



**STANDING COMMITTEE ON
CHEMICALS & FERTILIZERS
(2009-10)**

FIFTEENTH LOK SABHA

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

**DEMANDS FOR GRANTS
(2010-2011)**

SEVENTH REPORT



**LOK SABHA SECRETARIAT
NEW DELHI**

April, 2010/ Chaitra 1932, (Saka)

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(DEPARTMENT OF PHARMACEUTICALS)**

DEMANDS FOR GRANTS

(2010-2011)

Presented to Lok Sabha on 26 04.2010

Laid in Rajya Sabha on 26. 04.2010

**LOK SABHA SECRETARIAT
NEW DELHI**

April, 2010/ Chaitra 1932, (Saka)

CONTENTS	PAGE No.
COMPOSITION OF THE COMMITTEE (2009-10)	(i)
INTRODUCTION	(iii)
REPORT PART -I	
I. INTRODUCTORY	1-2
II. ELEVENTH FIVE YEAR PLAN	3-4
III. DEMANDS FOR GRANTS FOR THE YEAR 2010-11	5-7
IV. HEAD-WISE ANALYSIS OF DEMANDS FOR GRANTS (2010-11)	8-33
(A) Major Head 3451- Secretariat –Economic Services	8
(B) Major Head 2552 - North Eastern Area	9 -10
(C) Major Head 2852 - Pharmaceutical Industries	11-22
(i) National Institute of Pharmaceuticals Education & Research (NIPER)	12-14
(ii) National Pharmaceutical Pricing Authority (NPPA)	15-17
(iii) Pharmaceutical Promotion & Development Scheme (PPDS)	18
(iv) Pharmaceutical Export & Promotion Scheme	18
(v) Others (New Schemes)	19-21
(D) Major Head – 4857 Capital Outlay on Pharmaceutical Industries	22
(E) Major Head – 6857 Loan for Pharmaceutical Industries	23-33
(a) Bengal Chemicals & Pharmaceuticals Limited (BCPL)	25-27
(b) Hindustan Antibiotics Limited (HAL)	28-29
(c) Indian Drugs & Pharmaceuticals Limited (IDPL)	30-31
(d) Bengal Immunity Limited (BIL)	32
(e) Smith Stanistreet Pharmaceuticals Limited	33
V. MISCELLANEOUS	
(i) R&D Venture Fund	34-35
(ii) Jan Aushadhi Scheme	35-37
PART -II	
OBSERVATIONS AND RECOMMENDATIONS	38-42

APPENDICES

- | | | |
|------------|---|-------|
| I. | Minutes of the Fourteenth sitting of the Standing Committee on Chemicals and Fertilizers (2009-10) held on 31 March 2010 | 43-45 |
| II. | Extracts of Minutes of the Seventeenth sitting of the Standing Committee on Chemicals and Fertilizers (2009-2010) held on 16 April 2010 | 46-47 |

**COMPOSITION OF THE STANDING COMMITTEE
ON CHEMICALS & FERTILIZERS (2009-10)**

Shri Ananth Kumar - Chairman	
MEMBERS	
LOK SABHA	
2	Smt. Sushmita Bauri
3	Shri Prabhatsinh P. Chauhan
4	Shri K.D. Deshmukh
5	Shri Ganeshrao Nagorao Dudhgaonkar
6	Shri Madhu Koda
7	Shri N. Peethambara Kurup
8	Shri Baidyanath Prasad Mahato
9	Shri Ponnamm Prabhakar
10	Shri Ashok Kumar Rawat
11.	Shri Suresh Kumar Shetkar
12	Shri Ajit Singh
13	Shri N. Cheluvarayana Swamy
14	Shri Narendra Singh Tomar
&15	Shri T.K.S. Elangovan
&16	Shri Tapas Paul
**17	Shri Udayanraje Bhonsle
18 to 21	Vacant
RAJYA SABHA	
22	Shri J.D. Seelam
23	Shri Raghunandan Sharma
24	Dr. C.P. Thakur
25	Shri Brijlal Khabri
26	Shri A.A. Jinnah
27	Shri Raj Mohinder Singh Majitha
28	Shri Biswajit Daimary
**29	Prof. Anil Kumar Sahani
#30	Vacant
31	Vacant

* Consequent upon nomination to the Committee on Information Technology
Shri Tufani Saroj, MP (LS) ceased to be Member of the Committee w.e.f. 13.10.2009.

Vacancy arisen due to demise of Shri Mahendra Sahni, MP (RS) w.e.f. 6 November 2009.

& Nominated w.e.f. 11.01.2010.

** Nominated w.e.f. 26.02.2010.

SECRETARIAT

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

INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2009-10) having been authorised by the Committee to present the Report on their behalf present this Seventh Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2009-10.

2. The Committee examined the Demands for Grants pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2010-11 which were laid in Lok Sabha and Rajya Sabha on 11 March 2010.

3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 31 March 2010.

4. The Committee considered and adopted the Report at their sitting held on 16 April 2010.

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 2010-11 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;
20 April, 2010
30 Chaitra, 1932 (Saka)**

**ANANTH KUMAR
Chairman,
Standing Committee on
Chemicals and Fertilizers.**

REPORT

I. INTRODUCTORY

1. The Department of Pharmaceuticals in the Ministry of Chemicals and Fertilizers was created *vide* Notification dated 01 July 2008 issued by the Cabinet Secretariat in order to provide greater focus for the growth of the pharmaceuticals industry. Earlier, it was a part of the Department of Chemicals and Petrochemicals.

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 for Pharmacy 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.
- (xiv) Indian Drugs and Pharmaceuticals Limited.

(xv) Karnataka Antibiotics and Pharmaceuticals Limited.

(xvi) Rajasthan Drugs and Pharmaceuticals Limited.

3. The work of the Department has been organized into three Divisions that is Pharmaceuticals Industry division, Public Sector Undertakings division and R&D division comprising National Institute of Pharmaceutical Education & Research, (NIPER) and Research & Development. The National Pharmaceuticals Pricing Authority (NPPA), is an attached office of this Department and entrusted with fixation and revision of prices of Pharmaceuticals products under DPCO 1995. Beside this, 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 & development of KAPL & RDPL, the Government has approved de-linking of both these companies from HAL & IDPL respectively. The shares held by HAL & 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.

4. National Institutes of Pharmaceuticals Education & Research (NIPERs) are autonomous institutions under this Department.

II. ELEVENTH FIVE YEAR PLAN

5 Year – Wise Details of allocations under Eleventh Five year Plan

(Rs. in Crore)

S.No.	Scheme	11th Plan	2007-08		2008-09		2009-10		2010-11
			BE	RE	BE	RE	BE	RE	
1	Project Based Support to PSUs	220.17	23	28.2	30.00	20.00	30.00	24.4	40.00
2	Support to Autonomous Institutions	100.00	10.16	29.50	26.50	25.92	8.60	13.25	9.50
2.1	National Institute of Pharmaceutiical Education and Research (NIPER)	95.00	8.66	20.00	25.00	25.00	8.00	13.00	9.00
2.2	National Pharmaceutical Pricing Authority (NPPA)	5.00	1.50	9.50	1.50	0.92	0.60	0.25	0.50
3	Other Ongoing Schemes	8.00	1.05	2.00	1.25	1.21	2.50	2.30	1.50
3.1	Pharma Promotion and Development Scheme (PPDS)	7.50	1.05	1.50	1.00	1.00	2.00	2.00	1.25
3.2	IT/Secretariat	0.50		0.50	0.25	0.21	0.50	0.30	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
4.1	New Schemes for NIPER, Mohali	69.00	20.00	7.00	15.00	15.00	15.00	11.15	12.00
4.2	New Niper Like Institutes	514.00	10.00	10.00	35.00	25.26	50.00	33.50	56.50
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
45	Strengthening of NPPA	60.00	10.00		10.00	0.00	1.65	0.60	0.49
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
4.7	ERP, R&D Parks	5.00	0.01	1.00	0.00	0.00	1.50	2.00	5.00
4.8	Critical assistance for WHO pre-qualification for Pharma PSUs/R&D	75.00	0.01	1.00	10.00	10.00	10.00	10.00	14.00
4.9	New Schemes (to be introduced 2010-11)		1.02		0.00		20.00	7.00	25.00
	Total	1396.17	91.27	91.65	155.25	111.04	155.25	105.00	165.00

