

**32****STANDING COMMITTEE ON  
CHEMICALS & FERTILIZERS****(2016-17)****SIXTEENTH LOK SABHA****MINISTRY OF CHEMICALS AND FERTILIZERS  
(DEPARTMENT OF PHARMACEUTICALS)****DEMANDS FOR GRANTS****(2017-18)****THIRTY-SECOND REPORT****LOK SABHA SECRETARIAT****NEW DELHI*****March, 2017/ Phalguna, 1939 (Saka)***

**THIRTY-SECOND REPORT**

**STANDING COMMITTEE ON  
CHEMICALS AND FERTILIZERS  
(2016-17)**

**(SIXTEENTH LOK SABHA)**

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

**DEMANDS FOR GRANTS  
(2017-18)**

*Presented to Lok Sabha on 20 March 2017*

*Laid in Rajya Sabha on 20 March 2017*

**LOK SABHA SECRETARIAT  
NEW DELHI**

*March, 2017/ Phalguna, 1939 (Saka)*

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(iii)

**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS  
(2016-17)**

**Shri Anandrao Adsul - Chairperson**

**MEMBERS  
LOK SABHA**

2. Shri George Baker
3. Smt. Anju Bala
4. Shri B.N Chandrappa
5. ShriSankar Prasad Datta
6. Smt. Veena Devi
7. Shri R. Dhruvanarayana
8. Shri Innocent
9. Shri K Ashok Kumar
10. Shri Chhedi Paswan
11. Smt. Kamla Devi Patle
12. Shri S. Rajendran
13. Shri Kotha Prabhakar Reddy
14. Dr. Kulamani Samal
15. Dr. Uma Saren
16. Dr. Krishna Pratap Singh
17. Shri Taslimuddin
18. Smt. Rekha Arun Verma
19. Shri Kirti Vardhan Singh
20. Shri Pankaj Chaudhary
21. \$ Dr. (Smt.) Ratna De (Nag)

**RAJYA SABHA**

22. Shri Biswajit Daimary
23. Shri Prem Chand Gupta
24. Shri Sanjay Dattatraya Kakade
25. Shri Surendra Singh Nagar
26. Shri Narayan Lal Panchariya
27. Shri K Parasaran
28. Shri Palvai Govardhan Reddy
29. Dr. Sanjay Sinh
30. Shri Abdul Wahab
31. Smt. Roopa Ganguly

**SECRETARIAT**

- |    |                        |   |                         |
|----|------------------------|---|-------------------------|
| 1. | Smt. Rashmi Jain       | - | Joint Secretary         |
| 2. | Shri A.K. Srivastava   | - | Director                |
| 3. | Shri Nishant Mehra     | - | Under Secretary         |
| 4. | Shri S. Vijayaraghavan | - | Sr. Committee Assistant |

\$ Dr. (Smt.) Ratna De (Nag) MP, (LS) has nominated as a member of the Committee w.e.f 2.1.2017 in lieu of Sh. Shri Dasrath Tirkey MP, (LS)

**INTRODUCTION**

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2016-17) having been authorised by the Committee to submit the Report on their behalf present this Thirty Second Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2017-18.

2. The Committee examined the Demands for Grants (2017-18) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which were laid in Lok Sabha and Rajya Sabha on 07 February, 2017.

3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 22<sup>nd</sup> February, 2017.

4. The Report was considered and adopted by the Committee at their sitting held on 17 March, 2017.

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. The Committee also place on record their appreciation for the valuable assistance rendered to them by the officials of the Lok Sabha Secretariat attached to the Committee.

7. 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;**  
**17 March, 2017**  
**26 Phalguna, 1938 (Saka)**

**Anandrao Adsul**  
**Chairperson**  
**Standing Committee on**  
**Chemicals and Fertilizers**

**PART I****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. 1<sup>st</sup> 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 works have been allocated to the Department of Pharmaceuticals:

1. Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.
2. Medical Devices - Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.
3. Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceutical sector. Development of infrastructure, manpower and skills for the pharmaceutical sector and management of related information.
4. 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.
5. Promotion of public – private – partnership in pharmaceutical related areas.
6. International co-operation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
7. 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.
8. Technical support for dealing with national hazards in pharmaceutical sector.
9. All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.
10. All matters relating to National Institutes for Pharmacy Education and Research.
11. Planning, development and control of, and assistance to, all industries dealt with by the Department.

12. Bengal Chemicals and Pharmaceuticals Limited.
13. Hindustan Antibiotics Limited.
14. Indian Drugs and Pharmaceuticals Limited.
15. Karnataka Antibiotics and Pharmaceuticals Limited.
16. Rajasthan Drugs and Pharmaceuticals Limited.

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

1.4 **The detailed Demands for Grants (2017-18) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 7 February 2017. The demand shows a budgetary support of Rs.247.74 crore [(Rs. 247.68 crore (Revenue) + Rs.0.06 crore (Capital)]. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2017-18. The detailed analysis along with Observations/ Recommendations of the Committee are given in a separate chapter at the end of the Report. The Committee expect the Department to take all necessary steps for proper and timely utilization of funds ensuring completion of the various plans and projects in a time bound manner. The Committee also expect the Department to act on the recommendations of the Committee expeditiously.**

## CHAPTER-II

### AN OVERVIEW OF PHARMACEUTICALS INDUSTRY

#### Financial Performance of the Drugs and Pharmaceuticals Industry

The Annual turnover of the Indian Pharma Industry during 2015-16 was 1,85,388 crores. It represented a decline of 7.4% over the corresponding figure for 2014-15 i.e. 2,00,151 crores. The Compound Annual Growth Rate (CAGR) for last 5 financial years was 8.88%.

2.2 The absolute figures available from the data provided by Centre for monitoring Indian Economy Private Limited (CMIE) for the last 5 years is as per the following table.

<b>Income &amp; Expenditure Summary : Drugs &amp; Pharmaceuticals Industry</b>							
<b>Rs. Million: 2010-11 to 2015-16</b>							
<b>S. No.</b>	<b>Particular</b>	<b>2010-11</b>	<b>2011-12</b>	<b>2012-13</b>	<b>2013-14</b>	<b>2014-15</b>	<b>2015-16</b>
1.	Total Income	14,09,099	15,10,061	16,48,757	19,18,723	20,01,508	18,53,879
2.	Total expenses	11,58,652	14,21,040	15,18,117	17,53,437	18,36,297	16,44,004
3.	Profit before tax	4,39,716	3,18,476	3,38,153	4,39,199	4,56,616	4,50,514
4.	Profit after tax	2,77,945	1,17,337	1,52,141	1,89,291	1,90,994	2,17,781

Source Centre for monitoring Indian Economy Pvt. Ltd. (CMIE) data as on 15/02/2017

**Performance of Pharma Exports:** - During the decade ending 2015-16, India's drug exports grew at a CAGR of 11.9 per cent. This growth was backed by large number of drugs going off patent, rise in the number of drug approvals and access to new markets. According to the CMIE data, the trend in drug exports reversed in the ongoing financial year. During April-November 2016, drug exports fell by one per cent. This is on account of tightening of regulatory mechanism by various countries, price erosion in the US market and economic crisis in the emerging markets. For the year 2016-17 as a whole, drug exports are expected to dip by 0.4 per cent. The Quarterly financial indicators of Indian Pharma Industry reflecting the figures of percentage change over previous corresponding quarter are presented in the following table.

