2	**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2014-15)** **SIXTEENTH LOK SABHA**

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2014-15)

SECOND REPORT

LOK SABHA SECRETARIAT
NEW DELHI

December, 2014/ Agrahayana 1936, (Saka)

CC&F.No.2

SECOND REPORT

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2014-15)

(SIXTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2014-15)

Presented to Lok Sabha on 10 December 2014

Laid in Rajya Sabha on 10 December 2014

LOK SABHA SECRETARIAT
NEW DELHI
December, 2014/ Agrahayana 1936, (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2014-15)

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 Satish Kumar Gautam
9.	Adv. Joice George
10.	Shri K. Ashok Kumar
11.	Shri Kamalbhan Singh Marabi
12.	Shri Chhedi Paswan
13.	Smt. Kamala Devi Patle
14.	Shri Rajendran S.
15.	Shri Chandu Lal Sahu
16.	Dr. Kulamani Samal
17.	Dr. Uma Saren
18.	Dr. Krishan Pratap Singh
19.	Shri Tasleem Uddin
20.	Smt. Rekha Verma
21.	Vacant
RAJYA SABHA	
22.	Shri Biswajit Daimary
23.	Dr. M.S. Gill
24.	Shri Sanjay Dattatraya Kakade
25.	Shri Narayan Lal Panchariya
26.	Shri K. Parasaran
27.	Shri Garikapati Mohan Rao
28.	Dr. Sanjay Sinh
29. *	Shri Palvai Govardhan Reddy
30.	Vacant
31.	Vacant

SECRETARIAT

1.	Smt. Rashmi Jain	-	Joint Secretary
2.	Shri U.B.S. Negi	-	Director
3.	Shri A.K. Srivastava	-	Additional Director
4.	Smt. Emma C. Barwa	-	Deputy Secretary

Changed the nomination of Shri Murli Deora, Member of Rajya Sabha from the Committee on Chemicals and Fertilizers to the Committee on External Affairs w.e.f. 25-09-2014.
** Shri Palvai Govardhan Reddy, Member of Rajya Sabha nominated w.e.f. 08-10-2014*
Shri Mohanbhai Kalyanjibhai Kundariya nominated as Minister of State w.e.f. 09.11.2014
The term of Shri Brijlal Khabri, MP (RS) has expire w.e.f. 25.11.2014

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2014-15) having been authorised by the Committee to submit the Report on their behalf present this Second Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2014-15.

2. The Committee examined the Demands for Grants (2014-15) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which were laid in Lok Sabha and Rajya Sabha on 5 August, 2014.

3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 30 October 2014.

4. The Report was considered and adopted by the Committee at their sitting held on 8 December, 2014.

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. 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;
5,December, 2014
14,Agrahayana, 1936 (Saka)

Anandrao Adsul
Chairperson
Standing Committee on
Chemicals and Fertilizers

CHAPTER-I

INTRODUCTORY

1.1 The Department of Pharmaceuticals in the Ministry of Chemicals & Fertilizers was created on 01.07.2008 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 Following work have been allocated to the Department of Pharmaceuticals:

(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 (2014-15) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 5 August 2014 The demand shows a budgetary support of Rs.247.87 crore [(Rs. 207 crore (Plan) + Rs.40.87 crore (Non-Plan)]. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2014-15. The detailed analysis along with Observations/Recommendations of the Committee are stipulated in a separate chapter at the end of the Report. The Committee expect the Department of Pharmaceuticals to take the Committee's recommendation seriously and to act on them expeditiously. The Committee also expect that the Department will take all necessary steps for proper and timely utilization of funds ensuing completion of the various plans and projects in a time bound manner.

CHAPTER-II

AN OVERVIEW OF PHARMACEUTICAL INDUSTRIES

2.1 As per Center for Monitoring Indian Economy (CMIE) the net sales of the drugs & pharmaceutical industry returned to growth in the March 2013 quarter after falling by 1.6 per cent in the December 2012 quarter & accelerated thereafter. Aggregate net sales of the industry grew by 2.5 per cent in March 2013, 5.5 per cent in the June 2013 quarter and by 8.0 per cent in the September 2013 quarter.

2.2 The companies notched up satisfactory performance during the first half ended September 2013 despite several odds like quality problems in US, new drug Price Control Order, forex losses, interest burden and higher manufacturing costs. On May 15, 2013, the Department of pharmaceuticals notified the Drugs (Prices Control) Order 2013 under which prices of 348 medicines in the National List of Essential Medicines (NLEM) have been brought under price control. The DPCO 2013 replaced an earlier order of 1995 that regulated prices of only 74 bulk drugs.

2.3 The industry posted a growth of 9.7 per cent in net sales in the December 2013 quarter as compared to the corresponding period last year. This was the fourth consecutive quarter of growth in net sales. Although the industry reported a single-digit growth in net sales, its total income rose by a healthy 28.5 per cent. The acceleration in the sales growth was supported by domestic companies. With an aggregate sales growth of 11.9 per cent, the 146 listed domestic pharmaceutical companies significantly outperformed their multinational counterparts. Domestic companies account for around 80 per cent of the industry's revenues. The growth in net sales of domestic companies was broad-based with 68 per cent companies posting higher sales than year ago.

2.4 The Profit Before Depreciation Interest and Tax (PBDIT) net of prior period and extraordinary items grew 21 per cent in the June,2013 quarter then declined by 2 per cent in the September, 2013 quarter and rose to 18.9 per cent in the December, 2013 quarter as compared to the corresponding period last year. The PBDIT net of prior period and extraordinary items as a per cent of net sales stood at 14.19 per cent, 17.54 per cent & 17.55 per cent during the quarters ending June, 2013, September, 2013 and December 2013 respectively.

PHARMACEUTICAL INDUSTRY

2.5 The annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs.121015.92 Crore during the year 2012-13. The share of export of Drugs, Pharmaceuticals and Fine Chemicals is Rs. 55692.53 Crore. 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. This is realized through the country's strengths in the field of organic chemicals' synthesis and process engineering.

2.6 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 HIV/AIDS medicines. Many Indian companies are part of an agreement where major HIV/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 HIV/AIDS in Africa. Many US Schemes are sourcing Anti Retrovirals from Indian companies whose products are already US FDA approved.

2.7 The Indian Pharmaceutical companies maintain highest International standards in Purity, Stability and Safety, Health and Environmental (SHE) 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 actives pharma 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 Indian companies are now seeking regulatory approvals in USA in specialized segments like Anti-infectives, Cardiovasculars, CNS group. Along with Brazil & PR China, India has carved a niche for itself by being a top generic Pharma player.

2.8 Many Indian companies have got various international regulatory approvals for their plants, from agencies like USFDA, MHRA-UK, TGA-Australia, MCC-South Africa etc. India is the only country having the highest number of USFDA approved plants for generic drugs' manufacture outside USA. Major share of Indian Pharma exports is going to highly regulated markets like developed western countries & USA 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 upto 50% of their turnover from International business.

2.9 The policy of the Government continues to be to ensure availability of good quality life saving drugs at reasonable price and pay special attention to the poorer sections in the matter of health care.

2.10 Apart from this, in November, 2008, the Department launched Generic Drug Campaign by opening first Jan Aushadhi Generic Drug Store at Amritsar Civil Hospital on 25.11.08. Since

November, 2008, 199 Jan Aushadhi Stores have been opened in various parts of the country till 31st October 2014, out of which 99 are functional. A New Business Plan has been approved in August 2013 particularly to address the shortcomings and challenges identified in scaling up the activities. Under the new Plan, the process of identification of operating agencies has now been simplified and entities other than those sponsored by the State Governments are also proposed to be appointed as operating agencies for running the Jan Aushadhi Stores. As per the new Plan, societies/trusts/unemployed qualified pharmacists/entrepreneurs etc. would be eligible for appointment as operating agencies. Stores would now be opened even outside the hospital premises. By 2016-17, the Government plans to open 3000 new Jan Aushadhi stores. Basket of drugs has now been widened to 361 drugs covering all therapeutic categories.

Plan Outlay

2.11 Planning Commission has allocated Rs. 207.00 crore for the plan outlay for the schemes of the Department of Pharmaceuticals for the annual plan 2014-15. Broad Scheme-wise details are given below:-

I. Support of Existing PSUs		
1.	BCPL, HAL, IDPL & RDPL	HAL-Utility Set up, Agro Vet expansion & Upgradation of existing IV fluid Plant to WHO-GMP etc. Rs 16.79 crore. Projects for upgradation Rs. 7 crore for BCPL. IDPL-Restarting activities at Hyderabad Plant Rs.5 crore. RDPL-Capacity enhancement Rs. 1.21 crore.
II. Support to Autonomous Bodies		
2.	NIPER, Mohali	The Institute has been allocated Rs.20.00 crore in 2014-15 B.E (Plan) for continuing its ongoing research work in different areas of pre-clinical drug discovery and development etc. besides their regular master and doctoral program/training courses.
3.	New NIPER Institutes	The Union Government has approved setting up 6 New NIPERs (National Institutes of Pharmaceutical Education and Research) - one each at Gandhinagar (Gujarat), Hyderabad (Andhra Pradesh), Hajipur (Bihar), Kolkata (West Bengal), Guwahati (Assam) and Rae Bareli (Uttar Pradesh). Classes in all the six new NIPERs were started with the help of local Mentor Institutes from academic session of 2007-08 at Ahmedbad, Hyderabad, Hajipur & Kolkata and 2008-09 at Guwahati & Rae Bareli. An allocation of Rs. 67.00 crore in 2014-15 BE (Plan) been made for new NIPERs excepting NIPER, Guwahati. For NIPER, Guwahati requirement would be met out of available provisions for North-East to the tune of Rs.21.00 crore.
III. Other ongoing schemes		
4.	NPPA	Rs. 2 crore has been kept for the scheme “Consumer Awareness and Publicity through Print, electronic and other media”.

	PPDS	Rs. 2.00 crore has been kept for promotional activities, exhibition, seminars etc. for promotion of Indian pharmaceutical sector.
6.	IT/Secretariat	For providing IT/Secretariat services to the personnel of the Department, an amount of Rs. 1.00 crore has been kept.
7.	Creation of IPR facilitation center at Pharmaexcil	A provision of Rs. 1.00 crore has been made for creation of IPR facilitation centre.
8.	Critical assistance for WHO pre-qualification for pharma PSUs/R&D	The project for WHO-GMP compliance in RDPL is under consideration in this Department. An amount of Rs. 11.39 crore is required for the purpose. An amount of Rs. 4.55 crore has been released to RDPL as first installment. Rs. 10.00 crore has been allocated under this scheme for the year 2014-15. An amount of Rs. 6.84 crore has been allocated for RDPL for the year 2014-15 for the purpose. An amount of Rs. 3.16 crore has been allocated to IDPL for WHO-GMP compliance at Rishikesh Plant and revised Schedule-M GMP Gurgaon Plant.
9.	Jan Aushadhi Scheme	This is a flagship program of Department of Pharmaceuticals under which commonly required medicines will be made available under generic names and at affordable prices through dedicated outlets across the country. Apart from making the medicines accessible to poor sections of the society, this will also provide a platform for Public Sector Undertakings (PSU) to have foothold in the trade market. The purpose of making available socially relevant medicines will also be simultaneously served. An amount of Rs. 30 crore has been earmarked for Jan Aushadhi Scheme which involves opening of JASs in different States of the country, for advertisements and establishment cost of BPPI etc.

<u>New schemes introduced in 2014-15</u>

2.12 To enable it to execute competently and effectively the role entrusted to the newly created Department of Pharmaceuticals, some new schemes have been initiated in 2014-15 viz. Setting up of National centre for Research and Development (R&D) in Bulk Drugs (NCRDBD) at NIPER, Hyderabad. This has recently been approved at the total project cost of Rs. 54.20 crore along with operating cost for five years amounting to Rs. 37.43 crore .

2.13 An amount of Rs. 15 crore is kept for the other new schemes like Cluster Development Programme for Pharma Sector, Kala Azar Scheme of NIPER etc. under process. Cluster Development Programme would be a Central Sector Scheme to be implemented as Public Private Partnership (PPP) format for developing Pharma clusters.

<u>IMPORTS</u>

2.14 Imports of medicinal and pharmaceuticals products for the last three years were as under:

(Rupees in Crore)

Year	Import of Medicines & Pharmaceuticals Products
2010-11	11113.86

2011-12	14287.66
2012-13	16965.09

2.15 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. Manufacturers of Drugs and Pharmaceuticals are free to produce any drug approved by the Drug Control authorities. Imports of Drugs and Pharmaceuticals is done as per Foreign Trade Policy. However, import of some drugs and drug intermediates is still restricted under current Foreign Trade Policy. Imports which are restricted are basically due to common HS codes for some narcotic substances or similarity to some Ozone Depleting Substances (ODS).

<u>EXPORTS</u>

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

(Rupees in Crore)

Year	**Exports of Medicines & Pharmaceuticals Products**
2010-11	42353.28
2011-12	51393.29
2012-13	55692.53

<u>Pharma Export Promotion Council (PHARMEXCIL)</u>

2.17 The Department had played a pivotal role in the formation of Pharmexcil. The role of Pharmexcil is for facilitation of exports of Drugs, Pharmaceuticals, Biotechnology products, Herbal medicines and Diagnostics, to name a few. It is authorized to issue Registration-cum-Membership Certificate (RCMC) which is one of the requirements for the importers and exporters of commodities. In addition to this, Pharmexcil is concerned with giving export thrust to the various products through visits of delegations to various markets abroad, organizing of seminars, workshops and exhibitions. As a major area of work, Pharmexcil also holds Buyers/ Sellers meets and compiles detailed data base on pharma exports and problems in exporting pharma products.

<u>International Cooperation / Export Promotion Of Pharmaceuticals</u>

2.18 An important focus area for the Department of Pharmaceuticals is promotion of Indian Pharmaceutical Products in global market. The Department participated in the following International Cooperation events during 2013-2014:-

i) India-Ukrain Joint Working Group on Health Care and Pharmaceuticals held on 15th 16th April, 2013 at New Delhi;

ii) EU-India Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices at Brussels, 23-24 September,2013;

iii) India-Tunisia Joint Working Group on Drugs & Pharmaceuticals on 5th November, 2013

iv) 7th India-Russia Forum on Trade & Investment from 19– 21 September, 2013;

v) Department of Pharmaceuticals has signed a Memorandum of Understanding (MoU) with the State Administration of Ukraine on Medicinal Products for collaboration in the areas of Trade, Industry, Joint Venture, R&D in Pharmaceuticals and Bio-Pharmaceutical sector on 13th November, 2013 during the Fifth Session of the India-Ukraine Inter-Governmental Commission on Trade, Economic, Scientific, Technological, Industrial and Cultural Cooperation.

Proposed Major Area of International Cooperation

2.19 The Department proposes to leverage Inter-Country partnership through MoUs for formulating greater market access to Indian Pharma in key markets like Russia, Ukraine, Kazakhstan etc. amongst the CIS, Mexico, Brazil, Venezuela, etc in LAC region, Japan, ASEAN, etc in the East Asia, South Africa, Nigeria, Kenya, etc in Africa and some key Gulf Countries like Saudi Arabia, UAE, etc. It is also targeting focus on European countries like Spain, Greece, Germany, France and Italy for APIs and niche formulations.

