

# STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

### FIFTEENTH LOK SABHA

# MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS (2011-2012)

**NINETEENTH REPORT** 



# LOK SABHA SECRETARIAT NEW DELHI

August, 2011/ Sharvana 1933, (Saka)

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#### MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

# DEMANDS FOR GRANTS (2011-2012)

Presented to Lok Sabha on 04.08.2011

Laid in Rajya Sabha on 04.08.2011

# LOK SABHA SECRETARIAT NEW DELHI

August, 2011/ Sharvana 1933, (Saka)

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# COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

Shri (	Shri Gopinath Munde - Chairman MEMBERS LOK SABHA							
2	Smt. Susmita Bauri							
3	Shri Udayanraje Bhonsle							
4	Shri Prabhatsinh P. Chauhan							
5	Smt. Santosh Chowdhary							
6	Shri K.D. Deshmukh							
7	Adv. Ganeshrao Nagorao Dudhgaonkar							
8	Shri T.K.S. Elangovan							
9	Shri Madhu Koda							
10	Shri N. Peethambara Kurup							
11.	Shri Baidya Nath Prasad Mahato							
12	Shri Jagdambika Pal							
13	Shri Tapas Paul							
14	Shri Ponnam Prabhakar							
15	Shri Ashok Kumar Rawat							
16	Shri Suresh Kumar Shetkar							
17	Shri Ajit Singh							
18	Shri N. Chaluvaraya Swamy							
19	Shri Narendra Singh Tomar							
20	<sup>#</sup> Dr. Manda Jagannath							
21	Vacant							
	RAJYA SABHA							
22	Shri Silvius Condpan							
23	Smt. Naznin Faruque							
24	Shri A.A. Jinnah							
25	Shri Brijlal Khabri							
26	Prof. Anil Kumar Sahani							
27	Shri Raghunandan Sharma							
28	Dr. C.P. Thakur							
29	<sup>&amp;</sup> Shri Parshottam Khodabhai Rupala							
30	<sup>&amp;</sup> Shri Abani Roy							
31	<sup>&amp;</sup> Shri Biswajit Daimary							

#### **SECRETARIAT**

- Shri N. K. Sapra
   Shri Ashok Sarin
   Shri C.S.Joon
   Secretary
   Joint Secretary
   Director
- 4. Shri A.K.Srivastava Additional Director

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<sup>&</sup>amp; Nominated w.e.f. 21.09.2010

<sup>#</sup> Nominated w.e.f. 04.10.2010

#### INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2010-11) having been authorised by the Committee to present the Report on their behalf, present this Nineteenth Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2011-12.

- 2. The Committee examined the Demands for Grants pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2011-12 which were laid in Lok Sabha and Rajya Sabha on 11 March 2011.
- 3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 23 March 2011.
- 4. The Committee considered and adopted the Report at their sitting held on 18 July 2011.
- 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 2011-12 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 body of the Report.

New Delhi; 28 July, 2011 6 Shravana, 1933 (Saka) Gopinath Munde Chairman, Standing Committee on Chemicals and Fertilizers

#### **REPORT**

#### **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), <u>viz.</u> 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 are being 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.

#### **CHAPTER-II**

#### **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	200	7-08	200	8-09	2009	9-10	201	0-11	2011-12
			BE	BE RE E	BE	RE	BE	RE	BE	RE	BE
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
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
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
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
3	Other Ongoing Schemes	8.00	1.05	2.00	1.25	1.21	2.50	2.30	1.50	1.50	2.25
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
3.2	IT/Secretariat	0.50		0.50	0.25	0.21	0.50	0.30	0.25	0.25	0.25
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
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
4.2	New Niper Like Institutes	514.00	10.00	10.00	35.00	25.26	50.00	33.50	56.50		100.00
4.3	PEPS		1.00	1.00							
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
4.5	Strengthening of NPPA	60.00	10.00		10.00	0.00	1.65	0.60	0.49		2.00
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
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
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
4.9	New Schemes (to be introduced 2010-11)		1.02		0.00		20.00	7.00	25.00	1.71	12.04
	Total	1396.17	91.26	91.70	155.25	111.04	155.25	105.00	165.00	119.00	175.00

Note: The Planning Commission had approved Rs.1960 crore for various Plan Schemes of the then Department of Chemicals and Petrochemicals during the 11<sup>th</sup> plan period. Department of Pharmaceuticals was carved out therefrom in July 2008 and the amounts shown pertain to the relevant plan schemes in the pharmaceuticals sector being dealt with by the Department of Pharmaceuticals now.

2.2 As per Mid Term Appraisal of Eleventh Five Year Plan, out of Gross Budgetary Support (GBS) of Rs.1,396.2 crore, GBS to the tune of Rs.453.9 crore has been made in first four years

of Eleventh Plan. On being asked the reasons of such a lesser GBS in the first four years of Eleventh Plan, the Department in their written reply submitted as under:-

"Higher amounts under GBS were sought from Planning Commission in pending inprinciple approvals on various schemes. But Planning Commission did not accord approval on various schemes. The major allocation meant for the establishment of 6 New NIPER(s) also remained under utilized due to administrative reasons like acquiring suitable land in selected cities and procedural issue involving approval of Cabinet. Other schemes like setting up GLP compliant chemical/Biological Labs. and Large Animal Houses are being revamped".

#### **CHAPTER-III**

#### **DEMANDS FOR GRANTS FOR THE YEAR 2010-11**

3.1 The Ministry of Chemicals and Fertilizers presented to Parliament Demand No.8 on the Department of Pharmaceuticals on 11 March 2011. 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.

BUDGETARY ALLOCATIONS UNDER BOTH PLAN AND NON PLAN UNDER THE MAJOR HEAD AND THE CAPITAL HEAD DURING THE YEARS 2010- 2011 AND 2011-2012 ARE INDICATED BELOW:-

(Rs. in crore)

Major	Budget Estimates 2010-11			Revised Estimates 2010-11			Budget Estimates 2011-12		
Head	Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
Revenue	125.00	32.95	157.95	79.00	37.10	116.10	152.55	37.95	190.50
Capital	40.00	0.05	40. <i>0</i> 5	40.00	0.05	40. <i>0</i> 5	22.45	0.05	22.50
Total	165.00	33.00	198.00	119.00	37.15	156.15	175.00	38.00	213.00

The following statement showing the scheme-wise details of Plan outlays, physical and financial targets, achievement made with percentage, shortfall/excess, if any, with reasons in brief during the each Year of the 11<sup>th</sup> Plan has been submitted to the Committee :-

#### BE, RE and Actual Exp. (Plan) for 2008-09, 2009-10 and 2010-11 and BE 2011-12

(Rs. In Lakh)

		_ (NS. II EURI)									
		2008-09				2009-10			2010-11	2011-12	
S.No.	Head	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual upto 31.1.2011	BE
	Revenue										
1	Sectt.	25.00	21.00	21.00	50.00	30.00	25.56	25.00	25.00	5.00	25.00
2	NIPER	7500	6526.00	6846.00	5747.00	4715.00	5765.00	6100.00	4718.00	2795.00	10808.00
3	NPPA	1150	92.00	38.22	225.00	85.00	7.78	99.00	70.00	0.00	240.00
4	PEPS	3750	2365.00	1050.00	4750.00	1980.00	1855.00	4501.00	1772.00	288.00	2232.00
5	PPDS	100	100.00	184.86	200.00	200.00	87.26	125.00	125.00	63.00	200.00
6	NE Region			0.00	1553.00	1050.00	0	1650.00	1190.00	0	1750.00
7	HAL	0	0	615.00							
8	IDPL			200.00							
	Total Revenue	12525.00	9104.00	8955.08	12525.00	8060.00	7740.60	12500.00	7900.00	3151.00	15255.00
	Capital										
9	HAL				2000.00	950.00		1500.00	1500.00	250.00	685.00
10	BCPL	3000	2000	2000.00	1000.00	1490.00	2440.00	2500.00	2500.00	2000.00	60.00
11	BIL										
12	IDPL										1000.00
13	SSPL										
14	RDPL										500.00
	Total Capital	3000.00	2000.00	2000.00	3000.00	2440.00	2440.00	4000.00	4000.00	2250.00	2245.00
	Total	15525.00	11104.00	10955.08	15525.00	10500.00	10180.60	16500.00	11900.00	5401.00	17500.00

3.2 According to the Department during the year 2009-10 out of an amount of Rs.76.09 crore could be spent till 31 January 2010. But by the end of financial year Rs.101.8 crore was spent.