<b>Income &amp; Expenditure Summary: Drugs &amp; Pharmaceuticals Industry (Quarterly)</b>					
<b>Y-o-Y % change: Mar 2016 to Dec 2016</b>					
<b>S. No</b>	<b>Particulars</b>	<b>Mar-16</b>	<b>Jun-16</b>	<b>Sep-16</b>	<b>Dec-16</b>
1.	Total Income	4.57	3.37	3.77	5.1
2.	Net sales	7.38	2.52	2.91	4.1
3.	Total expenses	1.43	3.55	14.65	5.42
4.	Operating expenses	3.17	3.64	5.15	4.8
5.	Raw materials, stores & spares	-8.91	-3.71	-1.66	-1.81
6.	Salaries and wages	8.89	10.7	15.11	12.92



7.	Power & fuel	-13.16	12.38	11.7	18.52
8.	Interest expenses	14.26	13.36	0.63	-1.25
9.	Depreciation	-11.41	13.5	9.75	9.73
10.	PBT	12.95	-7.67	-4.79	8.02
11.	Total tax provision	1.46	-10.13	-16.33	17.7
12.	Net profit (PAT)	17.41	-6.82	-0.96	5.11
13.	Total expenses net of P& E	42.96	-6.81	-0.99	2.35
14.	PBDIT net of P& E	2.6	3.56	4.05	5.6
15.	PBDIT net of P&E	16.28	-2.57	-2.03	5.66
16.	PBDIT net of P&E & OI (Operating Profit)	18.47	-6.77	-5.45	2.93
17.	Count	151	151	149	128

**2.3 Performance of Pharma Imports:** - During April-November 2016, drug imports declined by 9.3 per cent. This was on account of withdrawal of customs duty exemption on a total of 71 drugs by the government. This move aimed at reducing the dependence on drug imports and encourage local production. For the year 2016-17, drug imports are likely to decline by 9.3 %.

### **Scheme for Financing Common Facility Centers (CFCs) at Bulk Drug Park**

**2.4** The vision of the Department of Pharmaceutical (DoP), Ministry of Chemicals & Fertilizers is to catalyze and encourage quality, productivity and innovation in Bulk Drug Sector and to enable the Indian Bulk Drug Industry to reduce the dependency on import of Bulk Drugs. For this, world class quality manufacturing facilities with high level of productivity with innovative capabilities are required. However, these are on one hand very capital intensive and cannot be established and opened by Bulk Drug Manufacturing Units on their own due to financial constraints.

**2.5** In this direction, the Department proposes in the first instance to start a scheme for Financing Common Facility Centres (CFCs) at 3 Bulk Drug/API Parks in the country at a total cost of Rs. 450 crores. Some of the indicative activities under this Common facilities are:

- i. Effluent Treatment Plants
- ii. Captive Power Plant
- iii. Steam and Cooling and water systems
- iv. Incubation facilities
- v. Common logistic facilities
- vi. Advance common testing centre
- vii. Regulatory awareness facility centre

**2.6** The objectives of this scheme are as under:-

- (i) Increasing the competitiveness, easy access to standard testing and infrastructure facilities and value addition in the domestic Bulk Drug Industry through creation of common world class facilities.

- (ii) Strengthening the existing infrastructure facilities in order to make Indian Bulk Drug Industry a global leader in Bulk Drug Exports.
- (iii) Reducing the cost of production by 20-25% in the Bulk Drug Park leading to better availability and affordability of Bulk Drug in domestic market.
- (iv) Exploiting the benefits arising due to optimization of resources and economies of scale.

Department of Expenditure's in-principle approval has been received for implementing the scheme.

## CHAPTER-III

### ANNUAL PLAN AND EXPENDITURE

The Department furnished the following information and comments on the Budget Proposal for Gross Budgetary Support and amount actually provided for different Scheme in Annual Plan 2017-18.

3.2 There is Gross Budgetary allocation of Rs.247.74 crore for the year 2017-18, out of which Rs.52.03 crore is towards Centre's Expenditure relating to Secretariat General Services for Department of Pharmaceuticals, NPPA and NIPER, Mohali and Rs.195.71 crores for Central Sector Schemes, against the proposed Budget Estimate of Rs.1468.88 crores (Centre's Expenditure Rs.95.53 crore + Central Sector Scheme Rs.1373.35 crore).

3.3 A statement showing scheme wise details of outlays, Gross Budgetary Support (GBS) for the year 2017-18, and scheme wise break-up of outlays approved, is given below:-

#### DEPARTMENT OF PHARMACEUTICALS 2017-18 (Budget Estimates)

(Rs. In crore)

Sl. No.	Scheme/Programme	BE 2017-18 Proposed	BE 2017-18 Approved
1.	NATIONAL INSTITUTES OF PHARMACEUTICALS EDUCATION & RESEARCH(NIPER)		
	Lumpsum Provision for N.E. Region (NIPER Guwahati)	200.02	31.50
	NIPER, Mohali	100.00	0.01
	NIPER, Ahmedabad	200.00	22.96
	NIPER, Hyderabad	200.00	20.00
	NIPER, Kolkata	10.00	9.00
	NIPER, Rae Bareli	100.00	8.50
	NIPER, Hajipur	10.00	6.00
	NIPER, Guwahati	0.00	0.00
	NIPER, Madurai	100.00	1.00
	NIPER, Chhattisgarh	10.00	0.01
	NIPER, Rajasthan	100.00	1.00
	NIPER, Maharashtra	100.00	0.01
	Setting Up National Centre For R&D Bulk Drugs	40.33	0.01
	NIPER Technical Support Group & Monitoring	1.00	0.00
	Scheme for Kala Azar and Anti TB Agents	0.01	0.00
	Total (NIPER)	1171.36	100.00
2.	National Pharmaceuticals Pricing Authority(NPPA)	8.00	4.00
3.	Assistance to PSUs		
	Loan to PSUs		
	IDPL	0.01	0.01
	HAL	0.01	0.01
	BCPL	28.10	0.01
	BIL	0.01	0.01
	RDPL	0.01	0.01
	SSPL	0.01	0.01
	Total (Assistance to PSUs)	28.15	0.06
4.	Development of Pharma Industry		

	Pharmaceuticals Promotion Development Scheme (PPDS)	2.00	2.00
	Creation of IPR Facilitation centre at Pharmaxil	0.01	0.00
	Cluster Development	50.00	10.00
	Pharmaceuticals Technology Upgradation Assistance Scheme(PTUAS)	0.01	0.00
	Setting up of Venture Capital Fund for financing drug design, discovery & innovation in Pharma Sector	0.01	0.00
	Setting up of Pharma Promotion Council	0.01	0.00
	Setting up of Medical Device Promotion Council	0.01	0.00
	Critical assistance for WHO pre qualification for Pharma PSUs/R&D	10.00	5.01
	Assistance to Bulk Drug Industry for Common Facilitation Center	0.00	0.01
	Assistance to Medical Device Industry for Common Facilitation Center	0.00	0.01
	Total (Development of Pharma Industry)	62.05	17.03
5.	Jan Aushadhi	103.79	74.62
	<b>Grand Total</b>	<b>1373.35</b>	<b>195.71</b>

3.4 When asked to give reasons for lesser approval (Scheme wise) by the Ministry of Finance, though the Department had proposed Rs. 1373.35 crore to be allocated during 2017-18, only Rs. 195.71 crore were approved by Ministry of Finance, and how the Department plans to achieve their targets with lesser allocation, the Department of Pharmaceuticals in its written reply stated as under:-

“As against a demand of Rs. 1373.35 crore Ministry of Finance allocated only Rs. 195.71 crore that is less allocation of Rs. 1177.64 crore. This is largely an amount of less allocation to NIPER by Rs. 1071.36 crore.

The meagre allocation of Ministry of Finance will hamper the construction activity of NIPER Guwahati, NIPER Ahmedabad. This will also affect the operationalization of new NIPERs”.

