23	STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2015-16) SIXTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS

(2016-17)

TWENTY-THIRD REPORT

LOK SABHA SECRETARIAT

NEW DELHI

April, 2016/ Vaisakha, 1938 (Saka)

CC&F.No.23

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(SIXTEENTH LOK SABHA)

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Presented to Lok Sabha on 28 April 2016

Laid in Rajya Sabha on 28 April 2016

LOK SABHA SECRETARIAT
NEW DELHI
April, 2016/ Vaisakha, 1938 (Saka)

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2015-16)

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri Idris Ali
3. Smt. Anju Bala
4. Shri B.N. Chandrappa
5. Shri Sankar Prasad Datta
6. Smt. Veena Devi
7. Shri R.Dhruvanarayana
8. Shri Innocent
9. Shri K. Ashok Kumar
10. Shri Kamalbhan Singh Marabi
11. Shri Chhedi Paswan
12. Smt. Kamala Devi Patle
13. Shri Rajendran S.
14. Shri Kotha Prabhakar Reddy
15. Shri Chandu Lal Sahu
16. Dr. Kulamani Samal
17. Dr. Uma Saren
18. Dr. Krishna Pratap Singh
19. Shri Taslimuddin
20. Smt. Rekha Arun Verma
21. Shri George Baker

RAJYA SABHA

22. Shri Biswajit Daimary
23.# Vacant
24. Shri Sanjay Dattatraya Kakade
25. Shri Mansukh L. Mandaviya
26. Shri Narayan Lal Panchariya
27. Shri K. Parasaran
28. Shri Garikapati Mohan Rao
29. Shri Palvai Govardhan Reddy
30. Dr. Sanjay Sinh
31. Shri Abdul Wahab

SECRETARIAT

1.	Smt. Rashmi Jain	-	Joint Secretary
2.	Shri A.K. Srivastava	-	Director
3.	Shir H. Ram Prakash	-	Additional Director
4.	Shri Nishant Mehra	-	Under Secretary

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the term of Dr. M.S. Gill, Member Rajya Sabha will expired w.e.f. 09.04.2016

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2015-16) having been authorised by the Committee to submit the Report on their behalf present this Twenty-third Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2016-17.

2. The Committee examined the Demands for Grants (2016-17) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which were laid in Lok Sabha and Rajya Sabha on 16 March, 2016.

3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 28 March, 2016.

4. The Report was considered and adopted by the Committee at their sitting held on 26 April, 2016.

5. The Committee wish to express their thanks to the Officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for their cooperation in furnishing the written replies and other material/ information and for placing their views before the Committee.

6. The Committee also place on record their appreciation for the valuable assistance rendered to them by the officials of the Lok Sabha Secretariat attached to the Committee.

7. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters at the end of the Report.

New Delhi;
26 April, 2016
6 Vaisakha, 1938 (Saka)

Anandrao Adsul
Chairperson
Standing Committee on
Chemicals and Fertilizers

PART I

CHAPTER-I

INTRODUCTORY

1.1 The Department of Pharmaceuticals, under the Ministry of Chemicals & Fertilizers 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.

1.2 The Department of Pharmaceuticals have been allocated with following work:

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

(ii) Promotion and co-ordination of basic, applied and other research in areas related to the Pharmaceuticals sector.

(iii) Development of infrastructure, manpower and skills for the Pharmaceuticals sector and management of related information.

(iv) 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.

(v) Promotion of public – private – partnership in pharmaceutical related areas.

(vi) International cooperation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.

(vii) 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.

(viii) Technical support for dealing with national hazards in pharmaceutical sector.

(ix) All matters relating to National Pharmaceuticals Pricing Authority including related functions of price control/monitoring.

(x) All matters relating to National Institutes of Pharmaceutical Education and Research.

(xi) Planning, development and control of; and assistance to, all industries dealt with by the Department.

(xii) Bengal Chemicals and Pharmaceuticals Limited.

(xiii) Hindustan Antibiotics Limited and its Subsidiaries and JVs.

(xiv) Indian Drugs and Pharmaceuticals Limited and its Subsidiaries.

(xv) Karnataka Antibiotics and Pharmaceuticals Limited.

(xvi) Rajasthan Drugs and Pharmaceuticals Limited.

(xvii) Bengal Immunity Limited.

(xviii) Smith Stanistreet Pharmaceuticals Limited.

1.3 The work of the Department has been organized into three Divisions *viz* Pharmaceuticals Industry Division, Public Sector Undertakings Division and R and D division comprising National Institute of Pharmaceutical Education and Research, (NIPER) and Research and Development. The National Pharmaceuticals Pricing Authority (NPPA), an attached office of this Department is entrusted with the work of fixation and revision of prices of Pharmaceutical products under Drug Price Control Order, 2013.

1.4 **The detailed Demands for Grants (2016-17) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 16 March 2016. The demand shows a budgetary support of Rs. crore [(Rs. 160 crore (Plan) + Rs.51.40 crore (Non-Plan)]. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2016-17. The detailed analysis along with Observations/ Recommendations of the Committee are given in a separate chapter at the end of the Report. The Committee expect the Department to take all necessary steps for proper and timely utilization of funds ensuring completion of the various plans and projects in a time bound manner. The Committee also expect the Department to act on the recommendations of the Committee expeditiously.**

CHAPTER-II

AN OVERVIEW OF PHARMACEUTICALS INDUSTRY

2.1 The annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs.165202.3 crore during the year 2014-15. The share of export of Drugs, Pharmaceuticals and Fine Chemicals is Rs.78792.3 crores. This segment of Industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. The industry has developed excellent GMP (Good Manufacturing Practices) compliant facilities for the production of different dosage forms. The strength of the industry is in developing cost effective technologies in the shortest possible time for drug intermediates and bulk activities without compromising on quality. This is realized through the country's strengths in organic chemicals' synthesis and process engineering.

2.2 The domestic Pharma Industry has recently achieved some historic milestones through a leadership position and global presence as a world class cost effective generic drugs manufacturer of AIDS medicines. Many Indian companies are part of an agreement where major AIDS drugs based on Lamivudine, Stavudine, Zidovudine, Nevirapine are supplied to Mozambique, Rwanda, South Africa and Tanzania which have about 33% of all people living with AIDS in Africa. Many US Schemes are sourcing Anti Retrovirals from Indian companies whose products are already US FDA approved.

2.3 The Indian Pharmaceutical companies maintain highest standards in Purity, Stability and International Safety, Health and Environmental Protection in production and supply of bulk drugs. This speaks of the high quality standards maintained by a large number of Indian Pharma companies as these bulk active ingredients are used by the buyer companies in manufacture of dosage forms which are again subjected to stringent assessment by various regulatory authorities in the importing countries. More of the Indian companies are now seeking regulatory approvals in USA in specialized segments like Anti-infectives, Cardiovascular and CNS group. Along with Brazil & China, India has carved a niche for itself by being a top generic Pharma player.

2.4 Many Indian companies have got various international regulatory approvals for their plants, from agencies like USFDA, MHRA-UK, TGA-Australia, MCC-South Africa etc. Outside USA, India has the highest number of USFDA approved plants for generic drugs manufacture. Major share of Indian Pharma exports is going to developed western countries and it speaks not only about excellent quality of Indian pharmaceuticals but also about the reasonableness of the prices. Some of the leading Indian Pharma companies derive 50% of their turnover from International business.

IMPORTS

2.5 Import of medicinal and pharmaceuticals products for the last three years were as under:

Year	Import of Bulk Drugs & Drug Intermediates*		Import of Drug Formulations & Biologicals*	
	Quantity in (Thousand kgs)	(Value in US $ Millions)	Quantity in (Thousand kgs)	(Value in US $ Millions)
2012-13	222147.44	3189.1	1765.64	1690.3
2013-14	246466.56	3146.8	2226.93	1491.7
2014-15	249944.64	3245.6	2764.27	1562.5
Total	**718558.64**	**9582.1**	**6756.81**	**4744.5**

The Figures of import for first 9 months of 2015-16 are as follows:-

2015-2016**(April-Dec)**	200134.83	2510.4	2307.20	1209.9

* **Source**: - Directorate General of Commercial Intelligence & Statistics, Kolkata.

The country is almost self-sufficient in case of formulations. The imports are being made on quality and economic considerations and not necessarily due to non-availability from domestic sources. Manufactures of Drugs and Pharmaceuticals are free to produce any drug approved by the Drug Control authorities.

2) Imports of Drugs & Pharmaceuticals is done as per Foreign Trade Policy and the provisions of the Drugs & Cosmetics Act. There are certain incentives available to the exporters of Drugs & Pharmaceuticals which enables them Customs duty-free import of all inputs, required to manufacture the export products in line with Advance Authorizations granted by the DGFT. The quantities of inputs are as per published Standard Input-Output Norms (SIONs). In case of the export product do not have published SIONs or the inputs are different from the published SIONs, ad-hoc norms are considered. Being the Administrative Department, the Department of Pharmaceuticals is actively engaged in processing Pharma Industry's applications for fixation of ad-hoc norms. More than 650 such applications, both for Pharma formulations and Bulk drugs & drug intermediates, were processed in the Department during 2015.

3) In addition to conveying ad-hoc norms, the Department has also recommended publication of additional SIONs for a number of pharmaceuticals formulations and as many as 33 new SIONs are understood to have already been finalized for notification by the DGFT.

4) Import of some the drugs & drug intermediates is still restricted under current Foreign Trade Policy. Imports are restricted basically due to common HS codes for some narcotic substances or similarity to some Ozone Depleting Substances (ODS). Applications received from the Pharma industry, through the DGFT, for import of either the Bulk Drugs or intermediates whose import is restricted, are processed in the Department and suitable inputs

are provided based upon the Actual User Status and essentially of usage of the chemicals to be imported.

5) Quite a few applications from the Pharma industry for import of certain dual purpose chemicals, particularly Sodium cyanide- included in the Schedule to the Insecticides Act, are also processed and suitable recommendations are conveyed to the Central Insecticides Board under the Ministry of Agriculture, in the capacity of Administrative Department, for grant of import permits to the Actual Users in Pharma Industry.

2.6 On being asked about the steps being taken to make the country self-reliant in Pharmaceutical sector and to reduce the dependence on imports, the Department in its written reply stated as under:-

> ”The country is almost self-sufficient in case of formulations. The imports are being made on quality and economic consideration and not necessarily due to non availability from domestic sources. As the pharmaceutical industry is dominated by the private sector, they are free to import as per Foreign Trade Policy under which import of certain drugs and drugs intermediates is restricted. Further, a Committee headed by Dr. V. M. Katoch has submitted recommendations for promoting domestic production of bulk drugs.
>
> Besides this, the following three task forces which was set up by the Department have submitted its report:-
>
> (i) Setting up of Task Force on Enabling the Private Sector to lead the growth of Pharmaceutical Sector.
>
> (ii) Setting up of Task Force to identify issues relating to the promotion of domestic production of high end Medical Devices and Pharmaceutical Manufacturing Equipment in the Country.
>
> (iii) Setting up of Task Force for development of manufacturing capabilities in each medical vertical in Pharmaceutical production.
>
> Once the recommendations of the Katoch Committee and the Task Forces are implemented it would further help in reducing the dependence on imports.

2.7 The Committee sought to know as to when will the Katoch Committee recommendations for formulations of a policy for promoting of manufacturing of bulk drugs be implemented, the Department in its written reply stated as under:-

> “The government is examining the recommendations of the Katoch Committee in consultation with the stakeholders. As the recommendation also entail use of financial outlays, the feasibility of implementation is being looked into and hence no time limits can be indicated at this stage”.

2.8 During the course of evidence, the Secretary of the Department briefed the Committee on Katoch Committee Report and stated as under:-

> “Our country is a big pharma power. We have a business of Rs. 2 lakh crore: Rs. 1 lakh crore is locally consumed; Rs. 1 lakh crore is exported to many countries. For making these formulations, the basic chemical is bulk drug and everything comes from China. At one point of time India was leading in bulk drugs. We were having very big units in public sector as well as private sector. When Chinese products were dumped in India, all our companies were closed. That is why IDPL, Hindustan Antibiotics and others closed down. Similarly, a lot of private units also closed down. Now, we are dependent on

China for our bulk drug needs. Though this dependency is very convenient because we are getting them at cheap rates, over a period of time it may result in problems because we have to take whatever quality is dumped. Secondly, over a period of time they may increase the rates also. The drug which was available at Rs. 1,000 a kilogram may be made available at Rs. 10,000. That would be a great drug security problem for the country. That is why the Katoch Committee had been formed and it suggested that we should develop our own make in India mechanisms to create bulk drug capacity. We are in the process now. We have worked out a policy. We have made presentations before the Prime Minister's Office and other officials. They have given some suggestions. Now, we want to create four-five bulk drug parks in the country. We will come out with the details shortly".

2.9 **EXPORTS**

Exports of medicinal and pharmaceuticals products for the last three years were as under: -

Year	Exports of Medicines & Pharmaceuticals Products (Rupees in Crore)
2012-13	79840
2013-14	90341
2014-15	94275

2.10 When the Committee asked about the percentage of share of the Indian Pharma Companies and Multi-National Pharma Companies in the export of Pharma sector and the steps being taken to boost the export of Pharma products, the Department in its written reply stated as under:-

"The data regarding percentage share of Indian Pharma Companies and Multi-National Pharma Companies is not maintained in the department. The Foreign Trade Policy administered by Ministry of Commerce and Industry provides incentives to boost various sectors including export of Pharma products".

2.11 When asked by the Committee as to how does the Department evaluates the growth of the Pharmaceuticals industry in the country over the years, the Department of Pharmaceuticals in its written reply stated as under:-

"The Pharma sector has recorded a very impressive growth over the years. This sector has from being an importer has become self-sufficient in most of the drugs. This growth has primarily been driven by private sector. The sale value of drug manufactured in the country during 2014-15 was Rupees 1,65,202.30 crores. [Source: Pharmatrac/NPPA/DGCIS] ".

2.12 On being enquired by the Committee about the factors which have impeded self-sufficiency/growth of Pharmaceuticals sector in the country, the Department in its written reply stated as under:-

"The country at present is almost self-sufficient in the Pharmaceutical Sector. It has become from a net importer to one of the main exporters of generic medicines. This is due to industry‟s ability to develop cost effective technologies in the shortest possible time for drug without compromising on quality. This is realized through the country strengths in organic chemicals‟ synthesis and process engineering. The imports are not only because of availability or otherwise of a product but also because of economic consideration".

MEDICAL DEVICES

2.13 Medical devices industry is a multi-product industry, producing wide range of products. Manufacturing and trade in medical devices is also growing quite steadily. Double digit growth rates indicate its importance in health care. Medical devices industry mostly depends on imports. Most hi-tech innovative products and technology originate from a well-developed eco-system and innovative cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports.