Clarifying under-utilization of funds during the year 2010-11 the Department in a written reply submitted as under:-

"The under utilization is mainly due to the following reasons:

- a) The various infrastructural development activities of new NIPERs could not be started for want of various procedural requirements like allotment of land, appointment of consultant, apraisal of EFC, approval of Cabinet etc.
- b) The New Schemes for which an allocation of Rs. 25.00 crore was made, also could not get final approval.
- c) HAL could not draw funds for upgradation of fermentation facilities for manufacturing of Erythromycin Thiocynate due to delay in technology tie up.
- d) Funds earmarked for setting up GLP Compliant Chemical and Biological Labs and GLP compliant Large Animal House in PPP mode could not be released. The Department is now redrawing the schemes. EOI has been published in the Economic Times and Times of India on 12.3.2011 inviting applications for appointment of consultant."
- 3.3 On being asked to give reasons for non-utilisation of funds earmarked for North-Eastern Region while incurring the actual expenditure during the years 2009-10 and 2010-11, the Department in its written note submitted as under:-

"In 2009-10, the entire RE allocation of Rs.10.50 crore was released to NIPER, Guwahati for infrastructural development. During 2010-11, as against the allocation of Rs.16.50 crore, since reduced to Rs 11.90 crore during RE 2010-11, only an amount of Rs.1.00 crore was released to NIPER, Guwahati. EFC has already appraised the Phase-I of the Scheme of New NIPER(s) and the actual expenditure shall increase considerably after the Cabinet approval".

3.4 A statement indicating the Major Heads under the Demand No.8 and Budget Estimates (BE) 2011-12 (Plan and Non-Plan) for each of the Heads is as under:-

(Rs. In crore)

SI.No.	Major Head	Item	BE 2011-12
1.	3451	Secretariat Economic Services	7.89
2.	2552	North-Eastern Areas	17.50
3.	2852	Pharmaceutical industries	165.11
4.	4857	Capital outlay on pharmaceutical industries	00.00
5.	6857	Drugs and pharmaceutical industries	22.50
		Total	213.00

#### **CHAPTER-IV**

### **HEAD-WISE ANALYSIS OF DEMANDS FOR GRANTS (2011-12)**

#### A. MAJOR HEAD 3451

#### Secretariat – Economic Services

Total Allocation for the year 2011-12 is Rs.7.89 crore as indicated below:-

(Rs.in crore)

BE			RE	BE		
20	2010-11		2010-11		11-12	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan	
0.25	7.34	0.25	7.45	0.25	7.64	

4.1 On being asked by the Committee as to how the total allocation of Rs.7.89 crore would be utilized, the Department in its reply stated that Rs.0.25 crore under Plan *is* for *I*nformation Technology and Rs.7.64 crore for salary and related expenditure of the employees of the Department.

#### B. MAJOR HEAD -2552

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

Total allocation for the year 2011-12 under this head is Rs.17.50 crore which is given below:-

(Rs.in crore)

				(	
BE	2010-11	-11 RE 2010-11		BE 2	011-12
Plan	Non-Plan	Plan Non-Plan		Plan	Non-Plan
16.50		11.90		17.50	

4.2 On being asked as to how the Government propose to utilize the amount of Rs.17.50 crore during the current year 2011-12, the Department stated as follows:-

"The Government propose to utilize the amount during 2011-12 for core construction and developmental activities of NIPER, Guwahati. Further, the recurring expenditure of NIPER (Guwahati) would also met from this head".

#### C. MAJOR HEAD 2852

#### **Pharmaceutical industries**

Total allocation for the year 2011-12 under this head is Rs.165.11 crore as indicated below:-

(Rs.in crore)

				<b>\</b> -	,
BE	BE 2010-11		0-11 RE 2010-11		011-12
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
108.25	25.61	66.85	29.65	134.80	30.31

4.3 The Committee have been informed that the above allocation also includes the allocations made for (i) National Institute of Pharmaceutical Education Research (NIPER), (ii) National Pharmaceutical Pricing Authority (NPPA) (iii) Pharmaceuticals Promotion and Development Scheme (PPDPS) (iv) Pharmaceutical Export Promotion Scheme (PEPS) and (v) others (New Schemes). The details of the various schemes are given in the succeeding paragraphs:-

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

#### Establishment of NIPER, SAS Nagar

4.4 In 1991, National Institute of Pharmaceutical Education and Research (NIPER), Mohali was established as a Society under the Societies Registration Act, 1860. NIPER, Mohali was established as an Autonomous Institution in June 1998 by an Act of Parliament. This Institute has been created as a Centre of Excellence for higher training, research and development in pharmaceutical science and technology and to impart degrees in MS (Pharm)/ M. Pharm./ M.Tech. (Pharm), MBA(Pharm) and Ph.D. The structuring of curricula is unique having interdisciplinary research approach.

#### Objectives of NIPER, MOHALI

- Human resource development
- Advanced research in new and emerging areas
- National/ International collaborative research
- Sponsored projects
- Media and curriculum development
- Establishment of National Centres
- Promotion of community and institutional Pharmacy
- Study of sociological aspects of drug use/ abuse

#### Establishment of New NIPERs

4.5 The Cabinet granted in-principle approval to the setting up of six new NIPERs at Hajipur, Hyderabad, Ahmedabad, Rae Bareli, Guwahati and Kolkata in terms of the amended NIPER Act, 1998. These New NIPERs will cater to the growing demand of the pharmaceutical industry for highly trained man power for continuous growth of the pharmaceuticals sector. At present, new NIPERs are functioning with the assistance of the Mentor Institutes.

#### Starting of classes at New NIPERs

4.6 Pursuant to the approval of the Cabinet in respect of setting up of six new NIPERs, classes were started from the academic Session 2007-08 with the help of Mentor Institutes at Ahmedabad, Hyderabad, Kolkata and Hajipur. The classes were started at NIPER, Guwahati and Rae Bareli in the year 2008-09.

The Committee on Chemicals and Fertilizers in their Seventh Report (15<sup>th</sup> Lok Sabha) pertaining to Demands for Grants 2010-11 had <u>inter-alia</u> recommended that all the six NIPERs should become fully functional by April 2011.

#### Status of Infrastructural work in new NIPERs

- In August 2007, the Union Cabinet accorded in-principle approval to the setting up of new NIPERs and commencement of courses with the help of Mentor Institutes. Expenditure Finance Committee (EFC) at its meeting held on 20.1.2011 has since appraised the Detailed Project Reports (DPRs) submitted by the consultant and approved the setting up of New NIPERs in Phase-I. Estimated capital cost of Rs.633.15 crore and recurring cost of Rs.116.52 crore (net of receipt) is subject to availability of suitable land at six locations. A proposal is, accordingly being placed before the Cabinet for establishment of new NIPERs.
- 4.8 When asked about the status of acquisition of land for each new NIPER in order to save further loss of time from the concerned State Governments, the Department in its reply stated as under:-

"Government of Gujarat has already allotted land at Gandhinagar and executed lease deed in favour of NIPER.

At Guwahati, the State Government has allotted 100 acres of land. However, the land is yet to be (i) demarcated, (ii) approach road to the site provided and (iii) lease deed to be executed. This is being pursued with the State Government of Assam.

At Kolkata, the land allotted is inadequate and also under development by the State Government Agency. State Government has since been requested for allotment of at least 50 acres of land on priority so as to commence construction of new NIPER Campus.

Similarly, State Government of Bihar has been requested to allot 50 acres of land at Hajipur on priority basis so as to plan and commence construction of NIPER Campus. The matter is being discussed further with State Government officials.

The issue of allotment of land by UP Government for NIPER, Rae Bareli has been taken up again with the State Government.

In case of Andhra Pradesh, it is proposed to discuss the matter with the State Government of Andhra Pradesh for allotment of land for NIPER at any place in Hyderabad, other than IDPL land."

4.9 The Secretary, Department of Pharmaceuticals during the course of evidence submitted as under:-

"------ for our programme of opening six new NIPERs, the EFC meeting has taken place; the plan is in order. We simply have to go to the Cabinet now and get its approval. Once the Cabinet approval is there, we will immediately start construction from next year onward. It may take two to three years to do the construction because these are big campuses. We have got the financial provisions for the next year and we will get the funding in the next plan."

Total allocation to NIPERs for the year 2011-12 is Rs.132.31 crore as indicated below:-

/Re	in	crore)	١
(NS.	. 11 1	CIOLE	,

20	BE 2010-11		RE 0-11	BE 2011-12		
Plan	Non-Plan	Plan	Non-Plan	Plan Non-Pla		
61.00	61.00 19.04		24.04	108.08	24.23	

4.10 About the reasons for increase in allocation of Plan and Non-Plan for BE 2011-12 from RE 2010-11 for NIPERs, the Department in a written reply informed the Committee as under:-

"In 2011-12, Rs 125.58 crore has been provided for all NIPERs against the allocation of Rs 59.08 crore at RE 2010-11. The increased allocation is justified to provide for planning and commencement for construction of campuses for new NIPERs.

