6

STANDING COMMITTEE ON
CHEMICALS & FERTILIZERS

(2014-15)

SIXTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS

(2015-16)

SIXTH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

20 April, 2015/ 30 Chaitra, 1936 (Saka)

CC&F.No.6

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(SIXTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2015-16)

Presented to Lok Sabha on 20 April 2015

Laid in Rajya Sabha on 23 April 2015

LOK SABHA SECRETARIAT
NEW DELHI
20 April, 2015/30 Chaitra 1936, (Saka)

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Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri Idris Ali
3. Smt. Anju Bala
4. Shri B.N. Chandrappa
5. Shri Sankar Prasad Datta
6. Smt. Veena Devi
7. Shri R. Dhruvanarayana
8. Shri Satish Kumar Gautam
9. Shri K. Ashok Kumar
10. Shri Kamalbhan Singh Marabi
11. Shri Chhedi Paswan
12. Smt. Kamala Devi Patle
13. Shri Rajendran S.
14. Shri Chandu Lal Sahu
15. Dr. Kulamani Samal
16. Dr. Uma Saren
17. Dr. Krishan Pratap Singh
18. Shri Taslimuddin
19. Smt. Rekha Verma

20.* Shri Innocent

21.* Shri Kotha Prabhakar Reddy

RAJYA SABHA

22. Shri Biswajit Daimary
23. Dr. M.S. Gill
24. Shri Sanjay Dattatraya Kakade
25. Shri Narayan Lal Panchariya
26. Shri K. Parasaran
27. Shri Garikapati Mohan Rao
28. Dr. Sanjay Sinh

29.* Shri Palvai Govardhan Reddy

30.% Shri Mansukh L. Mandaviya

31.% Dr. Chandrapal Singh Yadav

SECRETARIAT

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

Changed the nomination of Shri Murli Deora, Member of Rajya Sabha from the Committee on Chemicals and Fertilizers to the Committee on External Affairs w.e.f. 25-09-2014.
** Shri Palvai Govardhan Reddy, Member of Rajya Sabha nominated w.e.f. 08-10-2014*
Shri Mohanbhai Kalyanjibhai Kundariya Nominated as Minister of State w.e.f. 09.11.2014
The term of Shri Brijlal Khabri, MP (RS) has expire w.e.f. 25.11.2014
Changed the nomination of Adv. Joice George, Member of Lok Sabha from the Committee on Chemicals and Fertilizers to the Personnel, Public Grievances, Law and Justice w.e.f. 24-12-2014.
**Shri Innocent, and Shri Kotha Prabhakar Reddy, Member of Lok Sabha nominated w.e.f. 22-12-2014*
% Shri Mansukh L. Mandaviya, Member of Rajya Sabha nominated w.e.f. 31-12-2014
% Dr. Chandrapal Singh Yadav, Member of Rajya Sabha nominated w.e.f. 29.01.2015

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2014-15) having been authorised by the Committee to submit the Report on their behalf present this Sixth Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2015-16.

2. The Committee examined the Demands for Grants (2015-16) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which were laid in Lok Sabha and Rajya Sabha on 17 March, 2015.

3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 26 March, 2015.

4. The Report was considered and adopted by the Committee at their sitting held on 16 April, 2015.

5. The Committee wish to express their thanks to the Officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for their cooperation in furnishing the written replies and other material/ information and for placing their views before the Committee.

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

New Delhi;
16 April, 2015
26 Chaitra , 1936 (Saka)

Anandrao Adsul
Chairperson
Standing Committee on
Chemicals and Fertilizers

CHAPTER-I

INTRODUCTORY

1.1 The Cabinet Secretariat notified creation of a new Department, namely the Department of Pharmaceuticals, under the Ministry of Chemicals & Fertilizers which came into being w.e.f. 1st July 2008 with the objective to give greater focus and thrust on the development of pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to pharmaceutical sector which required integration of work with other ministries.

1.2 Following work have been allocated to the Department of Pharmaceuticals:

(i) Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.

(ii) Promotion and co-ordination of basic, applied and other research in areas related to the Pharmaceuticals sector.

(iii) Development of infrastructure, manpower and skills for the Pharmaceuticals sector and management of related information.

(iv) Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.

(v) Promotion of public – private – partnership in pharmaceutical related areas.

(vi) International cooperation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.

(vii) Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.

(viii) Technical support for dealing with national hazards in pharmaceutical sector.

(ix) All matters relating to National Pharmaceuticals Pricing Authority including related functions of price control/monitoring.

(x) All matters relating to National Institutes of Pharmaceutical Education and Research.

(xi) Planning, development and control of; and assistance to, all industries dealt with by the Department.

(xii) Bengal Chemicals and Pharmaceuticals Limited.

(xiii) Hindustan Antibiotics Limited and its Subsidiaries and JVs.

(xiv) Indian Drugs and Pharmaceuticals Limited and its Subsidiaries.

(xv) Karnataka Antibiotics and Pharmaceuticals Limited.

(xvi) Rajasthan Drugs and Pharmaceuticals Limited.

(xvii) Bengal Immunity Limited.

(xviii) Smith Stanistreet Pharmaceuticals Limited.

1.3 The work of the Department has been organized into three Divisions *viz* Pharmaceuticals Industry Division, Public Sector Undertakings Division and R and D division comprising National Institute of Pharmaceutical Education and Research, (NIPER) and Research and Development. The National Pharmaceuticals Pricing Authority (NPPA), an attached office of this Department is entrusted with the work of fixation and revision of prices of Pharmaceutical products under Drug Price Control Order, 2013.

1.4 **The detailed Demands for Grants (2015-16) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 17 March 2015. The demand shows a budgetary support of Rs. crore [(Rs. 210 crore (Plan) + Rs.49.02 crore (Non-Plan)]. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2015-16. The detailed analysis along with Observations/ Recommendations of the Committee are stipulated in a separate chapter at the end of the Report. The Committee expect the Department of Pharmaceuticals to take the Committee's recommendation seriously and to act on them expeditiously. The Committee also expect that the Department will take all necessary steps for proper and timely utilization of funds ensuring completion of the various plans and projects in a time bound manner.**

CHAPTER-II

AN OVERVIEW OF PHARMACEUTICAL INDUSTRIES

PHARMACEUTICAL INDUSTRY

2.1 The annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs.128044.29 crore during the year 2013-14. The share of export of Drugs, Pharmaceuticals and Fine Chemicals is Rs.63293.91 crores. This segment of Industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. The industry has developed excellent GMP (Good Manufacturing Practices) compliant facilities for the production of different dosage forms. The strength of the industry is in developing cost effective technologies in the shortest possible time for drug intermediates and bulk activities without compromising on quality. This is realized through the country's strengths in organic chemicals' synthesis and process engineering.

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

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

2.4 Many Indian companies have got various international regulatory approvals for their plants, from agencies like USFDA, MHRA-UK, TGA-Australia, MCC-South Africa etc. Outside USA India has the highest number of USFDA approved plants for generic drugs' manufacture.Major share of Indian Pharma exports is going to developed western countries and it speaks not only about excellent quality of Indian pharmaceuticals but also about the reasonableness of the prices. Some of the leading Indian Pharma companies derive 50% of their turnover from International business.

2.5 IMPORTS

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

Year	Import of Medicines & Pharmaceuticals Products (Rupees in Crore)
2011-12	14287.66

Year	Import of Medicines & Pharmaceuticals Products (Rupees in Crore)
2012-13	16965.09
2013-14	17944.05

The country is almost self-sufficient in case of formulations. The imports are being made on quality and economic considerations and not necessarily due to non-availability from domestic sources. Manufacturers of Drugs and Pharmaceuticals are free to produce any drug approved by the Drug Control authorities.

Imports of Drugs and Pharmaceuticals is done as per Foreign Trade Policy. However, import of some drugs and drug intermediates is still restricted under current Foreign Trade Policy. Imports which are restricted are basically due to common HS codes for some narcotic substances or similarity to some Ozone Depleting Substances (ODS).

2.6 **EXPORTS**

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

Year	Exports of Medicines & Pharmaceuticals Products (Rs. in Crore)
2011-12	544906.73
2012-13	602016.70
2013-14	690236.77

2.7 **PHARMA EXPORT PROMOTION COUNCIL (Pharmexcil)**

The Department had played a pivotal role in the formation of Pharmexcil consequent to the recommendation from 9th Five Year Plan Working Group Report on Drugs and Pharmaceuticals. In the light of this, the Department constantly interacts with Pharmexcil in their work areas. The role of Pharmexcil is for facilitation of exports of Drugs, Pharmaceuticals, Biotechnology products, Herbal medicines and Diagnostics, to name a few. It is authorized to issue Registration-cum-Membership Certificate (RCMC) which is one of the requirements for the importers and exporters of commodities. In addition to this, Pharmexcil is concerned with giving export thrust to the various products through visits of delegations to various markets abroad, organizing of seminars, workshops and exhibitions. As a major area of work, Pharmexcil also holds Buyers/ Sellers meets and compiles detailed data base on pharma exports and problems in exporting pharma products.

2.8 **Pharmaceuticals Promotion Development Scheme (PPDS)**

The Objective of Pharmaceuticals Promotion Development Scheme (PPDS) is promotion, development and export promotion in Pharmaceutical sector by extending financial support for conduct of 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. Under PPDS the Department of Pharmaceuticals on its own or through financial support by way of Grant-in aid to the Institutions, organizations, Voluntary organizations or Non Government Organizations as mentioned in Rule 206 of GFR 2005,

i) Conduct Training/knowledge improvement programs/activities on issues/subjects relevant to growth of pharmaceutical industry. An indicative list of subject is as under:-
   a) Quality Management System/Quality Improvement Program
   b) How to handle USFDA notice?
   c) Success Story Presentation-Pharmaceutical Entrepreneur
   d) Government regulations/guidelines for clinical trials in India versus USA, EU etc.
   e) Waste Management

ii) Organize Summits, Convention, Exhibitions, Pharmacy week, meetings etc. in India and abroad and produce promotional materials like films, displays etc.

iii) Conduct research studies, sector reports etc.

iv) Purchase books, quality standards, pharmacopoeias, magazines, directories, software for developing information data banks, developing e-learning modules ets.

v) Give awards to achievers in pharmaceutical industry.

vi) For any other activity not covered under above categories which may be decided by the Department of Pharmaceuticals from time to time.

2.9 **Workshops for Capacity Building of Pharma Industry for compliance to WHO GMP Standard**

Department of Pharmaceuticals in association with Federation of Indian Chamber of Commerce and Industry (FICCI) and WHO is organizing the workshops on Capacity Building of SME's in strengthening quality management systems and best practices for the process improvements, global regulatory requirements and compliance, including WHO GMP requirements of Pharma Industry and Regulation at Bengaluru, Chennai, Gandhinagar, Indore and Mumbai.

2.10 When asked by the Committee as to how does the Department evaluate the growth of the Pharmaceutical industry in the country over the years, the Department in its written reply stated as under:-

"The Pharma sector has recorded a very impressive growth over the years. This growth has primarily been driven by private sector. As per Industry Outlook of Economic Intelligence Service of Centre for Monitoring of India Economy Pvt. Ltd., Mumbai, the sale value of drugs manufactured in the country during the last three years is as under:-

Sl. No.	Year	Production (in Crores)
1	2011-2012	1,20,582.43
2	2012-2013	1,19,421.12
3	2013-2014	1,28,044.29

2.11 When asked by the Committee about the reasons for gradual increase in the import of Medicinal and Pharmaceutical products over the last three years and the ways in which the Department will justify its increased imports in view of 'Make in India' campaign launched by the Prime Minister, the Department in its written reply stated as under:-

"The imports are not made only because of availability. It is also because of economic consideration. The Government has taken various measures to realise the dream of 'Make in India' in pharmaceutical sector. In this direction, the Government had constituted a Committee under the chairmanship of Secretary, Department of Health and Research. The mandate of this Committee was to carefully study the whole issue of Active Pharmaceutical Ingredients (APIs) of critical importance by identifying important APIs and then working out a package of interventions/concession required to build domestic production capabilities and examine the cost implications. The Committee has now submitted its report. Based on the recommendations of the Committee and stakeholders consultations, the Department would come up with a policy on promotion of production of APIs in India. Besides this, with a vision to catalyze and encourage quality, productivity and innovation in pharmaceutical sector and to enable the Indian pharmaceutical industry especially Small and Medium Entreprises to play a leading role in a competitive global market, a scheme titled Cluster Development Programme for Pharma Sector (CDP-PS) is being implemented".

2.12 On being enquired by the Committee about the steps taken or being taken to make the country self reliant in pharmaceutical sector and to reduce the dependence on imports, the Department in its written reply stated as under:-

"The country is almost self-sufficient in case of formulations. The imports are being made on quality and economic consideration and not necessarily due to non-availability from domestic sources. As the pharmaceutical industry is dominated by the private sector, they are free to import as per Foreign Trade Policy under which import of certain drugs and drugs intermediates is restricted. Further, a Committee headed by Dr. V. M. Katoch has submitted recommendations for promoting domestic production of bulk drugs. In the light of these recommendations, the Government is formulating a National Policy for Promoting (APIs)/ Bulk Drugs and intermediates".

2.13 When the Committee asked about the percentage of share of the Indian Pharma Companies and Multi-National Pharma Companies in the export of Pharma sector and the steps being taken to boost the export of Pharma products, the Department in its written reply stated as under:-

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

CHAPTER-III

ANNUAL PLAN AND EXPENDITURE

3.1 When the Committee asked a note on the Budget Proposals, showing the Gross Budget Support (GBS) and the amount actually provided by the erstwhile Planning Commission/Niti Aayog for different schemes in Annual Plan 2015-16 along with their comments, the Department in its reply stated as under:

"Vide communication no. 22016/1/2014-Fin.II dated 10.11.2014, the Department of Pharmaceuticals, while forwarding the Statement of Proposal for pre-budget discussions (RE 2014-15 and BE 2015-16) in respect of Demand No.8- Department of Pharmaceuticals, to the Budget Division, Department of Economic Affairs, Ministry of Finance, had communicated a BE 2015-16 Plan requirement of Rs 871.63 crore (Revenue- Rs 728.11 crore and Capital- Rs 143.52 crore). Subsequently, after finalizing their Plan requirements for Annual Plan 2015-16, the Department of Pharmaceuticals forwarded a proposal to Department of Expenditure, Ministry of Finance, seeking an enhanced budgetary support allocation of Rs 1590.78 crore for 2015-16. This covered funds requirements for development of 6 old NIPERs and 3 new NIPERs, National Centre for R&D in Bulk Drugs at NIPER, Hyderabad, revival package (MDRS) for HAL & IDPL, measures for making all CPSE's WHO-GMP compliant, giving renewed focus to Jan Aushadhi Scheme via Strategic Action Plan 2015 etc.

However, vide communication no. 2 (16)-B(CDN)/2015 dated 15th February 2015, the Budget Division, Department of Economic Affairs, Ministry of Finance have communicated a Plan Allocation of Rs 210 crore only for FY 2015-16 for Department of Pharmaceuticals. Extant instructions regarding allocation for North Eastern Region, Scheduled Caste Sub-Plan and Tribal Sub-Plan were to be adhered to. The allocation indicated by M/O Finance is as follows:-

(Rs. In crore)

Department of Pharmaceuticals	BE 2014-15	BE 2015-16
Central Plan	**207.00**	**210.00**
Pharmaceuticals Industries	149.82	150.00
Central Assistance to WHO	10.00	10.00
Jan Aushadhi Scheme	30.00	35.00
New schemes	15.00	15.00
Creation of IPR facilitation Centre	1.00	0.00
Others	1.18	0.00

This allocation falls far short of the urgent funds requirements projected by this Department for carrying out its laid down mandate and its Vision for development of Indian Pharmaceuticals Industry under "Make in India" initiative, to make India a largest global provider of quality medicines .The domestic pharma sector also has a social relevance from the angle of ensuring availability, access and affordability of medicines to the common man. A severe cut in outlay would have an adverse impact on the implementation of the Plan Schemes being undertaken by this Department and the targets set for the 12th Five Year Plan . In 2014-15, as a result of lesser allocation, the Department was compelled to spread thinner allocations amongst its various Schemes. The Department of Pharmaceuticals has obtained necessary approvals/ clearances required for implementation of Plan Schemes and has speeded up the process of obtaining the others. This is expected to favorably impact the pace of expenditure henceforth.

It may also be noted that for the 12th Five Year Plan, the Department of Pharmaceuticals has proposed an outlay of Rs 12341.89 crore covering various Schemes to the Planning Commission, against which an allocation of Rs 2968 crore was approved. For the first three years of the 12th Five Year Plan, against a proposed outlay of Rs 2566.86 crore (Rs 1127.45 crore for 2012-13, Rs 567.60 crore for 2013-14 and Rs 871.81 crore for 2014-15) sought by the Department of Pharmaceuticals, the Planning Commission allocated a Plan provision of Rs 583 crore only i.e. Rs 188 crore each for 2012-13 and 2013-14, and Rs 207 crore for 2014-15. The balance outlay available for this Department, out of the total approved 12th Plan outlay of Rs 2968 crore, is Rs 2385 crore."

3.2 When the Committee asked about the reasons for this absymally low allocation of funds in BE 2015-16, the Department in its written reply stated as under:-

"For the first three years of the 12th Five Year Plan, Rs 583 crore in total were allocated to this Department by the Planning Commission. Against a balance outlay of Rs 2385 crore (against total approved outlay of Rs 2968 crore for 12th Plan), to be made available in remaining two years of 12th Plan, only Rs 210 crore was made available for BE 2015-16 by Ministry of Finance. Thus, as may be seen, out of a total provision of Rs 2968 crore approved for D/O Pharmaceuticals for the 12th Plan period, only Rs 793 crore was actually made available to this Department, in the first four years of the 12th Plan. This allocation falls far short of the urgent funds requirements projected by this Department for carrying out its laid down mandate. A severe cut in outlay would have an adverse impact on the implementation of the Plan Schemes being undertaken by this Department as it would be compelled to spread thinner allocations amongst its various schemes".