2.20 When asked about the reasons for gradual increase in the import of Medicinal and Pharmaceutical products over the last three years, the Department in its written reply stated as under:-

> " As the pharmaceutical industry has grown, the demand for various raw materials has increased resulting in increase of import of medicines and pharmaceutical products"

2.21 On being enquired about the steps taken or 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".

2.22 On being 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 of Pharmaceuticals stated in writing as under:-

> "The data regarding percentage share of Indian Pharma Companies and MNC Pharma companies is not maintained in the Department of Pharmaceuticals. The Foreign Trade Policy administered by Ministry of Commerce and Industry provides incentives to boost various sectors including export of Pharma products. DoP after stakeholders consultation forward its recommendations to Ministry of Commerce and Industry for appropriate consideration and inclusion in the Foreign Trade Policy"

CHAPTER-III

FIVE YEAR PLANS AND ANNUAL PLAN

3.1 The details of scheme-wise plan outlays during each year of 12th five year plan are as under: (Rs. in Crore)

S. No.	Name of the Scheme	Total GBS allocation for the 12th Plan	Yearly Allocation During 12th Five Year Plan				
			2012-13	2013-14	2014-15	2015-16	2016-17
1	Pharma Promotion and Development Scheme (PPDS)	10.00	2.00	2.00	2.00	2.00	2.00
2	Intellectual Property Rights Facilitation Centers	5.00	1.00	1.00	1.00	1.00	1.00
3	NIPER, Mohali	255.00	24.00	12.00	20.00	99.50	99.50
4.	New NIPERS*	1005.00	70.00	76.50	88.00	385.25	385.25
5.	Setting up National Centre for R&D in Bulk Drugs in NIPER, Hyderabad	60.00	0.00	0.00	2.00	29.00	29.00
6	Jan Aushadhi Scheme	200.00	20.00	25.00	30.00	62.50	62.50
7.	Up gradation of Medium Enterprises (MEs) to WHO-GMP Standards etc.	175.00	2.00	0.00	6.00	83.50	83.50
8.	Consumer Awareness Scheme NPPA	20.00	4.00	4.00	2.00	5.00	5.00
9.	I.T Plan Secretariat	4.00	1.00	1.00	1.00	0.50	0.50
10.	Project Based Support of existing to PSU	700.00	30.00	36.50	40.00	296.75	296.75
11.	New Scheme / initiatives for 12th Plan	534.00	34.00	30.00	15.00	227.50	227.50
	Total	**2968.00**	**188.00**	**188.00**	**207.00**	**1193.00**	**1193.00**

*Includes North East allocation

Out of the total approved outlay of Rs. 2968 crore during the 12th Plan period, Planning Commission has allocated Rs.583 crore for the first three years of the plan period and the balance outlay of Rs.2386 crore (Rs.1193 + Rs.1193) has been redistributed for the remaining two years of the 12th Five Year Plan period.

3.2 While for 2012-13 BE was Rs.188 crore, RE was Rs.85 crore and Actual expenditure was Rs.51.87 crore only.

3.3 The Committee were informed that the Department had proposed an outlay of Rs. 566.80 crore for the year 2013-14; Planning Commission has approved Rs. 188.00 crore.

Details of scheme-wise allocation and percentage achievement in terms of financial targets for 2013-14 (i.e. second year of the 12th Five Year Plan) is given in the Table below.

(Rs. in crore)

Sr. No.	Name of the Scheme	Outlay			Achieve-ment (%)
		2013-14 BE	2013-14 RE	Actual	Actual Vs RE
I	**Project Based Support to PSUs**	29.66	9.22	9.22	100.00
II	**Support to Autonomous Institutions**				
1	National Institute of Pharmaceutical Education and Research(NIPER)	12.00	0	0	-
2	New NIPER Institutes				
	a) NIPER, Ahmedabad	20.00	6.94	6.79	97.84
	b) NIPER, Hajipur	3.70	3.50	3.50	100.00
	c) NIPER, Guwahati (NE)	18.80	3.00	2.88	96.00
	d) NIPER, Kolkata	4.50	4.50	4.41	98.00
	e) NIPER, Hyderabad	25.00	23.00	23.00	100.00
	f) NIPER, Rai Bareli	4.50	4.70	4.50	95.74
	Total NIPER	**76.5**	**45.64**	**45.08**	**98.77**
3	National Pharmaceutical Pricing Authority(NPPA)	4.00	0.0036	0.0036	100.00
III	**Other Ongoing Schemes**				
1	Pharma Promotion and Development Scheme (PPDS)	2.00	1.25	0.93	74.40
2	IT/Secretariat	1.00	1.00	0.96	96.00
3	Creation of IPR facilitation center at Pharmexcil	1.00	0.25	0.25	100.00
4	Critical assistance for WHO -GMP PSUs	6.84	0	0	-
5.	Jan Aushadhi Scheme	25.00	15.20	15.20	100.00
6.	New Schemes 12th Plan -Drug discovery of Anti-tubercular agent & Kala Azar	30.00	2.44	2.44	100.00
	Total	**188.00**	**75.00**	**74.07**	**98.76**

3.4 When asked to give reasons for lesser allocation of funds by the Planning Commission under various schemes for the first three years of the 12th Five Year Plan, the Department in its written reply stated as under:-

"Planning Commission had approved an outlay of Rs. 2968 crore for the 12th Plan period. However the actual budget allocation by the Planning Commission during the first three years was only Rs. 188 crore, Rs. 188 crore and Rs. 207 crore respectively.

It may be seen that for Annual Plan 2010-11, against a BE of Rs.165 crore (RE was restricted to Rs.119 crore), actual expenditure incurred amounted to Rs. 69.66 crore. Further, against a BE of Rs. 175 crore for Annual Plan 2011-12 (RE was Rs.77.78 crore), actual expenditure incurred was Rs.40.33 crore only. For Annual Plan 2012-13, Department of Pharmaceuticals proposed an outlay of Rs.1127.45 crore against which outlay approved by Planning Commission was Rs. 188 crore (RE was Rs.85 crore), actual expenditure incurred was Rs.51.26 crore .

For Annual Plan 2013-14 the Department proposed an outlay of Rs. 567.60 crore. However, Planning Commission allocated only Rs. 188.00 crore (RE of Rs.75 crore) and actual expenditure incurred was Rs.73.9 crore. At the time of giving approval for Annual Plan outlays, Planning Commission had indicated that the total outlay of the Department be maintained at the same level as in the previous year. A suitable scheme-wise break-up was worked out within this overall outlay, by the Department.

For the year 2014-15, the Department had proposed an outlay of Rs. 871.81 crore to Planning Commission against which Planning Commission approved only Rs. 207

crore, which works out to just 10 percent more than last year's allocation of Rs. 188 crore. While approving the outlay for 2014-15, the Commission inter alia observed, that:-

I. Planning Commission has determined the Gross Budgetary Support (GBS) for various Ministries/Departments to be reflected in the Union Budget for 2014-15 after taking into consideration the demands for various Ministries/Departments but within the constraint of available resources.

II. At least 10% of GBS should be earmarked for north-eastern states.

III. Scheme wise provision may be made for SCSP/TSP and gender budgeting as per the guidelines issued by the Planning Commission & M/o Finance from time to time."

3.5 On being asked to give reasons for higher allocation for the last two years of the 12th Plan under various Scheme, Scheme-wise and the way the Department proposes to utilize the funds under various schemes, the Department in its written reply stated as under:-

"Out of the total approved outlay of Rs. 2968 crore during the 12th Plan period, Planning Commission approved Rs.583 crore for the first three years of the plan period and the balance outlay of Rs.2385 crore has been redistributed for the remaining two years of the 12th Five Year Plan period i.e. Rs 1193 crore in each of the two years. The Department proposes to utilize the funds in 2015-16 and 2016-17 on various schemes with a major focus on (i) Establishment of six new NIPERS (ii) Strengthening of Pharma CPSUs (iii) Starting of new schemes of Pharma (iv) NIPER, Mohali (v) Up gradation of Medium Enterprises (MEs) to WHO-GMP Standards (vi) Opening of new Jan Aushadhi stores (vii) Setting up National Centre for R&D in Bulk Drugs in NIPER, Hyderabad etc. The Department will utilize the funds according to the specific requirement of funds under these schemes.

<u>Scheme -- Project based support to PSUs</u>

3.6 Project Based Support is a scheme to provide Plan loans to Pharma CPSEs for their specific projects; it also includes loans to be provided under the Revival Schemes. The 2nd Rehabilitation Plan of HAL and the Revival Plan of IDPL is under consideration of this Department.

<u>Physical and Financial progress during 2012-13 and 2013-14.</u>

Year	Physical Progress	Financial progress
2012-13	IDPL has started preliminary works like appointment of staffs, tender activities from the released amount of Rs. 5.00 crore for restarting manufacturing operations at IDPL, Hyderabad Plant.	B.E. allocation for the year 2012-13 was Rs. 20.00 crore. **<u>IDPL:</u>**Rs. 15.00 crore was allocated for IDPL, Hyderabad for restarting its operations. Approval of Ministry of Finance for release of funds for the IDPL project was received only on 31.3.13. The amount of Rs 15.00 crores was reduced to Rs 5.00 crores at RE stage which was released. **<u>HAL</u>**: Rs. 3.00 crore for HAL's 'Upgradation of Large Volume parenteral with facilities compliant to WHO GMP' – the funds could not be released as the Ministry of Finance did not approve release of fresh funds to HAL as it is a defaulter in repayment of earlier loans taken from Government of India. **<u>BCPL</u>**: Rs 2.00 crore for 'Implementation of ERP system at BCPL could not be released as Planning Commission did not approve the ERP project.
2013-14	IDPL: Rs.1.22 crore released to Orissa Drugs & Chemicals Limited (ODCL), a	As against BE allocation of Rs 29.66 crore only Rs 9.22 crore was released.

	unit of IDPL in September, 2013 have been fully utilized and corresponding physical activities Planned in Phase I in making the plant Schedule M compliant have been completed. Since further funds of Rs 1.80 crore for completing the schedule M works was released towards financial year end, physical work is underway. HAL: Funds of Rs 6.20 crore were released to HAL in March, 2014. Tendering is underway.	IDPL: An amount of Rs 6.19 crore was allocated. Since IDPL could not substantially spend Rs 5.00 crore released in previous year for IDPL, Hyderabad, no further funds were released for the project. However, an amount of Rs 3.02 crore was released to ODCL to complete project for Schedule M compliance. HAL: Rs 14.17 crore for two projects of HAL were reduced to Rs 6.20 crore at RE stage and on receipt of 'in-principle' approval of Planning Commission, this amount was released. BCPL: Rs 9.30 crore allocated at BE stage was reduced to Nil at RE stage as complete proposals of BCPL were not received in the Department.

Scheme -- Critical Assistance Scheme (Grant for WHO GMP Compliance)

WHO-GMP Standards Compliance

3.7 Schedule 'M' compliance is a statutory requirement for any Pharma manufacturing plant as per Drugs & Cosmetics Act, 1945. Now, with increasing export driven competition in both domestic and export sector, no Pharma manufacturing company can survive without compliance to International Standards. WHO-GMP Standards/Compliance is now mandatory for acceptance of product both domestically and internationally.

3.8 Under the Scheme the grant is provided to Pharma CPSEs for WHO-GMP compliance. A fund of Rs. 10.00 crore was allocated for the year 2012-13 i.e. the first year of 12th Five Year Plan. At present the proposal for the WHO, GMP Compliance in RDPL is being considered under this Scheme.

Physical and Financial progress during 2012-13 and 2013-14.

Year	Physical Progress	Financial progress
2012-13	For WHO GMP compliance project, RDPL is in the process of tendering.	**RDPL**: For WHO GMP compliance project, B.E. allocation for the year 2012-2013 was Rs. 10.00 crore. Under this scheme, Planning Commission granted in-principle approval for Phase-II project on WHO GMP Compliance in RDPL at a total cost not exceeding Rs. 14.46 crore of which GOI share was to be Rs. 11.38 crore. It was decided to release the amount in three installments (40%+40%+20%). The 1stinstallment of Rs 4.55 crore was released in October, 2012.
2013-14	While in some cases tenders have been accepted and are under finalization. In other cases retendering is underway as the response in the earlier tenders was poor.	As against the BE allocation of Rs 6.84 crore, the amount was reduced to NIL at RE stage, as no amount could be released since funds released earlier could not be substantially spent.

CHAPTER-IV

DEMANDS FOR GRANTS FOR THE YEAR 2014-15

4.1 The details of Scheme-wise Outlays proposed by the Department and finally approved by Planning Commission for the year 2014-15 are as under:-

(Rs. in crore)

Sr. No.	Name of the Scheme	2014-15 Proposed	2014-15 BE
I	**Project Based Support to PSUs**	140.06	30.00
II	**Support to Autonomous Institutions**		
1.	National Institute of Pharmaceutical Education and Research(NIPER), Mohali	88.40	20.00
2.(a)	New NIPER Institutes	193.00	67.00
(b)	North East (NIPER Guwahati)	100.00	21.00
3.	Setting up National center for R&D in NIPER	25.00	2.00
4.	National Pharmaceutical Pricing Authority(NPPA)	4.00	2.00
III	**Other Ongoing Schemes**		
5.	Pharma Promotion and Development Scheme (PPDS)	2.00	2.00
6.	IT/Secretariat	1.00	1.00
7.	Up-gradation of MEs to WHO-GMP Standards etc.	200.50	6.00
8.	Creation of IPR facilitation center at Pharmexcil	1.00	1.00
9.	Critical assistance for WHO GMP for Pharma PSUs	8.84	10.00
10.	Jan Aushadhi Scheme	48.01	30.00
11.	New Schemes	60.00	15.00
12.	**Total**	**871.81**	**207.00**

4.2 On being enquired by the Committee about the reasons for significant lesser amount of outlays approved by the Planning Commission and the manner in which the Department plans to achieve their targets the Department in its written reply explained as under:-

> "Though the Department had proposed an outlay of Rs. 871.81 crore to Planning Commission for the year 2014-15, Planning Commission approved only Rs. 207 crore which works out to be just 10 percent more than last year allocation of Rs. 188 crore. While approving the outlay for 2014-15, the Commission inter alia observed, that:-
>
> I. Planning Commission has determined the Gross Budgetary Support (GBS) for various Ministries/Departments to be reflected in the Union Budget for 2014-15 after taking into consideration the demands for various Ministries/Departments but within the constraint of available resources.
>
> II. At least 10% of GBS should be earmarked for north-eastern states.
>
> III. Scheme wise provision may be made for SCSP/TSP and gender budgeting as per the guidelines issued by the Planning Commission & M/o Finance from time to time".

4.3 Budgetary allocation under Plan and Non-Plan under Major Head during the year 2013-14 and 2014-15 is indicated below:-

(Rs. in crore)

Major Head	Budget Estimates 2013-2014			Revised Estimates 2013-2014			Budget Estimates 2014-2015		
	Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
Revenue	158.34	40.29	198.63	65.78	35.30	101.08	177.00	40.83	217.83
Capital	29.66	0.04	29.70	9.22	5.03	14.25	30.00	0.04	30.04
Total	**188.00**	**40.33**	**228.33**	**75.00**	**40.33**	**115.33**	**207.00**	**40.87**	**247.87**

4.4 When asked to justify the increase in BE 2014-15 of Rs.247.87 crore as compared to RE 2013-14 of Rs.115.33 crore, the Department of Pharmaceuticals stated as under:-

> " In the case of Non- Plan funds the RE figures of 2013-14 is Rs. 40.33 crore and the BE allocation for 2014-15 is. Rs. 40.87 crore, this reflects only a marginal increase. The Non-Plan ceilings are decided by Ministry of Finance. In the case of allocation of ceilings for Plan Funds, Planning Commission approved Rs. 207 crore (BE) for 2014-15, which works out to be around 10 percent more than Annual Plan 2013-14 allocation of Rs. 188 crore (BE). The total for Plan & Non-Plan comes to Rs. 247.87 crore (BE) for the Year 2014-15.The increase is required for the various upcoming Plan schemes of the Department".

