35	***STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2012-13)*** ***FIFTEENTH LOK SABHA***

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2013-2014)

THIRTY-FIFTH REPORT

LOK SABHA SECRETARIAT
NEW DELHI

April, 2013/ Vaisakha 1935, (Saka)

CC&F.No.35

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STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2012-13)

(FIFTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS

(2013-2014)

Presented to Lok Sabha on 30 April 2013

Laid in Rajya Sabha on 30 April 2013

LOK SABHA SECRETARIAT
NEW DELHI
April, 2013/ Vaisakha 1935, (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2012-13)

Shri Gopinath Munde - Chairman	
MEMBERS	
LOK SABHA	
2.	Shri S. Alagiri
3.	Shri Gajanan D. Babar
4.	Shri P.P. Chauhan
5.	Shri K.D. Deshmukh
6.	Shri Sher Singh Ghubaya
7.	Shri Sk. Nurul Islam
8.	Shri Sakti Mohan Malik
9.	Shri Paswan Kamlesh
10.	Shri Amarnath Pradhan
11.	Shri Ashok Kumar Rawat
12.	Shri Tufani Saroj
13.	Shri Suresh Kumar Shetkar
14.	Shri Raju Shetti
15.	Shri G.M. Siddeshwara
16.	Shri D. Venugopal
17. ^	Shri Sai Prathap Annayyagari
18.*	Vacant
19.#	Vacant
20.	Vacant
21	Vacant
RAJYA SABHA	
22.	Shri Biswajit Daimary
23.	Shrimati Naznin Faruque
24.	Shri A.A. Jinnah
25.	Shri Brijlal Khabri
26.	Shri Dilipbhai Pandya
27.	Shri Raghunandan Sharma
28. %	Vacant
29. ^	Vacant
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	-	Under Secretary

*** Shri P. Balaram Naik appointed as a minister of state**
#Shri Vitthalbhai Hansrajbhai (LS) has resigned w.e.f. 03 .01.2013
^ Shri Sai Prathap Annayyagarin (LS) nominated w.e.f. 09.01.2013.
% Dr. Vijay Mallya (RS) has resigned w.e.f. 26.02.2013
^ Shri K.C. Tyagi (RS) nominated w.e.f. 07.03.2013.
^ Shri Pyarimohan Mohapatra (RS) has resigned w.e.f. 22.03.2013
 # Shri K.C. Tyagi (RS) has resigned w.e.f. 01.04.2013

INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2012-13) having been authorised by the Committee to submit the Report on their behalf, present this Thirty-Fifth Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2013-14.

2. The Committee examined the Demands for Grants (2013-14) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which were laid in Lok Sabha and Rajya Sabha on 14 March 2013.

3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 20 March 2013.

4. The Report was considered and adopted by the Committee at their sitting held on 26 April 2013.

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/ Recommendations of the Committee have been printed in bold letters at the end of the Report.

New Delhi;
26 April, 2013
6 Vaisakha, 1935 (Saka)

Gopinath Munde,
Chairman,
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 to provide greater focus for the growth of the Pharmaceuticals industry.

1.2 Following work has 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 (since closed).
(xviii) Smith Stanistreet Pharmaceuticals Limited (since closed).

1.3 The work of the Department has been organized into three Divisions that is 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 fixation and revision of prices of Pharmaceutical products under Drug Price Control Order, 1995.

1.4 There are five Central Public Sector Undertakings (CPSUs), viz. Indian Drugs and Pharmaceuticals Limited (IDPL), Hindustan Antibiotics Limited (HAL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Bengal Immunity Limited (BIL) and Smith Stanistreet Pharmaceuticals Limited (SSPL). Earlier Karnataka Antibiotics and Pharmaceuticals Limited. (KAPL) was a joint venture between Hindustan Antibiotics Limited (HAL) and the State Government of Karnataka and Rajasthan Drugs and Pharmaceuticals Limited (RDPL) was a joint venture of Indian Drugs and Pharmaceuticals Limited (IDPL) and the State Government of Rajasthan. In order to sustain the growth and development of KAPL and RDPL, the Government has approved de-linking of both these companies from HAL and IDPL respectively. The shares of KAPL held by HAL have now been transferred to the President of India w.e.f. 1st October, 2009 and similarly shares of RDPL held by IDPL have been transferred to the President of India w.e.f. 17th August, 2010. The shareholding of respective States in these joint ventures would continue to remain unaffected.

1.5 National Institutes of Pharmaceuticals Education and Research (NIPERs) are autonomous institutions under the Department of Pharmaceuticals.

1.6 The detailed Demands for Grants (2013-14) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 14 March 2013. The demand shows a budgetary support of Rs 228.33 crore [(Rs.188.00 crore (Plan) + Rs.40.33 crore (Non-Plan)]. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2013-14. The detailed analysis along with Observations/Recommendations of the Committee are presented at the end of the Report.

CHAPTER-II

AN OVERVIEW OF PHARMACEUTICAL INDUSTRIES

2.1 As per the Annual Report 2012-13 of the Department, net sales of the industry grew by 14.7 percent in the quarter ending June 2012 as compared to the year ago quarter. The depreciation in the value of rupee against the USD, though favorable for the export-oriented drug companies had an adverse impact on the profits of companies. The industry imports around 38 percent of its raw material requirements which exerted pressure on the profit margins. Huge forex losses brought down the profit of the drugs & pharmaceuticals industry in the June 2012 quarter. The industry's Profit After Tax slumped during the quarter.

2.2 The drugs & pharmaceuticals industry performed well in the second quarter ending September 2012. Rising sale from the US generic market, strong growth in domestic market, robust growth in other income and slower growth in expenses boosted the financial performance of the drugs & pharmaceuticals industry. Net sales of the industry grew by a healthy 13.2 percent in the September 2012 quarter as compared to the year ago quarter. Other income increased during the quarter due to forex gains made by some companies. Raw materials expense, the largest cost component of the industry, rose by a slower percent as compared to the growth in sales. In the absence of forex losses, other expenses also fell. Resultantly, the industry's operating expenses corresponding to goods sold rose by a slower percent. This improved the core operating performance of the industry. A healthy operating performance and a robust growth in other income boosted the financial performance of the drugs & pharmaceuticals industry.

2.3 The sales growth of the pharma industry is likely to remain healthy in the second half of the year 2012-13. The Pro Generic policy of developed markets and strong demand scenario in the developing market. Export volumes are likely to remain healthy due to strong demand for generic drugs. On a yearly basis, the rupee continues to remain weak. Hence, export realizations are also likely to remain strong.

2.4 **IMPORTS:** As per the Directorate General of Commercial Intelligence and Statistics (D.G.C.I.S.) Kolkata, value of imports of "Medicinal and Pharmaceuticals Products" for the period 2003-04 to 2011-12 is as under:-

(Rs. in crore)

Year	Value of Import of 'Medicinal and Pharmaceuticals Products'	Growth (%)
2003-04	2956	3.18
2004-05	3139	6.19
2005-06	4515	43.84
2006-07	5866	29.92
2007-08	6734	14.79
2008-09	8649	28.43
2009-10	9959	15.15
2010-11	11,114	11.60
2011-12(P)	14385	29.43

2.5 It may be observed that the imports have shown a growth of 29.43% in the year 2011-12 compared to previous year. The country is almost self-sufficient in production of most of formulations/ pharmaceuticals products. As such imports are being resorted to on quality & economic considerations and not necessarily due to non-availability from domestic sources. Manufacturers of Drugs & Pharmaceuticals are free to produce any drugs approved by the Drug control authorities.

2.6 Import of Drugs & Pharmaceuticals is regulated as per the Foreign Trade Policy of Government of India. Import of some drugs and drug intermediates are restricted under current Foreign Trade Policy. These restrictions are basically due to common HS codes assigned to some narcotic substances or similarity to some Ozone Depleting Substances (ODS) with pharmaceutical products.

2.7 **EXPORTS :** As per DGCIS, Kolkata Export of Drugs and Pharmaceuticals and Fine Chemicals for the period 2003-04 to 2010-11 are below:-

(Rs. in crore)

Year	Value of Import of 'Medicinal and Pharmaceuticals Products'	Growth (%)
2003-04	15,213	18.61
2004-05	17,228	13.25
2005-06	21,230	23.23
2006-07	25,666	20.89
2007-08	29,354	14.37
2008-09	39,821	35.66
2009-10	42,456	6.62
2010-11	48,810	14.97
2011-12(P)	63,347	29.76

It may be observed that the exports have shown a growth of 29.78% in the year 2011-12 compared to previous year.

2.8 **<u>Export and Import of Medicinal and Pharmaceutical Products</u>**

As per Economic Survey (2012-13), it has been indicated that Medicinal and Pharmaceutical products to the tune of $ 1933.00 million were imported during the year 2011-12. This figure rose to $2040 million during the year 2012-13.

2.9 When asked to give reason for increase in the value of import of Medicinal and Pharmaceutical products as compared to last years, the Department in its written reply stated as under:-

> "India is almost self dependent in formulations, however, nearly 30% of requirements of bulk drugs are imported. The Indian Pharmaceuticals Industry is dominated by Private manufacturers and the source of raw material is decided by them based on its economies and other factors. Due to cheap input cost of fermentation related bulk drugs in China the import has shown a trend of increase".

2.10 When the Committee, asked about steps taken/supposed to be taken to make us self reliant in pharmaceutical sector and to minimize the dependence on import, the Department in its written reply stated as under:-

> "India is almost self dependent in formulations, however, nearly 30% of requirements of bulk drugs are imported. The Indian Pharmaceuticals Industry is dominated by Private manufacturers and the source of raw material is decided by them based on its economy and other factors. However, various schemes like Cluster Development, Venture Fund etc., have been planned for growth of the Industry".

2.11 On being asked by the Committee as to whether we also export some pharmaceutical products, the Department in its written reply stated as under:-

> "India is among the top 20 pharmaceutical exporting countries globally and the export was worth Rs. 47363 crore. during 2010-11 which is nearly 45% of total turnover of Indian Pharma Industry. Indian drugs are exported to around 200 countries in the world with highly regulated markets of USA, UK etc. The top five exporting destination countries are USA, Russia, Germany, Austria and UK with USA alone accounting for almost 20% of total export. The major therapeutic categories of export are antiinfective, antiasthmatic and anti hypertensive".

CHAPTER-III

FIVE YEAR PLANS AND ANNUAL PLAN

(a) Twelfth Five Year Plan
(b)

3.1 Scheme wise Plan Outlays during Twelfth Five Year Plan is as under:-

S. No.	Name of the Scheme	Total GBS allocation for the 12th Plan	Yearly Allocation During 12th Five Year Plan (Rs.in crore)				
			2012-13	2013-14	2014-15	2015-16	2016-17
1.	**Pharma Promotion and Development Scheme (PPDS)**	10	2	2	2	2	2
2.	**Intellectual Property Rights Facilitation Centers**	5	1	1	1	1	1
3.	**NIPER, Rae Bareli**	148	4.50	25.50	50	50	18
4	**NIPER, Hyderabad**	162	22	40	40	40	20
5.	**NIPER, Kolkata**	164	4.50	25.50	30	40	64
6.	**NIPER, Hajipur**	143	3.70	25.30	35	50	29
7	**NIPER, Gandhinagar**	167	16.50	28.50	40	30	52
8	**NIPER, Guwahati**	171	18.80	30	46.20	30	46
9	**NIPER, Mohali**	255	24	45	60	70	56
	(i) Continuing Scheme	150	24	25	40	40	21
	(ii) New Scheme (including NIPER-Pharma-Incubator)	105	-	20	20	30	35
10	**Opening of new NIPER at Madurai**	50.00	-	10	15	10	15
11	**Setting up National Centre for R&D in Bulk Drugs in NIPER, Hyderabad**	60.00	-	15	15	15	15
12	**Jan Aushadhi Scheme**	200	20	45	45	45	45
13	**Up gradation of SMEs to WHO-GMP Standards**	175	10	30	45	50	49
14	**Consumer Awareness and publicity through print and electronic media including NPPA**	20	4	4	4	4	4
15	**I.T Plan Secretariat**	4	1	0.80	0.80	0.80	0.80
16	**Project Based Support of existing PSU**	700	20	140	250	200	80
17	**New Scheme / initiatives for 12th Plan (Includes Interest Subsidy for Schedule M compliance & ERP R&D Park)**	534	36	100	150	150	100
	Total	**2968**	**188**	**567.6***	**829**	**787.8**	**596.8**

***Rs.567.60 crore was demanded for 2013-14 but allocation received is only Rs.188.00 crore**

3.2 On being asked to give details regarding actual utilization of the allocation of Rs.188.00 crore for the year 2012-13, and to indicate under-utilisation of funds if any in any of the schemes, the Department in its written reply submitted as under:-

"Details of scheme-wise outlays and percent achievement in terms of financial targets for 2012-13 (i.e. first year of the 12th Five Year Plan) is given in the Table below.