As regards non-Plan, the allocation of Rs 19.04 crore in BE 2010-11 was made for NIPER, Mohali. But this did not meet the annual requirement of the Institute. At RE 2010-11, additional requirement of Rs 5.00 crore has been projected by NIPER, Mohali. Considering the requirement of funds in 2010-11, requirement of funds to the tune of Rs 27 crore was projected for 2011-12, but the actual allocation has been Rs 24.23 crore only."

#### (II) National Pharmaceutical Pricing Authority (NPPA)

4.11 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:

- (i) To implement and enforce the provisions of the Drugs (Price Control) Order (DPCO), 1995 in accordance with the power delegated to it.
- (ii) To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
- (iii) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- (iv) To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.
- (v) To deal with all legal matters arising out of the decisions of the Authority
- (vi) To render advice to the Central Government of changes/revisions in the drug policy.
- (vii) To render assistance to the Central Government in parliamentary matters relating to drug pricing.

The total Budget allocation to NPPA for the year 2011-12 is Rs.8.28 crore as given below:-

	(Rs.in crore)						
BE		RE		BE			
2010-11		2010-11		2011-12			
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan		
0.99	6.07	0.70	5.41	2.40	5.88		

4.12 When the Committee desired to know the reasons for increase in allocation in BE under the head Plan funds from 2010-11 to 2011-12, the Department in a written reply stated as under:-

"NPPA had earlier submitted 5 new plan schemes to the Planning Commission in 2007 for the current 11th five year plan amounting to Rs. 49.95 crore as per the details given below:-

SI.	Scheme	Amount
No.		(Rupee in lakh)
1.	Building Robust and Responsive Statistical	215
	System for NPPA	
2.	Creation of NPPA Cells in States	2638
3.	Scheme for Interaction with States	152
4.	Proposal for Consumer Awareness and Publicity	1828
	through Print, electronic and other medium	
5.	Proposal for strengthening the existing Monitoring	162.60
	and Enforcement work	
	Total	4995.60

- 4.13 Out of above five schemes Planning Commission has initially accorded in principle approval for the scheme at S. No. 1, i.e. Building Robust and Responsive Statistical System for NPPA in March 2008. Planning Commission has further conveyed its "in principle approval" for the scheme at S. No.4, i.e. "Proposal for Consumer Awareness and Publicity through Print, electronic and other medium" on 29.10.2010. Efforts are being made to expedite 'in principle approval' from the Planning Commission for the remaining three schemes at (S.No..2, 3 and 5 in the Table given below the succeeding paragraph), viz. Creation of NPPA Cells in States, Scheme for Interaction with States and Proposal for strengthening the existing Monitoring and Enforcement work.
- 4.14 It has been further submitted by the Department that budget allocation of Rs.240.00 lakh (2.4 crore) has been made for the year 2011-12 as Planning Commission is actively considering these remaining schemes for according its 'in principle approval'. The Scheme-wise allocation of the funds for the year 2011-12 is as under:-

SI. No.	Scheme	Amount (Rupee in lakh)
1.	On-going Scheme of Computerization of NPPA	40
	Other Plan Schemes	
1.	Building Robust and Responsive Statistical System for NPPA	30
2.	Creation of NPPA Cells in States	60
3.	Scheme for Interaction with States	15
4.	Proposal for Consumer Awareness and Publicity	75
	through Print, electronic and other medium	
5.	Proposal for strengthening the existing Monitoring and Enforcement work	20
	Total	240

#### (iii) Pharmaceutical Promotion and Development Scheme (PPDS)

Total allocation for the year 2011-12 is Rs.2.00 crore

(Rs.in crore)

BE		RE		BE	
2010-11		2010-11		2011-12	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
1.25		1.25		2.00	

4.15 When asked to give reason for increased allocation of Rs. 75 lakh as compared to RE 2010-11 to be utilized during the year 2011-12, the Department stated as under:-

"There is an increase of only Rs 75 lakh in the PPDS plan allocation. 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 follows:-

- (i) Activities for the Pharma sector by promoting seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ Consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector.
- (ii) All miscellaneous activities relating to promotion of Pharma sector for production, exports and investments.
- 4.16 When asked to furnish the details of achievements made by this Scheme, the Department stated as under:-

"The scheme titled "Pharmaceutical Promotion and Development Scheme (PPDS)" is being operated in the Department of Pharmaceuticals for which a sum of Rs. 1.25 crore was allocated in RE - 2010-11. Through this scheme, various seminars, studies etc. were conducted which helped the domestic pharmaceuticals industry especially the small scale sector to cope up with the challenges of the multinational companies of developed countries. This scheme has helped in the growth of Indian Pharmaceuticals industry including the export of pharmaceuticals which has grown from Rs. 6,256 crore in 1998-99 to Rs. 42,154 crore in 2009-10".

#### (iv) Pharmaceutical Export and Promotion Scheme

Total Allocation for the year 2011-12 is Rs.0.20 crore.

(Rs.in crore)

BE		RE		BE		
20	2010-11		2010-11		2011-12	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan	
	0.50		0.20		0.20	

- 4.17 When asked about the reasons for decrease in Non-Plan allocation during the year 2011-12 as compared to Non-Plan allocation for the year 2010-11, the Department, in reply stated that Funds to the tune of Rs. 0.50 crore were projected by this Department for allocation in the BE 2011- 2012. However, the Ministry of Finance has restricted the same at the RE 2010-11 to Rs. 0.20 crore".
- 4.18 On being asked to give the details of the achievements made by this scheme, the Department in its written note submitted as under:-

"The PEPS under Non-Plan is an 'Other Administrative Expenditure' (OAE) head and expenditure pertains to any administrative expenditure pertaining to the plan schemes under PEPS, thus showing less requirement under 2011-12.

Through various Schemes like PEPS, some seminars/studies etc. were conducted which helped the domestic pharmaceuticals industry especially the small scale sector to cope with the challenges of the multinational companies of developed countries. This scheme has helped in the growth of Indian Pharmaceuticals industry including the exports of pharmaceuticals which has grown from Rs. 6,256 crore in 1998-99 to Rs. 42,154 crore in 2009-10".

#### (v) Others

Total allocation for the year 2011-12 is Rs.22.32 crore as indicated in the following Table:-

(Rs.in crore)

BE		RE		BE	
2010-11		2010-11		2011-12	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
45.01		17.72		22.32	

#### **New Schemes for Pharmaceuticals**

4.19 As per the outcome budget 2011-2012, following new schemes have been launched:-

#### **New Schemes for NIPER, Mohali**

Rs. 8.62 crore has been allocated in 2011-12 BE (Plan) for NIPER, Mohali towards its New Research Schemes in the field of pharmaceuticals as well as for several new schemes for infrastructural development like hostel, residence etc.

#### **New NIPER like Institutes**

The Union Government has approved setting up of 6 New NIPER (National Institute for Pharmaceutical Education and Research) like Institutes - one each at Ahmedabad (Gujarat), Hyderabad (Andhra Pradesh), Hajipur (Bihar), Kolkata (West Bengal), Guwahati (Assam) and Rae Bareli (Uttar Pradesh) during the 11<sup>th</sup> Plan. Classes in all the six new NIPERs have been started with the help of local Mentor Institutes from the academic session of 2008-09. An allocation of Rs. 82.50 crore in 2011-12 BE (Plan) for this purpose has been made for new NIPERs excepting NIPER, Guwahati. For NIPER, Guwahati requirement would be met out of available provisions for North-East to the tune of Rs.17.50 crore.

#### Interest Subsidy for SMEs for Schedule 'M' compliance

To keep pace with the development of Pharmaceutical Industry in the developed countries, Schedule 'M' to the Drugs and Cosmetics Rules- 1945 relating to Good Manufacturing Practices, were amended in 2004. To aid manufacturers, especially in the Small Scale Sector, to comply with Schedule 'M' provisions, Interest Subsidy for these small units was proposed. This scheme has since been tweaked with CLCSS being implemented by O/o Development Commissioner, Ministry of Micro Small and Medium Enterprises (MSME).

#### Strengthening of NPPA

For the current 11<sup>th</sup> Five year plan period 2007-08 to 2011-12, NPPA submitted five new schemes to the Planning Commission/Department with an outlay of Rs 49.96 crore. These schemes were designed to strengthen NPPA and help it in discharging its mandate in an effective manner. However, only one scheme titled "Proposal for Building Robust and Responsive Statistical System for NPPA" with an outlay of Rs 2.15 crore was approved. The new scheme titled "Proposal for Building Robust and Responsive Statistical System for NPPA" started in 2007-08 will continue. For the current financial year 2011-12, an outlay of Rs. 2.00 crore has been provisioned.

#### Creation of IPR facilitation centre at Pharmaexcil

A provision of Rs. 0.50 crore has been made for creation of IPR facilitation centre.

#### Critical assistance for WHO pre-qualification for pharma PSUs/RandD

Rs. 6.28 crore has been allocated for upgradation of manufacturing facilities in the Pharma PSUs conforming to WHO-GMP standards so as to enable them to focus on exports at global level.

