. to create a central faculty of pharmaceutical instrumentation and analysis for use by the researches within and outside the Institute;
9. to have a centre to experiment and innovate and to train teachers and other workers in the art or science or pharmaceutical teaching;
10. 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;
11. 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;
12. to organise national or international symposia, seminars and conferences in selected areas of pharmaceutical education, from time to time;
13. to arrange courses catering to the special needs of the developing countries;
14. 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
15. 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.

5.2 Admission Procedure:

The students at all NIPERs are admitted through Joint Entrance Examination. The admission procedure followed for various courses offered by each NIPER in the country is as follows:

In the month of April every year advertisement is floated for Masters and PhD programme. Accordingly, applications are invited on the basis of eligibility.

Masters'- B Pharm + GPAT qualified
PhD-MS (Pharm)/M Pharm/M Tech (Pharm)/M Sc. + GATE/GPAT/NET qualified Applications are sorted on the basis of eligibility.
Eligible candidates appear for Joint Entrance Exam Scheduled on second Sunday of June every year.
Result of passed candidates floated on net.
Basis of final selection:
Written + Counseling is held for Masters candidates.
Written + GD/Interview/Counseling is held for MBA
Written + Interview + Counseling is held for PhD candidates.

Reservation policy of Govt. of India is fully followed in admitting the students to various courses.

Academia Industry Linkage:

Department has identified that Academia-Industry linkage is a basic requirement for translating research into development (commercialization) and Innovation; and also to fix accountability among Educational Institutions. Accordingly, the issue has been pursued with NIPERs and Public and Private Pharma Industry with regular reviews and visits. NIPERs have signed MoUs with Private Pharma Industry and CPSE as under:

NIPER	Private Pharma Industry
Hyderabad	1. Dr. Reddy Labs
	2. Bharat Biotech
	3. NATCO
Ahmedabad	4. Cadila Pharmaceuticals
	5. Cadila Healthcare (Zydus)
	6. Sahjanand Technologies
	7. Johnson & Johnson
Mohali	8. Sun Pharma
	9. Wockahardt
	10. Panacea Biotech
	11. Medley Pharmaceuticals Ltd.
	12. Dow Chemical International Pvt. Ltd.
	13. Tirupati Medicare Ltd.
	14. Kwality Pharmaceuticals Ltd.
	15. Celeste Life Sciences Pvt. Ltd.

With Central Public Sector Enterprises

NIPER	CPSEs
Mohali	16. Rajasthan Drugs and Pharmaceuticals Ltd., Jaipur.
Ahmedabad	17. Hindustan Anti-biotics Limited, Pune.
Guwahati	18. i) NATCO Pharma ii)Karnataka Antibiotics & Pharmaceuticals Limited, Bengaluru.
Hajipur	19. Bengal Chemicals and Pharmaceuticals Limited, Kolkata
Kolkata	20. Bengal Chemicals and Pharmaceuticals Limited, Kolkata
Rae Bareli	21. Indian Drugs & Pharmaceuticals Limited Rishikesh/Gurgaon/ Hyderabad.

5.3 NIPER, MOHALI

NIPER Mohali 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 Mohali has a campus that caters for research facilities for ten different fields, three boys hostels and a girls hostel, one married hostel unit, 133 quarters for the NIPER staff.

NIPER Mohali comes from different parts of the country. In year 2016 students belongs to approx. 22 different states and 2 UT. Most of the students belongs to Middle and low income group. NIPER, Mohali has an own residential campus. Board of Governors has been constituted to oversee its functioning.

1. **Achievements**:

In 2016, the Institute has published 51 articles in journals of repute (till Sept. 2016). NIPER has filed 12 patents in 2015 and 1 patent has been granted till date this year. Since the inception of academic programme (till Sept. 2016), 2692 students have passed out (Masters 1960, MBA 487 & Ph.D. 245).

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, neuro degeneration 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.

D. Other areas

i. Chemo-enzymatic synthesis of drugs

ii. Monograph on herbals is being developed.

iii. Study of the effect of RNA aptamers on stabilization of misfolded proteins

iv. Assessment of an appropriate and reliable method to diagnose neuropathic pain

3. Academic and Non-Academic staff:-

Man-Power	Sanctioned	In Position	Vacancies
Academic	61+1* = 62	30	31+1* = 32
Non-Academic	217+6**=223	127	90+6**=96

*indicates post of Director **indicates posts created by BoG

4. Total funds allocated during the last 4 years:

(Rs. in crores)

Year		Allocation BE	Allocation RE	Total Release
2012-13	Plan	24.00	0.00	0.00
	Non-Plan	27.55	22.82	22.82
2013-14	Plan	12.00	0.00	0.00
	Non-Plan	23.57	19.20	19.20
2014-15	Plan	20.00	17.03	0.00
	Non-Plan	00.05	20.87	20.87
2015-16	Plan	20.00	9.79	9.79
	Non-Plan	27.48	27.48	27.48
2016-17	Plan	00.01	0.00	0.00
	Non-Plan	27.48	27.48	27.48

5. Students:

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

Level Masters/ Doctorate	Degree MS/MBA/ M.Tech/Ph.D	Discipline	No. of students admitted	
			2015-16	2016-17
Masters'	M.S.(Pharm.)	Medicinal Chemistry	43	43
Doctoral	PhD		02	05
Masters'	M.S.(Pharm.)	Pharmacoinformatics	19	19
Doctoral	PhD		01	01

Masters'	M.S.(Pharm.)	Natural Products	16	16
Doctoral	PhD		03	01
Masters'	M.S.(Pharm.)	Traditional Medicine	05	05
Masters'	M.S.(Pharm.)	Pharmaceutical Analysis	09	09
Doctoral	PhD		02	00
Masters'	M.S.(Pharm.)	Pharmacology & Toxicology	23	23
Doctoral	PhD		04	06
Masters'	M.S.(Pharm.)	Regulatory Toxicology	09	10
Masters'	M.Tech.(Pharm.)	Pharmaceutical Technology (Formulations)	07	07
Doctoral	PhD		00	00
Masters'	M.Tech.(Pharm.)	Pharmaceutical Technology (Process Chemistry)	14	16
Doctoral	PhD		00	00
Masters'	M.Tech.(Pharm.)	Pharmaceutical Technology (Biotechnology)	10	10
Doctoral	PhD		00	00
Masters'	M.S.(Pharm.)	Pharmaceutics	17	17
Doctoral	PhD		06	06
Masters'	M.S.(Pharm.)	Biotechnology	29	31
Doctoral	PhD		05	02
Masters'	M.Pharm.	Pharmacy Practice	08	07
Doctoral	PhD		02	01
Masters'	M.Pharm.	Clinical Research	07	08
Masters'	MBA (Pharm.)	Pharmaceutical Management	45	38

6. Teacher-Student ratio:-

Course	Ratio
Ph.D.	1:3
Masters' (Science)	1:14
MBA (Pharm.)	1:27*

* Guest faculty members are also taking classes

7. Placement:

The status of last 2 years placements status: in campus/off campus is as under:

Batch	Total Number of Students Placed	Campus Placement	Went for Higher Studies	Off Campus Placement
2013-15	143	92	11	40
2014-16	142	142	N.A.	N.A.

N.A. Data not available

8. Innovation / knowledge transfer:

i. Patents and Commercialisation: 179 (filed)/38 (granted)/07 (licensed)
ii. Research income earned from industry: Rs.1.65 crores (receipts in 2016-17 till date)
iii. Citation per faculty: 798 (2016 till date)

9. Institution leadership

i. Recognized as among the top 100 Indian Innovator companies and research organizations (2014) (Thompson Reuters)

ii. Recognized as one of the four institutes in the country with AAAA+ ranking by Career360 magazine (Outlook group) (March 2014)

iii. Awarded Thomson Reuters Innovation Award 2011

iv. Astra Zeneca endowment fund set up (Rs. 60 lakh)

v. Bristol-Myer-Squibbs has funded one student each for PhD and Masters' programme since 2008

vi. Eli Lilly and Merck have granted funds for carrying out research work

vii. Chosen as one of the destinations (apart from USA and UK) by Government of Kazakhstan for award of *Bolashak* scholarship to its nationals to pursue research programme in pharmaceutical sciences

viii. Received state and national awards for efforts to promote Rajbhasha

10. Impact of NIPER

The success of NIPER, Mohali has encouraged the GoI to set up more NIPERs across the country to meet the growing demands of the pharmaceutical sector. In addition, NIPER has carried out training programmes for personnel from India and abroad under ITEC-SCAAAP, capacity building programmes (World Bank-sponsored) and SMPIC. Participated in re-building of public sector enterprises like IDPL, BCPL, HAL, etc.

Training and analytical services provided to small and medium-scale enterprises (SMEs): Setting up of a centre for SMEs Member of committee evaluating 'Investigational New Drugs' (IND) applications Member of committee revising Indian pharmacopeia Contribution of monographs to Ayurvedic pharmacopeia of India Carried out study on "Impact of TRIPS on pharmaceutical prices with special focus on generics in India", under the work plan of WHO biennium and MHFW (GOI)

Events/ workshops carried out by the institute:-

February 14-16, 2016	Industry Academia Meet
February 22-24, 2016	International Symposium on Integrated Drug Development: Chemistry, Manufacturing and Control (CMC)
March 28, 2016	Seminar on 'Applications of Dissolution Techniques in Pharmaceutical Formulations' (SMPIC)

5.4 NIPER Ahmedabad

NIPER Ahmedabad started functioning in 2007-08 under Mentor Institute B.V. Patel PERD Centre (up to 31 July 2016). Since then it is functioning at its own campus in temporary building. In absence of Board of Governors, Steering Committee under the Chairmanship of Secretary (Pharma) looks after administrative work of NIPER Ahmedabad. Dr. Kiran Kalia is its Director from 16.11.2014.

1. Achievements:

316 M.S Pharm. students have graduated from NIPER Ahmedabad and well placed in various Pharma industries in India and abroad. NIPER Ahmedabad has started Chapter with Foreign Universities like John Hopkins and Harvard University USA. More than 70 papers have been published in various reputed Journals. 10 Patents have been filed where faculty or student of NIPER Ahmedabad was one of the inventors. Out of this 3 patents have been filed from Feb 2016 till date.

2. Details of faculty & staff :

i. Regular Faculty: 01 (Director)
ii. Contractual Faculty: 14
iii. Contractual Admin and technical staff: 10

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

(Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2013-14	20	6.94	6.79
2014-15	20	4.5	4.5
2015-16	21.96	19.76	19.76
2016-17	21.96	19.48	19.48

Name of the Department/Disciplines

Number and Names Departments/ Disciplines (with opening year)

Sr No	Department	Year of opening
01	Biotechnology	2007
02	Natural Products	
03	Pharmaceutics	
04	Medicinal Chemistry	2010
05	Pharmaceutical analysis	
06	Pharmacology& Toxicology	
07	Medical Devices	2012

4. Students

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

MS/MBA/M.Tech/Ph.D	Discipline	No. of students admitted	
		2015-16	2016-17
MS	7 Disciplines	56	74
Ph. D	NIL	9	9

5. Teacher-Student ratio : 1: 10 (14 Faculty : 140 students)

6. Employability/ Placements Status:-

List of companies participated in the year 2016	Placement
Torrent pharmaceuticals Ahmedabad, Cadila Pharmaceuticals Ltd Ahmedabad, Zydus Healthcare Ltd Ahmedabad, INTAS Pharmaceuticals Ahmedabad, Piramal Healthcare Ltd Ahmedabad, Sun Pharmaceuticals Ltd Vadodara, Sahjanand Laser Technologies ltd Gandhinagar, Lupin Pharmaceuticals Pune	100%

7. Recognition to Faculty:

As an initiative to establish international collaboration NIPER Ahmedabad has started theme based research collaboration with faculties of Harvard Medical School and MIT, USA. The present focus area of collaboration is Neurodegenerative diseases. The faculties of NIPER Ahmedabad are in collaboration with following foreign universities:

8. Peer review system:

NIPER Mohali carried out peer review of NIPER Ahmedabad from 5-6 May 2016.

