27

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2011-12)

FIFTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2012-2013)

TWENTY-SEVENTH REPORT

सत्यमेव जयते

LOK SABHA SECRETARIAT
NEW DELHI

May, 2012/Vaisakha 1934, (Saka)

CC&F No.27

TWENTY-SEVENTH REPORT

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(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS (2012-2013)

Presented to Lok Sabha on ***02.05.2012***

Laid in Rajya Sabha on ***02.05.2012***

LOK SABHA SECRETARIAT
NEW DELHI

May, 2012/Vaisakha 1934, (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2011-12)

Shri Gopinath Munde - Chairman	
MEMBERS	
LOK SABHA	
2.	Shri Prabhatsinh Pratapsinh Chauhan
3.	Shri K. D. Deshmukh
4.	Smt. Paramjit Kaur Gulshan
5.	Shri Yashbant N.S. Laguri
6.	Shri Baidya Nath Prasad Mahato
7.	Shri Sakti Mohan Malik
8.	Shri O.S. Manian
9.	Shri Kamlesh Paswan
10.	Shri N. Peethambara Kurup
11.	Shri Ponnam Prabhakar
12.	Shri Ashok Kumar Rawat
13.	Shri Sivakumar alias Ritheesh
14.	Shri Tufani Saroj
15.	Shri Suresh Kumar Shetkar
16.	Shri Raju Shetti
17.	Shri Adagooru Viswanath
18.	Shri Om Prakash Yadav
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 Parshottam Khodabhai Rupala
27.	Shri Raghunandan Sharma
28.	Dr. C.P. Thakur
29.&	Shri Dilipbhai Pandya
30.^	Vacant
31#	Vacant

SECRETARIAT

1.	Shri C.S.Joon	-	Joint Secretary
2.	Shri A.K. Srivastava	-	Additional Director
3.	Smt. Emma C. Barwa	-	Under Secretary
4.	Shri Ajit Kumar Sahu	-	Committee Officer

& Nominated w.e.f. 17.09.2011.

Vacancy arisen due to demise of Shri Silvius Condpan, MP (RS) w.e.f. 10 October 2011.

^ Vacancy arisen because of retirement of Prof. Anil Kumar Sahani, Member of Rajya Sabha on 02.04.2012.

INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2011-12) having been authorised by the Committee to present the Report on their behalf present this Twenty-Seventh Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2012-13.

2. The Committee examined the Demands for Grants pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2012-13 which were laid in Lok Sabha and Rajya Sabha on 29 March 2012.

3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 12 April 2012.

4. The Committee considered and adopted the Report at their sitting held on 27 April 2012.

5. The Committee express their thanks to the Officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for furnishing the material and other information, which they desired in connection with the examination of Demands for Grants of the Department for the year 2012-13 and for giving evidence before the Committee.

6. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the Part-II of the Report.

New Delhi;
30 April, 2012
10 Vaisakha, 1934 (Saka)

Gopinath Munde
Chairman,
Standing Committee on
Chemicals and Fertilizers

REPORT

PART-I

CHAPTER-I

I. INTRODUCTORY

1.1 The Department of Pharmaceuticals in the Ministry of Chemicals and Fertilizers was created *vide* Notification dated 01 July 2008 to provide greater focus for the growth of the pharmaceuticals industry.

1.2 The Department of Pharmaceuticals deals with the following subjects:-

(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 held by HAL and IDPL in these companies transferred to the President of India. 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.

An Overview of Pharmaceutical Industries

1.6 While giving details regarding growth, imports, exports in the pharmaceutical industry in its Annual Report 2011-12, the Department of Pharmaceuticals has stated that the annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs. 1,04,944.35 Crores during the year 2010-11. The share of export of Drugs, Pharmaceuticals and Fine Chemicals is more than Rs. 47551.26 crore. This segment of Industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. The industry has developed excellent GMP (Good Manufacturing Practices) compliant facilities for the production of different dosage forms. The strength of the industry is in developing cost effective technologies in the shortest possible time for drug intermediates and bulk activities without compromising on quality. This is realized through the country's strengths in organic chemicals' synthesis and process engineering.

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

1.8 Many Indian companies maintain highest standards in Purity, Stability and International Safety, Health and Environmental (SHE) protection in production and supply of bulk drugs even to some innovator companies. This speaks of the high quality standards maintained by a large number of Indian Pharma companies as these bulk actives are used by the buyer companies in manufacture of dosage forms which are again subjected to stringent assessment by various regulatory authorities in the importing countries. More of Indian companies are now seeking regulatory approvals in USA in specialized segments like Anti-infectives, Cardiovasculars, CNS group. Along with Brazil & PR China, India has carved a niche for itself by being a top generic Pharma player. **(A.R. Pg.23)**

1.9 **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 2002-03 to 2010-11 is as under:-

(Rs. in crore)

Year	Value of Import of 'Medicinal and Pharmaceuticals Products'	Growth (%)
2002-03	2865	-
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	10,937	9.82

1.10 It may be observed that the imports shown declined in growth in the year 2010-11 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.

1.11 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.

1.12 EXPORTS : As per DGCIS, Kolkata Export of Drugs and Pharmaceuticals and Fine Chemicals for the period 2002-03 to 2010-11 are below:-

(Rs. in crore)

Year	Value of Import of 'Medicinal and Pharmaceuticals Products'	Growth (%)
2002-03	12,826	-
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	47,551	12.00

1.13 The detailed Demands for Grants (2012-13) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 29 March 2012. The demand shows a budgetary support of Rs 231.09 crore [(Rs.188.00 crore (Plan) + Rs.43.09 crore (Non-Plan)]. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2012-13. The detailed analysis along with Observations/Recommendations of the Committee are presented in the succeeding chapters of the Report.

CHAPTER-II

FIVE YEAR PLANS AND ANNUAL PLAN

(a) ELEVENTH FIVE YEAR PLAN

2.1 **Year – Wise Details of allocations under the Eleventh Five year Plan are as under:-**

(Rs. crore)

S.No.	Scheme	11th Plan	2007-08		2008-09		2009-10		2010-11		2011-12	
			BE	RE	BE	RE	BE	RE	BE	RE	BE	RE
1	**Project Based Support to PSUs**	**220.17**	**23.00**	**28.20**	**30.00**	**20.00**	**30.00**	**24.40**	**40.00**	40.00	22.45	22.45
2	**Support to Autonomous Institutions**	100.00	10.16	29.50	26.50	25.92	8.60	13.25	9.50	59.78	17.36	12.25
2.1	National Institute of Pharmaceutical Education and Research (NIPER)	95.00	8.66	20.00	25.00	25.00	8.00	13.00	9.00	59.08	16.96	12.00
2.2	National Pharmaceutical Pricing Authority (NPPA)	5.00	1.50	9.50	1.50	0.92	0.60	0.25	0.50	0.70	0.40	0.25
3	**Other Ongoing Schemes**	**8.00**	**1.05**	**2.00**	**1.25**	**1.21**	**2.50**	**2.30**	**1.50**	**1.50**	**2.25**	**1.20**
3.1	Pharma Promotion and Development Scheme (PPDS)	7.50	1.05	1.50	1.00	1.00	2.00	2.00	1.25	1.25	2.00	1.00
3.2	IT/Secretariat	0.50		0.50	0.25	0.21	0.50	0.30	0.25	0.25	0.25	0.20
4	**New Schemes Initiated in XIth Plan**	**1068.00**	**57.05**	**32.00**	**97.50**	**63.91**	**114.15**	**65.05**	**114.00**	**17.72**	**132.94**	**41.88**
4.1	**New Schemes for NIPER, Mohali**	69.00	20.00	7.00	15.00	15.00	15.00	11.15	12.00		8.62	5.85
4.2	New Niper Like Institutes	514.00	10.00	10.00	35.00	25.26	50.00	33.50	56.50		100.00	25.79
4.3	**PEPS**		1.00	1.00								0
4.4	**Interest Subsidy for Schedule M/Compliance for Mes**	340.00	15.00	11.80	27.00	13.15	15.00		0.01	0.01	0.00	0
4.5	Strengthening of NPPA	60.00	10.00		10.00	0.00	1.65	0.60	0.49		2.00	1.80
4.6	Creation of IPR Facilitation Centre at Pharmaexil	5.00	0.01	0.20	0.50	0.50	1.00	0.80	1.00	1.00	0.50	0.45
4.7	ERP, RandD Parks, Jan Aushadhi	5.00	0.01	1.00	0.00	0.00	1.50	2.00	5.00	5.00	3.50	3.50
4.8	Critical assistance for WHO pre-qualification for Pharma PSUs/RandD	75.00	0.01	1.00	10.00	10.00	10.00	10.00	14.00	10.00	6.28	4.49
4.9	New Schemes (to be introduced 2010-11)		1.02		0.00		20.00	7.00	25.00	1.71	12.04	0
	Total	**1396.17**	**91.26**	**91.70**	**155.25**	**111.04**	**155.25**	**105.00**	**165.00**	**119.00**	**175.00**	**77.78**

2.2 In the mid-term appraisal of schemes and programmes, the Planning Commission has made following assessment in respect of Department of Pharmaceuticals:-

> "In its Mid-term appraisal report, Planning Commission did not make any specific recommendation in respect of Department of Pharmaceuticals as such. However, recognizing that the government had established the Department of Pharmaceuticals for the promotion and coordination of basic and applied research in areas related to the pharmaceutical sector, it was recommended that the Pharmaceutical Research and Development Programme, presently being pursued by DST would be transferred to Department of Pharmaceuticals at the end of Eleventh Plan.