4.20 When asked about the progress made in these schemes, the Department of Pharmaceuticals in their written reply has stated as under:-

The progress in the New Schemes of Pharma is as follows:

- a) For Creation of IPR Facilitation Centre, Rs 50 lakh has been allocated in 2011-12. The progress so far includes Facilitation Centres already opened at Mohali and Hyderabad for assisting the industry in export related issues and procedures.
- b) For Critical Assistance for WHO pre- qualification, Rs 6.28 crore has been allocated in 2011-12. Rs 33.53 crore has been released till 14.3.2011, out of which, Rs 22.79 crore has been released to HAL for compliance in Tablet, Capsule and Liquid Sections, and also for Erithromycin Thiocyanate, Rs 6.29 crore has been released to BCPL for QC labs, Rs 4.45 crore has been released to IDPL for GMP compliance of its various units.

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#### **Loans for Pharma Industries**

- 4.21 The Department has 5 running PSUs under its administrative control, <u>viz</u>. Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs and 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 process, Government of India has since approved rehabilitation schemes for revival of HAL and BCPL. The rehabilitation scheme of IDPL is under consideration.
- 4.22 Apart from these PSUs, there are two closed PSUs namely, Bengal Immunity Limited (BIL), Kolkata and Smith Stanistreet Pharmaceuticals Limited (SSPL), Kolkata and two Joint Ventures of HAL namely Maharashtra Antibiotics and Pharmaceuticals Limited (MAPL), Nagpur and Manipur State Drugs and Pharmaceuticals Limited (MSDPL), Imphal and one Joint Venture of IDPL namely, Orissa Drugs and Chemicals Limited (ODCL). All these Joint Ventures are loss making and closed.

4.23 Further, in the interest of continued growth and development of KAPL and RDPL, on 2 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. 1 October 2009. Similarly, transfer of shares from IDPL to the President of India has been effected in the books of RDPL w.e.f. 17 August 2010.

Loan given to Public Sector Pharma Industries for the year 2011-12 is Rs.22.50 crore as indicated below:-

(Rs.in crore)

BE		RE		BE	
2010-11		2010-11		2011-12	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
40.00	0.05	40.00	0.05	22.45	0.05

#### Bengal Chemcals and Pharmaceuticals Limited (BCPL) (a)

- 4.24 BCPL is 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, the Company was taken over by the Government and it was nationalized on 15 December 1980. A new public sector company in the name and style of Bengal Chemicals and Pharmaceuticals Limited (BCPL) was incorporated on 17 March 1981.
- 4.25 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). 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 guite popular.
- 4.26 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 14 January 1993. The main factors responsible, as identified by BIFR for continuous loss by BCPL since 1980 are as follows:-
  - (i) Poor condition of the plants:- This is due to:-
    - Schedule 'M' partially implemented in Maniktala and Kanpur
    - Plants are almost fully depreciated -Book value less then Rs. 5 crore

- Huge repair and maintenance cost being incurred
- Immediate renovation of building and machinery required
- (ii) Inefficiency in operation-
  - Plant capacity under utilized
  - High cost of raw material due to inefficient sourcing of raw material
  - Over staffing- High cost extra employees force.
- (iii) Inadequate marketing set up
  - Marketing set up of the Company is limited to regional markets- East.
  - Sales are mainly based on Government orders and tenders and institutional supply and leading to lack of production, planning and inventory management.
  - Huge discounts are offered to promote sales in terms of Government and trade discounts.
  - No focus on retail markets and lack of field force set up.
  - Distribution network not aligned to market requirements, operation mainly through depots.
  - Negligible advertising spending.
- 4.27 On being asked the reasons for continuous loss of BCPL since 1980 in spite of the fact that many measures have been taken by the Government for rehabilitation and whether any targets have been fixed for its profit making, the Secretary, Department of Pharmaceuticals stated that there were many ups and downs and there was some delay in execution orders, plant machinery etc. and presently delay is due to stay by Kolkata High Court on the construction of new facility.
- 4.28 As the Company incurred continued losses since 1980, a Revival Package was accordingly prepared and approved by the BIFR on 4 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.
- 4.29 Finally, based on the requirements for modernization of plants and 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.
- 4.30 The recommendations of BRPSE were confirmed by the Cabinet Committee on Economic Affairs (CCEA) which approved the BRPSE Scheme in its meeting held on 21 December 2006. The Revival Scheme include interalia:-
- (i) Cash infusion by GOI 207.19 crore
- (ii) Write off/Waiver of

Loans/Interest - 233.41 crore

4.31 Parliament has approved writing off the GOI loans and interest of Rs. 233.41 crore Rs.201.59 crore have since been released by the Government out of Rs. 207.19 crore cash infusion component. The company has appointed Consultants for undertaking the work of upgradation and modernization of plant and machinery including compliance with Schedule 'M'/WHO GMP standard. The work has since commenced at Maniktala, Panihati and Kanpur and would be completed by end of Financial Year 2010-11.

Loans given to BCPL for the year 2011-12 are as under:-

(Rs.in crore)					rcrore)
BE 2010 11		RE		BE	
2010-11		2010-11		2011-12	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
25.00	0.01	25.00	0.01	0.60	0.01

#### (b) <u>HINDUSTAN ANTIBIOTICS LIMITED (HAL)</u>

- 4.32 Hindustan Antibiotics Ltd. (HAL), Pimpri, Pune was incorporated on 30 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 and Pharmaceuticals Ltd. (MAPL) at Nagpur (Maharashtra-since closed) and Manipur State Drugs and Pharmaceuticals Ltd. (MSDPL) at Imphal (Manipur-since closed). Karnataka Antibiotics and 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.
- 4.33 After establishment, the company made profits for several years. However, the company started incurring continuous losses since 1993-94. The following reasons have been attributed for the continuous losses made by the Company:-
  - "(I) <u>Strategic issues</u> HAL was originally established for the production of basic bulk drugs like Penicillin, Gentamycin, Streptomycin etc. with an objective of making the life saving drugs available at affordable price and, therefore, making profits was not the objective of the Company. The working of the Company was quite normal till 1972 when war in Gulf Region started. Consequent to increase in oil prices, the energy cost which constitutes a major part of its expenditure doubled but the Government did not allow the Company to increase the price of Penicillin, being common man's drug. Consequently, the Company had to borrow money from the Government as well as from Financial Institutions at high interest rates. The high interest burden affected the Company's operations adversely. Although the Company requested the Government for waiver of loans and interest accumulated thereon, the Government agreed only for restructuring loans by converting accumulated interest into further loans.

(II) <u>Organisational / Management issues</u> - The organisational set-up of HAL has inherent problems like other Public Sector Undertakings in which the focus is more procedural oriented rather than result oriented. The inability of the Company to attract the best talent in the market due to low compensation package compared to its competitors has also affected its managerial effectiveness.

#### (III) Operational issues:-

- (a) The Company is engaged mainly in low value, low margin products in which it has to face cut throat competition from small scale units as well as private sector companies and due to inherent cost disadvantage, being a public sector undertaking, the operational viability of the Company was getting affected.
- (b) After discontinuation of the financial support by the Govt. of India since liberalisation of the economy, the Company had to resort to borrowings from outside at heavy interest rate which substantially increased the interest burden of the Company.
- (c) For the purpose of exporting formulation drugs of the Company, the Company's plants have to be continuously upgraded to meet the required GMP standard and since this requires heavy capital investment on regular basis, due to lack of financial support from the Govt. of India, the Company could not make the required capital investments leading to the competitive disadvantage to the Company.
- (d) The working capital cycle of the Company was affected because of financial difficulties. The Company could not procure the raw materials at competitive price due to shortage of working capital leading to high cost of production and, subsequently, pressure on the profit margin of the Company's products. The delay in payment from the Govt. Institutions and Hospitals causes further cash flow problems to the Company

#### (IV) <u>Marketing issues</u>:-

- (a) As explained above, the Company has been originally concentrating on the Govt. Institutions/Hospital business for the purpose of marketing its products. As long as there was price preference for the public sector undertakings in the Govt. purchases and the budgetary support was given by the Govt. of India, the Company could keep its marketing operations going without any difficulties. However, after liberalisation, the Govt. withdrew the purchase and price preference to the Company's products and also stopped the budgetary support to the Company. This situation made the marketing of the Company's products difficult due to its comparative higher costs and the severe competition from the private sector companies.
- (b) Subsequent to liberalisation of the economy, the Company tried to enter into prescription market for its products. However, in this segment the private sector companies are already dominant and they have also built-up strong brands which the company was not able to do in the past. The performance in this segment is, therefore, a time consuming exercise. The marketing cost of the Company's products was also comparatively higher because of high establishment expenses, distribution cost and commission to the intermediaries.
- (c) Efficiency of the marketing staff was also comparatively low because of inherent job security to the field staff and inadequate incentive for the better performance of the field staff.