(Rs.in crore)

		Outlay			**Achievement (%)**
Sr. No.	Name of the Scheme	2012-13 BE	2012-13 RE	2012-13 Actual Exp. (Till now)	Actual vs RE (Till now)
I	Project Based Support to PSUs	20.00	10.00	0.00	Nil
II	Support to Autonomous Institutions				
1	National Institute of Pharmaceutical Education and Research(NIPER),Mohali	24.00	0.00	0.00	-
2	New NIPER like Institutes				
	a) NIPER, Ahmedabad	16.50	16.50	5.14*	31.2%
	b) NIPER, Hajipur	3.70	1.70	*	-
	c) NIPER, Guwahati	18.80	13.00	3.00*	23%
	d) NIPER, Kolkata	4.50	1.75	1.75*	100%
	e) NIPER, Hyderabad	22.00	22.00	20.29*	92.02%
	f) NIPER, Rai Bareli	4.50	3.00	3.00*	100%
	Total NIPER	94.00	57.95	33.18	57.25%
3	National Pharmaceutical Pricing Authority(NPPA)	4.00	4.00	0.52	13.00%
III	Other Ongoing Schemes				
1	Pharma Promotion and Development Scheme (PPDS)	2.00	1.00	0.38	38.0%
2	IT/Secretariat	1.00	1.00	0.42	42.0%
3	Interest Subsidy for Schedule M compliance/Upgradation of SMEs to WHO-GMP standards etc.	2.00	0.00	0.00	-
4	Creation of IPR facilitation center at Pharmaexcil	1.00	0.50	0.00	Nil
5	ERP (GLP/GCP/Animal House Lab)	4.00	0.00	0.00	-
6	Critical assistance for WHO pre-qualification for pharma PSUs/R&D	10.00	4.55	4.55	100.0%
7.	Jan Aushadhi Scheme	20.00	4.50	1.66	36.89
8.	New Schemes	30.00	1.50	1.32	Nil
	Total	188.00	85.00	42.03	47.89%

* More funds are being released

3.3 The reason for underutilization of funds along with Status of funds allocated and released during 2012-13 are given below:-

"***<u>NIPERs</u>***

In respect of NIPERs Rs. 33.18 crore was released. The proposal for release of balance Rs. 23.06 crore has been sent to IFD for concurrence. . Funds to NIPER, Mohali could not be released for want of utilization certificates. As regards, new NIPERs, proposals have been sent to IFD for concurrence for releasing funds to NIPER, Guwahati and Ahmedabad for construction of NIPER campuses. Concurrence of IFD is awaited.

PTUAS

Utilization in r/o Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) is nil for the year 2012-13 as the scheme has not been approved by the Planning Commission.

NPPA

NPPA has incurred Rs.52.34 lakhs under the Consumer Awareness and Publicity Schemes during the year 2012-13 against the total allocation of Rs.400 lakhs in BE & RE 2012-13. However, NPPA has surrendered Rs.347 lakhs during the year 2012-13 for want of permission from Planning Commission to allow NPPA to incur full expenditure instead of sharing in ratio of 50:50 with D/o Consumer Affairs. As per requirement of the Planning Commission, NPPA has submitted proposal in SFC format to DOP on 13.3.2013, which is under examination in the department.

Pharmaceutical Promotion & Development Scheme (2012-13)

Total amount of sanctions issued till date is Rs. 60,55,474/- The proposal regarding a in-depth study on regulations requirements in various countries through a study on International Drug harmonization in Indian Pharmaceutical Industry for export promotion, could not be approved due to technical reasons as per General Financial Rules (GFR)

Creation of IPR Facilitation Centre (2012-13) (Plan) (BE – Rs.1.00 crore) (RE – Rs.0.50 crore)

The proposal received from Pharmexcil for grant of Rs.51.00 lakh is under consideration in the Department.

Support to PSUs (Project based support):

The project proposal for Rs. 10.00 crore as assistance to HAL and IDPL were mooted. However, IFD/ Ministry of Finance did not concurred with the proposals. Hence, under utilization.

Jan Aushadhi Scheme:

The Department of Pharmaceuticals & BPPI have been regularly requesting and following up with various State Governments/UTs for opening of JADS in their States. However, response has not been encouraging. In several States including Tamil Nadu, Mizoram, Sikkim, Andhra Pradesh, Andaman & Nikobar Islands, Jan Aushadhi Drug Stores are yet to be opened. Expenditure of funds therefore could not be made as planned and expected. Planning Commission accorded in principle approval for release of only Rs. 4.50 crore as Working Capital to BPPI. However, as an amount of Rs. 2.84 crore still remained unutilized with BPPI, IFD agreed to release only Rs. 1.66 crore."

3.4 During the course of the evidence, the Secretary Department of Pharmaceuticals stated as under:-

> "...the entire Plan allocation was less than Rs.200 crore, which was mainly allocated for the PSUs, NIPER and for some new Schemes which have been thought out. Being a new Department, Sir, the clearance of the Schemes and also going through the whole process of drawing up the Schemes have taken some time. But I am glad to report that most of them have now reached a stage, where, I think, in the next year we should be able to make substantial progress.

Overall, if you see, the plan was Rs. 188 crore; the RE was reduced to little over Rs. 85 crore; and the performance, at the end was about Rs. 45 crore to

Rs. 46 crore. This could have much higher. There were proposals, which were ready for being financed but because of the fiscal discipline in a sense, we could not release more than 15 per cent on a scheme in March. The money for about Rs. 20 crore plus could not be released. Had that been the case, our performance against RE would have been above 80 per cent. But because money could not be released, it could not be captured here".

(b) ANNUAL PLAN 2013-14

3.5 In a written reply on Scheme-wise outlays proposed by the Department and finally approved by the Planning Commission regarding Annual Plan 2013-14, the following details were provided by the Department:-

(Rs. in crore)

Sr. No.	Name of the Scheme	2013-14 Proposed	2013-14 Approved
I	**Project Based Support to PSUs**	133.16	29.66
II	**Support to Autonomous Institutions**		
1	National Institute of Pharmaceutical Education and Research(NIPER)	25.00	12.00
2	New NIPER like Institutes		
	a) NIPER, Ahmedabad	28.50	20.00
	b) NIPER, Hajipur	25.30	3.70
	c) NIPER, Guwahati	30.00	18.80
	d) NIPER, Kolkata	25.50	4.50
	e) NIPER, Hyderabad	40.00	25.00
	f) NIPER, Rai Bareli	25.50	4.50
	g) NIPER Pharma –Incubator,opening new NIPER Madhurai, National cenre for R&D Hyderabad	45.00	0.00
3	National Pharmaceutical Pricing Authority(NPPA)	4.00	4.00
III	**Other Ongoing Schemes**		
1	Pharma Promotion and Development Scheme (PPDS)	2.00	2.00
2	IT/Secretariat	0.80	1.00
3	Interest Subsidy for Schedule M compliance/Upgradation of SMEs to WHO-GMP standards	30.00	0.00
4	Creation of IPR facilitation center at Pharmaexcil	1.00	1.00
5	ERP (GLP/GCP/Animal House Lab)	0.00	0.00
6	Critical assistance for WHO pre-qualification for pharma PSUs/R&D	6.84	6.84
7.	Jan Aushadhi Scheme	45.00	25.00
8.	New Schemes 12th Plan	100.00	30.00
	Total	**567.60**	**188.00**

3.6 On being asked by the Committee as to why lesser allocation of Rs.188.00 crore were approved by the Planning Commission for 2013-14 even though the Department had proposed Rs.567.60 crore and also how the Department plans to achieve their targets with lesser allocations, the Department in its written reply submitted as under:-

"Though the Department had proposed an outlay of Rs. 567.60 crore, Planning Commission allotted only Rs. 188.00 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. Hence the total Annual Plan Outlay was maintained at Rs.188 crore and a suitable scheme-wise break-up was worked out within this overall outlay.

While approving the outlay for 2013-14, the Commission inter alia observed, that:-

i. Planning Commission has determined the Gross Budgetary Support after taking into consideration the resource availability for the year 2013-14 and demands of various Ministries/Departments
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.
iv. Adequate provision may be made for programmes/schemes pertaining to Information Technology, e-governance and related areas to improve overall administrative efficiency.

However, all out efforts will be made to get the enhanced allocation during the subsequent years and the target will be achieved."

3.7 When the Committee asked to give details of the efforts made by Department of Pharmaceuticals to get proposed outlay of Rs.567.00 crore, the Department in its written reply stated as under:-

"At the time of Annual Plan discussions, the Department of Pharmaceuticals had proposed an outlay of Rs.567 crore for the Annual Plan 2013-14. Discussions at senior level were held with the Planning Commission to get the outlay of 567 crores. But the Planning Commission has determined the Gross Budgetary Support after taking into consideration the resource availability for the year 2013-14 and demands of various Ministries/Departments. 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 (which was Rs.188 crore). Hence the total Annual Plan Outlay 2013-14 was maintained at Rs.188 crore".

3.8 When the Committee asked about initiatives being taken by the Department pursuant to the observations/suggestions of the Planning Commission, the Department in its written reply stated as under:-

"Planning Commission had indicated vide their letter dt. 9th Feb. 2013 that the total outlay of the Department be maintained at the same level as in the previous year i.e. Rs.188 crore. The matter was discussed with Adviser/Jt. Adviser Planning Commission & it was reiterated by them that GBS allocation cannot be increased beyond Rs. 188 crore for the year 2013-14. As such the total Annual Plan Outlay 2013-14 was maintained at Rs.188 crore and a suitable scheme-wise break-up was worked out within this overall outlay as mentioned by the Planning Commission. 10% of GBS was earmarked for north-eastern states. Adequate provision was made for programmes/ schemes pertaining to Information Technology, e-governance and related areas to improve overall administrative efficiency."

CHAPTER-IV

DEMANDS FOR GRANTS OF THE DEPARTMENT FOR THE YEAR 2013-14

4.1 The Demand of grants of the Ministry of Chemicals and Fertilizers presented to Parliament on the Department of Pharmaceuticals on 14.3.2013 included a provision for the expenditure of the Secretariat, North Eastern Areas, Industries, loan for Pharma Industries, under the control of Department of Pharmaceuticals.

4.2 Budgetary allocation under Plan and Non Plan under Major Head during the year 2012- 2013 and 2013-2014 are indicated below:-

BUDGETARY ALLOCATION UNDER PLAN AND NON PLAN UNDER MAJOR HEAD AND CAPITAL DURING THE YEAR 2012- 2013 and 2013-2014

(Rs. in crore)

Major Head	**Budget Estimates 2012-13**			**Revised Estimates 2012-13**			**Budget Estimates 2013-14**		
	Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
Revenue	168.00	43.04	211.04	75.00	36.79	111.79	158.34	40.29	198.63
Capital	20.00	0.05	20.05	10.00	--	10.00	29.66	0.04	29.70
Total	**188.00**	**43.09**	**231.09**	**85.00**	**36.79**	**121.79**	**188.00**	**40.33**	**228.33**

In this context, the Department in its written reply stated as under:-

"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 of the society in the matter of health care. Consistent with this policy, Government of India approved rehabilitation scheme for revival of HAL and BCPL. The rehabilitation scheme of IDPL is under consideration. As the HAL is still incurring losses, the Second Rehabilitation Plan of HAL is also under active consideration of Govt. of India. The amount of Rs. 29.66 crore as allocated for project based support to PSUs has been earmarked to be utilized for the following purposes:-

(Rs.in crore)

S.No	**PSU**	**Scheme**	**Total Amount required for project**	**Provision for the year 2013-14**
i	**HAL**	Expanding the Capacity of Large Volume Parenterals (IV Fluid)	45.00	14.17
ii)	**BCPL**	statutory obligations towards Land and Revenue and fees for obtaining statutory approvals from the State and Central Drug Controller, KDA & KMC, Factory Directorate, Pollution Control Board, Fire and Legal issues under implementation of Revival Scheme of BCPL	9.30	9.30
iii)	**IDPL**	i) Terminal Dues/Gratuity of Retiring Employees	3.00	3.00
		ii) Upgradation of premises for NIPER at IDPL	2.90	2.90
		iii) liquid oral (2nd line) at Gurgaon plant	1.00	0.29
			Total	**29.66**