It was also recommended by the Planning Commission that institutional structure on skill development put in place during the Eleventh Plan needs to bridge the various gaps in the evolving skill eco-system, which involves interventions on various fronts such as focusing on skills infrastructure required to impart skills to help the youth acquire employment in emerging sectors, inter alia in pharmaceuticals, where opportunities are abundant and the wages attractive. Towards this aim, the Department is already in the process of setting up six more National Institutes of Pharmaceutical Education and Research-one each at Rae bareilly, Kolkata, Guwahati, Hajipur, Ahmedabad and Hyderabad; besides the one already functioning at Mohali .

(b) ANNUAL PLAN 2012-13

2.3 In a written reply on Scheme-wise outlays proposed by the Department and finally approved by the Planning Commission regarding Annual Plan 2012-13, following details have been provided by the Department:-

(Rs. Crore)

Sr. No.	Name of the Scheme	2012-13 Proposed	2012-13 Approved
I	**Project Based Support to PSUs**	197.26	20.00
II	**Support to Autonomous Institutions**		
1	National Institute of Pharmaceutical Education and Research(NIPER)	132.00	24.00
2	New NIPER like Institutes	187.50#	74.00
	a) NIPER, Ahmedabad		16.50
	b) NIPER, Hajipur		3.70
	c) NIPER, Guwahati		18.80
	d) NIPER, Kolkata		4.50
	e) NIPER, Hyderabad		22.00
	f) NIPER, Rai Bareli		4.50
3	National Pharmaceutical Pricing Authority(NPPA)	8.19	4.00
III	**Other Ongoing Schemes**		
1	Pharma Promotion and Development Scheme (PPDS)	2.00	2.00
2	IT/Secretariat	2.00	1.00
3	Interest Subsidy for Schedule M compliance/Upgradation of SMEs to WHO-GMP standards	240.00	2.00
4	Creation of IPR facilitation center at Pharmaexcil	6.50	1.00
5	ERP (GLP/GCP/Animal House Lab)	10.00	4.00
6	Critical assistance for WHO pre-qualification for pharma PSUs/R&D	1.00	10.00
7.	Jan Aushadhi Scheme	40.00	20.00
8.	New Schemes	302.00	30.00
	Total	**1128.45**	**188.00**

Inter-se distribution not made.

2.4 On being asked why lesser allocation of Rs.188.00 crore were approved by the Planning Commission for 2012-13 even though the Department had proposed Rs.1128.45 crore and also how the Department plans to achieve their targets with lesser allocation, the Department in its written reply submitted as under:-

"The Department of Pharmaceutical sought funds in 2012-13 based on the proposals included in the report of the Working Group on Drugs and Pharmaceuticals for the XII Plan. The Commission is yet to approve the proposals included in the report. Enhanced funds may be provided after the Commission adopts and approves the XII Plan Outlays".

CHAPTER-III

DEMANDS FOR GRANTS OF THE DEPARTMENT FOR THE YEAR 2012-13

3.1 The Ministry of Chemicals and Fertilizers presented to Parliament Demand No.8 on the Department of Pharmaceuticals on 29.3.2012. The Demand included a provision for the expenditure of the Secretariat, North Eastern Areas, Industries, loan for Pharma Industries, under the control of Department of Pharmaceuticals. The Note on Demands for Grants for the year 2012-13 of the Department of Pharmaceuticals is given in the Annexure.

3.2 Budgetary allocation under Plan and Non Plan under Major Head during the year 2011- 2012 and 2012-2013 are indicated below:-

(Rs. in crore)

Major Head	Budget Estimates 2011-12			Revised Estimates 2011-12			Budget Estimates 2012-13		
	Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
Revenue	152.55	37.95	190.50	55.33	38.25	93.58	168.00	43.04	211.04
Capital	22.45	0.05	22.50	22.45	0.05	22.50	20.00	0.05	20.05
Total	**175.00**	**38.00**	**213.00**	**77.78**	**38.30**	**116.08**	**188.00**	**43.09**	**231.09**

3.3 The following statement shows the scheme-wise details of Plan expenditure for BE, RE and Actual Exp. for 2009-10, 2010-11 & 2011-12 and BE 2012-13 :-

BE, RE and Actual Exp. (Plan) for 2009-10, 2010-11 & 2011-12 and BE 2012-13

(**Rs.in lakh**)

S. No	Head	2009-10			2010-11			2011-12			2012-13
		BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
	Revenue										
1	Sectt.	21	30	25.56	25	25	12.06	25	20.00	19.00	100
2	NIPER	6526	4715	5765	6100	4718	3065	10808	3586.00	3380.00	7520
3	NPPA	92	85	7.78	99	70	15.81	240	205.00	16.00	400
4	PEPS	2365	1980	1855	4501	1772	1032.8	2232	844.00	45.00	6700
5	PPDS	100	200	87.26	125	125	68.84	200	100.00	68.00	200
6	NE Region		1050	0	1650	1190	0	1750	778.00	0.00	1880
	Total Revenue	**9104**	**8060**	**7740.6**	**12500**	**7900**	**4194.51**	**15255.00**	**5533.00**	**3528.00**	**16800**
	Capital										
7	HAL		950		1500	1500	250	685	685.00		300
8	BCPL	2000	1490	2440	2500	2500	2500	60	60.00	60.00	200
9	IDPL							1000	1000.00	461.00	1500
10	RDPL							500	500.00		
	Total Capital	**2000**	**2440**	**2440**	**4000**	**4000**	**2750.00**	**2245.00**	**2245.00**	**521.00**	**2000**
	Total	**11104**	**10500**	**10180.6**	**16500**	**11900**	**6944.51**	**17500.00**	**7778.00**	**4049.00**	**18800**

3.4 When asked to state the reason for decrease in RE 2011-12 which is Rs.77.78 crore as compared to Plan BE 2011-12 which is Rs.175.00 crore , the Department stated as under:-

"Work relating to construction of NIPER campus could not be initiated in 2011-12 as envisaged. As such, funds allocated for new NIPERs could not be utilized.

There was, therefore, under utilization of funds in respect of construction of Campus of new NIPERs (including Guwahati) to the extent of Rs.81.94 crore. New schemes also could not be introduced to the extent Rs.12.04 crores. Similarly Rs 2 Crores under Critical assistance scheme for WHO GMP and Rs One Crore for Pharma Promotion scheme were revised due to expenditure levels".

The following statement shows the scheme-wise details of Non-Plan expenditure for BE, RE and Actual Exp. for 2009-10, 2010-11 & 2011-12 and BE 2012-13 :-

BE, RE and Actual Exp. (Non-Plan) for 2009-10, 2010-11 & 2011-12 and BE 2012-13

(Rs. In Lakh)

S.No.	Sub-Head	2009-10			2010-11			2011-12			2012-13
		BE	RE	Actual Exp.	BE	RE	Actual	BE	RE	Actual	BE
	Revenue										
1	Sectt.	732	656	508.83	734	745	719.38	764	762	722	894
2	NPPA	706	577	517.44	607	541	486.11	588	581	536	635
3	PEPS	50	100	7.89	50	20	0.71	20	5	5	20
4	NIPER	1739	2000	2092	1904	2404	2064.00	2423	2477	2477	2755
	Total Revenue	**3227**	**3333**	**3126.16**	**3295**	**3710**	**3270.20**	**3795**	3825	3740	4304
	Capital										
5	SSPL	1	1	0	1	1	0	1	1	0	1
6	BCPL	1	1	0	1	1	0	1	1	0	1
7	BIL	200	1	0	1	1	0	1	1	0	1
8	IDPL	1	2	0	1	1	0	1	1	0	1
9	HAL	1	2	0	1	1	0	1	1	0	1
	Total Capital	**204**	**7**	**0**	**5**	**5**	**0**	**5**	5	0	5
	Grand Total	**3431**	**3340**	**3126.16**	**3300**	**3715**	3270.20	3800	3830	3740	4309

3.5 A statement indicating the Major Heads under the Demand No.8 and Budget Estimates (BE) 2012-13 (Plan and Non-Plan) for each of the Heads is as under:-

(Rs. In crore)

Sl.No.	Major Head	Item	BE 2012-13
1.	3451	Secretariat Economic Services	9.94
2.	2852	Pharmaceutical industries	182.30
3.	2552	North-Eastern Areas	18.80
4.	6857	Non-Plan Loans to Public Enterprises	0.05
5.	6857	Investment in Public Enterprises	20.00
		Total	**231.09**

CHAPTER-IV

HEAD-WISE ANALYSIS OF DEMANDS FOR GRANTS (2012-13)

(a) MAJOR HEAD 3451

4.1 **Secretariat –Economic Services**

(Rs.in crore)

BE 2011-12			RE 2011-12			BE 2012-13		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
0.25	7.64	7.89	0.20	7.62	7.82	1.00	8.94	9.94

4.2 On being asked to provide reasons for substantial increase in Plan allocation in BE 2012-13 as compared to RE 2011-12, the Department in its written reply has stated as under:-

> "As service and official work automation including e-governance has become necessary in present time, procurement of necessary hardware and software has become necessary. Under this obligation fund are required during the 2012-13 for IT automation. It is also obligatory, in terms of Planning commission instructions that around 2% of total Budget of the Department should be kept for IT automation".