4.5 The Committee enquired about the reasons for higher allocation of Rs.177.00 crore in BE 2014-15 as compared to RE of Rs.65.78 crore in 2013-14 under Plan Head and also the manner in which the Department proposes to utilize the funds, the Department in its written reply explained as under:-

> "Planning Commission has approved Plan Funds of Rs. 207 crore (BE) for the Year 2014-15 which works out to be just 10 percent more than last year allocation of Rs. 188 crore(BE). The allocation for Plan Head Revenue is Rs. 177 crore& Capital Head is Rs. 30 crore. During the last three years the expenditure on Plan Schemes is showing a rising trend. As there was higher requirements of funds under various schemes, the BE for 2014-15 was higher. The Department shall be utilizing the funds for various upcoming schemes like establishment of six new NIPERs, strengthening of Pharma CPSUs, Up gradation of Medium Enterprises (MEs) to WHO-GMP Standards, opening of new Jan Aushadhi stores, Setting up National Centre for R&D in Bulk Drugs in NIPER, Hyderabad, other new schemes etc".

4.6 When asked to explain the reasons for higher allocation of Rs.40.83 crore in BE 2014-15 under Non- Plan Head Revenue as compared to Rs.35.30 crore in RE 2013-14, the Department in its written reply stated as under:-

> "Non Plan ceilings for both BE and RE are decided by Ministry of Finance keeping in view several factors, such as present salary to staff, future outflow, increments, DA increases, increase in other allowances, office expenses, etc. The Non Plan ceilings of the Department at RE 2014-14 was at Rs. 40.33 crore, the same as at BE level. The ceiling for BE 2014-15 has been decided at Rs. 40.87 crore after considering all the relevant factors. The Revenue (Non Plan) had an allocation of Rs. 40.29 crore at BE stage this was further reduced to 35.30 crore for making allocation of Rs. 5.00 crore to HAL (Capital /Non Plan) head of account at RE stage. There is only a marginal increase in the total Non Plan Section in 2014-15 as compared to RE 2013-14".

4.7 A statement showing the Budget Estimates, Revised Estimates and Actual Expenditure for the last three years (year-wise) and Budget Estimates for the year 2014-15 showing separately for Plan and Non-Plan expenditure is as follows:-

PLAN **(Rs. in Crores)**

		2011-12			2012-13			2013-14			2014-15
S.No.	**Head**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
	Revenue										
1	Sectt.	0.25	0.20	0.19	1.00	1.00	0.63	1.00	1.00	0.82	1.00
2	NIPERs	108.08	35.86	33.80	75.20	44.95	37.42	69.70	42.64	45.07	87.00

S.No.	Head	2011-12			2012-13			2013-14			2014-15
		BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
3	NPPA	2.40	2.05	0.16	4.00	4.00	0.00	4.00	0.00	0.00	2.00
4	Other Schemes	22.32	8.44	0.45	67.00	11.05	7.53	62.84	17.89	17.89	64.00
5	PPDS	2.00	1.00	0.68	2.00	1.00	0.68	2.00	1.25	0.93	2.00
6	NE Region	17.50	7.78	0.00	18.80	13.00	0.00	18.80	3.00	0.00	21.00
	Total Revenue	**152.55**	**55.33**	**35.28**	**168.00**	**75.00**	**46.26**	**158.34**	**65.78**	**64.71**	**177.00**
	Capital										
7	HAL	6.85	6.85		3.00	5.00	0.00	14.17	6.20	6.20	16.79
8	BCPL	0.60	0.60	0.60	2.00	0.00	0.00	9.30	0.00	0.00	7.00
9	IDPL	10.00	10.00	4.61	15.00	5.00	5.00	6.19	3.02	3.02	5.00
10	RDPL	5.00	5.00				0.00		0.00	0.00	1.21
	Total Capital	**22.45**	**22.45**	**5.21**	**20.00**	**10.00**	**5.00**	**29.66**	**9.22**	**9.22**	**30.00**
	Total	**175.00**	**77.78**	**40.49**	**188.00**	**85.00**	**51.2**	**188.00**	**75.00**	**73.9**	**207.0**

Non Plan

S. No.	Head	2011-12			2012-13			2013-14			2014-15
		BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
1	**Revenue**										
2	Sectt.	7.64	7.62	7.22	8.94	7.59	7.42	9.00	8.75	8.50	11.72
3	NPPA	5.88	5.81	5.36	6.35	6.27	5.89	7.71	7.34	6.71	12.07
4	PEPS	0.20	.05	.05	.20	0	0	.0	0.01	0.01	0.01
	NIPER	24.23	24.77	24.77	27.55	22.93	22.82	23.57	19.20	19.20	17.03
	Total Revenue	**37.95**	**38.25**	**37.40**	**43.04**	**36.79**	**36.13**	**40.29**	**35.30**	**34.42**	**40.83**
5	**Capital**										
6	SSPL	.01	.01	0	.01	0	0	0	0		
7	BCPL	.01	.01	0	.01	0	0	0.01	0.01	0.00	0.01
8	BIL	.01	.01	0	.01	0	0	0.01	0.01	0.00	0.01
9	IDPL	.01	.01	0	.01	0	0	0.01	0.01	0.00	0.01
10	HAL	.01	.01	0	.01	0	0	0.01	5.00	5.00	0.01
	Total Capital	**0.05**	0.05	0	**0.05**	0	0	0.04	5.03	5.00	0.04
	Grand Total	**38.00**	**38.30**	**37.40**	**43.09**	**36.79**	**36.13**		**40.33**	**39.42**	**40.87**

4.8 On being asked to give reasons for less allocation of Rs.0.04 crore in BE 2014-15 against RE of Rs.5.00 crore in 2013-14 under Non-Plan Capital Head, the Department in its written reply stated as under:-

> "The BE allocation in the Capital (Non Plan) Section was initially kept at 0.04 crore indicating a token provision of Rs 1.00 lakh to each of the four PSUs. However, due to a financial crunch in HAL, the salary could not be paid for four to five months to the

employees of HAL. In order to provide interim relief to the employees of HAL, a Non-Plan loan of Rs. 5.00 crore was released to HAL from the Contingency Fund of India for which a provision of Rs. 5.00 crore was made at the RE stage after due re-appropriation of funds from Plan to Non-Plan".

4.9 On being enquired by the Committee in respect of HAL about the significant reduction from RE of Rs.5 crore for the year 2013-14 to BE of Rs..01 crore for the year 2014-15, the Department in its written reply clarified as under:-

"Due to financial crunch in HAL, the salary could not be paid for four to five months to the employees of HA during 2013-14. In order to provide interim relief to the employees of HAL, a Non Plan Loan of Rs. 5.00 crore was released to HAL from the Contingency Fund of India for which a provision of Rs. 5.00 crore was made at the RE stage under non-plan head. The loan from Contingency Fund of India was recouped after approval of Parliament for re-appropriation from Plan to Non Plan. During BE 2014-15 a token provision has been made to cater to any emergent situations, such as last year".

4.10 The scheme-wise Outlays by way of Gross Budgetary support in respect of 2012-13 (Actuals), 2013-14 (BE), 2013-14 (RE) ,2013-14 (Actuals) and 2014-15 (BE) are given below:

(Rs. in crore)

Sr. No.	Name of the Scheme	2012-13 (Actuals)	2013-14 (BE)	2013-14 (RE)	2013-14 (Actuals)	2014-15 BE
I	Project Based Support to PSUs	5.00	29.66	9.22	9.22	30.00
II	Support to Autonomous Institutions					
1	NIPER,Mohali	0.00	12.00	0.00	0.00	20.00
2	New NIPER Institutes	37.42	76.50	45.64	45.08	88.00
3	Setting up National center for R&D in Bulk Drug					2.00
4	National Pharmaceutical Pricing Authority	0.52	4.00	0.00	0.00	2.00
III	Other Ongoing Schemes					
5	Pharma Promotion and Development Scheme	0.68	2.00	1.25	0.93	2.00
6	IT/Secretariat	0.63	1.00	1.00	0.96	1.00
7	Up-gradation of MEs to WHO-GMP Standards	0.00				6.00
8	Creation of IPR facilitation center at Pharmaexcil	0.00	1.00	0.25	0.25	1.00
9	Critical assistance for WHO for Pharma PSUs	4.55	6.84	0.00	0.00	10.00
10	Jan Aushadhi Scheme	1.66	25.00	15.20	15.20	30.00
11	New Schemes- Drug Discovery Anti-Tubercular Agent and Kala Azar	1.32	30.00	2.44	2.44	15.00
12.	Total	51.78	188.00	75.00	74.08	207.00

Project Based Support to PSUs

4.11 On being asked to give reasons regarding significant increased funds for Project Based Support to PSUs to Rs. 30.00 crore in BE 2014-15 which is three times of RE 2013-14 of Rs. 9.22 crore, the Department in its written reply submitted as under:-

"As there was higher requirements of funds from the PSUs, the BE for the 2014-15 for Project Based Support to PSUs allocated at higher side. Out of Rs. 30.00 crore, Rs. 13.21 crore has already been released. The status of release of funds is given below:

Status of Release of Fund for Plan Schemes to PSUs during the year 2014-15 as on 22.09.2014

Rs. In crore

S.No.	Scheme	Head	2014-15			Status of release of funds with % of achievement and reasons for shortfall etc. with the efforts made by the ministry to achieve the targets
			Company Organi-sation	BE	RE	
1	2	3	4	5	6	7
1	Support of PSUs (Project based support) **(Loans to PSUs)**	Plan Capital Loan for Pharma Industries	HAL	**16.79**	NA	**Rs. 8.21**crore released to HAL for utility set up for formulations (Rs. 2.21 crore) & expansion of agro-vet facilities (Rs. 6.00 crore) A proposal for the release of Rs. Rs. **6.28**crore is under process. The 'in-principle' approval of Planning Commission received on 22.09.2014. Further action is being taken.
			BCPL	**7.00**	NA	Proposal received from BCPL on 19.09.2014. Further action is being taken.
			IDPL	**5.00**	NA	Sanction issued for release of fund.
			RDPL	**1.21**	NA	No proposal received till date. Reminder sent to RDPL for sending proposal.
2	Critical Assistance Scheme **(Grant for WHO GMP Compliance**	New Schemes of Pharma	RDPL	**6.84**	NA	No request received for release of 2nd installment. RDPL intimated that funds released for the project has been utilized for some other purpose. A committee set up to reassess the project. The report of Committee, received is being processed.
			IDPL	**2.00**	NA	Proposal for WHO GMP compliance at Rishikesh Plant of IDPL received from IDPL, has been sent after FD's approval for 'in-principle' approval of Planning Commission.
				1.16	NA	Proposal for Revised Schedule-M GMP Gurgaon Plant of IDPL received from IDPL has been sent after taking IFD's approval for 'in-principle' approval of Planning Commission.

CHAPTER-V

HEAD-WISE ANALYSIS OF DEMANDS FOR GRANTS (2014-15)

(a) MAJOR HEAD 3451

Secretariat –Economic Services

(Rs.in crore)

BE 2013-14			RE 2013-14			BE 2014-15		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
1.00	**9.00**	**10.00**	**1.00**	**8.75**	**9.75**	**1.00**	**11.72**	**12.72**

5.1 On being asked to give reasons for increase in Non Plan allocation from Rs. 11.72 crore in BE 2014-15 as compared to Rs. 8.75 crore in RE 2013-14, and the manner in which the Department is likely to spend the amount, The Department in its written reply stated as under:-

> " The enhancement of Non-Plan allocation to Rs. 11.72 crore in BE 2014-15 from Rs. 8.75 crore in RE 2013-14 is on account of increase in DA rate announced by the Government from time to time, release of annual increment to officials of the department and payment of wages to outsourced staff against vacant posts in the department, office expenses, etc"

(b) MAJOR HEAD 2852

Pharmaceutical industries

(Rs.in crore)

BE 2013-14			RE 2013-14			BE 2014-15		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
138.54	31.29	169.83	61.78	26.55	88.33	155.00	29.11	184.11

5.2 On being asked the reasons for substantial increase in Plan allocation from Rs.61.78 crore in RE 2013-14 to Rs.155 crore in BE 2014-15 and as to how the Department envisage to utilize the increased allocation, the Department in its written reply stated as under:-

> "Department shall be utilizing the funds for various upcoming schemes of Pharma like establishment of six new NIPERs, strengthening of Pharma CPSUs, Up gradation of Medium Enterprises (MEs) to WHO-GMP Standards, opening of new Jan Aushadhi stores, Setting up National Centre for R&D in Bulk Drugs in NIPER, Hyderabad, other New Schemes etc".

5.3 On being asked the reasons for substantial decrease in RE 2013-14 (Rs.88.33 crore) as compared to BE 2013-14 (Rs.169.83 crore) especially when Pharmaceutical Industries in the country needed to be given necessary boost for its development, the Department in its written reply stated as under:-

> "The allocation for Pharmaceutical Industries as mentioned above includes the allocations made for (i) National Institute of Pharmaceutical Education Research

(NIPER), Mohali and new NIPERs, (ii) National Pharmaceutical Pricing Authority (NPPA) (iii) IPR facilitation Center (iv) Pharmaceuticals Promotion & Development Scheme (PPDS) (v) Critical Assistance Scheme (Grant for WHO GMP Compliance) (vi) Jan Aushadhi scheme etc.

As regards NIPERs, plan funds with respect to NIPER Mohali could not be released for want of third party evaluation and Economic Finance Committee (EFC) approval of the plan and schemes. With respect to new NIPERs, the proposed construction activity could not progress during the year. In Jan Aushadhi scheme BE allocation of Rs 25.00 crore was reduced to Rs. 15.20 crore at RE stage and the same was released during the Year. In Critical Assistance Scheme (Grant for WHO GMP Compliance) BE allocation of Rs 6.84 crore was reduced to NIL at RE stage, no amount could be released since funds released earlier could not be substantially spent. Consumer Awareness and Publicity through Print, Electronic and Other Media, a budgetary provision of Rs. 4.00 crore has been provided but the amount could not be spent due to non-finalization of the scheme. Pharmaceuticals Promotion and Development Scheme (BE-Rs 2 crore) & Creation of IPR Facilitation Center at Pharmexcil (BE-1 crore) were also reduced at RE stage due to evaluation of the schemes by an outside agency empanelled by the Planning Commission.

The utilization of Plan Funds during the first six months for the Year 2013-14 was low as a result the RE (Plan) was reduced. The reduction in RE 2013-14 is to the tune of Rs. 76.76 crore under Plan head and Rs. 4.74 under Non-Plan head. However during the next six months of 2013-14 almost the entire amount of RE was spent during the Year 2013-14. The expenditure under various upcoming schemes is likely to go up as the work under these schemes progresses".

(c) MAJOR HEAD -2552

<u>Lumpsum Provision for Project/Scheme for the benefit of N.E.Region & Sikkim</u>

(Rs.in crore)

BE 2013-14			**RE 2013-14**			**BE 2014-15**		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
18.80	-	18.80	3.00	-	3.00	21.00	-	21.00

5.4 When asked the reasons for quantum increase in Plan allocation from Rs. 3.00 crore in RE 2013-14 to Rs.21.00 crore in BE 2014-15, the Department in its written reply stated as under:-

"The higher provision of Rs. 21.00 crore in BE 2014-15 is for meeting expenditure in connection with proposal for construction of new campus of NIPER, Guwahati and establishment related expenditure to run the institute".