9. Research:

The Institute conducted research in Diabetes, Cancer, Neurodegenerative Disease, Infectious diseases, Tissue repair, regeneration and Medical Implants.

10. Awards:

Gandhiyan Young Technological Innovation (GYTI) awarded at Rashtrapati Bhawan.

11. Patents and Commercialisation: 03 Patent has been filed. onwards.

Impact of NIPER :

NIPER Ahmedabad is being regarded as one of the best centres of Pharmaceutical Education which is evident from the Participation of top ranking Pharma Companies in placement activity and 100% placement of students. At the time of admission counselling NIPER Ahmedabad is among the top choices of the students.

Various events carried out by the institute.

5.5 NIPER Guwahati

NIPER Guwahati started functioning in 2008 under Mentor Institute Guwahati Medical College Guwahati, Assam. In absence of Board of Governors, Steering Committee under the Chairmanship of Secretary (Pharma) look after administrative work in NIPER Guwahati. Dr. USN Murthy is Director of the Institute from 3.11.2016 onwards.

1. Achievements:-

(a) Ph.Ds– 21 (enrolled), Degrees awarded – 07, Thesis submitted-01
(b) Total M.S. (Pharm.) (since inception)- Students enrolled – 285
Graduated - 222 (61 students are currently pursuing their P.G. courses)
(c) Among the graduated students, many of them got admission into Ph.D. programs in various National & International Universities/Institutes. Rest of the students got placed in various Pharmaceutical Industries and Consultancies viz., Novartis, Novo Nordisk, Biocon, Quintilles, etc.
(d) Publications: In total, 85 research papers have been published in various National and International Journals.

2. Details of faculty & staff:-

Director	: 01
Academic Staff: Assistant Professors	: 03
Lecturer	: 01
System Engineer & Faculty (Application of Computers)	: 01
DST Women Scientist	: 01
Guest Faculties	: 15
Non-Academic Staff	: 21

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

(Rs. in crores)

Year	Allocation BE	Allocation RE	Total Release
2013-14	18.8	3	2.88
2014-15	21	4	3.91
2015-16	21	21	21
2016-17	19.50	19.50	19.50

4. Students:-

i) Degrees/programmes offered and Subjects offered (with year)

Masters/ Doctoral	MS/MBA/ M.Tech/Ph.D.	Discipline		
			2015-16	**2016-17**
Masters	MS (Pharm)	Pharmacology and Toxicology	18	20

Masters	MS (Pharm)	Biotechnology	5	7
Masters	M. Pharm.	Pharmacy Practice	3	8
Doctoral	Ph.D.	Pharmacology and Toxicology	2	2
Doctoral	Ph.D.	Biotechnology	1	2
Doctoral	Ph.D.	Pharmacy Practice	1	1

5. Teacher-Student ratio: 1:5

6. Employability/ Placements Status

In the academic session 2015-16, 9 students got admission into Ph.D programmes in reputed national institutes like NISER; NIPER-Mohali; NIPER-Hajipur; IIT-Guwahati; NIPER-Guwahati and INST, Mohali. Another 11 students have been recruited by different companies like Novartis; Novo Nordisk; Shree Dhootapapeswar Ayurvedic Research Foundation (SDARF); Glocal School of Pharmacy, Glocal University, Saharanpur; Global Data Research Center, Hyderabad; Quintiles etc. through on/off campus placement. Two students have been selected for BCIL internship program.

7. Recognition to Faculty

Dr. Ranadeep Gogoi, Assistant Professor, Department of Biotechnology, NIPER-Guwahati participated in the In-Residence Programme for Inspired Teachers held from 23rd – 29th April, 2016 at Rashtrapati Bhavan, New Delhi.

8. Peer review system

NIPER Ahmedabad visited from 26th-28th April 2016 to analyse the progress of NIPER-Guwahati on several aspects and have given a good review which has been uploaded on the Institute's website.

9. Research

The Institute conducted research in Biotechnology, Cancer, Pharmacology & Toxicology, Pharmacy Practice, Pharmacovigilance and Haemovigilance. Ph.D. students currently enrolled: 13 (07 Pharmacology & Toxicology, 04 Biotechnology & 02 Pharmacy Practice)

10. Patents and Commercialization:

The institute is currently in the process of submitting one patent application in the area of Biopharmaceuticals. It will be further explored for its commercial value.

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 is further moving ahead in the field of Biopharmaceuticals and is the only NIPER to have a Synthetic Biology Laboratory, which is listed among the Indian Synthetic Biology labs.

12. Various events carried out by the institute:-

Animal House Eperiments

5.6 NIPER Hajipur

NIPER Hajipur started functioning in 2007 under Mentor Institute Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna. In absence of Board of Governors, Steering Committee under the Chairmanship of Secretary (Pharma) look after administrative work in NIPER Hajipur. Dr. Pradeep Das is the Project Director from 2007 till date.

1. **Achievements:**-

The Institute has awarded 263 students their Master's degree since its inception.

2. **Details of faculty & staff are appended below**:-

Academic : 9 (on contract)

Non-Academic : 10 (on contract)

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

(Rs. in crores)

Year	BE	RE	Total Release
2013 – 14	3.70	3.50	3.50
2014 - 15	4.00	4.00	4.00
2015-16	6.00	6.00	6.00
2016-17	6.00	5.00	5.00

4. Students:-

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

MS/MBA/ M.Tech/Ph.D	Discipline	No. of students admitted	
		2015-16	2016-17
M S Pharm	Biotechnology	04	10
M S Pharm	Pharmacoinformatics	08	13
M Pharm	Pharmacy Practice	13	11
PhD	Biotechnology	03	03
PhD	Pharmacoinformatics	01	01
PhD	Pharmacy Practice	02	02

5. Teacher-Student ratio 1:10

6. Employability/ Placements Status:

Most of the students passed out from the Institute have got their jobs at suitable places.

7. Teachers:

i. Recognition to Faculty: Faculty of the Institute has been invited for delivering lectures at different National level conferences. They have been invited as examiners in examinations and viva at Universities/Institutes.

ii. Peer review system: Performance of the faculty is being evaluated by renowned scientists of the country on annual basis. The annual contract of employment of the faculty is renewed on that basis.

8. Research:

The Institute conducted research in the fields of Biotechnology, Pharmacoinformatics, Pharmacy Practice, Cancer, HIV, Leishmaniasis and tRNA modification and their role in protein synthesis.

9. **Impact of NIPER**:

NIPER Hajipur has successfully produced 263 students in three disciplines namely, Biotechnology, Pharmacoinformatics and Pharmacy Practice who are either employed in different pharmaceutical industries or pursuing their higher education in different institutes or universities across the globe. Many of the ex-students are engaged as faculty at different institutions.

5.7 NIPER Hyderabad

NIPER Hyderabad started functioning in 2007 under Mentor Institute Indian Institute of Chemical Technology (IICT), Hyderabad. In absence of Board of Governors, Steering Committee under the Chairmanship of Secretary (Pharma) looks after administrative work in NIPER, Hyderabad. Dr. S. Chandrasekhar, Director CSIR – IICT is the Project Director from 3rd Nov, 2016 till date.

1. Achievements:-

Master Students Passed Out	: 598
Students pursuing Ph.D course	: 71
Doctoral degree awarded	: 10
Patents (filed)	: 07
Research Publications	: >300
Sanctioned extramural research projects	: 18

Total allocation by the Government during the last 4 years:-

(Rs. in crores)

Year	BE	RE	Total Release
2013-14	25.00	23.00	23.00
2014-15	22.00	14.00	14.17
2015-16	35.00	35.00	35.00
2016-17	35.00	35.00	35.00

2. Teacher-Student ratio

Faculty: Student ratio is 1:12

3. Employability/ Placements Status:-

Various reputed Companies like Novartis, Biocon, Dr Reddy's, GVK, Mylan, AstraZeneca, Shasun, Lupin, Aurobindo Biological E etc.participated in campus selection/placement. The status of percentage of last few years placements status of in campus students is as follows:

Year	2011	2012	2013	2014	2015	2016
In campus Placements (%)	91	88	85	82	82	80

4. Teachers

The Institute has some of the talented and dedicated faculty who come from the best institutions around the world. Associate fellow of AP Academy of Sciences were conferred to seven faculty of Institute for their outstanding contributions in scientific research.

Peer review system: 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.

5. Research

Active research areas: Focus areas: cancer, diabetes, anti-infective

- ✓ Design and synthesis of new chemical entities
- ✓ Development of screening assays
- ✓ Development of process & scale up technologies
- ✓ Novel drug delivery systems viz., nano-technology in drug delivery
- ✓ Development of new bio-analytical methods
- ✓ Drug metabolism and pharmacokinetic studies

Awards:-

a) Angelika Bierhaus Award 2016: by NEURODIAB (Diabetic Neuropathy study group of EASD) – 2016
b) Associate Fellows of Telangana Academy of Sciences by Telangana Academy of Sciences
c) R.V. Patil PharmaInnova Best Research Guide Award in Pharmacology category

6. Innovation / knowledge transfer

(i) Patents and commercialization- 7 patents filed
(ii) Research income earned from Industry- 33 Lakhs
(iii) Citation per faculty- Average 440 citations per faculty

7. Impact of NIPER:

Creating excellent human resources by imparting high quality education and training in pharmaceutical sciences which would help the pharmaceutical industry. Serving as an excellent research institute by focusing on thrust areas of national and international relevance. Fostering academic and industrial collaborations to address some of the key issues in the pharma sector.

Various events/ Workshops carried out by the institute:-

Date	Activity name	Target group
9th July 2016	Workshop on "Emerging Trends In Pharmaceutical Sciences"	Academia
12th & 13th August 2016	Quality Management in Bulk Drug and Formulation Manufacturing" @ NIPER Hyderabad	Academia & Industry

5.8 NIPER-Kolkata

NIPER, Kolkata is presently housed at the Indian Institute of Chemical Biology (IICB) – a premier Institute of the Council of Scientific & Industrial Research (CSIR), India, which is the Mentor Institute. In absence of Board of Governors, Steering Committee under the Chairmanship of Secretary (Pharma) looks after the administrative work of the institute. Dr. V. Ravichandiran, Director is the Director of the Institute since 6.7.2015.

1. Achievements till date:

Since inception, till date 325 students have been graduated. Among them, 220 are engaged in companies and academic institutions. Out of the seven batches, 66 students are carrying out Ph.D. in institutes including 12 in abroad and out of them 12 have been awarded the degrees.

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

(Rs. in crores)

.	Allocation BE	Allocation RE	Total Release
2013-14	04.50	04.50	04.40
2014-15	05.00	04.38	04.38
2015-16	08.00	08.00	06.30
2016-17	08.00	08.00	08.00

3. Teacher-Student ratio : 1:11

Students are satisfied with the mode of teaching and project work carried out by them.

4. Employability/Placements Status:

(i) Year wise Companies participated in campus selection/placements: Since inception, number of Pharma Companies came to NIPER-Kolkata to recruit students.

(ii) Placements status: in campus/off campus: 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 centres for teaching and higher studies.

Placement status during last two years		
M.S. (Pharm.)		
Year (Batch)	**Total No. of students**	**No. of students placed**
2013-2015 (7th)	49	20
2014-2016 (8th)	42	29

5. **Peer Review System**: Conducted from 28th to 29th April, 2016.

6. **Research:**

   a. **Active Research Areas**: Synthetic and plant based drug discovery, immunology and immune diagnostics, cellular and molecular biology, recombinant DNA technology and monoclonal antibody technology, novel drug delivery systems, chemical and biochemical process technology, etc.

   b. **Research Publications/Institution and per Faculty and High Impact factor**: 35 Nos. Research papers have been published in renowned international journals from the project work of the MS (Pharm.) students.