4.3 The following statement shows the scheme-wise details of Plan expenditure for BE, RE and Actual Exp. for 2010-11, 2011-12 & 2012-13 and BE 2013-14 :-

PLAN **(Rs. In crore)**

S.No.	Head	2010-11			2011-12			2012-13			2013-14
		BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
	Revenue										
1	Sectt.	0.25	0.25	0.12	0.25	0.20	0.19	1.00	1.00	0.39	1.00
2	NIPER	61.00	47.18	30.65	10808	35.86	33.80	75.20	44.95	27.55	69.70
3	NPPA	.99	.70	0.16	240	2.05	0.16	4.00	4.00	0.00	4.00
4	PEPS	45.01	17.72	10.33	22.32	8.44	.45	67.00	11.05	4.55	62.84
5	PPDS	1.25	1.25	.69	2.00	1.00	.68	2.00	1.00	0.38	2.00
6	NE Region	16.50	11.90	0	17.50	7.78	0.00	18.80	13.00	0.00	1880
	Total Revenue	**125.00**	**79.00**	**41.95**	**152.55**	**55.33**	**35.28**	**168.00**	**75.00**	**32.87**	**158.34**
	Capital										
9	HAL	15.00	15.00	2.50	6.85	6.85		3.00	5.00	0	14.17
10	BCPL	25.00	25.00	25.00	.60	.60	.60	2.00	0.00	0	9.30
12	IDPL				10.00	10.00	4.61	15.00	5.00	0	6.19
14	RDPL				5.00	5.00				0	
	Total Capital	**40.00**	**40.00**	**27.50**	**22.45**	**22.45**	**5.21**	**20.00**	**10.00**	**0**	**29.66**
	Total	**165.00**	**119.00**	**69.45**	**175.00**	**77.78**	**40.49**	**188.00**	**85.00**	**32.87**	**188.00**

Non Plan

S. No.	Head	2010-11			2011-12			2012-13			2013-14
		BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
1	**Revenue**										
2	Sectt.	7.34	7.45	7.19	7.64	7.62	7.22	8.94	7.59	6.64	9.00
3	NPPA	6.07	5.41	4.86	5.88	5.81	5.36	6.35	6.27	5.21	7.71
4	PEPS	.50	.20	0.01	0.20	.05	.05	.20	0	0	.01
	NIPER	19.04	24.04	20.64	24.23	24.77	24.77	27.55	22.93	21.14	23.57
	Total Revenue	**32.95**	**37.10**	**32.70**	**37.95**	38.25	37.40	**43.04**	**36.79**	**32.99**	**40.29**
5	**Capital**										
6	SSPL	.01	.01	0	.01	.01	0	.01	0	0	0
7	BCPL	.01	.01	0	.01	.01	0	.01	0	0	.01
8	BIL	.01	.01	0	.01	.01	0	.01	0	0	.01
9	IDPL	.01	.01	0	.01	.01	0	.01	0	0	.01
10	HAL	.01	.01	0	.01	.01	0	.01	0	0	.01
	Total Capital	**.05**	**.05**	**0**	**.05**	.05	0	**.05**	0	0	.04
	Grand Total	**33.00**	**37.15**	**32.70**	**38.00**	**38.30**	**37.40**	**43.09**	**36.79**	**32.99**	**40.33**

4.4 When the Committee asked to give reasons for lesser actual utilization of funds in 2012-13 as compared to 2011-12 in Plan outlays under Head Revenue, the Department stated as under:-

> "So far as NIPER is concerned, as per the above statement, Rs. 27.55 crore has already been spent in 2012-13. In addition proposals for release of Rs. 24.00 crore to NIPERs at Guwahati and Ahmedabad have been sent to IFD for concurrence. Assuming that IFD will agree, the actual expenditure will be Rs. 51.55 crore in 2012-13 as against Rs. 37.40 crore in 2011-12. As such there is no under-utilization of funds in respect of NIPERs in 2012-13 as compared to 2011-12".

4.5 When the Committee asked to give reasons for zero utilization during the year 2012-13 under the Head capital in Plan and Non Plan, the Department stated as under:-

> "The reasons for zero utilization during the year 2012-13 under the Head capital in Plan fund is that the proposals received from HAL & IDPL were not accorded concurrence by IFD/MoF. As regards zero utilization under the Head Capital in Non Plan, it is stated that only a token provision of Rs. 1 lakh each were made for SSPL, BCPL, BIL, IDPL & HAL for the year 2012-13".

CHAPTER-V

HEAD-WISE ANALYSIS OF DEMANDS FOR GRANTS (2013-14)

(a). MAJOR HEAD 3451

Secretariat –Economic Services

(Rs.in crore)

BE 2012-13			RE 2012-13			BE 2013-14		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
1.00	8.94	9.94	1.00	7.59	8.59	1.00	9.00	10.00

5.1 On being asked by Committee to provide reasons for substantial increase in Non-Plan allocation in BE 2013-14 as compared to RE 2012-13, the Department in its written reply stated as under:-

> **"**During the year 2012-13, many posts remained vacant and the Revised Estimates was to be brought down to Rs. 7.59 Crore from the BE of Rs. 8.94 Crore.
>
> For the year 2013-14, the BE has been proposed to Rs.9.00 Crore which is just Rs. 0.06 Crore more than the BE of previous year".

(b) MAJOR HEAD -2552

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

(Rs.in crore)

BE 2012-13			RE 2012-13			BE 2013-14		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
18.80	--	18.80	13.00	--	13.00	18.80	--	18.80

5.2 On being enquired by the Committee as to how the Department proposes to utilize the amount of Rs.18.80 crore during the current year 2013-14, the Department in its written reply stated as under:-

> "Rs. 18.80 crore allocated for 2013-14 is proposed to be utilized for management and construction of new Campus of NIPER, Guwahati. NIPER, Guwahati, has since signed an MoU with Engineering Projects (India) Ltd. (EPIL) on 23.01.2013 for construction of new Campus of NIPER, Guwahati".

(c). MAJOR HEAD 2852

(i) **Pharmaceutical industries**

(Rs.in crore)

BE 2012-13			RE 2012-13			BE 2013-14		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
148.20	34.10	182.30	61.00	29.20	90.20	138.54	31.29	169.83

5.3 When the Committee asked to give reasons for increase in allocation to Pharmaceutical Industries in BE 2013-14 from RE 2012-13, the Deparment in its written reply stated as under:-

> "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. Hence the total Annual Plan Outlay was maintained at Rs.188 crore and a suitable scheme-wise break-up was worked out within this overall outlay**.** It may be stated that BE for 2012-13 was higher at Rs. 148.20 crore for Pharmaceutical Industries".

5.4 The Committee were also informed in writing that the above allocation for Pharmaceutical Industries includes the allocations made for (i) National Institute of Pharmaceutical Education Research (NIPER), (ii) National Pharmaceutical Pricing Authority (NPPA) (iii) Pharmaceutical Export Promotion Scheme (PEPS) (iv) Pharmaceuticals Promotion & Development Scheme (PPDPS) and (v) others.

(II) **National Institute of Pharmaceutical Education Research (NIPER)**

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.

The details of allocation for NIPER for the year 2012-13 and 2013-14 are as under:-

(Rs.in crore)

BE 2012-13			**RE 2012-13**			**BE 2013-14**		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
75.20	**27.55**	**102.75**	**44.95**	**22.03**	**67.88**	**69.70**	**23.57**	**93.27**

5.7 On being enquired as to how the Department of Pharmaceuticals propose to utilize increase of Rs. 24.75 crore in the year 2013-14 as compared to Plan RE 2012-13, the Department in its written reply stated as under:-

> "In 2012-13, Plan funds could not be released to NIPER, Mohali for want of utilization certificates. Whereas, in 2013-14, funds will be released to NIPER Mohali. In addition, during 2013-14, the work relating to construction of NIPER Campus at Guwahati and Gandhinagar would commence. As such funds will be utilized fully in 2013-14".

5.8 When the Committee asked to give details of the progress of construction of campuses in six new NIPERS, the Department in its written reply stated as under:-

> "In 2007, Cabinet granted in-principle approval to the setting up of six new NIPERs and commencement of classes with the help of mentor Institutes. On 30.09.2011, Cabinet finally approved establishment of six new NIPERs.
>
> At present, land is available at Guwahati & Gandhinagar. Following approval of the Steering Committee the work relating to construction of NIPER Campus at Guwahati and Gandhinagar has since been awarded to PSUs viz Engineering Projects (India) Ltd (EPIL) & Hindustan Steelworks Construction Ltd (HSCL) respectively. An MoU with EPIL and HSCL has also been signed on 23.01.2013 and 30.01.2013 respectively for construction of new Campuses.
>
> For NIPERs Hyderabad, Kolkata, Rae Bareli & Hajipur, the matter is being pursued with the respective State Government for early allotment of land for NIPER, Campus".

5.9 When the Committee asked as to whether the Department of Pharmaceuticals has obtained the concurrence by IFD for release of funds for construction of new campuses of NIPER Gandhinagar and NIPER Guwahati, the Department in its written reply stated as under:-

> " IFD has since concurred for release of Rs. 1.57 crore and Rs. 2.22 crore for NIPER, Ahmedabad & NIPER Guwahati respectively".

5.10 When asked to elaborate the time line by which the construction of New campus of NIPER at Gandhinagar will be completed, the Department in its written reply stated as under:-

> "NIPER, Gandhinagar, has signed MoU with Hindustan Steelworks construction Limited (HSCL) for construction of its campus. Initial funds for mobilization are being released. Before commencing construction, HSCL will have to undertake soil & geo-technical investigation, clearances from local authorities, apart from preparing drawings & designs for approval by the competent authority. The time frame for completion of the project would be decided at the time design of the project is approved".

5.11 When asked whether any time frame has been fixed for construction of new campus of NIPER Guwahati by Engineering Projects India Ltd, the Department in its written reply stated as under:-

> " The time frame for construction would be laid by NIPER, Guwahati at the time of granting approval to the design of NIPER campus".

5.12 When asked about specific steps taken to persuade the respective State Governments to allot the land for the purpose, the Department in its written reply stated as under:-

> "Government of Andhra Pradesh has since agreed to allot 50 acres of land for NIPER Hyderabad. Matter is being finalized. Issue of allocation of land has been vigorously pursued with State Government of West Bengal, Bihar and Uttar Pradesh. A number of letters have been written at the level of Secretary and also from the Minister (Chemicals and Fertilizers). Secretary also discussed with Chief Secretary of Bihar and West Bangal in this regard. A meeting was convened on 23.11.2012 inviting representatives of the concerned State Governments to pursue the matter. The meeting was attended by officers from the Uttar Pradesh Government other could not attend though letters were sent assuring necessary action".

5.13 During the course of evidence, the Secretary of the Department of Pharmaceuticals stated as under:-

> "…Likewise, there are six new NIPERs. The only condition that was put by the Cabinet was that the land for new NIPERs had to be given by the State Governments free of cost. Till date, only two States, Gujarat and Assam have given us the land. We are hopeful of getting land in Raebareli and Hyderbad very soon. But there is still substantial progress to be made in case of Hajipur and Kolkata.
>
> The net effect of this has been that the allocations that were made in anticipation of lands being available so that campuses could be constructed, could not happen."

(iii) **National Pharmaceutical Pricing Authority (NPPA)**

5.14 The National Pharmaceutical Pricing Authority (NPPA) was established as an independent body of experts under the Ministry of Chemicals and Fertilizers by Gazette notification dated 29.08.1997. The Authority is entrusted with the task of price fixation / revision of the 74 scheduled bulk drugs and formulation containing any of the scheduled drugs under the Drugs (Prices Control) Order, 1995 as well as monitoring and enforcement of prices. NPPA also provides inputs to the Government for policy formulation and on other specific issues concerning affordable medicines to the consumer.

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

(1) To implement and enforce the provisions of the Drugs (Price Control) Order (DPCO), 1995 in accordance with the power delegated to it.

(2) To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.

(3) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.

(4) To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.

(5) To deal with all legal matters arising out of the decisions of the Authority.

(6) To render advice to the Central Government of changes/revisions in the drug policy.

(7) To render assistance to the Central Government in parliamentary matters relating to drug pricing.

5.15 The details of allocation for NPPA for the year 2012-13 and 2013-14 are as under:-

(Rs.in crore)

BE 2012-13			**RE 2012-13**			**BE 2013-14**		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
4.00	**6.35**	**10.35**	**4.00**	**6.27**	**10.27**	**4.00**	**7.71**	**11.71**

5.16 When asked to give reasons for increase in allocation of Non-Plan BE in the year 2013-14 as compared to the year 2012-13, the Department in its written reply stated as under:-

"The allocations under Non-Plan are for Secretariat Expenditure of NPPA. The increase is on account of payment of DA, increment etc. in 2013-14".