I. <u>National Institute of Pharmaceutical Education Research (NIPER)</u>

5.5 NIPER, SAS Nagar, Mohali was initially registered as a society under the Societies Act. The faculty for the institute was appointed in 1994. In 1998, Parliament enacted National Institute of Pharmaceutical Education & Research Act, 1998. NIPER was declared as an

"Institute of National Importance" under the Act of Parliament on 26th June 1998. NIPER is a member of Association of Indian Universities.

The main objectives of the Institute:

1. Nurture and promote quality and excellence in pharmaceutical education & research.
2. Toning up the level of pharmaceutical education and research by training the future teachers, research scientists and managers for the industry and profession.
3. Creation of National Centers to cater to the needs of the Pharmaceutical industry and other research and teaching institutes.
4. Collaboration with Indian industry to help it meet global challenges.
5. National/International collaborative research.
6. Study of sociological aspects of drug use and abuse and rural pharmacy etc.
7. Running programmes in drug surveillance, community pharmacy and pharmaceutical management.

Establishment of New NIPERs

5.6 In terms of the amended National Institute of Pharmaceutical Education and Research (NIPER) Act, 1998, the Government of India has set up six new NIPERs at **Hajipur, Hyderabad, Ahmedabad, Rae Bareli, Guwahati and Kolkata.** These New NIPERs will cater to the growing demand of the pharmaceutical industry for highly trained manpower for continuous growth of the pharmaceuticals sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present, new NIPERs are functioning with the assistance of the Mentor Institutes.

5.7 The details of budgetary allocation for NIPER for the years 2013-14 and 2014-15 are as under:- **(Rs.in crore)**

BE 2013-14			RE 2013-14			BE 2014-15		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
69.70	23.57	93.27	42.64	19.20	61.84	87.00	17.03	104.03

5.8 On being asked as to how the Department proposes to utilize increased Plan allocation from Plan allocation of Rs42.64 crore in RE 2013-14,to Rs.87.00 crore in BE 2014-15 the Department of Pharmaceuticals stated in writing as under:-

"The fund is proposed to be utilized for construction related activities of campus for NIPER, Guwahati & NIPER, Gandhinagar. Also, the project management consultant would be engaged for the two NIPERs for which land has since become available viz., NIPER Hyderabad and NIPER Rae Bareli. This would necessitate availability of enhanced resource to meet these additional requirements when compared with last year".

5.9 When asked about the time frame by when all new NIPER institutes would come out of the fold of the respective Mentor Institutes and function independently and steps being taken by the Department in this regard, the Department in its written reply stated as under:-

"The Department has already started the process for construction of new campus for NIPER, Guwahati and NIPER, Gandhinagar. The land has since been allocated for NIPER, Hyderabad and NIPER, Rai-bareli by the respective State Governments and the process of selection of Project Management Consultants (PMC) has been initiated. NIPER, Hajipur and NIPER, Kolkata are yet to be allocated land for which the matter has been taken up with the respective State Governments".

5.10 On being enquired about the progress of construction of campuses of six new NIPERS, the Department in its written reply stated as under:-

" At present, land is available at Guwahati, Gandhinagar, Hyderabad and Rai-bareli. The matter of construction of NIPER campus at Guwahati &Gandhinagar is under the active consideration of Steering Committee for new NIPERs. The land has since been allocated for NIPER, Hyderabad and NIPER, Rai-bareli also by the respect State Governments and the process of selection of Project Management Consultants (PMC) has been initiated. Minister (C&F) has since requested Chief Ministers of Bihar vide letters dated 10.4.2012 & 18.02.2014 and by the Department on 27.05.2014 to allot requisite land for construction of NIPER campus at Hajipur. West Bengal Government has allotted 35 acres land at Baruipur. It is being developed by the state Government agency viz. Kolkata Metropolitan Development Authority (KMDA). "

5.11 When the Committee asked as to whether the Department has any plan under consideration to bridge the gap between the academic research and industry by linking NIPER for PSUs, the Secretary, Department of Pharmaceuticals responded during the course of the evidence responded as under:-

"……Regarding academic research and industrial tie-up, the main purpose of starting National Institute of Pharmaceutical Education and Research Centres is to establish the linkage between industry as well as academics. We have started seven NIPERs and another NIPER is on its way. So, with these eight NIPERs coming up in full-fledged functioning, I think, we will be able to establish the industry and academic linkage to a great extent. That is what we are aiming. I think, very shortly we will establish these things."

5.12 On being asked about the status of NIPER, Hajipur and NIPER, Kolkata, the Secretary, Department of Pharmaceuticals during the course of evidence, added as under:-

"In Hajipur, it is functioning in a mentor institute. They have to give the land. That correspondence has been going on for a long time between the State Government and the Government of India. They have to give at least 100 acres of land. That was the original concept of this programme. But we started the programme in a mentor institute. Now they have given about 50 acres of land and we want to start the building construction shortly.

First, they gave the undertaking. Subsequently, at the time of identifying land, it becomes a problem. They are not able to get access to 100 acres of land."

II. National Pharmaceutical Pricing Authority (NPPA)

5.13 The functions of NPPA, inter-alia include fixation and revision of prices of scheduled drug under the Drug (Price Control) Order, 1995 (DPCO'95)/DPCO, 2013, as well as monitoring and enforcement of prices. NPPA also provided inputs to Government for policy formulation and on other specific issues concerning affordable medicines to the consumers.

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

5.14 Salient features of DPCO, 2013 are :

* The National List of Essential Medicines (NLEM) has come under price control.
* Ceiling price calculations are based on "market based data" wherein "Average Price to retailer" is considered for pricing.

5.15 Price Fixation

Under the provisions of the Drugs (Price Control) Order, 2013, the prices of scheduled formulations which are based on the NLEM-2011 issued by Ministry of Health & Family Welfare are to be fixed based on market based data. No one is permitted to sell any scheduled drug / formulation at a price higher than the ceiling price fixed by NPPA / Government. NPPA has fixed the ceiling prices of 440 formulations packs under DPCO, 2013. NPPA is in the process of colleting market based information for fixing the prices of remaining formulations.

5.16 The details of budgetary allocation for NPPA for the year 2013-14 and 2014-15 are as under:- **(Rs.in crore)**

BE 2013-14			RE 2013-14			BE 2014-15		
Plan	Non-Plan	Total	Plan	Non- Plan	Total	Plan	Non-Plan	Total
4.00	7.71	11.71	-	7.34	7.34	2.00	12.07	14.07

5.17 On being asked to give reasons for increase in Non-Plan allocation in BE 2014-15 as compared to the Non-Plan RE 2013-14, the Department in its written reply explained as under:-

"As far as NPPA is concerned, the reasons for higher allocation are given below:

(Rs in Lakhs)

Sl. No.	Object head	BE 2013-14	RE 2013-14	Actual Exp 2013-14	BE 2014-15	Reasons for higher allocation in BE 2014-15 as compared to RE 2013-14.
1	SALARY	338.00	350.00	314.17	450.00	To make provision for expected increase in staff strength, DA, increment, pay & allowances of the existing staff.
2	MEDICAL TREAT-MENT	30.00	8.00	5.30	30.00	Medical claims from the staff members were expected to be higher in 2014-15 as compared to 2013-14. Besides, many of the posts lying vacant were expected to be filled up in 2014-15. With increase in number of staff, medical claims are also expected to be more. Therefore, the same BE as in 2013-14 was proposed in 2014-15 also, i.e., Rs. 30 lakh.
3	DOMESTIC TRAVEL	30.00	25.00	24.97	35.00	To make provision for more meetings at State Level, for payment for old pending bills of M/s Balmer&Lawrie for the period from 2006 to 2010, and expected increase in air fare and increase in number of visits.
4	FOREIGN TRAVEL	8.00	7.00	2.55	8.00	To meet the foreign travel expenses for one or two visits, Rs. 8 lakh were kept in 2014-15.
5	RENT, RATES & TAXES	138.00	140.00	137.72	295.00	New Delhi YMCA has withdrawn its arbitration case regarding vacation of office premises on a mutual understanding with NPPA that NPPA would pay New Delhi YMCA rent at par with other tenants in the building. Accordingly, NPPA have to pay New Delhi

Sl. No.	Object head	BE 2013- 14	RE 2013-14	Actual Exp 2013-14	BE 2014-15	Reasons for higher allocation in BE 2014-15 as compared to RE 2013-14.
						YMCA rent @ approxRs. 22 lakh per month for the office premises.
6	OFFICE EXPENSES	120.00	80.00	79.71	150.00	In 2013-14 the funds were reduced from Rs. 120 lakh to Rs. 80 lakh due to which NPPA could not make payments of many pending bills. Keeping in view the rise in prices of various items, purchase of new office equipments like computers, printers, furniture, etc. and to clear pending bills, Rs. 150 lakh were proposed for 2014-15.
7	OTHER ADMN. EXP.	5.00	2.00	1.17	7.00	In order to meet the expenses relating to training / seminars / conferences, etc., Rs. 7 lakh were proposed for 2014-15.
8	PROF-ESSIONAL SERVICE	30.00	70.00	50.08	150.00	To make provision for payment of (i) approx. Rs. 60 lakh in 2014-15 to be made to M/s IMS Health; (ii) Rs. 54.0 lakh in 2014-15 to be made to M/s IDPL in r/o Sh. Sunil Chopra, Consultant(Legal) for the period from Jan'2003 to Aug'2014. (iii) Payments in respect of hired Consultants//Programmers, advocates/court fees, etc.
Sl. No.	**Object head**	**BE 2013- 14**	**RE 2013-14**	**Actual Exp 2013-14**	**BE 2014-15**	**Reasons for higher allocation in BE 2014-15 as compared to RE 2013-14.**
9	WAGES	70.00	50.00	53.97	80.00	To make provision for (i) expected increase in wages of Casual Workers (TS) due to annual increment, increase in DA etc. (ii) expected increase in payments for outsourced staff due to increase in wages rates by Delhi Govt., increased payments to outsourcing agencies due to re-tendering.
10	OTA	2.00	2.00	0.91	2.00	-
	Total	**771.00**	**734.00**	**670.55**	**1207.00**	

5.18 When asked to give reasons for no Plan allocation in RE 2013-14, the Department replied in writing as under:-

> " The Plan Scheme of Consumer awareness and Publicity through Print, Electronic and other Media was yet to be finalized by NPPA till the far end of the financial year 2013-14. This however, did not receive the approval of the competent authority, therefore the BE of Rs.4 crore has been reduced to Rs 0.00 Crore at the RE stage".

5.19 On being enquired about the effectiveness of DPCO, 2013 in enforcing the prices of all essential medicines, the Department in its written reply explained as under:-

> "The Central Government notified the Drug (Prices Control) Order, 2013 (DPCO, 2013) on 15th May, 2013, in supersession of the DPCO, 1995. 628 medicines as specified in the 'National List of Essential Medicines, 2011' are covered under price control category under DPCO, 2013. As provided under DPCO, 2013, the ceiling prices of these scheduled medicines are fixed based on the market based data, *inter alia*, by taking simple average prices of all those manufacturers who have market share more than or equal to 1% of total market turnover on the basis of Moving Annual Turnover (MAT) of a specified medicine. The ceiling price is derived by adding 16% margin on the simple average price to the retailer (PTR) for the specified medicine. As provided for under the Order, the local taxes if actually paid, wherever applicable on actual basis, will be added with the ceiling price to arrive at the Maximum Retail Price to the consumers.
>
> As per the provisions of DPCO, 2013, no person shall sell the scheduled formulations at prices higher than the ceiling price (plus local taxes as and wherever applicable) so fixed and notified by the Government. However, all the existing manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price lower that the ceiling price (plus local taxes as applicable) so fixed and notified by the Government shall maintain their existing maximum retail price for a period of one year.

Out of the 628 NLEM medicines specified in the Schedule-I of DPCO, 2013, NPPA has fixed / notified the ceiling prices in respect of 489 medicines upto 15th September, 2014 under provisions of the said order. The price notifications are available in the public domain at the official website of NPPA (www.nppaindia.nic.in).

5.20 It is mentioned that the significant reduction in prices have been effected on the medicines notified under DPCO, 2013 as compared to the highest price prevalent prior to the price fixation of those formulations. The overall profile of price reduction is as under:-

Statement showing reduction in price with respect to maximum price

% reduction with respect to Maximum Price	No. of drugs
0<= 5%	46
5<=10%	44
10<=15%	53
15<=20%	43
20<=25%	62
25<=30%	55
30<=35%	30
35<=40%	34
Above 40%	122
	489

5.21 In order to fix the ceiling prices in respect of the remaining NLEM medicines, NPPA has made sincere efforts to obtain / collect the data from all available sources like IMS-Health, PharmaTrac, Pharma Industry Associations, Marketing Companies etc. In addition, NPPA took up the matter with Department of Health, Drugs Controller General (India), State Health Secretaries and State Drugs Controllers for providing the information / data so as to enable NPPA to fix prices of remaining NLEM medicines under provisions of DPCO, 2013.

5.22 DPCO, 2013 also provides for monitoring of the production and availability of scheduled formulations and the active pharmaceuticals ingredients contained in the scheduled formulations. In this regard, the manufacturers/ importers/ marketing companies of the scheduled formulations and Active Pharmaceutical Ingredients are required to furnish information as stated in Form- III of the said order quarterly.

5.23 On being asked as to whether any instance of shortage of Listed Essential Medicines has come to the notice of NPPA after the implementation of DPCO, 2013, the Department responded in writing as under:-

" NPPA regularly monitors the availability of essential medicines in the country through Drugs Control Administration of State Governments. Whenever shortage is reported by the State Drug Controllers or comes to its notice otherwise, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage. NPPA also collects samples from the market as a part of enforcement activity and also to ascertain shortage / non availability of medicines and takes remedial measures as may be called for.

Further, to check the adequate availability of essential medicines in the country, Para 21 (i) of DPCO, 2013 provides for submission of quarterly return as stated in Form- III of the said order by the manufacturer/ importer/marketer of scheduled medicines and Active Pharmaceutical Ingredients contained in scheduled formulations.

Recently the scarcity of certain essential medicines, namely, Anti-Snake Venom, Rabies vaccine, Rabies Immunoglobulin, Albumin Injection and Anti-malarial combination of Sulfadoxine + Pyrimethamine Tablets has been reported to the NPPA. The concerned manufacturers of these drugs seem not to be maintaining normal supply of the medicines in domestic market and / or Institutions. In this regard, NPPA vide its notification S.O. No. 2292 (E) dated 09.09.2014 has directed all the concerned manufacturers / importers to comply with the requirements contained in para 21(1) and furnish the month-wise production and sale figures for the last 12 months under para 29 of the said Order".

5.24 On being pointed out that the cost of drugs is very high for cancer patients, the Secretary of the Department responded during the oral evidence as under:-

"For cancer, doctors mostly prescribe patented drugs which are very costly as they are produced by multinational companies"

In this regard, the representative of the Department further explained as under:-

"under the policy of the Government, we have Drug Price (Control) Order, 2013 under which for the list of medicines which are considered essential is notified by the Health Ministry and we fix the prices through NPPA. We call it as the National List of Essential Medicines. There are 680 medicines. There are 29 different groupings – cancer, blood-related diseases, and analgesics. Out of 680, some medicines are repeated in different categories. Finally, 628 medicines are listed in our National List of Essential Medicines. Now, the power is related to fixing of prices for them. Only in extraordinary circumstances, the Government can regulate pricing structure of other medicines. As on date, 489 medicines' prices have been notified by the NPPA.