6 It is observed that out of an outlay of Rs.1396.17cr earmarked for the Eleventh Five Year Plan only Rs.472.69 cr. have been allocated for the Department during the first four years. Thus, an amount

of Rs.923.48 should be allocated and spent under Plan expenditure, during the last year of the Eleventh Plan. When asked about the reasons for uneven allocation, the Department submitted as under:-

“The Department had proposed Schemes/Projects and allocations for the balance amount of Rs.993.90 crores for the FY 2010-11 (Rs.559.70 crores) and 2011-12 (Rs.434.20 crores) initially to Planning Commission during proposals for FY 2010-11 in various Schemes relating to Project Based Support to PSUs, Support to Autonomous Institutions, National Institute of Pharmaceutical Education and Research (NIPER), National Pharmaceutical Pricing Authority (NPPA), Other ongoing Schemes, Pharma Promotion and Development Scheme (PPDS) IT/Secretariat, New Schemes Initiated in XIth Plan, New Schemes for NIPER, Mohali, New Niper Like Institutes, PEPS, Interest Subsidy for Schedule M/Compliance for Mes, Strengthening of NPPA, Creation of IPR Facilitation Centre at Pharmexcil, ERP, R&D Parks and Critical assistance for WHO pre-qualification for Pharma PSUs/R&D. However, out of Rs.539.70 crores proposed by the Department, Planning Commission allocated only Rs.165.00 crores due to inter-alia limited resources.

Accordingly, the Department would be able to use the outlay finally allocated for FY 2010-11 and consequently for 2011-12 in light of above”.

III DEMANDS FOR GRANTS FOR THE YEAR 2010-11

7 The Ministry of Chemicals and Fertilizers presented to Parliament Demand No.8 on the Department of Pharmaceuticals on 11 March 2010. 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.

8 The Demands for Grants for the Department of Pharmaceuticals for the year 2010-11 which have since been voted by Parliament are as follows:-

Major Head	Budget Estimates 2010-11		
	Plan	Non-Plan	Total
Revenue	125.00	32.95	157.95
Capital	40.00	0.05	40.05
Total	165.00	33.00	198.00

Budget Estimates 2009-10 were as under:-

Major Head	Budget Estimates 2009-10		
	Plan	Non-Plan	Total
Revenue	125.25	35.01	160.26
Capital	30.00	0.07	30.07
Total	155.25	35.08	190.33

Statement showing BE & RE 2009-10 and Exp (Plan & Non-Plan) & BE 2010-11 (Plan & Non-Plan)

(Rs. In Crore)

S.No.	Sub-head	BE 2009-10	RE 2009-10	Exp. as on 31.1.2010	BE 2010-11
	Plan				
	Revenue				
1	I.T.	0.50	0.30	0.12	0.25
2	PPDS	2.00	2.00	0.42	1.25
3	NPPA	2.25	0.85		0.99
4	PEPS	47.50	19.80	10.00	45.01
5	NIPER	57.47	47.15	39.65	61.00
6	N.E. Region	15.53	10.50	1.50	16.50
	Total Revenue	125.25	80.60	51.69	125.00
	Capital loan to PSUs				
1	BCPL	10.00	14.90	24.40	25.00
2	HAL	20.00	9.50		15.00

	Total Capital	30.00	24.40	24.40	40.00
	Total Plan	155.25	105.00	76.09	165.00
	Non-Plan				
	Revenue				
1	Sectt.	7.75	6.56	3.86	7.34
2	NPPA	6.26	5.77	4.31	6.07
3	PEPS	1.00	1.00	0.08	0.50
4	NIPER	20.00	20.00	18.50	19.04
	Total Revenue	35.01	33.33	26.75	32.95
	Capital Loan top PSUs				
1	SSPL	0.01	0.01		0.01
2	BCPL	0.01	0.01		0.01
3	BIL	0.01	0.01		0.01
4	IDPL	0.02	0.02		0.01
5	HAL	0.02	0.02		0.01
	Total Capital	0.07	0.07	0.00	0.05
	Total Non-Plan	35.08	33.40	26.75	33.00
	Grand Total (Plan+Non-Plan)	190.33	138.40	102.84	198.00

9 Clarifying under-utilization of funds during the year 2009-10 the Department in a written reply submitted as under:-

“Ministry of Finance has reduced the BE 2009-10 from 190.33 crore to Rs. 138.40 crore at RE Stage. The total expenditure of only Rs. 102.84 crores as on 31 January 2010 was 74.31 per cent of RE 2009-10 due to the fact that several proposals were pending with the Planning Commission for ‘in-principle’ approval. However, the expenditure as on 31 March 2010 is Rs.133.45 crores.

It has been further added by the Department in a written reply that the allocation under RE was reduced to Rs.138.40 crore by Ministry of Finance keeping in view the pace of expenditure in the first six months”

10 On being asked regarding the ‘NIL’ expenditure in respect of NPPA, the Department in its written note submitted as under:-

“An amount of Rs.2.25 crore was allocated to NPPA under Plan for computerization programme and strengthening of NPPA by way of building a Robust and Responsive Statistical System, which was restricted at RE stage to Rs. 0.85 crore only. Out of Rs. 0.85 crore, only Rs. 0.45 crore has been spent as four out of five schemes proposed are still awaiting approval of the Planning Commission”.

11 During the course of evidence, the Secretary, Department of Pharmaceuticals stated that new schemes for NPPA have not been cleared by the Planning Commission. Four schemes out of five schemes are still pending. For finalization of the Pharma Policy, only one scheme has been cleared, and that is on the Pharmaceutical Census. Now, the data of the Pharmaceutical Census has just started coming in. He further added that expenditure on NPPA is not zero but very insignificant. He promised that during the current year it would be picked up as per allocation by Planning Commission and related approval of schemes. It was elaborated by him that the insignificant amount that pertains to authorization is Rs.44.95 lakh. The authorization is what the Department has to pay on pay and account basis from one organization to another. Thus NPPA has paid to NIC for their computerization programme. Therefore, the expenditure of NPPA for financial year 2009-10 may be considered as Rs.44.95 lacs.

12 A statement indicating the Major Heads under the Demand No.8 and Budget Estimates (BE) 2010-11 (Plan & Non-Plan) for each of the Heads is as under:-

(Rs. In crore)

Sl.No.	Major Head	Item	BE 2010-11
1.	3451	Secretariat Economic Services	7.59
2.	2552	North-Eastern Areas	16.50
3.	2852	Pharmaceutical industries	133.86
4.	4857	Capital outlay on pharmaceutical industries	00.00
5.	6857	Drugs and pharmaceutical industries	40.05
		Total	198.00

Headwise analysis of each of the schemes is given in next chapter.

IV HEAD-WISE ANALYSIS OF DEMANDS FOR GRANTS (2010-11)

A. MAJOR HEAD 3451

Secretariat –Economic Services

Total Allocation is Rs.7.59 crore

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
0.50	7.75	0.30	6.56	0.25	7.34

13 On being asked about the reasons for decrease in Plan BE 2010-11 compared to Plan RE 2009-10, the Department in their reply stated as under:-

“The Plan Allocation for Secretariat Economic Services includes expenditure on IT items only. Since after IT Hardware Optimization it was felt that less quantity of hardware had to be procured so the amount was decreased from Rs.30 lakhs to Rs.25 lakhs”.

14 When asked about the reasons for a hike in BE 2010-11 under Non-Plan as compared to the RE 2009-10, the Department in a written reply stated as under:-

“There is increase of just 12% over the RE 2009-10. This is on account of grant of increment, payment of DA and filling up of vacancies against the newly created posts”.