## CHAPTER-IV

## DEMANDS FOR GRANTS FOR THE YEAR 2017-18

## DEMAND NO.8

BUDGETARY ALLOCATION FOR REVENUE AND CAPITAL HEADS FOR THE YEARS 2016-17 AND 2017-18.

(Rs.in crore)

Major Head	Budget Estimates 2016-17			Revenue Estimates 2016-17			Budget Estimates 2017-18		
	Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
	211.30	0.10	211.40	211.30	0.10	211.40	247.68	0.06	247.74

(Notes on Demands for Grants 2017-18)

4.2 On being asked to give justification for increase in allocation from Rs.211.30 crore in RE 2016-17 under Revenue Head to Rs.247.68 crore in BE 2017-18, the Department in its written reply stated as under:-

“In RE 2016-17, Rs. 49.75 crore of PMBJP has been allocated while in BE 2017-18, Rs. 74.62 crore is for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). The increased amount in respect of PMBJP will be used in the effective implementation of PMBJP and opening of more ‘Pradhan Mantri Bhartiya Janaushadhi Kendra’ (PMBJK) across the country.

The other increase relates to Secretariat Economic Services, of Department of Pharmaceutical, the total allocation of which is Rs. 13.30 crore in BE 2017-18 under various heads for establishment relates expenditure, which shall be utilized”.

4.3 On being asked to give justification for decrease in allocation from Rs.0.10 crore in RE 2016-17 under Capital Head to Rs. 0.06 crore in BE 2017-18, the Department in its written reply stated as under:-

“Under the Capital Head like last year i.e. RE 2016-17 there was only token provision of Rs. 0.10 crore (Rs.0.04 crore for Non Plan + Rs. 0.06 crore for Plan) kept for PSUs. During the current year BE 2017-18, basically due to abolition of distinction of Plan and Non Plan Head, Rs.0.01 crore has been kept as token provision for each PSUs (total of Rs. 0.06 crore)”.

Establishment Expenditure of the Centre

(i) Secretariat

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
12.66	-	12.66	12.66	-	12.66	13.30	-	13.30

4.4 On being asked to give justification for increase in allocation from Rs. 12.66 crore in RE 2016-17 under Capital Head to Rs. 13.30 crore in BE 2017-18, the Department in its written reply stated as under:-

“The overall increase in Secretariat Economic Service relates to Major Head – 3451, Object Heads (Salaries, Domestic Travel, Office Expenses and Other Administration Expenses) of the Department of Pharmaceuticals, which shall be utilized to meet normal increase under such object heads”.

(II) National Pharmaceutical Pricing Authority (NPPA)

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
16.66	-	16.66	13.16	-	13.16	15.00	-	15.00

4.5 On being asked to give justification for increase in allocation from Rs. 13.16 crore in RE 2016-17 under Revenue Head to Rs. 15.00 crore in BE 2017-18, the Department in its written reply stated as under:-

“The overall increase in National Pharmaceutical Pricing Authority (NPPA) relates to Major Head – 2852, Object Heads (Salaries and Rent Rates Taxes) of the Department of Pharmaceuticals, which shall be utilized to meet normal increase in salaries and also rent rates taxes”.

Central Sector Scheme/Projects

(I) National Institutes of Pharmaceutical Education and Research (NIPERs)

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
127.48	-	127.48	127.48	-	127.48	127.73	-	127.73

4.6 On being asked to give justification for increase in allocation from Rs. 127.48 crore in RE 2016-17 under Revenue Head to Rs. 127.48 crore in BE 2017-18, the Department in its written reply stated as under:-

“The NIPER Division has allocated funds to all NIPERs on their need basis. The EFC proposals of NIPER-Madurai, Guwahati and Ahmadabad were referred to Department of Expenditure. However, DoE has requested NITI Aayog to review the functioning of the existing NIPERs. The outcome of EFCs would be based on review of NIPERs by the NITI Aayog, which is awaited. The matter relating to allocation of land for NIPERs Kolkata, Hajipur and Raebareli have been taken up with the respective State Governments. This will also affect the operationalization of new NIPERs”.

## (II) Jan Aushadhi Scheme

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
35.00	-	35.00	49.75	-	49.75	74.62	-	74.62

4.7 On being asked to give justification for increase in allocation from Rs. 49.75 crore in RE 2016-17 under Revenue Head to Rs. 74.62 crore in BE 2017-18, the Department in its written reply stated as under:-

“The increased amount in respect of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) will be used in the effective implementation of PMBJP and opening of more ‘PradhanMantriBhartiyaJanaushadhi Kendra’ (PMBJK) across the country to achieve the target of 3000 stores”.

## (iii) Development of Pharmaceutical Industry

## Budgetary Allocations

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
19.50	-	19.50	8.25	-	8.25	17.03	-	17.03

4.8 On being asked to give justification for increase in allocation from Rs. 8.25 crore in RE 2016-17 under Revenue Head to Rs. 17.03 crore in BE 2017-18, the Department in its written reply stated as under:-

“The Department has prepared an umbrella Scheme for Development of Pharma Industry wherein schemes like Creation of IPR Facilitation Centre at Pharmaxil, Setting up of Venture Capital Fund for financing drug design, discovery & innovation in Pharma Sector, Setting up of Pharma Promotion Council and Setting up of Medical Devices Promotion Council are proposed to be dropped and Schemes for Assistance to Bulk Drugs Industry for Common Facilitation Centre, Assistance to Medical Device for Common Facilitation Center, Cluster Development are proposed to be taken up for promoting the growth of Pharma & Medical device industry. Besides, the Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) and Pharmaceuticals Promotion Development Scheme (PPDS) are also proposed to be continued to facilitate growth of the industry. The proposal is presently under consideration with Ministry of Finance and after its appraisal and approval, the Department will seek additional funds.

In so far as, Critical Assistance to WHO Prequalification is concerned, there is no increase of the amount during BE 2017-18”.

**Scheme for Financing Common Facility Centres (CFCs) at Medical Device Parks;**

4.9 Medical device industry is a multi-product industry, producing wide range of products. India is growing as a key market for Medical Devices and Diagnostics. Indian

Medical Device industry depends on imports up to an extent of almost 70%. Most hi-tech innovative products and technology originate from a well-developed eco-system and innovation cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports.

4.10 The Department has a proposal for scheme for “Development of Common Facilitation Centres for Medical Devices” in medical device parks under the Umbrella scheme for “Development of Pharmaceuticals Industry”. This sub-scheme proposes for Financing Common Facility Centres (CFCs) at Medical Device Parks in the country at a total cost of Rs.250 crores. The manufacturing parks would include following facilities:

- i. Component Testing centre,
- ii. Electro-magnetic interference laboratory,
- iii. Biomaterial/Biocompatibility testing centre,
- iv. Medical grade low vacuum molding,
- v. Cabinet molding, injection molding centres,
- vi. 3 D designing and printing for medical grade products,
- vii. Sterilization & Toxicity testing centre,
- viii. Radiation testing centre,
- ix. Warehousing,
- x. Regulator’s office,
- xi. Other facilities commonly required in manufacturing of medical devices

Focus will be on creating an Eco System for High End Medical Device Manufacturing and Import Substitution with an eye for Export Market and States have selected separate verticals within medical devices segment suiting their regional capacities, availability of natural resources and expertise.

4.11 On being asked to explain about the medical devices parks, During the course of evidence, the Secretary Department of Pharmaceuticals stated as under:-

“it is a location where all medical device manufacturers can set their establishments and the Government will provide the basic infrastructure like land at a cost, roads, electricity and the other facilities. So the manufacturers who are interested in medical device segment, they can come and set up their establishments there. We have said that if a park is established, we will be providing some common facilities there so that the cost of production becomes less and medical device industry will therefore, become competitive. We guess that by our intervention, the cost of manufacturing medical devices will become 30 per cent less. Thereby the medical device will become globally competitive.