7. **Awards**:

   i. Certificate of Achievement Gold Award awarded to Dr V. Ravichandiran, Director, NIPER-Kolkata at UNIVERSITI TEKNOLOGI PETRONAS (UTP).

   ii. Certificate of Best Research Award also given to Dr V. Ravichandiran, Director at UNIVERSITI TEKNOLOGI PETRONAS (UTP)

8. **Patents and Commercialisation:** Nil

9. **Impact of NIPER:**

   i. A total of 325 students have graduated.

   ii. 220 students are engaged to work in companies/institutions.

   iii. 35 Research papers have been published.

10. **Various events/workshops organized by the institute:-**

Date	Activity name	Target group
28th May,2016	Meeting of Scientific Advisory Committee (SAC)	Institutional
20th June,2016	NIPER-Kolkata and Industrial Partners Meet	For all students & staff

21st June,2016	Observance of International Day of Yoga	For all students & staff
21st June,2016	Seminar on • Pharmaceutical Research Program & Infrastructure at University of Rhode Island. • Nutraceuticals from Natural Products	For all students & staff
25th July to 5th August,2016	National Skill Development and Hands-on Training on Quality Control of Biologicals" for Pharmacy Post Graduate Students of NIPER, Kolkata	For all students
29th – 30th July, 2016	National Workshop on TU&PP	For all students & staff
18th August, 2016	Rare Disease Course Launch Program	For all students

5.9 NIPER- RAIBARELI

NIPER Raebareli stated functioning in 2007-08 under Mentor Institute Central Drug Research Institute (CDRI), Lucknow, NIPER, Raebareli. In absence of Board of Governors Steering Committee under the Chairmanship of Secretary (Pharma) look after administrative work in NIPER Raebareli. Dr. Swaran Jeet Singh Flora is Director from 1st Nov, 2016 to till date.

1. **Achievements:-** Total 222 passed out since inception of the Institute.
2. **Academic/Non-Academic staff:-**

Position	**In Position (Sanctioned)**	**Vacancy**
Director	01	00

***Manpower – Academic**			
	In Position Faculty	**Vacancy**	**Total**
Total	**07**	**01**	**08**

***Manpower – Non-Academic**			
Department	**Position**	**In Position**	**Vacancy**
Total		**18**	**03**

*The Institute recruits teachers/staff on yearly contractual basis

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

(Rs. in crore)

Year	Allocation BE	Allocation RE	Total Release
2013-14	4.50	4.70	4.50
2014-15	15.00	4.45	4.45
2015-16	7.00	5.50	5.50
2016-17	7.00	6.25	6.25

4. Students:-

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

M.S. (Pharm.)	No of Students Admitted	
	2015-16	2016-17
Medicinal Chemistry	17	16
Pharmaceutics	13	13
Pharmacology & Toxicology	06	06

Total No. of M.S. (Pharm.) Students Admitted & Passed out in NIPER, Raebareli Till Date

Sl. No.	Batch	M.S. (Pharm.) Discipline No. of Students Admitted			Total No. of Students			
		Med. Chem.	Pharma-ceutics	P&T	Admit-ted	Drop-ped	Passed Out	Failed
1	2008-10	10	10	-	20	-	20	-
2	2009-11	14	14	-	28	-	28	-
3	2010-12	15	15	-	30	-	30	-
4	2011-13	16	15	-	31	-	31	-
5	2012-14	16	16	7	39	02	37	-
6	2013-15	18	15	6	39	-	38	01
7	2014-16	19	13	6	39	01	38	-
8	2015-17	19	14	6	39	03	Pursuing	-
9.	2016-17	16	14	6	36	01	Pursuing	-
	Total	**143**	**126**	**31**	**300**	**07**	**222**	**01**

5. Teacher-Student ratio - 1:10

6. Employability/ Placements Status:-

Placement Status during last two years are as under:-

Batch	Year	Total of Students	No. of Students Placed
6th	2013-15	39	15
7th	2014-16	38	16

7. Teachers:-

1. Recognition to Faculty = NA
2. Peer review system – Performance of teachers is being evaluated by taking feedback from the students.

8. Research

Research Publications

Year	Total of Publications
2010-11	02
2011-12	02
2012-13	04
2013-14	09
2014-15	08
2015-16	04

9. Impact of NIPER

- Creating excellent human resource by imparting high quality education in pharmaceutical sciences.
- Serving as an excellent research institute by focusing on thrust areas of national and international relevance.

10. Various events/workshops carried out by the institute:-

Date	18th-19th March, 2016
Activity Name	8th NIPER (RBL) – CSIR-CDRI Symposium

3rd Convocation of 5th & 6th Batch Students held on 11th December, 2015

8th NIPER (RBL)-CSIR-CDRI Symposium organized on 18th – 19th March, 2016

Dr. S.J.S. Flora, Director, NIPER-Raebareli with Staff and Students

Chapter 6

PUBLIC SECTOR UNDERTAKINGS

6.1 Central Public Sector Undertakings

6.2 Cabinet Decision on Pharma PSU

6.3 Indian Drugs & Pharmaceuticals Ltd. (IDPL)

6.4 Hindustan Antibiotics Ltd. (HAL)

6.5 Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL)

6.6 Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)

6.7 Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)

CHAPTER–6
PUBLIC SECTOR UNDERTAKINGS

6.1 Central Public Sector Enterprises (CPSEs)

There are five Central Public Sector Enterprises (CPSEs) under the administrative control of the Department of Pharmaceuticals. Of the five PSUs, three viz. Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and referred to Board for Industrial & Financial Reconstruction (BIFR). Rajasthan Drugs & Pharmaceuticals Limited (RDPL) has also reported losses for since the year 2013-14. Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) is the only profit making CPSE.

(As on 2015-16)

	HAL	IDPL	RDPL	BCPL	KAPL
Established in	1954	1961	1978	1980 Nationalized	1981
Classification	Sick	Sick	Incipient Sick	Sick	Profit making
Net worth (in cr.)	-488.10	- 7147.23	-24.65	-184.60	127.81
Turnover (in cr.)	15.12	84.22	36.53	88.19	326.90
Operating profit/loss(in cr.)	-52.43	11.33	-13.50	13.33	33.97
Liabilities (in cr.)	1250	10779.20	121.05	230.55	9.06
Referred to BIFR	1997	1992	No	1992	NA
No. of employees	2000 (in 1997)	11000 (in 1992)	191 (in 2013)	1467 (in 1992)	
Employees as on date	1010	42	152	332	712
Officer level	250	7	52	70	239
Worker level	760	35	100	262	473
VRS earlier given	2007- 485 employees	1992 - 4000 2003 - 6000	NIL	2006 - 2016 180 employees	2015 2 employees
Total land	267 acre	2003 acre	9.35 acre	72.89 acre	37.34 acre
Leasehold	Nil	1022 acre	9.35 acre	1.10 acre	Nil
Freehold	267 acre	981 acre	Nil	71.79 acre	37.34acre

Initiatives taken to improve the performance of CPSEs during 2016-17 are as follows:

1. Performance Management – Regular review of performance of CPSEs – Performance review meetings of all CPSEs was held.
2. Pharma Park Development – The matter of Pharma Park in IDPL, Hyderabad/IDPL, Rishikesh/IDPL, Chennai is under consideration of Government of India.
3. Status of WHO-GMP in RDPL – The Company has embarked upon expansion, modernization and upgradation programme (Phase II) to quality for WHO-GMP certification to become eligible for exploring International Markets as well as for participating in the Internationally Funded Projects of Government of India and other Government.
4. InBCPL – Ointment & Betalactam Block and Panihati Project have been completed while Cephalosporin Block is under commissioning. Besides this, OSD Project & ASVS Project are being commissioned

6.2 Cabinet decisions on Pharma PSUs

A rehabilitation proposal for the sale of part of surplus and vacant land of Hindustan Antibiotics Limited (HAL) for meeting its mounting liabilities was considered by the Cabinet on 27.04.2016. While considering the proposal, the Cabinet had directed that the following Ministers may comprehensively examine the status of all Pharmaceutical Companies in the public sector and suggest the future course of action:

(i) Minister of Finance; Minister of Corporate Affairs; and Minister of Information and Broadcasting;
(ii) Minister of Road Transport and Highways; and Minister of Shipping and
(iii) Minister of Chemicals and Fertilizers.

The Ministers comprehensively examined the status of all Pharmaceutical Companies in the public sector in their meetings on 19.05.2016, 19.12.2016 and 20.12.2016 and noted that all PSUs except KAPL are sick or incipient sick. IDPL, BCPL and HAL were declared sick and formally referred to BIFR since 1992, 1993 and 1997 respectively. The earlier revival/rehabilitation packages of IDPL, HAL & BCPL have failed to achieve desired results. The production activities in RDPL too have stopped after fire in the plant in October, 2016. HAL and RDPL are not in a position to even pay the salaries to their employees. All these companies possess substantial land assets.
After detailed deliberations, the Ministers recommended as under:

i. Only that much of surplus land of HAL, IDPL, RDPL and 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 Department to close IDPL and RDPL and HAL and 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.

Cabinet in its meeting held on 28.12.2016 approved the recommendations of the Ministers' as mentioned above.

6.3 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 Registered Office of the Company is located at IDPL Complex, Dundahera, Gurgaon and its Head Office at SCOPE Complex, Lodhi Road, New Delhi. The main objectives of the company were to create self-sufficiency in respect of essential life saving medicines, to free the country from dependence on imports and to provide medicines to the millions at affordable prices. IDPL was basically conceived and established as a part of Healthcare Infrastructure and has played a pioneering infrastructural role in the growth of Indian Drugs Industry base.

IDPL has three main Plants at Rishikesh (Uttarakhand), Gurgaon (Haryana), Hyderabad (Telangana) and two 100% wholly owned subsidiaries, namely, IDPL (Tamil Nadu) Ltd. Chennai (Tamil Nadu) and Bihar Drugs & Organic Chemicals Ltd. (BDOCL) at Muzaffarpur (Bihar). In addition, IDPL has one Joint Venture, promoted in collaboration with Industrial Promotion & Investment Corporation of Orissa Limited (IPICOL) the State Government of Odisha, namely Odisha Drugs & Chemicals Ltd. (ODCL) Bhubaneswar.

Past Achievements :

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 did reasonably well on this account despite the fact that it was the first integrated and monolithic venture in the Public Sector engaged in production of low margin products. IDPL earned Profit before Depreciation, Interest & Tax (PBDIT) from 1965 to1968 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. Today, it can fulfil other needs to meet gaps in Public Health by supplying essential life saving drugs.

Ointment Manufacturing Unit

FBD & RMG

Reasons of sickness:

The IDPL continued to function on the basis of its old model of sixties which lost its relevance to a great extent by eighties. In the circumstances, the net worth of the IDPL became negative in 1982-83. The main causes were -

(i) large monolith-type integrated production facilities (typical model followed in 1950s-1960s) producing chemicals, Bulk Drugs and Formulations;

(ii) Out dated Plant & Machinery and obsolete technology for Bulk Drugs (but for formulations not outdated)

(iii) Excess manpower (13283 in 1983-84), high Wages/Salary bill and maintenance of huge Township, Schools and Hospitals in all locations of IDPL.

(iv) Frequent changes at top level Management (average tenure of Chairman & Managing Director was 18 months)

(v) Medicines manufactured by IDPL were under Drugs Price Control Order (DPCO) by the Government prior to liberalization in 1991.

(vi) Shift in Government policy resulting in shifting of the canalization agency from IDPL to State Trading Corporation (STC).

(vii) Intense competition from private Pharmaceuticals Sector Companies which did not have to bear burden of social infrastructure of setting up and maintaining Townships, Schools, Hospitals etc. and had learner production facilities. Due to shortage of Working Capital Production has been stopped in October 1996 at Rishikesh, Hyderabad & Muzaffarpur Plant.