B. MAJOR HEAD -2552

North Eastern Area

Total Allocation is Rs.16.50 crore

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
15.53	--	10.50	--	16.50	--

15 Regarding utilization of an increase of Rs.6 crore in BE 2010-11 as compared to RE 2009-10, the Department stated as under:-

“Since the expenditure of NIPER Guwahati is the only component for North-Eastern Region and lot of work on core construction activities will take place so these extra expenditure of Rs. 6 crores would be required for 2010-11”.

16 When asked about the reasons for decrease in the Plan allocation in Revised Estimates during the year 2009-10 the Department in a written reply have stated as under:-

“Since approval for the core construction activities could be taken during later period of 2009-10 so RE had to be reviewed. The BE also got reduced in RE 2009-10”.

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

17. The provision is for implementing projects/schemes for North Eastern Region and Sikkim. Department of Pharmaceuticals came into existence only in July 2008. However, during 2007-08 and 2008-09, actual provision for NE was Rs. 20.90 crore and Rs. 29.50 crore respectively against the total outlay of Rs.209 crore (BE) and Rs.295 crore (BE), respectively under the (undivided) Department of Chemicals & Petrochemicals, of which Department of Pharmaceuticals was a part till then. During 2009-10, an amount of Rs.10.50 crore is to be spent on the NIPER, Guwahati against outlay of Rs. 155.25 crore (reduced to Rs.

105 crore at RE stage). In addition, a major thrust is being given for the North East, which will require Plan Outlays to undertake the projects.

18 When asked as to why very little expenditure of Rs.1.50 crore as on 31 January 2010 has been indicated in respect of N.E. region for the year 2009-10, in the statement showing BE &RE 2009-10 and Exp. (Plan and Non-Plan) and BE 2010-11 (Plan and Non-Plan) of the Department of Pharmaceuticals, the Department has furnished the following details:-

“As per instructions of Ministry of Finance 10 per cent of total Plan Funds are mandatory for North Eastern Region. During 2009-10, allocation in NE Region has been reduced from Rs. 15.53 crore to Rs. 10.50 crore at RE stage. Department of Pharmaceuticals has only one scheme in NE Region i.e. NIPER, Guwahati. The expenditure on NE Region incurred in respect of NIPER, Guwahati is taken from NE Region and booked to the Functional Head of NIPER, which has already been done and an amount of Rs. 10.50 crore has been released to NIPER, Guwahati after re-appropriation of the same from NE Region to Function Head of NIPER”.

19 On being asked about the other schemes in North-Eastern Areas in addition to NIPER Guwahati, the Secretary, Department of Pharmaceuticals during the course of evidence submitted as under:-

“At the moment we have two schemes under consideration. One is the scheme for NIPER. The second scheme is the National Centre for Research & Development of Phyto-Pharmaceuticals. We will start the work in the next year. The third one is-we have just now agreed with the State Government and the hon.Chief Minister of Assam has also very kindly agreed to it – a Pharma Park in Guwahati in respect of small scale units for the manufacture of pharmaceutical products. So, from next year we will have three schemes for the North-East.”

C. **MAJOR HEAD 2852**

Pharmaceutical industries

Total allocation is Rs.133.86 crore

20 The total allocation under Major Head 2852 is as under:-

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
109.22	27.26	69.80	26.77	108.25	25.61

21 The above allocation includes the allocations made for (i) National Institute of Pharmaceutical Education Research (NIPER), (ii) National Pharmaceutical Pricing Authority (NPPA) (iii) Pharmaceuticals Promotion & Development Scheme (PPDPS) (iv) Pharmaceutical Export Promotion Scheme (PEPS) and (v) others (New Schemes). The details of these schemes are given in the succeeding paragraphs.

MAJOR HEAD 2852

(i) National Institute of Pharmaceuticals Education and Research (NIPER)

22 The Budget Estimates/Revised Estimates during 2009-10 and 2010-11 for NIPER are given below:-

(Rs. in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
57.47	20.00	47.15	20.00	61	19.04

23 The National Institute of Pharmaceutical Education & Research (NIPER). SAS Nagar, Mohali, Punjab was set-up as an “Institute of National Importance” under an Act of Parliament on 26 June 1998. It is an Autonomous institution under the aegis of Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India. The main objective of the Institute is to nurture and promote quality and excellence in pharmaceutical education & research. NIPER is a member of Association of Indian Universities and Association of Commonwealth Universities. There are 23 members on the Board of Governors under the Chairmanship of Secretary, Department of Science and Technology.

24 When asked about the achievements of the Department since inception of NIPER, the Department replied as under:-

“Through setting up of NIPERs the Government has fulfilled the demand of pharmaceutical industry to meet its long drawn demand of highly skilled trained manpower. This would also help in providing better healthcare to people in the long run. The main objective of the Institute is to nurture and promote quality and excellence in pharmaceutical education and research.

25 As per Outcome Budget an allocation of Rs. 12.00 crore has been allocated in 2010-11 (Plan) for NIPER, Mohali towards its New Research Schemes in the field of pharmaceuticals as well as several new schemes for infrastructure development like hostel, residence, auditorium, etc.

26 Following the success of NIPER, Mohali the Union Cabinet gave in-principle approval for setting up of six National Institutes of Pharmaceutical Education and Research (NIPER) at Ahmedabad (Gujarat), Hyderabad (Andhra Pradesh), Hajipur (Bihar), Kolkata (West Bengal), Rae Bareilly (U.P.) and Guwahati (Assam) in August 2007. These NIPERs have started awarding Masters & Doctoral Degrees in different streams of pharmaceutical sciences and would give more emphasis on R&D activities of pharmaceutical industry. These new NIPERs would be equipped with R&D infrastructure of International standards having various specializations suited to the needs of the Industry. The students would be exposed to cutting edge technology to meet the newer challenges of the industry. Once fully established, the intake of students in various NIPERs would be about 200-250 each and after all the seven NIPERs become functional, about 1,500 highly skilled trained manpower would be available for Pharma industry annually”.

27 As per Outcome Budget an allocation of Rs. 40.00 crore in 2010-11 (Plan) for this purpose has been made for new NIPERs (excepting NIPER, Guwahati). For NIPER, Guwahati the requirement would be met out of available provisions for North-East to the tune of Rs. 16.5 crore.

28 **Status Of Patents Filed By NIPER**

It has been submitted by the Department in its written note that 103 patents were filed by NIPER. On being asked about the number of patents granted, the Committee were informed that only 14 patents have been granted till now. As regards the status of patents filed by NIPER, SAS Mohali, the position is as under:-

Year	Patents Filed	Patents Granted*
2001	5	-
2002	16	1*
2003	16	-
2004	7	1
2005	7	1
2006	17	7
2007	14	2
2008	11	5
2009	8	1
2010	2	1
Total	103	18 (14 NIPER + 4 external funding agencies e.g. CSIR

29 On being asked as to why only 14 patents were granted out of 103 patents filed, the Department in their note submitted as under :-

“The delay is because of procedural reasons and delay on part of the Indian Patent Office, New Delhi in processing the patent applications. The normal time for grant of a patent range from 3-4 years. Publication occurs after 18 months and thereafter examination starts, which takes around 12-15 months. However, if owing to backlog, there is a delay in conducting examination of patents by the patent office, grant of patent gets delayed.

(ii) National Pharmaceutical Pricing Authority (NPPA)

30 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 August 1997. The Authority is entrusted with the task of price fixation / revision of the 74 scheduled 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 and on other specific issues concerning affordable medicines to the consumer.

31 **As per Detailed Demands for Grants (2010-11)** Budget allocation to NPPA for the years 2009-10 and 2010-11 are as under:-

(Rs. in crores)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
2.25	6.26	0.85	5.77	0.99	6.07

32 When asked about the reasons for decrease in Plan allocations to Rs. 0.85 crore at RE stage from Rs.2.25 crore at BE, the Department in their reply stated as under:-

“Five new schemes namely Building Robust & 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 amounting to Rs 49.95 crore were submitted to the Planning Commission for the current 11th Five year plan. However, out of these five schemes, in principle approval in respect of the plan scheme “Building Robust & Responsive Statistical System for NPPA” has only been received from the Planning Commission; as a result of which requirement of funds under the plan scheme has to be reduced from Rs. 2.25 crore (BE 2009-2010) to Rs. 0.85 crore (RE 2009-2010).”