2.14 It is estimated that the global market for medical devices is over US$ 220 billion. United States of America, with about 45% market share is the dominant market for medical devices in the world followed by European market with a share of 30% and Japan with a share of 10%. Medical devices sector in India is relatively small as compared to the rest of the manufacturing industry, though India is one of the top twenty markets for medical devices in the world and is the 4th largest market in Asia after Japan, China and South Korea. Although accurate data is not available, an educated guess would place the sector at about Rs. 30,900 Crores in production terms. The medical devices industry can be broadly classified as consisting of (a) medical disposables and consumables(31.3%); (b) medical electronics, hospital equipments, surgical instruments (53.7%); (c) Implants (7.1%); and (d) Diagnostic Reagents(7.9%). Medical devices Industry in India is predominantly import driven accounting for over 65% of the total market and approximately 80% of import in categories (b), (c) and (d).

2.15 At present, the Indian medical devices industry is fragmented into small and medium enterprise category and is primarily manufacturing products such as disposables/medical supplies. Requirement for high end medical equipments are met by multinational companies. It is estimated that there are about 800 manufacturers in the country and based on their turnover.

2.16 Large multinational corporations (MNC) controlling the global industry backed by multiple approvals, certification of accredited organizations and capacity to produce verified clinical trial record are able to control the major share compared to the home grown devices which lacked standardization, certification or seal of quality approval even from local authority. Lack of national regulation helped the foreign multinational corporations in doing business in this sector. The Drugs and Cosmetics (Amendment) Bill, 2015 for providing a separate chapter for regulation of the complete range of medical devices is now under legislative process.

2.17 Besides, the others issues facing the Indian medical device industry include training and capacity building programme, interaction with medical device regulators, policy to promote local manufacture of medical devices, granting subsidies and incentives and promoting higher education relevant to medical devices industry to bring fresh talent and techniques into research and development. There does not exist a single nodal authority for medical device industry.

2.18 During the course of evidence, the Secretary, Department of Pharmaceuticals highlighting the importance of Medical Devices stated as under:-

> "...I would not say that we are facing shortage of staff but the design of our department itself is very small. Over a period of time we are likely to increase staff strength. Now, the medical devices subject has been given to us. Like bulk drugs, we are dependent on medical devices also from other countries. So, we have to create capacities for manufacturing medical devices used in the hospitals in India itself. For that, we have asked for about 20 staff members to be created and the Government is likely to concur".

Further elaborating on the subject, the Secretary added the following:-

> "..We want to create Medical Devices Manufacturing Parks in the country. The Department of Health has initiated action to create one park in Tamil Nadu. They have identified a land of about 400 acres exclusively for medical devices manufacturing. Similarly, the Department of Electronics has got exclusive electronics manufacturing parks where medical electronics can fit in. Likewise, we want to create four or five private and Government sponsored Medical Devices Park. One such park we want to establish in IDPL land in Hyderabad. Hyderabad has got surplus land of about 400 acres. Out of this 200 acres will be used exclusively for manufacturing medical devices in Hyderabad. Similarly, the Government of Andhra Pradesh is going to lay a foundation stone for a separate medical devices manufacturing park. Similarly, we have got proposals to create parks in the State of Gujarat. Likewise, where the Governments are forthcoming we are trying to create these parks where large number of private units can come up and set up their units. In the Government sector, public sector undertaking today there is no great organisation except HLL, Hindustan Latex Ltd. They produce certain products and they are likely to organise separate parks for manufacturing medical devices.."

CHAPTER-III

ANNUAL PLAN AND EXPENDITURE

3.1 The Department furnished the following information and comments on the Budget Proposal for Gross Budgetary Support and amount actually provided for different Scheme in Annual Plan 2016-17.

> "For Annual Plan 2016-17, the Department of Pharmaceuticals proposed an outlay of Rs 2891.473 crore to the D/o Expenditure, M/o Finance. This covered urgent funds requirement for development of NIPERs, setting up National Centre for R&D in Bulk Drugs in NIPER Hyderabad, revival package for HAL, measure of making all CPSEs WHO-GMP Compliant, giving renewed focus to Jan Aushadhi Scheme, Cluster Development Programme, PPDS Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) (newly proposed), Setting up of Venture Capital Fund for financing Drug Design, Discovery & innovation in pharma sector (newly proposed), setting up of Pharma Promotion Council (newly proposed, Setting up of Medical Device Promotion Council (newly proposed, NIPER Technical Support Group and Monitoring (newly proposed) etc. However, a Plan allocation of Rs. 160 crore only was made available by M/o Finance.
>
> This allocation falls far short of the urgent funds requirements projected by this Department for carrying out its laid down mandate and its Vision for development of Indian Pharmaceuticals Industry under "Make in India" initiative, to make India a largest global provider of quality medicines. The domestic pharma sector also has social relevance from the angle of ensuring availability, access and affordability of medicines to the common man. A severe cut in outlay would have an adverse impact on the implementation of the Plan Schemes being undertaken by this Department and the targets set for the 12th Five Year Plan. The Department of Pharmaceuticals has obtained necessary approvals/clearances required for implementation of Plan Schemes and has speeded up the process of obtaining the others. This is expected to favorably impact the pace of expenditure henceforth.
>
> It may also be noted that for the 12th Five Year Plan, the Department of Pharmaceuticals had proposed an outlay of Rs 12341.89 crore covering various Schemes to the Planning Commission, against which an allocation of Rs 2968 crore was approved. For the first four years of the 12th Five Year Plan, against a proposed outlay of Rs 4156.84 crore (Rs.1127.45 crore for 2012-13, Rs 566.80 crore for 2013-14, Rs871.81 crore for 2014-15 and 1590.78 crore for 2015-16) sought by the Department of Pharmaceuticals, the Planning Commission/M/o Finance allocated a Plan provision of Rs 793crore only i.e Rs 188 crore each for 2012-13 and 2013-14 Rs 207 crore for 2014-15 and Rs 210 crore for 2015-16 Thus, the balance outlay available for this Department, for the 5th year of the 12th Five Year Plan, out of the total approved 12th Plan outlay of Rs 2175 crore".

3.2 A statement showing scheme wise details of Plan outlays proposed for the year 2016-17, and scheme wise break-up of outlays approved, is as below:-

PLAN 2015-16 (BE) **(Rs. In crore)**

Sl.No.	Scheme/Programme	BE 2016-17 (Proposed)	BE 2016-17 (Approved)
1.	Secretariat and Economic Services	-	-
2.	Lumpsum Provision for N.E. Region (NIPER Guwahati)	174.70	19.50
3.	NIPER, Mohali	199.455	0.01
4.	NIPER, Ahmedabad	197.29	21.96
5.	NIPER, Kolkata	173.948	6.00
6.	NIPER, Hyderabad	193.02	35.00
7.	N IPER, Rae Barely	176.59	7.00
8.	NIPER, Hajipur	174.10	6.00
9.	NIPER, Madurai	174.10	1.00
	New NIPER		
	NIPER, Rajasthan	0.01	1.00
	NIPER, Maharashtra	0.01	0.01
	NIPER, Chhattisgarh	0.01	0.01
	Setting up National Centre for R&D for bulk drugs	36.75	0.01
	NIPER Technical Support Group and Monitoring	1.00	0.50
	NPPA	8.00	5.45
5	Development of Pharma Industry		
5.1	Pharmaceuticals Promotion Development Scheme (PPDS)	2.00	2.00
5.2	Creation of IPR Facilitation centre at Pharmaxil	1.00	0.01
5.3	Scheme for Development of Pharma Industry		
5.03.01	Scheme for Kala Azar and Anti Tubercular Agents	2.44	2.43
5.03.02	Cluster Development	60.00	10.00
5.03.03	Pharmaceuticals Technology Upgradation Assistance Scheme(PTUAS)	500.00	0.01
5.03.04	Setting up of Venture Capital Fund for financing drug design, discovery & innovation in Pharma Sector	500.00	0.01
	Setting up of Pharma Promotion Council	5.00	0.01
	Setting up of Medical Device Promotion Council	5.00	0.01
	Pharma Export promotion Scheme	-	-
	Critical assistance for WHO pre qualification for Pharma PSUs/R&D	5.00	5.00 + 0.01 for N.E
6	Jan Aushadhi	155.00	34.99+ 0.01 for N.E
18.	Loan to PSU		
	IDPL	24.20	0.01
	HAL	111.50	0.01
	BCPL	30.00	0.01
	BIL	-	0.01
	SSPL	-	0.01
	RPDL	3.14	0.01
	KAPL	0.01	-
	Total	**2891.473**	**160.00**

3.3 When asked to give reasons for lesser approval (Scheme wise) by the Ministry of Finance, though the Department had proposed Rs. 2891.43 crore to be allocated during 2016-17, only Rs. 160 crore were approved by Ministry of Finance, and how the Department plans to achieve their targets with lesser allocation, the Department of Pharmaceuticals in its written reply stated as under:-

"The Ministry of Finance communicated a Plan outlay of (Gross Budgetary Support) Rs 160.00 crore for the year 2016-17 to the D/o Pharmaceuticals. No Scheme wise break up was communicated by them. The Scheme wise allocation of this provision of Rs 160.00 crore has been determined by the Department based on the inter-se scheme -

wise priorities and within the reduced allocation of Rs. 160.00 crore made available. No reasons for this reduced allocation have been communicated by the Ministry of Finance".

3.4 A statement showing the Budget Estimates, Revised Estimates and Actual Expenditure for the last three years (year-wise) and Budget Estimates for the year 2016-17 showing separately for Plan and Non-Plan expenditure;

Plan

(Rs in crore)

S.No.	Head	2013-14			2014-15			2015-16			2016-17
		BE	RE	Actual	BE	RE	**Actual	BE	RE	Actual (asOn 19.2.2016	BE
	Revenue										
1	Sectt.	1.00	1.00	0.91	1.00	1.00	0.7329	1.00	1.00	0.5360	-
2	NIPERs	69.70	42.64	45.07	87.00	31.80	35.47	98.96	84.21	93.6320	80.50
3	NPPA	4.00	0.00	0.00	2.00	2.00	2.00	5.00	3.00	1.4931	5.45
4	Other Schemes	62.84	17.89	17.89	64.00	20.70	9.4975	82.00	39.17	26.3147	52.47
5	PPDS	2.00	1.25	0.93	2.00	1.50	1.4459	2.00	2.00	0.9012	2.00
6	NE Region	18.80	3.00	0.00	21.00	4.00	3.91	21.00	21.00	21.00	19.52
	Total Revenue	**158.34**	**65.78**	**64.80**	**177.00**	**61.00**	**53.0563**	**209.96**	**150.38**	**143.8770**	**159.94**
	Capital										
7	HAL	14.17	6.20	6.20	16.79	14.49	14.49	0.01	-	-	0.01
8	BCPL	9.30	0.00	0.00	7.00	7.00	7.00	0.01	-	-	0.01
9	IDPL	6.19	3.02	3.02	5.00	5.00	5.00	0.01	-	-	0.01
10	RDPL		0.00	0.00	1.21	0.00	0	0.01	-	-	0.01
11	SSPL									-	0.01
12	BIL									-	0.01
	Total Capital	**29.66**	**9.22**	**9.22**	**30.00**	**26.49**	26.49	**0.04**	**-**	**-**	**0.06**
	Total	**188.00**	**75.00**	**74.02**	**207.00**	**87.49**	79.4563	**210.00**	**150.38**		**160.00**

*74.02 crores (without recovery) (Rs.74.02 crores-Rs.5.84 crore recovery = Rs.68.18 crores

** provisional

3.5 When asked the reasons for increase in BE 2016-17 to Rs.52.49 crore from Rs.39.17 crore in RE 2015-2016 for other schemes and how the Department of Pharmaceuticals propose to utlise the increased amount during 2016-17, the Department in its written reply stated as under:-

"The "Other Schemes" and the allocations thereof the Department are as under:-
i) Creation of IPR Facilitation centre at Pharmaxil,(Rs. 0.01 crore) ii) Pharmaceuticals Technology Upgradation Assistance Scheme(PTUAS),(Rs.0.01 crore) iii) Cluster Development. (Rs. 10 crore) iv) Scheme for Kala Azar and Anti Tubercular Agents.(Rs. 2.44 crore) v) Setting up of Venture Capital Fund for financing drug design, discovery & innovation in Pharma Sector,(Rs 0.01 crore) vi) Setting up of Medical Device Promotion Council (Rs. 0.01 crore) vii) Setting up of Pharma Promotion Council,(Rs. 0.01 crore)

viii) Critical assistance for WHO pre qualification for Pharma PSUs/R&D, (Rs. 5.00 crore) ix) Jan Aushadhi.(Rs. 35 crore), etc."

Non Plan

(Rs. In crore)

Head	**2013-14**			**2014-15**			**2015-16**			**2016-17**
	BE	**RE**	**Actual**	**BE**	**RE**	****Actual**	**BE**	**RE**	**Actual**	**BE**
Revenue										
Sectt.	9.00	8.75	8.50	11.72	9.69	8.60	11.28	9.64	8.44	12.66
NPPA	7.71	7.34	6.74	12.07	9.31	8.36	10.21	7.64	7.01	11.21
PEPS	.01	0.01	0.01	0.01	0.01	0.00	0.01	-	-	0.01
NIPER	23.57	19.20	19.20	17.03	20.87	16.50	27.48	27.48	27.48	27.48
Total Revenue	**40.29**	**35.30**	**34.45**	**40.83**	**39.88**	33.46	**48.98**	**44.76**	**42.93**	**51.36**
Capital										
SSPL	0	0								-
BCPL	0.01	0.01	0.00	0.01	0.00		0.01		-	0.01
BIL	0.01	0.01	0.00	0.01	0.00		0.01		-	-
IDPL	0.01	0.01	0.00	0.01	0.00		0.01		-	0.01
HAL	0.01	5.00	5.00	0.01	9.67	9.67	0.01	24.25	24.25	0.01
RDPL	-	-	-	-	-	-	-	-	-	0.01
Total Capital	0.04	5.03	5.00	0.04	0.00		0.04	24.25	24.25	0.04
Grand Total	**40.33**	**40.33**	**39.45**	**40.87**	**9.67**	**9.67**	**49.02**	**69.01**	**67.18**	**51.40**

*The savings/surrender figure shown is as on 10.03.2015 and the same is provisional. However, the actual surrender/savings figures shall be based on the expenditure to be booked till 31.3.2015

3.6 When asked to give reasons for reduced allocation in BE 2016-17 Rs.51.40 crore from RE 2015-16 Rs.69.01 crore , the Department in its written reply stated as under:-

"Rs. 69.01 crore is the RE figure during the year 2015-16 under Non Plan which includes Rs. 24.25 crore as Loan given to HAL by drawing supplementary through Contingency Fund of India as per the demand raised. Hence the same is higher compared to BE of Rs. 51.40 crore during the year 2016-17".

3.7 During the course of evidence, the Secretary Department of Pharmaceuticals informed the Committee about the fund allotment to the Department as under:-

"...budget allocation for the Department is substantially less. That has been because during the past years the Department also could not perform sufficiently though money was given at the rate of Rs.200 crore per year. It varies from time to time but Rs.200 crore is the limit. Out of Rs.200 crore, every year in the RE it gets cut to Rs.100 crore. Out of Rs.100 crore out expenditure used to be Rs.70 crore or Rs.80 crore. So, the Department's spending capacity has been very very poor in the past. As a result, even today when we ask for more money it is not forthcoming. For the current year we needed about Rs.2,800 crore. But what is given is only Rs.160 crore for the current year. With Rs.160 crore the Department can hardly survive. We can give salaries to the people and we can manage in the most economic way. Nothing substantial could happen in the Department. If substantial should happen in the Department I think we need more allotment, especially for the NIPER sector because we have laid foundation stone for NIPERs in Guwahati and Ahmedabad and we are going to lay foundation stone for Hyderabad and Madurai. For all these things we require at least Rs.200 crore per year. That is the expenditure requirement. But we get hardly Rs.10 crore or Rs.5 crore. With that money we cannot even do the compound wall for the NIPERs. So, we require badly additional fund allotment which we think we can get in the subsequent supplementary budget and other REs.