Revival status since 1.4.1994

The Board for Industrial & Financial Reconstruction (BIFR) declared IDPL as a sick industrial Company on 12th August. 1992. On 10.2.1994 BIFR approved the Rehabilitation Scheme under Section 17(2) of SICA for its implementation w.e.f. 1.4.1994. The package sanctioned by BIFR in 1994 failed primarily because (i) full funds were not released to the Company as envisaged (ii) capital restructuring was not done (iii) banks did not provide adequate working capital requirements (iv) working capital were diverted to meet fixed expenses of subsidiary units. (v) Land could not be sold (vi) sales targets were fixed at very ambitious levels. On 23.1.1996, 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.

After failure to privatize IDPL, BIFR ordered its winding–up on 4.12.2003. Govt. filed an appeal before Appellate Authority for Industrial Financial Reconstruction (AAIFR) on 10.2.2004 against BIFR order. AAIFR admitted the appeal filed by the Government on 2.8.2005 and directed that a Road Map for revival of IDPL be submitted. Ministry/ Department constituted an Expert Committee under the Chairmanship of Director NIPER and Technical Audit of the Plants & Machineries carried out by the Committee. The Committee found the Plant & Machineries for production of formulations in a reasonably good shape which could be optimally utilized with minimal investment for compliance of Scheme-M requirements. It was also opined that the emerging position of IDPL in the present market scenario was to be conceptualized. IDBI supported the recommendations of the Expert Committee. Having regard to these developments, AAIFR in its hearing held on 13.9.2005 set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for Rehabilitation of IDPL and to pass further orders in accordance with Law.

The Draft Rehabilitation Scheme (DRS) was prepared by IDPL in consultation with ICRA Management and submitted to the BRPSE for consideration and recommendation. After approval of the BRPSE, 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). 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. In view of the observations made by GoM, IDPL appointed a leading consultant Company E&Y to carry out the feasibility study. E&Y report was submitted to the Ministry/DoP.

A revised DRS again prepared in consultation with IDBI (OA) taking cut off date as 31st March, 2011. In the BIFR meeting held on 20.8.2014 cut off date was approved as 31.3.2014. Accordingly, the revised updated DRS was prepared taking cut off date 31.3.2014 and submitted to the DoP/ Ministry in January 2015. the Cabinet in its meeting held on 28.12.2016 recommended for closure of IDPL on 9th January, 2017after meeting its liabilities by selling the surplus land.

IDPL 100% WHOLLY OWNED SUBSIDIARIES

IDPL (Tamil Nadu), Chennai.

IDPL (Tamilnadu) Chennai was incorporated in September, 1965. Initially, it was a Surgical Instruments Plant and later diverted for Formulations Plant. In terms of revival package approved by BIFR in 1994 the Plant was converted into a 100% wholly owned subsidiary in the name and style of IDPL (Tamilnadu) Limited, Chennai with effect from 1.4.1994. IDPL (Tamilnadu) is a Schedule-M compliant Plant and engaged in manufacture about 20-25 pharmaceuticals formulations. The production achieved for the F.Y. 2015-16 was Rs. 10.28 crores.

Dissolution Apparatus-Quality Control

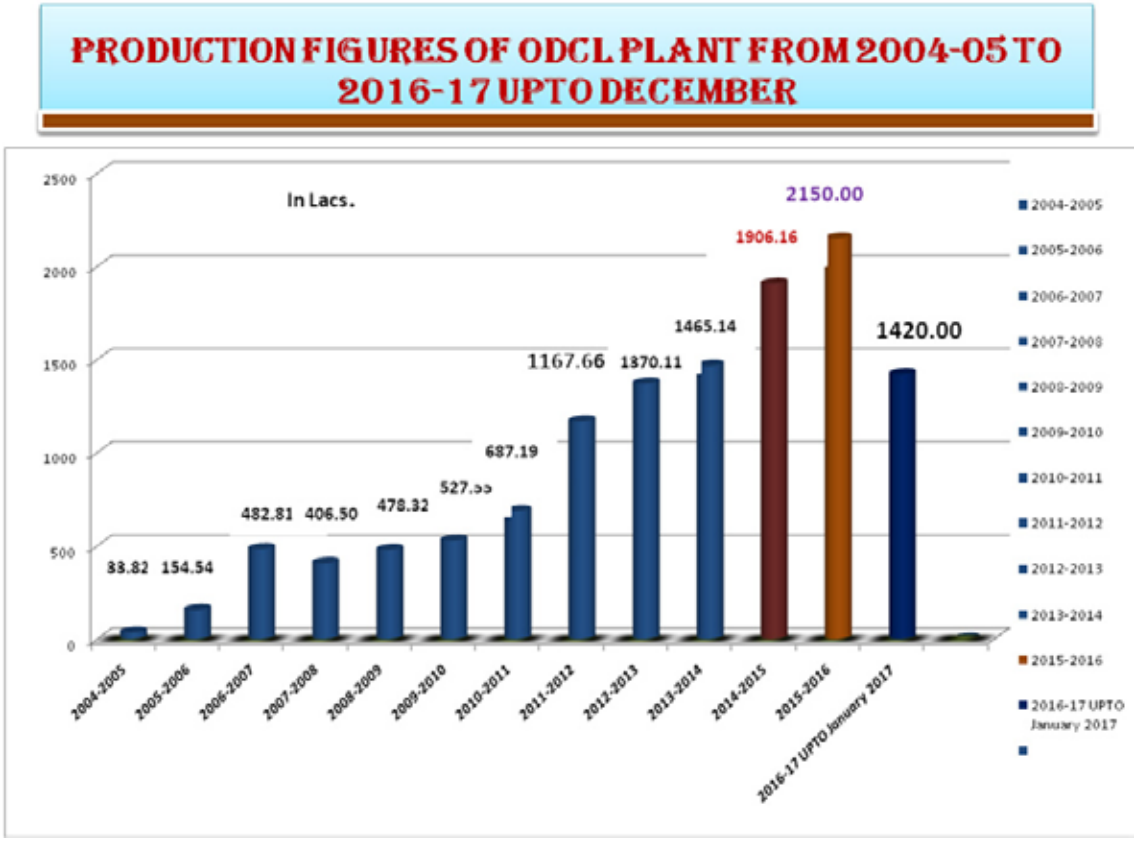
Wet Lab-I Quality control

Bihar Drugs & Organic Chemicals Ltd. (BDOCL, Muzaffarpur

Bihar Drugs & Organic Chemicals Ltd., Muzaffarpur was incorporated in 1979, converted into 100% wholly owned subsidiary w.e.f. 1.4.1994. At present there is no production activity in BDOCL since November, 1996.

Orissa Drugs and Chemicals Ltd (ODCL) (Joint Venture) of IDPL and Government of Odisha;

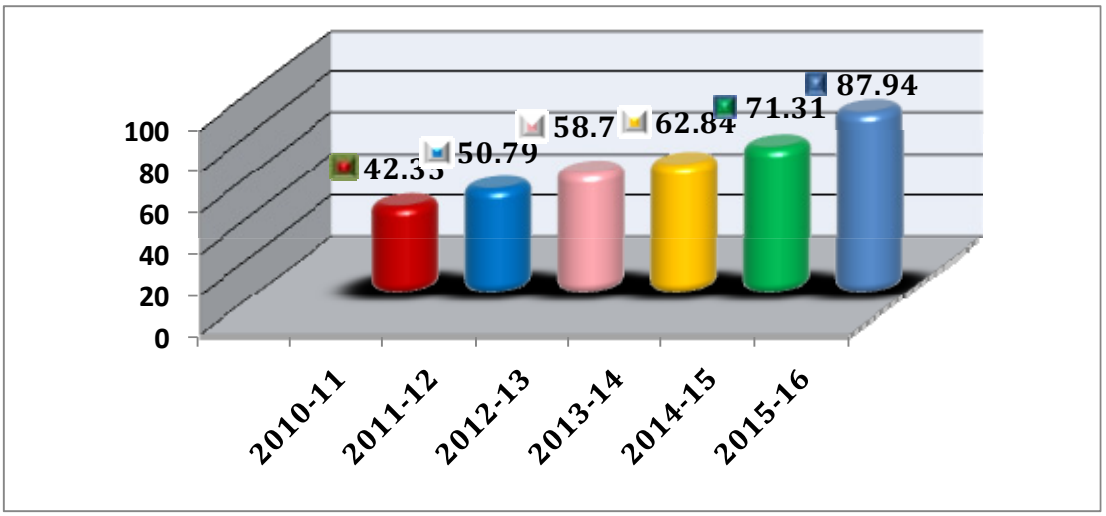
Orissa Drugs & Chemicals Limited (ODCL) was incorporated in 1979 and commissioned for production from September, 1983. ODCL is a Joint Venture promoted by Indian Drugs & Pharmaceuticals Ltd. (IDPL) holds 51% of the equity shares and Industrial Promotion & Investment Corporation of Orissa (IPICOL) hold equity shares of 49%. 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. ODCL presently is manufacturing formulations in the form of Tablets, Capsules, Powder, ORS and Injectables etc. ODCL Plant is Schedule-M compliant and production for the F.Y. 2015-16 was Rs.21.50 crores which was the highest ever achieved and operational profit Rs. 145.50 lakhs .



IDPL TODAY - Presently IDPL is engaged in manufacturing about 130 formulations. **I**n-house production of formulation during the year 2015-16 was Rs**.** 87.94 crores and sales Rs. 86.41 crores.

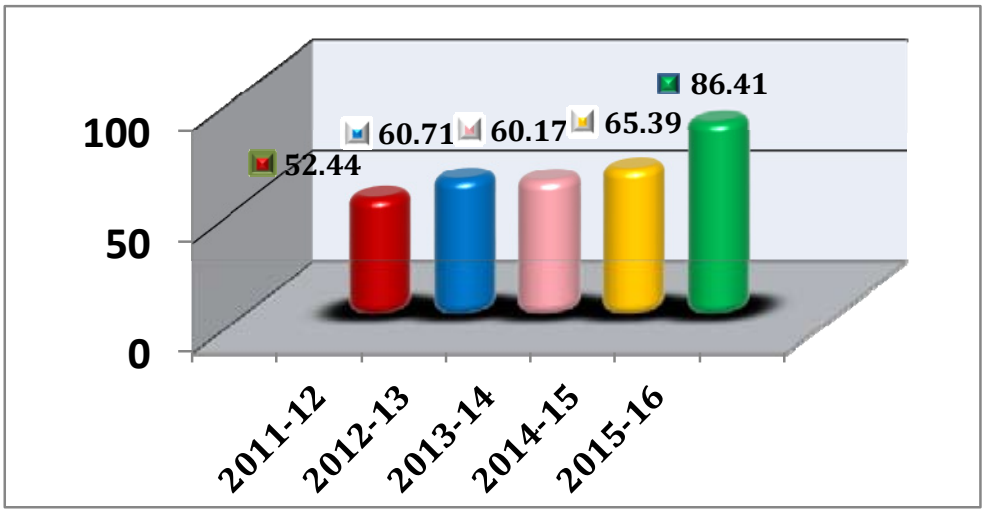
Production & Sales Performance:

Govt. had sanctioned fund for modernizing/ schedule -M compliance of Rishikesh, Gurgaon, IDPL(TN) Chennai and ODCL, Bhubaneswar Plants. Govt. of also release fund of Rs 15.00 Cr for making Hyderabad Plant in operational. This plant is almost ready and can be utilized for production of many life saving drugs namely HIV, TB drugs etc. This is going to be WHO GMP compliant unit which will help it to enter export markets also. The production achieved after 2011-12 to 2015-16 is as under: Last year IDPL achieved record in-house production of Rs 88 crores (approx.)



Sales :

Sales performance shows a continuous growth in the company. The supplies are being made in time. The delivery period of supply is 30-40 days, but many a times IDPL has supplied the medicines even before the delivery date and customers are appreciating this.



Modernization of Plants with the assistances of Government of India

The Up-gradation and Modernization of IDPL Plants are in progress. It is expected to complete the modernization work of its Plant at Gurgaon and and Rishikesh very soon. Rishikesh Plant is Schedule 'M' compliant and is WHO-GMP compliant and received COPP for 4 products. Whereas Gurgaon Plant is also Schedule-M for Tablet Section. IDPL will re-start its Hyderabad Formulation Unit during the current F.Y. 2016-17.