3.3 A statement showing scheme wise details of Plan outlays proposed for the year 2015-16, and scheme wise break-up of outlays approved, is as below:-

PLAN 2015-16 (BE)

(Rs. In crore)

Sl.No.	Scheme/Programme	BE 2015-16 (Proposed)	BE 2015-16 (Approved)	BE 2015-16*
1.	Secretariat and Economic Services	1.00	1.00	1.00
2.	Lumpsum Provision for N.E. Region (NIPER Guwahati)	70.00	21.00	74.68
3.	NIPER, Mohali	148.07	20.00	150.42
4.	NIPER, Ahmedabad	70.00	21.96	136.59
5.	NIPER, Kolkata	5.00	8.00	76.14
6.	NIPER, Hyderabad	86.17	35.00	134.12
7.	N IPER, Rae Bareily	50.00	7.00	72.82
8.	NIPER, Hajipur	7.10	6.00	74.58
9.	NIPER, Madurai	20.00	1.00	110.99
10.	New NIPERs proposed by Department NIPER, Bhopal NIPER, Andhra Pradesh NIPER, Karnataka #New NIPERs as per Budget Speech 2015-16 of Hon'ble Finance Minister Chattisgarh, Maharashtra Rajasthan		# No Budget provision as yet has been made for these NIPERs	100.00 100.00 100.00
11.	NPPA	32.33	5.00	9.17
12.	Setting up National Centre for R&D for bulk drugs	22.00	22.00	19.75
13.	Creation of IPR Facilitation centre at Pharmaxil	1.00	0.00	2.00
14.	Critical assistance for WHO pre qualification for pharma PSUs/R&D	12.00	10.00	25.50
15.	Jan Aushadhi	24.00	35.00	49.81
16.	PPDS	2.00	2.00	3.00
17.	New Schemes (Kala Azar and Tubercular Agent etc. Upgradation to SMEs to WHO GMP Setting up Medical Devices at Gandhi	177.44	15.00	208.19

	Nagar, Gujarat.)			
18.	Loan to PSU			
	Bengal Chemicals and Pharmaceuticals Ltd (BPCL)	26.74	0.01	26.74
	Hindustan Antibiotics Limited (HAL)	101.60	0.01	101.60
	Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL)	3.68	0.01	3.68
	Indian Drugs and Pharmaceuticals Limited (IDPL)	11.50	0.01	10.00
	Total	**871.63**	**210.00**	**1590.78**

***vide D.O letter dated 19/2/15 from Minister (C&F) to Finance Minister, it has been proposed to increase B.E 15-16 to Rs. 1590.78 crores to take care of new initiatives.**

3.4 The Plan activities undertaken during 2014-15 along with expenditure incurred vis-à-vis BE and RE for the year (scheme-wise) is as follows:-

"The Department had proposed an outlay of Rs. 829.00 crore for the year 2014-15; Planning Commission has approved Rs. 207.00 crore. Details of scheme-wise allocation and percentage achievement in terms of financial targets for 2014-15 (i.e. third year of the 12th Five Year Plan) is given in the Table below:-

(Rs. in crore)

S.No	**Name of the Scheme**	**Outlay**			**Achievement %)**
		2014-15 BE	**2014-15 RE**	**Actual (Upto 13.03.2015)**	**Actual Vs RE**
I	**Project Based Support to PSUs**	30.00	26.49	26.49	100.00
II	**Support to Autonomous Institutions**				
1	National Institute of Pharmaceutical Education and Research(NIPER), Mohali	20.00	0.05	0.00	-
2	New NIPER Institutes				
	a) NIPER, Ahmedabad	20.00	4.50	4.50	100.00
	b) NIPER, Hajipur	4.00	4.00	4.00	100.00
	c) NIPER, Guwahati (North East)	21.00	4.00	3.45	86.25
	d) NIPER, Kolkata	5.00	4.38	4.37	99.00
	e) NIPER, Hyderabad	22.00	14.17	14.17	100.00
	f) NIPER, Rai Bareli	15.00	4.45	4.45	100.00
	g) NIPER, Madurai	1.00	0.25	0.00	00.00
	Total NIPER	**108.00**	**35.80**	**34.94**	**98.00**
3	National Pharmaceutical Pricing Authority(NPPA)	2.00	2.00	2.00	100.00
III	**Other Ongoing Schemes**				
1	Pharma Promotion and Development Scheme (PPDS)	2.00	1.50	1.16	78.00
2	IT/Secretariat	1.00	1.00	0.56	56.00
3	Creation of IPR facilitation center at Pharmexcil	1.00	0.50	0.00	
4	Critical assistance for WHO -GMP PSUs	10.00	6.84	0.00	-
5.	Jan Aushadhi Scheme	30.00	9.67	0.00	
6	National center for R&D in bulk drugs	2.00	0.25	0.00	0.00
7.	New Schemes 12th Plan (Cluster Development, Kala Azar, Upgradation of SMEs to WHO GMP)	21.00	3.44	0.71	21.00
	Total	**207**	**87.49**	**65.86**	**75.27**

Plan Outlay

3.5 Planning Commission has allocated Rs. 210.00 crore as the Plan outlay for the schemes of the Department of Pharmaceuticals for Annual Plan 2015-16. Broad Scheme-wise details are given below:

I. Support to PSUs (Central Sector Scheme)

S.No	PSU	Projects	BE 2015-16 - Provision for the year 2015-16 (Rupees in Crore)
i)	HAL	Draft proposals in EFC FORMAT, PRESCRIBED BY NitiAyog (Planning Commission) would be submitted for approval of NITI Ayog.	0.01
ii)	BCPL	The proposal is to restart Anti Snake Venom Serum 9ASVS)Project which was halted due to court case.	0.01
iii)	IDPL	Third & final installment of Rs.5.00 crore is to be released during 2015-16 of the total project of Rs.15.00 crore for Civil & other related work at Hyderabad Plant.	0.01
iv)	RDPL	Proposal for the project in EFC format would be submitted to NITI Ayog for approval.	0.01
		Total	0.04

II. Support to Autonomous Bodies:

2.	NIPER, Mohali	The Institute has been allocated Rs.20.00 crore in 2015-16 B.E (Plan) for continuing its ongoing research work in different areas of pre-clinical drug discovery and development etc. besides their regular master and doctoral program/training courses.
3.	New NIPER Institutes	The Union Government has approved setting up 6 New NIPERs (National Institutes of Pharmaceutical Education and Research) - one each at Ahmedabad (Gujarat), Hyderabad (Andhra Pradesh), Hajipur (Bihar), Kolkata (West Bengal), Guwahati (Assam) and Rae Bareli (Uttar Pradesh). Classes in all the six new NIPERs were started with the help of local Mentor Institutes from academic session of 2007-08 at Ahmedbad, Hyderabad, Hajipur& Kolkata and 2008-09 at Guwahati & Rae Bareli. An allocation of Rs. 78.96 crore in 2015-16 BE (Plan) been made for new NIPERs excepting NIPER, Guwahati. For NIPER, Guwahati requirement would be met out of available provisions for North-East to the tune of Rs.21.00 crore.

III. Other ongoing scheme

4.	NPPA	Rs. 5 crore has been kept for the scheme "Consumer Awareness and Publicity through Print, electronic and other media".
5	PPDS	Rs. 2.00 crore has been kept for promotional activities, exhibition, seminars etc. for promotion of Indian pharmaceutical sector.
6.	IT/Secretariat	For providing IT/Secretariat services to the personnel of the Department, an amount of Rs. 1.00 crore has been kept.
7.	Setting up of National centre for Research and Development (R&D) in Bulk Drugs (NCRDBD)	A provision of Rs. 22.00 crore has been made for creation of IPR facilitation centre.
8.	Critical assistance for WHO pre-qualification for pharma PSUs/R&D	A total amount of Rs.10.00 crore has been allocated under this scheme for the year 2015-16. This amount will be utilized by the following PUSs for making their plants WHO-GMP compliance:- 1) IDPL(Gurgaon) 2) IDPL(Chennai)

		3) IDPL(Rishikesh) 4) ODCL Outcome:- The ODCL and IDPL Chennai and partly IDPL (Rishikesh) Plants will be made WHO-GMP compliance
9.	Jan Aushadhi Scheme	This is a flagship program of Department of Pharmaceuticals under which commonly required medicines will be made available under generic names and at affordable prices through dedicated outlets across the country. Apart from making the medicines accessible to poor sections of the society, this will also provide a platform for Public Sector Undertakings (PSU) to have foothold in the trade market. The purpose of making available socially relevant medicines will also be simultaneously served. An amount of Rs. 35.00 crore for 2015-16 has been earmarked for JanAushadhi Scheme which involves opening of JASs in different States of the country, for advertisements and establishment cost of BPPI etc. Expected Outcome : Revitalization of Jan Aushadhi Scheme through Strategic Action Plan 2015. Under the new Plan Pilot Project will taken up at Delhi and will be expanded other state Capitals and Districts in phased manner.

IV. <u>New schemes to be introduced in 2015-16</u>

To enable it to execute competently and effectively the role entrusted to the newly created Department of Pharmaceuticals, some new schemes are proposed to be initiated in 2015-16. An amount of Rs.15.00 crore has been earmarked for new schemes to be launched by the Department for the financial year 2015-16.

3.6 When the Committee asked about the reasons for lesser allocation of funds to Support the Existing PSUs by Planning Commission for the annual plan 2015-16, the Department in its written reply stated as under:-

> "For BE 2015-16 PSU Division has proposed Rs.142.02 crore to IFD, but it was reduced to Rs.0.04 crore".

3.7 When the Committee asked to explain the way in which the funds allocated for NIPER Mohali and New NIPER Institutions will be used by the Department for enhancement of the performance of NIPER Institutes, the Department in its written reply stated as under:-

> "Rs.20.00 crore has been allocated to NIPER, Mohali at BE stage for 2015-16 to meet expenditure on various Plan Schemes which are under EFC consideration. The allocation of Rs.78.96 crore for new NIPERs i.e. Ahmedabad, Hajipur, Hyderabad, Kolkata, Raebareli and Madurai for 2015-16 is keeping in view of the proposed construction of new campuses at NIPER, Gandhinagar and Hyderabad. Allocation of Rs.21.00 crore for 2015-16 for NIPER, Guwahati is keeping in view of the proposed construction of new campus. But the funds will be insufficient if NIPER buildings are to be completed in two years".

3.8 When the Committee asked about the time limit fixed for RDPL and IDPL Plants become fully WHO-GMP compliant, the Department in its written reply stated as under:-

> "Upgradation of RDPL to WHO-GMP Standards is going on and expected to be completed in 6 months provided the budget provided in financial year 2014-15 is released in the current year full. Given the less budgetary provision upgradation of IDPL to WHO-GMP will remain partial".

3.9 When the Committee asked to give details of New Schemes proposed to be introduced in 2015-16 and the action plan of the Department to fully utilize the funds earmarked for the purpose during 2015-16, the Department in its written reply stated as under:-

"The new scheme of 'Cluster Development Programme for Pharma Sector' (CDP-PS) has been approved in January, 2014 and further action for selection of Project Management Consultant is under process. After selection of Project Management Consultant, financial assistance may be provided to the qualifying Special Purpose Vehicle (SPV) for creation of common facilities.

As regards, the action plan pertaining to existing scheme on Anti TB and Kalaazar, the Department of Pharmaceuticals proposes to monitor the said scheme under this head through the Review Committee".

3.10 **FINANCIAL REVIEW**

The scheme-wise Outlays by way of Gross Budgetary support in respect of 2013-14 (Actuals), 2014-15 (BE), 2014-15 (RE) and 2015-16 (BE) are given below:

(Rs. in crore)

Sr. No.	Name of the Scheme	2013-14 (Actual)	2014-15 (BE)	2014-15 (RE)	2014-15 (Actual upto 12.03.2015)	2015-16 BE
I	Project Based Support to PSUs	9.22	30.00	26.49	19.49	00.04
II	Support to Autonomous Institutions					
1	NIPER,Mohali	0.00	20.00	0.05	0.00	20.00
2.	New NIPER Institutes	45.08	67.00	31.75	34.94	78.96
3.	Lumpsum Provision for NE Region (NIPER Guwahati)	0.00	21.00	4.00	0.00	21.00
4.	Setting up National center for R&D in Bulk Drug	0.00	2.00	0.25	0.00	22.00
5.	National Pharmaceutical Pricing Authority	0.00	2.00	2.00	2.00	5.00
III	Other Ongoing Schemes					
6	Pharma Promotion and Development Scheme	0.93	2.00	1.50	1.16	2.00
7	IT/Secretariat	0.91	1.00	1.00	0.56	1.00
8	Creation of IPR facilitation center at Pharmaexcil	0.25	1.00	0.50	0.00	00.00
9	Critical assistance for WHO for Pharma PSUs	00.00	10.00	6.84	0.00	10.00
10	Jan Aushadhi Scheme	15.20	30.00	9.67	0.00	35.00
11	New Schemes-	2.44	21.00	3.44	0.71	15.00
12.	Total	74.03	207.00	87.49	58.86	210.00

3.11 When the Committee asked about the reasons for reduction in BE 2014-15 from Rs. 30 crore to Rs.26.49 at RE stage for Project Based Support to PSUs and for lesser allocation of Rs. 0.04 crore in BE 2015-16 under the scheme as compared to RE 2014-15 of Rs.26.49 crore, the Department in its written reply stated as under:-

"Delay in expenditure is the reason for less RE during 2014-15. For BE 2015-16 PSU Division has proposed Rs.142.02 crore".

3.12 When asked by the Committee to give reasons for allocating more funds to NIPER Mohali in BE 2015-16 i.e. Rs.20 crore as compared to RE 2014-15 of Rs.0.05 crore, the Department in its written reply stated as under:-

> "Rs.20.00 crore was allocated to NIPER, Mohali for BE 2014-15 but could not be released for want of Third Party Evaluation and EFC approval of these schemes. Third Party Evaluation has been completed and EFC is expected to be completed soon".

3.13 On being asked by the Committee about the reasons for allocating more funds to Critical Assistance for WHO for Pharma PSUs i.e. Rs. 10 crore in BE 2015-16 as compared to Rs.6.84 crore in RE 2014-15, the Department in its written reply stated as under:-

> "Rs.10.00 crore in BE 2015-16 are provided for the following schemes-

IDPL (Gurgaon)	Critical Assistance for WHO Pre-qualification
ODCL	Critical Assistance for WHO Pre qualification
IDPL(Chennai)	Critical Assistance for WHO Pre qualification
IDPL (Rishikesh)	Critical Assistance for WHO Pre qualification "

3.14 A statement showing the Budget Estimates, Revised Estimates and Actual Expenditure for the last three years (year-wise) and Budget Estimates for the year 2014-15 showing separately for Plan and Non-Plan expenditure**.**

PLAN
*74.02 crores (without recovery) (Rs.74.02 crores-Rs.5.84 crore recovery = Rs.68.18 crores) **

S.No.	Head	2012-13			2013-14			2014-15			2015-16
		BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	****Actual**	**BE**
	Revenue										
1	Sectt.	1.00	1.00	0.63	1.00	1.00	0.91	1.00	1.00	0.56	1.00
2	NIPERs	75.20	44.95	37.42	69.70	42.64	45.07	87.00	31.80	31.49	98.96
3	NPPA	4.00	4.00	0.00	4.00	0.00	0.00	2.00	2.00	2.00	5.00
4	Other Schemes	67.00	11.05	7.53	62.84	17.89	17.89	64.00	20.70	0.71	82.00
5	PPDS	2.00	1.00	0.68	2.00	1.25	0.93	2.00	1.50	1.16	2.00
6	NE Region	18.80	13.00	0.00	18.80	3.00	0.00	21.00	4.00	3.45	21.00
	Total Revenue	**168.0**	**75.00**	**46.26**	**158.34**	**65.78**	**64.80**	**177.00**	**61.00**	**39.37**	**209.96**
	Capital										
7	HAL	3.00	5.00	0.00	14.17	6.20	6.20	16.79	14.49	14.49	0.01
8	BCPL	2.00	0.00	0.00	9.30	0.00	0.00	7.00	7.00	*7.00	0.01
9	IDPL	15.00	5.00	5.00	6.19	3.02	3.02	5.00	5.00	5.00	0.01
10	RDPL			0.00		0.00	0.00	1.21	0.00	0	0.01
	Total Capital	**20.00**	**10.00**	**5.00**	**29.66**	**9.22**	**9.22**	**30.00**	**26.49**	26.49	**0.04**
	Total	**188.00**	**85.00**	**51.26**	**188.00**	**75.00**	***74.02**	**207.00**	**87.49**	26.49	**210.00**

provisional

Non Plan Rs. In crore

S. No.	Head	2012-13			2013-14			2014-15			2015-16
		BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	****Actual**	**BE**
1	**Revenue**										
2	Sectt.	8.94	7.59	7.42	9.00	8.75	8.50	11.72	9.69	8.60	11.28
3	NPPA	6.35	6.27	5.89	7.71	7.34	6.74	12.07	9.31	8.36	10.21
4	PEPS	.20	0	0	.01	0.01	0.01	0.01	0.01	0.00	0.01
	NIPER	27.55	22.93	22.82	23.57	19.20	19.20	17.03	20.87	16.50	27.48
	Total Revenue	**43.04**	**36.79**	**36.13**	**40.29**	**35.30**	**34.45**	**40.83**	**39.88**	33.46	**48.98**
5	**Capital**										
6	SSPL	.01	0	0	0	0					
7	BCPL	.01	0	0	0.01	0.01	0.00	0.01	0.00		0.01
8	BIL	.01	0	0	0.01	0.01	0.00	0.01	0.00		0.01
9	IDPL	.01	0	0	0.01	0.01	0.00	0.01	0.00		0.01
10	HAL	.01	0	0	0.01	5.00	5.00	0.01	9.67	9.67	0.01
	Total Capital	**0.05**	0	0	0.04	5.03	5.00	0.04	0.00		0.04
	Grand Total	**43.09**	**36.79**	**36.13**	**40.33**	**40.33**	**39.45**	**40.87**	**9.67**	**9.67**	**49.02**

**The savings/ surrender figure shown is as on 10.3.2015 and the same is provisional. However, the actual surrender/savings figures shall be based on the expenditure to be booked till 31.3.2015.