(b) MAJOR HEAD -2552

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

(Rs.in crore)

BE 2011-12			RE 2011-12			BE 2012-13		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
17.50	--	17.50	7.78	--	7.78	18.80	--	18.80

4.4 When asked to give reasons for increase in Plan allocation in BE 2012-13 as compared to RE 2011-12, the Department in its written reply has stated as under:-

> "10% of Plan expenditure is earmarked for development of the North Eastern Region. In 2011-12 RE Plan allocation was Rs.77.78 crores. In 2012-13 BE Plan allocation is Rs.188.00 crores. This explains increase in 2012-13 for provision development of North Eastern Region".

(c) MAJOR HEAD 2852

4.5 **Pharmaceutical industries**

(Rs.in crore)

BE 2011-12			RE 2011-12			BE 2012-13		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
134.80	30.31	165.11	47.35	30.63	77.98	148.20	34.10	182.30

4.6 When asked to give reasons for increase in allocation to Pharmaceutical Industries in BE 2012-13 from RE 2011-12, the Department in its written reply has stated as under:-

> **"**The increased allocation for new NIPERs in 2012-13 (BE) vis-à-vis RE 2011-12 is due to provision for construction of NIPER Campus at Gandhinagar and Guwahati. It is also due to introduction of new courses at new NIPERs, Jan Aushadhi Scheme and New Scheme".

4.7 The Committee have been informed that the above allocation 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. The details of the various schemes are given in the succeeding paragraphs.

(i) National Institute of Pharmaceutical Education Research (NIPER)

4.8 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 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.

New NIPER like Institutes

4.9 The Union Cabinet gave in principle approval for setting up of six National Institutes of Pharmaceutical Education and Research (NIPER), one each at Ahmedabad (Gujarat), Hyderabad (Andhra Pradesh), Hajipur (Bihar), Kolkata (West Bengal), Rae Bareli (U.P.) and Guwahati (Assam), in August 2007. In September 2011, Union Cabinet approved establishment of these six new NIPER at an estimated cost of Rs.750 crore for Phase I of the project.

4.10 The details of allocation for NIPER for the year 2011-12 and 2012-13 are as under:-

(Rs.in crore)

BE 2011-12			**RE 2011-12**			**BE 2012-13**		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
108.08	24.23	132.31	35.86	24.77	60.63	75.20	27.55	102.75

4.11 When asked how the Department of Pharmaceuticals propose to utilize increase of Rs.42.12 crore in the year 2012-13 as compared to RE 2011-12, the Department in its written reply informed the Committee as under:-

> **"**The enhanced provision for new NIPERs would be utilized by continuing to focus on education and commencement of construction of NIPER Campus at Guwahati and Gandhinagar, as land is available at these two places".

4.12 During the course of evidence, while giving details regarding construction of new NIPERs, the Secretary, Department of Pharmaceuticals has stated as under:-

> "We have plan to set up six more NIPERs. There is a proposal that in the Twelfth Plan we set up additional ten. The Planning Commission has identified that at least, a gap in human resource availability of over 20 lakh by 2020. So, there is a critical area where the Department of Pharmaceuticals is trying to intervene. Unfortunately, when the six NIPERs were approved by the Government of India, the Cabinet had put a condition that land would be provided free of cost by the State Government. Out of six, we have only been able to get land in Guwahati and Ahmedabad but in four other places which are Rae Bareli, UP; Hazipur, Bihar; and Hyderabad, we have not been able to get land. Therefore, not much investment has been done. The hon. Minister is in constant touch with the Chief Ministers. So, we hope that given the dire need for these institutions which is so critical for the youth of those areas, we will get the land. In fact, if you notice even in the plan performance, there is a huge gap between what was earmarked and what was spent. It is largely because the money that was earmarked for these new NIPERs, we have not been able to spend. The reason is that we have not got land
>
> We will be taking up construction of the NIPERS in Ahmedabad and Guwahati in this year. We hope we get land in other places and similarly we will do in those States also. Requirement for human resources will be met largely, we hope, through these six NIPERS that are coming up and hopefully the other ten, if it is approved by the Cabinet during the Twelfth Plan".

(ii) National Pharmaceutical Pricing Authority (NPPA)

4.13 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.

4.14 During the course of evidence, while speaking regarding affordability and availability of medicines, the Secretary, Department of Pharmaceuticals, informed the Committee that :-

> **"**We are involved in the control of prices. There has been regime of control on prices ever since 1962. Policies have changed over a period of time. The last control order was issued in 1995. There have been subsequent draft policies which have been circulated but not implemented. But now the proposal is before the Group of Ministers and I am glad to report to the Committee that the GoM is due to meet on the 25th of this month. The recommendations of the GoM will go to the Cabinet and the Cabinet in their wisdom will approve the policy. The proposal is that we have identified 348 essential drugs and medicines which are put in certain formulations and based on those drugs prices are recommended to be controlled. At present of course there are only about 74 drugs which are controlled and the formulations are more. Hopefully, even on the affordability and availability of medicines, the Cabinet would soon take a decision".

4.15 Further, in replies to certain queries regarding fixing of prices of scheduled and non-scheduled drugs, during the course of evidence, the member secretary, NPPA has stated as under:-

> "Operating the DPCL 1995, there are 74 scheduled drugs defined in the first schedule of the DPCO. These scheduled drugs as well as any formulations containing these drugs are controlled by the NPPA. We fix their prices on cost based formula which is given in t he DPCO in para 7. The prices fixed by us of the scheduled drugs are final and nobody can sell the drugs over and above the prices which we are fixing. You have mentioned about the paracetamol. It is a non-scheduled drug. We have no control over the launch price. Every company launch this under their own cost. What we are doing, as Secretary has rightly pointed out, we do not allow it to exceed 10 per cent in a year. That is what we are doing. In the non-scheduled category, we have noticed that there is much more margin. But because of our constraints we cannot do anything. We have brought this matter to the notice of the Government also. We have our constraints in this area".

The details of allocation for NPPA for the year 2011-12 and 2012-13 are as under:-

(Rs.in crore)

BE 2011-12			RE 2011-12			BE 2012-13		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
2.40	5.88	8.28	2.05	5.81	7.86	4.00	6.35	10.35

4.16 While providing details regarding the allocation for the year 2012-13, the Department in a written reply has provided as under:-

"For the year 2012-13 an amount of Rs.400 lakh (Plan) has been provided.

NPPA in 2007 has sent following Five New Plan Schemes amounting to Rs.49.95 crores for the plan period 2007-08 to 2011-12:-

Sl. No.	Scheme	Amount (Rupee in lakh)
1.	Building Robust & Responsive Statistical System for NPPA	215.00
2.	Creation of NPPA Cells in States	2638.00
3.	Scheme for Interaction with States	152.00
4.	Proposal for Consumer Awareness and Publicity through Print, electronic and other medium	1828.00
5.	Proposal for strengthening the existing Monitoring and Enforcement work	162.60
	Total	**4995.60**

4.17 Out of these, scheme at Sl. No. 1 was initially approved by the Planning Commission and implemented during the 11th Five Year Plan 2007-08 to 2011-12. In-principal approval of the Planning Commission in respect of scheme at Sl No. 4 was received in February, 2011.

NPPA has been provided an amount of Rs.400 lakh (Plan) for the year 2012-13. The scheme-wise allocation of funds is as under:

Sl. No.	**Scheme**	**Amount (Rupee in lakh)**
A.	**On-going Scheme of Computerisation of NPPA**	**38.00**
B.	**Other Plan Schemes**	
1.	Building Robust & Responsive Statistical System for NPPA	**20.00**
2.	Creation of NPPA Cells in States	
3.	Scheme for Interaction with States	
4.	Consumer Awareness and Publicity through Print, electronic and other medium	**342.00**
5.	Strengthening the existing Monitoring and Enforcement work	
	Total	**400.00**

(iii) Pharmaceutical Export Promotion Scheme (PEPS)

4.18 The details of allocation for PEPS for the year 2011-12 and 2012-13 are as under:-

(**Rs.in crore)**

BE 2011-12			**RE 2011-12**			**BE 2012-13**		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
--	0.20	0.20	--	0.05	0.05	--	0.20	0.20

4.19 When asked to give reasons for increase in allocation in Non-Plan BE 2012-13 from RE 2011-12, the Department in its written reply has stated as under:-

"To facilitate pharmaceutical export promotion the Department maintains such data on the various aspects of pharmaceutical information related to major countries. Various reports related to domestic pharmaceuticals industry as well as global Pharma market are to be procured. Availability of such information helps the Government of India in preparing such Memoranda of Understanding with various countries".