Further elaborating in the issue the Secretary, submitted the following :-
Similar is the case for New Initiatives like venture capital fund, technology upgradation fund. For all these segments we need more allotment. That is all"

CHAPTER-IV

DEMANDS FOR GRANTS FOR THE YEAR 2016-17

4.1 Budgetary allocation under Plan and Non-Plan under Major Head during the year 2015-16 and 2016-17 is indicated below **(Annexure I)**:-

(Rs. in crore)

Major Head	**Budget Estimates 2015-16**			**Revised Estimates 2015-16**			**Budget Estimates 2016-17**		
	Plan	Non Plan	Total	Plan	Non Plan	Total	Plan	Non-Plan	Total
Revenue	209.96	48.98	258.94	150.38	44.76	195.14	159.94	51.36	211.30
Capital	0.04	0.04	0.08	-	24.25	24.25	0.06	0.04	0.10
Total	**210.00**	**49.02**	**259.02**	**150.38**	**69.01**	**219.39**	**160.00**	**51.40**	**211.40**

The Committee have been informed that the actual expenditure by the Department during 2015-16 was Rs.143.20 crore under Plan and Rs.70.09 crore under Non-Plan.

4.2 When asked by the Committee about the reasons for the increase in Revenue Head from Rs. 195.14 crore in RE 2015-16 to Rs.211.30 crore in BE 2016-17 and how the Department propose to utilise the increased amount, the Department of Pharmaceuticals in its written reply stated as under:-

> "The increase under Revenue Head to Rs 211.30 crore in 2016-17. BE is on account of increase of both Plan & Non Plan provisions compared to RE 2015-16. Under Plan (Revenue), an increase of 6.36% in total allocation has been made in BE 2016-17 over RE 2015-16 but this provision is less than the provision of Rs. 209.96 crore made in BE 2015-16 (Plan Revenue). The provisions are proposed to be utilised for pressing requirements of Plan Schemes such as NIPERs, including new NIPERs, Jan Aushadhi Scheme, setting up of National Centre for R&D in Bulk Drugs, Critical Assistance for WHO for Pharma PSUs, PPDS, Cluster Development Programme etc".

4.3 On being asked by the Committee to give reasons for drastic reduction in allocation from Rs.24.25 crore in RE 2015-16, to Rs.0.10 crore in BE 2016-17 under Capital Head, the Department in its written reply stated as under:-

> "As per Demand, Rs.24.25 crores of Non-Plan Loans were granted to Hindustan Antibiotics Limited to make payment of arrears of salaries and other contingent expenditures by the way of sanction of Rs.11.50 crore at the time of 1st Technical supplementary and 2nd Supplementary Demand for Grants 2015-16 through Contingency Fund of India. However in BE 2016-17,under Plan provision an amount of Rs 0.06 crore has been allocated which is higher them the BE 2015-16 Plan allocation of Rs 0.04 crore . Thus under plan provisions an increased amount has been provided for Assistance to PSUs i.e IDPL, HAL, BCPL etc. It may be noted that though Rs 0.06 crore has been provided under Plan Capital head, it is far short of the actual requirements under this head. In view of pressing requirements of ongoing and new Plan Schemes, out of a total reduced Plan allocation of Rs. 160 crore, Rs. 159.94 crore was provided under Revenue Head and only Rs. 0.06 crore could be made available under Capital Head".

HEAD-WISE ANALYSIS OF DEMANDS FOR GRANTS (2016-17)

i. MAJOR HEAD 3451- <u>Secretariat – Economic Services</u>

(Rs.in crore)

BE 2015-16			RE 2015-16			BE 2016-17		
Plan	**Non Plan**	**Total**	**Plan**	**Non Plan**	**Total**	**Plan**	**Non Plan**	**Total**
1.00	11.28	12.28	1.00	9.64	10.64	-	12.66	12.66

ii. MAJOR HEAD 2852: <u>Pharmaceutical industries</u>

(Rs.in crore)

BE 2015-16			RE 2015-16			BE 2016-17		
Plan	**Non Plan**	**Total**	**Plan**	**Non Plan**	**Total**	**Plan**	**Non Plan**	**Total**
187.96	37.70	225.66	128.38	35.12	163.50	160.00	51.40	211.40

4.5 On being asked to give justification for increase in Plan allocation from Rs.128.38 crore in RE 2015-16 to Rs.160 crore in BE 2016-17, the Department in its written reply stated as under:-

> "The total R.E. 2015-16 (Plan) for the Department is Rs.150.38 crore. The total allocation of B.E. 2016-17 (Plan) for the Department is mere Rs.160.00 crores only compared to Rs.2891.47 crores proposed by the Department for B.E. 2016-17(Plan)".

iii. MAJOR HEAD 2852:

<u>National Institute of Pharmaceuticals Education and Research (NIPER)</u>

(Rs.in crore)

BE 2015-16			RE 2015-16			BE 2016-17		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
98.96	27.48	126.44	84.21	27.48	111.69	80.50	27.48	107.98

4.6 On being asked the reasons for decrease in allocation for BE 2016-17 to Rs.107.98 as compared RE 2015-16 Rs.111.69 crore and how does the Department plan to utilize and ensure optimum utilisation of funds of Rs.107.98 crore allocated to NIPER for the year 2016-17, the Department in its written reply stated as under:-

> "NIPER Division requested to allocate Rs. 1500.98 crore. However, against this only Rs. 100.00 crore has been allocated to NIPER Division. The reason for less allocation of fund at BE stage can only be clarified/justified by the Ministry of Finance".

iv. MAJOR HEAD 2852: <u>National Pharmaceutical Pricing Authority (NPPA)</u>

(Rs.in crore)

BE 2015-16			RE 2015-16			BE 2016-17		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
5.00	10.21	15.21	3.00	7.64	10.64	5.45	11.21	16.66

4.7 On being asked the reason for increase in allocation in BE 2016-17 to Rs.16.66 crore as compared to RE 2015-16 Rs.10.64 crore and how the Department proposes to utilise the increased amount, the Department in its written reply stated as under:-

"NPPA will utilize the Plan Funds of Rs. 5.45 crore under Plan Scheme of Consumer Awareness, Publicity and Price Monitoring. The Scheme has 2 components - a central component and a state component. The central component includes the joint publicity campaign by the NPPA and Department of Consumer Affairs on a 50:50 cost sharing basis. The state component comprises setting up of Price Monitoring and Resource Units (PMRUs) at the State/Union Territories to provide all necessary support to the State Drug Controllers in carrying out monitoring and enforcement activities under the Drugs (Prices Control) Order, 2013 in their respective jurisdictions.

The Non-Plan funds of Rs. 11.21 crore provided in BE 2016-17 will be utilized under various Object Heads such as Salary, Wages, Rent, Rates & Taxes, Office Expenses, Domestic Travel, Foreign Travel, Professional Services, Other Administrative Expenses, etc as per funds provided under each Object Head".

V. MAJOR HEAD 2852: <u>Jan Aushadhi Scheme</u>

(Rs.in crore)

BE 2015-16			RE 2015-16			BE 2016-17		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
35.00	--	35.00	16.92	--	16.92	35.00	--	35.00

4.8 When asked to give reasons for higher allocation for the Jan Aushadhi Scheme from RE 2015-16 Rs.16.92 crore to Rs.35 crore in BE 2016-17 and the action plan of the Department to utilize optimally the funds earmarked for the Scheme for the year 2016-17, the Department in its written reply stated as under:-

"For the year 2015-16, an amount of Rs. 35 crore was earmarked for Jan Aushadhi Scheme. This Budget Estimate was reduced to Rs. 16.9147 Crore in the Revised Estimation. For the year 2016-17, the Budget Estimate (BE) has been kept at the same level as for the year 2015-16 i.e Rs. 35 Crore. For the Financial year 2016-17, it has been decided to open 3000 Jan Aushadhi Stores by the end of March 2017. In addition the product basket of Jan Aushandi Stores would be increased to 577 medicines, 165 surgical and consumables covering almost all the major therapeutic categories. Besides to create awareness an effective media campaign through various media system e.g. print media, electronic media etc. is to be run. Hence, the Budget of Rs. 35 Crore for the year 2016-17 for Jan Aushadhi Yojana will be utilized fully. It is expected that more funds may be required to meet the targets".

VI MAJOR HEAD -2552:

<u>Provision for Northeastern Region & Sikkim</u>

(Rs.in crore)

BE 2015-16			RE 2015-16			BE 2016-17		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
21.00	**-**	**21.00**	**21.00**	**--**	**21.00**	**19.49**	**0.01**	**19.50**

4.9 On being asked to give reasons for reduced allocation for Plan BE 2016-17 to Rs.19.50 crore from Rs.21.00 crore in RE 2015-16 and the how the Department to utlise the funds optimally during the year 2016-17, the Department in its written reply stated as under:-

> "The construction work of campus of NIPER, Guwahati has already been started. To ensure timely completion of the construction work, NIPER division requested to allocate Rs. 174.70 crore. However, against this only Rs. 19.50 crore has been allocated to NIPER division. The reason for less allocation of fund at BE stage can only be clarified/justified by the Ministry of Finance. During 2015-16, an amount of Rs. 21.00 crore was allocated and the same was utilized. In fact more funds are required to complete the construction work in time. For this purpose, an amount of Rs. 20.00 crore was demanded under 3rd Supplementary Grant, but no fund has been allocated".

CHAPTER-V

IMPORTANT AUTHORITY/SCHEMES/INITIATIVES

A NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

5.1 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.

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

Salient features of DPCO, 2013.

- The National List of Essential Medicines (NLEM), 2011 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 pricesof scheduled formulations are based on "market based data" unlike cost based calculations under DPCO, 1995.
- The 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.

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

- To implement and enforce the provisions of the Drugs (Price Control) Order (DPCO), 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 drugs, 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 on the decisions of the Authority.
- To render advice to the Central Government on changes/revisions in the drug policy.
- To render assistance to the Central Government in parliamentary matters relating to drug pricing.

5.2 **Price Fixation:**

Under the market-based approach adopted in DPCO, 2013, the ceiling price of a scheduled drug is determinedby first working out the simple average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular drug 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.

The DPCO 2013 contains 680 scheduled drug formulations spread across 27 therapeutic groups, which effectively comes to 628 scheduled drug formulations if we net those appearing in more than one therapeutic group. NPPA has fixed the ceiling prices of 530 formulations under DPCO, 2013 as on 31st October 2015. For remaining 98 formulations, NPPA has not been able to fix the ceiling prices due to non-availability of market based data.

The status of fixation of ceiling prices under DPCO, 2013 is given as under:

Pricing Status of scheduled formulations as on 31.10.2015

Sl. No.	Particulars		
1	Total number of NLEM medicines		680
2	Medicines appearing in more than one therapeutic group of DPCO, 2013		52
3	Net medicines for which prices are to be fixed		628
	Break up of number of items dealt under different category		
4	Ceiling prices fixed upto 25th Authority Meeting (held on 29.10.2015)	530	
5	Ceiling price fixation pending due to non-availability of Market based price data	98	
	Total =(4)+(5)		628

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 has also notified 247 retail prices of new drugs on request of the manufacturers till 31st October, 2015.

NPPA is also empowered, in extra-ordinary circumstances, if it considers necessary to do so in public interest, to fix the ceiling price or retail price of any drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified. NPPA may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year. Accordingly, NPPA has fixed prices of 106 non-scheduled anti-diabetic and cardio vascular medicines under paragraph 19 of DPCO, 2013 on 10.7.2014.

5.3 **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 would be tantamount to overcharging the consumer, which is liable to be recovered from the pharmaceutical company along with interest thereon from the date of overcharging. The excess collection on account of overcharging along with interest is recoverable as arrears to land revenue under the Public Demand Recovery Act. 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.

No manufacturer shall increase the maximum retail price of a non-scheduled drug formulation more than ten percent of maximum retail price during preceding twelve months.

The notified ceiling price with respect to scheduled formulations is valid for a period of five years from the date of original price notification, but subject to annual revision to be notified by NPPA which would be effective from the first day of April every year as per the annual wholesale price index (WPI) notified by the Department of Industrial Policy and Promotion with respect to the previous calendar year. The revision may mean increase or decrease in ceiling price depending upon whether the WPI is positive or negative.

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 undertakes market surveillance of prices of scheduled drugs 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 complaintsreceived from individuals / NGOs/VIP references, etc.

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 2007-08 to 2015-16 (upto October, 2015) are given as under:

Year	No. of Samples Collected	Prima Facie Violations detected	Referred for Overcharging
2007-2008	1450	840	456
2008-2009	520	284	172
2009-2010	464	246	208
2010-2011	553	225	216
2011-2012	559	156	152
2012-2013	626	165	163
2013-2014	993	389	389
2014-2015	3898 #	924	924
2015-2016*	2104 #	382	382

*387 cases under process on 31.10.2015
#Cases of Overcharging referred from State Drug Controllers are included under the column 'Samples Collected'.

5.4 When asked to give details about the recovery of the overcharged amount, status of recovery of the overcharged amount and whether any methods like mediation and arbitration has been followed for the quick recovery of the overcharged amount , the Department in its written reply stated as under:-

"Since inception of NPPA, there are 1389 cases as on 29.02.2016 (1250 cases under DPCO 1995 & 139 cases under DPCO 2013) where demand notices have been issued by NPPA to Pharmaceutical companies. The status of these cases is as under:

(Rs. in Crores)

Sl.No	Particulars	DPCO 1995	DPCO 2013	Cumulative (Aug, 97 to 29.02.2016)
1	No. of cases	1250	139	1389
2	Overcharged amount demanded including interest whenever updated	4861.52	74.4	4935.92
3	Total amount realised	316.31	68.6	384.91
4	Amount outstanding (2-3)	4545.21	5.80	4551.01
5	Cases under Litigation including Cases referred to collector but contested by the companies in the court of law and in r/o Cipla Ltd. & its associate , where no coercive action can be initiated as per order of Supreme Court	3673.36	24.96	3698.32
6	Cases referred to Collector & amount still to be recovered	67.85	0.01	67.86
7	Pending with BIFR/ Official Liquidator	5.41	0	5.41
8	Amount pending in respect of the overcharging cases under process (4-(5+6+7)	798.59	-19.17	779.42

Further, the demand raised in 37 overcharging cases under DPCO, 2013 amounting to Rs. 145.11 crore against the petitioner companies have been treated as show cause notices in pursuance of order dated 24.11.2015 passed by the Hon'ble High Court of Delhi in various writ petitions filed by them.