- (d) The Company's capacity to introduce new products at regular intervals was also limited due to inability to internally develop the new products as per the requirement of the market due to financial constraints.
- (V) Technology and market access issues:- The Penicillin Plant of the Company was leased to HMGB, a Joint Venture Company between HAL and DSM Anti-Infectives India (DAI India), in 1995 by which the latest Penicillin Technology was inducted and the production level was raised from 800 MMU p.a. to 2400 MMU p.a. with substantial reduction in the cost of production. However, the operations of the Joint Venture were required to be closed because of the Govt. decision to remove Penicillin G from the negative list of import and allowing the import of the same under OGL. As a result, the imported Penicillin G dumped by countries like China in India almost killed the Penicillin industry in India as none of the Penicillin producers could compete with the imported Penicillin. The Company was heavily dependent on the lease rent and income from utilities and services provided to HMGB and since the operations of HMGB were closed in December 2003, its cash flow has been severely affected. Some immediate measures are required to be taken by the Govt. to avoid the dumping of Penicillin in India by outside countries so as to enable the domestic Penicillin industry to survive and compete in the Indian market".
- 4.34 As the company started incurring continuous losses since 1993-94 the company was referred to 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.

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:-

S. No.	Particulars	Amount (in crore)
1.	Cash infusion	Rs.137.59*
2.	Write off/exemptions from Government of India	Rs.267.57
ა.	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.)

4.35 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.

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

Loans given to HAL for the year 2011-12 are as under:-

(Rs.in crore)

BE	BE 2010-11 RE 2010-11		BE 2010-11		BE 2	011-12
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan	
15.00	0.01	15.00	0.01	6.85	0.01	

#### (c) INDIAN DRUGS AND PHARMACEUTICALS LIMITED (IDPL)

- 4.37 Indian Drugs and Pharmaceuticals Limited (IDPL) was incorporated on 5 April 1961 with the primary objective of creating self sufficiency in essential life saving drugs and medicines. The Company has presently three manufacturing Plants, one each at Rishikesh (Uttarakhand), Hyderabad (Andhra Pradesh) and Gurgaon (Haryana). IDPL has two wholly owned Subsidiaries, namely, IDPL (Tamil Nadu) Ltd., Chennai (Tamil Nadu) and Bihar Drugs and Organic Chemicals Ltd. at Muzaffarpur (Bihar). In addition, IDPL had earlier two joint sector undertakings, promoted in collaboration with the respective State Governments. These are Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL), Jaipur, and Orissa Drugs and Chemicals Ltd. (ODCL), Bhubaneshwar. However, after decision of Government to de-link RDPL from IDPL, now RDPL is a Central Joint Venture PSU.
- 4.38 IDPL was formally declared sick by the Board for Industrial and Financial Reconstruction (BIFR) on 12 August 1992. A revival package for the company was formulated and approved by BIFR on 10 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 later on, 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.
- 4.39 However, given the possibility of revival of the Company, Department of Chemicals and Petrochemicals filed an appeal against the order of BIFR in Appellate Authority for Industrial and Financial Reconstruction (AAIFR) on 10.2.2004. AAIFR in its hearing held on 13.9.2005 set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL.

- 4.40 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.
- 4.41 Accordingly, in a meeting held under the Chairmanship of the then Minister (Chemicals and Fertilizers) it was decided to revive all the five units of IDPL in a phased manner and a Draft Rehabilitation Scheme was prepared for revival of the Company. The Board for Reconstruction of Public Sector Enterprises (BRPSE) in its meeting held on 9 March 2007, recommended the scheme for approval of the Government.
- 4.42 The scheme was placed before the Cabinet for approval. The Cabinet considered the proposal at its meeting held on 17.5.2007 and referred it to GoM for consideration at the first instance. GoM was, accordingly constituted on 1.6.2007. The first meeting of the GoM was held on 11.10.2007. Based on the recommendations of the GoM and the Draft Rehabilitation Scheme prepared earlier, a Pre-feasibility Report was prepared by an expert agency, Ernest and Young. Due to notification of elections, the GoM could not consider further steps on the Pre-feasibility Report. After the formation of new Government, it has been decided to place the matter before the Cabinet. The Cabinet Note is being finalised accordingly.
- 4.43 Presently, under different class of Therapeutic medicines, around 80 drugs including tablets, capsules, injection, vitamins, etc. are being manufactured in various plants of IDPL. Additionally, IDPL is engaged in setting up of a new Cephalosporin plant at an estimated cost of Rs.13.00 crore at its premises in Gurgaon. This plant will help the company in further growth of production and sales.

Loans given to IDPL for the year 2011-12 are as under:-

(Rs.in crore)

BE 2010-11			RE 0-11	BE 2011-12	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
	0.01		0.01	10.00	0.01

The Committee on Chemicals and Fertilizers during their visit to BCPL plant at Kolkata on 13 July, 2010 were given a Memorandum by Bengal Chemicals Karamchai Samiti which inter-alia stated as under:-

- (i) Company had received G.M.P licence for production of Tablet and Capsule since eight months and for a period of about seven months they have produced almost nothing in Tablet section and very small quantity in capsule section (The total work force was kept idle for GMP work for last three years).
- (ii) Company which had made a loss of about Rs.20 crore (unaudited) for the year 2008-09 can ill afford to have unutilized fund of Rs.1.20 crore.
- (iii) Five machines which were bought recently had been kept idle for years together.
- (iv) Goods worth Rs.35 lakh expired in stores due to bad planning of the management.
- (v) The Company is incurring more and more loss every year.

#### (d) BENGAL IMMUNITY LIMITED (BIL)

- 4.44 Bengal Immunity Limited (BIL) is 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 18 May 1978. It was nationalised w.e.f. 1 October 1984 and a new public sector Company in the name and style of Bengal Immunity Limited was incorporated on the 1 October 1984. The company has two manufacturing units, one each at Baranagar at Kolkata (West Bengal) and at Dehradun (Uttrakhand).
- 4.45 The Board for Industrial and Financial Reconstruction (BIFR) formally declared the Company sick on 9 March 1993. BIFR heard the case from time to time. In the hearing held on 13 September 2002, BIFR formed its prima-facie opinion to wind up the Company. The opinion was confirmed by BIFR in the hearing held on 25 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 30 September 2003.
- 4.46 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.
- 4.47 The Committee, constituted to explore the possibility of revival of Bengal Immunity Limited (BIL) recommended revival of BIL through public private partnership 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 has 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.

Loans given to BIL for the year 2011-12 are as under:-

(Rs.in crore)

BE 2010-11		RE 2010-11		BE 2011-12	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
	0.01		0.01		0.01

#### (e) <u>SMITH STANISTREET PHARMACEUTICALS LTD.</u>

- 4.48 Smith Stanistreet Pharmaceuticals Limited, a sick Company in the private sector in the name and style of Smith Stanistreet Company Limited set up in 1821 and its management was taken over by the Government of India with effect from 4 May 1972. The company was nationalised on 1 October 1977, and a new public sector Company in the name and style of Smith Stanistreet Pharmaceuticals Limited (SSPL) was incorporated on 19 July 1978. The company has its registered office at 18, Convent Road, Kolkata (West Bengal).
- 4.49 The Company was formally declared sick by the Board for Industrial and Financial Reconstruction (BIFR) on the 21 December 1992. The BIFR approved a revival package for the Company on the 31 August 1994. The Revival Package was for a period of ten years beginning from 1994-95. The same was declared as having failed during the hearing on October 17, 2000.
- 4.50 The BIFR heard the case on the 3 December 2001 and confirmed its prima facie opinion that it was just, equitable and in public interest that the Company should be wound up. With the approval of the Cabinet, VSS was introduced in the Company. The Company has since relieved all the employees under VSS as on 30 September 2003. The Company is closed.
- 4.51 The Official Liquidator has been appointed by the Hon'ble High Court of Calcutta vide its Order dated 12.1.2006. The Registered Office, Plant and machinery and other assets have since been taken over by the Official Liquidator.

Loans given to Smith Stanistreet Pharmaceutical Ltd for the year 2011-12 are as under:(Rs.in crore)

BE 2010-11		RE 2	010-11	BE 2011-12		
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan	
	0.01		0.01		0.01	

#### (f) RAJASTHAN DRUGS and PHARMACEUTICALS LIMITED (RDPL)

4.52 Rajasthan Drugs and Pharmaceuticals Limited is a profit making Central PSU with Mini Ratna status with Government of India having 51% of the equity shares and the Rajasthan

Industrial Development and Investment Corporation RIICO having 49% equity. Earlier, this was a joint sector undertaking of Indian Drugs and Pharmaceuticals Limited (IDPL) in collaboration with the RIICO. The Company was incorporated in 1978 and the commercial production was commissioned in April 1981. The Company has its manufacturing unit and the registered office located at V.K.I. Industrial Area, Jaipur (Rajasthan). This is a formulation unit engaged in the production of Tablets, Capsules, Liquid Orals, ORS Powder and Opthalmic Medicines in a Schedule 'M' compliant facility and selling of medicines of high quality at reasonable rates to the Government of Rajasthan, Central Government Institutions, viz ESIC, Defence, Railways, other PSUs and also to other State Government Institutions. In order to enhance its market share and also in its endeavour to improve the profitability of the organization, it has planned for diversifying its marketing activities into Pharma Prescription Markets (Open Trade Sales), Veterinary Markets, Marketing of Ayurvedic and other Indian System of medicines.