4.20 When asked to give details regarding achievements made by this Scheme, the Department in its written reply has stated as under:-

"Reports related to pharma industries have been procured which gives a picture of Indian Pharma Industry and helps in taking views on various issues related to domestic as well as international trade. The department is in the process of consultation for finalization of such Memoranda with countries such as Ukraine, Azerbaijan and other CIS countries. Similarly, in coordination with the Ministry of Commerce the Department is also in consultation with countries such as Brazil in Latin America".

(iv) Pharmaceuticals Promotion & Development Scheme (PPDS)

4.21 Pharmaceuticals Promotion & Development Scheme **(**PPDS) aims at the promotion, development and export promotion in the Pharma sector. Under this scheme, 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 are undertaken; besides miscellaneous activities relating to promotion of Pharma sector for production, exports and investment.

The details of allocation for PDPS for the year 2011-12 and 2012-13 are as under:-

(Rs.in crore)

BE 2011-12			RE 2011-12			BE 2012-13		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
2.00	--	2.00	1.00	--	1.00	2.00	--	2.00

4.22 When asked to give reasons for decrease in Plan expenditure in RE 2011-12 as compared to BE 2011-12, the Department in its written replies has stated as under:-

"Funds to the tune of Rs.2.00 crores were projected by this Department for allocation in BE 2011-12. However Ministry of Finance keeping in expenditure incurred upto 30.09.2011 has restricted the same at the RE to Rs.1.00 crore"

4.23 On being asked to give reasons for increase in Plan allocation in BE 2012-13 as compared to Plan RE 2011-12, the Department in its written replies has stated as under:-

"The enhanced budget allocation was proposed keeping in view the international IPR scenario where Department would have more promotion and developmental activities which are as below:-

(1) 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.

(2) All miscellaneous activities relating to promotion of Pharma sector for production, exports and investments".

(v) Others

4.24 The details of allocation under 'Others' for the year 2011-12 and 2012-13 are as under:-

(Rs.in crore)

BE 2011-12			RE 2011-12			BE 2012-13		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
22.32	--	22.32	8.44	--	8.44	67.00	--	67.00

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

> "Rs. 67 crores consists of Rs. 30 crores for new schemes to be introduced, Rs. 20 crores for Jan Aushadhi Schemes, Rs. 10 crores for critical assistance for WHO Pre Qualification, Rs. 4 crores for ERP, Rs. 1 crore for creation of IPR Facilitation Centres at Pharmaxcil and Rs. 2 crore for Interest Subsidy for Schedule M Compliance".

CHAPTER-V

PUBLIC SECTOR UNDERTAKINGS

5.1 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 and 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 schemes for revival of HAL and BCPL. The rehabilitation scheme of IDPL is under consideration.

5.2 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) and Manipur State Drugs & Pharmaceuticals Limited (MSDPL), Imphal (closed) and one Joint Venture of IDPL namely, Orissa Drugs & Chemicals Limited (ODCL).

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

5.4 Non- Plan loans and investments in Public Enterprises in the Pharmaceutical Sector for the year 2011-12 and 2012-13 are as indicated below:-

(Rs.in crore)

BE 2011-12			**RE 2011-12**			**BE 2012-13**		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
22.45	0.00	22.45	22.45	0.00	22.45	20.00	0.05	20.05

(a) <u>Bengal Chemicals & Pharmaceuticals Limited (BCPL)</u>

5.5 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 on the 17th March, 1981.

5.6 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.

5.7 Post 1980, company continued its operations. However, due to continued losses, the company was declared sick by the Board for Industrial and Financial Reconstruction

(BIFR) on 14th January, 1993. 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.

5.8 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.

5.9 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 inter alia:

(i) Cash infusion by GOI - ` 207.19 crore
(ii) Write off/Waiver of Loans/Interest - ` 233.41 crore

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

5.11 The Committee note that in the Outcome Budget 2012-13, the Department of Pharmaceuticals has mentioned that an amount of Rs.2.00 crore has been allocated in 2012-13 to BCPL for new Web based ERP (Enterprise Resource Planning) package.

5.12 When asked to elaborate how this ERP package will help in revival of BCPL, the Department in its written reply has stated as under:-

> **"**New web based ERP system is necessary for the entire organization which will cover all the areas of the Organization like Materials Management, Marketing, Production, Finance, Stores etc and will give necessary data back up for decision making at various levels of Management as well as periodic reports will be generated for all the departments using such software.
>
> The benefits of new ERP Package, which will help revival of Bengal Chemicals & Pharmaceuticals Ltd., will be as follows:-
>
> (i) Data entered into the system will be recorded giving date and time. Management can track day to day operation and easily get MIS reports over web.
> (ii) MIS will be generated from any point over web using valid user ID and password.
> (iii) Due to centralized database, management can track day to day production, sales, realization and financial position of the company.
> (iv) Periodical Accounts can be drawn at any interval as per choice of Management.
> (v) Party ledger will be available at any point of time.
> (vi) Trial balance and other accounts schedule related to closing will be prepared automatically.
> (vii) As per demand CAG can access any time the server of BCPL from anywhere.
> (viii) Link can be provided to Department of Chemicals & Pharmaceuticals for their access if required".

(b) Indian Drugs & Pharmaceuticals Limited (IDPL)

5.13 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.

5.14 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.

5.15 While giving details in its Annual Report 2011-12 regarding the revival of IDPL, the Department of Pharmaceuticals has stated that 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.

5.16 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.

5.17 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 Monitoring Agency on behalf of BIFR, supported the recommendations for revival of IDPL subject to certain conditions.

5.18 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.

5.19 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. Cabinet considered the proposal at its meeting held on 17.5.2007 and referred it to 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.

5.20 When asked to give details regarding progress in approval of the Modified Revival Plan for IDPL, the Department in its written reply has stated as under:-

> **"**Draft Note for the Cabinet has been prepared. However Department of Pharmaceuticals desired that IDPL may request E&Y 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. At present the Draft Cabinet Note is under submission".
>
> In the mean while BIFR meeting was held on 10.01.2012 and 21st March, 2012 (case No. 503/1992). The Board directed that the copy of E&Y report be submitted to BIFR as well IDBI (Operating agency) and IDBI to examine the report, prepare Draft Rehabilitation Scheme (DRS) and call a meeting of secured creditors. It was further indicated that the report can be considered simultaneously by the BIFR and Ministry for taking early view in the matter. The response from IDBI, the Operating Agency is still awaited".

5.21 The Department in its Outcome Budget 2012-13 in had stated that Rs.15.00 crore has been allocated for revival of IDPL.

5.22 In this regard, when asked to clarify how the Department is going to utilize Rs.15.00 crore funds with regard to revival of IDPL, the Department in its written reply has stated as under:-

> **"**Proposed allocation of Rs 15.00 crore in 2012-13 is not for revival of IDPL, but to help company to restart its Hyderabad Plant which is closed at present. This fund allotment will help the company to make liquid oral section operational at Hyderabad Plant (where presently there is no production activity) and help IDPL to create additional production facilities for socially relevant medicines which are in great demand".

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

5.23 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.

5.24 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.

5.25 Based on the Scheme, the Government approved the Rehabilitation of the company on 9th March 2006 followed by BIFR approval on 5th June 2007.

5.26 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.

5.27 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.)*

5.28 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.

5.29 Further, Government has additionally approved proposals of ` 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 ` 20.17 crores and for up gradation of manufacturing facilities of Tablet, Capsule and Liquid Sections complying to WHO-GMP standardsat an estimated cost of ` 10.00 crore in order to make the company further viable.

5.30 The Committee note that in its Outcome Budget 2012-13, the Department has stated that an amount of Rs. 3.00 crore has been allocated in 2013-13 to HAL for up gradation of capacity of large volume/parentral with facilities complying to WHO-GMP compliance.

5.31 In this regard, when asked to give details regarding how the amount is to be utilized, the Department in its written reply has stated as under:-

> **"**The proposal for the expansion of large volume parenterals with facilities complying to WHO-GMP compliance in HAL at the cost of Rs. 45 crore is under consideration of the Department. The Standing Finance Committee of the Department has appraised the project in its meeting held on 16.03.2012 and given in-principle approval for the same. Planning Commission has also given the in-principle approval to the project. However, as per the observation of the competent authority project is under further examination and evaluation. After the approval of the competent authority the fund will be utilized for the purpose".

(d) <u>Karnataka Antibiotics & Pharmaceuticals Limted (KAPL)</u>

5.32 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.

5.33 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. The company has also ISO-9001 and ISO 14001 accreditation.

5.34 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.

5.35 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.

5.36 During the visit of the Committee to Bangalore on 12.11.2011, the representatives of Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) had apprised the Committee that prices of drugs made by KAPL are slightly higher than that of small and medium drug manufacturers due to the fact that KAPL maintains the highest standard of drug manufacturing, As such, it is difficult for them to compete with small and medium enterprises where drug prices are cheaper in tender process.

5.37 When asked about the competition faced by KAPL from Small and Medium Enterprises in tender process, and steps the Department has planned to make KAPL competitive in domestic market, the Department in its written reply has stated as under:-

> **"**In view of competition faced by KAPL from Small and Medium Enterprises in tender process, Department is considering to extend the Purchase Preference Policy to the CPSEs. The proposal is under active consideration of the Department".

(e) <u>Rajasthan Drugs and Pharmaceuticals Limited</u>

5.38 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).