Action for recovery of the overcharged amount along with interest thereon is a continuous process and NPPA takes action as per the provisions of DPCO"1995/ DPCO"2013 read with EC Act 1955. The recovery of the overcharged amount is affected due to Court orders passed by the various High Courts and also by Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation order / notification issued by NPPA / Government under DPCO 1995. Inclusion of some Bulk Drugs under Price Control (schedule-I of DPCO, 1995) has also been challenged by the pharma companies in different courts of India. NPPA / Government is defending such cases through SG, ASG"s and Senior Government Counsels. Whenever necessary, NPPA files urgent application in the Courts for vacation of interim orders and also for early hearing / disposal of the case. NPPA has recently streamlined its guidelines regarding action in overcharging cases which will expedite the entire process in a transparent and effective manner.

It is further stated that NPPA so far has not adopted any method like mediation and arbitration for quick recovery of the overcharged amount. On the advice of the DoP, NPPA has prepared a draft for One Time Settlement (OTS) with an aim of quick recovery of overcharged amount and sent to DoP on 8.2.2016. NPPA is waiting for its formal approval. However NPPA files urgent application in the courts for vacation of interim orders and also for early hearing/ disposal of the case. The cases referred to Collectors for recovery of the outstanding demanded amount from the company are followed with them vigorously. The cases under process with NPPA are also followed up with the concerned companies vigorously.

5.5 During the course of evidence, the Secretary of the Department on the issue of selling of drug at higher cost stated as under:-

"Sir, this is done by, National Pricing Authority, suppose they find a particular company is selling a particular drug at a high cost, they fix a particular cost level. If a particular company is selling a drug at a higher cost, if it is found by inspections, then our people calculate and they say that this is the amount we have over-charged. So, we have got Rs. 4000 crore worth of over-charging amount due from the companies. We have recovered at least Rs. 389 crore or so. We have been able to recover only 10 per cent. All the remaining amounts are pending in courts and disputes. Usually what happens is that when we send notices they go to courts and courts after courts and they never repay this money. So, that is why we thought that we could give one time settlement so that companies can find it easy to sort out this particular issue. But suppose we say that you pay 50 per cent of the amount, only principal amount and no interest, if such a decision is taken, then companies will be very happy and we could also recover the money. A proposal was worked out two years back. It was approved by the hon. Minister. Then it went to the Finance Ministry. The Finance Ministry said that we should not give this one time settlement."

5.6 The Secretary further added that:-

"Sir, that is the whole issue. In Government of India, a clerk can spoil the entire thing. So, the Finance Ministry did not approve this. Now we have re-worked. We have got a proposal ready from the NPPA. We will again send the proposal with justification. It is because the Finance Ministry thinks that the entire money could be recovered which is very difficult. For another 20 years we cannot recover this money. After 20 years even if we recover the entire money, the value will be half of this only. If we give concession, we will get money and the companies would also be happy. So, we are re-working the scheme and we will justify the entire proposal and we will again send it to the Finance Ministry".

B NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPER)

5.7 Government of India had set up a National Institute of Pharmaceutical Education & Research, Mohali as a Society in the year 1991and it was given statutory recognition by an Act of Parliament in 1998. Later on, six more NIPERs has been set up one each at Ahmedabad (Gujarat), Hyderabad (Andhra Pradesh), Hajipur (Bihar), Kolkata (West Bengal), Guwahati (Assam) and Rae Bareli (Uttar Pradesh) at an estimated cost of Rs.750.00 crore in phase-I. In 2012, NIPER, Madurai was approved. The hon'ble Finance Minister during Budget Speech for 2015-16 announced three new NIPERs at Maharashtra, Rajasthan and Chhattisgarh and these NIPERs are in the process of setting up.

5.8 The National Institute of Pharmaceutical Education & Research, Mohali was established as a mother institution to set standards of excellence for pharmaceutical sciences and for research and development in the field of pharmaceuticals. It is the first national level institute in India in the field of Pharmaceutical sciences and has been declared as an "Institute of National Importance" under the Act of Parliament on 26th June, 1998. National Institute of Pharmaceutical Education & Research, Mohali has been provided with full-fledged campus together with regular faculties. However, the remaining six New NIPERs are yet to be provided with buildings and regular faculty. In the year 2016-17 it is proposed to construct buildings and provide regular faculties for the new NIPERs. However, the budgetary provision is very limited to take up the same. Thus a supplementary demand is being proposed.

5.9 In 2016-17 an allocation of Rs.**77.96 crore** BE (Plan) has been made for new NIPERs excepting NIPER, Guwahati **including a provision of Rs.1.00 crore for NIPER, Madurai**. For NIPER, Guwahati requirement would be met out of available provisions for North-East to the tune of Rs.**19.50 crore**.

5.10 **New NIPERs**: New NIPERs will cater to the increased demand of the pharmaceutical industry for highly trained men power for continuous growth of the pharmaceuticals sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present all the new NIPERs are functioning with the help of Mentor Institutes.

(i) NIPER, Ahmedabad

The State Govt. has allotted land free of cost for Construction of campus at NIPER Gandhinagar. The foundation stone for NIPER Ahmedabad has been laid on 16.12.2015 and the construction work will start shortly. To start the construction work, during the financial year 2016-17 the Department proposed an amount of Rs.197.29 crore. However, only an amount of Rs. 21.96 crore has been allocated for the above stated purpose during 2016-17. The fund allocated is proposed to be utilized in meeting establishment expenditure and for construction activities of new campus for NIPER, Ahmedabad.

(ii) NIPER, Hajipur:-

Land has not been provided by State Government to NIPER, Hajipur despite relentless endeavours. The matter has been taken up with the concerned State Governments for allocation of land for NIPER, Hajipur. Even in the recent Eastern States Standing Committee meeting held at Ranchi by the secretary Inter State Council on 29.01.2016, the Bihar State Government representative informed that Government of Bihar stand remains the same as earlier. The funds required for meeting expenses for establishment related to essential expenditure to run the Institute.

(iii) NIPER, Guwahati:-

The State Govt. has allotted land free of cost for Construction of campus at NIPER Guwahati. The Department had since awarded the work of construction of NIPER campus from concept to completion at Guwahati to Engineering Project India Ltd. (EPIL). The hon’ble Minister (C&F) laid the foundation stone for NIPER Guwahati on

30.05.2015. Already Rs.20 crores(approx.) work has been done. The construction work has already been started. In fact a proposal for allocation of additional fund amounting to Rs 20.00 cr for construction work at NIPER Guwahati has been sent to Ministry of Finance to increase the pace of the construction work. The Department proposed an amount of Rs.174.70 crore for the purpose. However, only an amount of Rs.19.50 crore has been allocated for the above stated purpose during 2016-17 which is not sufficient. The fund allocated is proposed to be utilized in meeting Establishment expenditure and for construction activities of new campus for NIPER, Guwahati.

(iv) NIPER, Kolkata:-

National Institute of Pharmaceutical Education & Research (NIPER), Kolkata was set up to nurture and promote quality and excellence in Pharmaceutical education and research at Masters and Ph. D level after the State Government committed to provide 100 acre of land free of cost. Government of West Bengal has been requested to allocate 100 acres of land free of cost without encumbrance. The matter has been followed up vigorously with the State Government. However, response from the State Government is yet to be received. Both Union Minister & Secretary have taken up the matter with Chief Minister of West Bengal & Chief Secretary respectively. Regrettably, the Government of West Bengal earlier allocated 35 acres with a demand to pay Rs.71.00 crore as external development charges. The Union Government is not able to pay this amount as this was not mandated by the Cabinet while allocating funds for NIPERs. The State Government now offers only 30 acres which is totally insufficient. The funds required for meeting expenses for establishment related and essential expenditure to run the Institute.

(v) NIPER, Hyderabad:-

Memorandum of Understanding (MoU) has been signed between NIPER, Hyderabad and National Project Construction Corporation (NPCC) Ltd. on 09.12.2015 for construction of NIPER campus as well as National Centre for Research and Development in Bulk Drugs(NCRDBD). In the proposed BE 2016-17, Department has sought Rs.193.02 crore for NIPER, Hyderabad and Rs.36.75 crore for NCRDBD so that the construction of NIPER campus as well as of NCRDBD can be completed well in time. However, only an amount of Rs.35 crore for NIPER, Hyderabad and Rs.0.01 crore for NCRDBD have been allocated for the above stated purpose during 2016-17. The fund allocated is proposed to be utilized in meeting Establishment expenditure and for construction activities of new campus for NIPER, Hyderabad.

(vi) NIPER, Rae Bareli:-

The State Government has allotted land free of cost for construction of campus at NIPER, Raebareli. The NIPER, Raebareli has taken possession of land. The funds required for meeting expenses for establishment related and essential expenditure to run the Institute and for construction activities of new campus for NIPER, Rae Bareli. In the proposed BE 2016-17, the Department has sought Rs.176.59 crore. However, an amount of Rs.07.00 crore has been allocated during 2016-17 for NIPER, Raebareli.

(vii) NIPER, Madurai:-

For setting up of NIPER in Tamil Nadu, Government of Tamil Nadu has allocated land at Madurai. In the proposed BE 2016-17, the Department has sought Rs.174.10 crore. However, an amount of Rs.1.00 crore has been allocated during 2016-17 for the above said purpose.

5.11 When asked regarding proposals for new NIPERs, the Secretary Department of Pharmaceuticals during the course of evidence stated as under:-

> "We have recommended new NIPER proposals but in this year budget they have not announced new NIPERs. When the old themselves are pending for want of funds, I do not think we should recommend a new proposal"

5.12 During the course of evidence the representative from NIPER, Ahmedabad stated as under:-

> "For NIPER, Ahmedabad, we got land in 2008. Now, our BOQ has already been approved and we are waiting for the funds to be sanctioned. Our tender document is also ready but until and unless we get the approval of funds, we cannot release the tender. So we cannot start the construction work. I request that it may be taken seriously"

5.13 When asked about the setting up of more NIPERs, the Secretary, Department of Pharmaceuticals during the course of evidence stated as under:-

> "Last year, apart from the seven institutes, one institute is coming up at Madurai. Land has been allotted and they have been waiting for construction. We have to get certain approvals of the Cabinet which we are processing. Besides, three more NIPERs have been approved by the Government of India. One is at Chhattisgarh, the second is Maharashtra and the third one is Rajasthan. At all these places, we have identified land except Chhattisgarh and we will be initiating acting to start the courses by locating the mentor institutes. During the current year, we thought Karnataka will be able to get one NIPER because our Minister has been pitching for it for some time. Madhya Pradesh has also been pitching for one. We thought we could get NIPERs at bifurcated State of Andhra Pradesh. So, we thought we could get these three more NIPERs also. But, somehow the Government of India did not approve this thing because they know other NIPERs which have been announced are running short of funds. So, once these things improve, slowly we can go for new NIPERs".

5.14 When asked about concentrating some attention on the North Eastern India, the Secretary, Department of Pharmaceuticals during the course of evidence stated as under:-

> "In the Northeast we have NIPER in Guwahati. A separate complex is being constructed at a cost of about Rs.500 crore. We have started the work and last year we spent about Rs.20-30 crore. During the current year we are likely to spend more amount and a new campus will come in about a year's time for the Northeast. If that comes up it will have a separate identity to promote pharmaceutical research especially in phyto-chemicals. Northeastern region has got a lot of flora and using them they will produce a lot of phyto-chemicals in that areas".

C. <u>Jan Aushadhi Scheme</u>

5.15 Jan Aushadhi scheme is being implemented in the country through Bureau of Pharma PSUs of India (BPPI) under the administrative control of Dept. of Pharmaceuticals. This noble project launched in 2008 could not achieve its desired objectives.

Progress achieved during 2015-16.

5.16 BPPI has analyzed the existing status and progress of the Scheme in a big way through organising brain storming sessions and discussions with various stake holders and formulated Strategic Action Plans to achieve the objectives set by the Government. Key areas of significance identified were Availability, Acceptability, Accessibility, Affordability, Awareness and Effective Implementation of the Scheme. For effective implementation of the Scheme, the BPPI, has also been strengthened. The augmentation of the product basket of the Jan Aushadhi Scheme from 425 medicines whose quality is approved by National Accreditation Board for Testing and Calibration Laboratories (NABL), covering almost therapeutic categories and 100 surgical items to 577 medicines and 165 surgical consumables is under progress. To ensure regular and uninterrupted availability of medicines to all the needy people through Jan Aushadhi Store, a Central Ware-house has been established and the requite number of Carrying and Forwarding (C&F) agents have also been appointed. Besides, the supply chain is monitored regularly by BPPI.

5.17 As on 10.3.2016, 263 stores (spread over 21 States/UTs) are functional in the country. Out of these 263 stores, 164 stores have been opened in the year 2015-16. It is expected that total 300 stores would be opened up to 31.03.2016. It has been decided to open 3000 Jan Aushadhi Stores by the end of March, 2017.

5.18 **Major changes in Jan Aushadhi Scheme Action Plan:**

Financial support to JAS: An amount of Rs.2.5 lakhs shall be extended to NGOs/agencies/individuals establishing JAS in government hospital premises where space is provided free of cost by Govt. 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

5.19 JAS run by private entrepreneurs / pharmacists / NGOs / Charitable organizations that are linked with BPPI headquarters through internet shall be extended an incentive up to Rs. 1.5 lakhs. This will be given @ 10% of monthly sales subject to a ceiling of Rs. 10,000/- per month up to a limit of Rs. 1.5 lakhs. In NE 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. 1.5 lakhs.

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

5.20 **Awareness:** BPPI intends to create awareness about Jan Aushadhi and its stores in the towns where Jan Aushadhi Stores are already established using integrated media platform. Facelift of the Jan Aushadhi stores is required with standardized branding across all old stores as well as in the new stores. Various publicity channels like print media, visual media, SMS and other direct communication methods will be taken up. BPPI has already taken part in 4 exhibitions / workshops, Dhan Foundation at Indian Habitat Centre, Perfect Health Mela 2015, IITF 2015, and India Pharma Expo 2016.

5.21 **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 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 Govt. departments. Seminars / Workshops inviting Doctors, Scientists, Government officials and other stakeholders will be also organized.

5.22 During the course of evidence the Secretary, Department of Pharmaceuticals on the opening of 3,000 Jan Aushadi Stores in the year 2016 stated as under:-

> "Jan Aushadhi was started in 2008. From 2008 till 2014 we had only 100 shops in operation. Now we have about 265 shops. Almost 165 shops were opened in the last one year. And we intend to upscale it to 3,000 shops by this year end. It is a very massive target but we have worked out programmes, we have streamlined the procedures, we are strengthening the organization which is entrusted with the responsibility of opening these shops, we are improving the supply chain mechanism and we are involving a large number of NGOs and charitable and private hospitals so that our expenditure is less and with low expenditure we can open many shops. If we have to open these in government hospitals, we have to give Rs.2.5 lakh grant to the hospital. If we have to open them in private sector other than government hospitals, our expenditure is very less. With no expenditure we can open these shops. So, we are

adopting that methodology. And we are also likely to get more funds in the RE stage depending upon our performance. Fund is not going to be a constraint for Jan Aushadhi stores. Earlier we used to get allotment of about Rs.35 crore per year and we used to spend hardly Rs.5 crore. That is why government is not giving much. But once we demonstrate that we can open many shops, I think Government will not hesitate to give more money for the Jan Aushadhi scheme.