4.53 In the interest of continued growth and development of the Company, it was de-linked from IDPL and the shares of IDPL have been transferred to Government of India. Further, Government of India has also invested Rs.2.00 crore in RDPL to enable it to upgrade, modernize and enhance capacity of its plants and to make them Schedule 'M' and WHO-GMP compliant. Rajasthan Industrial Development Investment Corporation (RIICO), other joint venture partner would bring an additional investment of Rs. 1.90 crore in RDPL. RDPL has been continuously generating profits for the last 10 years.

Loans given to Rajasthan Drugs and Pharmaceuticals Limited for the year 2011-12 are as under:(Rs.in crore)

BE 2010-11			E 0-11	BE 2011-12		
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan	
				5.00		

#### **CHAPTER-V**

#### **MISCELLANEOUS**

#### (i) R & D IN DRUGS AND PHARMACEUTICALS SECTOR

- 5.1 The Department is resolutely working towards building up basic support systems to create the enabling environment for R&D initiatives by creating the required infrastructure as well as mechanisms and linkages to facilitate R&D in this sector.
- 5.2 National Institute of Pharmaceutical Education and Research (NIPER), Mohali was established as 'Institute of National Importance' under the Act of the Parliament. It is a statutory body working under the aegis of Deptt. of Pharmaceuticals. Based on the performance of NIPER, Mohali and the demand of Pharma Industries six new NIPERs have since been set up following the approval of Union Cabinet at Ahmedabad, Hyderabad, Hajipur, Kolkata, Rae Bareli and Guwahati to create infrastructure for education and research for development of quality human resources in the country to meet the demand of the pharmaceutical industry as per changed global scenario.
- Natural Products, Biotechnology, Formulations and Regulatory Toxicology. The NIPER laboratories are fully equipped with modern equipments that are equivalent to the other laboratories set up in the world. All the available facilities are of international level and standards. A Technology Development Centre has been set up in the NIPER, Mohali.
- 5.4 The WHO accredited National Bioavailability Centre established with support of Department of Science and Technology, Government of India, is one of the two Centres to conduct bio-availability studies. The Institute has also set up the Good Laboratory Practices Compliant National Toxicology Centre, National Centre of Pharmaceuticals, and National Centre for Nanotechnology with the support of Deptt of Science and Technology.
- 5.5 A Natural Products Field Laboratory (NPFL) has also been set up at the Institute. This laboratory will act as a base for physical resources and related research work conducted in the study of Natural Products. An intensive course on 'Advanced Analytical Techniques: Basic Principles and Application for Quality Assessment of Drugs and Pharmaceuticals for Export' was organised at the Institute.

#### (ii) JAN AUSHADHI SCHEME

In November 2008, the Department launched Generic Drug Campaign by opening first Jan Aushadhi Generic Drug Store at Amritsar Civil Hospital on 25.11.2008. Since then 81 JAS have

been opened (till 22 February 2011) in the States of Punjab, Haryana, Uttrakhand, Orissa, Rajasthan, Andhra Pradesh, West Bengal, Union Territories of Chandigarh and Delhi. Bureau of Pharma PSUs of India (BPPI) is monitoring the opening of Jan Aushadhi Stores. It is also involved in promotion of the unbranded generic drugs and the Generic Drug Campaign. Initial target for opening of JAS was one JAS in each district of country. However, while reviewing the performance of Pharma PSUs and JAS on 27 September 2010, it was decided that all subdivisions of the Country, which would be around 3,000, should be targeted in due course to have one JAS at the location of Government hospitals. During 2011-12, a provision of Rs 3.50 crore has been made for this scheme.

For Jan Aushadhi, Rs 3.50 crore have been allocated in the year 2011-12. Up to 31.1.2011 Rs 3.72 crore have been released and 77 shops have been opened in various States".

The Department of Pharmaceuticals has since launched Generic Drug campaign in order to make available quality unbranded generic drugs at affordable rate to the people. As part of the Generic Drug Campaign started by the Department and Pharma CPSUs, first Generic Drug Store by the name of "Jan Aushadhi" 24X7 Generic Drug Store (JAGDS) was opened in the Civil Hospital, Amritsar on 25.11.2008 with the support and cooperation of the State Government of Punjab. So far, 81 JAGDS have been opened in different states.

5.7 The "Jan Aushadhi" initiative has made available quality drugs at affordable prices through dedicated stores selling generic medicines which are available at lesser prices but are equivalent in quality and efficacy as expensive branded drugs. Some comparative prices are:

Name of salt	Dosage	Pack	Market	Generics	Difference
			Price	Price	
			(Rs.)	(Rs.)	
Tab. Ciprofloxacin	250 mg	10	55.00	11.10	5 times higher
Tab. Ciprofloxacin	500 mg	10	97.00	21.50	4.5 times higher
Tab. Diclofenac	100 mg	10	36.70	3.50	10 times higher
Tab. Cetrizine	10 mg	10	20.00	2.75	7 times higher
Tab. Paracetamol	500 mg	10	10.00	2.45.	4 times higher
Tab Nimesulide	100 mg	10	25.00	2.70	9 times higher
Cough Syrup	110 mg	Liquid	33.00	13.30	2.5 times higher

5.8 The Bureau of Pharma CPSUs is involved in promotion of the unbranded generic drugs and the Generic Drug Campaign.

- 5.9 The Standing Finance Committee of the Department in its meeting held on 1.2.2010 to consider the scheme of Generic Drug Campaign approved the proposal. It is proposed to open JAS in each district of the country.
- 5.10 When asked to explain time to be taken by the Department to have JAS location at each of the Government hospitals, the Department in its written reply have stated as under:-

"Regarding the time limit for opening up of Jan Aushadhi Drug Stores, much depends upon the Health Policy followed by each state Government and the support and cooperation they extend to open such stores including allotting space in the district hospital and also identification of agencies to manage such stores".

5.11 When asked about the publicity given to promote awareness among the people about benefits of JAS, the Department in its written reply stated as under:-

"A joint multimedia publicity programme initiated by the Department of Pharmaceuticals with the Department of Consumer Affairs, Government of India is continuing, in order to popularise the Jan Aushadhi stores. Apart from this, State Governments and the agencies running the stores are also assisted to popularise the stores besides BPPI running of a Toll Free Helpline on Jan Aushadhi Campaign so that the benefit of the programme reaches the common man. Apart from this, Rs.25/- lakh have been provided to the Government of Punjab to mount publicity campaign on Jan Aushadhi programmes. Organizing Health Camps are also covered for spreading of awareness of the Jan Aushadhi Scheme and its advantages amongst the general public. In order to promote Jan Aushadhi campaign, BPPI have also participated in the India Pharma Summit, 2009 held on 30 November 2009 followed by an Exhibition of Chemicals, Pharmaceuticals, Ingredients India (CPHL India) from 1 to 3 December 2009 in Mumbai. On the direction of the Department of Pharmaceuticals, in the case of Orissa, a Jan Aushahdi Stall was established in collaboration with state Red Cross Society in the Exhibition organised by Press Information Bureau on Public information Campaign on Bharat Nirman at Bhubaneswar from 27 -31 March, 2010 besides undertaking publicity on Jan Aushadhi campaign. BPPI assisted in putting up an Exhibition Stall on Jan Aushadhi during the Rath Yatra at Puri from 13 to 21 July 2010 in the Social Service Camp organized by Indian Red Cross Society, Orissa State Branch. Besides this, BPPI have also participated in Public Information Campaign organized by Press Information Bureau in Balasore, Orissa from 26 February 2011 to 28 February 2011 by way of establishing a Jan Aushadhi stall in associating with state Red Cross Society. In West Bengal, for making the Jan Aushadhi Scheme successful, BPPI assisted M/s. Bengal Chemicals and Pharmaceuticals Limited to install a stall in 34th Sunderban Mela 2011 from 3 January 2011 to 12 January 2011 at South 24 Parganas to promote Jan Aushadhi campaign".

5.12 During the course of evidence, the Secretary, Department of Pharmaceuticals stated that in Jan Aushadhi Scheme nearly 315 drugs are taken which are in much demand and which come under the National List of Essential Medicines. It was also submitted by him that initially the production will be made by public sector. If the public sector cannot do on its own, then production would be done privately under loan license system within one year. The Secretary, Department of Pharmaceuticals further informed that the new plan for Jan Aushadhi is in the final stage and the estimated budget is Rs.90.00 crore and this estimate would be presented to Planning Commission for approval.