Product profile and Range:

Presently, IDPL is manufacturing nearly 90 (PPP) products and 25-30 (Non-PPP) products in the form of Capsules, Tablets, Dry Syrup, Liquid Oral and Injection, based on mainly following therapeutic groups: Antibacterial/Anti-infective, Analgestic /Anti-inflammatory, Gastrointestinal, Respiratory Tract, Contraceptive, Vitamins/ Mineral, Anti allergic, Anti-fungal , Anti-malarial, Anti diabetic Cardiovascular.

New Products launched – Cefexime 100 mg, & 200 mg., Cefuroxime, Axetil 250mg & 500mg., Aceclofenac 100mg, Aceclofenac 100mg. + Paracetamol 500mg, Glimpride 1mg & 2mg, Atorvastatin 10mg, & 20mg., Ciporal 250mg & 500mg, Metformin 500mg, Pentoprazole 40mg.

Popular Brands: Deacos syrup, Sukcee Tab, Cebxin-Z are the popular brands of IDPL.

Marketing: Share of Institutions and retail: Company is only supplying to Institutional and Govt Departments who place orders on PPP. As per PPP Govt Institutions can buy 103 medicines from 5 CPSU at NPPA certified prices. Major Institutional of IDPL are ESIC, Ministry of Health & Family Welfare, Defence, Railways, State Governments/ Corporations and Public Sector Enterprises Hospitals who place orders under different categories of Therapeutic Medicines. Apart from above the IDPL is fully supporting Pradhan Mantri Jan Aushadhi Pariyojana Programme of Govt of India

Distribution network if any; Company is selling its products to Institutions through distribution networks of 19 Depots (C&F) located all over the country.

Manpower

Company has 45 regular employees and 136 on contract as on 31.12.2016 including 100% wholly owned Subsidiaries. The company has not been permitted to go for regular appointment. Company hired contractual manpower in statutory and critical positions only to look after the day-to-day affairs of Production, Sales and other essentially activities only.

IDPL has also played a major role in the strategic National Health Programmes like Family Welfare Programme & Population Control (Mala-D & Mala-N) anti-malarials (Chloroquine) and prevention of dehydration (ORS) by providing quality medicines. IDPL has encouraged indigenous production and intervention for price control in market by

manufacturing Generic Grugs. IDPL has been supporting Government in meeting emergent situations arising due to National calamities like Cyclone, Flood, and Earthquake etc. Last year in Odisha, Uttrakhand and J&K floods. IDPL contributed significantly by providing lifesaving medicines on time.

6.4 Hindustan Antibiotics Ltd. (HAL)

Hindustan Antibiotics Ltd. (HAL), a wholly owned Central Public Sector Undertaking under the administrative control of the Departments was incorporated in 1954. The registered office and manufacturing facilities of the company are located at Pimpri, Pune, Maharashtra. The Company was set up for manufacturing of bulk drugs and lifesaving drugs and formulations. Over the years several new products were added / undertaken for manufacturing like those used in agriculture and veterinary medicines. The authorized share capital of the Company is Rs.100 crores. As on 31st March, 2016, the subscribed and paid-up share capital is Rs.71.71 crores.

Production and sales:

(Rs. in Crores)

	2013-14	**2014-15**	**2015-16 (Prov.)***
Production	27.66	17.28	14.45
Sales Turnover	30.11	18.54	15.12
Net Profit(Loss)	(84.23)	(70.55)	(74.68)

*Provisional

HAL is passing through critical financial crisis due to shortage of working capital required for running its operations. Salaries of the employees and many of the statutory payments like Provident Fund, Gratuity, Income tax, Sales Tax etc. are also outstanding. The working capital facilities are also not forthcoming from the Banks as the Company's account has become NPA. The Company is incurring losses since 1992 and was declared sick in 1997. Rehabilitation plan of 2006 for Rs. 137.59 crore (Rs. 80.63 crore budgetary support and interest free loan Rs. 56.96 crore) did not succeed.

Second rehabilitation proposal for infusion of Rs. 670.46 crores was proposed. However, the Cabinet approved selling of its surplus and vacant land to Government/PSUs/Autonomous Bodies to meet its liabilities. The Government also approved waiver of Rs. 307.23 crore of Central Government loans and deferment of liabilities amounting to Rs. 128.68 crores and sanctioned immediate loan of Rs. 100 crores for meeting salaries, wages and critical expenses. It has been further decided to strategically sell the Company after meeting its liabilities, effecting VRS/VSS and cleansing the balance sheet.

PRODUCTION:

The total value of production during the year 2015-16 is Rs.14.45 crores as compared to Rs.17.28 crores during the previous year.

In addition to Cephalosporin and Penicillin powder injectable, Tablets, Capsules, Agriculture product (Streptocycline) and Narcotic Detection Kit contributed to the production. Capacity utilization and the production of various products were affected due to non-availability of bulk and packing material as per the plan due to working capital shortage. In the total production of Rs. 14.45 crores, single product Streptocycline contributed Rs.10.95 crore (75.76% of total Production) against Rs. 9.57 crores in the previous year. Narcotic detection kit production value was 0.78 crores (5.4% of total production).

Since new high speed Form-Fill-Seal Machine for Streptocycline pouch was commissioned in Nov'15, capacity of Streptocycline pouch production is enhanced to 180 lacs pouch/annum from 72 lacs pouch / annum.

SALES:

During the year, the Company achieved sales turnover of Rs.1.51 crores compared to Rs.18.54 crores during the previous year. Marketing Dept. have successfully achieved following activities during 2015-16

a) Manufactured and supplied various range of formulations to BPPI under Jan Aushadhi worth of Rs. 100 lacs.

b) Successfully developed and supplied skin de-contamination kits and Prussian Blue Tablets to Institute of Nuclear Medicine and Allied Sciences (INMAS), Defense Establishment.

c) Supplied Narcotic Kits to Narcotic Control Bureau worth of Rs. 75 lacs.

Subsidiaries:

Maharashtra Antibiotics & Pharmaceuticals Ltd. (MAPL) has been ordered for winding up by BIFR and the said order has been confirmed by AAIFR. The winding up order has been stayed by the Hon'ble High Court at Bombay, Nagpur Bench on the Writ Petition filed by the Group of Employees of MAPL. As per the order of the Hon'ble High Court at Bombay, Nagpur Bench, the Voluntary Separation Scheme (VSS) in MAPL has been implemented and all the employees have been relieved under the VSS with the help of the funds released by the Govt. of India. Additionally, the Govt. of India has also released non-plan loan amounting to Rs.8.5 crores for payment of outstanding dues of

the employees of MAPL through the Company and the amount has been disbursed to the employees of MAPL.

The operations of Manipur State Drugs & Pharmaceuticals Ltd. (MSDPL) have been closed as per the decision made by its Board of Directors and necessary compensation on closure of MSDPL has been paid to the employees of MSDPL through the funds released by the Govt. of Manipur.

6.5 Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL)

Karnataka Antibiotics and Pharmaceuticals Ltd. is a profit making joint sector Company incorporated in the year 1981 [with 59% shares by Government of India and 41% shares by Government of Karnataka through Karnataka Antibiotics and Pharmaceuticals Ltd.]. The basic objective of the company was to make available life-saving drugs of good quality to Karnataka Government hospitals and other institutions along with Private Medical Practitioners. The Company has WHO-GMP Certified Manufacturing facilities for Dry Powder Injectable, Liquid Injectable, Tablets, Capsules, Dry Syrups and Suspensions. The paid – up share capital of the company as on date is Rs. 13.49 crores.

Production and Sales performance:

(Rs. In crores)

Years	Production	Sales
2013-2014	275.73	241.59
2014-2015	281.81	274.24
2015-2016	342.01	326.92
2016-2017 (Upto Sept`2016)	178.78	177.02

Past achievements:

- Mini Ratna – II CPSE
- ISO 9001 (QMS) and ISO 14001 (EMS)
- PIC/S Certification

Pharma – Trade

No	Products	Therapy Segments	NLEM	Monopoly	Market Value
1	Grenil Group	Anti-migraine	No	No	Rs. 12.00 Crores
2	Cyfolac Group	Pre & Probiotics	No	No	Rs. 4.00 Crores
3	Remcc Group	Cough & Cold	No	No	Rs. 3.00 Crores
4	Zinfe Group	Haematinic	No	No	Rs. 2.00 Crores
5	Verclav Group	Antibiotic	Yes	No	Rs. 2.00 Crores

Agrovet:

Sl. No.	Name of the Product	Therapy Segments	Monopoly	Market Value
01	K Cycline Powder (Agro)	Insecticides	No	5.00 Crores
02	Kalvimin Group	Feed Supplement	No	2.50 Crores
03	K-Live	Hepato-Protective	No	2.00 Crores

Distribution network:

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. The Domestic operations spans throughout the country manned by a highly dedicated Professional Field Force and backed by a well-knit Channel of Distribution ensuring Karnataka Antibiotics and Pharmaceuticals Ltd.'s presence at the Metro as well as Micro Markets.

Karnataka Antibiotics and Pharmaceuticals Ltd. has its Branches located in all the State Head Quarters. The Company also has an excellent Distribution Network at almost 20 Branches at Major Cities catering to the respective State areas through Channel Marketing. The supplies are made effective through approved Stockists to Retailers, Nursing Homes & 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 the Customers, where many of the MNCs and Private Pharma Players have a major share. The Company is also dependent on PPP Policy for Institutional Business, where the concentration is on Govt. Hospitals, State Govt Hospitals, Corporates, PSU Hospitals, Defence & Insurance. It has potential to expand in Trade Segment & also to increase volumes by focusing on CPSE Hospitals and large Corporate Hospitals.

AGROVET:

The Company is focusing on Agro dealers and Department of Agriculture / Horticulture for Agro Products. Products are being focused on Veterinary Practitioners,

Farmers, Animal Husbandry Departments of all States and Milk Unions for Veterinary Products and Feed Supplements.,

NEW PRODUCTS:

Sl. No.	Products	Therapeutic Category
1	Numol SP	NSAID with Proteolytic Agent
2	Pop-e	Platelet Boosting Agent
3	Uterine Tonic	Removal of retained Placenta and for faster involution of Uterus in Farm Animals
4	Bloat Remedy Liquid	Herbal for bloat, flatulence and colic in Farm Animals

FUTURE PLANS:

The Cephalosporin Project has started production from December 2016.

6.6 Bengal Chemicals & Pharmaceuticals Ltd.(BCPL)

Bengal Chemicals and Pharmaceuticals Limited (BCPL), erstwhile Bengal Chemical and Pharmaceutical Works Limited (BCPW) were set up in 1901 by Acharya Prafulla Chandra Roy, a renowned scientist and academician. Government of India nationalised BCPW in 1980 under the name Bengal Chemicals & Pharmaceuticals Limited (BCPL) in 1981.

The Company is Headquartered in Kolkata, BCPL is engaged in the business of industrial chemicals (Alum), branded and unbranded generic pharmaceuticals, hair oil and disinfectants such as phenol, naphthalene balls, bleaching powder, toilet cleaners and floor cleaners. At present, the Company has four factories; at Maniktala and Panihati in West Bengal, Mumbai and Kanpur.

Maniktala Unit: This unit primarily produces Division II products which include branded as well as unbranded generic pharmaceuticals. The Company has commissioned and started commercial operation of its Tablet, Capsule and Ointment sections of Maniktala factory at Kolkata. The Injectable section is under commissioning and Company will be able to commercialize the operation of Injectable Section in this financial year itself.