We have one which has been set up by Andhra Government. We will be rendering assistance there. As on today, there is only one park. At least 30 investors have already shown interest.

4.12 When the Committee asked about the status of opening of Pharma Park in Tamil Nadu, the Secretary, Department of Pharmaceuticals stated as under:-



“The Government of India does not establish pharma parks. We have a scheme for assisting a pharma park if the State Government is establishing one. So, if the State Government establishes a pharma park, we will give the common facilities there as I just now explained. By providing the common facilities, we can decrease the production cost by 30 per cent. So, the manufacturers there will become more competitive. I will check. I can forward it to the State Government. It is for them to take up the pharma park. We will do our part of the work there”.

#### Other Central Sector Expenditure

##### (I) Assistance to PSUs

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
-	0.10	0.10	-	0.10	0.10	-	0.06	0.06

4.13 On being asked to give justification for reduction in allocation from Rs. 0.10 crore in RE 2016-17 under Capital Head to Rs. 0.06 crore in BE 2017-18, the Department in its written reply stated as under:-

“It is only a token provision of Rs. 0.01 crore kept for each PSUs(i.e HAL, IDPL, SSPL, BIL, BCPL, RDPL) under Capital Head BE 2017-18”.

##### F. Development Heads (Economic Services)

##### (i) Industries

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
179.12	-	179.12	172.37	-	172.37	202.86	-	202.86

4.14 On being asked to give justification for increase in allocation from Rs. 172.37 crore in RE 2016-17 under Revenue Head to Rs. 202.86 crore in BE 2017-18, the Department in its written reply stated as under:-

“The substantial increase(Rs. 25 crore) relates to allocation of Rs. 74.62 crore under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) which will be used in the effective implementation of PMBJP and opening of more Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) across the country”.

##### (iii) Loan for Chemical and Pharmaceutical Industries

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
-	0.10	0.10	-	0.10	0.10	-	0.06	0.06

4.15 On being asked to give justification for decrease in allocation from Rs. 0.06 crore in RE 2016-17 under Capital Head to Rs.0.06 crore in BE 2017-18, the Department in its written reply stated as under:-

“ So far as utilisation of reduced amount of Rs. 0.06 crore during 2017-18 is concerned, it submitted that it is only a token provision of Rs. 0.01 Crore kept for each PSU viz. HAL, RDPL, SSPL, BIL, BCPL and IDPL under capital head BE 2017-18. So far as revival of sick Pharma PSUs is concerned it is submitted that the Government has decided on 28.12.2016 to sell that much of surplus land of Hindustan Antibiotics Ltd (HAL), Indian Drugs & Pharmaceuticals Limited (IDPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL) to Government agencies as would be required to clear their outstanding liabilities, implement Voluntary Retirement Scheme(VRS)/Voluntary Separation Scheme (VSS) to pave way for their closure, manage the remaining land in accordance with guidelines of Department of Investment and Public Assets Management/ Department of Public Enterprises and if need be, vest it in a Special Purpose Vehicle (SPV). The Government has decided that after liabilities have been met, balance sheet cleansed and VRS/VSS effected, IDPL and RDPL be closed & HAL and BCPL sold strategically.

G. Total Economic Services

(i) Others

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
191.78	0.10	191.88	185.03	0.10	185.13	216.16	0.06	216.22

4.16 On being asked to give justification for increase in allocation from Rs. 185.03 crore in RE 2016-17 under Capital Head to Rs.216.16 crore in BE 2017-18, the Department in its written reply stated as under:-

“The substantial increase (Rs. 25 crore) relates to allocation of Rs. 74.62 crore under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) which will be used in the effective implementation of PMBJP and opening of more Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) across the country”.

North Eastern States

(Rs.in crore)

Budget Estimates 2016-17			Revised Estimates 2016-17			Budget Estimates 2017-18		
Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
19.52	-	19.52	26.27	-	26.27	31.52	-	31.52

4.17 On being asked to give justification for increase in allocation from Rs. 26.27 crore in RE 2016-17 under Revenue Head to Rs.31.52 crore in BE 2017-18, the Department in its written reply stated as under:-

“Construction of NIPER, Guwahati is in full swing. The fund will be fully utilized”.

## CHAPTER-V

### PUBLIC SECTOR UNDERTAKINGS

#### Central Public Sector Enterprises(CPSEs)

There are five Central Public Sector Enterprises(CPSEs) under the administrative control of the Department of Pharmaceuticals. of the five PSUs, three viz. Indian Drug & Pharmaceuticals Limited(IDPL),Hindustan Antibiotics Limited(HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and referred to Board for Industrial & Financial Reconstruction(BIFR). Rajasthan Drugs & Pharmaceuticals Limited (RDPL) has also reported losses for since the year2013-14.

5.2 Karnataka Antibiotic & Pharmaceuticals Limited(KAPL) is the only profit making CPSE.

	HAL	IDPL	RDPL	BCPL	KAPL
<b>Established in</b>	1954	1961	1978	1980 Nationalized	1981
<b>Classification</b>	Sick	Sick	Incipient Sick	Sick	Profit making
<b>Net worth ( in cr.)</b>	-488.10	- 7147.23	-24.65	-184.60	127.81
<b>Turnover ( in cr.)</b>	15.12	84.22	36.53	88.19	326.90
<b>Operating profit/loss (in cr.)</b>	-52.43	11.33	-13.50	13.33	33.97
<b>Liabilities ( in cr.)</b>	1250	10779.20	121.05	230.55	9.06
<b>Referred to BIFR</b>	1997	1992	No	1992	NA
<b>No. of employees</b>	2000 (in 1997)	11000 (in 1992)	191 (in 2013)	1467 (in 1992)	
<b>Employees as on date</b>	1010	42	152	332	712
<b>Officer level</b>	250	7	52	70	239
<b>Worker level</b>	760	35	100	262	473
<b>VRS earlier given</b>	2007- 485 employees	1992 - 4000 2003 - 6000	NIL	2006 - 2016 180 employees	2015 2 employees
<b>Total land</b>	267 acre	2003 acre	9.35 acre	72.89 acre	37.34 acre
<b>Leasehold</b>	Nil	1022 acre	9.35 acre	1.10 acre	Nil
<b>Freehold</b>	267 acre	981 acre	Nil	71.79 acre	37.34acre

5.3 Initiatives taken to improve the performance of CPSEs during 2016-17are as follows:

1. Performance Management–Regular review of performance of CPSEs–Performance review of all CPSEs was held.
2. Pharma Park Development–The matter of Pharma Park in IDPL,Hyderabad IDPL, Rishikesh IDPL, C h e n n a i is under consideration of Government of India.
3. Status of WHO-GMP in RDPL–The Company has embarked upon expansion, modernization and upgradation programme (PhaseII) to quality for WHO-GMP certification to become eligible for exploring International Markets as well as for participating in the Internationally Funded Projects of Government of India and otherGovernment.
4. In BCPL–Ointment & Betalactam Block and Panihati Project have been completed while Cephalosporin Block is under commissioning. Besides this OSD Project& ASVSProject are being commissioned.

#### CABINET DECISIONS ON PHARMA PSUS

5.4 After detailed deliberations, the Ministers recommended as under:

- i. Only that much of surplus land of HAL, IDPL, RDPL and BCPL as would be required to meet the liabilities be sold through open competitive bidding to Government agencies and the outstanding liabilities be cleared from the sale proceeds. Voluntary Separation Scheme/ Voluntary Retirement Scheme also

be implemented in these PSUs to pave way for their closure. Remaining part of the land should be managed in accordance with guidelines of Department of Investment and Public Asset Management (DIPAM) and Department of Public Enterprises (DPE) in this regard and if need be, vested in a SPV created for this purpose.