Recently we have opened 108 shops in one State alone and that is Chhattisgarh. Like that, now we are discussing with many other States like Andhra Pradesh, Telangana. We are discussing this with the Northeastern States like Assam, Jammu and Kashmir, Himachal Pradesh, Punjab, Haryana, even Delhi. I think when we demonstrate to open many stores, fund will not be a constraint".

5.23 When asked the reason for poor achievement of Jan Aushadi Yojana, during the course of evidence the Secretary Department of Pharmaceuticals stated as under:-

"The Jan Aushadi Scheme was initiated in the year 2008. The idea is to sell generic drugs at very cost effective rates of about 30 per cent or 40 per cent to the people. A few States in the entire country are already distributing generic drugs in government hospitals. For example, Tamil Nadu Government has been distributing them for the past about 30 years free of cost in government hospitals. So, there is no incentive to open such shops in Tamil Nadu Government hospitals.

Andhra Pradesh, Rajasthan and a few other States like West Bengal started Jan Aushadi Stores. Rajasthan started at least 100 stores. West Bengal started similar 100 stores. But they also thought that in the government hospitals they should supply generic drugs as in the case of Tamil Nadu. They also wanted to adopt that model. West Bengal thought they should adopt their own model. Recently they started to purchase branded drugs, which are very popular among the public, at cost price and they are able to give the entire drugs to the public at 50 per cent price. When people come to know of 50 per cent reduction, everybody goes and purchases that. That is a very successful scheme. They have closed all Jan Aushadi outlets and introduced this scheme. Similarly, Rajasthan Government introduced a free drug scheme in government hospitals and closed Jan Aushadi stores. So, whatever Jan Aushadi stores were opened have been closed down in certain States.

The second important hurdle is that there should be generic drugs prescribed by doctors for giving out in Jan Aushadi stores. Usually doctors do not want to prescribe them if they see that they are cheap. They think cost effective drug means poor quality drug. That impression is there even among doctors which is not true. The same drugs are branded and they are sold at high rates by the private companies.

....I am just talking about the general impression. They often demand doctors to prescribe branded drugs; otherwise, they think low cost drugs are not good. Now, we are trying to change the image. We are educating the doctors and patients and trying to increase the number of shops

5.24 When asked if the Jan Aushadhi Scheme is re-launched, how many shops are going to be opened in the near future, the Secretary of the Department stated as under:-

"Regarding Jan Aushadhi Scheme, as I mentioned we had only small number of shops in the beginning. From 2008 to 2015 we had only 99 shops. We have scaled up and in one year alone we have opened 135 shops during the last year that is because we have re-worked the entire scheme. Earlier they were supplying only 100 drugs. In practice it used to come to less than 100 drugs. There was no good supply chain mechanism. In a particular place a drug is doing very well but for supply of the drug it used to take more time. Like a private company, if a drug is sold the next day you should be able to replace but our supply chain was very-very weak.

There was not much of awareness created. Training for doctors was not given. Now, we have re-worked the scheme in such a way that at any point of time our drugs will be numbering about 400 plus, that means 400 drugs will be available for all the therapist groups. Apart from 400 drugs we are also supplying 150 surgical items, like cotton injections. So, today at any point of time we can definitely have 550 products available. We are also trying to increase the number by another 100. Even if we supply 450-500 products I think that is a great success and a lot of things will go to our people.

As I mentioned, Sir, we are concentrating on places where there is scope for improved business for Jan Aushadhi. In Some State hospitals it will never go. Most States have not encouraged opening of Jan Aushadhi shops. We had a meeting of all State Health Secretaries and discussed with them. We asked them to send proposals to open shops in their Government hospitals. Everybody said that they are giving free drugs to the people. They used to give 40 or 50 drugs, maximum 100 drugs.

Under the impression that they are giving free drugs, they do not want any other shop to come in. So, they are never cooperative. But despite all these difficulties, we individually discuss with the people. We try to convince them and we have asked them to open shops. For instance, recently we discussed with the concerned officers of the Chhattisgarh Government. But they said that they cannot open shops because already they are giving free drugs and that there is no scope for Jan Aushadi shops. Then same day, we took extra effort and met the Health Minister and the Chief Minister. We explained them the advantages. Even after that, with a great amount of reluctance, they said that you can open some shops in Government hospitals. They have not opened them inside the hospital. People from outside also can purchase medicines from there. They have given strategic locations in the hospital premises. So, we could open 108 shops last month. These shops were opened by the hon. Prime Minister who visited Chhattisgarh for implementing various other State Government schemes. We made use of that particular occasion to open shops.

Similarly, we are now working with the Government of Kerala where we intend to open at least 300-400 shops. We have already signed an MoU. We have signed MoU with the Lions Club which wants to open such shops in its own hospitals. We want to open such shops in common service centres which are under the Department of Information Technology. They have common service centres in remote areas where people come and get common facilities like certificates and all these things. In 2000 centres, they want to open Jan Aushadhi shops. They have already given the applications to the State Drug Controller authorities for getting the drug licence. So intend to open these shops in all the remote areas. I think we will be able to cover all the remote areas during the current year. That is the reason why we have said that 3000 shops will be opened during the current year. I think we will upscale the Jan Aushadhi scheme. The intention of our Members that poor people should get drugs at a very cost effective rates, I think that dream will be fulfilled during the current year. We are taking all necessary steps to see that the Jan Aushadhi scheme is successful.

The cooperation of the State Governments is required very much because most of the Government hospitals require such facilities.

Sir, we have approached Members of Parliament to sanction mobile vans. We have designed a particular mobile vehicle. In fact, we have received proposals from more than 20 Members of Parliament. They have sanctioned Rs.15 lakh per vehicle. We will be launching these vehicles formally. These vehicles will go to difficult areas and they will supply these drugs.

Sir, in Arunachal Pradesh we are opening 27 shops. We have got proposals from Assam, Tripura and Manipur. We want to inaugurate more number of shops in north-east India".

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

5.25 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. The Ministry has introduced **Cluster Development Programme for Pharma Sector (CDP-PS)** on 27.10.2014.

5.26 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.

The Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant –in – aid to be released in various phases for creation of identified infrastructure and common facilities in the form of CommonFacility Centers(CFC) to Special Purpose Vehicles (SPVs) set up for the purpose.

5.27 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
- TrainingCentre
- EffluentTreatmentPlant
- R&D Centres
- CommonLogistics Centre

5.28 Projects and Development India Limited (PDIL) has been chosen as the Project Management Consulting (PMC) for implementing the scheme. They have called for EOI/SPV and in the first lot, out of the six EOIs, one was found suitable by the Scheme Selection Committee (SSC) to be located in Tamilnadu. SSC has requested PDIL to call fresh EOI which they have done and the last date of receipt of the EOIs is 31/12/2015.

5.29 **Reasons for shortfall in achievements**: Cluster Development Programme for Pharma Sector is a new scheme which was approved in February 2014. Projects and Development India Limited (PDIL) has been chosen as the Project Management Consulting (PMC) for implementing the scheme. They have called for EOI/SPV for the 1st Phase, out of the six EOIs, one was found suitable by the Scheme Selection Committee (SSC) to be located in Tamilnadu. SSC has requested PDIL to call fresh EOI which they have done and the last date of receipt of the EOIs was 31/12/2015. After that PDIL has extended the date till 31.01.2016. The meeting of Scheme Steering Committee (SSC) was held on 23/02/2016 to review the response to EOIs and implementation of the Scheme.

5.30 When asked to give reasons for no allocation of funds for the new schemes of Pharmaceuticals in BE 2016-17, the Department in its written reply stated as under:-

> "No grant in aid was released under the cluster development scheme during 2015-16 as none of the group of companies qualified for grant in spite of two rounds of EOIs. Presently, the Project Management Consultant (PMC) has been requested to review the whole process and suggest remedial measures. Till 2015-16, the grants for cluster scheme was covered under the head of new schemes but from this budget, the allocation has been made for cluster scheme separately. Although, a sum of Rs. 60 crore was requested for BE 2016-17 for the Cluster Development Scheme for Pharmaceutical Sector (CDP-PS). However, provision of Rs. 10 crores has been made in BE 2016-17 and supplementary requirements depending on the progress of scheme may be made with the approval of Ministry of Finance".

E <u>R& D in Drugs and Pharmaceuticals sector</u>

5.31 Pharmaceuticals Industry in India has a unique and exciting opportunity to grow by innovation ld research, development, and new drug discovery. However, R&D Indian Pharma sector is still in a nascent stage. As per Detailed Project Report (DPR) submitted by M/s Ernst & young (E&Y) to the Department of Pharmaceuticals in December 2014 the R&D spending of top Indian Pharmaceuticals was around only 4-6 % of net sales.

The main **hindrances** to the development of R&D in Indian Pharma Industry are:-

- It is difficult for domestic companies to produce a molecule based on their own research efforts due to shortage of funds required to sustain long period of drug discovery.
- Indian Pharma companies are facing strong competition from generic medicine producer from developing countries. Thus for these companies, selling generic drugs will not be enough. For growth and sustenance, innovative drugs need to be developed instead of reverse engineering generic drugs.

5.32 One of the major **mandates** of Department of Pharmaceuticals of India (DoP) is to promote R&D in the Pharmaceuticals sector. To achieve this mandate, DoP has already taken the following initiatives:

(a) Existing Scheme:-

Scheme for Development of new drugs for TB&Kalazar by NIPER, Mohali.

Department of Pharmaceutical is running following two interdepartmental collaborative project with NIPER, Mohali for development of new drugs for Tuberculosis and Kala Azar.

> (I)Target specific New Drug Discovery for Anti Tubercular Agents Project on Target Specific New Drug Discovery for Anti Tubercular Agent aims at discovering high affinity ligands that can be developed into efficacious and less toxic drugs against. TB among other things, this proposal use technique of post genomic era in identifying the role of specific gene in causing and contracting diseases. Phase I of the project has duration of 3 years and Phase II of 2 years. The total cost of the project is Rs.

4,88,00,000/-. The fund is to be released in four equal instalments of Rs. 1.22 crore for the project. The first two instalments have been released.

(II) Target specific new drug Discovery against Kala Azar. The Kala Azar project aims at discovering new drugs to fight against Kala Azar. The focus of the Project is to putting together a concerted effort to discover affinity ligands that can be developed into efficacious and less toxic drugs against Kala Azar. It also consists of two phases Phase I of the project has duration of 3 years and Phase II of 2 years. The cost of project is Rs. 4,88,00,000/-. The fund is to be released in four equal instalments of Rs. 1.22 crore for the project. The first two instalments have been released.

(b) PROPOSED SCHEMES:-

5.33 In order to encourage Pharma Innovation and Research and Development following proposals are under examination in the Department.

(1) Venture Capital Fund- Research and Development in Pharma sector being a very expensive proposition, many Indian Pharma companies have limitation in financial terms. To benefit the sector, a scheme for setting up of Venture Capital Fund (VCF) of Rs 1000 crores for financing R&D in Drugs & Pharmaceuticals is to be taken up during 12^{th} Plan. The Venture Capital Fund (VCF) for the segment is proposed as the traditional form of debt financing is not appropriate for promoting innovation which is a high risk business with very high probability of failure.

(2) The Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) is designed for the medium enterprises (MEs) in the Pharma sector. Through this scheme, MEs in the Pharma sector would be extended assistance through provision of soft loan to them to meet the stringent quality NORMS LIKE WHO-GMP norms as well as other GMP norms followed by various highly regulated market like USA, Europe, UK etc. This scheme essentially envisages making fund available at lower interest rates for procurement of machinery and equipment and other necessary accompaniments that should facilitate the MEs to achieve WHO-GMP norm compliance. The scheme proposes provision of soft loan @ 5 per cent p.a with a ceiling of Rs 5 crore of which 20 per cent i.e Rs. 1 crore should come as promoter's contribution. This implied that he ceiling for soft loan under this scheme would be Rs. 4.00 crore. This scheme is proposed to be managed and operationalized by SIDBI under the overall supervision of the Department of Pharmaceuticals. SIDBI would get commission for the services rendered.

(3) In order to enhance the national potential for Drug Discovery and Innovation the Department is in the process of preparing a DetailedProjectReport (DPR) in this regard. For the purpose, the Department has engaged M/s Ernst and Young limited (M/s E&Y) a global level consultant.

CHAPTER-VI

PUBLIC SECTOR UNDERTAKINGS

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

A. KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED (KAPL)

6.2 KAPL is a Profit making Joint Sector Company incorporated in the year 1981 (with 59% share by Government of India and 41% share by Government of Karnataka through KSIIDC). The basic objective of the Company is to make available life saving drugs of good quality to Government Hospitals and other Institutions along with Private Medical Practitioners. The Company has WHO-GMP Certified manufacturing facilities for Dry Powder Injectables, Liquid Injectables, Tablets, Capsules, Dry Syrups and Suspensions. The paid-up share capital of the Company as on date is Rs. 13.49 crores.

PRODUCTION AND SALES:

(Rs. in crore)

Particulars	2012-13	2013-14	2014-15	Upto 30.09.2015
Production	247.39	275.13	281.81	163.36
Sales	223.58	241.59	247.24	152.22

6.3 The Company has been mainly focusing on Prescription Market as Medical Professional as our Customers, where many of the MNCs and Private Pharma Players have a major share. The Company is also dependant on PPP Policy for Institutional Business, where our concentration is on Govt. Hospitals, State Government Hospitals, Corporates, PSU Hospitals, Defence and Insurance. Has potential to expand in Trade Segment and also to increase volumes by focusing on CPSE Hospitals and large Corporate Hospitals. Also need to look at increase in Product Mix and Injectable Range. Another opportunity for expansion is in ayurvedic Range, where Ayurveda, a holistic and complete treatment was invented by India**.**

6.4 When asked to give details about scheduled start of Cephalosporin Project, the Department in its written reply stated as under:-

> "No, Sir. During the commissioning of some of the utilities, teething troubles were observed with respect to some critical parts such as mechanical seals of the pumps which had to be procured by the vendors for commissioning the respective utilities

which had to be procured by them and this took considerable amount of time as these items were not readily available and had to be manufactured specific to the order from the contractor. It may be stated that no Budgetary Support is provided to Karnataka Antibiotics Pharmaceuticals Limited (KAPL). Remobilizing the vendors of various utilities and equipments took considerable time. Visits were made to vendors locations for discussion and to expedite completion".

6.5 When asked to give details of the advantage of Cephalosporin Project, the Department in its written reply stated as under:-

"It is a dedicated stand alone facility only for Cephalosporin Products. cGMP mandates Cephalosporin category of drugs shall have segregated and dedicated facility for manufacturing and testing similar to that of Penicillin Products. This gives an advantage of getting through various international regulatory approvals. This can give us a quantum jump in export business turnover".

B. RAJASTHAN DRUGS AND PHARMACEUTICALS LIMITED (RDPL)

6.6 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).