33. During the year 2008-09, RE (Plan) 2008-09 was also reduced to Rs.0.92 crore from BE (Plan) of Rs.11.50 crore.

34 It has been mentioned in the Outcome Budget 2010-11 that during the financial year 2009-10 funds to the tune of Rs.0.90 crore were allocated under the scheme of 'Strengthening of NPPA'. For the current financial year 2010-11, the provision of Rs.0.99 crore is being made.

35 On being asked about the present status of the schemes of NPPA proposed for Eleventh Five Year Plan, the Department in its written reply have stated as under:-

“For the Plan period 2007-08 to 2011-12, NPPA has sent the following five New Plan Schemes amounting to Rs.49.95 crore:-

Sl. No.	Scheme	Amount (Rupee in crore)
1.	Building Robust & Responsive Statistical System for NPPA	2.15
2.	Creation of NPPA Cells in States	26.38
3.	Scheme for Interaction with States	1.52
4.	Proposal for Consumer Awareness and Publicity through Print, electronic and other medium	18.28
5.	Proposal for strengthening the existing Monitoring and Enforcement work	1.62
Total		49.95

36 Out of these, the Scheme “Building Robust & Responsive Statistical System for NPPA” has since been approved by the Planning Commission. For the remaining schemes in principle approval of the Planning Commission is awaited. These schemes have been designed to strengthen NPPA and help it in discharging its mandate to ensure the availability of quality medicines at reasonable prices in an effective manner.

37 The scheme “Building Robust & Responsive Statistical System for NPPA” is to build a sound data-base so that the existing statistical system in NPPA is robust and responsive. Under this scheme, first Directory of Pharmaceutical manufacturing units in the Country has been prepared. This contains state-wise addresses of 10,563 pharmaceutical manufacturers in alphabetical order, their telephone numbers, e-mail addresses and website, wherever available, across the Country. Further a census of pharmaceutical

manufacturing units is in progress. This would provide details relating to composition of the Pharmaceutical units, their product, data relating to investment, R&D, employment, etc. and is intended to provide reliable and effective inputs for policy purposes. So far, Rs. 15.27 lakh have been incurred on this scheme. During the Financial Year (2009-2010), and amount of Rs. 16.80 Lakh is expected to be incurred under this scheme.

(iii) **Pharmaceutical Promotion & Development Scheme (PPDS)**

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
2.00	--	2.00	--	1.25	--

38 When asked to give reason for allocating less amount for Plan 2010-11 as compared to the year 2009-10, the Department stated as under:-

“Due to reduction in the total Plan Outlay of the Department by the Planning Commission, it was decided to keep Rs.1.25 crores under PPDS”.

(IV) **Pharmaceutical Export and Promotion Scheme**

As per budgetary papers 2010-11 (Notes on Demands for Grants) the Non-Plan allocation for the scheme are as follows:-

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
--	1.00	--	1.00	--	.50

(v) **Others (New Schemes)**

39 As per budgetary papers 2010-11 (Notes on Demands for Grants), the Plan allocation for new schemes during the year 2009-10 and 2010-11 is as follows:-

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
47.50	--	19.80	--	45.01	--

As per the outcome budget 2010-11 following new schemes have been launched

(i) **Interest Subsidy for small and medium enterprises for Schedule M compliance**

This Scheme has been launched 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, was amended in 2004. To aid manufactures, especially in the Small Scale Sector, to comply with Schedule M provisions, Rs. 15.00 crore was allocated in 2009-10 (Plan) as Interest Subsidy for these small units.

(ii) **Creation of IPR Facilitation Centre at Pharmaexil**

As per the Annual Report 2009-10 para 4.2 page 23 that the Working Group on Drugs and Pharmaceuticals for the Eleventh Five Year Plan (2007-2012) has recommended setting up of 3 IPR Facilitation Centres at 3 offices of Pharmaexil in order to disseminate information on IPRs and related issues to the Pharma Industry in an effective manner. For this purpose, a fund of Rs.5 crore has been proposed in the Working Group for the Eleventh Five Year Plan. The first centre has been opened at Hyderabad on 11 July, 2008 and the second one at Mohali on 26 November 2009. It is being planned to open another centre at Mumbai.

40 During the course of evidence the Secretary, Department of Pharmaceuticals submitted that IPR Facilitation Centres provide list of patent drugs, assist in filing the application and render other necessary assistance. IPR also provides legal assistance but do not provide lawyers for litigation.

41 As regards licensing out of patents, the Secretary, Department of Pharmaceuticals during the course of evidence submitted that only two patents were licensed. The Committee were further informed that licensing out of patents is a dedicated activity for which NIPER has initiated efforts. As part of efforts to promote licensing out of the NIPER patents, the Institute has recently activated an Institutional Intellectual Property Rights Cell w.e.f Feb.2010.

42 On being asked regarding the safeguards provided to small companies so as to ward off their medicines from usurping by big MNCs, for patenting, the Secretary, Department of Pharmaceuticals during the course of evidence stated that at present there is no such arrangement. In case an application is filed in India under Patent Right, then onus of opposing the patent lies on the industry and Patent Controller listens to both the parties.

(iii) ERP, R&D Parks

It is proposed to develop a Greenfield Medical Devices & Equipment Park near Sanand, Gujarat by NIPER, Ahmedabad in partnership with State Government of Gujarat. The proposal has since been sent to Planning Commission for 'in principle' approval.

(iv) Critical assistance for WHO pre-qualification for Pharma PSUs/R&D

This scheme is 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.

(v) New Schemes to be introduced in 2010-11

To enable it to execute competently and effectively the role entrusted to the newly created Department of Pharmaceuticals, it is proposed to introduce some important new schemes viz Environment and Hazard Management, Generic Drug Campaign, Pharma Brand India Initiative, etc. during the year 2010-11.

43 **The Scheme-wise allocation under New Schemes is given below:-**

(Rs. in Crore)

S.No.	Scheme	11th Plan	2007-08		2008-09		2009-10		2010-11
			BE	RE	BE	RE	BE	RE	BE
4.4	Interest Subsidy for Schedule M/Compliance for Mes	340.00	15.00	11.80	27.00	13.15	15.00		0.01
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
4.7	ERP, R&D Parks	5.00	0.01	1.00	0.00	0.00	1.50	2.00	5.00
4.8	Critical assistance for WHO pre-qualification for Pharma PSUs/R&D	75.00	0.01	1.00	10.00	10.00	10.00	10.00	14.00
4.9	New Schemes (to be introduced 2010-11)		1.02		0.00		20.00	7.00	25.00
	Total	425.00	16.05	14.00	37.50	23.65	47.50	19.80	45.01

D Major Head 4857

Capital Outlay on Pharmaceutical Industries

Total Allocation - NIL

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
--	--	--	--	--	--

44 On being asked about the reason of Nil allocation in Major Head 4857, the Department in a written reply stated as under:-

“Under Capital section there are two major heads, i.e. 4857 for Equity Investment and 6857 for Loans to PSUs. As the entire allocation for the PSUs in 2010-11 is as interest bearing loan and equity investment has not been provided for, therefore, the capital head of 4857 does not reflect any allocation.”

45 Clarifying ‘Nil’ allocation a representative of the Department of Pharmaceuticals stated as under:-

“Sir, that relates to equity investment. Whatever support we are rendering to the PSUs is by way of loan and not by way of equity support, which is why the figure is zero. We are giving an outlay of Rs.40 crore”.

46 Further, another official of the Department of Pharmaceuticals stated as under:-

“Actually, the Government is not always pro in term of giving equity. It will give loans so that the PSUs feel that they should take money only when it is most required and they also have to return it”.