5.13 As regards publicity campaign of Jan Aushadhi Programme, the Secretary, Department of Pharmaceuticals submitted before the Committee that a provision of Rs.40 crore has been proposed for the publicity campaign of Jan Aushadhi Programme. He further added that emphasis would be made to prescribe generic medicine by the doctor. In this regard, efforts are being made. As regards setting up of medical shop a sum of Rs.2 lakh would be given for doing so. The shops shall be run by NGOs, Red Cross Society and other institutions. In order to make the programme viable a running subsidy up to three years would also be provided.

#### (iii) IMPORT OF MEDICINES

- 5.14 The country is almost self-sufficient in case of formulations. The imports are being made on quality and economic considerations and not necessarily on non- availability from domestic sources. Manufacturers of Drugs and Pharmaceuticals are free to produce any drug approved by the Drug Control authorities.
- 5.15 Import of Drugs and Pharmaceuticals is done as per Foreign Trade Policy. However, Import of some drugs and drug intermediates is still restricted under current Foreign Trade Policy. Imports which are restricted are basically due to common HS codes for some narcotic substances or similarity to some Ozone Depleting Substances (ODS).
- 5.16 On being asked to elaborate the justification of import of medicinal and pharmaceutical products and the steps taken to manufacture cost effective and quality medicines indigenously, the Department in its reply stated as under:-
- I. To compete with the Multi National Companies (MNC), domestic manufacturers import API/ finished formulation from abroad keeping in view their economic consideration.
- II. At present, all drugs are de-licensed except for locational constraints under Industries Development and Regulation Act. The companies are required to only take manufacturing licenses from Drugs Controller General of India (DCGI) / States Drugs Controller (SDC) for marketing /importing their products. The Government has also provided various fiscal /non-fiscal incentives to boost production of drugs /medicines in the country.
- III. At present, all Pharmaceutical units are required to be Schedule 'M' compliant. The Department of Pharmaceuticals in collaboration with the Ministry of Micro Small and Medium Enterprises (MSME) has introduced a Scheme for Schedule 'M' Compliance by Small Scale Industries (SSI) Units in Pharma Sector under the overall umbrella of Credit Linked Capital Subsidy Scheme (CLCSS). Under the Scheme, the Pharma SSI units are eligible to get 15% (upto Rs.15.00 lakh )upfront capital subsidy on an institutional finance for an amount upto Rs.1.00 crore to be availed by them for inclusion of well established and improved technology to make themselves Schedule 'M' Compliant.

5.17 On being asked the reasons for increase in imports of drugs, the Secretary, Department of Pharmaceuticals stated that the main area of imports of drugs are bulk drugs and based on Active Pharmaceutical Ingredients (API), formulations are made. Almost forty per cent API are imported from China. If the import is made on low price then the formulation will be cheaper and the consumers will be benefited but if China increases the prices it would be a problem. A balance has to be created. The matter was taken up with Ministry of Commerce and Industries for imposing anti-dumping duty. Besides this, import is made on patented drugs which is used by cancer patients and these drugs are patented and can only be made by foreign companies, he added.

#### **OBSERVATIONS AND RECOMMENDATIONS**

#### Recommendations

- 1. The Committee are perturbed to note that there has been a trend that the allocated money under various schemes is underutilized and that too is not being properly and evenly spent by the Department of Pharmaceuticals. During the year 2010-11, an amount of Rs.125 crore was earmarked at BE stage which was reduced to Rs.79 crore at RE (under the Revenue Head) but only Rs.31.51 crore were spent by the Department upto 31 January 2011. Similarly, under the Capital Head, out of Rs.40.00 crore allocated for the year 2010-11, an amount of Rs.22.50 crore could be utilized till 31 January 2011. Thus, out of a total amount of Rs.165 crore provided at BE stage which was eventually reduced to Rs.119 crore at RE stage, only Rs.54.01 crore could be spent upto 31 January of 2010-11. Thus, less than 50 per cent of the revised allocation was utilized in the first 10 months which indicates that neither judicious allocations are being made by the Government nor allocated funds are utilized uniformly and to the optimum. The Committee cannot but reiterate the need for the Ministry to gear up their machinery and ensure that the sanctioned outlays are utilized uniformally so that the avowed objectives are fully achieved. The new initiatives by the Department are also necessary for the sustained growth of the pharma sector so that the creation of the Department of Pharmaceuticals as a distinct entity is fully justified.
- 2. The National Institute of Pharmaceutical Education and Research (NIPER) was set up in 1998 in Mohali, Punjab to nurture and promote quality and excellence in pharmaceutical education and research. The Government had also approved setting up of six more institutes under NIPER in 2007. The Committee, however regret to note that despite their earlier recommendation to make all the six institutes fully functional by April 2011, the matter is still at the stage of acquiring land except that in the State of Gujarat. While expressing their displeasure at the slow pace of work the Committee desire the Department of Pharmaceuticals to take necessary steps so that all the six Institutes of NIPER are made fully functional at the earliest.

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<sup>&</sup>lt;sup>®</sup> 7<sup>th</sup> Report on Demands for Grants for 2010-11

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- 3. The Committee note that the National Pharmaceutical Pricing Authority (NPPA) is responsible for price fixation/revision of drugs and formulations, monitoring the prices of decontrolled drugs and formulations and enforcing and implementing the provisions of the Drugs (Price Control) Order, 1995. An amount of Rs.8.28 crore (Rs.2.40 crore under the Plan and Rs.5.88 crore under Non Plan) has been earmarked for NPPA at BE 2011-12. NPPA had earlier submitted 5 new plan schemes to the Planning Commission in 2007 for the current 11th five year plan amounting to Rs. 49.95 crore. These schemes envisaged Building Robust and Responsive Statistical System for NPPA, Creation of NPPA Cells in States, Scheme for Interaction with States, Proposal for Consumer Awareness and Publicity through Print, electronic and other medium and Proposal for strengthening the existing Monitoring and Enforcement work. Out of these, Planning Commission had initially accorded in-principle approval in March 2008 for one scheme viz Building Robust and Responsive Statistical System for NPPA. Planning Commission is stated to have further conveyed its in- principle approval for another scheme, i.e. "Proposal for Consumer Awareness and Publicity through Print, electronic and other medium". According to the Department, efforts are being made to expedite in-principle approval from the Planning Commission for the remaining three schemes also. The Committee regret to point out that out of the five schemes proposed by NPPA for the Eleventh Five Year Plan in 2007, three schemes are yet to get in-principle approval of the Planning Commission. The Committee deprecate the inordinate delay on the part of the Department in getting requisite approval from Planning Commission for all the schemes. The Department should take up the issue with the Planning Commission regarding early approval of the schemes and implement the same expeditiously.
- 4. The Committee note that the Department has five Pharmaceutical PSUs under its administrative control, viz., Karnataka Antibiotics Pharmaceuticals Limited (KAPL), Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs Pharmaceuticals Limited (IDPL). Out of these five companies, only KAPL and RDPL are profit making and rest have been referred to BIFR. The Committee find that apart from these PSUs, there are two closed PSUs, viz. Bengal Immunity Limited (BIL), Kolkata and Smith Stainstreet Pharmaceuticals Limited (SSPL), Kolkata and two joint ventures of IDPL. It is disheartening to note that all the PSUs barring two are either closed or running in losses. One of the major reasons for losses suffered by PSUs is inefficiency in operation and poor marketing management and stiff competition from well entrenched private concerns. The Committee cannot but express their strong displeasure over the

performance of PSUs. The Committee are of the considered opinion that PSUs should improve their marketing strategy and overcome competition from private concerns and venture into the open market with full vigour. All pending proposals for the revival of pharma PSUs should be expeditiously considered and the Government should extend every possible help to revive them.

5. The Committee note that Bengal Chemicals and Pharmaceuticals Limited (BCPL) was declared sick by Board for Industrial and Financial Reconstruction (BIFR) on 14 Since the Company incurred continued losses since 1980, a Revival Package was prepared and approved by BIFR on 4 April 1995. The package was reviewed by BIFR from time to time, based on which a Modified Revised Rehabilitation Scheme was prepared and approved by BIFR on 14 January 2004. Further, based on the requirements for modernization of plants and machinery and taking into account the earlier schemes, the Board for Reconstruction of Public Sector Enterprises (BRPSE) recommended a 'Modified Revival Plan' for revival of BPCL on 25 August 2006. The recommendations of BPRSE were confirmed by the Cabinet Committee on Economic Affairs (CCEA) which approved the BPRSE scheme on 21 December 2006. The revival scheme included writing off/ waiver of loans/ interests of Rs.233.41 crore and cash infusion of Rs.207.19 crore by Government of India out of which, Rs.201.59 crore have since been released. BCPL is stated to have appointed Consultants for undertaking the work of upgradation and modernization of plant and machinery including compliance with schedule 'M/WHO GMP/ Standard. The Committee are constrained to point out that BCPL which was declared sick in 1993 is yet to be revived and a considerable time has been lost in the process. At this stage the Committee cannot but overemphasise the need for periodical monitoring of the implementation of the revival plan at the highest level so that the Company could carry out its operation at the earliest and is able to achieve its objectives. The Committee expect concrete action in a time bound framework by the Department in this behalf.