3.15 Under Plan Revenue Head for Other Schemes, BE 2014-15 is Rs.64 crore and RE 2014-15 is Rs.20.70 crore but the Actual Expenditure during the year 2014-15 was only Rs.0.71 crore and a large sum of funds under Plan for Other Schemes could not be spent. The Committee, therefore, asked the reasons as why a large sum of funds under Plan for other Schemes count not be spent and how does the Department propose to spent Rs.82 crore in BE 2015-16. In its reply, the Department stated as under:-

"Explanation is as under:-

(i) **<u>Scheme on targets specific new drugs discovery for Anti TB and Kalaazar</u>**:-

Against the allocated funds of Rs. 2.44 crore for the scheme on targets specific new drugs discovery for Anti TB and Kalaazar, a sum of Rs. 0.71 crore was released in current fiscal year. Balance amount could not be released as the Utilization Certificate was not provided by NIPER, Mohali.

(ii) **<u>Cluster Development Programme for Pharma Sector(CDP-PS):-</u>**

Cluster Development Programme for Pharma Sector (CDP-PS) got approval only in January, 2014 and further action for selection of Project Management Consultant is under process. It was expected that after selection of Project Management Consultant, financial assistance may be provided to the qualifying Special Purpose Vehicle (SPV). However, due to delay in selection the BE 2014-15 was reduced at RE stage. In order to utilise the complete allocation of Rs 125 crore for the scheme in the 12th Five Year Plan, the increase has been proposed.
Ministry of Finance for granting relaxation for spending in last quarter/month of March. Since certain amount released earlier was diverted, the matter was got investigated before deciding to release funds. This took time. Planning Commission did not grant approval for WHO GMP projects of IDPL.

The Department proposes to approach the NITI Ayog again for its approval to WHO (GMP) projects in IDPL

As indicated earlier, the funds released earlier for Jan Aushadhi Scheme had remained unutilized and there was no demand for funds from BPPI. Hence, funds were not released in 2014-15. The Jan Aushadhi Scheme is being revisited. Accordingly, it is expected that funds would be utilized fully during 2015-16. Moreover, the funds released for the scheme in 2012-13 are being greatly utilized and it is expected that the entire allocation will be used in 2015-16.

As far as the Proposal for Setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad is concerned, it has been approved by the SFC and finalization of MOU with PMC is under process. Due to this, funds could not be released. After signing of MOU with PMC construction activity will be taken up to utilize the funds allocated for 2015-16".

3.16 Under non-Plan Revenue Head, BE 2014-15 is Rs. 40.83 crore and RE 2014-15 is Rs.39.88 crore against which Actual Expenditure is Rs.33.46 crore. and Rs.6.42 crore remained unspent during 2014-15. When the Committee asked about the reasons for this unspent amount and the action plan of the Department to utilize fully Rs.48.98 crore earmarked under non-Plan Revenue Head during 2015-16, the Department in its written reply stated as under:-

"DoP: Non-plan allocation of Rs.11.72 crore for BE 2014-15 (Sectt.) was reduced to Rs.9.89 crore for RE 2014-15 as per instructions of 10% cut of Department of Expenditure, Min. of Finance and due to some posts lying vacant, which could not be filled.

The plan of the Department to spend the amount of Rs.11.28 crore allocated in BE 2015-16 (in Sectt.) are as under:-

i) office expenditure and equipment expenditure + 10% increase

ii) In the salary head DA and other allowances are increased.

3.17 A statement showing Reasons for the unspent amount in 2014-15 and action plan for 2015-16 (Non-Plan) is given in **Annexure**.

3.18 During the course of evidence, the Secretary Department of Pharmaceuticals informed the Committee about the fund allotment to the Department as under:-

".. Sir. All the hon. Members and hon. Chairman have raised a large number of issues relating to our Department. I would like to answer them in three or four categories.

First, let me talk about fund allotment to the Department. This Department has been functioning from the year 2008 as was highlighted in the presentation. It was bifurcated from the Department of Chemicals and Petrochemicals and it is a very small Department. For the Twelfth Plan, we sent a lot of requirements for the fund allotment. In fact, we made various programmes and sent proposals for Rs. 12,000 crore for various new programmes for the pharmaceutical sector.

The Planning Commission recommended Rs.3000 crore totally for five years period. But, unfortunately, during the first four years, 2012 to 2015, the amount allotted was roughly only Rs.200 crore per year; first year it was Rs.188 crore, the second year. Rs.188 crore, third year, Rs.205 crore then Rs.207crore and now Rs.210 crore. Allotment is only Rs.200 crore per year as per the Plan schemes are concerned. Out of this Rs.200 crore, after six months when the revised Budget was calculated, based on the spending capacity of the Department, they slashed the money by 50 per cent. From Rs.204 crore it became Rs.100 crore. The Department could spend only 85 to 90 per cent of the revised budget. Ultimately, the Department could spend about Rs.70 to 80 crore per year. That has been the spending capacity of the Department for the past four years.

This is really a matter of great concern to all of us because pharmaceuticals is a very big sector in the country and mostly it is private sector driven. In fact, today, the overall production of pharmaceuticals in the country is to the tune of about Rs.1,80,000 crore. About 50 per cent is consumed locally, domestic consumption and 50 per cent is exported to more than 220 countries. That is the dimension of the pharmaceuticals industry in the country.

To cope up with this development and to help the small and medium sector pharmaceutical units, numbering about 8000, we thought we should spend more money. We should create more clusters. We should modernise these clusters. We should produce quality drugs and we should distribute drugs at affordable cost not only to the people of India but also to the other countries. That has been the objective of this Department. But unfortunately the spending from the beginning has been very-very less. That is one big issue which we are facing."

CHAPTER-IV

DEMANDS FOR GRANTS FOR THE YEAR 2015-16

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

(Rs. in crore)

Major Head	Budget Estimates 2014-2015			Revised Estimates 2014-2015			Budget Estimates 2015-2016		
	Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
Revenue	177.00	40.83	217.83	61.00	39.88	100.88	209.36	48.98	258.94
Capital	30.00	0.04	30.04	26.49	9.67	36.16	0.04	0.04	0.08
Total	**207.00**	**40.87**	**247.87**	**87.49**	**49.55**	**137.04**	**210.00**	**49.02**	**259.02**

(notes on Demands for Grants 2015-16)

4.2 When asked by the Committee about the reasons for the increase in Revenue Head from Rs. 217.83 crore in BE 2014-15 to Rs.258.94 crore in BE 2015-16 particularly in view of the fact that RE 2014-15 was Rs.100.88 crore, the Department in its written reply stated as under:-

> "The increase in total budgetary allocation for BE 2015-16 (Revenue) is on account of an increase in both Plan and Non-Plan provisions for the year, as compared to BE 2014-15. However, the proportion of Plan provision is consistent at about 81% of total allocation in both years. Under Plan (Revenue) an increase of 18.28% in total allocation has been made in BE 2015-16 over BE 2014-15 mainly on account of pressing requirements of Plan Schemes such as NIPERs, including new NIPERs, Jan Aushadhi Scheme, setting up of National Centre for R&D in Bulk Drugs, Critical Assistance for WHO for Pharma PSUs etc. On account of reduction in total Plan RE provisions from Rs 207 crore (BE 2014-15) to Rs 87.49 crore (RE 2014-15), reductions under Plan (Revenue) Head provision were made, at Rs 61 crore (RE 2014-15) from Rs 177 crore (BE 2014-15)".

4.3 On being asked by the Committee to give reasons for drastic reduction in allocation from Rs.30.04 crore in BE 2014-15, to Rs.0.08 crore in BE 2015-16 under Capital Head when in RE 2014-15 it was Rs.36.16 crore, the Department in its written reply stated as under:-

> "Total budgetary allocation under Capital Head in BE 2015-16 has witnessed a reduction on account of reduced provisions under both Plan and Non-Plan. Total budgetary allocation under Capital Head in RE 2014-15 witnessed an increase of 20.37% over BE 2014-15 on account of an enhancement in provision under Non-Plan amounting to Rs 9.67 crore as compared to Rs 0.04 crore in BE 2014-15. Plan provisions, on the other hand, declined to Rs 26.49 crore in RE 2014-15 from Rs 30 crore in BE 2014-15. In BE 2015-16, in view of pressing requirements for ongoing and new Plan Schemes, out of a total Plan allocation of Rs 210 crore, Rs 209.36 crore was provided under Revenue Head and only Rs 0.04 crore could be made available under Capital Head. Moreover, Budget Division, Department of Economic Affairs, Ministry of Finance, vide their letter no. 2(16)-B(CDN)/2015 dated 15.2.2015 to this Department communicating Plan allocation of Rs 210 crore for FY 2015-16, had also indicated/ fixed the schematic break-up of Plan allocation for FY 2015-16, as follows:-

(Rs. In crore)

Department of Pharmaceuticals	BE 2014-15	BE 2015-16
Central Plan	**207.00**	**210.00**
Pharmaceuticals Industries	149.82	150.00
Central Assistance to WHO	10.00	10.00
Jan Aushadhi Scheme	30.00	35.00
New schemes	15.00	15.00
Creation of IPR facilitation cenre	1.00	0.00
Others	1.18	0.00

This Deptt. had therefore to work out its Plan requirements within the broad scheme-wise break up allocated by M/O Finance".

4.4 When asked by the Committee to explain reasons for drastic cut in allocation of funds from Rs. 247.87 crore in BE 2014-15 to Rs.137.04 crore in RE 2014-15 but allocation in BE 2015-16 has been increased to Rs.259.02 crore, the Department in its written reply stated as under:-

"The total budgetary allocation was reduced from Rs 247.87 crore in BE 2014-15 to Rs 137.04 crore in RE 2014-15 by Ministry of Finance. It may be noted that at Plan RE 2014-15 stage, vis-à-vis Rs 207 crore provided for BE 2014-15, this Department had sought an enhanced provision of Rs 236.26 crore for RE 2014-15, against which only Rs 87.49 crore was actually made available by Ministry of Finance. For Plan BE 2015-16, at RE stage, in November 2014, this Department had sought Rs 871.63 crore. This request was subsequently enhanced by this Department after finalization of Plan proposals to Rs 1590.78 crore in February 2015, for Plan BE 2015-16, to address the long pending pressing needs of development of 6 old NIPERs and 3 new NIPERs, upgradation/ modernization of CPSUs, Jan Aushadhi Yojana, new schemes etc. As against the request of the Department, only Rs 210 crore was actually provided for Plan BE 2015-16 by Ministry of Finance. In the total allocation of Rs 259.02 crore for BE 2015-16, 81% i.e. Rs 210 crore is accounted for by Plan provisions".

HEAD-WISE ANALYSIS OF DEMANDS FOR GRANTS (2015-16)

(i) MAJOR HEAD 3451:Secretariat –Economic Services

(Rs. in crore)

BE 2014-15			RE 2014-15			BE 2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
1.00	11.72	12.72	1.00	9.89	10.89	1.00	11.28	12.28

4.5 When asked by the Committee to explain the reasons for decrease in allocation for Non-plan from Rs.11.72 crore in BE 2014-15 to Rs.9.89 crore at RE stage and how does the Department plan to spend the amount of Rs.11.28 crore allocated in BE 2015-16, the Department in its written reply stated as under:-

"Non-plan allocation of Rs.11.72 crore for BE 2014-15 was reduced to Rs.9.89 crore for RE 2014-15 as per instructions of 10% cut of Department of Expenditure, Ministry of Finance and due to some posts lying vacant, which could not be filled. The plan of the Department to spend the amount of Rs.11.28 crore allocated in BE 2015-16 are as under:-

i) office expenditure and equipment expenditure + 10% increase

ii) In the salary head DA and other allowances are increased".

(ii) MAJOR HEAD 2852: Pharmaceutical industries

(Rs.in crore)

BE 2014-15			RE 2014-15			BE 2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
155.00	29.11	184.11	56.00	30.19	86.19	187.96	37.70	225.66

4.6 When asked by the Committee about the reasons for drastic cut in Plan allocation at RE 2014-15 stage to Rs.56 crore from Rs.155 crore in BE 2014-15 especially when Pharmaceutical Industries in the country need to be given necessary boost for its growth and development and has now been increased to Rs.187.96 crore for BE 2015-16 and the justification for increase in Plan allocation from

Rs.56.00 crore in RE 2014-15 to Rs.187.96 crore in BE 2015-16, the Department in its written reply stated as under:-

"So far as Public Sector Undertakings are concerned, the expenditure incurred during 2014-15 under its 3 schemes is as follows:-

Sl. No.	Name of Scheme	SBG 2014-15	RE 2014-15	Actual 2014-15	Reasons for shortfall w.r.t. SBG
1.	Critical Assistance to Pharma CPSEs for WHO (GMP) Compliance	Rs. 10.00 crore	Rs. 6.84 crores	Sanction issued for Rs. 3.3 crore and file sent to Ministry of Finance for approval for release of balance Rs 3.54 crores.	Planning Commission did not approve projects totaling Rs 3.16 crores of IDPL
2.	Jan Aushadhi Scheme	Rs. 30.00 crore	Rs. 9.67 crores	Rs. 9.67 crores	non-utilization of funds released during 2012-13 by BPPI, and lack of demands for funds from BPPI. The amount of Rs. 9.67 crore was used for re-appropriation/ payment of salaries to employees of HAL.

However, it may be stated that till the time of finalization of RE only an amount of Rs. 8.21 crores was spent out of a total allocation of Rs. 70.00 crores allocated in SBG. This was responsible for cut in funds at RE stage. The delay occurred due to time taken in getting various approvals of Planning Commission, Ministryof Finance, SFC etc.

The allocation for the above mentioned two schemes in BE 2015-16 is as follows:-

Sl. No.	Name of Scheme	SBG 2015-16
1.	Critical Assistance to Pharma CPSEs for WHO (GMP) Compliance	Rs. 10.00 crore
2.	Jan Aushadhi Scheme	Rs. 35.00 crore

It is proposed to open large number of Jan Aushadhi Stores in 2015-16 and the fund of Rs. 35.00 crores would be utilized for that purpose. As for WHO (GMP) Compliance matter would be taken up with Planning Commission again for granting approval for WHO(GMP) Compliance work in IDPL. So far as NIPER is concerned the allocation of Rs.155 crore under Plan Scheme (Rs.87 crore for NIPERs) at BE stage 2014-15 was keeping in view of the proposed Construction of New Campuses for NIPERs of Guwahati,Gandhinagar and Hyderabad. However, these could not be materialized due to delay in selection of PMC, approval of design and estimates and signing of MOU. Now PMC for Gandhinagar and Guwahati have been finalized and construction work is going to start shortly. For NIPER, Hyderabad, MOU is under process. The justification for increase in provision of Rs.187.96 crore in BE 2015-16 is that the construction work for NIPERs Gandhinagar and Guwahati is going to start shortly and in r/o NIPER, Hyderabad, it will start after signing of MOU. Efforts will be made for optimum utilization of funds allocated for 2015-16.

As far as the proposal for Setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad is concerned, it has been approved by the SFC and finalization of MOU with PMC is under process. Due to this, funds could not be released. After signing of MOU with PMC construction activity will be takento utilize the funds allocated for 2015-16.

As regards Scheme on targets specific new drugs discovery for Anti TB and Kalaazar, it is stated that against the allocated funds of Rs. 2.44 crore for the scheme on targets specific new drugs discovery for Anti TB and Kalaazar, a sum of Rs. 0.71 crore was released in current fiscal year. Balance amount could not be released as the Utilisation Certificate was not provided by NIPER, Mohali

As regards Cluster Development Programme for Pharma Sector (CDP-PS) got approval only in January, 2014 and further action for selection of Project Management Consultant is under process. It was expected that after selection of Project Management Consultant, financial assistance may be provided to the qualifying Special Purpose Vehicle (SPV). However, due to delay in selection the BE 2014-15 was reduced at RE stage. In order to utilise the complete allocation of Rs 125 crore for the scheme in the 12th Five Year Plan, the increase has been proposed".

(iii) MAJOR HEAD 2852:

National Institute of Pharmaceuticals Education and Research (NIPER)

(Rs. in crore)

BE 2014-15			RE 2014-15			BE 2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
87.00	17.03	104.03	31.80	20.87	52.67	98.96	27.48	126.44

4.7 On being asked by the Committee about the drastic reduction in allocation for NIPER at RE 2014-15 stage to Rs.52.67 crore from Rs.104.03 crore at BE 2014-15, how does the Department plan to utilize and ensure optimum utilisation of funds of Rs.126.44 crore allocated to NIPER for the year 2015-16 and Whether the allocation of Rs. 126.44 crore is sufficient for setting up of New NIPER as envisaged by the Department, in its written reply, the Department stated as under:-

"The allocation for NIPERs in BE 2014-15 was keeping in view of the proposed Construction of New Campuses for NIPERs of Guwahati, Gandhinagar and Hyderabad. However, these could not be materialized due to delay in selection of PMC, approval of design and estimates and signing of MOU. Now PMC for Gandhinagar and Guwahati have been finalized and construction work is going to start shortly. For NIPER, Hyderabad, MOU is under process. Efforts will be made for optimum utilization of funds allocated for 2015-16. Allocation for NIPERs during 2015-16 is insufficient against the proposal of Rs.1128.57 crore. It is reiterated that presently there are 8 NIPERs. Of these except NIPER, Mohali none have permanent campus/building nor regular faculty. In addition in central budget Finance Minister speech 2015-16, three more new NIPERs are announced at Rajasthan, Maharashtra and Chhatisgarh. Under these circumstances the budget allocation will be insignificant to take up constructions and regular faculty recruitment. The Department plans to move supplementary budgetary demand".