5.39 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.

5.40 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.

(f) Bengal Immunity Limited (BIL)

5.41 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).

5.42 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.

5.43 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.

5.44 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

(i) National Pharmaceutical Pricing Policy

6.1 This Department has been exercising Drug Price Control on the basis of criteria mentioned in 'Modifications in Drug Policy, 1986' announced in September, 1994, which is based on production data of 1990.

6.2 The Government announced the 'Pharmaceutical Policy 2002' in February 2002. However, a public interest litigation filed in the High Court of Karnataka at Bangalore resulted in an Order dated 12-11-02, which stopped the Government from implementing the price control regime of the Pharmaceutical Policy 2002. This Department filed a Special Leave Petition (SLP) before the Supreme Court of India against the Order of the Karnataka High Court. The Supreme Court vide its order dated 10.3.2003 directed the Government to consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control.

6.3 Accordingly, a draft National Pharmaceuticals Policy was prepared by this Department after extensive discussions with various stakeholders, and in line with the declared objective of the Government in the National Common Minimum Programme(NCMP). This Policy was submitted to the Cabinet for its approval. The Cabinet considered the Policy in its meeting held on 11th January, 2007 decided that in the first instance be considered by a Group of Ministers(GoM). The GoM Chaired by Shri Sharad Pawar, Minister of Agriculture and Minister of Consumer Affairs, Food and Public Distribution held for meetings.

6.4 Following the formations of the new Government, the Department with the approval of the Minister of Chemicals and Fertilizers recommended continuation of GoM. The GoM has been accordingly constituted with the ministers of the notified Departments in the earlier GoM. The new GoM is yet to give its recommendation on the draft of National Pharmaceuticals Policy, 2006.

6.5 The Committee through their earlier recommendations made in the Twentieth Report on Action Taken by the Government on the recommendations contained in the Seventh Report of the Committee (2005-06), Twenty-Fifth Report on Demands for Grants (2008-09) and First Report on Demands for Grants (2009-10) expressed their displeasure regarding delay in finalization of the draft National Pharmaceutical Policy.

6.6 Further the Department of Pharmaceuticals prepared a draft National Pharmaceutical Pricing Policy, 2011[NPPP-2011] based on the criteria of essentiality and requirements as stipulated by Ministry of Health & Family Welfare.

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

> **"**The Department has already approached the Group of Ministers (GoM) who is looking into this issue. The meeting is scheduled to be held on 25.04.2012. The recommendation of the GoM is to be subsequently approved by the Cabinet. Hence, no time frame can be given".

(ii) Foreign Direct Investment (FDI)

6.8 Regarding the Policy on Foreign Direct Investment(FDI) and impact of FDI on Indian Drugs Industries in public and private sectors, the Department in a note explained as under:-

> "After the takeovers of domestic companies like Ranbaxy etc., there was a strong apprehension that these takeovers could affect the domestic Pharma Industry especially the Generic Industry.
>
> Department of Pharmaceuticals felt that such a takeover could increase possibilities of other such takeovers of Indian Pharma companies which could have impact on the Indian health care scenario as well as on pricing and availability of medicines in India. As such an appropriate assessment requires to be made. The Department of Pharmaceuticals had requested the Department of Commerce to conduct a study on the recent takeovers of Indian companies by the MNCs. Thereafter, the recommendation could be placed before the Economic Advisory Council to the Prime Minister and/or the Competent Authority.
>
> The Department of Commerce had entrusted the work to Ernst & Young who have since submitted their report to Department of Commerce. Department of Commerce has informed that the report has recommended continuation of the current FDI policy in pharmaceutical sector. However, in their opinion even if this policy is continued or suitably amended, there is an urgent need for attracting investments in new chemical entities research, bio pharmaceuticals, bio fermentation, clinical trails, testing, inspection and certification infrastructure cold chain, etc. steps may be initiated to encourage investment in these deficit areas of Indian Pharmaceutical industry. Similarly, steps need to be taken for reviewing in critical areas such as bio pharmaceuticals & APIs.
>
> With a view to examine the issued involved 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 Department of Pharmaceuticals were of the view that a change in the regulation governing FDI in the Pharmaceutical sector would not be justified at this stage. If however, the experience in the future indicates the emergence of adverse consequences, the matter be re-visited.
>
> 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 brown field 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.

6.9 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.

As per the above Press Note, this would be reviewed after the period 6 months".

6.10 When asked to provide details regarding Indian Pharmaceutical Companies that were taken over by MNCs, the Department in its written reply has stated as under:-

"Department of Industrial Policy & Promotion has informed that since April, 2004 to December, 2011, there have been 141 instances of Foreign Direct Investment in various Indian Drug Manufacturing Companies."

6.11 Further, when asked whether any studies being done to analyse likely impact of take over of Indian Pharma Companies by MNCs, the Department in its written reply has stated as under:-

"The Department of Commerce had entrusted the work of study on the recent taken over of domestic pharma industry to Ernst & Young. Ernst & Young have since submitted their report to Department of Commerce. Department of Commerce has informed that the report has recommended continuation of the current FDI policy in pharmaceutical sector".

(iii) <u>Jan Aushadhi Scheme</u>

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

6.13 For fulfilling this goal, a Campaign in the name of 'Jan Aushadhi Campaign' has been launched. The purpose of this campaign is to make available medicines at affordable prices for all, especially the poor and the disadvantaged. Under this campaign, less priced quality unbranded generic medicines will be made available through Jan Aushadhi Stores which inherently are less priced but are of same and equivalent quality, efficacy and safety as compared to branded generic medicines.

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

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

6.16 The first Jan Aushadhi Generic Drug Store was opened in Civil Hospital, Amritsar on 25th November, 2008 and with the active support and cooperation of the State Government of Punjab, the stores were opened not only in all districts of Punjab but also being opened at block level too. The campaign has now been spread besides in Punjab, also in the States of Haryana, Uttrakhand, Rajasthan, Andhra Pradesh, Odisha, West Bengal, Jammu & Kashmir, Himachal Pradesh & UT of Delhi and Chandigarh by having opened 117 Jan Aushadhi Generic Drug Stores so far (till 29.03.2012). Efforts are on to open more number of stores.

The Jan Aushadhi Campaign will help:

(i) Improve access to healthcare in as much as cost of treatment would come down substantially. This would enable the Public Health System to increase the coverage.
(ii) Secure a socio- economically viable mechanism / institutional arrangement for efficacious sales of Pharma CPSU products, thereby improving their viability.
(iii) Promote & encourage private industry to sell their quality unbranded generic products through these retail outlets.
(iv) Ensure successful implementation of the Jan Aushadhi campaign would dispel the myth that quality of medicines is linked to price and demonstrate that quality medicines can be sold at substantially lower prices.
(v) Educate doctors that unbranded generic medicines provide a better option than branded products since quality of generic medicines can be equally efficacious and safe at much lower prices.
(vi) Create Consumer awareness & involve private & charitable bodies & NGOs by making them part of the campaign.
(vii) Reduce promotional cost and profits for the benefit of patients etc.

6.17 When asked how the therapeutic coverage of generic drugs are proposed to be increased under the Jan Aushadhi Scheme, the Department in its written reply has 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. The coverage should be extensive to meet the maximum demand of the patients. 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, besides limited coverage of the therapeutic categories. In order to tide over this situation and to increase the range of medicines, association of State PSUs and manufacturers in the private sector is being examined to address the issue of wider coverage of the therapeutic categories".

6.18 Further, regarding geographic coverage of the Jan Aushadhi Scheme, the Department in its written reply has stated as under:-

"As regards geographic coverage of the Jan Aushadhi Scheme, as per the proposed Business Plan, it intends to open 612 Jan Aushadhi stores by the end of 2012-13 in the first phase and it also has a proposal to open at least five Jan Aushadhi Stores in each of the 630 districts of the country covering approximately 3000 sub-divisions in the second phase. The opening up of the Jan Aushadhi Stores however largely depends upon the Health policies being followed by the State Governments and also on the extent of cooperation the States extends for opening of the stores. The State Governments are required to provide space in the Government Hospitals for the stores and also to identify the operating agencies to run the stores. So far under the Jan Aushadhi campaign 117 Jan Aushadhi Stores have been opened in eleven States and UTs namely Punjab, Haryana, Delhi, Rajasthan, Andhra Pradesh, Odisha, West Bengal, Uttarakhand, Jammu & Kashmir, Himachal Pradesh and UT of Chandigarh".

(iv) Research And Development (R&D)

6.19 While giving details regarding R&D in the Indian pharmaceutical industry in Outcome Budget 2012-13, the Department of Pharmaceuticals has stated as under:-

"Innovative R&D is critical in Pharma industry. Here, the New Drug Discovery Research (NDDR) has to keep pace with the emerging pattern of diseases as well as responses in managing existing diseases where target organisms are becoming resistant to existing drugs. The NDDR is an expensive affair. It is encouraging to observe that at least 10 Indian companies are engaged in new drug discovery research in the areas of infections, metabolic disorders like diabetes, inflammation, respiratory disorders, obesity and cancer. Most of these companies have increased their R&D spending to over 6% of their respective sales turnovers. Some Indian companies have out licensed some new molecules in the asthma and diabetes segments to foreign companies. Introduction of Product Patent for Pharmaceuticals is an important feature for Indian Pharma R&D scenario. This has boosted the confidence of MNC Pharma companies on India where a number of western Pharma companies have entered into R&D collaborations with Indian Pharma companies in the field of NDDR. Some Indian companies have got US-FDA approvals for their new molecules as Innovative New Drugs (IND).