Panihati Unit: Panihati unit, located near Kolkata, primarily produces Division I (Alum) and Division III products which include Pheneol, Naphthalene Balls, and other disinfectants. Commercial production in most of the renovated production-blocks such as Alum, Pheneol, Napthalene and White Tiger have commenced

Mumbai Unit: Mumbai unit produces Hair Oil under the brand name ‘Cantharidine’. The commercial space developed has been leased out to third parties for generation of

additional sources of income. Commercial space of the order of 43,206 sq. ft. has presently been leased out by the company

Kanpur Unit: Kanpur Unit, set up in 1949, primarily produces Division II products which includes tablets and capsules and small quantity of Hair Oil.

Popular brands:

Pheneol – Lamp brand, White Tiger, Naphthalene, Cantharidine Hair Oil. The Company was referred to BIFR in 1992. The revival package of Rs 490.60 Cr, approved by the Government in 2006, comprised of restructuring of exiting 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 continued to run in losses. However, the financial performance is improving from 2014-15 onwards. For the half year ended on 30th September, 2016, Company not only reported PBDIT of Rs.10.97 Crore but also reported a Net Profit of Rs.1.16 Crore which is first time in the last 63 years history of the Company.

Plant Machinery and capacity:

SL No	PRODUCTS	UNIT	INSTALLED CAPACITY Per Annum For 2016-17	PRODUCTION For (2015-16)	PRODUCTION For Ist Half (2016-17)
1	ALUM	MT	8000.00	4081.92	2520.00
3	TABLETS	CR	15.00	11.63	4.61
4	CAPSULES	CR	15.00	7.19	2.28
5	OINTMENTS	MT	60.00	37.01	20.07
6	HAIR OIL	KL	600.00	151.80	60.00
7	PHENEOL	KL	3000.00	1588.90	960.00
8	NAPTHALENE	MT	450.00	123.44	72.29
9	DISINFECTANTS	KL	1200.00	729.97	287.0

Modernisation of Plants(Government assistance projects and status)

(Rs. in Cr.)

Projects	Investments	Status
Ointment & Common items –Maniktala	29.92	Completed
Betalactam Block-Maniktala	33.53	Completed
Cephalosporin Block- Maniktala (Now Non-Betalactum Block)	31.34	To be completed

Panihati Project	27.95	Completed
OSD project at Kanpur	34.44	To be completed
ASVS - Maniktala	2.90	Stopped for want of fund
Pre-operative expenses	17.07	-
Total	**177.15**	

Distribution network if any:

The company has a strong distribution network pan India with 10 Depots and 11 C&F Agencies.

Performance:

Details of Production, Turnover and Financial Performance are as under:

(Rs. in Crores)

Particulars	2013-14	2014-15	2015-16	2016-17 (Half-year ended on 30 Sept. 2016)
Production	19.70	64.10	106.70	49.27
Turnover	17.06	45.84	88.19	40.44
Total Income	36.63	65.53	112.76	51.37
Gross Margin(PBDIT)	(20.36)	1.65	11.24	10.97
Interest Expenses (Finance cost)	12.85	15.36	16.42	7.66
Depreciation	2.15	3.95	3.61	3.34
Net Profit(Loss)	1.16	(9.13)	(17.32)	(36.55)

DPE's rating:

Year	MOU Assessment	Corporate Governance
2014-15	"Good"	"Fair"
2015-16	"Excellent"	"Excellent"

Future projects:

ASVS Project: The Company is planning to start ASVS Project as the product is not available in the country at the moment in required quantity as both the Government sector units namely BCPL and Central Research Institute (CRI), Kasuali, have stopped production of ASVS for the last 10 years. Due to non-availability of fund and also due to project cost escalation the project could not be commissioned. The total project cost for ASVS block as on date is Rs 31.00 Cr.

MoU Targets for 2016-17:

Rs. in Cr.

Production	110.00
Turnover	90.00

Management of Bengal Chemical with Shri Jitendra Trivedi, Director, Department of Pharmaceuticals, Government of India, during Annual General Meeting held on 24th October, 2016

Seminar held on 03/11/2016 on "Public Participation in promoting integrity and eradicating corruption"

6.7 Rajasthan Drugs & Pharmaceuticals Ltd. (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% 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 Company is engaged in production of Tablets, Capsules, Liquid Orals, ORS Powder & Ophthalmic medicines in a Schedule 'M' compliant facility. The company has a well-equipped laboratory with modern equipment like HPLC, FTIR, etc., for ensuring high quality parameters. The company is also working towards obtaining ISO 9001:2008 & WHO-GMP certifications. The Company has enhanced its manufacturing capacities by installing new machines and at the same time the workers have also acquired skills and expertise for attaining high productivity.

The Company is engaged in manufacture and selling of medicines of high quality at reasonable rates to the Govt. of Rajasthan, Central Government Institutions, viz ESIC, Defence, Railways, other PSUs and also to other State Govt. Institutions. RDPL is a partner in the novel and noble endeavor of Govt. of India in the implementation of 'JAN AUSHADHI' programme where quality generic medicines are made available to the public at large in the country at affordable prices.

Production and Sales performance:

Rs. in crore

Years	Production	Sales
2013-2014	54.93	43.51
2014-2015	25.04	24.90
2015-2016	39.78	36.53
2016-2017 (Upto Oct`2016)	3.77	6.97

Product Profile:

The Company has been dealing in following products:

- Anti-Biotic
- Anti-Malarial
- Antacids
- Analgesic, Anti-Pyretics & Anti-Inflammatory
- Anti-Emetics
- Anti-Spasmodics
- Anti-Diarrhoeal / Anti-Amoebic
- Cough Expectorants
- Anti-Allergic
- Anti-Bacterials
- Anti-Fungal
- Vitamins & Minerals
- Opthalmic Preparations
- Oral Rehydration Salt (ORS)
- Anti Retro Viral
- Anti Hypertension

Future Projects:

The Company has embarked upon expansion, modernization & up-gradation programme (Phase II) to qualify for WHO-cGMP certification to become eligible for exploring International Markets as well as for participating in the Internationally Funded Projects of GOI and other Governments. Due to fire at its plant in October, 2016, the production activities have stalled.

Chapter 7

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

CHAPTER – 7
NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

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

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

3. Salient features of DPCO, 2013.

- The National List of Essential Medicines (NLEM), notified by the Ministry of Health & Family Welfare is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of DPCO, 2013 which constitutes the list of scheduled medicines for the purpose of price control.
- Ceiling prices of scheduled formulations are fixed based on 'market based data'.
- Price control is applied to specific formulations with reference to the medicine (active pharmaceutical ingredient), route of administration, dosage form / strength as specified in the First Schedule.
- The National List of Essential Medicines 2015 (NLEM 2015) was notified by the Ministry of Health and Family Welfare in December 2015. NLEM 2015 was thereafter notified as the First Schedule of DPCO 2013, in March 2016, by the Department of Pharmaceuticals.

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.

5. Price Fixation:

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 local taxes.

NLEM 2015 contains 929 scheduled drug formulations spread across 30 therapeutic groups, which effectively comes to 814 scheduled drug formulations if we net those appearing in more than one therapeutic group and formulations in different pack sizes. 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 540 formulations under DPCO, 2013 as on 15th Nov 2016. For remaining formulations, NPPA is in the process of fixation of ceiling prices.

The status of fixation of ceiling prices under DPCO, 2013 (revised Schedule-I based on NLEM 2015) is given as under:

Pricing status of scheduled formulations as on 15th November 2016

Particulars	NLEM 2015 (New)	NLEM 2015 (Common)	Total	NLEM Explanation I to Schedule-I	Grand Total
1	2	3	4 (2+3)	5	6 (4+5)
A. Entries in the Schedule	380	434	814		814
A1 Additional count for the packsizes/material		39	39		39
B. Ceiling Prices Notified/approved	254	244	498	42	540

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.

% reduction with respect to Maximum Price	No. of formulations
0<= 5%	129
5<=10%	74
10<=15%	67

15<=20%	68
20<=25%	61
25<=30%	42
30<=35%	33
35<=40%	18
Above 40%	48
Total formulations	540

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 (antidiabetic and cardiovascular under para 19 of DPCO 2013 in July, 2014.

The fixation of ceiling prices of scheduled formulations listed in NLEM 2015 (revised Schedule-I) has enabled savings of Rs. 2345.50 crore to the consumers. Fixation of ceiling prices of scheduled formulations under original Schedule-I enabled savings of 2422.24 crore to the consumers. The para 19 price notifications resulted in savings of approximately Rs. 350 crore to the consumers. Regulation of prices of medicines under DPCO 2013 by NPPA has thus resulted in net savings of approximately Rs. 5203.29 crores to the consumers (as on 14.01.2017).

NPPA has also notified 407 retail prices of 'new drugs' [those qualifying as 'new drugs' as per para 2/u) of DPCO, 2013] on request of the manufacturers till 15th November 2016.

6. Monitoring and Enforcement:

Non-compliance with the notified ceiling price in case of scheduled drug formulations or, in other words, the MRP breaching ceiling price plus applicable local taxes tantamounts to overcharging the consumer. Such overcharged amounts are recovered from the pharmaceutical company along with interest thereon from the date of overcharging. The overcharging amount thus collected is deposited in the Consolidated Fund of India. 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. Further, non-compliance of price notification issued by NPPA, depending upon the gravity of the offence, could also attract prosecution under the Essential Commodities Act (ECA), 1955.

Para 20 of DPCO, 2013 stipulates that manufacturer can increase the maximum retail price of a non-scheduled formulation not more than ten percent of maximum retail price of the preceding twelve months.

The notified ceiling price with respect to scheduled formulations is subject to annual revision as per the annual Wholesale Price Index (WPI) for the preceding calendar year notified by the Department of Industrial Policy and Promotion (DIPP). The ceiling prices, thus revised on the basis of WPI are notified by NPPA, to be effective from the first day of April of the succeeding year. The WPI for the year 2015 was notified as (-) 2.7105% by the DIPP. The ceiling prices of 530 scheduled formulations (for which prices were fixed under original Schedule-I NLEM 2011) were accordingly revised, vide notification dated 2nd March, 2016.

NPPA had also clarified that ceiling prices of scheduled formulations which have become non-scheduled after adoption of NLEM-2015 as the revised Schedule-I of DPCO, 2013, will continue to remain under price control till 1st April 2017.

Monitoring and enforcement under the provisions of DPCO, 2013 is the joint responsibility of NPPA and the State Drug Controllers. NPPA, along with State Drugs Controllers also undertake market surveillance of prices of scheduled and non-scheduled formulations under which following activities are done:

- Purchase of samples by NPPA officers from across the country,
- Examination of test samples received from State Drug Controllers,
- Examination of complaints received from individuals / NGOs/VIP references, etc.
- Analysis of Pharmatrac data

Based on analysis, specific cases are identified for recovery of overcharged amounts; and fixation of prices, wherever required.

NPPA also monitors the availability of essential formulations and identifies shortages, if any, and takes remedial steps.

Monitoring and Enforcement activities from 2010-11 to 2015-16 (upto October, 2016) are given as under:

Year	No. of Samples Collected	Prima Facie Violations detected	Referred for Overcharging
2010-2011	553	225	216
2011-2012	559	156	152
2012-2013	626	165	163
2013-2014	993	389	389
2014-2015	3898 #	1020	1020
2015-2016	2947 #	613	613
2016-2017	1426 #*	279	279

*including 503 cases under process on 31.10.2016

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

7. New Initiative:

'Pharma Sahi Daam' an android version of Mobile App was developed by NPPA and launched officially by Hon'ble Minister (Chemicals & Fertilizers/Parliamentary Affairs) on 29th August, 2016 on the occasion of NPPA Foundation Day to provide information to consumers on prices of scheduled medicines which are under price regulation as well as prices of non-scheduled medicines. This app helps consumers to check the ceiling prices of medicines and to verify whether medicines are being sold within the approved price range and also to detect any case of overpricing by pharmaceutical company/chemist. In case of overpricing the consumer can lodge a complaint through Pharma Jan Samadhan website. (http://nppaindia.nic.in/redressal.html).