E **Major Head 6857**

Loans for Pharma Industries

Total Allocation is Rs.40.05 crore

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
30.00	0.07	24.40	0.07	40.00	0.05

47 The Department has 4 running PSUs under its administrative control viz. Bengal Chemicals & Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL), Indian Drugs & Pharmaceuticals Limited (IDPL) and Karnataka Antibiotics & Pharmaceuticals Limited (KAPL); all of which, except KAPL, are loss making and have been declared sick.

48 Apart from above PSUs, there are two closed PSUs, viz 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 & Manipur State Drugs & Pharmaceuticals Limited (MSDPL), Imphal and two Joint Ventures of IDPL, namely Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Jaipur & Orissa Drugs & Chemicals Limited (ODCL). All these Joint Ventures except RDPL are loss making and have been closed.

49 However, consistent with the policy of ensuring availability of good quality of life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL. The rehabilitation scheme of IDPL is under consideration.

50 Further, in the interest of continued growth and development of KAPL & RDPL, the Government has approved on 2 January 2009, to de-link KAPL & RDPL from HAL & IDPL and transfer to the Government of India the shareholding of HAL & IDPL in KAPL & RDPL respectively. The Government of India has also invested Rs. 7.10 crore in KAPL (through HAL) for upgrading its manufacturing facilities conforming to WHO-GMP standards and setting up a new WHO-GMP compliant Cephalosporin plant.

Other joint venture partner, viz. Karnataka State Industrial & Investment Development Corporation (KSIIIDC) would bring in additional investment of Rs. 4.90 crore in KAPL. Similarly, the Government of India has also invested Rs. 2.00 crore in RDPL (through IDPL) for upgrading its manufacturing facilities conforming to WHO-GMP standards as also to enhance its manufacturing capacity in tablets, capsules and liquid sections.

51 Other joint venture partner, viz. Rajasthan Industrial & Investment Corporation (RIICO) would bring in additional investment of Rs. 1.90 crore. Transfer of shares from HAL to the President of India has been effected in the Books of KAPL w.e.f. 1st October 2009. As regards de-linking of RDPL from IDPL, transfer of shares from IDPL to the President of India is under process.

(a) **Bengal Chemicals and Pharmaceuticals Limited (BCPL)**

Loans given to BCPL are as under:-

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
10.00	0.01	14.90	0.01	25.00	0.01

52 The Bengal Chemicals & Pharmaceuticals works was a sick company in the private sector. It was nationalized on 15 December 1980. A new public sector company in the name and style of Bengal Chemicals & Pharmaceuticals Limited was incorporated on the 17 March 1981. The BCPL continues to be a sick company.

53. The company was formally declared sick by the Board for Industrial and Financial Reconstruction (BIFR) on the 14 January 1993. A revival package was approved by the BIFR on the 4 April 1995. The package was reviewed by BIFR from time to time. As a result, BIFR sanctioned a Modified Revised Rehabilitation Scheme on 14 January 2004 for the revival of BCPL. This envisages a number of reliefs and concessions from the Government and other agencies.

54 The Modified Revised Rehabilitation Scheme sanctioned by BIFR was further modified by the Company keeping in view its requirements for modernization of plants & machinery and placed before BRPSE for its recommendations. The Board for Reconstruction of Public Sector Enterprises (BRPSE) at its meeting held on 25 August 2006 recommended the modified revival plans for approval.

55 The company has four manufacturing units one each at Maniktala at Kolkata, Panihati at North 24 Parganas (West Bengal), one at Mumbai and at Kanpur (UP). The company manufactures and markets wide range of industrial chemicals, a large number of Drugs and Pharmaceuticals besides Cosmetics and Home Products. In the Home Products, the well known products include Cantharidine Hair Oil and Lamp Brand Phenol.

56 On 21 December 2006, the Government approved the Revival Scheme for BCPL which inter alia involves Cash Infusion of Rs. 207.19 crore and write off/waiver of Government of India Loan and interest thereon as on 31 March 2005 to the extent of Rs. 233.41 crore.

57 When asked about the latest position of revival package of BCPL, the Department in a written reply submitted that an all out effort would be made by the Department so that revival plan of BCPL is implemented as per schedule. It was further added by the Department that the following steps have been taken in respect of releasing of funds and monitoring the implementation.

(i) **Release of Funds**

58 The Cabinet Committee on Economic Affairs (CCEA) approved the Rehabilitation Scheme of BCPL on 21 December 2006 which inter alia involves Cash infusion of Rs. 207.19 crore. Out of Rs. 207.19 crore, Rs. 117.19 crore (Rs. 55 crore CAPEX & Rs. 62.19 crore Non-CAPEX) was released on 31 March 2007 and after that only Rs. 50.00 crore was released during the last three years ending 2009-10 (upto August 2009) against Rs. 75.00 crore. After August 2009, additional fund of Rs. 14.40 crore have also been released and attempts for release of Balance Rs. 25.60 crore is being made as per the urgent requirements of BCPL.

(ii) **Review/monitoring**

- a) Monthly Review Meetings are held in the Department
- b) Inspection visits by the Higher Officers of this Department to BCPL to see the implementation of Projects taken up under revival scheme.
- c) Weekly internal meetings under the chairmanship of Director (Finance), BCPL to review the Project implementation and Production Sale follow up.
- d) Preparation and implementation of Web enabled software for Real Time Project Implementation Reporting and follow-up.

59 On being asked as to how the Department of Pharmaceuticals will ensure that funds are actually utilized for the purpose for which they are released, the Department replied as under:

“Implementation of Projects taken up under revival scheme and also the progress made by the BCPL in respect of Production and Sales are being monitored in this Department with special care on monthly/weekly basis. Special care is taken that the project money does not get diverted for other purposes”.

(b) **HINDUSTAN ANTIBIOTICS LIMITED (HAL)**

The loans given to HAL are as under:-

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
20.00	00.02	9.50	0.02	15.00	0.01

60 The Hindustan Antibiotics Limited (HAL), Pimpri, Pune was incorporated on the 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 three joint sector units promoted by HAL in collaboration with the respective State Governments. These are the Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bangalore (Karnataka), the Maharashtra Antibiotics & Pharmaceuticals Limited (MAPL). at Nagpur (Maharashtra) since closed and the Manipur State Drugs & Pharmaceuticals Limited (MSDPL) at Imphal (Manipur since closed). In addition there was a joint venture, namely, HMGB, with a private sector company Max GB since discontinued.

61 As the company had been incurring losses continuously since 1993-94, it was referred to the BIFR in January, 1997. BIFR declared the company formally sick on 31 March 1997. The BIFR appointed the Industrial Development Bank of India (IDBI), Mumbai as the Operating Agency for a techno-economic viability study and report. The first rehabilitation scheme prepared by HAL was revised on the directions of the BIFR and the Government.

62 Hindustan Antibiotics Limited was earlier engaged in the manufacture of bulk drugs mainly Penicillin, Streptomycin, Gentamycin, Hamycin, Aureofungin and other formulation products. At present, the fermentors as well as major portion of utilities equipments like Boilers, Compressors, Chillers, Effluent treatment etc. are lying idle. HAL can utilize these facilities either for the production of Penicillin G or for Erythromycin Thiocyanate which are required in large quantities in India.

63 On being asked about the reasons for not utilizing these facilities by HAL so far, the Department stated as under:-

“HAL invited offers for utilizing these fermentation facilities for manufacture of Penicillin in leading newspapers several times from 2004 onwards. However, there was no response and facilities could not be utilized. Poor response was due to dumping of fermentation based products offered by China at prices not viable for Indian manufacturers. As such the facilities could not be utilized”.

64 Dwelling upon the utilization of the aforesaid equipment, the Department in their written reply stated that HAL plans to utilize these fermentation facilities now for manufacture of Erythromycin based antibiotics since manufacturing of Pen-G is not viable. The proposal has been finally cleared by Planning Commission in March 2010 and funds are expected to be released in financial year 2010-11.