(iv) MAJOR HEAD 2852:

National Pharmaceutical Pricing Authority

(Rs.in crore)

BE 2014-15			RE 2014-15			BE 2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
2.00	12.07	14.07	2.00	9.31	11.31	5.00	10.21	15.21

4.8 On being asked the reason for increase in allocation in BE 2015-16 to Rs.15.21crore as compared to RE 2014-15 Rs.11.31 crore, the Department in its written reply stated as under:-

"The Plan Scheme of Consumer Awareness and Publicity through Print, Electronic and Other Media of NPPA is a joint publicity campaign by the NPPA and Department of Consumer Affairs on a 50:50 cost sharing basis. Budget allocation under the scheme for the years 2014-15 and 2015-16 are given as under:

(Rs. in crore)

2014-15			2015-16
BE	RE	Actual (as on 20.3.2015)	BE
2.00	2.00	2.00	5.00

As the Department of Consumer Affairs regretted to part finance their share, the scheme could not be implemented during 2013-14. Therefore, budget allocation of Rs. 2.00 crore only was provided for the year 2014-15. Concerted efforts were made by NPPA to persuade the Department of Consumer Affairs for re-examining the possibility of implementing the joint publicity campaign by allocating a matching contribution. The Department of Consumer Affairs has now agreed for participating in the scheme from 2014-15.

The entire budget allocation of Rs. 2.00 crore has been released for bringing out 3 (three) colour print advertisements (two half page and one quarter page) in various national and regional newspapers. In 2015-16, more publicity campaign and wider mode of publicity will be carried out for which additional allocation of funds will be required. Thus, an increase in BE 2015-16 as compared to RE 2014-15"

(v) MAJOR HEAD 2852: Jan Aushadhi Scheme

(Rs.in crore)

BE 2014-15			RE 2014-15			BE 2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
30.00	-	30.00	9.67	-	9.67	35.00	-	35.00

4. 9 Keeping in view the drastic reduction in Plan allocation in RE 2014-15 to Rs.9.67 crore for Jan Aushadhi Scheme as compared to BE 2014-15 Rs.30 crore and allocation of for the scheme in BE2015-16 Rs.35 crore, when asked as to whether this allocation is sufficient to achieve the targets set by the Department under the Scheme and the action plan of the Department to utilise optimally the funds earmarked for the Scheme for the year 2015-16, the Department in its written reply stated as under:-

"The BPPI was having adequate funds, released during 2013-14. Thus no fresh demand for additional funds during the financial year 2014-15 for BPPI.

The Jan Aushadhi Scheme has already been approved and the amount is proposed to be released for various components approved under the New Business Plan. However, the new business plan 2013 is being revisited to improve the performance of the scheme under the title Strategic Action Plan 2015 using funds approved under over all funds approved in new business plan"

(VI) Major Head 2852:
Setting up of National Centre for Research and Development for Bulk Drugs

(Rs.in crore)

BE 2014-15			RE 2014-15			BE 2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
2.00	-	2.00	0.25	-	0.25	22.00	-	22.00

4.10 When the Committee asked the reasons for drastic increase in allocation of funds to Rs.22 crore for the scheme National Centre for Research and Development for Bulk Drugs and how does the Department Plan to utilise and ensure optimum utilisation of funds during the year 2015-16 as only Rs.2 crore was allocated in BE 2014-15?

"The Proposal for Setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad has been approved by the SFC and finalization of MOU with PMC is under process. Due to this, funds could not be released. After signing of MOU with PMC construction activity will be taken to utilize the funds allocated for 2015-16".

(vii) Major Head 2852: New Schemes of Pharmaceuticals

(Rs.in crore)

BE2014-15			RE2014-15			BE2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
21.00	-	21.00	3.44	-	3.44	15.00	-	15.00

4.11 When asked the reason for reduction of funds from Rs.21 crore BE 2014-15 to Rs. 03.44 at RE stage and substantial increase in the funds to Rs.15 crore in BE 2015-16. and how the Department plan to utilise and ensure optimum utilisation of funds for the purpose during the year 2015-16, alongwith new schemes of Pharmaceuticals, the Department in its written reply stated as under:-

"Following are the two schemes under the Head for New Schemes of Pharmaceuticals**:-**

(i) **Scheme on targets specific new drugs discovery for Anti TB and Kalaazar**:-
Against the allocated funds of Rs. 2.44 crore for the scheme on targets specific new drugs discovery for Anti TB and Kalaazar, a sum of Rs. 0.71 crore was released in current fiscal year. Balance amount could not be released as the Utilisation Certificate was not provided by NIPER, Mohali.

(ii) **Cluster Development Programme for Pharma Sector (CDP-PS):-**
Cluster Development Programme for Pharma Sector (CDP-PS) got approval only in January, 2014 and further action for selection of Project Management Consultant is under process. It was expected that after selection of Project Management Consultant, financial assistance may be provided to the qualifying Special Purpose Vehicle (SPV). However, due to delay in selection the BE 2014-15 was reduced at RE stage. In order to utilise the complete allocation of Rs 125 crore, the increase has been proposed"

(viii) MAJOR HEAD -2552:
Lumpsum Provision for Project/Scheme for the benefit of N.E. Region & Sikkim

(Rs.in crore)

BE 2014-15			RE 2014-15			BE 2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
21.00	-	21.00	4.00	--	4.00	21.00	-	21.00

4.12 On being asked by the Committee about the reasons for drastically reducing the allocation to Rs. 4 crore at RE stage from Rs.21 crore in BE 2014-15 stage for Lumpsum Provision for Project/Scheme for the benefit of N.E .Region & Sikkim, and again Rs. 21 crore has been allocated under BE 2015-16 for the purpose and about the plan of action of the Department to utilize the funds optimally during the year 2015-16 for the purpose, the Department in its written reply stated as under:-

> "The allocation was kept for construction activities at NIPER, Guwahati which could not be started. Now MOU has been signed and construction is going to start shortly and it is expected that funds allocated for 2015-16 will be utilized optimally"

(IX) MAJOR HEAD -6857: <u>Non Plan Loans to Public Enterprises</u>

(Rs.in crore)

BE 2014-15			RE 2014-15			BE 2015-16		
Plan	Non-Plan	Total	Plan	Non-Plan	Total	Plan	Non-Plan	Total
-	0.04	0.04	-	9.67	9.67	-	0.04	0.04

4.13 When the Committee asked about the reasons for the increase in Non-Plan Loans to Public Enterprises at RE stage to Rs.9.67crore from Rs.0.04 crore in BE 2014-15. and how the Department utilized the funds allocated during the year 2014-15 and whether the funds of Rs.0.04 crore allocated for 2015-16 is sufficient to meet the non-plan expenditure of sick units like BCPL, IDPL and HAL during the year 2015-16, the Department in its written reply explained as under:

> "The increase at RE stage to Rs. 9.67 crore is due to provision made for recoupment of an advance as loan drawn from Contingency Fund of India for payment of salaries to the employees of HAL. The funds have been utilized by making payment of salaries to the staff of HAL. A token provision of Rs. 0.04 crore under non-plan expenditure of sick units like BCPL,IDPL and HAL is kept for 2015-16. The token provision for Central Pharma Public Enterprises will have negative impact on their performance".

CHAPTER-V

IMPORTANT SCHEMES

I. National Institute of Pharmaceuticals Education and Research (NIPER)

5.1 NIPER, SAS Nagar, Mohali was initially registered as a society under the Societies Act. The faculty for the institute was appointed in 1994. In 1998, Parliament enacted National Institute of Pharmaceutical Education and Research Act, 1998. NIPER was declared as an "Institute of National importance" under the Act of Parliament on 26th June 1998. NIPER is a member of Association of Indian Universities.

The main objectives of the Institute:

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

5.2 Setting up of New NIPER Institutes

With a view to further boost research and development and enhance availability of trained manpower in the field of Pharmaceuticals and to set standards of excellence for Pharmaceutical Sciences, besides fulfilling the long pending demand from Indian Pharmaceutical Industry and Profession, the Union Government has approved setting up of 6 New NIPER Institutes - one each at Gandhinagar (Gujarat), Hyderabad (Andhra Pradesh), Hajipur (Bihar), Kolkata (West Bengal), Guwahati (Assam) and Rae Bareli (Uttar Pradesh) at an estimated cost of Rs.750.00 crore in Phase I. However, the six New NIPERs are yet to be provided with buildings and regular faculty. In the year 2015-16 it is proposed to construct buildings and provide regular faculties for the six NIPERs. However, the budgetary provision is very limited to take up the same. Thus a supplementary demand is being proposed. Further the Department proposed setting up of three new NIPERs at Andhra Pradesh, Madhya Pradesh and Karnataka. However, the Finance Minister Budget Speech for 2015-16 lists three new NIPERs at Maharashtra, Rajasthan and Chhattisgarh but budgetary details are not known.

5.3 With this, the Government 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. With the opening of six more NIPERs there are now seven NIPERs in the country. The intake of students in various NIPERs would be about 200-250 each when all the seven NIPERs become fully functional, and about 1500 highly skilled trained manpower would be available for pharma industry annually.

5.4 In 2015-16 an allocation of Rs. 78.96 crore BE (Plan) has been made for new NIPERs excepting NIPER, Guwahati including a provision of Rs.1.00 crore for NIPER, Madurai. For NIPER, Guwahati requirement would be met out of available provisions for North-East to the tune of Rs.21.00 crore.

5.5 The work relating to construction of NIPER Campus at Guwahati and Gandhinagar has since been awarded to Engineering Projects (India) Ltd (EPIL) and Hindustan Steelworks Constructions Ltd. (HSCL), respectively. MoU has been signed between NIPER and the selected entities viz & EPIL & HSCL on 23.1.2013 and 30.1.2013 respectively. The layout drawings and cost estimates for the proposed construction has since been prepared and are under finalization.

5.6 For Budget Allocation for NIPERs please see para 4.7 above.

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

"For the current year we wanted about Rs.1,600 crore because we have worked various proposals and we have got clearances. We want to create world class NIPERS. The hon. Chairman was asking about the NIPERS. I will explain what it is. For three new NIPERS we want to construct new buildings each at a cost of about Rs.200 crore. So, for these three NIPERS alone we need Rs.600 crore for the current year. That is why we have sent a proposal for Rs.871 crore in the beginning. Subsequently, we revised the Budget to Rs.1,600 crore. Ultimately, during the current year we have received only Rs.210 crore based on the past performance of the Department. This year, the Department is fully geared to perform and implement the schemes in a big way but this is what we have received from the Department of Expenditure. We hope to get the remaining amount in the Supplementary Budget which will start in another two months time. In the Supplementary Budget we will be able to get substantial money to see that all our aspirations are fulfilled. That is one issue of fund allotment to the Department and funding capacity of the Department which I would like to tell the Chairman.

Further the Secretary stated that the Department has not spent the money because it got into all the procedural difficulties. Like to construct one NIPER the State Governments have to give 100 acres of land free of cost for construction then only NIPER is sanctioned. The State Government promised to give 100 acres of land but ultimately when it came to allotment of land they could give only 18 acres to 50 acres of land. That is hardly sufficient and that is why we could not take up the issue in a big way and start construction activities immediately. For instance, Bihar Government gave only 13 acres of land in a place called Hazipur. When we wanted 100 acres of land the response of the Government is please construct multi-storey building in Hazipur. Hazipur is a rural area and I do not think there is any justification to build a multi-storey building in a place called Hazipur. We are corresponding with the Government of Bihar to give us at least 60-70 acres of land, which they have promised to give us in a nearby area. Likewise, the Government of West Bengal promised to give 100 acres of land. Ultimately, they have given about 40 acres of land. Not only that they want Rs.70 crore to be paid for the land while the original agreement was to give 100 acre of land free of cost. Likewise, we encounter difficulties in allotment of land and that is why we are not able to get substantial allotment for construction of NIPERs in various State Governments.

The third category is about construction of NIPER in Rae Bareli. 30 acres of land has been given in Rae Bareli. It is a remote area. We want to see that this particular project gets substantial, more than 60-70 acres of land, land at least in a reasonably good location in Rae Bareli so that we can start construction work.

We have got land allotted by the Government of Gujarat. Scheme is ready and we are going to start the construction very shortly.

Similarly, it is available in Guwahati and we are going to start the construction. In Hyderabad also we have got the land ready. We have got all the designs approved and we will start construction in three NIPERs. So, for the current year we will be able to spend Rs.600 crore provided the money is allotted. That is what we want to get from the Ministry of Finance. Such types of procedural difficulties have come in the way during the past to implement our various programmes".

II. National Pharmaceutical Pricing Authority (NPPA)

5.8 The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizer was formed by the Govt. of India vide Resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia include fixation and revision of prices of scheduled drug under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation on other specific issues concerning making available affordable medicines to the consumers.

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

Salient features of DPCO, 2013.

- Drug formulations listed under the National List of Essential Medicines under price control.
- Ceiling price calculations are based on "market based data" as opposed to cost based under DPCO, 1995.
- Controls only drug formulation price as opposed to both bulk drugs and their formulations under DPCO, 1995.

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

(i) To implement and enforce the provisions of the Drugs (Prices Control) Order (DPCO), 1995 / 2013 in accordance with powers 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.

5.10 **Price Fixation** :

Under the provisions of the Drugs (Price Control) Order, 2013, the prices of scheduled formulations which are based on National List of Essential Medicines (NLEM)-2011 issued by the Ministry of Health and Family Welfare are to be fixed based on market based data. No one is permitted to sell any scheduled drug / formulation at a price higher than the ceiling price fixed by NPPA/Government. NPPA has fixed the ceiling prices of 509 formulation packs under DPCO, 2013. NPPA is in the process of collecting market based information for fixing the prices of remaining formulations.

5.11 Out of NLEM 2011, NPPA has fixed the ceiling prices of 509 formulations packs under DPCO 2013. NPPA has also notified 139 retail price of new drugs on request of the manufacturers till 28th February, 2015.

5.12 NPPA is also empowered, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, to fix the ceiling price or retail price of any Drug for such period, as it may deem fit and where the ceiling price or retails price of the drug is already fixed and notified, the NPPA may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year. Accordingly, NPPA has fixed prices of 108 non-scheduled anti-diabetic and cardio vascular medicines under paragraph 19 of Drug Price Control Order, 2013 on 10.7.2014 based on the internal guideline issued by the NPPA on 29.05.2014. Although, the said internal guideline of the NPPA has been withdrawn with effect from 22.09.2014 but the concerned notification for price fixation of the said non-scheduled medicines continue to be in force. As per the provisions of DPCO, 2013, no person shall sell the scheduled formulations at prices higher than the ceiling price (plus local taxes as and wherever applicable) so fixed and notified by the Government.

5.13 **Monitoring and Enforcement** :

The prices of medicines which are not covered in the Schedule - I of DPCO, 2013 are also monitored by NPPA. As provided in the DPCO, 2013, no manufacturer shall increase the maximum retail price of a non-scheduled drug more than ten percent of maximum retail price during preceding twelve months. Where ever the increase is beyond ten percent of maximum retail price, NPPA is empowered to reduce price to the level of ten percent of maximum retail price for next twelve months. The manufacturer shall be liable to deposit the Overcharged amount, if any, along with interest thereon from the date of increase in price in addition to the penalty. However, there is no control on the launch price of non-scheduled medicines. Concerned manufacturer of such medicines fix the launch price themselves.

NPPA is also entrusted with the job of monitoring the availability of drugs and to identity shortages, if any, and to take remedial steps to make the drugs available. NPPA is carrying out this responsibility mainly through the State Drugs Controllers and other available information. As and when the reports for shortages of particular drug(s), in any part of the country are received, the concerned company is asked to rush the stock and to make the drugs available.

5.14 **Recovery of Overcharged amount**:

Since inception of NPPA, there are 1138 cases as on 28.02.2015 (1087 cases under DPCO 1995 & 51 cases under DPCO 2013) where demand notices have been issued by NPPA to Pharmaceutical companies amounting to Rs.4052.03 crore (Rs.3902.43 crore under DPCO 1995 & Rs.149.60 crore under DPCO 2013) for selling their medicines at prices higher than the price fixed by NPPA / Govt. of which Rs.371.60* crore (Rs.307.48 crore under DPCO 1995 & Rs.64.12 crore under DPCO 2013) has been recovered till 28.02.2015 leaving a balance of Rs.3680.43 crore (Rs.3594.95 crore under DPCO 1995 & Rs.85.48 crore under DPCO 2013). Out of the balance amount of Rs.3680.43 crore, Rs.3485.01 crore (Rs.3457.86 crore including cases in r/o M/s Cipla Ltd. & its associate companies wherein no coercive action can be taken in pursuance of the order of Supreme Court of India under DPCO 1995 & Rs.27.15 crore under DPCO 2013) is pending in various High Courts & Supreme Court, Rs.51.86 crore is pending for recovery with Collectors of various States under DPCO 1995, Rs.5.05 crore is pending with BIFR / Official liquidators under DPCO 1995 & Rs.139.50 crore (Rs.81.17 crore under DPCO 1995 & Rs.58.33 crore under DPCO 2013) is under process.

Action for recovery of the overcharged amount alongwith interest thereon is a continuous process and NPPA takes action as per the provisions of DPCO'1995/ DPCO'2013 read with EC Act 1955. The recovery of the overcharged amount is affected due to Court orders passed by the various High Courts and also by Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation order / notification issued by NPPA / Government under DPCO 1995. Inclusion of some Bulk Drugs under Price Control (schedule-I of DPCO, 1995) has also been challenged by the pharma companies in different courts of India. NPPA / Government is defending such cases through SG, ASG's and Senior Government Counsels. Whenever necessary, NPPA files urgent application in the Courts for vacation of interim orders and also for early hearing / disposal of the case.