There are many of the medicines which are in the International List of Essential Medicines and the NPPA has prescribed prices for a number of medicines, but our medicine pricing policy is limited to formulations. Take the example of paracetamol. Only for 500 mg the NPPA can fix prices and not for 625 mg or 1000 mg or 250 mg. The price policy is only for the formulation. Similarly, there are a number of medicines, which are used for cancer treatment, the prices of which are fixed by the NPPA, but they are also formulation-based".

III. Pharmaceuticals Promotion & Development Scheme (PPDS)

5.25 The details of budget allocation for PPDS for the year 2013-14 and 2014-15 are as under:-

(Rs.in crore)

BE 2013-14			RE 2013-14			BE 2014-15		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
2.00	-	2.00	1.25	-	1.25	2.00	-	2.00

5.26 When the Committee asked about the reasons for higher allocation of BE 2014-15 of Rs.2 crore as against RE 2013-14 of Rs.1.25 crore for Pharma Promotion and Development Scheme, the Department in its written reply stated as under:-

"According to the scheme pharmaceutical industry associations or other associations/bodies/voluntary organisations may be given grant-in-aid for conducting promotional activities including seminars, conferences, workshops, exhibitions, arranging delegation to and from India, conducting studies and purchase of important publications etc. Under Pharmaceuticals Promotion and Development Scheme, proposals are received from various organizations viz. FICCI, CII, Pharmexcil, IIM, IEG etc. which are examined by the Department. The Department regularly consults Pharma Industry Association for identifying the areas of concern where support/initiative by the Government is required and Seminars, Studies etc. are conducted to address those issues.

The following steps have been taken/proposed to be taken for the improvement in the implementation of the schemes

(a) The Ministry of Finance had directed that before approving continuation of the Schemes in the XII Plan, the schemes may be subjected to evaluation through an independent, impartial and reputed agency and accordingly, MITCON Consultancy and Engineering Services Limited, PUNE was engaged for conducting the independent evaluation of the working of the PPDS in XI Five Year Plan. MITCON has recommended that all existing activities under the PPDS need to be continued in the XII FYP and need to be scaled up in number of events as well as budgets for each program. It has suggested clubbing of various activities in separate categories with apportionment of budget to achieve a balance between various activities, topics to be covered, expectations of the various target groups and stakeholders. These recommendations have been considered and have been suitably incorporated in the PPDS.

(b) The report of the evaluating agency for working of Creation of IPR Facilitation Centre scheme has been received. The recommendations are under consideration for improving the scheme. "

5.27 On being asked as to how does the Department evaluate the growth of the Pharmaceutical industry in the country over the years, the Department in its written reply stated as under:-

"The financial performance of the Drugs & Pharmaceutical Industry for the years 2008-09 to 2012-13 in percentage based as CMIE Industry Outlook is given in the table below:-

Sl. No.	Particulars	2008-09	2009-10	2010-11	2011-12	2012-13
1.	Sales	16.49	10.95	13.73	15.97	09.69
2.	Total Expenses	21.49	06.79	18.24	16.43	05.17
3.	PBDITA net of P&E&OI&FI	21.46	17.65	09.61	14.31	08.71
4.	PAT net of P&E	-18.09	54.23	02.1	-02.87	25.42
5.	No. of Companies data - Count	407	435	438	369	288

The industry had consistently showed a growth in sales of around 10%.

5.28 When asked about factors which have impeded self-sufficiency/growth of Pharmaceutical sector in the country, the Department in its written reply stated as under:-

> "The Drugs & Pharmaceutical Industry have showed a respective growth of 10% annually. The industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. As such no impediments are recognised in the growth of pharmaceutical sector in the country".

CHAPTER-VI

PUBLIC SECTOR UNDERTAKINGS

6.1 The Department has 5 running PSUs under its administrative control viz. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Bengal Chemicals & Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL). Out of these KAPL and RDPL are profit making and BCPL, HAL & IDPL are BIFR referred Companies. However, RDPL during the year 2013-14, has registered losses for the first time. As the HAL is still incurring losses, a 2nd Rehabilitation Plan is under consideration of this Department. The rehabilitation scheme of IDPL is also under consideration.

6.2 Apart from these CPSEs, there are two closed CPSEs namely, Bengal Immunity Limited (BIL), Kolkata and Smith Stanistreet Pharmaceuticals Limited (SSPL), Kolkata (liquidated) and two Joint Ventures of HAL namely Maharashtra Antibiotics & Pharmaceuticals Limited (MAPL), Nagpur (closed) & Manipur State Drugs & Pharmaceuticals Limited (MSDPL), Imphal (closed) and one Joint Venture of IDPL namely, Orissa Drugs & Chemicals Limited (ODCL).

I. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL)

6.3 Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) is a profit making Mini Ratna Central PSU having 59% of the equity shares of GoI and 41% of equity shares of Karnataka State Industrial and Investment Development Corporation (KSIIDC). The paid up share capital of the company as on date is Rs.13.49 crores. The Company was incorporated on 13th March, 1981 and the commercial production started from August, 1984. The manufacturing units and the registered office of the company is located at Bangalore (Karnataka). The main products are Pharmaceuticals formulations like tablets, capsules, injectables, etc.

6.4 Earlier, it was a Joint Sector Undertaking of Hindustan Antibiotics Limited (HAL) in collaboration with KSIIDC. But in the interest of continued growth and development of the company, the Government has implemented the delinking of KAPL from HAL and transferred the shareholding of HAL in KAPL in favour of Government of India. The Government of India has invested Rs. 7.10 crore in KAPL for upgrading its manufacturing facilities conforming to WHO-GMP standards and setting up a new WHOGMP compliant Cephalosporin plant.

6.5 It has been continuously generating profits for the last 13 years and the performance of the company has improved over the years.

II. Rajasthan Drugs and Pharmaceuticals Limited (RDPL)

6.6 Rajasthan Drugs and Pharmaceuticals Limited (RDPL) is a consistently profit making 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) hold 51% and 49% respectively. The company 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).

6.7 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 High Performance/ Pressure Liquid Chromatography (HPLC), Fourier Transform Infrared Spectroscopy (FTIR) etc., for ensuring high quality parameters.

6.8 In order to ensure a sustainable growth and development of the company, the Government has delinked RDPL from Indian Drugs & Pharmaceuticals Ltd. (IDPL) (the original promoter representing GOI) and transferred the shareholding of IDPL in RDPL to Government of India in August 2010.

6.9 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. The Company is a partner in the novel and noble endeavor of Government of India in the implementation of Jan Aushadhi Scheme where quality generic (unbranded) medicines are made available to the public at large in the country at affordable prices through sales outlets.

6.10 When asked the parameters set up to qualify for WHO (GMP) Certification, the Department in its written reply stated as under:-

> "Schedule 'M' compliance is a statutory requirement for any Pharma manufacturing plant as per Drugs & Cosmetics Rules, 1945. Now, with increasing export driven competition, no Pharma manufacturing company can survive without compliance to International Standards. WHO-GMP Standards/Compliance is now mandatory for acceptance of product internationally. Under the system of WHO-GMP standards, quality assurance is a key criteria. The Pharmaceuticals products are required to be manufactured in a way that takes account of the requirements of quality production processes grouped together as "Good Manufacturing Practices (GMP)" more recently Current GMP i.e., cGMP.

6.11 On being asked as to when will RDPL plan to be fully WHO-GMP compliant, the Department in its written reply stated as under:-

> "The Project for expansion, modernization WHO cGMP (Phase –II) was initiated in the year 2011-12 with an out-lay of Rs. 1446.09 lacs which has been approved by the Planning Commission and Department of Pharmaceuticals, GOI for Rs. 1284.09 lacs in 2012-13. It is funded to the tune of Rs. 1139 lacs as grant-in-aid. The balance to be incurred by the Company from its internal resources. The Company has received the first installment of Rs. 455 lacs from DOP, Govt. of India.6.12

6.12. On being enquired as to why RDPL failed to utilize Rs.4.55 crore during 2012-13, and the steps being taken to utilize funds allocated during the current year, the representative of the Department during the course of evidence, stated as under:-

> "Sir, there was some management problem in RDPL. There was no MD. New MD has joined recently. Now there is new action plan and there is partnership with Ministry of Health. They have many medicines for AIDS. So, they have a GMP Plant taking orders of production. So RDPL is going to be in the right track".

III. <u>Hindustan Antibiotics Limited (HAL)</u>

6.13 Hindustan Antibiotics Ltd. (HAL), Pune was incorporated on 30th March, 1954. This is the first Public Sector Company in drugs and Pharmaceuticals,with its plant at Pimpri. The company produces a wide range of Pharmaceutical formulations including agro-vet products. There are two joint sector units promoted by HAL in collaboration with the respective State Governments. These are Maharashtra Antibiotics & Pharmaceuticals Ltd. (MAPL) at Nagpur, Maharashtra (since closed) and Manipur State Drugs & Pharmaceuticals Ltd. (MSDPL) at Imphal, Manipur (since closed). Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bangalore, which was earlier a Joint Sector Undertaking of HAL in collaboration with Karnataka Government, has since been delinked from HAL after approval of the Government.

6.14 After establishment, the company made profits for several years. However, as the company started incurring continuous losses since 1993-94, it was referred to the Board for Industrial & Financial Reconstruction (BIFR) in January, 1997. BIFR declared the company formally sick on 31.3.1997 and appointed Industrial Development Bank of India (IDBI), Mumbai as the Operating Agency for a Techno-Economic Viability Study and Report. Accordingly, a Rehabilitation Scheme was prepared by HAL which was later revised on the directions of the BIFR and the Government.

6.15 Based on the Scheme, the Government approved the package for Rehabilitation of the company on 9th March 2006, followed by BIFR approval on 5th June 2007. The Rehabilitation Scheme inter alia included the following:-

Sl No.	Particulars	Amount (in crore)
1	Cash infusion	Rs.137.59*
2	Write off/exemptions from Government of India	Rs.267.57
3	Sacrifices by Banks, financial institutions and PSUs	Rs.103.34
	Total	Rs.508.50

(*This includes interest free loan of Rs. 56.96 crore to be repaid by HAL by sale of land within a period of two years.)

6.16 The entire cash infusion of Rs.137.59 crore has been released to the Company. Parliament has approved writing off of loan and waiver of interest to the extent of Rs.259.43 crore. As regards generation of Rs.56.96 crore as part of Cash Infusion, BIFR issued guidelines for sale of land as per the Rehabilitation Scheme through an Assets Sale Committee.

6.17 Further, the Government had approved proposals for setting up new powder injectable facilities for Cephalosporin and upgradation of existing vialling facilities for Betalactum (Penicilllin) Antibiotics complying to WHO-GMP standards and for upgradation of manufacturing facilities of Tablet, Capsule and Liquid Sections complying to WHO-GMP standards to make the company further viable.

6.18 HAL has completed the work on Cephalosporin block in a record time of 9 months and obtained WHO-Certification for the same. Work relating to upgradation of existing vialling facilities for Betalactum Antibiotics has also been completed. As HAL is still incurring losses, the second rehabilitation package for HAL is under consideration. The modified Draft Rehabilitation Scheme has been submitted to BIFR by IDBI, operating agency in February, 2014 and presently the scheme is under consideration of BIFR.

6.19 When asked about the basic reasons for the sickness of HAL and whether any specific time frames have been chalked out for its rehabilitation, the Department in its written reply stated as under:-

"<u>Part A - Basic reasons for sickness of HAL</u>

The first Rehabilitation Scheme for HAL was sanctioned after the approval from Govt. of India by BIFR in June, 2007 involving the cash infusion of Rs. 137.59 crores. However, some major components of the first Rehabilitation Scheme could not be implemented by the Company leading to further losses and the the acute financial problems being faced by the Company.

<u>Part B – Time frame and action taken for rehabilitation of HAL</u>

The Modified Draft Rehabilitation Scheme (MDRS) for HAL based on the report submitted by IFCI Limited, a professional Consultant, involving the cash infusion of Rs. 497.45 crores was submitted by IDBI, the Monitoring Agency to BIFR on 17th February,

2014. At the BIFR hearing held on 1st May, 2014, the MDRS submitted by IDBI was considered and it was observed by the BIFR Bench that the scheme for rehabilitation of the Company would need Govt. approval in the first instance and thereafter the same would be considered by the Bench. The Bench also desired that the Department of Pharmaceuticals should apprise the Bench about detailed road map for the revival of the Company.

BIFR vide letter dated 7th July, 2014 while rejecting MDRS addressed to IDBI sought certain clarifications regarding the MDRS submitted by IDBI to BIFR.

6.20 Department of Pharmaceuticals on 11th July, 2014 informed HAL that the fund requirement of Rs. 497.45 crores for the revival of HAL would be made from the budgetary support instead of sale of land, which was envisaged earlier in the MDRS. HAL was asked to modify MDRS accordingly by way of filing a supplementary in BIFR by IDBI. Accordingly, HAL has revised the MDRS with the assumption that the entire fund requirement for the revival of HAL would be made available by the Govt. of India from budgetary support and submitted the same to IDBI with a request to resubmit the same to BIFR for its consideration and approval.

6.21 IDBI on 31st July, 2014 has sought certain clarifications / comments in respect of the revised MDRS which were also furnished by HAL vide its letter dated 6th August, 2014. IDBI on 12th September, 2014 requested for position of statutory dues as on 31st March, 2014 as audited by the Statutory Auditors which need to be submitted to IDBI based on which the revised MDRS would be finalized by IDBI. The Statutory Auditors are in the process of completing the audit of the statutory dues and other current liabilities of the Company and the same will be submitted to IDBI by the Company shortly.

IDBI will then circulate the revised proposal to the Banks and Government / Statutory Departments seeking their views / opinions on the same and then a joint meeting of the stake holders of the Company will be convened by IDBI for finalizing MDRS before submitting to BIFR.

6.22 The Secretary of the Department added during the course of evidence as under:-

> "They are producing products worth Rs. 1-2 crore only. We are asking them to produce at least Rs. 10 crore worth of products per month, and towards that we are giving working capital advance to them and from next month onwards they will start working for at least Rs. 10 crore worth of drugs every month. These drugs will be purchased by the Jan Aushadhi scheme, and they will be circulated".

6.23 On being asked about the present status of HAL, the representative of the Department during the course of oral evidence, stated as under:-

> "Presently, they are undergoing second Modified Rehabilitation Scheme with BIFR. So, we are engaging with them, and IDBI is the monitoring agency to see how best the rehabilitation plan can be made, which includes revival and addressing the management issues. IFCI is the consulting agency, and they have prepared the plan. We have submitted that plan to the Planning Commission, and they have made certain

observations to refine and revise it. So, based on that, again the consulting agency has prepared the revised rehabilitation plan, and that plan is going to be discussed with the bankers and also BIFR. The bankers meeting is schedule next week, but as we are tied up, so we are asking the bankers to have a new date. So, we will get the new plan's financial viability done because already one plan we have prepared and with that plan it could not be revived. Now, we are working on the second plan. So, the second plan should be financially sound; it should be operationally sound; and technically sound too.

The product profiles should match with the market demand. We cannot take old generation medicines to be sold in the present market as it will not work. So, technologically, operationally and financially the validation process is going on, and soon we will go to the BRPSC also because HAL has big Government loans. If Government loans are there, then the Government has to take a decision. We are requesting some waiver / exemptions, and we are working on it.".

IV. <u>Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata</u>

6.24 The BCPL has four manufacturing units at Maniktala (Kolkata), Panihati in North 24 Parganas (West Bengal), Mumbai (Maharashtra) and Kanpur (UP). Besides, the company is having nine sales outlets and three C&F agencies spread all over India. The company manufactures and markets a wide range of industrial chemicals, drugs and Pharmaceuticals besides cosmetics and home products. In the home products, the well known products include Cantharidine Hair Oil and Lamp Brand Phenol.