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

The loans given to IDPL are as under:-

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
--	0.02	--	0.02	--	0.01

65 The Indian Drugs & Pharmaceuticals Limited (IDPL) was incorporated on 05 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 (Uttaranchal), Hyderabad (Andhra Pradesh) and Gurgaon (Haryana). IDPL has two wholly owned subsidiaries, namely, IDPL (Tamil Nadu) Limited, Chennai (Tamil Nadu) and Bihar Drugs & Organic Chemicals Limited at Muzaffarpur (Bihar). In addition, IDPL has two joint sector undertakings, promoted in collaboration with the respective State Governments. These are Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Jaipur, and Orissa Drugs & Chemicals Limited (ODCL), Bhubaneshwar.

66 Indian Drugs and Pharmaceuticals Ltd. (IDPL), Gurgaon is a sick company under reference to Board for Industrial & Financial Reconstruction (BIFR) since 1992. A rehabilitation package for revival of IDPL was placed before the Cabinet. The Cabinet considered the package at its meeting held on 17 May 2007 and referred it to Group of Ministers (GoM) for consideration at the first instance.

67 The Group of Ministers considered the rehabilitation proposal for revival of IDPL at its meeting held on 11 October 2007. The GoM advised that revival plan of IDPL should be based on public interest goals, which the organization would be expected to serve when revived. Examples of these could be assistance to Government in response to public health emergencies, interventions to make generic medicines affordable and available, etc.

68 Considering the advice of GoM at its meeting held on 11 October 2007, IDPL engaged Ernst & Young (E&Y) to prepare pre-feasibility report for its revival. Taking into account the pre-feasibility report, a modified rehabilitation plan for revival of IDPL was prepared for consideration of GoM. However, before the proposal could be considered, General Elections were announced. Chairman of GoM, therefore, desired that the matter be taken up after new Government is formed after the Lok Sabha Elections. With the Constitution of the new Government after the elections, the Department with the approval of Minister (C&F) has recommended that the proposal be placed before the Cabinet for decision. The Cabinet Secretariat has since asked the Department to submit Note for the Cabinet for revival of IDPL.

69 As per the written replies furnished by the Department, the note for Cabinet for revival of IDPL is being finalized by them after the formation of new Government. On being asked about the reasons for delay in finalizing the note for cabinet and the present status of IDPL the department submitted as under:-

“As the stakes for revival of IDPL are high and the revival package is large, Department of Pharmaceuticals is in the process of examining the proposal from all aspects of its implementability to take a view before placing the same before the Cabinet”.

(d). **BENGAL IMMUNITY LIMITED (BIL)**

Loans given to BIL are as under:-

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
--	0.01	--	0.01	--	0.01

70 The 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 nationalized w.e.f. 01 October 1984 and a new public sector company in the name and style of Bengal Immunity Limited was incorporated on the 01 October 1984. The company had two manufacturing units, one each at Baranagar at Kolkata (West Bengal) and at Dehradun (Uttaranchal).

71 On 13 September 2002, BIFR formed its prima-facie opinion to wind up the company. The opinion was confirmed by BIFR at the hearing held on 25 February 2003. With the approval of the Cabinet, VSS was introduced. The company relieved all employees under VSS as on 30 September 2003.

72 The company is closed. The Kolkata High Court has already appointed the Official Liquidator. However, the appointment of Liquidator in respect of BIL has been stayed on a Writ Petition filed by the BIL Employees Union and thereafter the Department of Pharmaceuticals on the ground that a Committee has been constituted to look into the issue of revival of BIL looking to the order passed by AAIFR.

73 The Committee, constituted to explore the possibility of revival of Bengal Immunity Limited (BIL), recommended revival of BIL through public private partnership mode.

74 The constitution of the Committee was by reason of the order passed by the Appellate Authority for Industrial & Financial Reconstruction (AAIFR). As such, AAIFR also heard initially short listed five companies. Subsequently, AAIFR called all five companies who met the eligibility criteria.

75 AAIFR, inter alia, asked the Government to consider and evaluate proposals from 5 short listed companies mentioned in the Report of the Committee. SBI Caps have been appointed for evaluation of proposals of 5 short-listed companies as per the order-dated 03 March 2008 passed by AAIFR. The recommendations of SBI CAPS have since been received and are under consideration.

(e) **SMITH STANISTREET PHARMACEUTICAL LTD.**

Loan given to Smith Stanistreet Pharmaceutical Ltd is as under:-

(Rs.in crore)

BE 2009-10		RE 2009-10		BE 2010-11	
Plan	Non-Plan	Plan	Non-Plan	Plan	Non-Plan
--	0.01	--	0.01	--	0.01

76 It is 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 4th May, 1972. The company was nationalized on 1st 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).

77 The company was formally declared sick by the Board for Industrial and Financial Reconstruction (BIFR) on 21st December, 1992. The BIFR approved a revival package for the company on the 31st 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 17 October 2000.

78 The BIFR heard the case on 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.

79 The Official Liquidator has been appointed by the Hon'ble High Court of Calcutta vide Order dated 12 January 2006. The Registered Office, Plant & machinery and other assets have since been taken over by the Official Liquidator.

V MISCELLANEOUS

(i) R&D VENTURE FUND

80 As per the written reply furnished by the Department of Pharmaceuticals, the Department is in process of finalizing a Pharma R&D Venture Fund which would cater to the requirement of R&D of Drug Discovery and Innovation. It has also been mentioned that the Government would provide an initial corpus which could leverage such amount by raising resources from public and private institutes as well as existing funds within India and overseas.

81 When asked to give the details of R&D Venture Fund, the Department in their written reply furnished the following facts:-

“Department of Pharmaceuticals(DoP) has initiated to launch a scheme called “Venture Finance and Incubation Fund for Innovative R&D in Pharmaceuticals” to promote and support R&D in Pharma industry and industries engaged in the manufacture of biomedical devices. Under this scheme, the DoP provides partial financial support in the following areas:

- i. Development of innovative steps in generic and bio similar drugs, novel formulations.
- ii. Quality improvement of the essential drugs and those related to neglected diseases in the Indian and developing world context.
- iii. Novel drug delivery systems and stem cell as well as nano-pharma products based on r-DNA technologies.
- iv. Biomedical devices which are belonging to the class as medicated stents and other advanced products.
- v. Innovation for prevention of hazard and pollution in Pharma industry and
- vi. Included but not limited to other frontier areas of Pharma research including computer aided drug design, pharmaco- kinetics and molecular research for NCEs

82 The project is expected to result in significant benefits in term of raising the technological level of the industry concerned, high turnover, energy and material savings/recovery, foreign exchange savings and

earnings, or safer and eco-friendly process/product or large scale diffusion and utilisation of demonstrated technologies.

83 The project is under examination of Planning Commission for their 'in principle' approval. It has been further added that the proposal regarding the establishment of R&D Venture Fund is currently under the examination of the Department and a specialized agency – National Institute of Public Finance and Policy (NIPFP) – an institution under the Ministry of Finance, Government of India is proposed to be engaged for this task. Based on the report of NIPFP further steps would be taken”

(ii) **JAN AUSHADI SCHEME**

84 The Department of Pharmaceuticals has 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 this 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 November 2008 with the support and cooperation of the State Government of Punjab. So far 39 JAGDS have been opened in different States.

85 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 Price	Generics Price	Difference
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. Cetirizine	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

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

The Department proposed to open JAS in each district of the country, in the year 2009-10 and for this a modest provision of Rs. 5.00 Crore has been sought from the Planning Commission. Depending upon the success of the Programme in 2009-10, enhanced funds would be sought from the Planning Commission in 2010-11.

87 When asked whether any feasibility study has been conducted by the Department for opening Jan Aushadi stores in villages to achieve the objective of providing quality generic drugs at affordable prices to the common man, the Department in a written reply stated as under:-

“An assessment was made for Jan Aushadhi Scheme in the Pharma Advisory forum chaired by the then Minister (C,F & S). Also an Expert Committee of Doctors, Senior Officials, representatives of NGO, AIIMS, RML etc. advised on the implementation of the Programme. As regards Rajiv Gandhi Yojana, views were asked from state Governments”.