5.17 Regarding Departmental Schemes of National Pharmaceutical Pricing Authority (NPPA) the Department in its outcome budget has stated as under:-

"National Pharmaceutical Pricing Authority (NPPA) is, inter-alia, entrusted with the mandate of fixation/revision of prices of schedule bulk drugs/formulation under DPCO 1995, and enforcement of their prices. It is empowered to take final decisions on these matters subject to review by the Central Government when considered necessary. In order to ensure availability of essentials drugs at affordable prices, it also monitors the prices of decontrolled drugs/formulation and oversees the implementation of the provisions of the Drugs (Price Control) Order-1995."

5.18 NPPA has sent the following Five New Plan Schemes amounting to Rs.4952 lakh for the plan period 2012-13 to 2016-17:-

Sl. No.	**Scheme**	**Amount (Rupee in lakh)**
1.	Creation of NPPA State Government Cells in States	2638.00
2.	Scheme for Interaction with States	152.00
3.	Proposal for Consumer Awareness and Publicity through Print, electronic and other media	2000.00
4.	Proposal for strengthening the existing Monitoring and Enforcement work	162.60
	Total	**4952.60**

5.19 In-principle approval of the Planning Commission in respect of scheme at Sl No. 3 was received in February, 2011 and it was implemented during the 11th Five Year Plan 2007-08 to 2011-12. The aim of the scheme is to familiarize the general public about the role and functions of the NPPA and the Government's decisions. NPPA has been provided an amount of Rs.400 lakh (Plan) for the year 2013-14. In view of the new Pharmaceutical Policy, it has been decided to continue only with Consumer Awareness and Publicity through Print, electronic and other media scheme.

5.20 The role of NPPA would continue under new National Pharmaceuticals Pricing Policy (NPPP) 2012 announced by the Government on 07.12.2012 and the new DPCO which is under finalization. For Annual Plan 2012-13, following 3 schemes are proposed:

A. Ongoing Scheme of Computerization of NPPA: The computerization will help in accuracy and timely completion of day-to-day work of NPPA and strengthen the fixation of prices of drugs more effectively. Problems due to inadequate staff will also be lessened to some extent. The software called Integrated Management System developed by NIC has been developed. Since inception of NPPA prices of 510 Bulk Drugs and 11514 Formulations have been fixed/revised. Of these prices of 9 Bulk Drugs and 461 formulations were revised/ fixed during 2011-12 (upto October 2011). Further expenditure during 2013-14 is required for maintenance/enhancement/modification of the software as per the new National Pharmaceuticals Pricing Policy (NPPP) 2012 and the new DPCO, which is under finalization, UPS batteries and to meet the hardware requirement of NPPA, an amount of Rs.0.30 crore is proposed for 2013-14.

B. Building a Robust and Responsive Statistical System (Pharmaceutical Census of India): This scheme started in 2007-08 and will continue in 2013-14 and Rs. 20 lakh is likely to be incurred during the year 2013-14 on the scheme as the work relating to collection of data in respect of Pharma Industries awarded to M/s. ICRA Management Consulting Services Ltd., Noida is likely to be completed in 2013-14.

C. Proposal for consumer awareness through print, electronic and other media: This scheme was approved in February, 2011. The aim of the scheme is to familiarize the general public about the role and functions of the NPPA and the government's decisions. During 2012-13 an expenditure Rs. 52 lakh was incurred on publishing an advertisement in the newspapers. Initially, the Scheme was to be implemented jointly with Department of Consumer Affairs on cost sharing basis. But since Department of Consumer Affairs has decided not to continue with the scheme,

Planning Commission was requested to allow NPPA to operate the scheme independently. In this regard, Planning Commission has directed to submit the proposal in SFC format which is under process.

(iv) **Pharmaceutical Export Promotion Scheme (PEPS)**

5.21 The details of allocation for NPPA for the year 2012-13 and 2013-14 are as under:-

(Rs.in crore)

BE 2012-13			**RE 2012-13**			**BE 2013-14**		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
--	**0.20**	**0.20**	**--**	**--**	**--**	**--**	**0.01**	**0.01**

5..22 When the Committee asked to give reasons for decrease in allocation in Non-Plan BE 2013-14 from BE 2012-13, the Department in its written reply stated as under:-

"Under this Scheme, the proposals of Industry Associations are considered with a view to promote the export of Indian Pharmaceutical Products. No proposals were received from any of the Pharma Associations in 2012-13, therefore, allocation in BE 2013-14 has been decreased".

(v) Pharmaceuticals Promotion & Development Scheme (PPDS)

5.23 Pharmaceutical Promotion & Development Scheme (PPDS) aims at the promotion, development and export promotion in the Pharma sector. Under this scheme, the following activities for promoting the industry are undertaken:

i. Activities for the Pharma sector by promoting seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies / consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector.

ii. All miscellaneous activities relating to promotion of Pharma sector for production, exports and investments.

5.24 The details of allocation for PPDS for the year 2012-13 and 2013-14 are as under:-

(Rs.in crore)

BE 2012-13			**RE 2012-13**			**BE 2013-14**		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
2.00	**--**	**2.00**	**1.00**	**--**	**1.00**	**2.00**	**--**	**2.00**

5.25 When asked to give reasons for increase in Plan allocation in BE 2013-14 as compared to Plan RE 2012-13, the Department in its written reply stated as under:-

"In so far as PPDS is concerned, the enhanced budget allocation was proposed keeping in view the international IPR scenario where Department would have more promotion and developmental activities.

(vi) Others

(Rs.in crore)

BE 2012-13			**RE 2012-13**			**BE 2013-14**		
Plan	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**	**Plan**	**Non-Plan**	**Total**
67.00	**--**	**67.00**	**11.05**	**--**	**11.05**	**62.84**	**--**	**62.84**

5.26 When the Committee asked to provide details regarding allocation made under different schemes separately under the item 'others', the Department in its written reply stated as under:-

"The others consist of six new schemes as detailed below along with allocation.

S. No.	**SCHEMES**	**BE 2012-13**	**RE 2012-13**	**BE 2013-14**
1	Interest Subsidy for Schedule M compliance	2.00	0.00	0.00
2	Creation of IPR facilitation center at Pharmaexcil	1.00	0.50	1.00
3	ERP, R & D park	4.00	0.00	0.00
4	Critical assistance for WHO pre-qualification for Pharma PSUs	10.00	4.55	6.84
5	Jan Aushadhi Scheme	20.00	4.50	25.00
6	New schemes to be introduced in respective years	30.00	1.50	30.00
	Total	**67.00**	**11.05**	**62.84**

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 consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL. The rehabilitation scheme of IDPL is 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 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).

6.3 Further, in the interest of continued growth and development of KAPL & RDPL, On 2nd January 2009, Government approved de-linking of KAPL & RDPL from HAL & IDPL and transfer the shareholding of HAL & IDPL in KAPL & RDPL respectively to Government of India. Transfer of shares from HAL to the President of India have been effected in the Books of KAPL w.e.f. 1st October 2009. Similarly, transfer of shares from IDPL to the President of India have been effected in the Books of RDPL w.e.f. 17th August 2010.

6.4 Regarding the position of allocation of funds for the schemes being implemented under the PSU division and efforts made so far to resolve the objections raised by the Finance Department, the Department in its written reply stated in a tabular form as under:-

Release of Fund for the year 2012-13

S. No.	Scheme	Head	BE 2012-13	RE 2012-13	Status of release of funds
1	**2**	**3**	**4**	**5**	**6**
1	Support to PSUs (Project based support) **(Loans to PSUs)**	Capital Loan for Pharma Industries	HAL-3.00	5.00	Ministry of Finance has not approved release of any fresh loan to HAL. A d.o. letter from Secretary (Pharma) was written to the Secretary (Expenditure) requesting reconsideration. However, no response has been received from Ministry of Finance.
			BCPL-2.00	0.00	The fund was allocated to BCPL for introducing the ERP system in BCPL at a cost of Rs. 2.00 crore. However, Planning Commission did not approve the proposal. The matter was further taken up with the Planning Commission. However, no response has been received from Planning Commission.
			IDPL-15.00	5.00	The fund allocated for the revival of liquid oral manufacturing Section at Hyderabad unit of IDPL. As IDPL has been defaulter in repayment in loan, the IFD has advised to merge this proposal in the Revival scheme. However, a d.o. letter from Secretary (Pharma) was written to Secretary (Finance). As a result the approval has been received from the Ministry of Finance on 28.03.2013 and Rs. 5.00 crore has been released to IDPL for the purpose.
			Total-20.00	Total 10.00	
2	Critical Assistance Scheme (Grant for WHO GMP Com -pliance)	New Schemes of Pharma	10.00	4.55	The approval/observation of Planning Commission for the project for the WHO-GMP Compliance in RDPL received. An amount of Rs. 4.55 crore has already been released as 1st installment for WHO-GMP Compliance in RDPL.

6.5 During the course of evidence sitting held on 20.3.2013, the Secretary, Department of Pharmaceuticals informed the Committee as under :-

> "…There are concerns, obviously, that the pace of expenditure has been low. I would explain as we go into details that we could not finance the PSUs because some of them are defaulters with the Government of India. There is a stipulation that if you are a defaulter, you cannot get more money. So, we could not finance the PSUs..."

6.6 On being enquired as to how the Department proposes to rehabilitate the PSU which are defaulters with the Government of India, the Department in its written reply stated as under:-

> "The role of the Public Sector pharmaceutical companies in making the life saving drugs available for the common people, especially to the poor segment of the people in the country, has been well documented and accepted by the Government. The latest approach paper of the Planning Commission for the Health Sector which has specifically acknowledged this fact and has recommended that the Public Sector Pharma companies will have to be

strengthened for implementing the various initiatives for the Health Sector, being planned by the Government in the near future. The recent initiative of the Govt. of India to make the essential medicines available to the poor people of the country free of cost will also be implemented effectively if the Public Sector Pharma companies like BCPL, HAL, IDPL etc supply the high quality life saving drugs for these schemes at affordable prices. In view of these strategic reasons, the Department of Pharmaceuticals is making all out efforts for the rehabilitation of the sick Pharma PSUs even though they are defaulters with the Government of India on account of non-payment of loans and interest accrued thereon”.

(a) Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata

6.7 BCPL was a chemicals manufacturing company set up in the private sector in 1901 by Dr. Acharya P.C. Roy, the great visionary and scientist. Later on being sick, it was taken over by the Government and nationalized on 15th December, 1980. A new public sector company in the name and style of Bengal Chemicals & Pharmaceuticals Limited (BCPL) was incorporated in March, 1981.

6.8 The company has four manufacturing units one each at Maniktala (Kolkata), Panihati at North 24 Parganas (West Bengal), one at Mumbai (Maharashtra) and one at 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 are quite popular. Post 1980, company continued its operations.

6.9 However, due to continued losses, the company was declared sick by the Board for Industrial and Financial Reconstruction (BIFR) on 14th January, 1993. A Revival Package was accordingly prepared & approved by the BIFR on 4th April, 1995. The package was reviewed by BIFR from time to time, based on which a Modified Revised Rehabilitation Scheme was then prepared. BIFR approved this Modified Scheme on 14.1.2004. Finally, based on the requirements for modernization of plants & machinery and taking into account the earlier Schemes, the Board for Reconstruction of Public Sector Enterprises (BRPSE) at its meeting held on 25.8.2006 recommended a modified revival plan for revival of BCPL.

6.10 The recommendations of BRPSE were confirmed by the Cabinet Committee on Economic Affairs (CCEA) which approved the BRPSE Scheme in its meeting held on 21st December 2006. The Revival Scheme which include interalia:

(i) Cash infusion by GOI Rs. 207.19 crores

(ii) Write off / Waiver of Rs. 233.41 crores

Loans/Interest

Parliament has approved writing off of GOI loans & interest of Rs. 233.41 crore and cash infusion component of Rs. 207.19 crore. The component as approved by the Government has been released. The company has appointed Consultants for undertaking the work of upgradation & modernization of plant & machinery including compliance with Schedule 'M'***/*** WHO- GMP standard**.**

6.11 Upgradation& Modernization Projects including capacity augmentation for Chemical Plants at Panihati (West Bengal) and in Pharmaceutical *BCPL- Mumbai Building* Plants at Maniktala (Kolkata) and Kanpur have been undertaken. In addition, Greenfield Projects for Cephalosporin and Betalactum range of products are under commissioning at Maniktala. Upgradation of Ointment, Stores Building, Batalactum, Cepahlosporin Blocks, ETP, Roads, drains etc. are also completed at Maniktala. Upgraded Phenol Manufacturing and filling, Composite Production Block, renovated Alum Plant, QC Block, Finished Goods Stores, Administrative Block and other allied services are in operation at Panihati after renovation. The Upgradation & Modernization of Tablet, ORS Powder, Liquid and Home Product Sections at Kanpur is in progress. Modernization of QA Block, Utilities, Amenities, ETP completed at Kanpur.