6.25 Since 1980, the company continued its operations. However, due to continued losses, the company was declared sick by the Board for Industrial and Financial Reconstruction (BIFR) on 14th January, 1993.

6.26 When asked to furnish the names of the consultants appointed by the Company for undertaking the work of upgradation and modernization of plant and machinery etc and status of the progress of work so far in this regard and the time-limit fixed for this purpose, the Department in its written reply stated as under:-

"The Company appointed following consultants for upgradation and modernization of Plant & Machinery.
1) M/s. Zen Marketing - This consultant firm was appointed for project work of different plants of the Company appointed in 2007. Their allocated job has been already completed.
2) M/s. NNE Pharma Plan - This consultant firm was appointed on 10/06/2008 for Greenfield projects of Betalactum& Cephalosporin Blocks at Maniktala, Kolkata and Oral solid dosage project at Kanpur. They are presently on the job as different projects in Maniktala and Kanpur factories of the Company have not yet been completed.

6.27 When asked the reasons for gradual decrease in Production and Sales turnover during the past 3 years, the Department stated in writing as under :-

" Acute shortage of working capital and expiry of Purchase Procurement Policy in the year 2011, are the main reasons for gradual decrease in Production and Sales turnover of BCPL".

6.28 On being enquired by the Committee about the steps being taken by the Department for providing sufficient working capital to run the BCPL Plant, the Department in its written reply stated as under:-

"The Purchase Preference Policy has been renewed for another 5 years with effect from December 2013".

6.29 When asked about Purchase Procurement Policy and the reason for not being extended beyond August, 2011, the Department stated in writing as under:-

" The Purchase Preference Policy was earlier introduced in the year 2005 w.e.f 7.8.2006 for five years. The same had expired on 6.8.2011. Now the policy has been extended w.e.f. 10.12.2013 in the name of Pharmaceuticals Purchase Policy".

6.30 When asked as to whether the Department proposes to provide interest free non-plan loan of Rs. 40 crore to BCPL for repayment of liabilities with bank and vendors to restart normal production immediately, the Department stated in writting as under:-

" At present there is no proposal being considered for providing interest free non-plan loan to BCPL for repayment of liabilities with bank and vendors. A fund of Rs. 7.00 crore is allocated to BCPL under project Based Support. The proposal received from BCPL is under consideration of this Department".

6.31 On being asked about the mechanism adopted by the Department for the revival plan of BCPL, the Department in written reply stated as under:-

" The Company has been directed to commission the projects which have already achieved physical completion namely Ointment Block, Betalactum and Cephalosporin at Maniktala immediately".

6.32 When asked whether BCPL is facing the problem of procurement of raw material and the steps taken by the Department to address this issue, the Department in its written reply stated as under:-

"No specific issue in procuring Raw material except shortage of working capital".

6.33 When asked whether funds allocated by the Government for revival of BCPL has been efficiently and optimally utilized, the Department in its written reply stated as under:-

" Details of utilization of funds allocated by the Government of India, as furnished by BCPL may be seen as under:-

(Rs.in Lacs)

Sl.No	Particulars	Amount Sanctioned	Amount Utilised	Balance Amount
1	Capital Expenditure	14500.00	13241.47	1258.53
2	Loan/Outstanding dues repayment	1749.00	804.00	945.00
3	Grant in Aid for VRS	2000.00	1220.98	779.02
4	Grant in Aid for Arrear Salary	2470.00	2031.00	439.00

Sl.No	Particulars	Amount Sanctioned	Amount Utilised	Balance Amount
5	Grant for R&D / QC	629.00	294.79	334.21
6	**Total(1 to 5)**	**21348.00**	**17592.24**	**3755.76**
7	Less:- Fund utilised for other purposes			
	a) Working Capital with the approval of Ministry/Board		2700.00	
8	Total(6-7)			1055.76
9	Funds available with company (including interest earned)			**1858.23**

6.34 When asked to give details of the number of projects successfully completed/undertaken for revival of BCPL, the Department replied in writing as under:-

> " The number of projects successfully completed / undertaken for revival of BCPL, are furnished below:
> 1) Chemical & Home products modernization and expansion at Panihati Factory Kolkata
> 2) Central Store and Common Utility block at Maniktala.
> The company has physically completed three projects namely Ointment Block, Betalactum block and Cephalosporin block at Maniktala. The commissioning and commercial operation yet to be started as the fund required is not available at this point of time".

V. <u>Indian Drugs & Pharmaceuticals Limited (IDPL), Gurgaon</u>

6.35 Indian Drugs and Pharmaceuticals Ltd (IDPL) was incorporated on 5th April, 1961 for achieving India's goal towards self-sufficiency and self-reliance in the field of drugs and pharmaceuticals, particularly with the primary objective of creating self sufficiency in essential life saving drugs and medicines. IDPL is the largest Central Pharma Public Sector Undertaking in India with plants at Rishikesh (Uttarakhand), Hyderabad (Andhra Pradesh) and Gurgaon (Haryana) and 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 sector undertaking, promoted in collaboration with the Orissa State Government, namely, Orissa Drugs & Chemicals Ltd. (ODCL) Bhubaneswar.

6.36 IDPL played a major role in the strategic National HealthProgrammes like Family Welfare Programme & Populations Control (Mala-D & Mala –N) anti-malarials (Chloroquine) and prevention of dehydration (ORS) by providing quality medicines.

6.37 IDPL was formally declared sick by the Board for Industrial & Financial Reconstruction (BIFR) on 12th August, 1992.

6.38 When asked about the observations raised by BIFR in the DRS submitted by IDBI,the Department replied in writing as under:-

"Observations raised by BIFR on the DRS submitted by IDBI are given as under:-

The DRS is prepared by taking cut-off date (COD) as 31.3.2013. But the Hon'ble Bench has not approved the above COD. OA should get approve the above cut-off date in the next hearing."

6.39 On being asked by when IDPL be fully revived and whether any time frame has been fixed for revival of IDPL, the Department in its written reply stated as under:-

"The process of Revival of IDPL as per the Laws, Rules & Procedures laid down by the Government of India is underway. No time frame can be indicated because other agencies of the Government are also involved. However, the process is at an advanced stage and all efforts are being made to bring the process to conclusion at the earliest. At present, the MDRS is being modified by IDBI, as per the cut off date approved by the BIFR in its last hearing held in September, 2014.

6.40 On the issue of restructuring or revival of the sick units, the Secretary Department of Pharmaceuticals during the course of evidence replied as under:-

"There is a programme. For both Hindustan Antibiotics as well as IDPL, a revival project is under discussion with BRPAC and BIFR"
We have already prepared the project report which is under discussion. I think, it will go to the Cabinet very shortly.
Today there is no budgetary provision because it requires more than Rs. 500 crore.

Before the rehabilitation package is ready, the Department is giving money from the regular budget to the sick units to start some activities. For instance, for IDPL Hyderabad, we have already sanctioned Rs. 15 crore to revive the tablet making and capsule making projects. Those projects are going on. From June, 2015 that project will be through and they will be able to produce"

6.41 When the Committee pointed out that out of five PSUS, only profit making PSU is KAPL, and also utilization of money provided in majority of scheme is very low, , the Secretary, Department of Pharmaceuticals during the course of evidence explained the position as under:-

" Sir, regarding the overall utilization of funds, for the past two years, year one and year two of the 12th Plan, we got allotment of about Rs.188 crore each. But we can say that the overall utilization of the Department is only 40 percent. It is not 100 percent. Though the initial allotment itself is poor, the Department could not utilize the entire money and utilization is only 40 percent. One important reason is that certain specific projects intended for these five PSUs, we could not release money because even if we make provision for the Scheme, the Ministry of Finance guidelines say that we should not release funds to sick units which have become defaulters. We have already given loans to these companies. Take for instance, Hindustan Antibiotics Ltd (HAL). It is one of the premier PSUs started in India. Both HAL and IDPL had glorious time during the beginning years at the time of Independence. They did very good business. They did give very good service. But over a period of time, they became very sick. In fact, IDPL had 12,000 employees. But today, all the IDPL units have become sick and they have to be rehabilitated."

The Secretary further added as under:-

"They became sick because of policy changes IDPL was started with the main purpose of giving essential medicines at a lower cost to the people in the country. It served its purpose. It was never run on commercial lines like the drug companies in India which run today. The main objective of IDPL was social. They produce cheap and specific drugs, and they do not go for all types of drugs. They produce certain specific drugs which are used in India to treat basic diseases. That was their mandate on which IDPL did in a big way. It had a glorious time. But now it has to recast its policy. It has to stand on its own legs by commercializing, by producing the drug which is in great demand throughout the world. That type of rehabilitation package is undergoing. I think, we will be shortly coming out with the rehabilitation package for IDPL. Once that comes through, I think, IDPL will regain its old glorious days because it has vast extent of land, about 2,000 acres of land. It has the land potential and new policies are coming up in the Government of India. In fact, for bulk drug production, that is going to be a major hub in India. Today, 80 per cent of the bulk drugs are coming from China. We are dependent on China to a great extent. If for any reason China is not able to provide these bulk drugs to India, we may have to close down all our drug units in India. Today they are transacting to an extent of about Rs.1,80,000 crore. It is such a big industry but we are dependent on China. We are going to change this space. We are going to create capacity for bulk drugs in India. The policy will be coming out very shortly in a month's time or so. Once that policy comes, with the vast potential of land that both IDPL and Hindustan Antibiotics Limited have, I think, we can revive these units to produce bulk drugs in a very big way which will help our country to attain self-reliance in bulk drugs. This is as far as sick units of pharmaceutical units are concerned".

"Similarly, we have units. Rajasthan Pharma is there. It is not a very sick unit. Only last year they could not make profits. I think, they can be revived without any difficulty".

"Our unit at Kolkata, Bengal Chemicals also started reviving. They are producing a lot of good quality drugs. They improved their performance to a great extent. Earlier they were producing quality drugs for Rs.20 crore. Today, they increased it to Rs.30 crore or Rs.40 crore. It is on its way up. So, we may be able to revive these units without any difficulty. Our difficulty is only with IDPL and Hindustan Antibiotics Limited and we are attending to them".

6.42 On being asked as to how PSU become sick, the Secretary of the Department explained as under:-

"First of all, our Government decision making process takes a lot of time. For instance, it takes at least ten years to take a decision on the rehabilitation package. Many agencies are involved".

He further added as under:-

"Sir, we have to speed up our functioning, which I accept. The Department has to speed up its functioning".
"We have to speed up our activities. We should take quick decisions."
" In the name of procedures, we have lost a lot of time.".
" We will find out where we have lacked and we will try to rectify. ".

6.43 When the Committee asked to examine the proposal to revive IDPL again after restructuring, the Secretary of the Department during the course of the evidence stated as under:-

"Sir, as was discussed earlier, IDPL rehabilitation programme is on the anvil. It is under active discussion and very shortly the matter will go to the Cabinet for a decision. Once that decision comes through, we will be able to rehabilitate IDPL to its olden days. We will do that for both Hindustan Antibiotics and IDPL".

He further added as under:-

"It is actively under consideration".

6.44 On being enquired as to whether Rishikesh Plant of IDPL has been closed, the representatives of the Department during the course of evidence stated as under:-

"First of all I would like to say that IDPL which is at present running, we are doing good work day by day production is increasing every year. Five years ago, we used to produce 50 medicines, now we are producing 110 medicines and you are talking about Rishikesh Plant where we are providing 50 medicines We are providing medicines for every category. Tablet and Capsule of different verities and being delivered to them. Our client are mostly in Government and then State Government or hospital of Central Government like Railways, Defence, hospitals of ESIC, all agencies every where we are supplying. You have raised revival and particularly you have emphasized for Hyderabad Plant. Planning Commission and Ministry have already allotted funds to them for revival of Hydraulic Plant. We are working on the project and about 40 percent of the work has already done by us. Since it is easy to built a fresh but it is difficult to produce new things in old building. As a result thereof, we become a little handicapped, various things are to be relocated but as already stated by the Secretary it would be operationalise fully by June next year. It is already going on in Rishikesh, we will do by December, on all the four plant, have been scheduled. You talked about Rishikesh Plant then we have made production above them about 20 crores and WHO-GMP has been done. Our products are WHO-GMP so we are ready for export also if required. We are doing lot of hard work to make them right. We are trying that we would bring it back to track, as you have said."

CHAPTER-VII

MISCELLANEOUS

A Other ongoing Schemes of Pharmaceutical

7.1 The details of allocation for Others for the year 2013-14 and 2014-15 are as under:-

(Rs.in crore)

BE 2013-14			RE 2013-14			BE 2014-15		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
62,84	**-**	**62.84**	**17.89**	**-**	**17.89**	**64.00**	**-**	**64.00**

7.2 When asked to give the reasons for increased Plan allocation from Rs.17.89 crore in RE 2013-14 to Rs.64.00 crore in BE 2014-15, and the manner in which Department intends to utilize the increased BE allocation in the current financial year, the Department in its written reply stated as under:-

"The details regarding allocation made under various schemes/activities under the item 'others' are given in the table below:

Plan Schemes:

(Rs. in crore)

S.No.	**Head**	**2013-14**			2014-15
		BE	RE	Actual	BE
	Revenue				
	Other Schemes				
i.	Up-gradation of MEs to WHO-GMP Standards				6.00
ii.	Creation of IPR facilitation center at Pharmaexcil	1.00	0.25	0.25	1.00
iii.	Setting up National center for R&D in Bulk Drug	0.00	0.00	0.00	2.00
iv.	Critical assistance for WHO for Pharma PSUs	6.84	0.00	0.00	10.00
v.	Jan Aushadhi Scheme	25.00	15.20	15.20	30.00
vi.	New Schemes- Drug Discovery Anti-Tubercular Agent and Kala Azar	30.00	2.44	2.44	15.00
	Total	**62.84**	**17.89**	**17.89**	**64.00**

7.3 The increased Plan allocation from Rs.17.89 crore in RE 2013-14 to Rs.64.00 crore in BE 2014-15 is due to increased allocation with respect to Jan Aushadhi Scheme, Critical assistance for WHO for Pharma PSUs, Up-gradation of MEs to WHO-GMP Standards, Setting up National center for R&D in Bulk Drug & New Schemes- Drug Discovery Anti-Tubercular Agent and Kala Azar. These are upcoming & new schemes of the department which require increased allocation of funds for its progress. The BE allocation for the Year 2013-14 was Rs. 62.84 crore.

B **Research and Development in Drugs and Pharmaceuticals Sectors National Centre for Research and Development in Bulk Drug (NCRDBD) at NIPER, Hyderabad**

7.4 This project has been conceptualized based on existing gap analysis of pharmaceutical and bulk drug R&D practices, global scenario and requirement of both internal and external stakeholders. The NCRDBD is proposed to become an innovative R&D provider in the field of bulk drugs in offering competitive and eco-friendly technologies in specified areas products and processes. This Centre will also provide centralized research facilities and technologies, analytical facilities and consulting services for process improvement and optimization. Special emphasis will be given to the empowerment of MSME sector. The Centre would utilized the talent pool within the NIPER, Hyderabad, to address the R&D problem of the Pharma industry. The students too would be exposed to the industrial problems which help them to devise innovative products and processes to address them. The interaction with industry will also serve as good placement avenue for the student. The Phama industry specially the SME sector requires such centre since individual units cannot afford to have their captive R&D facilities.