88 When asked whether specific steps are being taken by the Department to encourage participation of State Governments in the Jan Aushadi Scheme, the Department in a written note informed as under:-

“Chief Secretaries of all States have been requested to encourage opening of Jan Aushadhi Outlets in the district hospitals in their States. There has been encouraging response from some of the States like Rajasthan and Punjab. Some more State Governments like Orissa, Andhra Pradesh, Himachal Pradesh and Delhi have now shown interest in the Scheme. Meetings have been held by Secretary (Pharma)/Joint Secretary (Pharma) with Chief Ministers (eg. Assam, Delhi, Himachal Pradesh etc). MOS (C&F) has presently written letters to a number of Chief Ministers and spoken personally to them”. The Department further submitted that 43 Jan Aushadhi Generic Drug Stores have been opened in different States so far.

89 When asked about the steps contemplated by the Department for making the opening of Jan Aushadi Stores mandatory in remaining States, the Department responded in its written reply as under:-

“Under this Scheme, the State Government has to provide space in Government Hospital premises for running of the outlets (Jan Aushadhi Store). 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 Jan Aushadhi Store. The operating agency for Jan Aushadhi Store is nominated on the basis of the recommendations of the State Government. Chief Secretaries of all States have been requested to encourage opening of Jan Aushadhi Outlets in the district hospitals in their States. As such no instructions have been issued for mandatory opening of Jan Aushadi Stores in the remaining States”.

90 During the course of evidence, the Secretary, Department of Pharmaceuticals informed that at present 231 medicines are being sold by the Jan Aushadi Stores.

91. On being asked whether vaccines are provided by the Jan Aushadi Stores the Secretary Department of Pharmaceuticals during the course of evidence stated that at present there is no such provision. He further stated as under:-

“....actually the vaccines are not within the mandate of this Department. The second reason is that we could yet have introduced vaccines but most of the vaccines like the HIV AIDS programmes are distributed free of cost through the Public Distribution System. Putting it in the Jan Aushadi Store and charging a price for it may not seem to be very good”.

OBSERVATIONS AND RECOMMENDATIONS

1 The Committee note that out of an outlay of Rs.1396.17 crore for the 11th Five Year Plan (2007-12) for the Department of Pharmaceuticals, the allocation in the first four years, i.e. from 2007-08 to 2010-11 is Rs.566.77 crore which is about 40% of the total plan allocation. Thus, an amount of Rs.829.40 crore which comes to about 60% will have to be provided during the last year of the 11th plan i.e. 2011-12. During these years, the outlays sanctioned by the Planning Commission were well below the amounts asked for by the Department. The Committee are inclined to conclude that the approach of the Planning Commission in this case has been totally unrealistic and not conducive at all to enable the Department of Pharmaceuticals to achieve the expected plan targets. The Committee, therefore, desire that the Planning Commission should ensure that the remaining outlay (60% of the plan) is provided in the last two years of the plan by increasing the allocation at 2010-11 RE stage and in 2011-12 so that the Department is able to plan and utilize the resources for achieving the laid down targets.

2 What has caused concern to the Committee is the fact that during the year 2009-10, the Department could spend only Rs.76.09 crore (upto 31 January 2010) as against BE of Rs.155.25 crore and RE Rs.105.00 crore This indicates that the Department has not been able to utilize even the reduced funds which have been made available to them during 2009-10. Similar was the position even in each of the three years of the plan, a fact which was commented upon by the Committee in their earlier Report. The Committee are inclined to conclude that on the one hand Department has not been provided the requisite funds by the Planning Commission and on the other even the curtailed allocation has not been fully utilized by them. The Committee desire that the Ministry gear up their machinery and ensure that the sanctioned outlays are utilized in a proper manner during the last two years of the plan period 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.

3 The National Institute of Pharmaceuticals 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 approved setting up of six more institutes under NIPER in 2007. The Committee have been informed that classes in some streams of pharmaceutical sciences have already started. Keeping in view the laudable objectives of NIPER and its performance the Committee desire that necessary formalities should be expeditiously completed so that these six institutes become fully functional by April 2011.

4 The budgetary grant for NIPER during 2009-10 was Rs.57.04 crore under plan allocation and Rs.20 crore under non plan allocation at BE stage. The plan allocation was, however, reduced to Rs.47.15 crore at RE stage and the actual plan expenditure upto 31 January 2010 was Rs.39.65 crore. For this year, i.e. 2010-11, Rs.61 crore has been provided as plan allocations and Rs.19.64 crore as non plan allocation at BE stage. The Committee hope that these funds will be fully utilized and NIPER would be able to develop quality and excellence in pharma education and research so as to strengthen its links with industry both at national and international levels.

5 The National Pharmaceutical Pricing Authority (NPPA) is responsible for price fixation/revision of drugs and formulations. NPPA also monitors the prices of decontrolled drugs and formulations, enforce and implement the provisions of the Drugs (Price Control) Order, 1995. An amount of Rs.7.06 crore (0.99 crore under plan and Rs.6.07 crore non plan) has been earmarked for NPPA at BE 20010-11. The major part of this allocation is meant for the new scheme 'Proposal for Building Robust and Responsive Statistical system for NPPA'. The Committee note that out of the five schemes proposed by NPPA for the Eleventh Five Year Plan, four schemes are yet to get in-principle approval of the Planning Commission. The Committee feel that half-hearted approach can never produce the desired results. They, therefore, strongly recommend that the Department should expeditiously take up the issue with the Planning Commission regarding early approval of the schemes proposed by the NPPA. The Committee may be apprised of the progress made in this regard.

6 The Public Sector Undertakings (PSUs) in the pharmaceuticals sector were expected to enable and ensure production and availability of medicines to the common people at large. The Committee regret to note that the present status of the pharma PSUs are, in general, extremely dismal. Out of the seven pharma PSUs under the administrative control of the Department of Pharmaceuticals, two undertakings viz., the Smith Stanistreet Pharmaceuticals Limited (SSPL) and the Bengal Immunity Limited (BIL) have been closed and are under liquidation since 2003. Three PSUs, viz., the Indian Drugs and Pharmaceuticals Limited (IDPL), the Bengal Chemicals and Pharmaceuticals Limited (BCPL) and the Hindustan Antibiotics Limited (HAL) were declared sick and referred to the Board for Industrial and Financial Reconstruction (BIFR) as they were incurring continuous losses. They are now under different stages of revival/ rehabilitation packages. Only two companies, viz., the Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) and the Rajasthan Drugs and Pharmaceuticals Limited (RDPL) are currently making profits. Collectively, the pharma PSUs have been incurring losses continuously for the last several years. The Committee cannot but express their serious concern over the general plight of the pharma PSUs which ultimately has an adverse effect on the lives of common people in one way or the other. The Committee, therefore, recommend that all pending proposals for the revival of pharma PSUs should be expeditiously considered and Government should extend every possible help to bring the PSUs back to the track. The Committee desire to be apprised of the updated status in this behalf.

7 The Committee have been informed that at the instance of Cabinet Secretariat, a draft note is stated to have been prepared by the Department and is being finalized for consideration by the Cabinet for revival of IDPL, which had been discharging the social responsibility of manufacturing and providing drugs to the general public at reasonable rates. The revival of IDPL being of paramount importance, the Committee desire that the revival plan should be expedited at a much quicker pace. Steps should also be taken for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP standards. The Committee feel that by doing so IDPL would be able to effectively compete with the major pharmaceutical industries in private sector in respect of quality medicines and ultimately would instill confidence in the people. The Committee would therefore, expect concrete action by the Government in this behalf.

8 The Committee note that the revival scheme for Bengal Chemicals and Pharmaceuticals Ltd. (BCPL) has been approved by the Government. The Committee recommend that the revival plan of

the company which had been engaged in manufacturing and marketing a variety of products should be expedited with a missionary zeal in a time bound programme. They also desire that periodical monitoring of the implementation of the revival plan be done at the seniormost level in the Ministry so as to ensure that the revival plan is carried out at a fast pace and also that the funds are fully utilized. The Committee would therefore, expect concrete action in a time-bound framework by the Government in this behalf.