This is a formulation unit engaged in production of Tablets, Capsules, Liquid Orals, ORS Powder & Opthalmic medicines in a Schedule 'M' compliant facility. The company, under the quality management, has a well-equipped laboratory with modern equipments 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 also engaged in expansion, modernization and upgradation of its manufacturing facilities to WHO-GMP Standards. The company has carved for itself a name in the institutional market in India as a reputed manufacturer of high quality lifesaving drugs and other specialized medicines, with its marketing activities spread throughout the country. 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 proud to be a prime partner in the novel and noble endeavor of Govt. of India in the implementation of 'JANAUSHADHI' programme where quality generic medicines (unbranded) are made available to the public at large in the country at affordable prices. The company is further diversifying its activities into Pharma Prescription Markets (Open Trade Sales), Veterinary Markets, Marketing of Ayurvedic and other Indian system of medicines in order to enhance its market share and also in its endeavour to achieve profitability for the organization.

Financial Performance of the Company (Rs.in crore)

Year	Production	Sales
2012-2013	83.24	85.67
2013-2014	54.93	43.51
2014-2015	25.04	24.90
2015-2016 (Upto Oct. 2015)	14.31	13.46

6.7 When asked to give details about the completion of Phase-II project, the department in its written reply stated as under:-

"No, Sir. The Project is expected to be completed by July, 2016. Major reasons for delay in completion of the Phase II Plan are as under:

Inadequate number of quotations was received in response to various tenders floated for the Project. Hence, the tenders date had to be extended many times. ii) There was no Managing Director in the company for a considerable period due sudden demise (in 2014) of the then incumbent. iii) There was a condition of Pre-Audit while releasing the funds of Rs.6.84 crores in March, 2015 and the Pre-Audit was conducted in last week of December, 2015".

C. <u>BENGAL CHEMICALS AND PHARMACEUTICALS LIMITED (BCPL)</u>

6.8 Bengal Chemicals and Pharmaceuticals Limited (BCPL), erstwhile Bengal Chemical and Pharmaceutical Works Limited (BCPW) were constituted 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.BCPL was declared sick in 1993 and was sanctioned scheme for revival in 1995 by Board for Industrial & Financial Reconstruction (BIFR). In 2004, the scheme of revival was modified and the plan was sanctioned by BIFR.

Business Operations

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.

Manufacturing Locations: At present BCPL has four factories; at Maniktala and Panihati in West Bengal, Mumbai and Kanpur.

<u>**Sickness and Revival:**</u> The Company was referred to BIFR in 1992. The revival package for BCPL was approved by the Government on 21st December 2006. The package of Rs 490.60 Cr was approved which 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.

6.9 When asked to give details of ASVS Project and its advantages/benefits, and whether the ASVS Project will help in the revival of BCPL and when will the ASVS Project be fully implemented, the Department in its written reply stated as under:-

> " (i)The details of the ASVS (Anti Snake Venom Serum) Project is as under:
> Primarily the project was part of Revival Package with an estimated amount of Rs. 11.00 crore as sanctioned during the year 2007. The company completed Basic and Detailed Engineering activities and started the civil construction work at Maniktala. The project was stopped due to litigation initiated by the private builder adjoining the BCPL factory and subsequent stay order issued by the Court. By the time the project was stopped the company had spent an amount of Rs. 2.90 crore.The revised Project Cost as per the current estimate is Rs. 29.64 crore and the balance fund required to complete ASVS project is Rs. 26.74 crore.
>
> (ii) The Advantage/benefits are as under:
>
> No alternative successful therapy. High degree of mortality and morbidity in the absence of treatment. The diseases in which they are used represent a heavy toll of human suffering. Largely affects children and farmers in rural communities. Unfortunately there are a number of problems for developing countries in accessing and using anti venoms-WHO. There is huge gap between supply and demand, only one or two companies manufacture ASVS. Earlier BCPL, having good share in marketing ASVS and is a profitable product.
>
> (iii) It will help in revival of BCPL. No specific Budget provision is provided for this project in BE 2016-17. However a token provision of Rs.0.01 crore is made under Project based support to PSU for BCPL".

6.10 During the course of the evidence on the revival of Bengal Chemicals and Pharmaceuticals Limited, the Secretary of the Department stated as under:-

> "Today, Bengal Chemical and Pharmaceuticals is improving. It is the first chemical and pharmaceutical company in India. At one point of time, it was the premier company. Then it became sick. The Government sanctioned a rehabilitation package. Package has been implemented but there was great amount of delay and other things. Now it is on its way to progress. Now we are marketing to an extent of about Rs 100 crore per year. Earlier, it used to be only Rs 20 to 25 crore. Within two years time, it has increased to Rs 100 crore. In another two or three years' time, at the same rate it will reach Rs 400 crore transaction. We can hear more from the M.D. of Bengal Chemicals and Pharmaceuticals.
>
> It was Rs 50 crore in 2013-14. Last year, it was Rs 23 crore. This year, we are going to touch Rs 100 crore. We are going to make a gross profit of Rs. 8 to 10 crore this year. From a loss making unit, we are now making gross profit. We are improving day by day. We have two pending projects, one at Kanpur and the other is a more prestigious anti-snake venom project. For these, we were requesting for additional grants. It was cost escalation per se, otherwise funds was allocated in 2007. We just put Rs 3 crore investments into that and stopped it. We require another Rs 27 crore which is not forthcoming for the last two years.

If this Rs 27 crore is sanctioned for anti-snake venom project, we can supply this to entire country and can also export it."

D. <u>Hindustan Antibiotics Ltd. (HAL)</u>

6.11 HAL is passing through critical financial crisis due to shortage of working capital required for running its operations. Due to this financial crisis its operations are running at very low level. 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 Deptt.of Pharmaceuticals considering the financial crisis being faced by HAL directed the Company to make the 2nd Rehabilitation Package which should include modernisation of plant & machinery, requirement of working capital, VRS cost, new Utility-Set-up for Formulation business, waiver of government loans and interest etc.

IFCI Ltd. a Consultant appointed by Govt. of India prepared Techno-economic Viability (TEV) Report and submitted to the Govt. of India. On the basis of the TEV Report submitted by IFCI and the direction given by GOI the detailed proposal was prepared by the Company and submitted to IDBI. On the basis of the proposal of the Company the MDRS is finalized by IDBI. The MDRS envisages the infusion of Rs.670.46 crores, the details of which are given below. It is proposed in the MDRS that the entire funds required for the scheme is to be generated by the sale of Company's vacant land.

The said MDRS of the Company is under active consideration of the Govt. of India.

<u>NEW PROJECTS</u> :

6.12 The following new projects are taken up for capacity expansion and productivity improvement in 2015-16.

1. Expansion of Steptocycline Plant costing Rs.1.71 crores (Being Commissioned)
2. New Cooling Tower costing Rs.0.95 crores (Commissioned)
3. Briquette Based Boiler and Rationalisation of Steam header costing Rs.1.30 crores (Being Commissioned)
4) Upgradation of IV Fluid Plant costing Rs.6.28 crores (Being executed)

<u>NEW PRODUCTS</u> :

New speciality products are being introduced for specific requirement of the Defence Forces, Narcotic Control Bureau etc.

6.13 **<u>STATUS OF HAL AFTER IMPLEMENTATION OF MDRS.</u>**

1. All liabilities including statutory authorities, bank loans, manpower related (Gratuity, PF, other dues) will be fully cleared.
2. Salary / wage bill will be reduced by around Rs. 18-20 Crores due to VRS.

3. Formulation Plants will be upgraded to GMP standards and Streptocycline (Agro products) production capacity will be enhanced.
4. Utility cost will be reduced due to installation of Briquette based boiler, Efficient chiller and cooling tower.
5. Production will boost up to the levels of Rs. 130-450 Crores turnover over the period of time due to availability of working capital.

6.14 When asked about the current status of implementation of Modified Draft Rehabilitation Scheme (MDRS) with regard to HAL, the Department in its written reply stated as under:-

"The Note for Cabinet for Rehabilitation of Hindustan Antibiotics Ltd (HAL) is at final stage".

6.15 On being asked about arrears of salaries of the employees of HAL have been paid in full, the Department in its written reply stated as under:-

"If The arrears of the salaries of HAL employees for six months amounting to Rs. 24.25 crore has been released in the Current Financial year. The balance amount of arrears has been taken into account in the Rehabilitation proposal of HAL".

6.16 During the course of evidence, the Committee was informed by MD, HAL :-

"As regards Hindustan Antibiotics Limited, the situation is very pathetic.

Sir, it has not been closed. Salary for 17 months is pending. April 1st onwards we will not be getting electricity. Today onwards the workers in the plant are not allowing any Directors to enter the company. Actually, there were pending dues with all statutory authorities. There are also court cases. I have personally appeared five times before Provident Fund Authorities. There is a proposal which is pending for four years. A proposal was submitted in 1st June, 2012. Till date it has not been approved by Government of India. So, several times it has been amended, either decreasing the cost of the scheme or increasing the cost of the scheme.

6.17 The Secretary, of the Department also stated as under :-

"Sir, with regard to Hindustan Antibiotics, the situation is bad as he was mentioned because we have not given salary for more than 15 to 16 months. Last year we gave salary for six months. In fact, we diverted money meant for Janausdhi. Janausdhi gets Rs. 35 crore. From Janausdhi we took money and gave salary for six months. Every time salary has to be given we have to go to the Finance Ministry. It is very difficult to get money from the Finance Ministry. So, we have worked out a rehabilitation package for Hindustan Antibiotics Limited. In fact, two years back a decision was taken to sell about 12 acres of land. We had almost completed the sale except that we did not get money from the company, the Government of Maharashtra Housing Urban Development Agency. It was Rs. 18 crore per acre. They are ready to pay Rs. 111 crore. We have completed the formalities. It has to be approved by the Cabinet. We sent a separate proposal to the Department, but they said to combine it with the Rehabilitation package. Rehabilitation package whenever we make it, always some Department or the other find fault with it and they never approve it. Now, with great amount of efforts for the past two years we have completed the Rehabilitation package and we have sent it to the Cabinet Secretariat recently, despite the fact that a few Departments have not supported it. Many departments understand it and they agree saying that you sell 40 acres of land out 270 acres in Pune. If we sell 40 acres of land we can clear the entire arrears and they can start their operations afresh and they can become viable. Thousand families can survive and a big economy will happen in that area. But somehow some departments are not supporting this scheme at all. They are against PSUs. They say that PSUs have outlived.

They say that they do not want PSUs. You can never succeed. Earlier also you have not succeeded and in future also you will not succeed. We cannot go on spending money. It should be wound up. That is the type of reactions we get. Despite that we are sending the proposal to the Cabinet, both IDPL and HAL. We have simplified the entire rehabilitation package. We have given the simplest mechanism possible. If that approval comes through in the Cabinet, then I think we will be able to save these two organisations.

There are 1000 employees there and in fact, after getting this money, we want to send 500 persons on VRS".

6.18 MD, HAL has stated further:-

"Even if the Cabinet note is approved, the official process will take nine months to get the first instalment of payment after selling of the land. Till that time, we cannot survive under any circumstances because people are coming and telling that they will commit suicide in front of the office and many students have discontinued their engineering studies. There are also health problems with the employees. The situation is pathetic. In this context, I have given a request for interim relief. We can pledge our land to the Government as assets are already there. Something has to be done. Last year, we gave some amount for six months. But now they are helpless."

The Secretary of the Department stated as under:-

" I think very shortly, a decision will be taken either to rehabilitate or to close the unit".

E. INDIAN DRUGS AND PHARMACEUTICALS LIMITED (IDPL)

6.19 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 creating 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.

6.20 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 Undertaking, promoted in collaboration with the Odisha State Government, namely, Orrisa Drugs & Chemicals Ltd. (ODCL) Bhubaneswar. IDPL is a sick company in Public Sector within the meaning of Sick Industrial Companies (Special Provisions) act, 1985 (SICA).

Sickness and Revival if any

6.21 The role of IDPL was, however, not redefined even in the eighties. It 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 causes were (i) large monolith-type integrated production facilities (typical model followed in 1950s-1960s) producing chemicals, bulk drugs & formulations (ii) outdated plant & machinery and obsolete technology for bulk drugs (but for formulations not outdated) (iii) excess manpower (13283 in 1983-84) and high wage bill and maintenance of huge township, schools and hospitals. (iv) frequent changes at top management (average tenure of Chairman & Managing Director was 18 months) (v) medicines produced by IDPL were under price control by the Government prior to liberalization in 1991 (vi) shift in Government policy resulting in shifting of the canalization agency from IDPL to STC (vii) intense competition from private pharma 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. Production has been stopped in October1996 at Rishikesh& Hyderabad & Muzaffarpur Plant due to shortage of working capital.

Revival status since 1.4.1994

6.22 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 funds 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. Attempts were made in 2001-02 to privatize the Company. OA, 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, it would be feasible to revive

IDPL. Committee found the plant & machineries for production of formulations in a reasonably good shape which can 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 is 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.

Keeping in view of the above a DRS was prepared by IDPL in consultation with ICRA Management and submitted to the BRPSE for consideration and recommendation. After approval of the BRPSE and A Note for Cabinet Committee on Economic Affairs is prepared and submitted for approval on 11.5.2007. The Note was considered by CCEA in its meeting held on 17.5.2007 and referred the matter to Group of Minister (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. The observations made by GoM, IDPL appointed a leading consultant Company E&Y to carry out the feasibility study. E&Y report submitted to the Ministry/DoP.

A revised DRS again prepared by IDPL in consultation with IDBI (OA) taking cut off date as 31st March, 2011. BIFR observation that cut off date needed the approval of BIFR bench. Thereafter in the BIFR meeting held on 20.8.2014 cut off date was approved as 31.3.2014. Accordingly, the revised updated DRS has been prepared taking cut off date 31.3.2014 and submitted to the DoP/Ministry in January 2015 for consideration and approval. The DRS of IDPL is self-financing in nature in other words no fund will be sought from the Govt rather the present assets will be sold off and the fund released will be used to payoff secured creditors.

6.23 During the course of evidence, the CMD of, IDPL stated as under:-

> "Sir, the situation in IDPL was like that four years back when I joined. Now thankfully we have turned around and we made an operating cash profit of Rs. 4.38 crore last year. This year, our turnover is touching Rs.85 crore which will perhaps the highest in-house production ever achieved in the last 20 years. We are on a growth path and this year also, Rs. 8 to Rs. 10 crore cash profit will definitely be earned. So, things are on a recovery mode but the balance sheet needs to be cleaned up. The past liabilities of the Government of India which was paid in the form of VRS money need to be cleared up. We are not getting any working capital support from any banks. Surprisingly, this is such a company without banking support which is run on our own. We are managing our own cash flow and through our own deposits, we are using it for working capital needs. So, things have improved but the Government has to take a call on whether they want to revive IDPL or close it down because regular man power has virtually vanished. We have only 65 regular employees and including the contractual employees, we have only 200 persons. With 200 employees, we are touching Rs. 85 crores of turnover. Even

all the three plants have been modernised. The IDPL unit of Hyderabad which was to restart is almost ready and probably, in April or May, we will get it inaugurated by our hon. Minister. That plant which was closed in 2003 will be started. It will be GMP plant. Things have really been transformed. But we need Government support and they need to take a decision on whether they want to continue with the PSU or they want to shut it down. This is the situation of IDPL".