- ii. After liabilities have been met, balance sheet cleansed and the Voluntary Separation Scheme/Voluntary Retirement Scheme effected, the Department to close IDPL and RDPL and HAL and BCPL be put up for strategic sale.
- iii. While taking a decision to close the PSUs, the Department may also explore the possibility of hiving off the subsidiary companies of HAL and IDPL for private participation, wherever found viable.

Cabinet in its meeting held on 28.12.2016 approved the recommendations of the Ministers' as mentioned above.

## **I. Indian Drugs and Pharmaceuticals Ltd. (IDPL)**

### **Background:**

5.5 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 IDPL Complex, Dundahera, Gurgaon and its Head Office at SCOPE Complex, Lodhi Road, New Delhi. The main objectives of the company were to create 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.

5.6 IDPL has three main Plants at Rishikesh (Uttarakhand), Gurgaon (Haryana), Hyderabad (Telangana) and two 100% 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, promoted in collaboration with Industrial Promotion & Investment Corporation of Orissa Limited (IPICOL) the State Government of Odisha, namely Odisha Drugs & Chemicals Ltd. (ODCL) Bhubaneswar.

### **REVIVAL STATUS SINCE 1.4.1994**

5.7 The Board for Industrial & Financial Reconstruction (BIFR) declared IDPL as a sick industrial Company on 12th 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 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. while attempts were made in 2001-02 to privatize the Company. OA (IDBI) however, did not find any proposal worthy of recommendations to BIFR.

5.8 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 10.2.2004 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. The Committee found the Plant & Machineries for production of formulations in a reasonably good shape which could be optimally utilized with minimal investment for compliance of Scheme-M requirements. It was also opined that the emerging position of IDPL in the present market scenario was to be conceptualized. IDBI supported the recommendations of the Expert Committee. Having regard to these developments, AAIFR in its hearing held on 13.9.2005 set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for Rehabilitation of IDPL and to pass further orders in accordance with Law.

5.9 The Draft Rehabilitation Scheme (DRS) was prepared by IDPL in consultation with ICRA Management and submitted to the BRPSE for consideration and recommendation. After approval of the BRPSE, a Note for Cabinet Committee on Economic Affairs (CCEA) was prepared and submitted for approval on 11.5.2007. The Note was considered by CCEA in its meeting held on 17.5.2007 and it referred the matter to Group of Ministers (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. In view of the observations made by GoM, IDPL appointed a leading consultant Company E&Y to carry out the feasibility study. E&Y report was submitted to the Ministry/DoP.

5.10 A revised DRS again prepared in consultation with IDBI (OA) taking cut off date as 31st March, 2011. In the BIFR meeting held on 20.8.2014 cut off date was approved as 31.3.2014. Accordingly, the revised updated DRS was prepared taking cut off date 31.3.2014 and submitted to the DoP/ Ministry in January 2015. the Cabinet in its meeting

held on 28.12.2016 recommended for closure of IDPL on 9<sup>th</sup> January, 2017 after meeting its liabilities by selling the surplus land.

### **Modernization of Plants with the assistances of Government of India**

5.11 The Up-gradation and Modernization of IDPL Plants are in progress. It is expected to complete the modernization work of its Plant at Gurgaon and Rishikesh very soon. Rishikesh Plant is Schedule 'M' compliant and is WHO-GMP compliant and received COPP for 4 products. Whereas Gurgaon Plant is also Schedule-M for Tablet Section. IDPL will re-start its Hyderabad Formulation Unit during the current F.Y. 2016-17.

During the course of evidence the Secretary, Department of Pharmaceuticals submitted before the Committee that IDPL is not closed yet and now only closure decision is being taken. Before that the liabilities of IDPL will be met by selling of surplus land and then afterwards there will be closure".

## **II. Hindustan Antibiotics Ltd. (HAL)**

5.12 Hindustan Antibiotics Ltd. (HAL), a wholly owned Central Public Sector Undertaking under the administrative control of the Departments was incorporated in 1954. The registered office and manufacturing facilities of the company are located at Pimpri, Pune, Maharashtra. The Company was set up for manufacturing of bulk drugs and lifesaving drugs and formulations. Over the years several new products were added / undertaken for manufacturing like those used in agriculture and veterinary medicines. The authorized share capital of the Company is Rs.100 crores. As on 31st March, 2016, the subscribed and paid-up share capital is Rs.71.71 crores.

5.13 Second rehabilitation proposal for infusion of Rs. 670.46 crores was proposed. However, the Cabinet approved selling of its surplus and vacant land to Government/PSUs/Autonomous Bodies to meet its liabilities. The Government also approved waiver of Rs. 307.23 crore of Central Government loans and deferment of liabilities amounting to Rs. 128.68 crores and sanctioned immediate loan of Rs. 100 crores for meeting salaries, wages and critical expenses. It has been further decided to strategically sell the Company after meeting its liabilities, effecting VRS/VSS and cleansing the balance sheet.

**In their Twenty-Third Report (16<sup>th</sup> Lok Sabha) the Committee had recommended to take an early decision for salary of HAL employees. This was again recommended in the Action Taken Report i.e. 29<sup>th</sup> Report of the Committee.**

5.14 When asked to give the status regarding interim relief to the employees of HAL made, the Department in its written reply stated as under:-

“No interim relief has been given to HAL till date. However, the Government has approved a loan of Rs. 100 crore to HAL to meet the wages, salaries and other critical expenses of immediate nature. The loan will be repaid to the Government from the sale proceeds of the HAL land. Department has requested the Ministry of Finance to release the amount”.

5.15 When asked when will Ministry of Finance release the fund for loan amount of Rs. 100 crore to meet the wages, salaries and other critical expenses of immediate nature to HAL, the Department in its written reply stated as under:-

“The Ministry of Finance was requested to allocate a loan amount of Rs. 100 crore on 02.01.2017. Ministry of Finance had raised certain clarifications, which have been replied on 20.02.2017. Approval for loan of Rs. 100 crore has been conveyed by Ministry of Finance vide Id No. 7/12/2016-NS-1 dated 27<sup>th</sup> February 2017. Proposal for inclusion of same in third supplementary is being sent to Ministry of Finance”.

### **III. Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL)**

5.16 Karnataka Antibiotics and Pharmaceuticals Ltd. 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 Karnataka Antibiotics and Pharmaceuticals Ltd.]. The basic objective of the company was to make available life-saving drugs of good quality to Karnataka Government hospitals and other institutions along with Private Medical Practitioners. The Company has WHO-GMP Certified Manufacturing facilities for Dry Powder Injectable, Liquid Injectable, Tablets, Capsules, Dry Syrups and Suspensions. The paid – up share capital of the company as on date is Rs. 13.49 crores.

### **IV. Bengal Chemicals & Pharmaceuticals Ltd.(BCPL)**

5.17 Bengal Chemicals and Pharmaceuticals Limited (BCPL), erstwhile Bengal Chemical and Pharmaceutical Works Limited (BCPW) were set up in 1901 by AcharyaPrafulla Chandra Roy, a renowned scientist and academician. Government of India nationalised BCPW in 1980 under the name Bengal Chemicals & Pharmaceuticals Limited (BCPL) in 1981.

5.18 The Company is Headquartered in Kolkata, BCPL is engaged in the business 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. At present, the Company has four factories; at Maniktala and Panihati in West Bengal, Mumbai and Kanpur.