8. e- Initiatives:

(a) Pharma Jan Samadhan (PJS), a web enabled system was developed by the NPPA with the assistance of National Informatics Centre (NIC). It was launched on 12th March 2015. It serves as a robust e-governance tool for protection of consumer interest through effective implementation of the DPCO, 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 and refusal of supply or sale of medicines without good and sufficient reasons. Any individual or consumer organization or stockiest / distributor / dealer / retailer or State Drugs Controller can lodge a complaint online through the PJS portal. Action on the complaint received through PJS with complete information is initiated within 48 hours by the NPPA.

(b) Pharma Data Bank (PDB) - Integrated Pharmaceutical Database Management System (IPDMS): Launched on 25th June, 2015, IPDMS was developed by the NPPA in collaboration with the National Informatics Centre (NIC). This comprehensive online system provides a platform to the pharmaceutical manufacturer/ marketing/ importer/ distributor companies to file mandatory returns prescribed in Form II, Form III and Form V of DPCO, 2013. Application for price approval of 'new drug' in Form-I can also be filed through this portal. Online submission of application under Form IV will be made available shortly. 689 pharma companies have registered under IPDMS till 30th October, 2016 Information regarding 61646 products has been registered by pharma companies. PDB is expected to benefit industry, consumer and the regulator. It provides industry with a user friendly mechanism to comply with the mandatory requirement of filing

returns; NPPA would be able to fix prices on the basis of price disclosure by companies and remove its dependency on private databases; and the consumer will be able to access price data with respect to each scheduled / non-scheduled formulation and take informed decision on cost-effective treatment. Retailers will also have access to real time price data. It will also help NPPA to monitor price compliance.

9. Plan Scheme of Consumer Awareness and setting up of Price Monitoring and Resource Units (PMRUs):

NPPA is implementing a plan Scheme of 'Consumer Awareness, Publicity and Price Monitoring'. The Scheme creates general awareness about the availability of medicines, prices of medicines, ceiling prices of medicines fixed by the Government, precaution to be taken while purchasing medicines and about the functioning of NPPA. This helps to improve the accessibility of quality medicines at a reasonable price to the common people of the country.

The revised/modified scheme has two parts: - National Level Component and State/UT level Component. Under National level component, consumer awareness is created through print and electronic media through advertisements, radio jingles etc. The scheme also envisages conducting Research Studies on Availability of Essential Medicines, pharmaceuticals pricing and related issues, organizing consumer awareness workshops and purchase of test samples for price monitoring purpose. Under the State/UT level component grants-in-aid are given to States for setting up Price Monitoring and Resource Units (PMRUs) and purchase of test samples by the State Drugs Controller and their Field Offices.

NPPA initiated action for setting up of Price Monitoring and Resource Units (PMRUs) in States/Union Territories under the Scheme to provide necessary support to the State Drug Controllers to discharge the monitoring and enforcement activities mandated under the DPCO, 2013. Each Unit will function under direct supervision of the concerned State Drugs Controller. PMRUs will be the key collaborating partners of NPPA for information gathering and to ensure that the benefits of DPCO, 2013 trickle down to the grassroots level. The Scheme initially at the pilot stage is being implemented for a period of two years in seven states viz., Assam, Gujarat, Haryana, Kerala, Maharashtra, Manipur and Odisha.

10. Outreach activities:

NPPA organized a series of workshops / seminars at various places to help disseminate information about the implementation of DPCO, 2013 and on issues of availability, affordability, and accessibility of medicines. These workshops were

organized at Bangalore in collaboration with National Law School of India University in January 2016 and at NIPER Mohali in November 2016 (in collaboration with state governments of Punjab, Haryana, Himachal Pradesh & UT Admn. of Chandigarh). More such seminars are scheduled in 2016-17 as part of NPPA's outreach activities. These workshops brought many experts from the pharmaceutical sector, academicians, health experts, civil society activists, industry representatives and government officers who gave their perspectives on pharmaceutical pricing, patenting of medicines, innovations in the pharmaceutical sector and national and international best practices on the subject.

11. NPPA Foundation Day

The Foundation Day of NPPA was celebrated on 29th August, 2016 at Vigyan Bhawan, New Delhi in the gracious presence of Hon'ble Minister for Chemicals & Fertilizers and Parliamentary Affairs. On the occasion, a one-day National Seminar on "Affordable Medicines" was organized. The seminar discussed subjects related to overall drug ecosystem. Eminent speakers from different stakeholder groups, academia, lawyers, civil society activists, industry representatives and senior government officers made presentations on different subjects related to the pharmaceutical sector.

In order to promote the concept of affordable medicines, and to recognize the efforts of Department of Pharmaceuticals towards ensuring affordability, availability and accessibility of medicines, Hon'ble Minister for Chemicals & Fertilizers and Parliamentary Affairs, on the request of NPPA, announced that August 29 would be commemorated as 'Rashtriya Jan Aushadhi Diwas'. The proposal of the NPPA is under active consideration.

12. NPPA Logo

NPPA Logo was unveiled by the Hon'ble Minister (Chemicals & Fertilizers and Parliamentary Affairs) on the occasion of NPPA Foundation Day Celebrations on 29th August, 2016. The logo was selected after screening entries received through cloud-sourcing.

NPPA
AFFORDABLE MEDICINES FOR ALL

13. Recovery of overcharged amount:

Action for recovery of the overcharged amount along with interest thereon is a continuous process. NPPA takes action as per the provision of DPCO 1995/ DPCO 2013 read with relevant provisions of the Essential Commodities Act, 1955.

NPPA has initiated about 1467 cases of overcharging as on 31st October 2016 (1283 cases under DPCO 1995 and 184 cases under DPCO 2013), where demand notices have been issued to pharmaceuticals companies. The demanded amount works out to Rs. 4958.74 crore (4877.74 crore under DPCO 1995 and 81.00 crore under DPCO 2013) for sale of medicine at prices higher than that fixed by NPPA /Government. However only an amount of Rs. 598.80 crore (Rs 536.81 crore under DPCO 1995 and Rs. 61.99 crore under DPCO 2013) has been recovered on 31st October, 2016, from pharmaceutical companies. This includes an amount of Rs. 214 crore deposited by pharmaceutical companies in response to the verdict of the Supreme Court delivered on 20th July, 2016 in 109-111/2013, 153-164/2013, WC(C) 696/2013, WP(C) 983/2013, WP(C) 123/2014, WP(C) 135/2014 and WP(C) 346/2014. Out of the balance outstanding amount of Rs. 4359.93 crore, Rs. 3460.32 crore is still locked up in litigation.

The recent pronouncements of the Supreme Court and Bombay High Court in certain cases of overcharging have upheld the notifications issued by NPPA in regulation of ceiling prices of scheduled formulations and capping of MRP of certain non-scheduled formulations. The Hon'ble Supreme Court its judgment dated 21st October, 2016 in CA No. 329/2005-UOI vs Cipla, CA No 4005/2004, CA No. 9609-9610/2016, CA No. 9585/2016, CA No. 9586/2016 and CA No. 9561-9584/2016 has given legal approval to the norms and notifications issued by NPPA from 1995 to 2003 under DPCO 1995. Pharmaceutical companies in compliance with this judgment have started depositing the overcharged dues with government.

The Hon'ble High Court of Bombay on 26th September, 2016 dismissed WP 2700/2014 filed by India Pharmaceutical Alliance upholding price notifications issued by NPPA in respect of 106 antidiabetic and cardiovascular formulations on 10th July, 2014 under para 19 of DPCO, 2013. The SLP filed by IPA in the Supreme Court against the said judgement of the Bombay High Court was dismissed on 24th October, 2016. The judicial verdicts have sent a strong signal recognizing the requirement of regulation of prices of essential medicines in order to ensure affordable, available and accessible healthcare for all.

Chapter 8

IMPLEMENTATION OF RAJBHASHA

CHAPTER 8
IMPLEMENTION OF RAJBHASHA

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).

Hindi Prayog Protsahan Pakhwara, 2016

Hindi Prayog Protsahan Pakhwara was observed in the Department from 14th to 28th September, 2016 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 in unprecedented numbers and made this programme successful. Winners were awarded with cash prizes and Commendation Certificates.

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 2016-17,

Chapter 9

GENERAL ADMINISTRATION

9.1 Organizational Set Up

CHAPTER – 9
GENERAL ADMINISTRATION

9.1 ORGANISATIONAL SET UP OF THE DEPARTMENT

The main activities of the Department are policy making, sectorial planning promotion and Development of Pharmaceutical industries including medical devices. The administrative and managerial control of the public sector undertakings engaged in the manufacture of various, pharmaceutical items and some other organization is a major function of the Department.

2. The Department is headed by Secretary to the Government of India who is assisted by two Joint Secretaries.

3. There is an attached office namely “National Pharmaceutical Pricing Authority” which looks after Price fixation/revision of pharmaceuticals and other related matters. It also monitors the prices of decontrolled drugs and formulation and oversees the implementation of the provisions of the Drug (Price Control) Order.

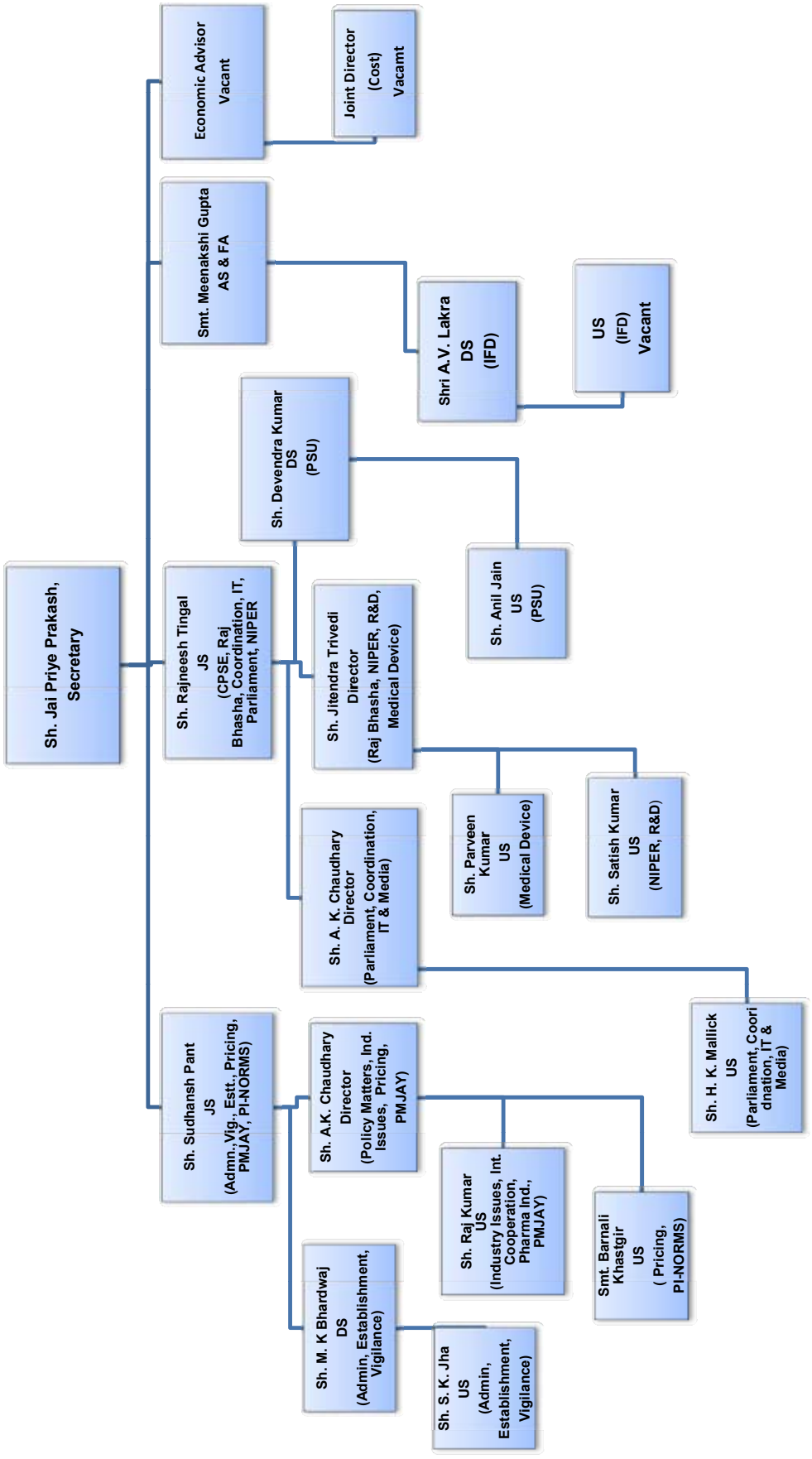
EMPLOYMENT OF SCHEDULED CASTES / SCHEDULED TRIBES / PHYSICALLY HANDICAPPED IN THE MAIN SCERETARIAT OF THE DEPARTMENT OF PHARMACEUTICALS