5.15 On being enquired by the Committee about steps being taken by NPPA to expedite the recovery of outstanding amount from the Pharmaceutical companies, the Department in its written reply stated as under:-

> "NPPA is actively pursuing the demands challenged by the companies in courts through Department of Legal Affairs and their nominated Law Officers, Central Government Standing Counsels, etc. Wherever the demand raised by NPPA has not been challenged in the courts and the company has not deposited the amount of demand, the matter is referred to the Collector concerned for recovery of the overcharged amount as arrears of land revenue under the Essential Commodities Act, 1955.
>
> Apart from recovery of outstanding amounts from the companies the overcharging division directs the companies to submit the control samples of the subsequent batches manufactured / marketed by them, in compliance of the ceiling prices notified by NPPA".

5.16 **Integrated Pharmaceutical Database Management System (IPDMS)**

With the help of NIC, a web-enabled application called Integrated Pharmaceutical Database Management System (IPDMS) is being developed to facilitate online submission Form-II, III and V of DPCO, 2013 by all drug manufacturers. The objective is to fix/ revise prices of scheduled formulations/ new drugs on the basis of data provided by manufacturers themselves; monitor availability of Scheduled Formulations in every part of the country; regulate and monitor the price rise of Scheduled and non-Scheduled Formulations; enforce notified price; detect price rise violation; and recover overcharged amount along with interest from the company.

After getting security clearance from NIC, the registration process was started on 18.09.2014. Till February, 2015, 351 pharma companies have already registered and 449 pharma companies are in the process of registration with the online system. So far 21,571 products have been registered and another 8053 are under process. This system would be beneficial to all stake holders, i.e., NPPA, the pharma industry and the consumers at large, in resolving the various problems being faced in the past. Industry will benefit from a user-friendly online reporting mechanism; NPPA will benefit from reliable database based on self-disclosure by companies, and consumers will benefit from access to comprehensive price database of medicines. The issue of overpricing/overcharging will also be effectively addressed by way of self-regulation by companies and a non-discretionary objective mechanism for proceeding against overcharging. It will bring about efficiency in implementation of DPCO 2013 with greater transparency.

5.17 **Pharma Jan Samadhan:**

Pharma Jan Samadhan (PJS) is a web enabled system developed by National Pharmaceutical Pricing Authority (NPPA) with the assistance of National Informatics Centre (NIC). The primary objective of PJS is to put in place a speedy and effective complaint redressal system with respect to availability and price of medicine. PJS serves as a robust e-governance tool for protection of consumer interest through effective implementation of the Drugs (Price Control) Order 2013. Consequent upon registration of a complaint by the complainant, the same reaches the designated officer of NPPA who verifies the complaint and initiates appropriate action for resolving it in a time bound manner.

5.18 **National List of Essential Medicines, 2011 (NLEM, 2011)**

NLEM, 2011 announced by the Ministry of Health and Family Welfare in the year 2011 has been included in the First Schedule of DPCO, 2013. NPPA has conducted a comprehensive study on the advice of Department of Pharmaceuticals for revision of NLEM-2011. NPPA has accordingly forwarded its recommendations to the Department of Pharmaceuticals covering (i) correction / modification of anomalies / discrepancies in description / specifications of the medicines contained in NLEM-2011 and (ii) addition of certain essential and widely used drugs into the NLEM-2011.

5.19 During the course of evidence, the representative from the Department of Pharmaceuticals also explained the position as under:-

> "Hon. Chairman and hon. Members of the Committee, the present pricing policy which is being followed is based on the National Pharmaceutical Pricing Policy of 2012 and subsequent to that a Drug Price Control Order was issued in May, 2013. Now, in this pricing policy, only those medicines which are mentioned in the Schedule I, they are under price control and Schedule I list comes from the National List of Essential Medicines. There is a list of essential medicines which is decided by the Ministry of Health and this list last was prepared in the year 2011. So, this 2011 National List of Essential Medicines is entirely included in the Schedule I of the DPCO. This includes 628 formulations, 628 medicines are included. National Pharmaceutical Pricing Authority (NPPA) is the authority with the Department which does the price fixation. They have already fixed the prices of 509 medicines. What was also presented during the power point presentation, in these 509 medicines there has been a price reduction of more than 40 per cent in 127 formulations, between 35 and 40 per cent in 34 formulations, between 30 and 35 per

cent in 30 formulations, between 25 to 30 per cent in 55 formulations and so on. So, in all these 509, the prices have come down from what they were before the prices were controlled. Some hon. Members raised the question, why can we not control the prices of more medicines, why only 628? The remaining which are there 628 and 509, the process is going on, it is a continuous process. Every month NPPA decides prices of some 10, 15, 20 medicines. It is an on-going. One hon. Member also suggested, does Government not have the powers to bring down the prices of all medicines? I would like to submit that these powers are vested in the Order and as many medicines as are brought under the Schedule I, they can be under price control. Now, this Schedule I, as I mentioned, has been linked with the National List of Essential Medicines. The process of revising the National List of Essential Medicines is also currently going on in the Ministry of Health. They have constituted a core committee which is revising the National List of Essential Medicines. So, when the National List of Essential Medicines gets revised and we have the 2015 version, instead of the 2011 version, if it recommends more medicines in that list, automatically more medicines would come under price control. So, in a way whatever medicines come in the National List of Essential Medicines, they will be covered under price control. That depends on the Ministry of Health whatever they feel is essential in terms of therapeutic segments, in terms of requirements of the Indian population at large, in terms of the disease burden. There is a technical committee which decides what all medicines should be there".

5.20 **Ongoing Scheme: Consumer Awareness through print, electronic and other media:**

The scheme is a joint publicity campaign by the NPPA and Department of Consumer Affairs on a 50:50 cost sharing basis. As the Department of Consumer affairs has requested to part finance their matching share, the scheme could not be implemented during 2014-15.

An outlay of Rs.2.00 crore has been provided for the Scheme in 2014-15. The Department of Consumer Affairs, who had earlier regretted to part finance their share, has now agreed to participate in the Scheme. An amount of the Rs.1.50 crore has been released for publishing two half page colour advertisements in the various national and regional newspapers. One advertisement was published on 8.1.2015. The second advertisement is being released shortly. For the balance amount of Rs.50.00 lakh, a proposal for bringing out a quarter page colour advertisement has been sent for approval.

Keeping in view the changing scenario in the pharma sector and the recommendations of various committees, a proposal for revision/modification of scheme and to rename it as "Scheme of Consumer Awareness & Publicity and Price Monitoring" from 2015-16 onwards has been sent for approval.

5.21 When the Committee asked to give details of any instances of shortage of essential Medicines/Drugs that have come to the notice of Government/NPPA after the implementation of DPCO 2013 and the remedial steps taken by the Department to address the shortages of Medicines/Drugs, the Department in its written reply stated as under:-

"Regarding shortage of drugs, it is stated that the availability of essential medicines is regularly monitored by the NPPA mainly through State Drugs Control Administration of the State Government. Whenever Shortages are reported by the State Drugs Controller or comes to its notice otherwise, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage.

In the recent past, short supply of certain essential medicines namely albumin injection, anti-snake venom, rabies vaccine, rabies immunoglobulin and anti-malarial combination of sulfadoxine + pyrimethamine tablet was reported to NPPA. In order to maintain normal supply of these medicines in the domestic market and / or institutions, NPPA issued notification vide gazette notification S.O. 2292(E) dated 09.09.2014 wherein the concerned manufactures / importers of the drugs were directed to ensure a smooth supply and to furnish a compliance report in this regard. In connection with specific shortages of Albumin injection reported in the country, NPPA has held a meeting with the major manufacturer / importer of Albumin injection. During the course of meeting, it was observed that the shortage of Human Plasma is one of the main constraint in expanding the production capacity of Human Albumin in the country. In this regard Chairman NPPA has written a D.O. letter on 02.04.2015 to the Additional Secretary, Department of Health regarding supply of Human Plasma to manufacturer of Human Albumin by NACO. There has been a reference from the Drugs Controller General (India) regarding non-availability of Injection Anti-Diptheria Serum in Post Graduate Institute of Medical Education & Research, Chandigarh. In order to make the drug available, in and around Chandigarh, all the concerned manufacturers have been advised for necessary action in the matter. In this regard, M/s Haffkine Bio- Pharmaceuticals Corporation Limited, a Govt. of Maharashtra undertaking has offered a quotation for supply of the said drug to Govt. Medical College and Hospital, Chandigarh while another manufacturer namely M/s Serum Institute of India Ltd., has informed that there is a shortage of plasma, however, they would expedite the process of getting the plasma in order to make the Diphtheria Antitoxin available".

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Further, there is a mechanism of monitoring the stock and availability of the essential drugs / scheduled drugs under para 21 (i) DPCO, 2013 that provides for submission of quarterly return in respect of production/ import and sales of scheduled medicines (NLEM medicines) and Active Pharmaceutical Ingredients contained in scheduled formulations as stated in Form- III of the said order by the manufacturer/ importer/marketer. Further, any manufacturer / importer wanting to discontinue manufacture / import of a scheduled formulation has to apply to NPPA in Form-IV of Schedule II of DPCO, 2013 at least 6 months in advance, and NPPA can direct the applicant to continue production / import upto 1 year.

Also, NPPA has recently launched 'Pharma Jan Samadhan' Scheme which provides consumers and others with an online facility to redress their complaint relating to pricing and availability of medicines. The primary objective of 'Pharma Jan Samadhan' is to put in place a speedy and effective complaint redressal system with regard to non-availability or shortage of any medicine, refusal of supply or sale of any medicine, overpricing of medicines etc".

III. <u>Jan Aushadhi Scheme</u>

5.23 Making available quality medicines at affordable prices is a key challenge for the Government. The prices of branded medicines are generally higher than generic medicines due to various reasons. With a view to achieve the objective of ensuring availability of quality medicines at affordable prices to all, the Government has been taking several regulatory and fiscal measures from time to time. In order to provide further relief to the common man in the area of healthcare, a countrywide Campaign for ensuring availability of generic medicines at affordable prices to all, in the name of "Jan Aushadhi Campaign", was launched by the Department of Pharmaceuticals, in November, 2008 in collaboration with the State Governments, as a direct market intervention strategy

5.24 **<u>Achievements/Shortcomings Of The Original Scheme</u>**

The poor performance of the Scheme was quite evident from the fact that, as against the target of opening one JAS in each of the 630 districts, only 178 JASs could be opened till March, 2015. Of these, only 98 JASs were operational. The Public Health Foundation of India (PHFI) was asked to study the Scheme and suggest remedial measures. Based on the Report of PHFI and ground level observations it was found that the following were mainly responsible for the scheme not being successful.

(a) Over dependence on support from State Government
(b) Poor Supply Chain management:
(c) Non-prescription of Generic Medicines:
(d) State Governments launching free supply of generic drugs:
(e) Lack of awareness among the Public:

A New Business Plan – To Overcome Shortcomings Of Original Scheme

With a view to remove the shortcomings noticed in the original Jan Aushadhi Scheme a revised New Business Plan has been worked out. The New Business Plan was approved in August, 2013. The new Business Plan takes care of major bottlenecks in implementation of the scheme so far. The proposed changes in the scheme under the New Business Plan are listed below:-

(i) **Relaxation of eligibility conditions for Operating entities:**

(ii) **Coverage of the Scheme**: In the consolidation phase, it is proposed to establish a complete supply chain in the States where Jan Aushadhi Scheme has a substantial presence. Efforts would be made to open as many stores as possible in these States

(iii) **Review of existing list of medicines:** Under the original Scheme only 319 medicines were listed for sale at the Jan Aushadhi stores. There was a need to review this list to provide maximum coverage to the newer molecules in demand, and also products under the NLEM. With this in view, a revised list of 361 medicines has been prepared, covering almost all therapeutic categories of drugs

(iv) **Supply Chain Management**: More suppliers of medicines are being roped in from other Public Sector Undertakings (PSUs) as well as private manufacturers. Procurement of drugs from private manufacturers is also necessitated by the fact that CPSUs have in-house capacity to manufacture only 138 products. An IT based Management Information System is to be used to ascertain availability of medicines in stores on a real time basis, and accordingly trigger supply of medicines through a transparent procurement process and supply chain, patterned almost on the model of Tamil Nadu Medical Services Corporation (TNMSC).

(v) **Sourcing of drugs :** To ensure regular and adequate supply of medicines, apart from procurement of medicines from the CPSUs, BPPI is to supplement supply by direct purchase of medicines from private sector companies through open tender process, as per the guidelines issued Central Vigilance Commission. The list includes 276 items out of the earlier list of 361 items identified for supply from Jan Aushadhi Stores and also top selling medicines belonging to 6 Therapeutic groups namely; (a) Anti-diabetic (b) Cardiac, (c) Gastro (d) anti-infective (e) Analgesic (f) Respiratory and Vitamins. All efforts are being made to make available the supplies within a few months time.

(vi) **Quality Control:** BPPI would ensure that only quality drugs are supplied through the Jan Aushadhi stores. To ensure this, it is essential that manufacturers of drugs are selected carefully and after due inspection of their facilities to ensure that they conform to required standards i.e. WHO-GMP compliance. Further, samples should be sent for testing on a regular basis. Any failure on the part of suppliers to comply with quality standards should trigger initiation of stringent actions, in addition to blacklisting the firms against future contracts. Though BPPI would ensure quality control through its own channels, the ultimate responsibility to ensure quality of medicines would rest with the manufacturers.

(vii) **Pricing of Drugs:** Out of the proposed list of 361 medicines, MRPs for 138 medicines, manufactured and supplied by the CPSUs, have already been fixed in consultation with NPPA. In respect of medicines procured from private manufacturers or other PSUs, MRP will be fixed on the basis of rates arrived through tender process plus trade margins and other incidental costs (including excise duty, if any, and VAT component). Beyond the 12th Plan period, an additional margin not exceeding 2% will also be collected to meet administrative expenses of BPPI. As the BPPI has to be run on 'no profit no loss' basis, the exact percentage would be worked out based on the volume of turnover at that time.

Given the unsatisfactory performance of the Jan Aushadhi Scheme – which has been operational since 2008, the Department is revisiting the scheme plan and formulating a strategic Action Plan 2015 with a paradigm shift to make quality medicines accessible through affordability and availability. The Strategic action plan includes (i) New Distribution System: Expansion beyond the exclusive JAS stores in retail markets through retailers and franchisee with signage exclusivity (ii) Enlargement of medicines basket, (iii) Team building with all stakeholders – Prescribers (Doctors), Doctors Associations, Medical Council of India, Chemists & Druggists Association, Consumer Association, State Governments, Regulators and all others by addressing their respective concerns (iv) Advocacy and perception management on quality of JAS medicines for brand building (v) Strengthening Bureau of Pharma Public Sector Undertakings of India (BPPI) (vi) improved Supply Chain Management (vii) Value Added Services in partnership other service providers – online/home delivery, post offices, co-operatives, insurance agencies etc. (viii) Recognition of Doctors, Distributors and retailers and NGOs actively engaged in generics.

Under the Strategic Action Plan 2015, a pilot initiative will be launched during 2015-16 to reach out all sections of society with results and will be expanded across the country in the coming 3 years covering all therapeutic groups.

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

"As far as Jan Aushadhi is concerned, again that is a very lofty scheme. It is a scheme which is required for our public in a very big way. The original idea was to start 630 stores one in each district. That particular scheme ultimately failed after 6-7 years of work mainly because of the role of the State Governments. The State Governments were to provide space in the hospitals. They have to find out an agency to run the shop and they have to take a very proactive step. But in spite of steps taken by the Government of India, many State Governments never cooperated by allotting the land in the hospital premises.

A few Governments started in a big way. For instance, the Rajasthan Government opened 54 shops. The sale of drugs was going on very well. But there was a sudden change in the policy of the Rajasthan Government. They said that they will supply free drugs to all the people who come to Government hospitals. That means they are going to give generic drugs. What Jan Aushadhi shops were supposed to do, this scheme of the Government has simplified that. In fact, the Tamil Nadu Government has been giving Jan Aushadhi drugs in all the Government hospitals. Now the Kerala Government is also giving. The Odisha Government has also started it. Likewise if all the Governments in the country decide to supply Jan Aushadhi drugs free of cost to all the patients, then I think there is no need for Jan Aushadhi scheme at all in the Government sector. Now we are ensuring that we are talking to all State Governments to see that this procedure of providing free drugs to all the patients through Government hospitals is implemented. But this Jan Aushadhi scheme should be made successful. We should never say that Jan Aushadhi scheme has failed in India. A country where millions of patients are suffering and are in need of cost effective drugs and when the Government of India has the requisite mandate and responsibility, we want to see that this scheme is successful. We are re-working the scheme. In fact, for the past four months, we have re-worked the scheme and we want to launch Jan Aushadhi in a new format from June 21st onwards in six States in the first phase. Then we will cover II and III phase States. Over a period of another one years' time, we want to see that Jan Aushadhi stores are available throughout the country in the medical colleges and district hospitals in the first phase.

Parallelly we are also working a scheme to see that Jan Aushadhi drugs are available not only in Government exclusive stores but also in all the private drug stores. A number of private drug units are there. We want to implement that scheme in a big way. We would like to experiment with that particular scheme from Delhi. It has got more than 1500 stores. We want to see that at least 800 stores the Jan Aushadhi drugs are available. In fact, we are asking our Prime Minister to start this programme. As the hon. Chairman has written to the Prime Minister about this particular scheme, we would like to launch this programme as the Prime Minister's Jan

Aushadhi Programme as a new scheme. Our hon. Ministers are reviewing it on a day-to-day basis.

The organisation which is responsible to implement this particular Jan Aushadhi scheme, the Bureau of Public Sector Pharmacy Companies was a very weak organisation. Now we are strengthening that organisation. We are telling them to see that drugs are procured and stored adequately. It is because once we start these stores, there should not be any shortage of drugs. In fact, the original scheme failed to a great extent because our supply chain management was improper. The shops are there and people are willing to buy and sell but the drug is not available. If a person comes up with a list of four drugs, only one drug is available and for three drugs he has to go to some other shop. So people started losing confidence in the Jan Aushadhi shops. So, we are rectifying all these defects and are strengthening this organisation. We are strengthening our purchase and supply management system. This time we want to ensure that Jan Aushadhi is very successful.