9 The Committee note that the Government has approved the rehabilitation scheme of Hindustan Antibiotics Limited (HAL). Further, the Government has sanctioned the scheme for upgradation of manufacturing facilities of HAL conforming to WHO- GMP standards. The Committee hope that HAL would be able to show perceptible improvement in its performance in the years to come and that the company would be able to generate profit, in addition to fulfilling its social obligations in a meaningful manner.

10 The Committee note that the Department of Pharmaceuticals is in the process of finalizing a Pharma R&D Venture Fund which would cater to the requirement of Research and Development of Drug discovery and innovation. However, while allowing the Venture Fund to cater to the requirement of fund for R&D the Committee expect the Department to take all care for indigenous patenting of such research and innovation. As per the scheme, the Government would provide an initial corpus that would leverage such amount in raising resources from public and private institutes as well as from existing funds within India and overseas. The Committee have been given to understand that the proposal is under examination of Planning Commission for its 'in-principle' approval. While appreciating the innovative scheme for raising funds for R&D by the Department, the Committee call upon the Planning Commission to hasten the process of according approval to this scheme, which is need of the hour.

11 The Committee appreciate the efforts made by the Department for the promotion of unbranded generic medicines through their Jan Aushadhi Stores (JAS). Considering the peculiar price advantage of medicines available through JAS, the Committee desire that the Government should take necessary steps for making mandatory the opening of Jan Aushadhi Stores in all Government Hospitals. *Further, the Committee feel that there is an urgent need to encourage participation of State Governments in the Scheme and, therefore, recommend that the Department*

should persuade the State Governments to allot specific space for opening of Jan Aushadhi Stores at least in the State Government Hospitals. The Committee also desire that the Department should conduct feasibility study for opening of Jan Aushadhi Stores in villages as well to achieve the objective of providing quality generic drugs at affordable prices to the common people. They also recommend that more drugs be brought under generic medicines so that the benefit of the cheap medicines is percolated to the public at large. At the same time, the Committee would also caution that the quality of medicines should not be compromised. There is also a need for giving adequate publicity in print and electronic media to make people aware of the availability of quality medicines at cheaper prices in Jan Aushadhi Stores.

New Delhi;
20 April, 2010
30 Chaitra 1932 (Saka)

ANANTH KUMAR
Chairman,
Standing Committee on
Chemicals and Fertilizers.

MINUTES

**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2009-10)**

FOURTEENTH SITTING

(31.03.2010)

The Committee sat from 1430 hours to 1615 hours.

Present

Shri Ananth Kumar - Chairman

Members

Lok Sabha

2. Smt. Sushmita Bauri
3. Shri Prabhatsinh P. Chauhan
4. Shri Ganeshrao Nagorao Dudhgaonkar
5. Shri N. Peethambara Kurup
6. Shri Baidyanath Prasad Mahato
7. Shri Ponnamm Prabhakar
8. Shri Narendra Singh Tomar
9. Shri T.K.S. Elangovan
10. Shri Tapas Paul

Rajya Sabha

11. Shri Raghunandan Sharma
12. Shri Brijlal Khabri
13. Shri A.A. Jinnah
14. Prof. Anil Kumar Sahani

Secretariat

- | | | | |
|----|----------------------|---|----------------------|
| 2. | Shri N. K. Sapra | - | Additional Secretary |
| 3. | Shri C. S. Joon | - | Director |
| 4. | Shri A.K. Srivastava | - | Deputy Secretary |

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

- | | |
|-------------------------------|--|
| 1. Shri Ashok Kumar, | Secretary |
| 2. Shri P.K.Sinha | Additional Secretary & Financial Adviser |
| 3. Shri Devendra Chaudhry, | Joint Secretary |
| 4. Shri Arun Jha, | Joint Secretary |
| 5. Shri P.V. Rajeev Sebastian | Economic Advisor |
| 6. Dr. A.K.Vishandas | Deputy Director General |
| 7. Shri Akhilesh Jha | Controller of Accounts |
| 8. Smt. Asha R Rungta | Director (Finance) |

II. REPRESENTATIVES OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

- | | |
|---------------------|------------------|
| 1. Dr. S.M. Jharwal | Chairman |
| 2. Shri Om Prakash | Member Secretary |
| 3. A.K.Singhal | Adviser, NPPA |

III. REPRESENTATIVES OF PSUs / AUTONOMOUS INSTITUTION

- | | |
|----------------------------|--|
| 1. Shri T. K. Ranganathan, | Managing Director,
Hindustan Antibiotics Ltd. |
| 2. Dr. Ms. Jayshree Gupta, | Chairman & Mg. Director,
Indian Drugs & Pharmaceuticals Ltd. |
| 3. Shri S. Kundu, | Managing Director,
Bengal Chemicals & Pharmaceuticals Ltd. |
| 4. Shri M.K. Nagendra | Managing Director,
Rajasthan Drugs & Pharmaceuticals Ltd. |
| 5. Shri S.L. Phadke, | Chairman & Mg. Director,
Karnataka Antibiotics & Pharmaceuticals Ltd. |

2. At the outset, Hon'ble Chairman welcomed the members of the Committee.
3. Thereafter, he called the officials of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), and the Public Sector Undertakings and invited their attention 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 Ministry and the PSUs introduced themselves. Thereafter, the Joint Secretaries of the Department of Pharmaceuticals gave power-point presentation on Demands for Grants (2010-11) During the power-point presentation, the Chairman raised certain queries which were replied to by the Secretary and other officials of the Department of Pharmaceuticals.
5. Subsequent to the power-point presentation, the Chairman and members of the Committee raised some questions which were answered by the Secretary (Department of Pharmaceuticals), and Chairman (NPPA). They also promised to furnish the requisite information in writing which was not readily available with them. The following issues related to the Department of Pharmaceuticals were discussed :-
 - (a) Performance of pharmaceuticals industry ;
 - (b) Schemes / programmes of the Department of Pharmaceuticals;
 - (c) Role of NIPER in the pharmaceutical industry ;
 - (d) Drugs price control ;
 - (e) Availability of Life Saving Drugs ;
 - (f) Generic Drug Campaign ;
 - (g) Revival of sick PSUs ; and
 - (h) Finalisation of National Pharmaceuticals Policy
 - (i) Jan Aushadhi Scheme
 - (j) Underspending during the year 2009-10
 - (k) Underutilization of funds in North Eastern Areas during the year 2009-10
 - (l) Investment in Pharmaceutical Industry
6. A verbatim record of the proceedings of the sitting has been kept.

THE WITNESSES THEN WITHDREW.

EXTRACT OF MINUTES

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
(2009-10)**SEVENTEENTH SITTING**

(16.04.2010)

The Committee sat from 1500 hours to 1600 hours.

Shri Ananth Kumar - in the Chair***Members******Lok Sabha***

2.	Smt. Sushmita Bauri
3.	Shri Ganeshrao Nagorao Dudhgaonkar
4.	Shri Ponnamm Prabhakar
5.	Shri Suresh Kumar Shetkar
<i>Rajya Sabha</i>	
6.	Shri J.D. Seelam
7.	Shri Raghunandan Sharma
8.	Shri C.P. Thakur
9.	Shri A.A. Jinnah
10.	Shri Anil Kumar Sahani

Secretariat

5.	Shri N. K. Sapra	-	Additional Secretary
6.	Shri Ashok Sarin	-	Joint Secretary
7.	Shri C. S. Joon	-	Director

2. At the outset, Hon'ble Chairman welcomed the members to the sitting of the Committee.

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

- (i) XX XX XX XX
- (ii) XX XX XX XX
- (iii) Demands for Grants (2010-11) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals),

4. The draft Report was adopted by the Committee with certain amendments.
5. The Committee authorised the Chairman to make consequential changes, if any, arising out of the factual verification of the Report by the Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers and present the same to both the Houses of Parliament.

The Committee then adjourned.

XX Matters not related to this Report.