The status of employment of Scheduled Castes / Scheduled Tribes / Other Backward Classes / Physically handicapped in the main Secretariat of the Department of Pharmaceuticals, as on 31.12.2016 is as under:-

Group	Total No. Of Posts	In position	Scheduled Castes	Scheduled Tribes	Other Backward Classes	Physically Handicapped
A	30	17	4	1	-	-
B	48	31	5	3	7	-
C	25	22	7	-	5	-
Total	103	70	16	4	12	-

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

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


Sh. Jai Priye Prakash, Secretary
Economic Advisor Vacant
Joint Director (Cost) Vacamt
Smt. Meenakshi Gupta AS & FA
Shri A.V. Lakra DS (IFD)
US (IFD) Vacant
Sh. Devendra Kumar DS (PSU)
Sh. Anil Jain US (PSU)
Sh. Rajneesh Tingal JS (CPSE, Raj Bhasha, Coordination, IT, Parliament, NIPER
Sh. Jitendra Trivedi Director (Raj Bhasha, NIPER, R&D, Medical Device)
Sh. Parveen Kumar US (Medical Device)
Sh. Satish Kumar US (NIPER, R&D)
Sh. A. K. Chaudhary Director (Parliament, Coordination, IT & Media)
Sh. H. K. Mallick US (Parliament, Coordnation, IT & Media)
Sh. Sudhansh Pant JS (Admn.,Vig., Estt., Pricing, PMJAY, PI-NORMS)
Sh. A.K. Chaudhary Director (Policy Matters, Ind. Issues, Pricing, PMJAY)
Sh. Raj Kumar US (Industry Issues, Int. Cooperation, Pharma Ind., PMJAY)
Smt. Barnali Khastgir US (Pricing, PI-NORMS)
Sh. M. K Bhardwaj DS (Admin, Establishment, Vigilance)
Sh. S. K. Jha US (Admin, Establishment, Vigilance)

Chapter 10

CITIZEN CENTRIC GOVERNANCE

10.1 Our Vision

10.2 Our Mission

10.3 Our Clients

10.4 Our Commitment

10.5 Our Services

10.6 Our Activities

10.7 RTI-2005

10.8 CPGRAMS

CHAPTER – 10
CITIZEN CENTRIC GOVERNANCE

10.1 Our Vision:

Based on the mandate given to the Department of Pharmaceuticals through the allocated functions a vision has been fixed in concurrence with the Cabinet Secretariat, which is as follows:

"India: The largest global provider of quality medicines at reasonable prices."

10.2 Our Mission:

1. Ensure availability of quality drugs at reasonable prices as per the Pharma Policy.
2. Development of Pharma Infrastructure and Innovative Development in Pharma Sector including through PPP.
3. Promote Pharma Brand India.
4 Encourage environmentally sustainable development of Pharmaceutical Industry.
5. To establish NIPERs as nationally and internationally recognized brand in the field of education and research of pharmaceutical sciences for the benefit of human kind.

10.3 Our Clients

- Citizens of India
- Pharmaceuticals and Medical Device Industry including Small and Medium Enterprises
- Pharmaceuticals companies seeking relief under DPCOs
- NPPA/ CPSUs/NIPERs

10.4 Our Commitment

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

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 consulations with all Industry Associations/stakeholders and to amend them whenever so required.

10.5 Our Services

We formulate and implement policies relating to drugs and pharmaceuticals, dyestuff and dye intermediates.

10.6 Our Activities

The key activities of the Department focus on:

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

10.7 Right to Information Act 2005

As per the provisions of the RTI Act 2005, all the relevant information relating to Department of Pharmaceuticals has been available on the web site in a manner, which is easily accessible and comprehensible to the public.

Central Public Information Officers and Appellate Authorities have been nominated in the department to provide information to the public.

10.8 CPGRAMS (Centralized Public Grievances Redress And Monitoring System)

Public Grievances received offline and through CPGRAMS are monitored and disposed off regularly.

Chapter 11

INFORMATION AND COMMUNICATION TECHNOLOGY

CHAPTER – 11
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 had 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 Servers and 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.

Local Area Network (LAN):

All work places in the department are connected on Local Area Network (LAN) which is upgraded to make it IPv6 compliant 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.

Website and Social Media

A vibrant revamped Bilingual Web Site of the Department, ie http://pharmaceuticals.gov.in was launched by the then Hon'ble Minister of State Shri Hansraj Gangaram Ahir in September' 2015 and is hosted at 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.

Website for Jan Aushadhi Scheme of the Department http://janaushadhi.gov.in) provides details of the scheme, list of generic medicines (unbranded) which are being dispensed through the Jan Aushadhi Stores (JAS) being setup in various districts of India. Website is revamped to facilitate the visitors to know the locations of the JAS already opened. It also provides comparative prices of Generic Medicines sold at Jan Aushadhi Stores and Branded Products.

Social media had enormous potential to reach people. To improve the quality of Government decision, 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 generic medicines, Educational and Research institutes NIPERs, etc. also is posted on Facebook and twitter pages of Department.

Video Conferencing:

Video Conferencing facility is operational for Secretary. 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, 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.

Work Flow Automation

Another initiative taken by Department towards Digital India is to implement automation of work flow inside the Department. e-Office is a standard product presently consists of e-File, e-Leave, e-Tour, Knowledge Management System (KMS), Personnel Information Management System (PIMS), Collaboration & Messaging Service (CAMS) and is aimed at increasing the usage of work flow and rule based file routing, quick search and retrieval of files and office orders, digital signatures for authentication, forms and reporting components. e-Office is being implemented to reduce duplicity of work, increases transparency and efficiency.

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, monitor and decision making and high availability of right information at right time.

- Aadhaar enabled Biometrics Attendance System (AEBAS) - Biometrics Attendance System records attendance of all employees (Permanent and Casual) of Department. Dept. of Pharmaceuticals has implemented AEBAS in the first phase and 17 finger reader devices are installed at offices of JS & above

level officers and at all sections. Tablet devices are also installed at all gates of Bhawans to facilitate officials/staff to mark the attendance.119 employees are registered and are marking the attendance regularly. Monthly register is generated for monitoring of attendance.

- SPARROW- Smart Performance Appraisal Report Recording online Window (SPARROW) application which allows online submission of APAR and processing of IAS officers is implemented successfully.
- Parliament Questions and Assurances System – Repository of Parliament Questions and reminder system of Assurances is developed to facilitate Officials to keep record of all answered question and pending assurances.
- Visitor Management System - eVisitor 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.
- Court Cases Monitoring System – This system is repository of all court cases of Department. It also keeps the track of forthcoming hearing dates of Cases and basic details of the case. It facilitates officials to generate useful reports.
- Online RTI-MIS – To dispose of and monitor RTI applications efficiently, Dept. has taken initiative to use Online RTI-MIS. Necessary training was imparted to concerned officials/staff to implement RTI-MIS successfully.
- CompDDO- CompDDO package implemented for processing salary of officials was upgraded to version 4.0 with additional features. This enables salary distribution through E-payment.
- Centralized Public Grievance Redress Monitoring System (CPGRAMS): CPGRAMS is implemented in the Department and all the attached office 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.
- Other e-Governance applications like RTI Request & Appeal Management Information System, e-Samiksha, Pragati and Foreign Visit Management System are functional in the Department to facilitate various sections.

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

- PSEs Performance Monitoring System- Performance of Public Sector Enterprises is to be monitored by Department and for the purpose; a web based application is under development to ensure monitoring and facilitate the top level officers in decisions making.
- Store Inventory System – Store Inventory System is being customised for implementation in the department. It will facilitate online issuance of items to employees and keep records of store and inventory.

Training:

NIC Computer Cell organises User Training for operational know how and awareness program to keep user well aware of use of latest IT technologies. Under Digital India Program, above said applications were implemented and training was imparted as when required. Training on e-Office is being imparted to all officers/staff (including JS level officials) of the department. All employees (including outsourced) were sensitized about operations of Aadhaar enabled *Biometrics* Attendance System (AEBAS). Concerned sections were trained on e-Samiksha, CPGRAMS, CompDDO, E-publishing, Court Cases Monitoring System. Training on Sparrow Software is imparted to all IAS officials.

E-office:

As per direction issued, E-office is being fully implemented in the department. Training has been imparted to all the employees including outsourced staff of the Department. Digital Signature has been provided to all the employees of the department upto the level of the office of MoS. E-office has become operational from 1st November, 2016. Target for 100 % implementation of E-office is set for 31-03-2017. As on date, above 90% work of the department is being done through E-office.

Chapter 12

ANNEXURE

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)

CHAPTER –12
ANNEXURE 1 [A]

List of Public Sector Undertakings

1 Indian Drugs & Pharmaceuticals Ltd, Dundahera Industrial Complex, Dundahera, Gurgaon, Haryana.

2 Hindustan Antibiotics Ltd, Pimpri, Pune, Maharahstra.

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 1 [B]

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

Sl. No.	Address and Organization	Name	Designation
1.	Indian Drugs & Pharmaceuticals Limited (IDPL), Gurgaon	Shri Sudhansh Pant	Chairperson & Managing Director
2.	Hindustan Antibiotics Limited (HAL), Pune-411010	Ms. Nirja Saraf	Managing Director
3.	Karnataka Antibiotics & Pharmaceuticals Limited (KALP), Banglore-700013	Shri K. M. Prasad	Managing Director
4.	Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata-700013	**Shri P.M. Chandraiah**	Managing Director
5.	Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Road No. 12 V.K.I Area Jaipur-302013	Shri S.B.Bhadrannavar	Managing Director

ANNEXURE 1 [C]

List of Responsibility Centers and Subordinate Organizations:

(NIPERs)

S. no.	Responsibility Centers and Subordinate	Address
1	NIPPER, MOHALI Dr. P.J.P. Singh (Registrar) Officiating Director is yet to be appointed.	SAS Nagar, NIPER Mohali, Punjab - 160062
2	NIPER, AHMEDABAD Dr. Kiran Kalia, (Director)	Palaj Opp. Air Force Station Head Quarter, Gandhinagar-382355, Gujarat
3	NIPER, HYDERABAD Dr. S. Chandrasekhar (Project Director)	IDPL Township, Balangar, Hyderabad-500007
4	NIPER, HAJIPUR Dr. Pradeep Das, (Project Director)	E.P.I.P. Campus, Industrial Area, Hajipur-844102, Bihar
5	NIPER KOLKATA Dr. V. Ravichandiran (Director)	Indian Institute of Chemical Biology (IICB, under CSIR), Mentor Institute for NIPER, Kolkata 4, Raja S.C. Mullick Road, Jadavpur, Kolkata-700032 (West Bangal)
6	NIPER GUWAHATI Dr. USN Murty (Director)	3rd Floor, Department of Pharmacology, Guwahati Medical College & Hospital Guwahati-781032, Assam
7	NIPER RAEBARELI Dr. SJS Flora (Director)	NIPER Raebareli, Shree Bhawani Paper Mill Road, ITI compound, Raebareli U.P. (India) - 229010

ANNEXURE – II

Organisational Chart of NPPA