7.5 The establishment of National Centre for Research and Development in Bulk Drug (NCRDBD) at NIPER, Hyderabad, , would involve an estimated total project cost of Rs.54.20 crore alongwith operating cost of Rs.37.43 crore for 5 years. An amount of Rs.2.00 crore has been allocated for the Scheme under Plan BE 2014-15.

C. **Foreign Direct Investment**

7.6 Foreign Direct Investment (FDI) up to 100% has been in operation in Pharmaceutical Sector since 2001. However, during the period of August 2006 to December 2010, acquisitions of some of the major Indian Pharma Companies like Ranbaxy and Piramal, led to a strong apprehension that these takeovers could affect the domestic Pharma Industry especially the Generic Medicines.

7.7 At present FDI in pharmaceutical sector is 100% through automatic route for greenfield investment and through Government approval route for brownfield investment. Further in brownfield investment 'non-compete' clause is not allowed except in special circumstances with the approval of Foreign Investment Promotion Board (FIPB).

7.8 When asked as to whether any proposal have been received by Department of Pharmaceuticals for both Greenfield and Brownfield projects in the pharmaceutical industry, the Department in its written reply stated as under:-

"No Greenfield FDI proposal has been received in Department of Pharmaceuticals as the same is under automatic route.

As regards, Brownfield FDI proposals concerning Pharmaceuticals are concerned, it is mentioned that after amendment in FDI Policy (w.e.f. 8.11.2011), a number of proposals are being received from FIPB unit of Department of Economic Affairs for comments of DoP. Details of proposals received since November, 2011 are as under:-

Year	**No of cases received**
2011 (w.e.f. Nov 2011)	04
2012	51
2013	70
2014 (Till date)	55

7.9 When asked as to whether any of the PSUs have undertaken joint ventures abroad or in the country with foreign entities, the Department in its written reply stated as under:-

"No PSUs have undertaken any joint ventures abroad or in the country with foreign entities".

D. <u>Generic Drugs Campaign</u>

7.10 Access to quality medicines at affordable prices is a key challenge for the Government. The prices of branded medicines are generally higher than generic medicines due to various reasons including limited regulation through Drug Prices Control Order, 1995 etc.

7.11 For fulfilling this goal, 'Jan Aushadhi Campaign' has been launched. The purpose of this campaign is to make available medicines at affordable prices for all, especially the poor and the disadvantaged.

7.12 Under this campaign, less priced quality generic medicines will be made available through Jan Aushadhi Stores which are of same and equivalent quality, efficacy and safety as compared to branded generic medicines.

7.13 Under this Scheme, the State Government has to provide space in Government Hospital premises for the running of the Jan Aushadhi Stores (JAS). Government hospitals, NGOs, Charitable Organizations and public societies like Red Cross Society, Rogi Kalyan Samitis typically constituted for the purpose could be operating agencies for the JAS. The operating agency for JAS was being nominated on the basis of the recommendations of the State government. The operational expenditure is met from trade margins admissible for the medicines. The State Governments concerned were also requested to ensure prescription of unbranded generic medicines by the Government doctors.

7.14 An amount of Rs.30 crore has been allocated for Jan Aushadhi Scheme in BE 2014-15 compared to Rs. 15.20 crore allocated in RE 2013-14 and Actual allocation to the tune of Rs.1.66 crore in the year 2012-13.

7.15 The Bureau of Pharma Public Sector Undertakings of India (BPPI), comprising all the Central Pharma PSUs (CPSUs), namely, IDPL, RDPL, KAPL, HAL and BCPL, was set up on 1st December 2008 with the major objective to have a focused & empowered structure to implement the Jan Aushadhi Campaign initiated by the Department of Pharmaceuticals. Initially it was set up as an independent, unincorporated body but subsequently, it was registered as a Society under the Societies Registration Act, 1860 with the Govt. of NCT of Delhi on 21st April, 2010. BPPI is monitoring the functioning of Jan Aushadhi Stores. It is also involved in promotion of the unbranded generic drugs.

7.16 The first Jan Aushadhi Generic Drug Store was opened in Civil Hospital, Amritsar on 25th November, 2008 and with the active support and cooperation of the State Government of Punjab, the stores were opened not only in all district headquarter of Punjab but also opened at block level too. The campaign has now been spread to other States of Haryana, Uttrakhand, Rajasthan, AndhraPradesh, Odisha, Jharkhand, West Bengal, Jammu & Kashmir, Himachal Pradesh & UT of Delhi and Chandigarh by having opened 199 Jan Aushadhi Generic Drug Stores so far (till 31.10.2014). Efforts are on to open more number of stores.

7.17 The New Business Plan of Jan Aushadhi Scheme has since been approved on 08.08.2013 by the Expenditure Finance Committee chaired by Secretary Pharma with representations from Ministry of Finance, Department of Expenditure and Planning Commission. After a detailed deliberation, the new Business Plan with an estimated cost of Rs. 148.82 crores, was approved.

7.18 An amount of Rs. 15.20 crore was released during 2013-14 as Grant in-Aid to BPPI to meet the expenses to open new Jan Aushadhistore as well as assist existing and functional Jan Aushadhi stores.

7.19 BPPI is managing its administrative expenses out of financial assistance being provided by the Central Government for the Jan Aushadhi Campaign. It is proposed to continue this arrangement for a further period of four years or till BPPI becomes self-sustainable, whichever is earlier. In order to sustain the activities of BPPI beyond 12th Five Year Plan, it is proposed to make provision for the collection of margin not exceeding 2% by BPPI.

7.20 On being asked by the Committee as to whether Jan Aushadhi Stores have been opened as per the new business plan for the year 2013-14 and whether the funds utilized for this purpose, the Department in its written reply stated as under:-

"The new business plan approved in August, 2013 had projected for opening of minimum 500 new Jan Aushadhi stores during the year 2013-14. However only 8 new Jan Aushadhi stores could be opened during the year 2013-14.

The new business plan for the year 2013-14 was approved in August, 2013 subject to the following conditions:-

i) A full-fledged procurement system is put in place and rate contract finalized and;

ii) IT based supply chain management solution is operationalized on pilot basis and;

iii) All the necessary arrangements such as warehouse, stockists, required manpower etc. are put in place to manage supply chain.

As explained in the detailed approved Business Plan, the old scheme suffered from some inherent bottlenecks, which include: (a) over dependence on support from State Government, which was not forthcoming (b) Poor supply chain management mainly on account of inadequate and untimely supply of medicines (c) non-prescription of generic medicines (d) Health policies of Central/ State Governments for free supply of drugs and (e) lack of awareness. In addition, inadequate manpower in managing the affairs of BPPI was also a major impediment in proper implementation of the scheme.

Immediately after the new business plan was approved, focused attention has been given on the following activities during the last six months for successful implementation of the scheme:

(i) Availability of medicines
(ii) Creation of Central ware House
(iii) Management of Supply Chain
(iv) Quality Control
(v) Strengthening of BPPI
(vi) Appointment of Super Stockiest/C&F Agents
(vii) Opening of new Jan Aushadhi stores
(viii) Publicity campaign

7.21 Since incurring expenditure as per the approved new business plan was subjected to certain conditions mentioned above and these conditions could be accomplished only towards the end of 2013-14, no fund from the allocation of 2013-14 could be utilized during 2013-14, and expenditure incurred during 2013-14 was met from the un-utilized fund from the previous year.

7.22 When asked as to how does the Department propose to utilize the estimated cost of Rs. 148.82 crore for new Business Plan, the Department in its written reply stated as under:-

"Out of the estimated cost of Rs. 148.82 crore for the period 2013-14 to 2016-17, allocation of Rs. 25.00 crore was made for the year 2013-14.The entire amount of Rs. 15.20 crore sanctioned for the year 2013-14 could not be utilized. Due to unspent amount, available, no fund has been sanctioned for the year 2014-15, so far is being used for incurring expenditure for the year 2014-15. Based on the present progress in implementation of the Jan Aushadhi Scheme, fund requirement would be assessed in the year 2014-15. Future requirements for the remaining two years viz. 2015-16 and

2016-17 would depend on the progress made in the current year and utilization of already sanctioned amount. Further, BPPI has been asked to expedite opening of new Jan Aushadhi Stores. The matter of opening new JAS has also been taken up with Health Ministers of all the states in Government Hospitals at the level of Minister (C&F)".

7.23 When asked why out of 164 stores opened only 87 are running and the reasons why others are not running, the Secretary, explained as under:-

"In many places, they have opened these stores and they have closed them also. For instance, Rajasthan started in a big way. Sir, 54 stores were opened in Rajasthan. Then, subsequently, the Government changed its policy and introduced free drugs to all the patients in hospitals.

That is a good thing. So, naturally, our attention is to see that these shops are distributed to other States. In fact, the cooperation of the States is important. Many States are not deciding to open shops. We encounter such difficulties. But opening one store in one district is not a big problem. Before that, we should reach out to our doctors' community, we should educate them about the advantages of these generic drugs and also we should impress upon them to prescribe generic drugs to the patients. If they do not do that, this scheme will never take off. That is why we are attempting to give publicity so as to reach the doctors by way of training programme.

E **Cluster Development Programme**

7.21 Cluster Development Programme for Pharma Sector is a new scheme which was approved in February 2014 and currently the selection of Project Management Consultant is being processed. To create/upgrade the common facilities in the area where there is a cluster of Pharma Manufacturers, the Department has come up with a scheme, "Cluster Development Programme for Pharma Sector" (CDP-PS). The total outlay of the scheme is Rs125 Crs for the 12th plan period. Through this scheme, the cluster of small and medium enterprises can avail financial assistance for common facilities like Common Testing Facilities, Training Centres, Effluent Treatment Plant, Common Logistics Centres etc.

7.24 On being asked about cluster approach, the Secretary, Department of Pharmaceuticals during the course of evidence explained as under:-

"We have already created a large number of pharma clusters in India at places like Hyderabad, Chennai, Maharashtra and Gujarat, Uttarakhand and Himachal Pradesh. Many pharma clusters have come up over a period of time. They lack certain common facilities, like quality testing facility, library facility, training facility, effluent treatment plant etc. These things are lacking at many places. To provide for all these things, we have made a proposal of about Rs. 125 crore. Recently, we have given the sanction. For the current year, the initial allotment is Rs. 6 crore which would be used to start the process. From the next two years, we will spend substantial money and create common facilities in these pharma clusters. That is the cluster approach ……

…..We will provide it at places where the pharma clusters have already come up and not in one place. They have come up in many States. We will provide these facilities so that they become full-fledged clusters…….. Quality testing facilities will also be there as they have to go to distant locations for obtaining quality certificates. If it is within the cluster, it makes their work easy".

OBSERVATIONS/ RECOMMENDATIONS

The Committee note that the Planning Commission had approved an outlay of Rs.2968 crore for the 12th Plan period. However, the actual budget allocation by the Planning Commission during the first three years was only 583 crore (Rs. 188 crore, Rs. 188 crore and Rs. 207 crore respectively) and the balance outlay of Rs.2386 crore (Rs.1193 + Rs.1193) has been redistributed for the remaining two years of the 12th Five Year Plan period. For Annual Plan 2010-11, against a BE of Rs.165 crore (RE was restricted to Rs. 119 core), actual expenditure incurred amounted to Rs.69.66 crore. Further, against a BE of Rs.175 crore for Annual Plan 2011-12 (RE was Rs.77.78 crore), actual expenditure incurred was Rs.40.33 crore only For Annual Plan 2012-13, Department of Pharmaceuticals proposed an outlay of Rs.1127.45 crore against which outlay approved by Planning Commission was Rs. 188 crore, RE was Rs.85 crore and actual expenditure incurred was Rs.51.78 crore which is 60.92% of RE outlay. For Annual Plan 2013-14, the Department proposed an outlay of Rs. 567.60 crore. However, Planning Commission allocated only Rs. 188.00 crore, RE was Rs.75 crore and actual expenditure incurred was Rs.74.07 crore which is 98.76 % of the RE. For the year 2014-15, the Department proposed an outlay of Rs. 871.81 crore to Planning Commission against which Planning Commission approved only Rs. 207 crore, which works out to just 10 percent more than last year's allocation of Rs. 188 crore. According to the Department, actual expenditure incurred in previous years would have been one of the criteria for allocation of funds in subsequent years. As a result of lesser allocations than the proposed outlays, the Department was compelled to spread thinner allocations amongst its various schemes during the year 2014-15. As for illustration, a provision of Rs. 20 crore for NIPER, Mohali has been made against proposed amount of Rs.88.40 crore. Similarly, a provision of Rs.88 crore has been made for New NIPERs as against the proposed amount of Rs.193 crore. Rs. 6 core was allocated for upgradation of MEs to WHO-GMP Standards etc. as against proposed amount of Rs.200.50 crore. For New Scheme, only Rs.15 crore was allocated against proposed amount of Rs.60 crore. The Committee therefore, strongly feel that the allocations made by the Planning Commission should commensurate to the outlays proposed by the Department. However, the Committee are anguished to note that the Department even failed to utilize fully, the outlay provided at RE stage during the year 2012-13 and 2013-14. Since various schemes of the Department are of paramount importance, any reduction in the allocation will have an adverse impact on the implementation of the schemes undertaken by the Department. It is therefore imperative for the Department to take proactive role in this regard and ensure

optimum utilisation of its resources to avoid substantial reduction of outlay at RE stage. The Committee recommend that the Planning Commission should provided adequate budgetary allocation to the Department at RE stage under various Head for effective implementation of its various schemes. The Committee would like to be apprised of the initiatives under taken by the Department in this regard.

2. The Committee note that under the Head Plan Capital Loan for Phama Industries, BE allocation for the year 2014-15 under the scheme Support for PSUs is Rs.16.79 crore for HAL, for BCPL the allocation is Rs. 7 crore, for IDPL it is Rs.5 crore and for RDPL the allocation is Rs.1.21. Further, under Critical Assistance Scheme (Grant for WHO-GMP compliance). for BE 2014-15 an amount of Rs.6.84 crore has been allocated to RDPL and Rs.3.16 crore (Rs.2 crore + Rs.1.16 crore) has been allocated to IDPL under the Head New Scheme for Pharma. The Committee are distressed to note from the status of release of funds that no proposal has been received from RDPL in respect of loans to PSUs. Similarly RDPL has not requested for release of second installment in respect of Grant for WHO GMP Compliance as the funds received for the project had been utilized for some other purpose. A Committee has been set up to reassess the project and its report is being processed. The Committee ,therefore, would like to to know the reasons for non-receipt of any proposal from RDPL for their Project Based Support (Loans to PSUs) as well as for Grant for WHO GMP Compliance. The Committee also stress that funds allocated to the Department for the year 2014-15 should be fully and prudently utilized to enable them to take the load of allocation of funds of last two years of 12th Five Year Plan. The Committee, would like to be apprised of the action taken in this regard.