As regards the Hindustan Antibiotics Limited (HAL), the Government approved the 6. rehabilitation of the company on 9 March 2006 followed by BIFR approval on 5 June 2007. The rehabilitation plan included writing off the loan and waiving interest to the extent of Rs.259.43 crore and releasing of entire cash infusion of Rs.137.59 crore to the company. Further for cash generation of Rs.56.96 crore, as part of cash infusion, BIFR had issued guidelines for sale of land as per the Rehabilitation Scheme through Assets Sale Committee. Action in this regard is stated to be under progress of HAL. In addition, the Government has approved proposals of Rs.30.17 crore received from HAL for setting up a new power injectable facilities at the estimated cost of Rs.20.17 crore and for upgradation of manufacturing facilities of tablet, capsule and liquid section at estimated cost of Rs.10.00 crore in conformation to WHO- GMP standards. The Committee expect the HAL to fully utilize the funds sanctioned for its revival and endeavour considerable improvement in its performance and also to generate profits, in addition to fulfilling its social obligations of manufacturing life saving drugs for the common man and economically weaker sections of the society.

7. Indian Drugs and Pharmaceuticals Limited (IDPL) incorporated in 1961 with the primary objective of creating self-sufficiency in essential life saving drugs and medicines was formally declared sick by the Board for Industrial & Financial Reconstruction (BIFR) in 1992. The Company is yet to be revived even though a revival package for the same was formulated and approved by BIFR in February 1994. From the facts placed before the Committee it is evident that the matter kept shuttling between the various Organizations such as BIFR, Expert Committee, NIPER, Board for Reconstruction and Public Sector Enterprises and Group of Ministers. It was eventually decided after the formation of new Government that the matter would be placed before the Cabinet. The Committee regret to observe that the draft Cabinet Note for revival of IDPL is stated to be still under submission to the Ministry of Chemicals and Fertilizers. The fact that the Department has taken too long a time to revive the Company is just regrettable. The Committee would like to be informed about the precise reasons as to why it has taken so much time in submission of the requisite draft note to the Cabinet. While emphasizing the need for expeditious action in this regard the Committee desire that the revival plan should be formulated and implemented without any further delay.

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8. As regards the promotion of unbranded generic medicines through Jan Aushadhi

Stores (JAS), the Committee have been informed that the following efforts are being made

by the Government:-

(i) Various correspondences/ meetings/ visits are being done with the authorities of

State Government for getting their support in opening of Jan Aushadhi Stores.

Possibilities are being explored to open the Jan Aushadhi Stores. Possibilities are

being explored to open the Jan Aushadhi Stores in the villages also.

(ii) All Pharma CPSUs have been instructed to take necessary action for increasing the

list of medicines supplied to the Jan Aushadhi Stores.

(iii) Necessary action has been taken for the publicity in print and electronic media in

consultation with Department of Consumer Affairs to make people aware of generic

drugs and their prices in the Jan Aushadhi Stores.

The Committee, taking note of these measures would like to be apprised at regular

intervals of the concrete progress made in ensuring that generic drugs are made available

at cheaper rate to the common man throughout the country at the earliest.

New Delhi;

28 July, 2011

6 Shravana, 1933 (Saka)

GOPINATH MUNDE, Chairman, Standing Committee on Chemicals and Fertilizers.

#### Annexure-I

# MINUTES OF THE NINTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

The Committee sat on Wednesday, the 23 March, 2011 from 1715 hrs. to 1815 hrs. in Committee Room, G074, Ground Floor, Parliament Library Building, New Delhi.

#### Present

#### Shri Gopinath Munde - Chairman

#### **Members**

#### Lok Sabha

- 2. Smt. Sushmita Bauri
- 3. Adv. Ganeshrao Nagorao Dudhgaonkar
- 4. Shri Tapas Paul
- 5. Shri Ponnam Prabhakar
- 6. Shri N. Chaluvaraya Swamy
- 7. Shri Narendra Singh Tomar
- 8. Dr. Manda Jagannath

#### Rajya Sabha

- 9. Prof. Anil Kumar Sahani
- 10. Dr. C.P. Thakur
- 11. Shri Abani Roy

#### Secretariat

1. Shri N. K. Sapra - Additional Secretary

2. Shri C. S. Joon - Director

3. Shri A.K. Srivastava - Additional Director

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

1.	Shri. Mukul Joshi	Secretary
2.	Shri. V. Rajagopalan	Additional Secretary & Financial Advisor (AS & FA)
3.	Dr. S.M. Jharwal	Chairman, National Pharmaceutical Pricing
		Authority (NPPA)
4.	Dr. A.K. Vishandas	Deputy Director General, Statistical
5.	Shri. Om Prakash	Member Secretary, National Pharmaceutical
		Pricing Authority (NPPA)
6.	Shri. N.K. Sharma	Deputy Director General, Economic Service
7.	Smt. Asha R. Rungta	Director (Finance)

### II. REPRESENTATIVES OF PSUs

1.	Shri. A.S. Vaidya	Managing Director, Hindustan Antibiotics Ltd. (HAL)						
2.	Shri. S. Kundu	Managing Director, Bengal Chemicals and Pharmaceuticals Ltd. (BCPL)						
3.	Shri. M.K. Nagendra	CMD, Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL) & Indian Drugs and Pharmaceuticals Ltd. (IDPL)						
4.	Shri. S.L. Phadke	Managing Director, Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL)						

- 2. At the outset, Hon'ble Chairman welcomed the members of the Committee and officials of Department of Pharmaceuticals and Public Sector Undertakings and stated that the sitting of Committee has been convened to take oral evidence of representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) on 'Demands for Grants of the Department for the year 2011-12'. The Chairman also invited their attention to the provisions contained in Direction 55(1) of the Directions by the Speaker, Lok Sabha regarding confidentiality of the Committee's proceedings.
- 3. To begin with, power point presentation was made by the Secretary of Department of Pharmaceuticals. Thereafter, Chairman and members of the Committee raised some queries which were replied to by the Secretary and other senior officials of the Department of Pharmaceuticals. They also assured to send the requisite information in writing which was not readily available with them. The following issues were discussed during the course of meeting:-
  - (i) Plan and non-plan expenditure of the Department;
  - (ii) Performance of pharmaceuticals industry;
  - (iii) Role of NIPER in the pharmaceutical industry;
  - (iv) Drugs price control;
  - (v) Generic Drug Campaign;
  - (vi) Revival of sick PSUs; and
  - (vii) Jan Aushadhi Scheme.
- 4. A verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

#### Annexure-II

# STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

# THIRTEENTH SITTING (18.07.2011)

The Committee sat on Monday from 1500 hours to 1600 hours.

#### **Present**

### Shri Gopinath Munde - Chairman

#### **Members**

#### Lok Sabha

- 2. Smt. Susmita Bauri
- 3. Shri Prabhatsinh P. Chauhan
- 4. Smt. Santosh Chowdhary
- 5. Shri K.D. Deshmukh
- 6. Adv. Ganeshrao Nagorao Dudhgaonkar
- 7. Shri Baidya Nath Prasad Mahato
- 8. Shri Jagdambika Pal
- 9. Shri Tapas Paul
- 10. Shri Ashok Kumar Rawat
- 11. Shri N. Chaluvaraya Swamy

### Rajya Sabha

- 12. Shri Silvius Condpan
- 13. Shri Brijlal Khabri
- 14. Prof. Anil Kumar Sahani
- 15. Shri Raghunandan Sharma
- 16. Shri Parshottam Khodabhai Rupala
- 17. Shri Abani Roy

#### Secretariat

- 1. Shri N.K. Sapra Secretary
- 2. Shri Ashok Sarin Joint Secretary
- 3. Shri C. S. Joon Director
- 4. Shri A.K. Srivastava Additional Director

2.	At the	outset,	Hon'ble	Chairman	welcomed	the	members	to	the	sitting	of	the
Comr	nittee.											
3.	The Co	mmittee	e thereaft	er took up 1	or consider	atior	the follow	ing	draf	t Repoi	ts:	



(vi) Draft Report on Demands for Grants (2011-12) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

4. The Committee adopted the draft reports with minor amendments and authorized the Chairman to present the same to both the Houses of Parliament.

The Committee then adjourned.

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\*\*\* Matters not related to this Report.