5.19 **Maniktala Unit:** This unit primarily produces Division II products which include branded as well as unbranded generic pharmaceuticals. The Company has commissioned

and started commercial operation of its Tablet, Capsule and Ointment sections of Maniktala factory at Kolkata. The Injectable section is under commissioning and Company will be able to commercialize the operation of Injectable Section in this financial year itself.

5.20 **Panihati Unit:** Panihati unit, located near Kolkata, primarily produces Division I (Alum) and Division III products which include 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

5.21 **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

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

#### **FUTURE PROJECTS:**

5.23 **ASVS Project:** The Company is planning to start ASVS Project as the product is not available in the country at the moment in required quantity as both the Government sector units namely BCPL and Central Research Institute (CRI), Kasuali, have stopped production of ASVS for the last 10 years. Due to non-availability of fund and also due to project cost escalation the project could not be commissioned. The total project cost for ASVS block as on date is Rs 31.00 crore.

5.24 In the Report No.29(ATR) of this Committee, at Recommendation No.9 the Committee observed with regard to Bengal Chemicals and Pharmaceuticals Ltd that BCPL has two pending projects, one at Kanpur and the other is a more prestigious anti-snake venom project. It requires Rs.27 crore investment and if it is sanctioned for Anti-Snake Venom Project it can be supplied to entire country and can also be exported.

5.25 When asked to give details whether Rs.27 crore has been sanctioned to BCPL for its anti-snake venom project, the Department in its written reply stated as under:-

“For anti-snake venom project, no amount was sanctioned to BCPL, as, the amount projected for this purpose before the Ministry of Finance was not allocated to the Department”.



5.26 When asked whether Ministry of Finance has given any reason for not allocating funds for anti-snake venom project, the Department in its written reply stated as under:-

“The Ministry of Finance has not given any reasons for not allocating any funds for the Anti-Snake Venom Serum Project (ASVS)”.

5.27 When asked to comment on the media Reports, that Government propose to disinvest BCPL inspite of its stellar performance in the recent past and whether other PSUs are also proposed to be disinvested, the Department in its written reply stated as under:-

“Regarding disinvestment, closure etc., a Committee under Vice Chairman, NITI Aayog after careful scrutiny and analysis of 74 loss making/ sick/ non-performing CPSEs, whose operations are of non-strategic nature, advised for revival/ sale/ closure/ management contract/ strategic disinvestment, as applicable in each case.

It is submitted that a rehabilitation proposal for the sale of part of surplus and vacant land of Hindustan Antibiotics Limited (HAL) for meeting its mounting liabilities was considered by the Cabinet on 27.04.2016. While considering the proposal, the Cabinet had directed that the following Ministers may comprehensively examine the status of all Pharmaceutical Companies in the public sector and suggest the future course of action:

- (i) Minister of Finance; Minister of Corporate Affairs; and Minister of Information and Broadcasting;
- (ii) Minister of Road Transport and Highways; and Minister of Shipping and
- (iii) Minister of Chemicals and Fertilizers.

Minister of Finance, Minister of Road Transport & Highways and Minister of Chemicals & Fertilizers comprehensively examine the status of all Pharmaceutical Companies in the public sector and noted that all PSUs except KAPL are sick or incipient sick. IDPL, BCPL and HAL were declared sick and formally referred to BIFR since 1992, 1993 and 1997 respectively. The earlier revival/rehabilitation packages of IDPL, HAL & BCPL have failed to achieve desired results. The production activities in RDPL too have stopped after fire in the plant in October, 2016. HAL and RDPL are not in a position to even pay the salaries to their employees. All these companies possess substantial land assets.

The Government has decided on 28.12.2016 to sell that much of surplus land of Indian Drugs & Pharmaceuticals Limited (IDPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL) Hindustan Antibiotics Limited (HAL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL) to Government agencies as would be required to clear their outstanding liabilities, implement Voluntary Retirement Scheme(VRS)/Voluntary Separation Scheme (VSS) to pave way for their closure, manage the remaining land in accordance with guidelines of Department of Investment and Public Assets Management/ Department of Public Enterprises and if need be, vest it in a Special Purpose Vehicle (SPV). The Government has decided that after liabilities have been met, balance sheet cleansed and VRS/VSS effected, IDPL and RDPL be closed & HAL and BCPL sold strategically”.

5.28 During the course of evidence, Managing Director of BCPL, stated as under:-

“Sir, BCPL was the first company which started ASVS Project and it is closed for the last ten years. Already Rs.3 crore has been spent upto 2010 and because of shortage of funds as well as some local issues like court cases (court cases was filed in 2010) the project could not be started and In 2013 the case was closed. About 33RCs are there now and they are old and cannot be used and has to be replaced. In India around 2 lakh people are bitten by snakes as per statistics. Each snake bites requires 10 to 15 vials.

During the course of evidence, the representative of the Department stated as under:-

“Our Department had requested to Finance Ministry Rs.27 crore for ASVS Project and the money was not sanctioned by them”.

The Committee also observe that the Department is not able to achieve its goals and all the schemes are not properly implemented .

The Committee observe that even after getting figure of 2 lakh people suffering from snake bite the Anti-snake Venom Project is being closed and the Committee feel that Department is not taking the matter seriously.

5.29 During the course of evidence, the Secretary Department of Pharmaceuticals stated that BCPL is in operating profit mode.

"Further, he stated that we are not selling equity. Strategic sale is only for better management. It is only for the better management of the company and I am not saying that we are going to do it. We will explore that. It is not necessary that it will take place in the previous year it is profit making company. If it is economically viable then we can take loan.

The cabinet decision is to explore whether it can be put on strategic sale after meeting the liabilities by selling the surplus land.

When asked how the Department is getting generic medicine from IDPL as it is closed.

Replying to the query, the Secretary, Department of Pharmaceuticals said that IDPL is not closed yet and now only closure decision is being taken before that the liabilities of IDPL will be met by selling of surplus land and then afterwards there will be closure”.

## **V. Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)**

5.30 Rajasthan Drugs & Pharmaceuticals Limited (RDPL) is a Central Public Sector Unit in Joint Sector with a total paid-up equity capital of Rs. 4.98 crores where Government of India (GoI) and Rajasthan State Industrial Development & Investment Corporation Limited (RIICO, Govt. of Rajasthan) hold 51% and 49% respectively. It was incorporated in 1978 and commercial production started in 1981. The Company has its manufacturing facilities & registered office at Road no. 12, VKI Industrial Area, Jaipur (Rajasthan).

5.31 The Company is engaged in production of Tablets, Capsules, Liquid Orals, ORS Powder & Ophthalmic medicines in a Schedule 'M' compliant facility. The company has a well-equipped laboratory with modern equipment like HPLC, FTIR, etc., for ensuring high quality parameters. The company is also working towards obtaining ISO 9001:2008 & WHO-GMP certifications. The Company has enhanced its manufacturing capacities by installing new machines and at the same time the workers have also acquired skills and expertise for attaining high productivity.

5.32 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. RDPL is a partner in the novel and noble endeavor of Govt. of India in the implementation of 'JAN AUSHADHI' programme where quality generic medicines are made available to the public at large in the country at affordable prices.

#### **Future Projects:**

5.33 The Company has embarked upon expansion, modernization & up-gradation programme (Phase II) to qualify for WHO-cGMP certification to become eligible for exploring International Markets as well as for participating in the Internationally Funded Projects of GOI and other Governments. Due to fire at its plant in October, 2016, the production activities have stalled.

5.34 On being asked to give the performance status of Rajasthan Drugs and Pharmaceuticals Limited, the Department in its written reply stated as under:-

“Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL) was incorporated on 02.11.1978 with an objective to supply lifesaving and other essential drugs to the State Government Medical Health Departments, Govt. of India & other Govt. Institutions. RDPL was initially a subsidiary of IDPL. However, the equity shares held by IDPL in the share capital of the RDPL was transferred to the President on 17.08.2010. As of now, 51% of equity is held by GOI and 49% by Rajasthan State Industrial Development and Investment Corporation Ltd. (RIICO) respectively.