6.12 The Department in its Outcome Budget 2013-14 in Chapter II para 2.3 has stated as under:-

> "An amount of Rs. 9.30 crore has been allocated in 2013-14 to BCPL for statutory obligations towards Land and Revenue and fees for obtaining statutory approvals from the State and Central Drug Controller, Kolkata KDA & KMC, Factory Directorate pollution Control Board, Fire and Legal issues under implementation of Revival Scheme of BCPL".

6.13 When the Committee asked to give details regarding the statutory approvals from the authorities mentioned above for issues under implementation of Revival Scheme, the Department in its written reply stated as under:-

> **"**BCPL has informed that Statutory approvals/clearances from Drug Controller, Kolkata Development Authority (KDA),Kolkata Municipal

Corporation (KMC), Factory Directorate, Pollution Control Board, Fire, Kolkata Electric Supply Corporation (CESC), Kanpur Electric Supply Authority (KESA) etc. are essential before commencement of operation of the plants under installation and commissioning. BCPL has paid small portion of it from Capital Expenditure (CAPEX) fund and working Capital and provisional clearances for commencement of construction have been obtained except electricity.
After full payment of statutory dues, final clearances are expected to be obtained within two months".

(b) Indian Drugs & Pharmaceuticals Limited (IDPL), Gurgaon

6.14 Indian Drugs and Pharmaceuticals Ltd (IDPL) was incorporated on 5th April, 1961 for achieving India's march 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.

6.15 IDPL was formally declared sick by the Board for Industrial & Financial Reconstruction (BIFR) on 12th August, 1992. A revival package for the company was formulated and approved by BIFR on 10th February,1994. However, after taking into account the performance of the company which fell short of the targets, the BIFR on 23.1.1996 treated the sanctioned package as failure, and thereafter in its meeting held on 4.12.2003 BIFR confirmed its prima-facie opinion about winding up of IDPL in terms of Section 20(1) of the Sick Industrial Companies (Special Provisions)Act, 1985.

6.16 However, given the possibility of revival of the company, Department of Chemicals & Petrochemicals (Now Department of Pharmaceuticals) filed an appeal against the opinion of BIFR in Appellate Authority for Industrial & Financial Reconstruction (AAIFR) on 10.2.2004.

6.17 Consequently, an Expert Committee was appointed in September, 2004, to study the Techno-Financial Feasibility of rehabilitating IDPL. In this connection, a Technical Audit of various plants of IDPL was also assigned to National Institute of

Pharmaceutical Education and Research (NIPER). NIPER in its report submitted to the Department on 31.8.2005, recommended revival of all plants of IDPL and its subsidiaries in phases for production of existing and new products. IDBI, the then Monitoring Agency on behalf of BIFR, supported the recommendations for revival of IDPL subject to certain conditions.

6.18 Accordingly, in a meeting held under the Chairmanship of the then Minister (C&F&S), it was decided to revive all the five units of IDPL in a phased manner. Hon'ble AAIFR at its hearing on 13.9.2005 set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL.

6.19 A Draft Rehabilitation Scheme for revival of Indian Drugs & Pharmaceuticals Limited (IDPL) was considered by the Board for Reconstruction of Public Sector Enterprises (BRPSE) at its meeting held on 9.3.2007 and recommended for approval. The scheme was placed before the Cabinet for approval. The Cabinet considered the proposal at its meeting held on 17.5.2007 and referred it to Group of Ministers (GoM) for consideration at the first instance. GoM was constituted on 1.6.2007. The first meeting of the GoM was held on 11.10.2007. Based on the recommendation of GoM and Draft scheme prepared earlier, a Pre-Feasibility Report was prepared by an Expert Agency, Ernst & Young. Now the revival scheme of the company is under the consideration of Central Government.

6.20 In its Action Taken reply on 27th Report on DFG 2012-13 to Recommendation No. 7 vide O.M No. 16(3)/2012-Fin.II dated 20.7.2012, the Department of Pharmaceuticals stated as under:-

> "Draft Note for the Cabinet has been prepared. However, E&Y was requested to re-assess the liabilities etc of IDPL. A re-assessment report of E&Y has since been received and being examined in the Department to finalize a Cabinet Note.
>
> In the mean while BIFR meeting was held on 10.01.2012 and 21.3.2012 (case no. 503/1992), the Board directed that the copy of E&Y report be submitted to BIFR as well as IDBI (Operating Agency) and IDBI to examine the report, prepare Draft Rehabilitation Scheme (DRS) and submit to BIFR by July, 2012".

6.21 When asked as to whether Cabinet Note with regard to revival of IDPL has been finalized, the Department in its written reply stated as under:-

> "The Cabinet Note will be finalized after receipt of Draft Rehabilitation Scheme (DRS) prepared by the IDBI – Operating Agency (OA) appointed by BIFR. Final DRS is to be submitted by IDBI to BIFR which is expected in the month of April, 2013".

6.22 When asked about the full revival of IDPL, the Department in its written reply stated as under:-

> **"**The process of Revival of IDPL is underway. No time frame for sanction of revival package 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".

(c) <u>Hindustan Antibiotics Limited (HAL)</u>

6.23 Hindustan Antibiotics Ltd. (HAL), Pimpri, Pune was incorporated on 30th March, 1954. This was the first Public Sector Company in drugs and pharmaceuticals. HAL has its plant located 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 de-linked from HAL after approval of the Government.

6.24 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 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.

6.25 Based on the Scheme, the Government approved the Rehabilitation of the company on 9th March, 2006 followed by BIFR approval on 5th June 2007. The Rehabilitation Scheme inter alia involved 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.)*

6.26 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. Action is under progress by HAL in this regard.

6.27 Further, Government has additionally approved proposals of Rs.30.17 crore received from HAL for setting up new powder injectable facilities for Cephalosporin and up gradation of existing vialling facilities for Betalactum (Penicillin) Antibiotics complying to WHO-GMP standards at an estimated cost of Rs. 20.17 crores and for up gradation of manufacturing facilities of Tablet, Capsule and Liquid Sections complying to WHO-GMP standards at an estimated cost of ` 10.00 crore in order to make the company further viable.

6.28 The Committee note that in its Outcome Budget 2013-14, the Department has stated that Provision of an amount of Rs.14.17 crore is for Expanding the Capacity of large Volume Parenterals (IV Fluid).

6.29 In this regard, when the Committee asked to give details as to how the amount of Rs.14.17 crore will be utilized, the Department in its written reply stated as under:-

"It has been informed by HAL that out of the total cost of project Rs. 45 cores, the amount of Rs. 14.17 for the first year will be utilized as under:-

Sr.	**Activity**	**Amount of funds required (Rs. lacs)**	**Remarks**
1.	Appointment of Project Consultant	6.60	
2.	Procurement of imported blow- fill-seal machine	489.25	25% machine cost considered in Ph-I
3.	Procurement of Indigenous components	811.15	50% machine cost considered in Ph-I
4.	Civil works	110.00	
	Total (Ph-I) expenditure	1417.00	

As seen above Rs. 14.17 Crores is required for starting up of Project activities including appointment of consultant basic engineering, procurement of long delivery process equipment including imported as *well as Indigenous equipments and civil works".*

6.30 When the Committee asked to give details with regard to implementation of second Rehabilitation plan of HAL, the Department in its written reply stated as under:-

"The process of preparation/ approval of 2^{nd} Rehabilitation Plan of HAL is underway and efforts are being made to complete the process at the earliest. Since various other agencies are also involved in the process, no time frame can be indicated by the Department of Pharmaceuticals".

6.31 When the Committee enquired as to whether Ministry of Finance has given any reason for non approval / release of any fresh loan to HAL and also to elaborate the efforts made/being made by the Department to get the fresh loan to HAL, the Department in its written reply stated as under:-

"Para 8 - E (iii) of Ministry of Finance, Department of Economic Affairs' O.M. No. 5(3)-B(PD)/2011 dated 19.03.2012 regarding defaults in repayment/interest payment of Loan and Advances given to Public Sector Undertakings by the Central Government stipulates that 'whenever a fresh loan is to be sanctioned to a borrower who has earlier defaulted, the loan sanctioning authority must consider the question of recovery of defaulted dues. All releases to Public Sector Undertakings against budgeted outlays should be made only after adjusting the defaults, if any, pertaining to repayment of loans and interest. If for special and exceptional reasons such adjustments are not possible, specific orders of Secretary (Expenditure) should be obtained through Budget Division, before release of fresh loans.'
Accordingly in terms of the above provision, file was sent to Ministry of Finance for the approval of Secretary (Expenditure) to the proposal of sanctioning of loan of Rs. 5.00 crore to HAL for the project.
However, Ministry of Finance has denied any fresh loan to HAL in the light of the above said Ministry of Finance, Department of Economic Affairs' O.M. No. 5(3)-B(PD)/2011 dated 19.03.2012.
Further Secretary (Pharma) has written a d.o. letter dated 18^{th} February, 2013 to the Secretary (Expenditure) with the request to reconsider their decision explaining the current status of the HAL. However, no response has been received in this regard till date."

(d) <u>Rajasthan Drugs and Pharmaceuticals Limited (RDPL)</u>

6.32 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 4.98 crores where Government of India (GoI) and Rajasthan State Industrial Development & Investment Corporation Limited (RIICO) hold 51% and 49% respectively. It was incorporated in 1978 and commercial production started in 1981.

The Company has its manufacturing facilities & registered office at Road no. 12, VKI Industrial Area, Jaipur (Rajasthan).

6.33 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 further diversifying its marketing activities into Pharma Prescription Markets (Open Trade Sales), Veterinary Markets, Marketing of Ayurvedic and other Indian system of medicines in order to enhance its market share and also in its endeavour to improve the profitability of the organization.

6.34 When asked by the Committee to give reasons for less than 50% allocation of funds on Critical assistance for WHO pre-qualification for pharma PSUs/R&D for BE 2012-13 out of an amount of Rs. 10.00 crore only Rs. 4.55 crore was released for the purpose of WHO-GMP compliance in RDPL, the Department in its written reply stated as under:-

> **"**RDPL has applied for grant of Rs. 13.01 crore under "Critical Assistance for WHO Pre-qualification for Pharma PSUs" for making the plant WHO-GMP compliant. As per 'In-Principle' approval of Planning Commission, the share of the Department of Pharmaceuticals was worked out as Rs. 11.39 crore. The rest of the cost is to be shared by RDPL from their own sources. Out of the amount of Rs. 11.39 crore, Rs. 4.55 core has been released in the year 2012-13 as first Installment of Grant –in- Aid for upgradation and modernization of Plant/facilities to make it WHO-GMP compliant. Further funds will be released in two instalments upon utilization of funds already released & inspection of the work done".

6.35 On being enquired as to whether RDPL Plant is fully WHO-GMP compliant, the Department in its written reply stated as under:-

> **"**RDPL Plant is not fully WHO-GMP Compliant. The modernization/ upgradation work is in progress to make the plant WHO-GMP Compliant".

(e) <u>Karnataka Antibiotics & Pharmaceuticals Limited (KAPL)</u>

6.36 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 7.49 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. It is an MOU signing company.

6.37 Earlier it was a Joint Sector Undertaking of HAL in collaboration with KSIIDC. But in the interest of continued growth and development of the company, Government has implemented the delinking of KAPL from HAL and transferred the shareholding of HAL in KAPL to Government of India. Government of India had also 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. Other joint venture partner, viz. Karnataka State Industrial and Investment Development Corporation (KSIIDC) would bring in additional investment of ` 4.90 crore in KAPL.

6.38 It has been continuously generating profits for the last 11 years and the performance of the company has further improved and gone up especially on account of Purchase Preference Policy announced by the Department in August, 2006 for a period of five years.

6.39 Product range of the company includes Antibiotics, Anti-diabetic, cardiovasculars, pain management, general medicines and animal health products. Presently the Company is undertaking creation of separate manufacturing facilities for Cephalosporin product at an estimated cost of Rs.22.23 crores.. The Project is likely to be completed by end of the financial year 2011-12. When the project is completed, it will be possible for the Company to increase its exports, as new range of products can be added to export.