It includes everything. Now we are increasing the number of products also. Earlier there were 350 products, now we want to raise to 500 plus products including surgical carton, syringes, etc.

We are organising a meeting of Health Secretaries of six States. The first phase will come in the States of Maharashtra, Gujarat, Karnataka, Odisha, Government of Delhi and Assam.

In the second phase we are taking up the State of Uttar Pradesh. We want to do it in one go, but it would take a lot of time. Provided that the criticism that we are not doing anything, we are starting first phase in six States. We will definitely cover the State of Uttar Pradesh in the second phase”

CHAPTER-VI

PUBLIC SECTOR UNDERTAKINGS

6.1 The Department has 5 running PSUs under its administrative control viz. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Bengal Chemicals & Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL). Out of these KAPL is profit making, while RDPL has reported losses for the first time in 2013-14 and BCPL, HAL & IDPL are BIFR referred Companies. However consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL. However, as the HAL is still incurring losses, the 2nd Rehabilitation Plan of HAL including the sale of surplus land is under consideration of the Department. The rehabilitation scheme of IDPL is also under consideration.

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

A. KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED (KAPL)

6.3 KAPL is a profit making joint sector Company incorporated in the year 1981 [with 59% shares by Government of India and 41% shares by Government of Karnataka through KSIIDC]. The basic objective of the company was to make available life saving drugs of good quality to Karnataka Government hospitals and other institutions. The Company has been manufacturing facilities for Dry Powder Injectables, Tablets, Capsules, Dry Syrups and Suspensions. The paid – up share capital of the company as on date is Rs. 13.49 crores.

B. HINDUSTAN ANTIBIOTICS LIMITED (HAL)

6.4 Hindustan Antibiotics Ltd (HAL) is wholly owned Government company engaged in the Manufacturing & Marketing of Life Saving Drugs. HAL was established in 1954 with WHO / UNICEF assistance. HAL is the first Company to Manufacture the Antibiotics like Bulk drugs Penicillin, Streptomycin and Gentamycin. HAL has rare distinction of inventing two new molecules viz. Hamycin and Aureofungin. HAL has been instrumental in ensuring the availability of life saving drugs at affordable prices in the Country.

6.5 **Sickness and Revival**

(a) HAL was referred to BIFR in 1997. Rehabilitation Scheme was approved by BIFR on 5th June 2007 after series of hearings. As the Rehabilitation Scheme was not fully implemented, IFCI Ltd. was engaged in 2011 to evaluate the performance in implementation of sanctioned scheme, identifying reasons to achieve performance, suggest business plan for the company with future corporate strategy to make HAL's operation viable. HAL has prepared Business Plan based on recommendations of IFCI with following features:-

- Focus only on formulation business.
- Drastic cost cutting measures including VRS
- New utility set-up for Formulation

(b) **Second Rehabilitation package**

HAL had prepared Rehabilitation Scheme as directed and submitted to Ministry in June'12. This scheme has undergone changes many times and company has submitted revised scheme in Jan.'15 covering liabilities upto March.'14 This scheme is under consideration Features of the scheme are as under:-

i. Liabilities were covered upto March.'14.
ii. VRS for 500 persons
iii. Capital investment of Rs. 111.50 crores
iv. Outsourcing of the non-core area

(c) In addition to the support provided by the Government under Rehabilitation Scheme, Government has also 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. HAL has completed the work on Cephalosporin and also obtained WHO-Certification for the same. Work relating to upgradation of existing vialling facilities for Betalactum Antibiotics has been completed. However, HAL is still incurring losses. A 2nd Rehabilitation Plan of HAL is under consideration of this Department. IDBI, the operating agency has submitted DRA to BIFR in February, 2014 for its approval, which is awaited.

6.6 When asked to give details of the basic reasons for the sickness of HAL and whether BIFR has given any time frame for considering the proposal by IDBI (Operating Agency) and by when HAL would be fully rehabilitated? Also any specific time frame have been chalked out for its rehabilitation, and the efforts being made by the Department in this regard, the Department in its written reply stated as under:-

> "The basic reasons for the sickness of HAL are as follows :
> The first Rehabilitation Scheme for HAL was sanctioned after the approval from Govt. of India by BIFR in June, 2007 involving the cash infusion of Rs. 137.59 crores. However, some major components of the first Rehabilitation Scheme could not be implemented by the Company leading to further losses and the acute financial problems being faced by the Company.
> The causes for failure and the continuing sickness of the Company are as follows:-
>
> A) Although the Rehabilitation Scheme was sanctioned in June, 2007 the Consortium of Banks did not extend the desired working capital facilities to the company as envisaged in the sanctioned scheme.

HAL was forced to take short term corporate loan of Rs. 40 crores from Punjab National Bank and Rs. 20 crores from UCO Bank in the year 2008-09 to meet the working capital requirement.

In the Rehabilitation Scheme liabilities from 31st March, 2006 till November, 2008 was not covered and the loan amount was utilized mainly to cover these liabilities and only Rs. 50 crores was available for working capital.

B) HAL continued its operations thereafter without the much desired support from the banks for working capital. In the Rehabilitation Scheme, it was envisaged that Rs. 60 crores would be generated from bulk plants either by leasing or by utilizing the fermentation facilities. HAL could not take up the production of Penicillin-G since the operations was not commercially viable. Inspite of several efforts made for utilizing the fermentation facilities, HAL was unable to use the same, either for its own production or with the help of any leasing partner. The non-utilisation of the fermentation facilities adversely affected the operations of the Company in the following manner:

a) High utility cost for formulation
b) Higher fixed cost for formulations
c) Manpower required for utilization of the facilities could not be effectively used for production resulting in additional fixed cost of formulation production.
C) Historically HAL's sale are dependent on Govt. Institutional business and its presence in the Trade Market is minimum. The margins in the institutional business are very thin which has affected the profitability of the Company.

Due to introduction of Purchase Preference Policy (PPP), HAL could pick up its formulation sales in the institutional category in the initial period of 2-3 years after the sanction of the Rehabilitation Scheme. However, thereafter the sales started to decline because of non-materialising of various orders from Govt. Institutions due to shortage of working capital thereby affecting the production. Also the renewal / extension of the Purchase Preference Policy (PPP) which expired in August, 2011 took place only in February, 2014 affecting the orders from the Govt. Institutions.

The present marketing set-up of the Company is inadequate due to retirement of many of the Marketing Staff Members under VRS, retirement, resignation, etc. This limitation of the Marketing set-up also affected the sales of the Company.

The performance of the Company was satisfactory up to the 1973-74. However, its operations received set-back since 1974 when the oil crisis started. The company's financial position further deteriorated due to increase in competition, high interest rates, inadequate working capital and price control on the drugs manufactured by it under Drug (Price Control) Order (DPCO). No time frame has been given by BIFR for considering the proposal prepared by IDBI (Operating Agency). The MDRS submitted by IDBI is under active consideration of Department. Since various other agencies are also involved in the process, no time frame can be indicated by the Department of Pharmaceuticals".

6.7 When asked about the current status of 2nd Rehabilitation Plan of HAL, the Department in its written reply stated as under:-

"IDBI Bank (Operating Agency) vide its letter dated 6.2.2015 has prepared and submitted a Modified Draft Rehabilitation Scheme (MDRS) in r/o M/s Hindustan Antibiotic Limited (HAL) with Cut Off date 31.3.2014. The Board of Directors of the Company has approved MDRS.
Cost of the Scheme and Means of Finances, as per MDRS are as under:-

PARTICULARS		AMOUNT (Rs. in crore)
I)	Payment of Banks' Dues	178.14
II)	Payment of Statutory Dues	73.38
III)	Payment of Loan from ONGC	17.05

IV) Payment of Sundry Creditors	13.22
Sub-Total (I to IV)	281.79
V) Employee Related Dues:	
a) Salary Arrears	8.60
b) Credit Society	2.07
c) 1997 pay revision Arrears	45.37
d) Establishment cost including salaries from 1.4.2014 to 31.3.2015	44.00
Total (V)	100.04
VI) Cost of VRS	104.95
VII) Capital Expenditure	111.50
VIII) Working Capital Requirement*	44.00
IX) Provision of Contingencies @ 10% of proposed liability payout)	28.18
Total (V to IX)	388.67
Grand Total (I to IX)	670.46

* Includes payment of sundry creditors for raw material to the extent of Rs. 3 crore.

(b) **MEANS OF FINANCE**

Particulars	(Rs. in crores)
Sales proceeds from the vacant land HAL, BIFR Case No. 501/1997	670.46
Total	670.46

The MDRS/second revival package is under examination of this Department for expeditious rehabilitations. Already had one meeting with Secretary BRPSE on 16.3.2015".

6.8 The Committee visited HAL Plant at Pimpri, Pune 10.1.2015. During the discussion, HAL officials submitted that while there is infrastructure, the Plant could not function as there are no funds. Plant assets worth Rs. 300 crore have been lying idle and operations of the Company have come to a near standstill. The employees have not received their salary for more than six months. Accordingly to them, decline in production and sale in the Company is due to acute shortage of working capital which HAL is facing for the last 3-4 years.

It was further added by HAL officials that HAL had already submitted a 'ModifiedDraft Rehabilitation Plan' involving funds infusion to the tune of Rs.526.16 to the Ministry of Chemicals and Fertilizers which is awaiting BIFR and Cabinet approval. The Company also sought interim relief for day-to-day expenses including salary payments and statutory dues until the implementation of the Rehabilitation Scheme.

6.9 When asked about the reasons non receipt of salaries and other statutory dues to the employees of the company and the steps taken by Department of Pharmaceuticals in this regard to address the issue, the Department in its written reply stated as under:-

"The HAL could not pay salaries of the officers for the last 11 months and to the workers for the last 9 months as the financial condition of the company is very grim. A Modified Draft Rehabilitation Scheme has been prepared by the Operating Agency i.e. IDBI Bank for Rehabilitation. It is under active consideration of Deptt. . Also, a proposal has been submitted to M/o Finance for a loan of Rs.11.50 crores (Rs.10.50 crores for 3 months salary and Rs.1.00 crore for contingent expenditure) from Contingency Fund of India".

6.10 When asked to give details how the Department is going to resolve the acute shortage of working capital which HAL is facing for the last 3-4 years, the Department in its written reply stated as under:-

> "The MDRS/revival scheme submitted by IDBI- the operating agency appointed by BIFR includes a provision of Working Capital of Rs. 44.00 crore. The scheme (with a cost Rs. 670.46 crore) is under active consideration of Government".

C. <u>BENGAL CHEMICALS & PHARMACEUTICALS LTD.(BCPL)</u>

6.11 Bengal Chemicals and Pharmaceuticals Limited (BCPL), erstwhile Bengal Chemical and Pharmaceutical Works Limited (BCPW) was set up in 1901 by Acharya Prafulla Chandra Roy, a renowned scientist and academician. Government of India nationalised BCPW in 1980 under the name Bengal Chemicals & Pharmaceuticals Limited (BCPL) in 1981.BCPL was declared sick in 1993 and was sanctioned scheme for revival in 1995 by Board for Industrial & Financial Reconstruction (BIFR). In 2004, the scheme of revival was modified and the plan was sanctioned by BIFR.

Business Operations

6.12 Headquartered in Kolkata, BCPL is engaged in production and selling of industrial chemicals (Alum), branded and unbranded generic pharmaceuticals, hair oil and disinfectants such as phenol, naphthalene balls, bleaching powder, toilet cleaners and floor cleaners. The Company currently has four factories, eleven Sales Outlets and ten C&F Agencies spread across the country.

6.13 **Manufacturing Locations:**The registered and corporate offices of BCPL are located in Kolkata. At present BCPL has four factories; at Maniktala and Panihati in West Bengal, Mumbai and Kanpur.

Maniktala Unit**:**This unit primarily produces Division II products which include branded as well as unbranded generic pharmaceuticals. Under the BRPSE scheme several projects such as capacity expansion of tablets, capsules and ointment blocks, complete overhaul of ASVS and Liquid blocks and implementation of Greenfield projects were envisaged for the Maniktala unit. The ASVS project is planned to be taken up during 2015-16 .The Greenfield Projects (Betalactum & Cephaphosporin Blocks) and modernisation of Ointment block that were initiated as envisaged in the plan and will be commissioned by April 2015.

Panihati Unit.Panihati unit, located near Kolkata, primarily produces Alum and products like Pheneol, Naphthalene Balls, and other disinfectants. Commercial production in most of the renovated production-blocks such as Alum, Pheneol, Napthalene and White Tiger have commenced

Mumbai Unit**:** Mumbai unit, produces Hair Oil under the brand name 'Cantharidine'. The commercial space developed has been leased out to third parties for generation of additional sources of income. Commercial space of the order of 43,206 sq. ft. has presently been leased out by the company

Kanpur Unit:Kanpur Unit, set up in 1949, primarily produces Division II products which includes tablets and capsules and small quantity of Hair Oil.

6.14 **Past Achievements:** The company has retained its brand position in home products even during the crisis period and well set to capitalise on tense brands now.

6.15 **Sickness and Revival**, if any:The revival package for BCPL was approved by the Government on 21st December 2006. The package of Rs 490.60 Cr was approved which comprised of restructuring of exiting debts on the books of BCPL, capital investments, support for development of marketing infrastructure and promotional measures, grant for wage revision and implementation of VRS and funds for payment of non-Government dues.

6.16 When asked plan action of the Department for the revival of BCPL, the Department in its written reply stated as under:-

> "Government approved Rehabilitation Scheme for revival of BCPL on 21.12.2006. The rehabilitation scheme, inter alia, involved the following:
>
> (i) Cash infusion of Rs. 207.19 crore (Rs. 145.00 crore is meant for upgradation & modernization of manufacturing facilities conforming to WHO-GMP standards)
>
> (ii) Write off of Government of India, Loan and waiver of interest thereon of Rs. 233.41 crores.
>
> Status of implementation of MDRS projects (BCPL):

PARTICULARS	STATUS
Panihati: Civil Construction, plan & machinery, utilities ETP, Roads, drains Stores, Admn. Office.	Completed. Commercial production commenced
Maniktala:	
Stores Building	Completed
Utilities, ETP Roads, drains etc.	Completed.
Ointment Block	Commissioning Processing
Betalactum& Cephalosporin Block	Commissioning is in progress
ASVS Section	To be taken up in 2015-16
Kanpur:-	QA Block, Utilities, Amenities, ETP completed. Civil construction of OSD almost completed. HVAC, electrical work, utilities etc. not completed.
Tablet, ORS, renovation/ up gradation of existing blocks, QA, Utilities, amenity, sterile Block etc.	

6.17 When asked to furnish the names of consultant appointed by the company for undertaking the work of upgradation and modernization of plant and machinery including compliance with Schedule 'M'/WHO GMP standards, and the time-limit fixed for this purpose, the Department in its written reply stated as under:-

> "The Company appointed following consultants for upgradation and modernization of Plant & Machinery.
>
> 1) **M/s. Zen Marketing -** This consultant firm was appointed for project work of different plants of the Company appointed in 2007. Their allocated job has been already completed.

2) **M/s. NNE Pharma Plan** - This consultant firm was appointed on 10/06/2008 for Greenfield projects of Betalactum& Cephalosporin Blocks at Maniktala, Kolkata and Oral solid dosage project at Kanpur. They are presently on the job as different projects in Maniktala factories of the Company have not yet been completed. The project is likely to be completed in the year 2015-16.

An EFC Meeting in r/o BCPL for appraisal of Revised Cost Estimates of BCPL's projects was held on 13.1.2015. Approval to BCPL was accorded for utilizing unspent project fund available with BCPL for completion of Ointment & Betalactam Block. An amount of Rs.7.00 crores kept in Plan Budget for the year 2014-15 for commissioning of the Cephalosporin project is being released".

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

"Since the implementation of Revival Scheme since 2007-08, the BCPL is on the path of revival**.** The production, sales and gross margins during the past 9 months of 2014-15 surpassed the production and sales achieved during the last two financial years. Achievement during last 9 months of 2014-15 are given below:

(Rs in Crore)

Period	Production	Sale	Gross margin
2012-13	36.44	27.36	(5.98)
2013-14	20.24	16.87	(16.89)
9 months of 2014-15	46.86	35.61	4.46

Upon completion of Betalactum& Cephalosporin Blocks it is expected that the company will make a turn around".

D. INDIAN DRUGS AND PHARMACEUTICALS LIMITED (IDPL)

6.19 Indian Drugs & Pharmaceuticals Limited (IDPL) was incorporated as a public limited company on 5th April, 1961 under the Companies Act, 1956. The Registered Office of the Company is located at Dundahera, Gurgaon and its Head Office at SCOPE Complex, Lodhi Road, New Delhi. The main objectives of the company were creating self-sufficiency in respect of essential life saving medicines, to free the country from dependence on imports and to provide medicines to the millions at affordable prices. IDPL was basically conceived and established as a part of Healthcare Infrastructure and has played a pioneering infrastructural role in the growth of Indian Drugs Industry base.

IDPL has three main Plants at Rishikesh (Uttarakhand), Gurgaon (Haryana), Hyderabad (Telangana)) and two wholly owned subsidiaries, namely, IDPL (Tamil Nadu) Ltd. Chennai (Tamil Nadu) and Bihar Drugs & Organic Chemicals Ltd.(BDOCL) at Muzaffarpur (Bihar). In addition, IDPL has one Joint Venture Undertaking, promoted in collaboration with the Odisha State Government, namely, Orrisa Drugs & Chemicals Ltd. (ODCL) Bhubaneswar. IDPL is a sick company in Public Sector within the meaning of Sick Industrial Companies (Special Provisions) act, 1985 (SICA).

Past Achievements:

6.20 The main objective of setting-up IDPL was not to earn profits but to encourage indigenous production of pharmaceuticals and to support various health programmes of the Central Government. IDPL did reasonably well on this account despite the fact that it was the first integrated and monolithic venture in the Public Sector engaged in production of low margin products. IDPL earned Profit before Depreciation, Interest & Tax (PBDIT) from 1965 to1968 and again from 1971 to 1974. It earned net profit from five years continuously from 1974 to 1979; the Company lost its profitability primarily due to change in Government policy about import of bulk drugs for supplying to pharma Industry. The Imports which were canalized through IDPL till 1979 were entrusted to State Trading Corporation (STC). This was the task assigned to IDPL as per needs of the time. IDPL was thus divested of a profit making segment. Today, it can fulfill other needs to meet gaps in public health by supplying essential drugs.