6.24 When asked to give details about the precise steps being taken by the Department for the revival of closed/sick PSUs and whether any time limit/target has been fixed for the revival of closed/sick PSU, the Department in its written reply stated as under:-

"Notes for Cabinet for revival of sick PSUs namely Indian Drugs & Pharmaceuticals Ltd (IDPL) and Hindustan Antibiotics Ltd (HAL) are at the stage of finalization. The action for revival of these PSUs would be initiated once the approval of Cabinet is accorded. It is expected that within a period of four years the sick PSU would be revived".

6.25 On being asked to give details about the full revival of the sick Pharma PSUs (HAL, BCPL, IDPL) and be in a position to offer competition to the Private and Multi-national Pharma Companies, the Department in its written reply stated as under:-

" It is expected that within a period of four years after the receipt of approval of Cabinet, the sick Pharma PSUs Hindustan Antibiotics Ltd(HAL) and Indian Drugs Pharmaceutics Ltd(IDPL) would be revived fully. As during the course of revival the plants of these PSUs with the latest technology would be upgraded to WHO-GMP compliance, these PSU would be in position to offer competition to the Private and Multi National Pharma Companies".

BCPL is on the path of revival. The sale and production of the company for the last 2 years and current year are as under:

(Rs. In crore)

Period	Production	Sales
2013-14	19.71	17.06
2014-15	64.10	45.84
2015-16	100.00*	100.00*

*Anticipated "

PART II

OBSERVATIONS/RECOMMENDATIONS

1 Promotion of manufacturing of bulk drugs

The Committee note that the country is almost self-sufficient in case of formulations. However, for making these formulations, the basic chemical comes from China. Since the pharmaceutical industry is dominated by the private sector, they are free to import as per Foreign Trade Policy under which import of certain drugs and drugs intermediates is restricted.

The Committee also note that Indian Pharmaceutical Industry which was at one point of time leading producer in bulk drugs is now becoming increasingly dependent on China for its bulk drug needs. The Committee, further observe that in order to promote domestic production of bulk drugs, a Committee headed by Dr. V. M. Katoch was constituted which has submitted its recommendations. The Government is examining the recommendations of the Katoch Committee in consultation with the stakeholders. Besides this, three task forces have also been set up. All the three task forces have also submitted their reports, which is being examined.

The Committee, are of the strong view that overdependence on imports for its bulk drugs needs is not a healthy sign for the Indian Pharmaceutical Industry. The Committee observe that the recommendations of Katoch Committee and the three task forces are essential to boost the growth of Pharmaceutical Sector and reducing the overdependence on imports. The Committee would, therefore, like the Department to examine the recommendation of the Task Forces expeditiously and implement its recommendations in a time bound manner for the promotion of manufacturing of bulk drugs in the country. The Committee would like to be informed of the action taken in this regard.

2. Promotion of Indigenous Medical Devices Industry

The Committee note that medical devices industry is a multi-product industry, producing wide range of products. The industry can be broadly classified as consisting of medical disposables and consumables; medical electronics, hospital equipments, surgical instruments; Implants; and Diagnostic Reagents. Globally this industry is growing quite steadily and have shown double digit growth. However, medical devices industry in India mostly depends on imports which is over 65% of the total market. The Indian medical devices industry is fragmented into small and medium enterprise category and is primarily manufacturing products such as disposables/medical supplies.

Most of the requirement for high end medical equipments are met by multinational companies.

The Committee also note that Department wants to establish Medical Devices Manufacturing Parks in the country and the Department of Health has initiated action to establish one park in Tamil Nadu. The Department of Pharmaceuticals want to create four or five private and Government sponsored Medical Devices Parks. The Committee, also observe that One such park is to be established in IDPL land in Hyderabad and similarly, the Government of Andhra Pradesh is going to lay foundation stone for a separate medical devices manufacturing park. The Department has also got proposals to create parks in the State of Gujarat.

The Committee are of the view that the development of indigenous medical devices industry is of paramount importance and fits in realizing the Make in India goal of the Government. It will not only be instrumental in providing quality health care to its citizens but also would be helpful in creating new job opportunities for the skilled workers of the country. The Committee, therefore, recommend that the Department should take proactive measures toward developing indigenous medical devices industry so as to reduce our dependence on imports. The Committee, would also like the Department to expedite the process of establishment of those Medical Devices Manufacturing Industry Parks for which the proposals have already been received from various States. The Committee would like to know the initiatives taken to expedite the scheme and the progress made in the matter so far.

3. <u>Annual Plan and Expenditure</u>

The Committee note that for Annual Plan 2016-17, the Department of Pharmaceuticals proposed an outlay of Rs 2891.473 crore to the D/o Expenditure, M/o Finance but only Rs.160 crore was approved for BE 2016-17. The Committee are dismayed to note that this allocation falls far short of the urgent funds requirements projected by the Department for carrying out its laid down mandate and its Vision for development of Indian Pharmaceuticals Industry under "Make in India" initiative, to make India a largest global provider of quality medicines. The Committee observe that budget allocation for the Department is substantially less during the current year because of poor spending capacity in the past. The Committee feel that a severe cut in outlay would have an adverse impact on the implementation of the Plan Schemes being undertaken by the Department and the targets set for the 12th Five Year Plan. The Committee, therefore, recommend that the Department should take up the issue vigorously with the Ministry of Finance and impress upon them to allocate adequate

funds as per the demand of the Department for implementation of various important schemes. The Committee would like to be informed of the action taken by the Department in this regard.

4. Budgetary Allocation for the year 2016-17

The Committee note that BE under Plan expenditure was Rs.210 crore for 2015-16 and RE was Rs.150.38 crore against which the actual expenditure made by the Department of Pharmaceuticals was Rs.147.20 crore and for Non-Plan BE for 2015-16 was Rs.48.02 crore and RE was Rs.69.01 crore against which Actual expenditure was Rs.70.09 crore. The Committee observe that Department has been able to utilise 95% of the funds allocated under RE 2015-16. The Committee further note that the BE Plan expenditure for 2016-17 has been provided as Rs.160 crore and Non-Plan allocation is Rs.51.40 crore. The Committee also observe that Department need more funds for meeting its expenditure on various Plan Schemes like NIPER, JAS, Setting up of National Centre for R&D in Bulk Drugs, and Cluster Development Programme. These programmes are important for the development of Pharmaceutical Industries in the country and also for capacity building through NIPERS, and for expansion of Jan Aushadhi Scheme to make available generic drugs at affordable cost to common man.

The Committee, therefore recommend that the Department should strongly take up the matter with Ministry of Finance and convey the recommendations of the Committee for sanction of additional funds, for various important Plan schemes. The Committee would also like the Department to utilize the entire allocated budget and implement the Plan Schemes effectively.

National Pharmaceutical Pricing Authority (NPPA)

5. The Committee note that the National Pharmaceutical Pricing Authority (NPPA), is an independent body of experts in the Ministry of Chemicals and Fertilizers. Its functions inter-alia include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines. However, the Committee are dismayed to note that Since inception of NPPA, there are 1389 cases as on 29.02.2016 (1250 cases under DPCO 1995 & 139 cases under DPCO 2013) where demand notices have been issued by NPPA to Pharmaceutical companies for recovery of overcharged amount.

The Committee also observe that NPPA has prepared a draft for One Time Settlement (OTS) with an aim of quick recovery of overcharged amount and sent to Department of Pharmaceuticals for its formal approval. The earlier proposal sent two years back to Ministry of Finance was not accorded approval by it. The Committee, therefore recommend that the Department should take up the matter with Ministry of Finance again by strongly putting its case for One Time Settlement Scheme with full justification. The Committee desire to be apprised of the detailed action in this regard.

Cluster Development Programme for Pharma Sector

6 The Committee observe that Cluster Development Programme for Pharma Sector is a Central Sector Scheme which was approved in February 2014. . The total size of the scheme CDPPS is proposed as Rs.125 Crores for 12th Five Year Plan. The Committee also note that the Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant –in – aid to be released in various phases for creation of identified infrastructure and common facilities in the form of Common Facility Centers(CFC) to Special Purpose Vehicles (SPVs) set up for the purpose. 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 for Common Testing Facilities, Training Centre, Effluent Treatment Plant, R&D Centres, Common Logistics Centre.

Projects and Development India Limited (PDIL) has been chosen as the Project Management Consulting (PMC) for implementing the scheme. PDIL have called for EOI/SPV for the 1st Phase, out of the six EOIs, one was found suitable by the Scheme Selection Committee (SSC) to be located in Tamilnadu. SSC has requested PDIL to call fresh EOI which they have done and the last date of receipt of the EOIs was 31/12/2015. After that PDIL has extended the date till 31.01.2016. The meeting of SSC was held on 23/02/2016 to review the response to EOIs and implementation of the Scheme.

The Committee recommend the Department to implement the scheme expeditiously in a systematic, professional and transparent manner and ensure that the Steering Committee reviews the responses received in the EOIs at the earliest so that there is concrete progress in this regard. The Committee would like to be apprised about the progress made in the matter.

National Institute of Pharmaceutical Education & Research

7. The Committee note that the foundation stone for NIPER Ahmedabad has been laid on 16.12.2015 and for the construction work BOQ has already been approved and

without the approval of funds, tender cannot be released and construction work could not be started. The Department proposed an amount of Rs.197.29 crore. However, only an amount of Rs. 21.96 crore has been allocated for the above stated purpose during 2016-17 With regard to NIPER, Guwahati, the construction work has already been started. The Department proposed an amount of Rs.174.70 crore for the purpose. However, only an amount of Rs.19.50 crore has been allocated for the above stated purpose during 2016-17 which is not sufficient. With regard to NIPER Hyderabad, the Committee observe that Memorandum of Understanding (MoU) has been signed between NIPER, Hyderabad and National Project Construction Corporation (NPCC) Ltd. on 09.12.2015 for construction of NIPER campus as well as National Centre for Research and Development in Bulk Drugs(NCRDBD). The Department has sought Rs.193.02 crore for NIPER, Hyderabad and Rs.36.75 crore for NCRDBD. However, only an amount of Rs.35 crore for NIPER, Hyderabad and Rs.0.01 crore for NCRDBD have been allocated during 2016-17. The fund allocated is proposed to be utilized in meeting Establishment expenditure and for construction activities of new campus for NIPER, Hyderabad. With regard to NIPER, Rae Bareli possession of land has been taken. The funds required for meeting expenses for establishment related and essential expenditure to run the Institute and for construction activities of new campus for NIPER, Rae Bareli. In the proposed BE 2016-17, the Department has sought Rs.176.59 crore. However, an amount of Rs.07.00 crore has been allocated during 2016-17. With regard to NIPER Madurai For setting up of NIPER in Tamil Nadu, Government of Tamil Nadu has allocated land at Madurai. In the proposed BE 2016-17, the Department has sought Rs.174.10 crore. However, an amount of Rs.1.00 crore has been allocated during 2016-17 for the above said purpose. The Committee are of the view that due to lesser allocation of funds the construction of new NIPERs is going to be affected adversely. The Committee, therefore recommend that the Department should impress upon the Ministry of Finance to grant the required amount of funds for the expeditious construction of new NIPERs where land has already been allocated and construction activities have been initiated in full swing, as this will address the demand of pharmaceutical industry to meet the requirement of highly skilled manpower and also boost research and development in the sector.

JAN AUSHADI SCHEME

8 The Committee note that making quality medicines available at affordable prices remains a key challenge to the Government. To provide relief to common man and to ensure availability of generic medicines at affordable prices to all, the Department of

Pharmaceuticals launched a Jan Aushadhi Campaign in Novermber 2008 in collaboration with State Governments. The Committee note that Jan Aushadhi Scheme is being implemented by the Department of Pharmaceuticals through Bureau of Pharma PSUs of India. The Commitee note that as on 10 March 2016, 263 stores spread over 21 States/UTs are functional in the country.

The Committee also note that during the Budget Speech, 2016-17 the Finance Minister announced that the Government will reinvigorate the supply of generic drugs and open 3000 stores under Prime Minister's Jan Aushadhi Yojana towards this objective. The Committee observe that BE for 2015-16 for Jan Aushadhi Scheme was Rs.35 crore and the RE 2015-16 was Rs.16.92 crore and the Actual Expenditure during 2015-16 was Rs.16.91 crore which shows full utilisation. During 2016-17, the BE for Jan Aushadhi Scheme has been fixed at Rs.35 crore similar to previous year. The Committee is to point out that in order to achieve the 3000 stores objectives during the year the allocations may not be sufficient and more funds would be required during the course of the year. The Committee desire that Jan Aushadhi Stores should be opened in a well distributed manner in the country and the Department should ensure that all States, regions and difficult areas are also covered so that the scheme would serve its intended purpose. The Committee would also suggest that the Department should also commission more mobile vans to supply medicines to distant areas, far flung areas, difficult terrains so that the population at large can benefit from the scheme. The Committee observe that the State Governments have their own free drugs scheme and are hesitant and non-cooperative in certain places which makes this scheme difficult to take off. The doctors may also be sensitized and encouraged to prescribe such generic drugs that are available with Jan Aushadhi Stores. The Committee, therefore recommend that Department may utilise the allocated funds completely and promote the Scheme more effectively so that the objective of providing affordable medicines to all citizens is met.

9. <u>Public Sector Undertakings</u>

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

Bengal Chemical and Pharmaceuticals Ltd

The Committee also note that the performance of Bengal Chemical and Pharmaceuticals Limited is improving. The Government sanctioned a rehabilitation package which has been implemented now it is on its way to progress. Turnover of the Company was Rs 50 crore in 2013-14. Last year, it was Rs 23 crore. This year, it is going to touch Rs 100 crore and it is likely to make up a gross profit of Rs.8 to Rs.10 crore. BCPL have two pending projects, one at Kanpur and the other is a more prestigious anti-snake venom project. It requires Rs 27 crore investment and if it is sanctioned for anti-snake venom project, it can be supplied to entire country and can also be exported.

Hindustan Antibiotics Ltd

The Committee note with regard to HAL, Salary for 17 months is pending. The Committee also note that each time whenever salary is to be given, the Department has to go to the Finance Ministry. The Department has worked out a rehabilitation package for Hindustan Antibiotics Limited. It is sending the proposal for simplified rehabilitation package to the Cabinet, for both IDPL and HAL. The action for revival of the HAL would be initiated once the approval of Cabinet is accorded. The Committee also feel that if the Cabinet note is approved, the official process will take nine months to get the first instalment of payment after selling of the land. Till that time, it will be difficult for the employees of HAL to meet their ends meet. In this context, the Committee strongly feel that Department should strive to provide some interim relief to the employees of HAL so as to improve morale of the employees.

Indian Drugs & Pharmaceuticals Ltd

The Committee further note that Cabinet note for revival of sick PSUs namely Indian Drugs & Pharmaceuticals Ltd (IDPL) is being finalised. The Committee also feel that the Government has to take a call on whether they want to revive IDPL or close it down because regular man power has virtually vanished. The Committee further observe that the situation in IDPL has made a turn around with an operating cash profit of Rs. 4.38 crore made last year. This year, the turnover is touching Rs.85 crore and will perhaps be the highest in-house production ever achieved in the last 20 years. The Committee further note that IDPL is managing its own cash flow through its deposits, and is using it for working capital needs. The IDPL unit of Hyderabad will be

inaugurated and It will be Good Manufacturing Practice (GMP) plant. The Committee, feel that Government support is needed for revival of IDPL.