(f) <u>Bengal Immunity Limited (BIL)</u>

6.40 BIL was a sick company in the private sector in the name and style of Bengal Immunity Company Limited. The management of the company was taken over by the Central Government with effect from the 18th May, 1978. It was nationalized w.e.f. 1st October, 1984 and a new public sector company in the name and style of Bengal Immunity Limited was incorporated on the 1st October, 1984. The company has two manufacturing units, one each at Baranagar at Kolkata (West Bengal) and at Dehradun (Uttrakhand).

6.41 The Board for Industrial and Financial Reconstruction (BIFR) formally declared the company sick on 9th March, 1993. BIFR heard the case from time to time. In the hearing held on 13th September, 2002, BIFR formed its prima-facie opinion to wind up the company. The opinion was confirmed by BIFR in the hearing held on 25th February, 2003. With the approval of the Cabinet, VSS was introduced in the company. The company has since relieved all employees under VSS as on 30th September, 2003.

6.42 The company is closed. The Official Liquidator has already been appointed by the Kolkata High Court. However, on a Writ Petition filed by the BIL Employees Union, the appointment of Liquidator in respect of BIL has been stayed by High Court of Kolkata by its order dated 08.08.2005. High court of Kolkata also directed that AAIFR shall hear and dispose of the application of BIL Employees Unions. AAIFR in its order dated 9.11.2005 directed that possibility of revival through some other alternative Pharmaceuticals company or some firm producing some other goods using the available assets should be considered. Thereafter a Committee was constituted in this Department to look into the issue of revival of BIL looking to the order passed by AAIFR.

6.43 The Committee, constituted to explore the possibility of revival of Bengal Immunity Limited (BIL), recommended revival of BIL through Public Private Partnership (PPP) mode. Bids were then called on revival proposals and in continuation of orders of AAIFR dated 03.03.2008, 5 short listed companies were asked to give their proposals. Meanwhile, SBI Caps have also been appointed for preparation of Bid/ RFP document for subsequent bidding by the 5 short listed companies. SBI Caps has since submitted its report which is under examination.

CHAPTER-VI

MISCELLANEOUS

7.1 Pharmaceutical Policy

"The Department of Pharmaceuticals has notified the National Pharmaceutical Pricing Policy-2012(NPPP-2012). The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all.

The salient features of this policy are as under:

- All the medicines, as under National List of Essential Medicines (NLEM) -2011, that takes care of the healthcare needs of the majority of the population of the country, will come under Price Control.
- Nearly 614 formulations, spread over 27 therapeutic categories including HIV, diabetes, heart diseases, cancer etc will be under price control.
- The Prices of nearly 63% of medicines under NLEM-2011 will decrease by more than 20%. In some cases this reduction is even up to 80%of the present market price. For example Diclofenac 50mg tablet, priced at Rs. 4.65 per tablet will be capped at Rs. 1.97 per tablet.
- The total domestic pharma market is around Rs. 60,000 Crs and with the implementation of NPPP-2012, nearly Rs 15,000 Crs market will come under price control which is 25% of the domestic market.

7.2 When the Committee asked as to whether the Department has fixed any time limit regarding finalization of the final National Pharmaceutical Pricing Policy, the Department in its written reply stated as under:-

"The National Pharmaceutical Pricing Policy-2012 has been notified on 07.12.2012".

7.3 Research and Development

The Government has taken several policy initiatives for strengthening Research & Development in pharma sector. Due to measures such as fiscal incentives to R&D units in pharma sector and steps to streamline procedures concerning development of new drug molecules, clinical research and new drug delivery systems, this activity is seeing progress and new R&D set-ups with excellent infrastructure are coming up in the field of original drug discovery and some leading drug companies have licensed their NCEs to MNCs. It is gathered that a few products are expected to go for clinical trials in the next few years in the areas of Anti-infective, Anti-cancer and lifestyle segments.

7.4 On being asked by the Committee to give details regarding policy initiatives undertaken for strengthening Research & Development in Pharma sector and also elaborate new R&D setups that are coming up in the field of original drug discovery, the Department in its written reply stated as under:-

> "The Department has included in the Report of Working Group on Drugs & Pharmaceuticals Industry for the 12th Plan, submitted to the planning commission, a proposal for setting up Pharma Venture Capital Fund with an outlay of Rs. 500 crore for investment of identified funds into a newly created specialized private equity / Venture Capital that undertakes Research & Development (R&D) investments into companies in the Pharmaceutical industry**".**

7.5 When asked to give details about the R&D activities/initiatives taken or likely to be taken by all the PSUs, the Department in its written reply stated as under:-

> "No R&D activities /initiatives taken or likely to be taken by all the PSUs".

7.6 On being enquired by the Committee about the finalization of Detailed Project Report for developing India as a Drug Discovery & Pharma Innovation Hub 2020, the Department in its written reply has stated as under:-

> **"**In November 2011, M/s. Ernst & Young Private Limited (M/s E&Y), Gurgaon, was given an assignment as Global Level Consultant for preparation of Detailed Project Report for developing India as a Drug Discovery & Pharma Innovation Hub 2020. M/s E&Y has since submitted draft Detailed Project Report (DPR). It will be finalized soon in consultation with all stakeholders".

7.7 **Foreign Direct Investment**

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.

7.8 The Department of Pharmaceuticals requested the Department of Commerce to conduct a study on the takeovers of Indian companies by the MNCs. The Department of Commerce entrusted the work to Ernst & Young. Department of

Commerce informed that the report recommended continuation of the existing FDI policy (100% through automatic route) in pharmaceutical sector.

7.9 However, with a view to examine the issues involved in FDI in a broader perspectives, Planning Commission had, with the approval of the Hon'ble Prime Minister, constituted a High Level Committee (HLC) under the Chairpersonship of Shri Arun Maira, Member (Industry), Planning Commission to consider all the relevant aspects. The majority of the members of the Committee were of the view that the acquisitions in Pharmaceutical Sector should be monitored and controlled through Competition Commission of India (CCI).

7.10 The Hon'ble Prime Minister chaired a meeting to discuss the FDI policy in drugs and pharmaceutical sector on 10th October, 2011. The meeting deliberated upon the report of Shri Arun Maira, Member (industry) Planning Commission, which followed a CCEA decision to get greater clarity on the issue of FDI policy governing mergers and acquisitions in the pharmaceutical sector, while striking a balance between larger public health concerns and strengthening domestic manufacturing capacities. The following considered decisions were taken in the meeting:

(a) India will continue to allow FDI without any limits (100%) under the automatic route for Greenfield investments in the pharma sector. This will facilitate addition of manufacturing capacities, technology acquisition and development;

(b) In case of brownfield investments in the pharma sector, FDI will be allowed through the FIPB approval route for a period of upto six months. During this period, necessary enabling regulations will be put in place by the CCI for effective oversight on mergers and acquisitions to ensure that there is a balance between public health concerns and attracting FDI in the pharma sector. Thereafter, the requisite oversight will be done by the CCI entirely in accordance with the competition laws of the country.

7.11 Subsequently, Department of Industrial Policy & Promotion issued Press Note No. 3(2011 Series) dated 8.11.2011 amending the existing FDI policy under which 100% FDI was permitted through automatic route. As per Press Note 3(2011 Series) issued by Department of Industrial Policy and Promotion on 08.11.2011:-

(i) FDI, upto 100%, under the automatic route, would continue to be permitted for greenfield investments in the Pharmaceuticals sector.

(ii) FDI upto 100%, would be permitted for brownfield investment (i.e. investments in existing companies), in the pharmaceuticals sector, under the Government approval route.

7.12 On 03.12.2012, a meeting was held under the Chairmanship of Hon'ble Prime Minister and it was decided that FIPB shall continue to scrutinize proposals for FDI in brownfield Pharma till the CCI is equipped with the power to impose conditionalities on Mergers and Acquisitions with Public Health concerns.

7.13 On being enquired by the Committee as to whether any proposals have been received by Department of Pharmaceuticals for both Greenfield projects and Brownfield projects in pharmaceutical industry, the Department in its written reply stated as under:-

> **"**The foreign direct investment for Greenfield projects are through automatic route and therefore no proposals are received for approval of the investment.
>
> For FDI in Brown Field Investment in Pharmaceutical Sector, the proposals are received by the Foreign Investment Promotion Board (FIPB) which after taking into consideration the comments of the concerned Ministries/ Departments conveys the approval of the Government. The Department of Pharmaceuticals does not receive any proposal".

7.14 **Generic Drugs Campaign**

In November, 2008, the Department launched Generic Drug Campaign by opening first Jan Aushadhi Generic Drug Campaign store at Amritsar Civil Hospital on 25.11.2008. Since then 147 JAS have been opened (till 31st January 2013) in the States of Punjab, Haryana, Uttrakhand, Odhisha, Rajasthan, Andhra Pradesh, West Bengal, Jammu & Kashmir, Jharkhand, Union Territories of Chandigarh and Delhi. Bureau of Pharma CPSUs of India (BPPI) is monitoring the opening of Jan Aushadhi Stores. It is also involved in promotion of the unbranded generic drugs and the Generic Drug Campaign. Initial target for opening of JAS was one JAS in each district of country. However, while reviewing the performance of Pharma CPSEs and JAS on 27th September 2010, Secretary (Pharma) desired that all sub division of the Country, which would be around 3000, should be targeted in due course to have one JAS at the location of Govt. hospitals. A Business Plan of Jan Aushadhi Scheme in this regard is under consideration of this Department.

7.15 On being asked by the Committee as to how the Department plan to promote unbranded generic drugs, the Department in its written reply has stated as under:-

> "In order to promote the consumption of unbranded generic drugs in the country at affordable prices, the Department of Pharmaceuticals had earlier launched Jan Aushadhi Campaign in November'2008. The main objective of the campaign was to make available quality generic drugs at affordable prices to all through the Jan Aushadhi Generic Drug Stores. In so far as supply of generic drugs is concerned, presently all the five Central Pharma Public Sector Undertakings (CPSUs), namely, IDPL, BCPL, RDPL, BCPL & HAL are manufacturing and supplying generic drugs for sale at the Jan Aushadhi Drug Stores. Initially, a list of 319 generic medicines was drawn for supply through these five CPSUs. However, in view of the non-availability of sufficient working capital, these CPSUs were not able to maintain the supply chain of medicines. Now, the Government have given a working capital of Rs.4.50 cr., which will be used as a revolving fund, to be provided to these CPSUs in instalments as per the production plan given to the respective CPSUs, to improve the supply chain".

7.16 When asked by the Committee to provide details of approved Business Plan and by when Business Plan of JAS will be finalized by the Department with regard to opening of JAS at the location of Government Hospitals, the Department in its written reply has stated as under:-

> "A revised Business Plan for Jan Aushadhi Campaign is under finalization in the Department of Pharmaceuticals. The business plan will be ready by April,2013".

7.17 On being enquired by the Committee as to whether any strategy/publicity has been adopted to make Generic Drugs popular among common people, the Department in its written reply has stated as under:-

> "It may be relevant to point out here that Jan Aushadhi Campaign was launched in November, 2008 and the success of the campaign equally depends upon the role played by the Media Campaign in educating the common man and in particular, the poor and the disadvantaged, so that they can take benefit of this public welfare programme initiated by the Government, for which sufficient funds have been earmarked for the publicity of the Jan Aushadhi Campaign. Once the supply chain improves, BPPI would initiate necessary steps to launch media campaign particularly in those States where the Jan Aushadhi Programme has already been started so that people take full advantage of the availability of generic medicines at affordable prices at the Jan Aushadhi Stores. Besides, each State is also doing publicity in its own way. In this regard, the Department of the Consumer Affairs, Government of India, launched a joint multimedia publicity campaign along with the Department of Pharmaceuticals/BPPI to educate the public. Besides this, BPPI also brings out publicity material on Jan Aushadhi Campaign from time to time. A National Toll Free Helpline Number "1800-180-8080" is also being run since February, 2009 to promote Jan Aushadhi campaign.

7.18 When the Committee asked reasons for very less allocation of funds of Rs.20.00 crore on Jan Aushadhi Campaign for BE 2012-13 out of which only Rs. 1.66 crore was released for the purpose Jan Aushadhi Scheme, the Department in its written reply has stated as under:-

> "Planning Commission has accorded in Principal approval for release of Rs. 4.50 crore as Working Capital for existing functional Jan Aushadhi Stores to BPPI. Since an amount of Rs. 2.84 crore still remained unutilized with BPPI, IFD has agreed to release only Rs. 1.66 crore, which has been released. Upon finalization of revised Business Plan fresh releases can be considered".