RDPL is a Schedule-'D' CPSE in Chemicals & Pharmaceuticals Sector under the administrative control of M/o Chemicals & Fertilizers, D/o Pharmaceuticals. Its only operating unit and registered office is at Jaipur, Rajasthan.

RDPL is engaged in manufacturing and selling of drugs & pharmaceuticals to state government, central government Institutes, viz., ESIC, Defence, Railways, other PSUs and also to other state Government institutes.

The production activities have almost stopped after fire broke out in its plant in October, 2016 and is unable to pay salary to its employees for last 8 months.

The Government on 28.12.2016 approved the recommendations of the Minister of Finance, Road Transport & Highways and Chemicals and Fertilizers and decided to close RDPL after meeting its liabilities, effecting VRS/VSS and cleansing the balance sheet”.

5.35 Regarding Rajasthan Drugs and Pharmaceuticals (RDPL), the Department in its written reply stated that the production activities have almost stopped after fire broke out in its plant in October 2016 and is unable to pay salary to its employees for last 8 months.

5.36 Whether the Department has initiated any inquiry to look into the cause of fire in RDPL plant, the Department in its written reply stated as under:-

“Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL) has informed that a fire broke out on 12<sup>th</sup> October, 2016 due to short circuit during solution preparation for coating material in Stirrer & Colloidal Mill Machine. While making the solution there was sparking in stirrer machine and due to sparking the material for solution caught fire and the coating operator was badly injured due to fire. The coating section of Tableting area in production department at the Factory was badly affected due to fire. The production activities have almost stopped in the Company after the fire incident in the RDPL, plant.

The FIR was lodged with the Police and Insurance Claim has also been made. Taking cognizance of the incident, the Department deputed a senior officer to look into the affairs in the RDPL, including fire incident. The Department also instructed the Company to call an emergency Meeting of Board of Directors of RDPL, which was held on 5 December, 2016.

Due to paucity of funds RDPL has not been able to disburse salary to its employees for last 8 months. Ministry of Finance was requested on 17.01.2017 to provide a loan of Rs. 5 Crores to meet the day to day expenses of emergent nature. However Minister of Finance vide their communication dated 17.01.2017 has not approved the same due to paucity of funds and has informed that they may be approached in the next Financial year”.

5.37 When asked whether the RDPL was insured and the details of compensation paid by the insurance company, the Department in its written reply stated as under:-

“The Company is insured with M/s National Insurance Company Limited. The Company was insured for Rs. 41.80 crore for the period November, 2015 to November, 2016. RDPL has filed a claim of Rs. 11.71 crore with the insurance company. The claim in respect of loss of stock amounting to Rs. 94 lakh is under process and is likely to be passed soon. Further details sought by the Insurance Company in respect of building and machinery are being provided by RDPL”.

During the course of evidence, the Secretary, Department of Pharmaceuticals state that the regarding closure of PSUs the decision has been taken by Group of Ministers and it cannot be revised and two times efforts were made for revival and now it is not possible.

The Committee observe that Pharma PSUs supply medicine all over the country. If they are not revived then make it PPP mode, sell it to Private agencies and there is no other alternative.

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

“Sir, wherever there is possible option of strategic sale is there. RDPL and IDPL outstanding liabilities and strategic liabilities are more than Rs.10,000 crore and RDPL was in operating profit and now it was in loss.”

## CHAPTER-VI

### MISCELLANEOUS

#### **A PRADHAN MANTRI BHARTIYA JANAUSHADI PARIYOJANA**

The Jan Aushadhi Scheme was launched in the year 2008 with the aim of selling affordable generic medicines through dedicated sales outlets i.e. Jan Aushadhi Stores in various districts across the country.

6.2 The original target of the campaign was to establish Jan Aushadhi Stores in every district of our country. It has been renamed as Pradhan Mantri Jan Aushadhi Yojana, Recently, “Pradhan Mantri Jan Aushadhi Yojana” (PMJAY) has been renamed as “Pradhan Mantri Bhartiya Janaushadhi Pariyojana” (PMBJP) and “Pradhan Mantri Jan Aushadhi Kendra as Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK)

#### **Financial support to PradhanMantriBhartiyaJanaushadhi Kendra (PMBJK):**

6.3 An amount of Rs. 2.5 lakhs shall be extended to NGOs/agencies/ individuals establishing PMBJK in government premises like hospitals/ medical colleges/Railways/Sate Transport/ Co-operation/ Municipalities/ Post offices etc. where space is provided free of cost by Government to operating agency.

6.4 Trade margin to retailers and distributors: Trade margins have been revised from 16% to 20% for Retailers and from 8% to 10% for Distributors.

6.5 BPPI intends to create awareness about PMBJP and its PMBJK in the towns where PMBJKs are already established using integrated media platform. Facelift of the PMBJK is required with standardized branding across all old stores as well as in the new PMBJK.

6.6 Various publicity channels like print media, visual media, SMS and other direct communication methods will be taken up. BPPI has already taken part in many exhibitions/workshops, seminars, etc.

6.7 The success of this initiative is dependent on other agencies too, such as Ministry of Health & Family Welfare, different State Governments, active co-operation of Hon. Members of Parliament, Hon. Members of different Legislative Assemblies, IMA, Hospitals run by Private Groups and Charitable Institutions, NGOs, Practicing Doctors, etc. State Governments are having their own schemes like free distribution of medicines. Non-prescription of Generic Medicines by the doctors is another critical factor. BPPI is continuing its efforts to persuade Doctors to prescribe only generic medicines. For this BPPI is working in close association with other Organizations and Government

Departments. Seminars/Workshops inviting Doctors, Scientists, Government Officials and other Stakeholders will be also organized.

6.8 An amount of Rs.74.62 crore has been allocated under this Scheme in the year 2017-18. When asked how the Department is going to utilise the amount of Rs. 74.62 crore allocated to Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), the Department in its written reply stated as under:-

“The increased amount in respect of PMBJP will be used in effective implementation of PMBJP and opening of more ‘Pradhan Mantri Bhartiya Janaushadhi Kendra’ (PMBJK) across the country to achieve the target of 3000 PMBJKs”.

6.9 When asked to give details whether any survey has been done with regard to prescription of generic medicine by the doctors (private and Govt.), the Department in its written reply stated as under:-

“No Sir, No such survey has been done. However, inputs from various store owners and low volume of sales indicate that sufficient number of doctors are not prescribing generic drugs”.

6.10 When asked to give details opening JAS in all the districts of the country, the Department in its written reply stated as under:-

“The Government has set a target to open 3000 Pradhan Mantri Jan Aushadhi Kendras (PMJAK) across the country by 31<sup>st</sup> March, 2017 and it endeavors to cover all districts of the country by opening of PMBJKs under PMBJP”.

6.11 When asked for the successful running of Pradhan Mantri Jan Aushadhi Kendras (PMJAK) Pharmacists are required and in the villages they are not available and the benefits of this scheme will not be achieved.

Replying to the queries, during the course of evidence, the representative of the Department of Pharmaceuticals stated as under:-

“For running JAS Pharmacists is mandatory under Drugs and Cosmetics Act and Rules. As the sale of drugs is different from sale of other things and this act comes under the purview of Ministry of Health and Family Welfare and in their opinion Diploma and Degree holder and people doing three years course can operate JAS . They are also contemplating of starting a bridge course so that they can also sell medicine and final decision has been taken in this regard so far”.