R&D can be carried out in India at a fraction of the equivalent cost in Europe or USA. The attractiveness for India as a destination for R&D is by way of lower cost of manpower, infrastructure, cheaper maintenance of equipment, availability of raw materials at lower prices, top quality scientists and capability to conduct modern research under GLP, GMP guidelines. With the application of product patent regime in case of pharmaceuticals in India, the confidence levels of Western pharma companies in India for contract R&D work is going up. Leading Indian companies are also conducting clinical trials in India due to availability of upgraded infrastructural facilities. That the country is becoming a hub for clinical trials is reflected from the fact that several MNCs are using India as a base for running their Phase II and Phase III clinical trials.

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".

6.20 When asked to give the details regarding policy initiatives for strengthening Research & Development in pharma sector, the Department in its written reply has stated as under:-

"In November 2011, Department has awarded assignment to Ernst & Young (E&Y) as Global Level Consultant for preparation of Detailed Project Report (DPR) for developing India as a Drug Discovery & Pharma Innovation Hub 2020. The assignment is in two phases. In Phase I, E&Y would submit DPR. This would help the Department in making appropriate policies, frame strategies and action plans for being a pro active facilitator to make India as the Drug Discovery & Pharma Innovation Hub 2020. The DPR is expected in six months time.

In Phase II, E&Y would submit implementation documents for actual implementation of each recommendation accepted by the Department in Phase I, which would inter alia require formulation of programmes/schemes for the implementation of recommendations made in DPR 2020 Report".

6.21 On being asked to state in details about the R&D activities/initiatives taken or likely to be taken by all the Pharma PSUs, the Department in its written reply has stated as under:-

"KAPL- KAPL has informed that the company is not engaged in basic Research and Development activities and does only formulation development of drugs.

RDPL- RDPL has informed that the company does not have any Research and Development Department/Activities till date due to huge investment involved. Hence RDPL does not have and has not initiated any R&D activities till date.

IDPL-IDPL has informed that the company does not undertaken any R&D activities presently dues to constraints of manpower and resources.

BCPL- BCPL has informed that the at the moment, BCPL does not have separate R&D Centers hence, the Company is taking the help of reputed institutions like Jadavpur University, IIT Kharagpur etc. for development of new products, improvement in production process etc. However, Government of India sanctioned Rs. 6.29 crore for setting up a GLP complaint Quality control Laboratory and Products Development Laboratory . The Project has been completed and initiative for obtaining accreditions from Statutory Authorities have been started. In the meantime, the company has developed and marketed quite a few Cephalosporin formulations during last two years.

HAL- HAL is sick company under BIFR. At the moment, HAL does not have any separate R&D centre".

REPORT

PART-II

OBSERVATIONS AND RECOMMENDATIONS

1. FIVE YEAR PLANS

The Committee note that out of an outlay of Rs.1396.17 crore for the Eleventh Five Year Plan (2007-12) for the Department of Pharmaceuticals, the budget allocation for the period is only Rs.741.76 crore, which is only about 53% of the total outlay for the Eleventh Five Year Plan. Hence, during the entire five years of the Eleventh Five Year Plan, the allocation sanctioned to the Department of Pharmaceuticals is much below than that approved by Planning Commission. The Committee fail to understand this mis-match between the overall outlay for the Plan period and the funds actually provided to the Department and want an explanation from the Department of Pharmaceuticals. The Committee is also of the view that the Planning Commission while approving the allocation, should also be realistic so that there may not be much difference between approved allocation and the allocation actually disbursed to the Department.

The Committee also observe that there is underutilization of funds by the Department which may be one of the reasons for getting lesser allocation. The Committee, therefore, recommend that the Department should improve its physical performance in order to have a semblance between financial allocation and physical performance. This would also help the Department in obtaining more funds as per the stipulations of Planning Commission.

The Committee also note that in its Mid-term Appraisal Report, the Planning Commission has recommended that the Pharmaceutical Research and Development Programme (PRDP), which has been pursued by Department of Science and Technology (DST), would be transferred to Department of Pharmaceuticals at the end of Eleventh Five Year Plan. However, the Committee note with regret that no allocation has been made for the PRDP in the Detailed Demands for Grants for the year 2012-13. As PRDP is a vital programme in the area of pharmaceutical research and development, the Committee recommend that the Department should make concerted efforts towards getting allocation for the scheme from the next financial year and implement the same to achieve the desired goals.

2. DEMANDS FOR GRANTS

The Committee note that the budgetary allocation of the Department of Pharmaceuticals for the year 2011-12 was Rs. 213 crore, and the same was drastically reduced to Rs. 116.08 crore at the RE stage. Even this amount could not be utilized fully as the actual utilisation during the year 2011-12 is Rs. 77.89 crore. The Committee also note that the Department has attributed this reduction in funds in the year 2011-12 to under-utilization of funds to the extent of Rs. 81.94 crore in respect of construction of new NIPER campuses (including that in Guwahati). Also, new schemes could not be introduced to the extent of Rs. 12.04 crore. In view of this, the Committee conclude that there is lack of planning and implementation deficit on the part of the Department and hence, Committee reiterate# that the implementation machinery of the needs to be geared up so that sanctioned funds are properly and timely used to achieve the avowed objectives of the Department.

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3. NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPER)

The Committee note that establishment of NIPERs is a significant effort towards development of quality human resource for the growth of pharmaceutical sector in India. However, the Committee is concerned that work relating to construction of new NIPER campuses could not be initiated in 2011-12 and hence, the funds allocated for the purpose could not be utilized. The Committee note that availability of land has been a serious impediment in establishment of new NIPERs. Further, the Committee is dismayed to note that despite of availability of land at Guwahati and Ahmedabad, the construction of campus has not been started in 2011-12. This shows lack of proper planning and effort on the part of the Department. The Committee desire that the construction work at Guwahati and Ahmedabad should start immediately and the Department of Pharmaceuticals should make all necessary efforts towards acquisition of lands at other four places namely, Hyderabad, Hajipur, Kolkata and Rae Bareli. The Committee desire to be apprised about the Department's effort towards acquisition of land for New NIPERs at the above four places and also progress in the construction of campuses for new NIPERs.

4. NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

The Committee note that the National Pharmaceutical Authority (NPPA) plays vital role in fixation/revision of price of 74 scheduled bulk drugs and formulation containing any of the scheduled drugs under the Drugs (Price Control) Order, 1995 as well as monitoring and enforcement of prices. NPPA also provides inputs to the government for policy formulation. During the Eleventh Five Year Plan period (2007-2012), NPPA had proposed five new schemes amounting to Rs. 49.95 crore. These schemes are (i) Building Robust and Responsive Statistical System for NPPA; (ii) Creation of NPPA Cells in States; (iii) Scheme for Interaction with States; (iv) Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium; and (v) Proposal for strengthening the existing Monitoring and Enforcement work. The Committee note that out of these five schemes, Building Robust and Responsive Statistical System for NPPA was already approved by the Planning Commission and implemented during the Eleventh Plan period and in-principle approval in respect of the scheme, Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium was given in February, 2011 and in the budget allocation for the year 2012-13, funds are allocated only for these two schemes. However, the Committee are unhappy to note that other three schemes of the NPPA namely, Creation of NPPA Cells in States; Scheme for Interaction with States and Proposal for strengthening the existing Monitoring and Enforcement work, are yet to get in-principle approval of the Planning Commission. Hence, the Committee can not but reiterate its earlier recommendation@ that the Department should take up the issue with Planning Commission and make all out effort towards getting in-principle approval for the these three schemes. The Committee also desire to be apprised about the outcomes achieved in case of two schemes namely, Building Robust and Responsive Statistical System for NPPA and Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium.

@ 19th Report on Demands for Grants 2011-12

5. FINALISATION OF PHARMACEUTICAL POLICY

The Committee note that at present the Drugs (Price Control) Order(DPCO), 1995 allows control of prices of 74 scheduled bulk drugs and formulations containing any of the scheduled drugs defined in First Schedule of DPCO. They are disturbed to note that initially the Government announced Pharmaceutical Policy 2002. Then, a draft National Pharmaceutical Policy was prepared which has not been finalized till date in spite of the repeated recommendations# of the Committee to finalise the same. Further, new Group of Ministers (GoM) is yet to give its recommendation on draft National Pharmaceutical Policy 2006. As apprised to the Committee, the Department of Pharmaceuticals has now prepared a new Draft National Pharmaceutical Pricing Policy 2011 (NPPP 2011) based on the criteria of essentiality and requirements as stipulated by Ministry of Health and Family Welfare. The Committee also note that the draft National Pharmaceutical Pricing Policy (NPPP)-2011 proposes to bring 348 essential drugs and medicines under National List of Essential Medicines (NLEM)-2011 and associated medicines under price control. The Committee were informed that the draft Policy NPPP-2011 will now be examined by the Group Of Ministers (GoM) on 25.04.2012 and the recommendations of the GoM will go to the Cabinet and the Cabinet in their wisdom will approve the policy.