7.19 On being asked by the Committee as to how the Department proposes to spent 10% GBS earmarked to North-Eastern States, the Department in its written reply stated as under:-

> "The allocation will be utilized for management and construction of NIPER campus at Guwahati. Also all out efforts are being made to implement the Jan Aushadhi Scheme in as many NE States as possible; BPPI is pursuing the matter with the NE State Governments for opening of Jan Aushadhi Drug Stores".

7.20 When the Committee asked the basic reasons for reluctance by certain State Governments to open JAS particularly when the scheme is meant to provide generic medicines at affordable prices to the poor section of the society and efforts made by the Department to resolve their objections, the Department in its written reply stated as under:-

> **"**Under the Jan Aushadhi Campaign, at least one Jan Aushadhi Store in each district is intended to be opened, initially, wherever the State Governments extend their support and co-operation in allotting the space in the Government Hospitals or other suitable locations and also identifying the agencies to manage such stores amongst Hospitals/NGOs/Charitable/Co-operative/Government Bodies. Though Central Government is willing to open more stores, much depends upon the active support of the State Governments. It may be pointed out here that there are many States like Haryana, Rajasthan, Tamil Nadu, etc. which have their own health policies to provide all the medicines free of cost to in-patients as well as to out-patients. Similarly, there are States like West Bengal and Chhattisgarh, where they have decided to open medical stores in the Government Hospitals by inviting tenders from the parties and selecting the same on the basis of maximum discount offered by them on the maximum retail prices. In fact, 53 Jan Aushadhi Stores opened in Rajasthan were taken over by the State Government and converted into free distribution centers of medicines under the Mukhyamantri Nishulk Dava Yojana. Likewise, three Jan Aushadhi Stores opened in Haryana, two in Andhra Pradesh and three in West Bengal have also become non-functional in view of the policies of the State Governments. On its part Department of Pharmaceuticals and Bureau of Pharma Public Sector Undertakings of India (BPPI) have been pursuing with the State Governments for opening of Jan Aushadhi Stores. Recently requests have been received from Mizoram, Arunachal Pradesh, Sikkim and Andaman &

Nicobar Islands to open Jan Aushadhi Drug Stores for the welfare of the common man in their States/UTs. BPPI is actively pursuing the matter with the Health Departments of these States/UTs and working out the modalities to set up Jan Aushadhi Stores at the earliest. It may be mentioned that the States of Punjab and Odisha are opening more and more Jan Aushadhi Stores and Uttarakhand has also shown its interest in expansion of the scheme".

7.21 During the course of evidence, the Secretary Department of Pharmaceuticals stated as under:-

"…When the campaign for Jan Aushadhi was started it was proposed that one JAS should be opened in each district where cost generic medicines will be supplied. There were two conditions one JAS will be opened where it will be successful and where it will be recommended by State Government. Time and again it was requested to State Government that Government of India is interested in opening JAS. Where there are Government Hospitals there space for shops will be provided by Government and the doctors will prescribe medicine and it will be available cheap. Wherever we are getting proposals from State Government we are opening stores. In some States the Government is providing free medicine e.g Tamil Nadu , Rajasthan and Haryana and other schemes are also being run. West Bengal Government has asked us to close the JAS because they will start Fair price Medicine Shop. In the State of Tamil Nadu medicine is being provided free. Rajasthan has started its own stores and closed our JAS.."

7.22 On being enquired by the Committee about the reasons for steep difference in the prices of Jan Aushadhi Drugs and Drugs manufactured and sold by private firms, the Department in its written reply stated as under:-

"There is a big difference in the prices of generic medicines being sold through the Jan Aushadhi Outlets and the prices of branded medicines sold in the open market. The same is corroborated by the following illustration, which shows the vast price difference prevalent between the generic medicines being sold through the Jan Aushadhi Outlets and branded medicines sold in the open market:-

Name of salt	**Dosage**	**Pack**	**Average Market Price of Branded Medicines (Rs.)**	**Prices of Generic Medicines sold in Jan Aushadhi Outlets (Rs.)**	**Difference**
Antibiotic: **Ciprofloxacin**	250 mg	10	54.00	11.10	**5 times higher**
Pain Killer: **Diclofenac SR**	100 mg	10	51.91	3.35	**15.5 times higher**
Common Cold: **Cetrizine**	10 mg	10	37.50	2.75	**13.5 times higher**
Fever: **Paracetamol**	500 mg	10	13.56	2.45	**5.5 times higher**
Pain & Fever **Nimesulide**	100 mg	10	38.66	2.70	**14.3 times higher**
Cough Syrup		110 ml bottle	33.00	13.30	**2.5 times higher**

In the case of branded medicines because of competition, promotional efforts in selling such products, results in heavy expenses pushing up the cost. The heavy expenditure incurred by Pharma companies on R&D/Innovative activities is recovered by them through the cost of drugs. Besides this, in some cases, branded drugs enjoy patent protection and a number of drugs not covered under the regulation through the Drug Prices Control Order, 1995 etc. also results in the prices of medicines going up".

7.23 When asked by the Committee about the manner in which the Department propose to correct supply chain for making available a wide-range of cheaper medicines, generic quality medicines, the Department in its written reply stated as under:-

"The success of the Jan Aushadhi Scheme necessarily depends upon the coverage of all the therapeutic category of drugs, in addition to other contributing factors. Further, the coverage should be extensive to meet the maximum demand of the patients. In this context, it may be mentioned that at present only the medicines manufactured by the Central Pharma Public Sector Undertakings (CPSUs) under the Department of Pharmaceuticals are being sold at the existing Jan Aushadhi Stores and as such, the range of medicines being supplied by these CPSUs is limited, beside limited coverage of the therapeutic categories. In order to tide over this situation and to increase the range of medicines, it is imperative that other PSUs and manufacturers in the private sector are also roped in. BPPI has already initiated a proposal in this regard to improve the supply chain, which would adequately address the issue of wider coverage of the therapeutic categories, which is under active consideration of the Government".

7.24 **New Initiatives**

(i) Drug Discovery and Pharma Innovation Hub 2020

In its Annual Report 2012-13 in Chapter 7 para 7.1 the Department has stated as under:-

"to develop a roadmap to enhance the national potential for Drug Discovery and Innovation, a number of action points and future commitments have been enshrined in the 12th Five Year Plan. The Department engaged M/s Ernst & Young to prepare a Detailed Project Report (DPR) in this regard. M/s Ernst & Young has submitted a Draft Report. The draft Report would be finalized after consultation with the stakeholders viz. industries and scientific departments of the Government of India".

7.25 When the Committee asked to stipulate the time-limit by which the Draft Report is likely to be finalized, the Department in its written reply stated as under:-

"A meeting has been convened on 04.04.2013 to discuss with the stakeholders viz. industry & scientific departments the draft Detailed Project Report (DPR) submitted by Ernst and Young (E&Y) on Drug Discovery &Pharma Innovation Hub. Taking into account the feedback of stakeholders, the DPR would be finalized in May 2013".

(ii) National Centre for Research & Development in Drugs at NIPER, Hyderabad

In its Annual Report 2012-13 in Chapter 7 para 7.3 the Department has stated as under:-

> "It is proposed to set up a National Centre for R&D in bulk drugs at Hyderabad NIPER. The Centre would aim at development of technologies and process for cost competiveness, environmental impact management, risk management and development of safety in manufacturing operations, knowledge transfer platform between industry and academia.The research avenues for bulk drugs are: Drugs process innovation, Drug discovery and development, Analytical chemistry, Process engineering, cleaner technology, Polymorphism, Nanotechnology etc. The proposal has been accorded in principle approval by the Planning Commission subject to certain conditions".

7.26 When the Committee asked to elaborate the follow up steps taken/being taken by the Department to set up the proposed centre for R&D and time by which the same is likely to be fully functional, the Department in its written reply stated as under:-

> "Meeting of the Standing Finance Committee (SFC) was held on 12.03.2013 to appraise the proposal. The Committee has since desired certain clarifications with regard to synergy between National Institute of Pharmaceutical Education & Research (NIPER) and National Centre for R&D in Bulk Drug (NCRDBD), revenue generation projections, recurring expenditure, phasing of construction etc. The next meeting of the SFC is likely to be held in April 2013.
>
> NCRDBD would be part of NIPER, Hyderabad. As such, commencement of civil work would be dependent on allotment of land for NIPER, Hyderabad by the State Government. However, as per the projection made by NIPER, Hyderabad, it will take 30 months for construction of the building & installation of equipments etc".

OBSERVATIONS AND RECOMMENDATIONS

1. The Committee note that net sales of the industry grew by 14.7% in the quarter ending June 2012 as compared to a year ago quarter. Again, in the second quarter ending September 2012 the drugs and pharmaceuticals industry performed well. However, the Committee are concerned to note that the imports of 'Medicinal and Pharmaceuticals Products' had risen by 29.43 percent in the year 2011-12 as compared to previous year. As a result of which pressure was exerted on the profit margins of the industry. According to the Department, although the country is almost self-sufficient in production of most of formulations/ pharmaceuticals products, imports are resorted to on quality and economic considerations and not necessarily due to non-availability from domestic sources. Needless to say, the raw material expenses necessarily contribute towards the cost component of the quality medicine being sold to the common consumers. The Committee, are therefore of the view that it would be imperative if the import of raw material for production of medicine is resorted only if the same is absolutely necessary for the purpose. In fact, the Committee, expect the Department to encourage innovation and also intensive research and development in the field of pharma sector so that cheap but quality inputs are available within the country itself for production of quality but cheap medicine which would ultimately benefit the common man in the country. The Committee, therefore, recommend to take appropriate steps in this direction.

2. The Committee with great concern note that the budgetary allocation of Rs.188 crore for the year 2012-13 of the Department of Pharmaceuticals was drastically reduced to Rs.85 crore at RE stage. However, even this amount could not be utilized fully by the Department as the actual utilization during the year 2012-13 was only Rs.42.03 crore. The Department has attributed this reduction in funds in the year 2012-13 due to non-utilisation of funds to the extent of Rs.145.97 crore by National Institute of Pharmaceutical Education and Research (NIPER), Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), National Pharmaceuticals Pricing Authority (NPPA), Pharmaceutical Promotion and Development Scheme (PPDS) and Project Based Support to PSUs and Jan Aushadhi Scheme (JAS). However, the

Committee feel that the Department being the nodal agency, cannot escape their responsibility for gross under utilization of allocated funds for the year 2012-13 under various schemes which remains less by more than 50 per cent of the allocated funds. This only reflects the poor performance of the Department in achieving its financial and physical targets. The fact that various schemes/projects of the Department are still awaiting clearance/approval of the Integrated Finance Division (IFD) and / or the Planning Commission, also show the lack of will and concerted and coordinated efforts of the Department and the Institutes under them. The Committee now expect the Department of Pharmaceuticals to expedite the process of getting clearances/approvals from Planning Commission/ Integrated Finance Division (IFD) for the speedy implementation of various schemes so that the sanctioned funds do not remain under utilized. The under utilization of funds for the year 2012-13 by the Department is inspite of the earlier recommendations of the Committee on Demands for Grants 2010-11, 2011-12 and 2012-13 to utilize the sanctioned funds properly and timely to achieve the avowed objectives of the Department. The Committee, therefore strongly deplore the casual and lackadaisical attitude of the Department and their failure to fully utilize the funds allocated to them. The Committee, therefore, recommend that the Department should make all efforts and prepare its action plan before hand for optimum utilization of the funds meant for various schemes run by them. The Committee would like to be apprised of the steps taken by the Department in this regard.

3. The Committee note that out of total GBS allocation of Rs.2968.00 crore for the scheme wise Plan Outlays during Twelfth Five Year Plan, the Department of Pharmaceuticals had proposed Rs.567.60 crore for the year 2013-14 but the Planning Commission has approved only Rs.188.00 crore. The Committee also note that Planning Commission had indicated that the outlay of the Department be maintained at the same level as in the previous year. This was primarily due to gross underutilization of funds by the Department of during the year 2012-13. The Committee, feel that it is now the responsibility of the Department to impress upon the Planning Commission to allocate more funds for the remaining period of Twelfth Five Year Plan. The Committee expect the Department to act strongly.