Sickness and Revival if any

6.21 The net worth of the IDPL became negative in 1982-83. The causes were (i) large monolith-type integrated production facilities (typical model followed in 1950s-1960s) producing chemicals, bulk drugs & formulations (ii) outdated plant & machinery and obsolete technology for bulk drugs (but for formulations not outdated) (iii) excess manpower (13283 in 1983-84) and high wage bill and maintenance of huge township, schools and hospitals. (iv) frequent changes at top management (average tenure of Chairman & Managing Director was 18 months) (v) medicines produced by IDPL were under price control by the Government prior to liberalization in 1991 (vi) shift in Government policy resulting in shifting of the canalization agency from IDPL to STC (vii) intense competition from private pharma sector companies which did not have to bear burden of social infrastructure of setting up and maintaining townships, schools, hospitals etc. and had learner production facilities. Production has been stopped in October1996 at Rishikesh& Hyderabad & Muzaffarpur Plant due to shortage of working capital.

Revival status since 1.4.1994

6.22 The Board for Industrial & Financial Reconstruction (BIFR) declared IDPL as a sick industrial Company on 12^{th} August. 1992. On 10.2.1994 BIFR approved the Rehabilitation Scheme under Section 17(2) of SICA for its implementation w.e.f. 1.4.1994. The package sanctioned by BIFR in 1994 failed primarily because (i) full funds were not released to the Company as envisaged (ii) capital restructuring was not done (iii) banks did not provide adequate working capital requirements (iv) working capital funds were diverted to meet fixed expenses of subsidiary units. (v) Land could not be sold (vi) sales targets were fixed at very ambitious levels. On 23.1.1996, BIFR appointed Industrial Development Bank of India (IDBI) as Operating Agency (OA) for Techno-Economic Analysis and preparation of Revival Package. The issue of revival of the company remained pending in BIFR as well as with the Govt. Attempts were made in 2001-02 to privatize the Company. OA, however, did not find any proposal worthy of recommendations to BIFR.

After failure to privatize IDPL, BIFR ordered its winding –up on 4.12.2003. Govt. filed an appeal before Appellate Authority for Industrial Financial Reconstruction (AAIFR) on 10.2.2002 against BIFR order. AAIFR admitted the appeal filed by the Government on 2.8.2005 and directed that a Road Map for revival of IDPL be submitted. Ministry/ Department constituted an Expert Committee under the Chairmanship of Director NIPER and Technical Audit of the Plants & Machineries carried out by the Committee, it would be feasible to revive IDPL. Committee found the plant & machineries for production of formulations in a reasonably good shape which can be optimally utilized with minimal investment for compliance of Scheme-M requirements. It was also opined that the emerging positionof IDPL in the present market scenario is to be conceptualized. IDBI supported the recommendations of the Expert Committee. Having regard to these developments, AAIFR 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 and to pass further orders in accordance with law.

Keeping in view of the above a DRS was prepared by IDPL in consultation with CDRA Management and submitted to the BRPSE for consideration and recommendation. After approval of the BRPSE and A Note for Cabinet Committee on Economic Affairs is prepared and submitted for approval on 11.5.2007. The Note was considered by CCEA in its meeting held on 17.5.2007 and referred the matter to Group of Minister (GoM). GoM in its meeting held on 11.10.2007 advised that IDPL's revival plan should be based on public interest goals and ensuring the viability of the Company. The observations made by GoM, IDPL appointed a leading consultant Company E&Y to carry out the feasibility study. E&Y report submitted to the Ministry/DoP.

A revised DRS again prepared by IDPL in consultation with IDBI (OA) taking cut off date as 31st March, 2011. BIFR observation that cut off date needed the approval of BIFR bench. Thereafter in the BIFR meeting held on 20.8.2014 cut off date was approved as 31.3.2014. Accordingly, the revised updated DRS has been prepared taking cut off date 31.3.2014 and submitted to the DoP/Ministry in January 2015 for consideration and approval. The DRS of IDPL is self-financing in nature in other words no fund will be sought from the Govt rather the present assets will be sold off and the fund released will be used to payoff secured creditors.

6.23 When the Committee asked about the observations of BIFR on the DRS proposal submitted by IDBI and the response of the Department/IDBI thereto, the Department in its written reply stated as under:-

> "IDBI has submitted the DRS on 06.02.2015 . There has been no meeting of BIFR on IDPL since then. The next hearing is fixed on 09.06.2015. IDBI has recommended the scheme of revival out of sale of part of surplus land of IDPL at Gurgaon".

6.24 When asked to give details of time frame fixed for revival of IDPL, and efforts made by the Department in this regard, the Department in its written reply stated as under:-

> "Modified Draft Rehabilitation Scheme has been received in this Department. Further action is under process. No time frame has been fixed so far on revival of IDPL".

6.25 When asked by what time the new structure would be built at IDPL, Hyderabad, the Department in its written reply stated as under:-

> "The IDPL Hyderabad Formulation Plant is expected to be operational by September, 2015".

E. Rajasthan Drugs & Pharmaceuticals Limited (RDPL)

6.26 The company is engaged in manufacture and selling of medicines of high quality at reasonable rates to the Govt. of Rajasthan, Central Government Institutions, viz ESIC, Defence, Railways, other PSUs and also to other State Govt. Institutions with its marketing activities spread throughout the country. RDPL is proud to be a prime partner in the novel and noble endeavor of Govt. of India in the implementation of 'JANAUSHADHI' programme where quality generic medicines (unbranded) are made available to the public at large in the country at affordable prices. The company is further diversifying its activities into Pharma Prescription Markets (Open Trade Sales), Veterinary Markets, Marketing of Ayurvedic and other Indian system of medicines in order to enhance its market share and also in its endeavour to achieve profitability for the organization.

Past Achievements:

6.27 RDPL is serving the nation from last 36 years (approximate) in the field of providing quality medicines at affordable price with the motto "**Health for All**". RDPL supplied medicines in the Jan Aushadhi Scheme (A novel scheme by Department of Pharmaceuticals, Ministry of Chemical & Fertilizers, GoI), Free distribution scheme (Like for Govt. of Rajasthan), NRHM, NVBDS, Antimalarial programmes etc. We always emerged as contingent medicine provider to Governments and institutions, for example we supplied medicines to in case of Surat (Gujrat) plague epidemic, Latur (Maharastra) & Bhuj (Gujrat) earthquakes and now we are supplying medicine for Swine flu to various states. Product. The Company has been manufacturing and marketing total 190 products in various therapeutic category range.

Sickness and Revival, if any:

6.28 Currently no sickness, but reported loss first time during 2013-14.

Future projects:

6.29 RDPL is going to diversify its business in Ayurveda and Veterinary segment. In Ayurveda RDPL has good exposure of marketing and achieved a sale of Rs. 8.50 crore (Approximate) by product manufactured on loan licence basis. Now RDPL is planning to set up in house manufacturing facility for manufacturing facility in RDPL premises for Tablets & Powder dosage forms in year 2015-16 with support of Dept. of Pharmaceuticals.Similarly RDPL wants to set up a facility to manufacture the Veterinary Products in RDPL premises in year 2015-16 with support of Dept. of Pharmaceuticals. To complete the ongoing Expansion, Modernisaton, Schedule – M and WHO-GMP project.

6.30 On being asked about the rehabilitation of the Pharma PSUs, the Secretary, Department of Pharmaceuticals during the evidence stated as under:-

> "All the Members were talking about the public sector undertakings; Hindustan Antibiotics, IDPL and various other organisations. It is true the Department has taken a large number of years to rehabilitate these industries. Hindustan Antibiotics for instance has been crying for money but they have got arrears of about Rs.600 crores to be paid to various creditors, statutory dues, dues to banks, due to creditors, suppliers. To get Rs.600 crore all along efforts

were made to see that the money is obtained from the Government of India. Every time when the files were sent, the Government used to refuse. Once they gave money, about 10 years back, to rehabilitate Hindustan Antibiotics. That money was hardly sufficient. We asked for Rs.300 crore and what was given was only Rs.150 crore. As a result again, the industry became sick. There was no working capital. They had to urgently go to other banks to get working capital. They got the working capital and that interest accumulated. Now, more than Rs.600 crore due is there from Hindustan Antibiotics to other organisations.

We have now worked out a package. We have decided to sell the land. As the hon. Members might have seen, land proposal was finalised two years back. Land was put on bid. They offered Rs.18 crore per acre. We can get Rs.110 crore for 6.6. acre of land. When the file was processed there was a change of Secretary. The new Secretary said, let us not sell our valuable land, let us go back to the Government and ask for money, let us take sale of land as a last resort. So, the proposal was shelved. Again, the matter was taken to the Ministry of Finance. The Ministry said that they would not release money and asked us to find out resources from our own sources. Now, we have revived our proposal of sale of land. The proposal is getting ready.

Now in another 10 days time, we should be able to see that this proposal is taken to the Cabinet. We have prepared the Cabinet note. So, that is the position as far as the Hindustan Antibiotics is concerned. Now we have to take a decision about the sale of 6.6 acres of land. Subsequently, we have to get permission from the Cabinet to sell another 40 acres of land. Then only we should be able to mobilise about Rs.600 crore. So all these things naturally take a lot of time and we are fighting against time as also against various Departments which raise various queries. We answer these queries and ultimately, we have reached some stage. I am very confident that in another month's time, we should be able to see that these proposals reach the Cabinet for suitable decisions. This is regarding Hindustan Antibiotics.
Similar is the state for IDPL. It is also facing the same problem. It has accumulated a loss of about Rs.1200 crore. They have to pay to various banks and financial institutions as also creditors. Here again we have taken a decision to sell some land in Gurgaon. We will sell 45 acres of land. That proposal is also almost getting ready. It is not the case as Secretary I can immediately take a decision on these rehabilitation proposals. Before the file goes to the Minister, it has to go to various Departments. Before the note goes to the Cabinet, it has to go to various Ministries for their comments. It has to go to the organisation called BRPSC and BIFR. All these organisations put all kinds of queries and they make life actually difficult for all of us. That is the real difficulty that is why these things take a lot of time. In spite of all these difficulties, we have ensured that this Cabinet note is ready. In a month's time, these two Cabinet Notes will reach the Cabinet and we will be able to take a decision to rehabilitate them. Once the Cabinet decision comes, we will immediately see to it that further lands are sold, all the credits are settled and we will be able to infuse more money and are able to revive these two units. This is our plan as far as sick units are concerned.

These units have done yeoman service to the country. For instance, the Hindustan Antibiotics served its best. Then IDPL was asked to produce low value items. When all the private companies produced high value items and exported them, IDPL's mandate was to produce only low cost drugs so that they can be given to the Government hospitals in the country. So, they did a very good work. At one point of time, I think more than 15000 people were working the IDPL but today only 200 people are working. We are sitting on a property of about 2000 acres of land. So all the infrastructure is available and once we come out of this debt problem, I think we should be able to revive these two organisations successfully and make them as model public sector units in the country. That is the vision of the Department and we are working towards that".

OBSERVATIONS/RECOMMENDATIONS

OVERVIEW OF PHARMACEUTICAL INDUSTRIES

1. The Committee note that the annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs.128044.29 crore during the year 2013-14. This segment of Industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. The industry has developed excellent GMP (Good Manufacturing Practices) compliant facilities for the production of different dosage forms. The Indian Pharmaceutical companies maintain highest standards in Purity, Stability and International Safety, Health and Environmental (SHE) protection in production and supply of bulk drugs. The country is almost self-sufficient in case of formulations. However, the Committee note with concern that a large sum of money is being spent on imports by the country. During the year 2013-14, Rs.17944.05 crore was spent to import medicinal and pharmaceuticals products. According to the Department, the imports are being made on quality and economic considerations and not necessarily due to non-availability from domestic sources. However, the Committee is not satisfied with the explanation of the Department on this issue. The Committee are of the strong view that to realize the dream of 'Make in India' concept in pharmaceutical sector, the Government should boost and incentivize domestic bulk drug industry and discourage Indian pharmaceutical firms from importing. It is also essential that revival of closed/sick public sector units may be expedited to create capacity of bulk drugs in the country itself and to make the country self-reliant in bulk drugs as also recommended by the Committee in their 2nd Report. Incentives should be given for Research and development in the pharmaceutical sector. In this context, the Committee note that the Government had constituted a committee under the chairmanship of Secretary, Department of Health and Research. The mandate of this Committee was to carefully study the whole issue of Active Pharmaceutical Ingredients (APIs) of critical importance by identifying important APIs and then working out a package of interventions/concession required to build domestic production capabilities and examine the cost implications. The said committee has reportedly submitted its report. Based on the recommendations of the said committee and consultations with stakeholders, the Department would come up with a policy on promotion of production of APIs in India. The Committee now expect from the Department to expedite the process of forumlation of the policy on promotion of production of APIs in India. The Committee hope that as a result of the proposed policy, Indian pharmaceutical companies will be encouraged to produce bulk drugs in the country and consequently cheap and quality drugs will be available to the consumers in India. The Committee would like to know the initiatives taken to expedite the policy and the progress made in the matter so far.

ANNUAL PLAN AND EXPENDITURE

2. The Committee are constrained to note that an outlay of Rs 12341.89 crore was proposed by the Department for the 12th Five Year Plan covering various Schemes to the Planning Commission, against which an allocation of Rs 2968 crore was approved. However, for the first three years of the 12th Five Year Plan, against a proposed outlay of Rs 2566.86 crore (Rs 1127.45 crore for 2012-13, Rs 567.60 crore for 2013-14 and Rs 871.81 crore for 2014-15) sought by the Department, the Planning Commission allocated a Plan provision of Rs 583 crore only i.e. Rs 188 crore each for 2012-13 and 2013-14, and Rs 207 crore for 2014-15. The balance outlay available for this Department, out of the total approved 12th Plan outlay of Rs 2968 crore, is Rs 2385 crore. According to the Department, the allocation made to them falls far short of the urgent funds requirements projected by them for carrying out its laid down mandate and its Vision for development of Indian Pharmaceuticals Industry under "Make in India" initiative, to make India a largest global provider of quality medicines. According to the Department, the funds allocated for NIPER will be insufficient if NIPER buildings are to be completed in two years. Notwithstanding the position stated above, the Committee's examination revealed that the Department has not been able to spend the plan outlay allocated to them over a period of time and the actual utilization of funds by the Department had remained unsatisfactory. The Committee find that as against the Plan outlay of Rs. 188 crore in BE 2012-13 which was slashed to Rs. 85 crore at RE stage, only Rs. 51.26 crore was spent. For the year 2013-14, the actual expenditure was only Rs.74.02 crore against Rs.188 crore in BE 2013-14 which was reduced to Rs.75 crore at RE stage. The Plan outlay for the year 2014-15 was Rs.207 crore at BE stage which was curtailed to Rs. 87.49 crore at RE stage and out of which only Rs.65.86 crore was spent by the Department. Rs.20 crore was allocated to NIPER, Mohali in BE 2014-15 but the same could not be released for want of Third Pay Evaluation and EFC approval of these schemes. Delay in expenditure was the reason for reduction from Rs. 30 crore in BE 2014-15 to Rs. 26.49 core at RE stage for project based support to PSUs. Cluster Development Programme for Pharma sector was approved in January 2014 but there was delay in selection of Project Management consultant and therefore, due to delay in selection, the BE 2014-15 was reduced at RE stage. Similarly, funds could not be released for setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad. Under Plan Revenue Head for Other Schemes, BE 2014-15 was Rs.64 crore which was reduced to Rs.20.70 crore at RE 2014-15 stage but the Actual Expenditure during the year 2014-15 was only Rs.0.71 crore and a large sum of funds under Plan for Other Schemes could not be spent. Against the allocated funds of Rs. 2.44 crore for the scheme on targets specific new drugs discovery for Anti TB and Kalaazar, a sum of Rs. 0.71 crore was released in last fiscal year 2014-15 and balance amount could not be released as the Utilisation Certificate was not be provided by NIPER, Mohali. All these facts illustrated above clearly speaks about the poor performance of the Department in utilization of its plan allocation. In fact, the Department was candid enough to accept the fact that they could not spend the allotted

funds in the past. The Committee, therefore, feel that the Department can not achieve its avowed objectives and targets set for various schemes/programmes unless the funds are utilized by the Department optimally and efficiently. The Committee, therefore, recommend that the Department should make earnest efforts for optimum utilisation of funds allocated to them. The Committee would like to be apprised of the initiatives undertaken by the Department in this regard.

OPTIMUM UTILISATION OF FUNDS

3. The Committee note that total budgetary allocation was reduced from Rs 247.87 crore in BE 2014-15 to Rs 137.04 crore in RE 2014-15 by Ministry of Finance. The Department had sought an enhanced provision of Rs 236.26 crore for RE 2014-15, against which only Rs 87.49 crore was actually made available to them. For Plan BE 2015-16, at RE stage, in November 2014, the Department had sought Rs 871.63 crore. This request for Plan BE 2015-16 was subsequently enhanced by this Department after finalization of Plan proposals to Rs 1590.78 crore in February 2015, to address the long pending pressing needs of development of 6 old NIPERs and 3 new NIPERs, upgradation/ modernization of CPSUs, Jan AushadhiYojana, new schemes etc. As against the request of the Department, only Rs 210 crore was actually provided for Plan BE 2015-16 by Ministry of Finance. In the total allocation of Rs 259.02 crore for BE 2015-16, 81% i.e. Rs 210 crore is accounted for by Plan provisions. NIPER has been allocated Rs.126.44 crore in BE 2015-16 which according to the Department is insufficient against the proposal of Rs.1128.57 crore. In addition to 6 NIPERs, the Budget speech for 2015-16 lists three new NIPERs at Maharastra, Rajasthan and Chattisgarh. The Committee also note that Plan allocation of Rs. 155 crore in BE 2014-15 was reduced to Rs.56 crore at RE stage for Phamaceutical industries. Under Critical Assistance to Pharma CPSEs for WHO (GMP) Compliance scheme, Rs. 6.84 crore was allocated in RE 2014-15 and Rs. 10 crore allocated in Supplementary budget Grant (SBG), out of which Rs.3.3 crore could be sanctioned and the Planning Commission did not approve projects totaling Rs.3.16 crore of IDPL. Similarly, Rs. 9.67 crore was allocated at RE stage for the year 2014-15 for Jan Aushadhi Scheme as against Rs.30 crore at BE stage and actual expenditure was Rs.9.67 crore only.