The Committee hope that now the Department of Pharmaceuticals will not resort to dilly dallying tactics in finalizing the NPPP-2011 as done in the case of National Pharmaceutical Policy, which has been under consideration since 2002, so that common man can get the medicines at affordable prices.

Twentieth Report on Action Taken by the Government on the recommendations contained in the Seventh Report of the Committee (2005-06), Twenty-Fifth Report on Demands for Grants (2008-09) and First Report on Demands for Grants (2009-10).

6. AVAILABILITY AND AFFORDABILITY OF MEDICINES

The Committee also feel that there should not be much difference between the production price and sale prices of a medicine. For this purpose the Committee recommend that Department of Pharmaceuticals should have a tab on the production prices of medicines by different companies and ensure that its sale price do not exceed much beyond a reasonable rate. In such case, the Committee have their apprehension that some companies may resort to malpractices like projecting higher production cost. The Committee, therefore recommend Department of Pharmaceuticals to be cautious in this regard so as to curb the malpractice of gold plating by some of the companies.

7. REVIVAL OF INDIAN DRUGS AND PHARMACEUTICALS LIMITED (IDPL)

Indian Drugs and Pharmaceuticals Limited (IDPL), the largest Pharma Public Sector Undertaking, was formally declared sick in 1992. Regarding the revival process in respect of IDPL, the Committee note that though the draft Cabinet Note for revival of IDPL was already prepared, the Department requested Ernst & Young (E&Y) to re-assess the liabilities etc. of IDPL and now the Department is examining the report of E&Y to finalize the Cabinet Note. The same report of E&Y is also being examined by IDBI (Operating Agency) and the same may be considered simultaneously by Board for Industrial and Financial Reconstruction (BIFR) and the Ministry for taking early view in the matter. In view of this, the Committee strongly feel that the revival process in respect of IDPL is bogged down in the labyrinth of bureaucratic processes as two decades have passed since IDPL was formally declared sick. This shows nothing but the lackadaisical approach of the Department and other involved organizations towards this issue. In view of the sorry state of affairs regarding revival of IDPL, the Committee recommend that a time frame should be fixed, possibly in consultation with BIFR and other stake holders, so that responsibility can be fixed if the time frame is violated. The Committee desire to be appraised about further progress in this regard.

8. FOREIGN DIRECT INVESTMENT (FDI)

The Committee note that since April, 2004 to December, 2011, there has been 141 instances of Foreign Direct Investments (FDI) in various Indian Drug Manufacturing Companies. The Committee also note that after take over of many big domestic pharma companies like Ranbaxy etc. by Foreign Multi-National Companies (MNCs), there are apprehensions in some quarters that these take overs will not only have adverse impact on availability of medicines for common man at affordable prices but also affect the overall health care scenario in India. On the other hand, the Committee also notes that there is an urgent need for attracting foreign investments in the pharmaceutical sector, particularly in areas like new chemical entities reserve, bio-pharmaceuticals, inspection and certification infrastructure etc. In this context, the Department of Industrial Policy and Promotion (DIPP) Press Note No.3 (2011 series) dated 8.11.2011 which allows FDI up to 100% for brown field investment in pharmaceutical sectors, under government approval route is a temporary measure, as this would be reviewed after a period of six months. Committee feels that though there is need for attracting FDI in the Indian pharmaceutical sector, this should not be done at the cost of our national interest and country's capacity to produce life saving drugs at affordable prices should not be compromised. Therefore the Committee desire to be appraised about the impact of the current policy which allows 100% FDI for brown field investments in pharmaceutical sector under government approval route and also change in policy, if any, on FDI in pharmaceutical sector after the lapse of the stipulated six months period.

9. JAN AUSHADHI SCHEME

The Committee note that for success of the Jan Aushadhi Scheme, wide geographic and therauptic coverage is indispensable. Regarding the geographic coverage, so far, only 117 Jan Aushadhi Stores (JAS) are opened and the Business Plan of the Department proposes to open 612 Jan Ausadhi Stores(JAS) in the first phase. In the second phase, the proposal is to open at least 5 JAS in each of the 630 Districts of the country. The Committee feel that the plan of geographical expansion of JAS is rather slow and inadequate and hence, recommend that the Department should open JAS in a mission mode, in coordination with State governments. The Committee recommend that the Department should explore options like opening up of JAS through public private partnership and also individual entrepreneurs should also be encouraged to open JAS.

Regarding therauptic coverage, the Committee is unhappy to note that at present, only the medicines manufactured by the Central Pharma Public Sector Undertakings(CPSUs) are being sold at the existing JAS and as such, the range of medicines available at th JAS are limited. The Committee feel that this is one of the major weaknesses of the Jan Aushadhi Scheme. Hence, the Committee recommend that urgent steps should be taken by the Department to rope in State PSUs and private manufactures to increase the coverage of generic drugs at JAS.

10. RESEARCH AND DEVELOPMENT

The Committee note that innovative Research & Development is critical in the pharmaceutical industry. Particularly, New Drug Discovery Research (NDDR) is important yet expensive affair. The Committee also note that many Indian companies, often in collaboration with multi national pharma companies, are making significant effort in the area NDDR. However, as R&D, particularly NDDR is expensive, the Committee recommended that an interest free venture fund should be instituted to promote NDDR with India-specific focus. The Committee is worried to note that most of the pharma PSUs are not investing in R&D. The Committee desire that Department to develop a frame work for public-private partnership for R&D in Pharma Sector so that the pharma PSUs can collaborate with private sector, universities and research institutions in R&D work. The Committee note that the Department has awarded assignment to Ernst & Young (E&Y) as global level consultant for preparation of Detailed Project Report (DPR) for developing India as a Drug Discovery and Pharma Innovation Hub 2020. As the DPR is expected in six months, the Committee desire to be apprised about the recommendations in the DPR and action taken by the Department in this regard.

New Delhi
30 April, 2012
10 Vaisakha, 1934 (Saka)

Gopinath Munde
Chairman,
Standing Committee on
Chemicals and Fertilizers

ANNEXURE –I

(In Crores of Rupees)

MINISTRY OF CHEMICALS AND FERTILISERS

DEMAND NO. 8

Department of Pharmaceuticals

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

(In crores of Rupees)

	Major Head	Actual 2010-2011			Budget 2011-2012			Revised 2011-2012			Budget 2012-2013		
		Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
	Revenue	42.17	32.70	74.87	152.55	37.95	190.50	55.33	38.25	93.58	168.00	43.04	211.04
	Capital	*27.50*	...	*27.50*	*22.45*	*0.05*	*22.50*	*22.45*	*0.05*	*22.50*	*20.00*	*0.05*	*20.05*
	Total	**69.67**	**32.70**	**102.37**	**175.00**	**38.00**	**213.00**	**77.78**	**38.30**	**116.08**	**188.00**	**43.09**	**231.09**
1. Secretariat-Economic Services	3451	0.12	7.19	7.31	0.25	7.64	7.89	0.20	7.62	7.82	1.00	8.94	9.94
Industries													
Pharmaceutical Industries													
2. National Institute of Pharmaceuticals Education and Research (NIPER)	2852	30.65	20.64	51.29	108.08	24.23	132.31	35.86	24.77	60.63	75.20	27.55	102.75
3. National Pharmaceutical Pricing Authority (NPPA)	2852	0.38	4.86	5.24	2.40	5.88	8.28	2.05	5.81	7.86	4.00	6.35	10.35
4. Pharmaceutical Export Promotion Scheme (PEPS)	2852	...	0.01	0.01	...	0.20	0.20	...	0.05	0.05	...	0.20	0.20
5. Pharmaceuticals Promotion & Development Scheme (PPDS)	2852	0.69	...	0.69	2.00	...	2.00	1.00	...	1.00	2.00	...	2.00
6. Others	2852	10.33	...	10.33	22.32	...	22.32	8.44	...	8.44	67.00	...	67.00
Total-Pharmaceutical Industries		**42.05**	**25.51**	**67.56**	**134.80**	**30.31**	**165.11**	**47.35**	**30.63**	**77.98**	**148.20**	**34.10**	**182.30**
Total-Industries		**42.05**	**25.51**	**67.56**	**134.80**	**30.31**	**165.11**	**47.35**	**30.63**	**77.98**	**148.20**	**34.10**	**182.30**
7. Lumpsum provision for Project/Scheme for the benefit of the N.E. Region & Sikkim	2552	...	...	...	17.50	...	17.50	7.78	...	7.78	18.80	...	18.80
8. Non Plan Loans to Public Enterprises													
8.01 Smith Stainistreet Pharmaceuticals Ltd. (SSPL)	6857	...	...	...	...	0.01	0.01	...	0.01	0.01	...	0.01	0.01
8.02 Bengal Chemicals and Pharmaceuticals Ltd. (BCPL)	6857	...	...	...	...	0.01	0.01	...	0.01	0.01	...	0.01	0.01
8.03 Bengal Immunity Ltd. (BIL)	6857	...	...	...	...	0.01	0.01	...	0.01	0.01	...	0.01	0.01
8.04 Indian Drugs & Pharmaceuticals Ltd. (IDPL)	6857	...	...	...	...	0.01	0.01	...	0.01	0.01	...	0.01	0.01
8.05 Hindustan Antibiotics Ltd. (HAL)	6857	...	...	...	...	0.01	0.01	...	0.01	0.01	...	0.01	0.01
Total- Non Plan Loans to Public Enterprises		...	...	...	...	*0.05*	*0.05*	...	*0.05*	*0.05*	...	*0.05*	*0.05*
9. Investment in Public Enterprises	6857	27.50	...	27.50	22.45	...	22.45	22.45	...	22.45	20.00	...	20.00
Grand Total		***69.67***	***32.70***	***102.37***	***175.00***	***38.00***	***213.00***	***77.78***	***38.30***	***116.08***	***188.00***	***43.09***	***231.09***