The Committee, are of the view that steps to rehabilitate all the sick PSUs should be quickened. The Committee, therefore recommend that the Department should make vigorous efforts in coordination with all concerned authorities to rehabilitate the Pharma PSU's and meet their immediate requirement expeditiously.

New Delhi;
26 April, 2016
6 Vaisakha, 1938 (Saka)

Anandrao Adsul
Chairperson
Standing Committee on
Chemicals and Fertilizers

Annexure-I

MINISTRY OF CHEMICALS AND FERTILISERS

DEMAND NO. 8

Department of Pharmaceuticals

A. The Budget allocations, net of recoveries, are given below:

(In crores of Rupees)

	Major Head	Actual 2014-2015			Budget 2015-2016			Revised 2015-2016			Budget 2016-2017		
		Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
	Revenue	49.15	38.56	87.71	209.96	48.98	258.94	150.38	44.76	195.14	159.94	51.36	211.30
	Capital	*26.49*	*9.67*	*36.16*	*0.04*	*0.04*	*0.08*	...	*24.25*	*24.25*	*0.06*	*0.04*	*0.10*
	Total	**75.64**	**48.23**	**123.87**	**210.00**	**49.02**	**259.02**	**150.38**	**69.01**	**219.39**	**160.00**	**51.40**	**211.40**
BE 2016-2017													
1. Secretariat-Economic Services	3451	...	...	...	...	...	...	...	...	...	...	12.66	12.66
2. National Institute of Pharmaceuticals Education and Research (NIPER)	2552	...	...	...	...	...	...	...	...	...	19.50	...	19.50
	2852	...	...	...	...	...	...	...	...	...	80.50	27.48	107.98
	Total	...	...	...	...	...	...	...	...	...	*100.00*	*27.48*	*127.48*
3. National Pharmaceutical Pricing Authority (NPPA)	2852	...	...	...	...	...	...	...	...	...	5.45	11.21	16.66
4. Assistance to PSUs	6857	...	...	...	...	...	...	...	...	...	0.06	0.04	0.10
5. Development of Pharmaceutical Industry													
5.01 Pharma Promotion & Development Scheme (PPDS)	2852	...	...	...	...	...	...	...	...	...	2.00	...	2.00
5.02 Creation of IPR facilitation centre at Pharmaexcil	2852	...	...	...	...	...	...	...	...	...	0.01	...	0.01
5.03 Schemes for development of Pharamaceutical Industry	2852	...	...	...	...	...	...	...	...	...	12.47	0.01	12.48
5.04 WHO-GMP for Pharmaceuticals	2852	...	...	...	...	...	...	...	...	...	5.00	...	5.00
5.05 Provision for North East and Sikkim	2552	...	...	...	...	...	...	...	...	...	0.01	...	0.01
Total- Development of Pharmaceutical Industry		...	...	...	...	...	...	...	...	...	*19.49*	*0.01*	*19.50*
6. Jan Aushadhi Scheme													
6.01 Jan Aushadhi Scheme	2852	...	...	...	...	...	...	...	...	...	34.99	...	34.99
6.02 Provision for North East and Sikkim	2552	...	...	...	...	...	...	...	...	...	0.01	...	0.01
Total- Jan Aushadhi Scheme		...	...	...	...	...	...	...	...	...	*35.00*	...	*35.00*
RE 2015-2016													
7. Secretariat-Economic Services	3451	0.72	8.95	9.67	1.00	11.28	12.28	1.00	9.64	10.64	...	...	...

(In crores of Rupees)

	Major Head	Actual 2014-2015			Budget 2015-2016			Revised 2015-2016			Budget 2016-2017		
		Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
Industries													
Pharmaceutical Industries													
8. National Institute of Pharmaceuticals Education and Research (NIPER)	2852	35.48	20.87	56.35	98.96	27.48	126.44	84.21	27.48	111.69	...	...	...
9. National Pharmaceutical Pricing Authority (NPPA)	2852	2.00	8.74	10.74	5.00	10.21	15.21	3.00	7.64	10.64	...	...	...
10. Pharmaceutical Export Promotion Scheme (PEPS)	2852	...	...	...	...	0.01	0.01	...	...	...	...	...	...
11. Pharmaceuticals Promotion & Development Scheme (PPDS)	2852	1.45	...	1.45	2.00	...	2.00	2.00	...	2.00	...	...	...
12. Other ongoing schemes of Pharmaceuticals													
12.01 Jan Aushadhi Scheme	2852	...	...	...	35.00	...	35.00	16.92	...	16.92	...	...	...
12.02 Critical Assistance for WHO-GMP for Pharmaceuticals PSUs	2852	6.84	...	6.84	10.00	...	10.00	7.40	...	7.40	...	...	...
12.03 Creation of IPR facilitation centre at Pharmaexcil	2852	0.22	...	0.22	...	...	...	...	...	...	...	...	...
12.04 Setting up of National Centre for Research and Development for Bulk Drugs	2852	...	...	...	22.00	...	22.00	12.00	...	12.00	...	...	...
12.05 New Schemes of Pharmaceuticals	2852	2.44	...	2.44	15.00	...	15.00	2.85	...	2.85	...	...	...
Total- Other ongoing schemes of Pharmaceuticals		*9.50*	...	*9.50*	*82.00*	...	*82.00*	*39.17*	...	*39.17*	...	...	...
Total-Pharmaceutical Industries		**48.43**	**29.61**	**78.04**	**187.96**	**37.70**	**225.66**	**128.38**	**35.12**	**163.50**	...	...	...
Total-Industries		**48.43**	**29.61**	**78.04**	**187.96**	**37.70**	**225.66**	**128.38**	**35.12**	**163.50**	...	...	...
13. Lumpsum provision for Project/Scheme for the benefit of the N.E. Region & Sikkim	2552	...	...	...	21.00	...	21.00	21.00	...	21.00	...	...	...
14. Non Plan Loans to Public Enterprises													
14.01 Smith Stainistreet Pharmaceuticals Ltd. (SSPL)	6857	...	...	...	...	...	...	...	...	...	...	...	...
14.02 Bengal Chemicals and Pharmaceuticals Ltd. (BCPL)	6857	...	...	...	...	0.01	0.01	...	...	...	...	...	...
14.03 Bengal Immunity Ltd. (BIL)	6857	...	...	...	...	0.01	0.01	...	...	...	...	...	...
14.04 Indian Drugs & Pharmaceuticals Ltd. (IDPL)	6857	...	...	...	...	0.01	0.01	...	...	...	...	...	...
14.05 Hindustan Antibiotics Ltd. (HAL)	6857	...	...	...	...	0.01	0.01	...	24.25	24.25	...	...	...
Total- Non Plan Loans to Public Enterprises		...	...	...	...	*0.04*	*0.04*	...	*24.25*	*24.25*	...	...	...
15. Investment in Public Enterprises	6857	26.49	9.67	36.16	0.04	...	0.04	...	...	...	...	...	...
16. Actual Recoveries	2852	...	...	...	...	...	...	...	...	...	...	...	...
Grand Total		***75.64***	***48.23***	***123.87***	***210.00***	***49.02***	***259.02***	***150.38***	***69.01***	***219.39***	***160.00***	***51.40***	***211.40***
	Head of Dev	Budget Support	IEBR	Total	Budget Support	IEBR	Total	Budget Support	IEBR	Total	Budget Support	IEBR	Total

	Head of Dev	Budget Support	IEBR	Total	Budget Support	IEBR	Total	Budget Support	IEBR	Total	Budget Support	IEBR	Total
B. Investment in Public Enterprises													
4.01 Hindustan Antibiotics Ltd. (HAL)	12857	...	...	...	0.01	...	0.01	...	...	...	...	...	...
4.02 Bengal Chemicals and Pharmaceuticals Ltd. (BCPL)	12857	...	...	...	0.01	...	0.01	...	...	...	...	...	...
4.03 Indian Drugs and Pharmaceuticals Ltd. (IDPL)	12857	...	...	...	0.01	...	0.01	...	...	...	...	...	...
4.04 Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL)	12857	...	...	...	0.01	...	0.01	...	...	...	...	...	...
Total		...	...	...	**0.04**	...	**0.04**	...	...	...	...	...	...
C. Plan Outlay													
1. Chemical and Pharmaceutical Industries	12857	74.92	...	74.92	188.00	...	188.00	128.38	...	128.38	140.48	...	140.48
2. Secretariat-Economic Services	13451	0.72	...	0.72	1.00	...	1.00	1.00	...	1.00	...	...	...
3. North Eastern Areas	22552	...	...	...	21.00	...	21.00	21.00	...	21.00	19.52	...	19.52
Total		**75.64**	...	**75.64**	**210.00**	...	**210.00**	**150.38**	...	**150.38**	**160.00**	...	**160.00**

1. **Secretariat:** Provision is for the expenditure on Secretariat of the Department.

2. **National Institute of Pharmaceutical Education & Research (NIPER):** The first NIPER has been set up at S.A.S. Nagar (Mohali) near Chandigarh. The Institute seeks to promote excellence in the sphere of pharmaceutical education in India and to meet the current and future education and training needs of the pharmaceutical sector in India. The provision includes support for (i) day-to-day expenditure and Plan support for their ongoing Schemes and new Schemes in Pharmaceutical Education and Research; (ii) 7 new NIPERs, one each at Ahmedabad, Hyderabad, Hajipur, Kolkata, Guwahati, Rae Bareli and Madurai, and for one campus each at Maharashtra, Chhattisgarh and Rajasthan which are being envisaged; (iii) expenditure on Technical Support Group for NIPERs and (iv) for setting up of the National Centre for Research and Development of Bulk Drugs(NCRDBD) at Hyderabad.

3. **National Pharmaceutical Pricing Authority (NPPA):** As part of the new Drug Policy announced in September, 1994, an independent body of experts has been set up, which is responsible for price fixation/revision of prices of drugs and formulations and other related matters. It also monitors the prices of decontrolled drugs / formulations and oversees the implementation of the provisions of Drugs (Price Control) Order. This provision also includes allocation for Media Campaigns; establishment expenses of the Authority and for strengthening of the monitoring of the drug prices.

4. **Assistance to Public Sector Undertakings(PSUs):** Token provision has been kept for the Public Sector Undertakings.

5. **Development of Pharmaceutical Industries:** The provision is for Schemes like Pharmaceutical Promotion and Development Scheme (PPDS) for promotion of pharmaceuticals, organizing various seminars, workshops etc,. It also includes Schemes of Cluster Development and Scheme of Kala-Azar and Anti- TB Agents and token provisions for various newly proposed schemes.

6. **Jan Aushadhi Scheme:** The provision is for the Jan Aushadhi Scheme.

MINUTES OF THE TWELFTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2015-16)

The Committee sat on Monday, the 28 March, 2016 from 1500 hrs. to 1630 hrs. in Room No. G-074, Parliament Library Building, New Delhi.

PRESENT

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri B. N. Chandrappa
3. Smt. Veena Devi
4. Shri R. Dhruvanarayana
5. Shri Kamalbhan Singh Marabi
6. Shri S. Rajendran
7. Dr. Kulamani Samal
8. Dr. Krishna Pratap Singh
9. Shri Tasleem Uddin
10. Smt Rekha Arun Verma
11. Shri George Baker

RAJYA SABHA

12. Shri K. Parasaran

SECRETARIAT

1.	Smt. Rashmi Jain	-	Joint Secretary
2.	Shri A. K. Srivastava	-	Director
3.	Shri Nishant Mehra	-	Under Secretary

List of Witness

Department of Chemicals and Petrochemicals

1.	Shri V. K. Subburaj	Secretary
2.	Shri Bhupendra Singh	Chairman, NPPA
3.	Shri Sudhansh Pant	Joint Secretary
4.	Dr. M. A. Ahammed	Joint Secretary
5.	Ms. Sunanda Sharma	Economic Advisor
6.	Dr. Sharmila Mary Joseph K	Member Secretary, (NPPA)

PSU/ AUTONOMOUS INSTITUTIONS

1.	Shri Praveen Kumar	CMD, IDPL
2.	Dr.E. A. Subramanium	MD, BCPL
3.	ShriK. V. Verkay	MD, HAL
4.	Shri M. D. Sreekumar	CEO, BPPI
5.	Dr. Kiran Kalia	Director, NIPER, Ahmedabad
6.	Dr. Ahmed Kamal	Director, NIPER, Hyderabad
7.	Dr. V. Ravichandran	Director, NIPER, Kolkata
8.	Dr. P. K. Shukla	Director, NIPER, Raebarelli
9.	Dr. M. Rehman	Registrar, NIPER, Guwahati
10.	Shri Jitender Kumar	Deputy Registrar (Finance & Accounts), NIPER, Mohali

2. At the outset, Hon'ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) and other officials to the sitting. Their attention was invited to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

3. After the witnesses introduced themselves, the Joint Secretary of the Department of Pharmaceuticals made power point presentation to the Committee.

4. During the discussion, the Hon'ble Chairperson and Members of the Committee raised queries on several issues such as shortage of budgetary allocation for various schemes of the Department, revival of sick PSU's like HAL, BCPL, IDPL etc. Implementation of 'Jan Aushadhi Scheme', functioning of NIPER, role of NPPA, R&D, recovery of overcharged amount from pharma companies, etc. which were replied to by the Secretary, Department of Pharmaceuticals and other officials.

5. The Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee.

6. A copy of the verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

MINUTES OF THE FIFTEENTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2015-16)

The Committee sat on Tuesday, the 26 April, 2016 from 1500 hrs. to 1600 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

Shri Anandrao Adsul - Chairperson

Members

Lok Sabha

2. Smt. Anju Bala
3. Shri Sankar Prasad Datta
4. Smt. Veena Devi
5. Shri K. Ashok Kumar
6. Shri Kamalbhan Singh Marabi
7. Smt. Kamala Devi Patle
8. Shri S. Rajendran
9. Shri Chandu Lal Sahu
10. Dr. Kulamani Samal
11. Smt. Rekha Arun Verma
12. Shri George Baker

Rajya Sabha

13. Shri Biswajit Daimary
14. Shri Narayan Lal Panchariya
15. Shri Palvai Govardhan Reddy
16. Shri Abdul Wahab

Secretariat

1. Smt. Rashmi Jain - Joint Secretary
2. Shri A.K. Srivastava - Director
3. Shri H. Ram Prakash - Additional Director

2. At the outset, the Hon'ble Chairperson welcomed the members of the Committee.

3. The Committee thereafter took up for consideration the following draft Reports:

a) xxxx xxxx xxxx xxxx

a. xxxx xxxx xxxx xxxx

b. Demands for Grants (2016-17) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

4. The draft Reports were adopted by the Committee without any amendment.

5. The Committee authorised the Chairman to make consequential changes, if any, arising out of the factual verification of the Reports by the Department of Fertilizers, Department of Chemicals and Petrochemicals and Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers and present the same to both the Houses of Parliament.

6. xxxx xxxx xxxx xxxx

The Committee then adjourned.

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xxxx Matters not related to this Report.