3. The Committee note that National Institute of Pharmaceutical Education Research (NIPER) was declared as an "Institute of National Importance" under the Act of Parliament on 26th June 1998. One of the main purpose for starting these institutes is to establish the linkage with industry as well as academics. In addition to NIPER, SAS Nagar, Mohali, the Government has set up six new NIPERs at Hajipur (Bihar) , Hyderabad (Andhra Pradesh) , Gandhinagar (Gujarat) , Rae Bareli (Uttar Pradesh), Guwahati(Assam) and Kolkata (West Bengal). These new NIPERs will cater to the growing demand of the pharmaceutical industry for highly trained man power for continuous growth of the pharmaceutical sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present, these six new NIPERs are functioning with the assistance of Mentor Institutes. While the process for

construction of new campus for NIPER, Guwahati and NIPER, Gandhinagar has already started, the land for NIPER, Hyderabad and NIPER, Rae Bareli has been allotted by the respective State Governments and the process of selection of Project Management Consultants (PMC) has been initiated. NIPER, Hajipur and NIPER, Kolkata are yet to be allocated land for which the matter has been taken up with the respective State Governments. The Committee are extremely unhappy with the slow pace of progress in the acquisition of land and construction of new campus for new NIPERs. As a result, new NIPERs are still continuing to function with the assistance of their mentor Institutes In the absence of requisite infrastructure facilities, the Committee feel that it would be difficult for NIPERs to achieve its optimum level of efficiency imparting education and to focus on R&D. The Committee, therefore, recommend that the Department should make concerted and coordinated efforts to expedite the establishment of new NIPERs in their own campuses in a time bound manner so that they could achieve their avowed objectives to establish its links with pharmaceutical industry and nurture and promote quality and excellence in pharmaceutical education and research. They should pursue with respective State Governments at the highest level. Further, the process of selection of PMC for NIPER, Hyderabad and NIPER, Rae-Bareli for which land has already been acquired should also be expedited and be completed with in a fixed time frame. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

4. The Committee note that the functions of National Pharmaceutical Pricing Authority (NPPA) inter-alia include fixation and revision of prices of scheduled drugs under the Drug (Price Control) Order, 1995 (DPCO'95)/DPCO, 2013, as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation and on other specific issues concerning affordable medicines to the consumers. The Government has notified New DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995. Out of the 628 NLEM medicines specified in the Schedule-I of DPCO, 2013, NPPA has fixed / notified the ceiling prices in respect of 489 medicines upto 15th September, 2014 under provisions of the said order. In order to fix the ceiling prices in respect of the remaining NLEM medicines, NPPA has made sincere efforts to obtain / collect the data from all available sources like IMS-Health, PharmaTrac, Pharma Industry Associations, Marketing Companies etc. In addition, NPPA took up the matter with Department of Health, Drugs Controller General (India), State Health Secretaries and State Drugs Controllers for providing the information / data so as to enable NPPA to fix prices of remaining NLEM medicines under provisions of DPCO,

2013. The DPCO, 2013 also provides for monitoring of the production and availability of scheduled formulations and the active pharmaceuticals ingredients contained in the scheduled formulations. In this regard, the manufacturers/ importers/ marketing companies of the scheduled formulations and Active Pharmaceutical Ingredients are required to furnish information as stated in Form- III of the said order quarterly. NPPA regularly monitors the availability of essential medicines in the country through Drugs Control Administration of State Governments. Whenever shortage is reported by the State Drug Controllers or comes to its notice otherwise, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage. In this regard, the Committee were informed that recently the scarcity of certain essential medicines, namely, Anti-Snake Venom, Rabies vaccine, Rabies Immunoglobulin, Albumin Injection and Anti-malarial combination of Sulfadoxine + Pyrimethamine Tablets was reported to the NPPA. According to the Department, the concerned manufacturers of these drugs were not maintaining normal supply of the medicines in domestic market and / or Institutions. So, NPPA vide its notification S.O. No. 2292 (E) dated 09.09.2014 directed all the concerned manufacturers / importers to comply with the requirements contained in para 21(1) and furnish the month-wise production and sale figures for the last 12 months. In view of the foregoing, the Committee of the strong view that the prices of all essential drugs need to be regulated. In this regard, the role of the Government in procuring drugs and providing it at affordable price to the public can not be undermined. It is imperative for the Government/NPPA to urgently bring down the prices of all essential drugs so that the same are available to the common man, poor or the needy at affordable price. To keep this end in view, the Committee strongly feel that the scope of price control needs to be enlarged taking into consideration cost effectiveness, safety and efficacy and more and more therapeutic segments should be brought under price control. At the same time, NPPA/Government should be vigilant enough to ensure that all essential drugs are accessible to the public and a stock-out situation like the one as referred above should never arise. NPPA should also expedite the process of notifying the ceiling price of the remaining NLEM medicines i.e. 139 out of 628 NLEM medicines. The Committee would like the Department to act accordingly and be apprised of the initiatives taken by Department to fix/notify the prices of remaining NLEM medicines.

5. The Committee note that the Department has 5 running PSUs under its administrative control viz. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Bengal Chemicals &

Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL). Out of these KAPL and RDPL are profit making and BCPL, HAL & IDPL are BIFR referred Companies. However, RDPL during the year 2013-14, has registered losses for the first time though it is not a very sick unit in that way.

As the HAL is still incurring losses, a Modified Draft Rehabilitation Scheme (MDRS) based on the report submitted by IFCI limited, a professional Consultant, involving the cash infusion of Rs.497.45 crores was submitted by IDBI, the Monitoring Agency to BIFR on 17 February 2014. MDRS was subsequently revised by HAL with the assumption that the entire fund requirement for the revival of HAL would be made available by the Government of India from budgetary support. The Statutory Auditors are in the process of completing the audit of the statutory dues and other current liabilities of the company and the same will be submitted to IDBI by the company shortly. IDBI will then circulate the revised proposal to the Banks and Government/ Statutory Departments seeking their views/opinions on the same and then a joint meeting of the stake holders of the company will be convened by IDBI for finalizing MDRS before submitting to BIFR.

In the context of IDPL, the Committee were informed that the process of revival of IDPL as per the Laws, Rules & Procedures laid down by the Government of India is underway. No time frame can be indicated because other agencies of the Government are also involved. However, the process is at an advanced stage and all efforts are being made to bring the process to conclusion at the earliest. At present, the MDRS is being modified by IDBI, as per the cut off date approved by the BIFR in its last hearing held in September, 2014. During the course of evidence, the Committee were also informed that the rehabilitation programme of IDPL is under active consideration and very shortly the matter will go to the Cabinet for a decision. In this context, the Committee were also informed that 80% of the bulk drugs are coming from outside India and that has resulted in closing down of drug units in India. Therefore, the Department intends to create capacity for bulk drugs in India itself for which a policy will be brought out very shortly in a month's time or so. Once that policy is brought out, the Department hopes to revive IDPL and HAL to produce bulk drugs in a very big way which will help the country to attain self-reliance in bulk drugs.

As regards the BCPL, the Committee were informed that acute shortage of working capital and expiry of Purchase Procurement Policy in the year 2011 were the main reasons for gradual decrease in the production and sales turnover of the company. The said policy has since been renewed for another 5 years from December

2013. They are producing a lot of good quality drugs and have improved their performance to a great extent. Earlier they were producing quality drugs for Rs.10 crore which has since increased to Rs.30 to 40 crore.

In view of the foregoing, the Committee are extremely unhappy to note that no significant progress has been made over the years to revive the loss making/sick units particularly IDPL and HAL. During the course of evidence, the Secretary of the Department pointed out that a lot of time is lost in the Government decision making process as many agencies are involved therein. The Committee are, however, not satisfied with the explanation given by the Department as it is their responsibility to speed up its functioning/working and to act effectively and efficiently. The Committee are also of the view that over-dependence on outside countries for bulk drugs/critical raw material is very risky as any deterioration in relationship with them can potentially result in severe shortages in the supply of essential drugs to the country. There will also be a risk of increase in prices of the drugs where there is virtual monopoly. It is, therefore, essential that a well thought policy may be brought out with out further delay to create capacity of bulk drugs in the country itself and to attain self-reliance in bulk drugs for which revival of sick units would be extremely essential. The Committee, therefore, recommend that the Department should make vigorous efforts in coordination with all concerned to revive these sick units within a fixed time line. The Committee are of the strong view that the revival of these units is absolutely essential for the country to ensure availability and adequate quantity of drugs at an affordable price to the public. The Committee would like to be apprised of the action plan of the Department in this regard.

6. The Committee note that access to quality medicines at affordable prices is a key challenge for the Government. The prices of branded medicines are generally higher than generic medicines due to various reasons including limited regulation through Drug Prices Control Order, 1995 etc. For fulfilling this goal, 'Jan Aushadhi Campaign' has been launched. The purpose of this campaign is to make available medicines at affordable prices for all, especially the poor and the disadvantaged. Under this campaign, less priced quality generic medicines will be made available through Jan Aushadhi Stores (JAS) which are of same quality, efficacy and safety as compared to branded generic medicines. The Bureau of Pharma Public Sector Undertakings of India (BPPI) was set up on 1st December 2008 with the major objective to have a focused and empowered structure to implement the Jan Audhadhi Campaign initiated by the Department. BPPI monitors the functioning of Jan Aushadhi Stores and is also involved in promotion of the unbranded generic drugs. The first Jan Aushadhi Generic Drug

Store was opened in Civil Hospital, Amritsar on 25 November 2008. So far, 199 Jan Aushadhi Generic Drug Stores in various States have been opened and out of that only 99 are running as in many place these stores have been closed as the free drugs are being supplied to all the patients in hospitals by the State Governments.

The Committee also note that on the recommendation of this Committee in its 32nd Report (Recommendation No.9) regarding opening of more JAS on a mission mode, a revised Business Plan has been worked out by the Department which aims to open more than 3000 stores during 12th Plan period. However, the Committee regret to note that JAS is not being accepted either by the public or the drugs under the scheme are not being prescribed by the doctors to the patients. Even after six years, no efforts have been made by the Government to educate the peoples and to reach out the doctors' community in this regard. The Committee, therefore, recommend that a vigorous campaign should be launched by the Department to create awareness among the people about the generic drugs and Jan Aushadhi Stores and its quality, efficacy and safety comparable with branded medicines and to reach out to the doctors' community by way of conferences to impress upon them to prescribe generic drugs to the patients. The Committee desire that special emphasis be given by the Department for improving the functioning of the Jan Aushadhi Stores. The Committee also note that almost double amount has been earmarked for Jan Aushadhi Scheme in BE 2014-15 i.e Rs.30 crore as compared to Rs.15.20 crore in RE 2013-14. The Committee, therefore recommend that the increased amount should be utilized judiciously for opening more Jan Aushadhi stores in the remote areas where Jan Aushadhi stores are not in existence and for vigorous publicity campaign to create awareness amongst the people about generic drugs. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

7. The Committee note that the Department has come up with a scheme, Cluster Development Programme for Pharma Sector with the objective to create/upgrade the common facilities in the area where there is a cluster of Pharma Manufacturers. The total outlay of the scheme is Rs.125 crore for 12th Plan period. Through this scheme, the cluster of small and medium enterprises can avail financial assistance for common facilities like Common Testing Facilities, Training Centres, Effluent Treatment Plant, Common Logistics Centres. The Committee also note that the Department has already created a large number of Pharma clusters in the country at places like Hyderabad, Chennai, Maharashtra and Gujarat, Uttarakhand and Himachal Pradesh and many Pharma clusters will come up over a period of time. These Pharma clusters lack certain

common facilities, like quality testing facility, library facility, training facility, effluent treatment plant etc. An initial allotment of Rs.6 crore would be used to start the process and from next year onwards for the next two years, the Department will spend substantial amount of money and create common facilities in these Pharma clusters. The Committee expect the Department to implement the programme expeditiously in a systematic, professional and transparent manner. The Committee are of the view that these Pharma Cluster may also be associated with regional centres of NIPER and universities/colleges for their technical support and testing facilities. As a result thereof, the Committee hope that good quality medicines at affordable prices would be available to the common people. The Committee would like to be apprised of the progress made in the matter.

New Delhi;	**Anandrao Adsul**
5,December, 2014	**Chairperson**
14,Agrahayana, 1936 (Saka)	**Standing Committee on**
	Chemicals and Fertilizers

MINUTES

MINUTES OF THE FIFTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2014-15)

The Committee sat on Thursday, the 30 October, 2014 from 1500 hrs. to 1630 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

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. Shri Rangaswamy Dhruvanarayanan
7. Shri Satish Kumar Gautam
8. Adv. Joice George
9. Shri K. Ashok Kumar
10. Shri Kamalbhan Singh Marabi
11. Shri Chhedi Paswan
12. Shri S. Rajendran
13. Dr. Kulamani Samal
14. Dr. Uma Saren

RAJYA SABHA

15. Shri K. Parasaran
16. Shri Garikapati Mohan Rao
17. Shri Palvai Govardhan Reddy

SECRETARIAT

1. Smt. Rashmi Jain - Joint Secretary
2. Shri U.B.S. Negi - Director
3. Shri A.K. Srivastava - Additional Director

I. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

1. Shri V.K. Subburaj Secretary
2. Shri S.C. Khuntia AS & Financial Advisor
3. Shri Sudhansh Pant Joint Secretary
4. Dr. M.A. Ahammed Joint Secretary
5. Ms. Sunanda Sharma Economic Advisor

II. REPRESENTATIVES OF PSUs

1.	Shri Praveen Kumar	MD, Indian Drugs and Pharmaceuticals Ltd. (IDPL)
2.	Shri E.A. Subramanium	MD, Bengal Chemicals and Pharmaceuticals Limited (BCPL)
3.	Shri K.V. Varkey	MD, Hindustan Antibiotics Limited (HAL)
4.	Shri Suresh Bhandarnyar	MD, Rajasthan Drugs and Pharmaceuticals Limited (RDPL)
5.	Shri K.M. Prasad	MD, Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL)

III. AUTONOMOUS INSTITUTIONS

1.	Dr. K.K. Bhutani	Director, National Institute of Pharmaceutical, Education and Research (NIPER)
2.	Shri Sanwat Ram	CEO, Bureau of Pharma CPSUs of India (BPPI)
3.	Dr. Ahmet Kamal	Project Director, National Institute of Pharmaceutical, Education and Research (NIPER)

2. At the outset, Hon'ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) 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 Secretary, Department of Pharmaceuticals briefed the Committee about 'Demands for Grants' of the Department for the year 2014-15 and highlighted the Department's plans and priorities for the current financial year.

4. During the discussion, the Chairperson and Members of the Committee raised queries on several issues such as revival of sick PSU's, Implementation of 'Jan Aushadhi Scheme', functioning of NIPER, cluster approach, quality of drugs etc. which were replied to by the Secretary, Department of Pharmaceuticals and other officials.

5. The Chairperson, thereafter thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee and directed them to furnish the requisite information in writing on the points raised during the discussion, on which the information was not readily available with them.

6. The Committee also decided to hold the next sittings of the Committee on 18 and 19 November, 2014 to take the oral evidence of the non-officials and officials respectively on the subject 'Jan Aushadhi Scheme'.

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

The Committee then adjourned.

MINUTES

MINUTES OF THE EIGHTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2014-15)

The Committee sat on Monday, the 08 December, 2014 from 1500 hrs. to 1530 hrs. in Committee Room 'E', Parliament House Annexe, New Delhi.

PRESENT

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. Shri Rangaswamy Dhruvanarayanan
7. Shri Satish Kumar Gautam
8. Adv. Joice George
9. Shri K. Ashok Kumar
10. Shri Chhedi Paswan
11. Shri S. Rajendran
12. Shri Chandu Lal Sahu
13. Dr. Uma Saren
14. Smt. Rekha Verma

RAJYA SABHA

15. Shri Biswajit Daimary
16. Shri Narayan Lal Panchariya
17. Shri K. Parasaran
18. Shri Palvai Govardhan Reddy

SECRETARIAT

4. Smt. Rashmi Jain - Joint Secretary
5. Shri U.B.S. Negi - Director
6. Shri A.K. Srivastava - Additional Director

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

a) xxxx xxxx xxxx xxxx

b) Demands for Grants (2014-15) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals);

4. The draft Report relating to the Department of Pharmaceuticals was 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 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 xxxx Matters not related to this Report.