	Head of Dev	Budget Support	IEBR	Total	Budget Support	IEBR	Total	Budget Support	IEBR	Total	Budget Support	IEBR	Total
B. Investment in Public Enterprises													
9.01 Hindustan Antibiotics Ltd. (HAL)	12857	2.50	...	2.50	6.85	...	6.85	6.85	...	6.85	3.00	...	3.00
9.02 Bengal Chemicals and Pharmaceuticals Ltd. (BCPL)	12857	25.00	...	25.00	0.60	...	0.60	0.60	...	0.60	2.00	...	2.00
9.03 Indian Drugs and Pharmaceuticals Ltd. (IDPL)	12857	...	...	...	10.00	...	10.00	10.00	...	10.00	15.00	...	15.00
9.04 Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL)	12857	...	...	...	5.00	...	5.00	5.00	...	5.00	...	...	...
Total		**27.50**	**...**	**27.50**	**22.45**	**...**	**22.45**	**22.45**	**...**	**22.45**	**20.00**	**...**	**20.00**
C. Plan Outlay													
1. Chemical and Pharmaceutical Industries	12857	69.55	...	69.55	157.25	...	157.25	69.80	...	69.80	168.20	...	168.20
2. Secretariat-Economic Services	13451	0.12	...	0.12	0.25	...	0.25	0.20	...	0.20	1.00	...	1.00
3. North Eastern Areas	22552	...	...	...	17.50	...	17.50	7.78	...	7.78	18.80	...	18.80
Total		**69.67**	**...**	**69.67**	**175.00**	**...**	**175.00**	**77.78**	**...**	**77.78**	**188.00**	**...**	**188.00**

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

2. **National Institute of Pharmaceutical Education & Research (NIPER):** This Project has been set up at S.A.S. Nagar (Mohali) near Chandigarh. The Institute seeks to promote excellence in the sphere of pharmaceutical education in India and to meet the current and future needs of the pharmaceutical sector in India. The provision includes Non-Plan support for day-to-day expenditure and Plan support for their ongoing Schemes and new Schemes in Pharmaceutical Education and Research as well as for 6 new NIPERs, one each at Ahmedabad, Hyderabad, Hajipur, Kolkata, Guwahati and Rae Bareli.

3. **National Pharmaceutical Pricing Authority (NPPA):** As a part of the new Drug Policy announced in 1994, an independent body of experts has been setup, which is responsible for price fixation/revision of drugs and formulations and other related matters. It also monitors the prices of decontrolled drugs and formulations and oversees the implementation of the provisions of Drugs (Price Control) Order. The Non-Plan budget provision is for the establishment expenses of the Authority and Plan support is for strengthening of the monitoring of the drug prices.

5. **Pharma Promotion and Development Scheme (PPDS):** The budget provision has been made with a view to ensure promotion of pharmaceuticals, by organizing various seminars, workshops etc.

6. **Others:** Various new schemes towards technical upgradation and R&D in the field of Pharmaceuticals are proposed to be undertaken during the 12th Plan, including Jan Aushadhi Scheme.

7. **Lump sum provision for North-Eastern Region & Sikkim:** The provision is for implementing projects/schemes for North Eastern Region and Sikkim.

9. **Investment in Public Enterprises:** Represents equity and loans to the Public Sector Enterprises.

9.01. **Hindustan Antibiotics Ltd. (HAL):** This was incorporated in 1954 with the objective of producing life saving drugs in the country and to reduce dependence on imports of such drugs. It has got three projects in Maharashtra, Karnataka and Manipur. The provision of₹ 3 crore is for the activities related to Voluntary Retirement Scheme (VRS) and upgradation of existing facilities.

9.02. **Bengal Chemicals & Pharmaceuticals Ltd. (BCPL):** The company has four manufacturing units one each at Maniktala at Kolkata, Panihati at 24 Parganas (North), West Bengal, Mumbai and Kanpur (U.P.). The company manufactures and markets a wide range of industrial chemicals, sulphuric acid, ferric alum, a large number of drugs and pharmaceuticals besides cosmetics and home products. The provision of ₹ 2 crore is for its many schemes like balancing equipments for tablets, capsules & ointments; Setting up of manufacturing facilities for Anti Rabbies Vaccine & Other Vaccine in doses form; setting up of manufacturing facilities of Aerosol Spray and metered dose inhaler; setting up of Ayurvedic Section etc.

9.03. **Indian Drugs & Pharmaceuticals Ltd. (IDPL):** Presently IDPL's rehabilitation plan is under consideraton and it is expected that the year 2012-13, the first year of 12th Five Year Plan will also be the 1st year of implementation of IDPL's revival plan. Proposed outlay of ₹ 15 crore is for the activities related to revival of IDPL.

ANNEXURE –II

MINUTES

MINUTES OF THE SIXTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2011-12)

The Committee sat on Thursday, the 12 April, 2012 from 1430 hrs. to 1545 hrs. in Committee Room - C, Parliament House Annexe, New Delhi.

Shri Dilipbhai Pandya - In the *Chair*

Members

Lok Sabha

2.	Shri Prabhatsinh Pratapsinh Chauhan
3.	Smt Paramjit Kaur Gulshan
4.	Shri Yashbant N.S. Laguri
5.	Shri Baidya Nath Prasad Mahato
6.	Shri Ashok Kumar Rawat
7.	Shri Raju Shetti
8.	Shri Adagooru Viswanath
9.	Shri Om Prakash Yadav
Rajya Sabha	
10.	Shri A.A. Jinnah
11.	Shri Brijlal Khabri
12.	Shri Parshottam Khodabhai Rupala
13.	Shri Raghunandan Sharma

SECRETARIAT

1.	Shri C. S. Joon	-	Joint Secretary
2.	Shri A.K. Srivastava	-	Additional Director
3.	Smt. Emma C. Barwa	-	Under Secretary

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

1.	Shri Dilsher Singh Kalha	Secretary, (Pharmaceuticals)
2.	Dr.Raja Shekhar Vundru	Joint Secretary
3.	Shri V. Rajagopalan	Additional Secretary & Financial Advisor (AS &FA)

4.	Shri P.K. Bishi	Deputy Director General (DDG)
5.	Shri Om Prakash	Member Secretary, National Pharmaceutical Pricing Authority (NPPA)

II. REPRESENTATIVES OF PSUs

1.	Shri Praveen Kumar	MD, Indian Drugs and Pharmaceuticals Ltd. (IDPL)
2.	Shri. M.K. Nagendra	CMD, Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL)

2. At the outset, owing to the absence of Chairman of the Committee, due to his sickness the Committee chose Shri Dilipbhai Pandya, a member of the Committee, to act as Chairman in accordance with Rule 258(3) of Rules of Procedure and Conduct of Business in Lok Sabha.

3. Thereafter, the officials of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) and the Public Sector Undertakings 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.

4. Then the officials of the Department and others introduced themselves. Thereafter, the Secretary, Department of Pharmaceuticals briefed the Committee about the subject 'Demands for Grants of the Department for the year 2012-13'.

5. During the discussion, the Chairman and members of the Committee raised some queries which were replied to 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. XXX XXX XXX XXX

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

The Committee then adjourned.

MINUTES

MINUTES OF THE EIGHTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2011-12)

The Committee sat on Friday, the 27 April, 2012 from 1530 hrs. to 1600 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

Shri A.A. Jinnah - ***Acting Chairman***

Members

Lok Sabha

2.	Shri K.D. Deshmukh
3.	Smt. Paramjit Kaur Gulshan
4.	Shri Baidya Nath Prasad Mahato
5.	Shri Sakti Mohan Malik
6.	Shri O.S. Manian
7.	Shri N. Peethambara Kurup
8.	Shri Ashok Kumar Rawat
9.	Shri Sivakumar alias Ritheesh
10.	Shri Raju Shetti
11.	Shri Om Prakash Yadav
Rajya Sabha	
12.	Shrimati Naznin Faruque
13.	Shri Dilipbhai Pandya

Secretariat

1.	Shri C. S. Joon	-	Joint Secretary
2.	Shri A.K. Srivastava	-	Additional Director
3.	Smt. Emma C. Barwa	-	Under Secretary

2. As the Chairman could not attend the sitting due to pre-occupation, the members chose Shri A.A. Jinnah, 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) XXX XXX XXX XXX

b) XXX XXX XXX XXX

c) Demands for Grants (2012-13) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals);

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

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

The Committee then adjourned