In view of the foregoing, the Committee strongly feel that the funds allocated to the Department by the Ministry of Finance is abysmally low with reference to their proposals. In the absence of adequate funds available with them, the plan schemes/programmes undertaken by the Department would be adversely affected. The Committee, therefore, strongly feel that the Ministry of Finance should allocate the funds as per the proposed requirement of the Department and would like that the Department may strongly take up the matter with the Ministry of Finance. At the same time, the Department, on their part, should ensure that funds allocated to them are utilized optimally and evenly during the year to enable them to achieve

the physical targets set for various schemes/programmes which would in turn boost the sustained growth and development of pharma sector in the country. The Committee would like to be apprised of the initiatives undertaken by the Department in this regard.

NATIONAL INSTITUTE OF PHARMACEUTICALS EDUCATION AND RESEARCH (NIPER)

4 NIPER was declared as an "Institute of National importance" under the Act of Parliament on 26th June 1998. NIPER is a member of Association of Indian Universities. In addition to NIPER, SAS Nagar, Mohali the Government had set up six new NIPERs at Hyderabad, Hajipur, Ahmedabad, Rae Bareli, Guwahati and Kolkata. These New NIPERs will cater to the growing demand of the pharmaceutical industry for highly trained manpower for continuous growth of the pharmaceuticals sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present, new NIPERs are functioning with the assistance of the Mentor Institutes. However, the six New NIPERs are yet to be provided with buildings and regular faculty. In the year 2015-16 it is proposed to construct buildings and provide regular faculties for the six NIPERs. However, the budgetary provision is very limited to take up the same. Thus a supplementary demand is being proposed. Further the Department proposed setting up of three new NIPERs at Andhra Pradesh, Madhya Pradesh and Karnataka. The Budget Speech for 2015-16 lists three new NIPERs at Maharashtra, Rajasthan and Chhattisgarh. The Committee further observed that the work relating to construction of NIPER Campus at Guwahati and Gandhinagar has since been awarded to Engineering Projects (India) Ltd and Hindustan Steelworks Constructions Ltd. respectively. Further, the Committee noted that Department has not spent the money because it got into all the procedural difficulties. To construct one NIPER the State Governments have to give 100 acres of land free of cost and then only NIPER is sanctioned. The Committee have been apprised that State Governments do not provide adequate land that is why construction activities cannot be started immediately. The Committee therefore recommend that the Department of Pharmaceuticals should take up the matter with State Governments at the highest level and impress upon them to provide land for NIPER without any delay. Further they may also take up the matter with the Finance Ministry for required fund allotment after substantial work is in progress. The Committee would like to be apprised of the progress made in this regard.

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

5. The Committee note that the functions of NPPA, inter-alia include fixation and revision of prices of scheduled drug under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation on other specific issues concerning making available affordable medicines to the consumers. The Government has notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995 and as per the order the prices of scheduled formulations which are based on National List of Essential Medicines (NLEM)-2011 issued by the Ministry of Health and Family Welfare are to be

fixed based on market based data. No one is permitted to sell any scheduled drug / formulation at a price higher than the ceiling price fixed by NPPA/Government. NPPA has fixed the ceiling prices of 509 formulation packs under DPCO, 2013. NPPA is in the process of collecting market based information for fixing the prices of remaining formulations. The Committee were surprised to know that all the medicines are not listed in National List of Essential Medicines The Committee are of the view that all medicines are essential and is taken only when it is needed by the patient. All these medicines including Life Saving Drugs should be available in the market at affordable cost. To keep this in view, the Committee recommend that the scope of price control needs to be enlarged to make all the drugs available especially Life Saving Drugs in all parts of the country. The Government should also expedite the process of notifying the ceiling prices of the remaining medicines. The Committee would like the department to act accordingly and be apprised of the targets achieved in the matter.

RECOVERY OF OVERCHARGED AMOUNT BY NPPA

6. The Committee note that since inception of NPPA till 28.2.2015 there are 1138 cases (1087 cases under DPCO 1995 & 51 cases under DPCO 2013) where demand notices amounting to Rs.4052.03 crore have been issued by NPPA to Pharmaceutical companies for selling their medicines at prices higher than the price fixed by NPPA / Govt. of which Rs.371.60 crore has been recovered till 28.02.2015 leaving a balance of Rs.3680.43 crore. Out of the balance amount of Rs.3680.43 crore, Rs.3485.01 crore is pending in various High Courts & Supreme Court, Rs.51.86 crore is pending for recovery with Collectors of various States under DPCO 1995, Rs.5.05 crore is pending with BIFR / Official liquidators under DPCO 1995 & Rs.139.50 crore is under process. The Committee are given to understand that action for recovery of the overcharged amount along with interest thereon is a continuous process and NPPA takes action as per the provisions of DPCO'1995/ DPCO'2013 read with EC Act 1955. However, the process of recovery is affected due to orders passed by the various High Courts and also by Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation order / notification issued by NPPA / Government under DPCO 1995. Inclusion of some Bulk Drugs under Price Control (schedule-I of DPCO, 1995) has also been challenged by the pharma companies in different courts of India. NPPA / Government is defending such cases through senior Government Counsels. Whenever necessary, NPPA files urgent application in the Courts for vacation of interim orders and also for early hearing / disposal of the case. While appreciating these efforts, the Committee recommend that NPPA should vigorously pursue all the recovery cases and recover the overcharged amount from the companies. The Committee would also like to be apprised of the action taken in this regard.

JAN AUSHADHI SCHEME

7. The Committee note that under the Strategic Action Plan 2015, a pilot initiative will be launched during 2015-16 to reach out all sections of society with results and will be expanded across the country in the coming 3 years covering all therapeutic groups. The Committee were informed regarding Jan Aushadhi Scheme that the said Scheme will be launched in a new format from June 21st onwards in six States in the first phase. Rest of the States would be covered in second and third phases. Over a period of another one year time, Jan Aushadhi stores are expected to be opened throughout the country in the medical colleges and district hospitals in the first phase. The Committee were further informed that the organisation which is responsible to implement this particular Jan Aushadhi scheme, the Bureau of Public Sector Pharmacy Companies is very weak organisation. Now the Department is strengthening that organisation. The Department is telling them to see that drugs are procured and stored adequately. Now, the Department is increasing the number of products also. Earlier there were 350 products, now the Department want to raise it to 500 plus products including surgical carton, syringes, etc.

The Committee, would like the Department to sort out all procedural issue well before actually launching the Strategic Action Plan 2015. The Committee would like to be apprised of the progress in the mater ensuring that generic drugs are made available at cheaper rate to the common man throughout the country at the earliest.

PUBLIC SECTOR UNDERTAKINGS

8. The Committee note that the Department has 5 running PSUs under its administrative control viz. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Bengal Chemicals & Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL). Out of these KAPL is profit making, while RDPL has reported losses for the first time in 2013-14 and BCPL, HAL & IDPL are BIFR referred Companies. However consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL.

As the HAL is still incurring losses, the 2nd Rehabilitation Plan of HAL including the sale of some portion of surplus land has been approved by the Government. The Committee note that proceeds from sale of surplus land could generate a substantial amount for the revival of the company. The Committee expressed their displeasure that no significant progress on the proposal has been made. The Committee now expect that necessary action would be taken by the Government in the matter and the formalities would be finalised expeditiously to implement the 2nd rehabilitation Plan of HAL for the early revival of company and to ensure welfare of its employees.

As regard the sickness and Revival of BCPL the revival package for BCPL was approved by the Government on 21st December 2006. As envisaged in the Revival Scheme of BCPL, Government has so far released Rs. 207.19 crore in full as cash infusion component. The company has appointed Consultants for undertaking the work of up gradation & modernization of plant & machinery including compliance with Schedule 'M'/WHO GMP standards. The company is on the path of revival. The production sale and gross margin during the last 9 months of 2014-15 surpassed the production and sale during the last two financial year.

IDPL was declared as a sick industrial Company on 12th August. 1992. After failure to privatize IDPL, BIFR ordered its winding –up on 4.12.2003. AAIFR 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 and to pass further orders in accordance with law. GoM in its meeting held on 11.10.2007 advised that IDPL's revival plan should be based on public interest goals and ensuring the viability of the Company. Based on the observations made by GoM, in its meeting held on 11.10.2007, IDPL appointed a leading consultant Company E&Y to carry out the feasibility study. E&Y submitted its report to the Ministry/DoP. A revised updated Draft Rehabilitation Scheme (DRS) has been prepared taking cut off date 31.3.2014 and submitted to the DoP/Ministry in January 2015 for consideration and approval. The DRS of IDPL is self-financing in nature in other words no fund will be sought from the Government rather the present assets will be sold off and the fund released will be used to payoff secured creditors. The Committee are given to understand that Government has also decided to sell surplus land of IDPL , Gurgaon to generate revenue. The Committee hope that with the sale of land, the IDPL would generate revenue which would help them to revive IDPL, Gurgaon.

The Committee are, however, unhappy with the slow pace of progress to revive the sick PSUs in spite of their repeated recommendations in this regard. The Committee once again reiterate its recommendation that the Department should make vigorous efforts in coordination with all concerned to expedite the revival of the sick PSUs in time bound manner. The Committee would like to be apprised of the action plan by the Department in this regard.

New Delhi;	**Anandrao Adsul**
16 April, 2015	**Chairperson**
26 Chaitra, 1936 (Saka)	**Standing Committee on**
	Chemicals and Fertilizers

APPENDIX-I

A statement showing Reasons for the unspent amount in 2014-15 and action plan for 2015-16 (Non-Plan) is given below :-

(Rs.in Lakhs)

Sl. No.	Object head	BE 2014-15	RE (2014-15)	Expenditure booked upto 17.3.2015	BE 2015-16 (Tentative figures as informed by DOP)	Reasons for the unspent amount in 2014-15 and action plan for 2015-16.
1	SALARY	450.00	345.00	314.78	380.00	Due to non-filling of vacant posts and transfer of staff, the funds could not be fully utilized in 2014-15. At present, 2 posts of DD (Cost), and 2 post of Dir, are laying vacant. They are expected to be filled in 2015-16. Besides, provision has been made for increment/increased pay & allowances of the existing staff.
2	MEDICAL TREATMENT	30.00	15.00	4.86	10.00	Number and amount of medical claims from staff members remain uncertain.
3	DOMESTIC TRAVEL	35.00	22.00	22.00	25.00	NPPA officers are required to visit various cities of the country to collect samples as per RFD target. Therefore, provision has been made for payment of TA/DA to NPPA staff and payment to M/s BalmerLawrie.
4	FOREIGN TRAVEL	8.00	0.00	0.00	5.00	There was no foreign visit by NPPA officers during 2014-15. The provision has been made to meet the foreign travel expenditure in 2015-16.
5	RENT, RATES & TAXES	295.00	305.00	304.98	305.00	The current monthly lease rate being paid to YMCA is Rs. 2541529/-. Therefore, annual lease rent comes to Rs. 305 lakh.
6	OFFICE EXPENSES	150.00	80.00	86.84	100.00	Funds provided under RE have been fully utilized. In 2015-16, funds are required for (i) making payments of pending bills which could not be paid in 2014-15 due to budget constraints, and (ii) for purchase of samples of medicines for the purpose of monitoring of prices, meeting day to day expenditure to run the office like stationery, sanitary, hiring of vehicles, security guard, drinking water, computer softwares etc.
7	OTHER ADMN. EXP.	7.00	5.00	4.96	5.00	Funds provided under RE have been utilized. In 2015-16, funds will be utllized towards organization of National / regional / State level conferences / workshops / seminars.

Sl. No.	Object head	BE 2014-15	RE (2014-15)	Expenditure booked upto 17.3.2015	BE 2015-16 (Tentative figures as informed by DOP)	Reasons for the unspent amount in 2014-15 and action plan for 2015-16.
8	PROFESSIONAL SERVICE	150.00	88.20	89.71	120.00	Funds provided under RE have been fully utilized. In 2015-16, funds under the head are required for following: (i) Rs. 28 lakh plus taxes is expected to be paid to M/s Pharma Trac in 2015-16 for providing data on prices of medicines. (ii) Payment of Rs. 14 lakh plus taxes to M/s Pharma Trac which could not be made in 2014-15 is expected to be made in 2015-16 (iii) Payments for hired Consultants//Programmers (approx 12-15 Nos. in Tech / Legal/ Overcharging / Costing fields (iii) There are around 190 active court cases. Courts/ Advocates fees etc will be required to be paid.
9	WAGES	80.00	70.00	58.78	70.00	Funds under this head could not be utilized fully due to delay in finalization of tenders for hiring of DEOs/YPs and due to leaving of some DEOs/YPs engaged through outsourcing agency. In 2015-16, funds are required to make provision for (i) expected increase in wages of Casual Workers (TS) due to annual increment, increase in DA etc. (ii) expected increase in payments to outsourced staff due to increase in wage rates by Delhi Govt., increased payments to outsourcing agencies due to re-tendering.
10	OTA	2.00	0.80	0.76	1.00	-
	Total	**1207**	**931**	**887.67**	**1021**	

APPENDIX -II

MINUTES

MINUTES OF THE TWELFTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2014-15)

The Committee sat on Thursday, the 26th March, 2015 from 1500 hrs. to 1700 hrs. in Committee Room 'E', Parliament House Annexe, New Delhi.

PRESENT
Shri Anandrao Adsul - Chairperson
MEMBERS
LOK SABHA

2. Shri B.N. Chandrappa
3. Shri Satish Kumar Gautam
4. Shri K. Ashok Kumar
5. Shri Chhedi Paswan
6. Shri S. Rajendran
7. Shri Chandu Lal Sahu
8. Dr. Kulamani Samal
9. Dr. Uma Saren
10. Shri Tasleem Uddin
11. Shri Kotha Prabhakar Reddy

RAJYA SABHA

12. Shri Biswajit Daimary
13. Shri Narayan Lal Panchariya
14. Shri K. Parasaran
15. Shri Palvai Govardhan Reddy

SECRETARIAT

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

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

1.	Shri V.K. Subburaj	Secretary
2.	Shri Amit Khare	Member Secretary, National Pharmaceuticals Pricing Authority (NPPA)
3.	Shri Rajiv Yadav	SS & Financial Advisor (FA)
4.	Dr. M.A. Ahammed	Joint Secretary
5.	Ms. Sunanda Sharma	Economic Advisor
6.	Shri Sudhansh Pant	Joint Secretary

II. <u>AUTONOMOUS INSTITUTIONS</u>

1.	Dr. K.K. Bhutani	Director, National Institute of Pharmaceutical, Education and Research (NIPER)
2.	Shri Neeraj Rajvanshi	CEO, Bureau of Pharma CPSUs of India (BPPI)

III. REPRESENTATIVES OF PSUs

1.	Shri Praveen Kumar	CMD, Indian Drugs and Pharmaceuticals Ltd. (IDPL)
2.	Shri E.A. Subramanium	MD, Bengal Chemicals and Pharmaceuticals Limited (BCPL)
3.	Shri K.V. Verkey	MD, Hindustan Antibiotics Limited (HAL)

2. At the outset, Hon’ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) to the sitting. Their attention was invited to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

3. After the witnesses introduced themselves, the Secretary, Department of Pharmaceuticals briefed the Committee about Department's activities through Power Point Presentation.

4. During the discussion, the Hon'ble Chairperson and Members of the Committee raised queries on several issues such as revival of sick PSU's, like HAL, IDPL etc., Implementation of 'Jan Aushadhi Scheme', functioning of NIPER, quality and pricing of drugs, role of NPPA, recovery of overcharge amount from pharma companies, List of essential drugs etc., which were replied to by the Secretary, Department of Pharmaceuticals and other officials.

5. The Chairperson thereafter thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee.

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

The Committee then adjourned.

APPENDIX -III

MINUTES

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

The Committee sat on Thursday, the 16 April, 2015 from 1500 hrs. to 1600 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

Shri Anandrao Adsul - Chairperson

Members

Lok Sabha

2. Smt. Anju Bala
3. Shri Satish Kumar Gautam
4. Shri Chhedi Paswan
5. Dr. Kulamani Samal
6. Dr. Krishan Pratap Singh
7. Smt. Rekha Arim Verma
8. Shri Innocent
9. Shri Kotha Prabhakar Reddy

Rajya Sabha

10. Shri Narayan Lal Panchariya
11. Dr. Sanjay Sinh
12. Shri Palvai Govardhan Reddy
13. Shri Mansukh L. Mandaviya
14. Dr. Chandrapal Singh Yadav

Secretariat

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

2. At the outset, the Hon'ble Chairperson welcomed the members of the Committee.
3. The Committee thereafter took up for consideration the following draft Reports:
   a. xxxx xxxx xxxx xxxx
   b. xxxx xxxx xxxx xxxx
   c. Demands for Grants (2015-16) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)
4. The draft Reports relating to the Department of Fertilizers, Department of Pharmaceuticals and Department of Chemicals and Petrochemicals were adopted by the Committee without any amendment.
5. The Committee authorised the Chairman to make consequential changes, if any, arising out of the factual verification of the Reports by the Department of Fertilizers, Department of Chemicals and Petrochemicals and Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers and present the same to both the Houses of Parliament.
6. xxxx xxxx xxxx xxxx

The Committee then adjourned.

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xxxx Matters not related to this Report.