4. The Committee observe that the policy of the Government is to ensure availability of good quality life saving drugs at reasonable price and pay special attention to the poorer sections of the society in the matter of health care. Consistent with this policy, the Government of India has approved rehabilitation scheme for revival of HAL and BCPL. The rehabilitation scheme of IDPL is still under consideration. As the HAL is also still incurring losses, the Second Rehabilitation Plan of HAL is also under active consideration of the Government. An amount of Rs.29.66 crore has been allocated for Project Based Support to aforesaid PSUs. The Committee, therefore, recommend that the Department of Pharmaceuticals should expeditiously utilize the amount earmarked for project based support to these PSUs so that the performance of the PSUs Improves and the quality life saving drugs at reasonable price could be manufactured without any delay and supplied to the poor consumers. The Committee also note with concern that in case of HAL, out of Rs.45.00 crore required for their project, a provision of Rs.14.17 crore has been made for the year 2013-14. The Committee would, therefore, like to emphasize that a high powered Committee of the Department should visit the HAL to assess the ground reality and impress upon the Ministry of Finance to allocate the requisite amount for the rehabilitation of various schemes of HAL. The Committee would like to be informed of the progress made in this regard.

5. The Committee note that 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 Committee, also observe that in addition to NIPER, SAS Nagar, Mohali, the Government has set up six new NIPERs at Hajipur, Hyderabad, Ahmedabad, Rae Bareli, Guwahati and Kolkata. At present these six new NIPERs are functioning with the assistance of Mentor Institutes presently in the respective States. The work relating to construction of NIPER campuses at Guwahati and Gandhinagar has since been awarded to PSUs viz Engineering Projects (India) Ltd (EPIL) and Hindustan Steelworks Construction Ltd (HSCL) respectively. The State Government of Andhra Pradesh has agreed to allot 50 acres of land for NIPER Hyderabad and the issue is being finalized. The issue of allocation of land for

NIPER Kolkata, Hajipur and Rae Bareli are being pursued with the respective State Governments.

In view of the foregoing, the Committee regret to note that all six new NIPERs do not have their own campuses and still they continue to function with the assistance of Mentor Institutes even after a gap of more than 4-5 years. Considering the importance of these Institutes for the continuous growth of pharmaceuticals sector, it is but essential that all the new NIPER have their own campuses for their effective functioning for which these are meant for. In this regard the Committee reiterate its repeated recommendations on Demands for Grants 2009-2010, 2010-2011, 2011-2012 and 2012-2013 regarding completion of necessary formalities for construction of NIPER Campuses. While some progress has been made with regard to construction of NIPER Campus at Guwahati and Gandhinagar, the allotment of land for NIPER in the states of West Bengal, Bihar and Uttar Pradesh are still awaited. The Committee, therefore, recommend that the Department should vigorously and relentlessly pursue the matter with the concerned State Government so that the land is allocated for the purpose without any further delay. The Committee also expect that the Construction of NIPER campuses at Guwahati and Gandhinagar should be completed within a fixed time frame in order to avoid time and cost overruns. The Committee would like to be apprised of the action taken by the Department in this regard.

6. The Committee note that National Pharmaceutical Pricing Authority (NPPA) is, inter-alia, entrusted with the mandate of fixation/revision of prices of schedule bulk drugs/formulation under Drugs (Price Control) Order-1995 DPCO 1995, and enforcement of their prices. It is empowered to take final decisions on these matters subject to review by the Central Government when considered necessary. In order to ensure availability of essentials drugs at affordable prices, it also monitors the prices of decontrolled drugs/formulation and oversees the implementation of the provisions of the DPCO 1995. The Committee also note that the role of NPPA would continue under new National Pharmaceuticals Pricing Policy (NPPP), 2012 announced by the Government on 7.12.2012 and the new DPCO which is under finalization. The Committee hope that the new DPCO would help the NPPA to enforce the prices of all the medicines which are essential to take care of the health care of the large

section of the people of the country. The Committee, therefore recommend that the finalization of new DPCO may be expedited within a fixed time line. The Committee would like to be apprised of the action taken by the Department in this regard.

7. The Committee note that the Department of Pharmaceuticals 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. Further, being consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL. The rehabilitation scheme of IDPL is under consideration and for its revival, the Cabinet Note will be finalized after receipt of Draft Rehabilitation Scheme (DRS) prepared by the IDBI – Operating Agency (OA) appointed by BIFR. Final DRS is to be submitted by IDBI to BIFR which is expected in the month of April, 2013. As regards BCPL the Committee were informed that Statutory approvals/clearances from Drug Controller, Kolkata Development Authority (KDA), Kolkata Municipal Corporation (KMC), Factory Directorate, Pollution Control Board, Fire, Kolkata Electric Supply Corporation (CESC) Kanpur Electric Supply Authority (KESA) etc. are essential before commencement of operation of the plants under installation and commissioning. In this regard, BCPL has paid small portion of it from Capital Expenditure (CAPEX) fund and working Capital and provisional clearances for commencement of construction have been obtained except electricity. After full payment of statutory dues, final clearances are expected to be obtained within two months. The Committee also note that the process of preparation/ approval of 2nd Rehabilitation Plan of HAL is underway and efforts are being made to complete the process at the earliest. Since various other agencies are also involved in the process, no time frame can be indicated by the Department of Pharmaceuticals.

In view of the foregoing, the Committee are, anguished to note that revival process of sick PSUs is still going on a snail's space and the full

revival of these sick PSUs has yet to take place. In this regard, in their earlier reports on DFG 2009-10, 2010-11 and 2011-12 the Committee, recommended that the matter needs to be pursued by the Department vigorously with all concerned. Since the revival of these units is essential in order to ensure good quality of drugs at an affordable price to the majority of the people it is all the more important for the Department as a nodal agency to make concerted and coordinated efforts so that these units are revived within a fix time frame. The Committee, therefore, reiterate its earlier recommendation that Department of Pharmaceuticals should expedite the revival of all these sick PSUs without further delay. The Committee would like to be apprised of the time bound action plan of the Department in this regard.

8. The Committee note that the Department of Pharmaceuticals has notified the National Pharmaceutical Pricing Policy-2012(NPPP-2012) on 7.12.2012. The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required essential medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of Pharmaceutical industry, thereby meeting the goals of employment and shared economic well being for all. Under this policy all the medicines as under National List of Essential Medicines (NLEM) 2011 that takes care of the healthcare needs of the majority of the population of the country will come under Price Control. As a result therefore 25 percent of the total domestic pharma market will come under the price control and the prices of nearly 63 percent of medicines under NLEM-2011 will decrease substantially. The Committee, in its Report No. 29 had also recommended that the mandate of NPPA regarding fixing / revision of pricing of drugs should be broadened to include all the 348 essential drugs and medicines listed by the Department of Pharmaceuticals. The Committee, therefore, expect the Department of Pharmaceuticals to take up follow up steps to implement the Policy expeditiously without any further delay. The Committee would like to be apprised of the status of implementation of the policy within three months of the presentation of the Report.

9. The Committee note that in November, 2008, the Department launched Generic Drug Campaign by opening the first Jan Aushadhi Generic Drug Campaign Store (JAS) at Amritsar Civil Hospital on 25.11.2008. Since then 147 JAS have been opened (till 31st January 2013). The main objective of the campaign was to make available quality generic drugs at affordable prices to all through the Jan Aushadhi Generic Drug Stores which are quite cheaper than the branded medicine. The Government intends to open up one JAS in each district of the country. A revised Business Plan of Jan Aushadhi Scheme in this regard is under consideration of the Department and the same will be ready by April 2013 as informed by the Department. At present only the medicines manufactured by the Central Pharma Public Sector Undertakings (CPSUs) under the Department of Pharmaceuticals are being sold at the existing Jan Aushadhi Stores and as such, the range of medicines being supplied by these CPSUs is limited, beside limited coverage of the therapeutic categories. In order to tide over this situation and to increase the range of medicines. BPPI has initiated a proposal to improve the supply chain, which would adequately address the issue of wider coverage of the therapeutic categories, and the same is under consideration of the Government. The Committee believe that the proposal initiated by BPPI will be finalized expeditiously without any undue delay.. The Committee are distressed to note that the response from some of the States for the Jan Aushadhi Scheme is not very affirmative, without which it would be difficult to implement the scheme successfully in the entire country. As recommended by the Committee in their reports on Demands for Grants for the years 2012-13 the Department should open JAS in a mission mode, in coordination with State Governments. The Committee recommended that Department should explore options like opening up of JAS through public-private partnership and also individual entrepreneurs should also be encouraged to open JAS. Further, the Department should rope in State PSUs and private manufacturers to increase the coverage of generic drugs at JAS. The Committee would like to be apprised of the action taken by the Department in this regard.

10. The Committee note that the Department proposes to set up a National Centre for Research and Development in Bulk Drugs (NCRDBD) at NIPER Hyderabad. The Centre would aim at development of technologies and process

for cost competiveness, environmental impact management, risk management and development of safety in manufacturing operations, knowledge transfer platform between industry and academia. The research avenues for bulk drugs are Drugs process innovation, Drug discovery and development, Analytical chemistry, Process engineering, cleaner technology, Polymorphism, Nanotechnology etc. The Committee were informed that the proposal had been accorded in-principle approval by the Planning Commission subject to certain conditions. Keeping in view the avowed objectives of the proposed centre, the Committee desire that all necessary steps may be taken by the Department in coordination with all concerned so that the proposed centre is set up expeditiously within a fixed time frame.

New Delhi
26 April, 2013
06 Vaisakha, 1935 (Saka)

Gopinath Munde
Chairman,
Standing Committee on
Chemicals and Fertilizers

MINUTES

MINUTES OF THE NINTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2012-13)

The Committee sat on Wednesday, the 20 March, 2013 from 1530 hrs. to 1700 hrs. in Room No.62, Parliament House, New Delhi.

Present

Shri Gopinath Munde - Chairman

Members

Lok Sabha

2.	Shri Gajanan D. Babar
3.	Shri P.P. Chauhan
4.	Shri Sakti Mohan Malik
5.	Shri Amarnath Pradhan
6.	Shri Tufani Saroj
7.	Shri Raju Shetti
8.	Shri Sai Prathap Annayyagari
	Rajya Sabha
9.	Shri A.A. Jinnah
10.	Shri Dilipbhai Pandya
11.	Shri Raghunandan Sharma

Secretariat

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

I. <u>MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)</u>

1.	Shri Dilsher Singh Kalha	Secretary, (Pharmaceuticals)
2.	Shri P.C. Singh	Chairman (NPPA)
3.	Shri S.C. Khuntia	Additional Secretary and Financial Advisor
4.	Shri Shambhu Kallolikar	Joint Secretary
5.	Shri Pradeep Yadav	Joint Secretary
6.	Shri Kailash Pati	Economic Advisor
7.	Shri Ravindra Mathur	Director (Cost)

II. <u>REPRESENTATIVES OF PSUs</u>

1.	Shri M.K. Nagendra	CMD, Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL)
2.	Shri Praveen Kumar	MD, Indian Drugs and Pharmaceuticals Ltd. (IDPL)
3.	Dr. K.K. Bhutani	Director, National Institute of Pharmaceuticals Education & Research (NIPER)

2. At the outset, Hon'ble Chairman welcomed the members of the Committee. Thereafter, the officials of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals), the Public Sector Undertakings and the Autonomous Institutions were called and 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. Then the officials of the Department and others introduced themselves. Thereafter, the Secretary, Department of Pharmaceuticals briefed the Committee about 'Demands for Grants of the Department for the year 2013-14.

5. During the discussion, the Chairman and members of the Committee raised some queries which were replied by the Secretary, Department of Pharmaceuticals and other officials. They also assured to send the requisite information in writing which was not readily available with them.

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

The Committee then adjourned.

MINUTES

MINUTES OF THE TENTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2012-13)

The Committee sat on Friday, the 26 April, 2013 from 1500 hrs. to 1600 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

Shri Dilipbhai Pandya - Acting Chairman

Members

Lok Sabha

2.	Shri Gajanan D. Babar
3.	Shri Prabhatsingh P. Chauhan
4.	Shri Sher Singh Ghubaya
5.	Shri Kamlesh Paswan
6.	Shri Sai Prathap Annayyagari
Rajya Sabha	
7.	Shri Biswajit Daimary
8.	Shri A.A. Jinnah

Secretariat

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

2. As the Chairman could not attend the sitting due to pre-occupation, the members chose Shri Dilipbhai Pandya, member of the Committee, to act as the Chairman. The Acting Chairman welcomed the members to the sitting of the Committee.

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

a) Demands for Grants (2013-14) of the Ministry of Chemicals and Fertilizers (Department of Fertilizers);
b) Demands for Grants (2013-14) of the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals); and
c) Demands for Grants (2013-14) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

4. The draft Reports relating to the Department of Fertilizers and Department of Chemicals and Petrochemicals were adopted by the Committee without any

amendments. The draft Report relating to the Department of Pharmaceuticals was also adopted with some amendments.

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

The Committee then adjourned.