Further, the representative stated that there is no legal help available for this scheme and the Pharmacists do not have any authority to provide generic drugs in place of branded medicines.

6.12 The Committee also noted that medicine is generic and by getting company’s name the same medicine becomes branded and the prices of branded medicines are 16 times higher that of generic medicines. In our country poor people are there and they should get

medicine, with that mission the scheme are to be made and looking into shortcomings if any and addressing it and also looking into legal implications, then why this problem is there.

Replying to the queries, during the course of evidence, the representative of the Department of Pharmaceuticals stated as under:-

“In the present budget Hon’ble Finance Minister has said preference will be given for generic medicine and all the legal hurdles and problems faced by Ministry of Health and Family Welfare and other Ministries will be taken up and generic medicine gets its recognition, and the poor people will benefit from this.

The Committee observed that unless and until the doctors prescribe the generic medicine the scheme cannot make any headway and the committee feel that prescription of generic medicine by doctors should be made compulsory.

6.13 Giving details of the number of JAS in the country, one of the representative of the Department stated as under:-

“Sir, this figure has from 600 has gone up to 802 now. That is the figure before yesterday. As regards whether budget is sufficient, our original allocation was Rs.35 crore and because we have already utilised Rs.35 crore, we had sent a request to the Ministry of Finance for Rs.109 crore but we did not get any additional allocation. So, what we did is that Rs.14.75 crore extra from our own schemes where we were having savings have been re-appropriated. Now from Rs.35 crore, it became Rs.49.75 crore but Rs.14.75 crore is not additional allocation. It is from within our own budget. We reduced from some place where we thought we will have savings, we have put all in the Jan Aushadhi. You have said very rightly that we needed more funds. Definitely because of the pending liabilities, fund has become a very major factor. Now attainment of 3000 as on date appears to be difficult. Fund constraint is one reason but there are other issues also. Even though we are making our all out efforts and 14000 applications have been sanctioned in the last one month, we are hoping that out of these 14000, we are trying to hand hold and convert, at least, 1500 to 2000 of them into actual shops before the end of the year so that we can reach near 3000.”

## **B NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)**

6.14 The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers 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 formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

On being asked to furnish a note on Progress/Initiatives taken by NPPA during 2016-17, the Department in its written reply stated as under:-



"Since May, 2014, prices of 126 scheduled medicines have been notified bringing the total number of scheduled medicines whose prices have been notified to 530 under NELM 2011.

Government have notified ceiling prices of 662 formulations (as on 14<sup>th</sup> February, 2017) included in the National List of Essential Medicines 2015, after it was notified as the First Schedule of Drugs Price Control Order (2013) on 10<sup>th</sup> March, 2016. This has resulted in savings of about Rs. 2431.05 crore to the consumers. Capping of ceiling prices of coronary stents has resulted in net savings of Rs.4,450 crores to the general public in one year.

NPPA also fixed the prices of 106 non-scheduled formulations on 10.7.2014 under Para 19 of DPCO, 2013. Out of these 106 formulations, 22 are anti-diabetic formulations and 84 are cardio-vascular formulations. The price benefit to the common man on account of price fixation of these 106 formulations is estimated to be close to Rs. 350 crores per annum.

NPPA has also fixed the retail price of 441 'new drugs' up to 14.02.2017 (which fall within the purview of Para 2(u) of DPCO, 2013).

Since May, 2014, the National Pharmaceuticals Pricing Authority notified prices of 1286 formulations (i.e., 788 Ceiling Prices, 392 Retail Prices and 106 prices under para 19 of DPCO 2013). These formulations include antibiotics, anti-inflammatory medicines, respiratory medicines, gastrointestinal medicines and medicines used for treatment of cancer, diabetes, HIV, AIDS, heart diseases, etc.

**Monitoring and Enforcement activities from 2010-11 to 2015-16 (upto October, 2016) are given as under:**

Year	No. of Samples Collected	Prima Facie Violations detected	Referred for Overcharging
2010-2011	553	225	216
2011-2012	559	156	152
2012-2013	626	165	163
2013-2014	993	389	389
2014-2015	3898 #	1020	1020
2015-2016	2947 #	613	613
2016-2017	1426 #*	279	279

\*including 503 cases under process on 31.10.2016

#Cases of Overcharging referred from State Drug Controllers are included under the column 'Samples Collected'.

Government proceeds against companies which are found to have overcharged consumers in sale of medicines by issuing demand notices under the relevant provisions of the DPCO and the Essential Commodities Act.

NPPA has initiated about 1493 cases of overcharging as on 31<sup>st</sup> December, 2016 (1285 cases under DPCO 1995 and 208 cases under DPCO 2013), where demand notices have been issued to pharmaceuticals companies. The demanded amount works out to Rs. 5037.64 crore (Rs.4956.48 crore under DPCO 1995 and Rs.81.16 crore under DPCO 2013) for sale of medicine at prices higher than that fixed by NPPA /Government. However only an amount of Rs. 640.16 crore (Rs 536.81 crore under DPCO 1995 and Rs.103.35 crore under DPCO 2013) has been recovered on 31<sup>st</sup> December, 2016 from pharmaceutical companies. This includes an amount of Rs. 215 crore deposited by pharmaceutical companies in response to the verdict of the Supreme Court delivered on 20<sup>th</sup> July, 2016 in 109-111/2013, 153-164/2013,

WC(C) 696/2013, WP(C) 983/2013, WP(C) 123/2014, WP(C) 135/2014 and WP(C) 346/2014. Out of the balance outstanding amount of Rs. 4359.93 crore, Rs. 3460.32 crore is still locked up in litigation.

Recently the Supreme Court passed landmark judgments upholding the price notifications and demand notices issued by NPPA in some long pending overcharging cases in DPCO 1995 matters. Further, the Bombay High Court through a landmark judgment passed on 26<sup>th</sup> September, 2016 has upheld the price fixation notifications issued by NPPA under para 19 of DPCO 2013 whereby prices of some important cardiovascular and antidiabetic medicines were capped by NPPA. The judicial verdicts have sent a strong signal recognizing the requirement of regulation of prices of essential medicines in order to ensure affordable, available and accessible healthcare for all.

6.15 In the report No. 29<sup>th</sup> (ATR) of this Committee at recommendation No.5 regarding proposal for one time settlement of overcharge amount, the Department in its reply stated that the proposal on one item settlement scheme in respect of cases pertaining to recoveries of overcharge amount is under active consideration.

When asked to give details about the status of the proposal?

The Department in its written reply stated that the proposal is yet to be approved.

**OBSERVATIONS/RECOMMENDATIONS****RECOMMENDATION NO.1****SCHEME FOR FINANCING COMMON FACILITY CENTRES AT API PARKS**

The Committee note that the vision of the Department of Pharmaceutical (DoP), Ministry of Chemicals & Fertilizers is to catalyze and encourage quality, productivity and innovation in Bulk Drug Sector and to enable the Indian Bulk Drug Industry to reduce the dependency on import of Bulk Drugs. For this, world class quality manufacturing facilities with high level of productivity with innovative capabilities are required. However, these are on one hand very capital intensive and cannot be established and opened by Bulk Drug Manufacturing Units on their own due to financial constraints. The Committee also note that the Department proposes in the first instance to start a scheme for Financing Common Facility Centres (CFCs) at 3 Bulk Drug/API Parks in the country at a total cost of Rs. 450 crores. Some of the indicative activities under this Common facilities are Effluent Treatment Plants, Captive Power Plant, Steam and Cooling and water systems, Incubation facilities, Common logistic facilities, Advance common testing centre, Regulatory awareness facility centre.

The Committee are of the view that industry's dependence on imports for Bulk drugs is not good for the country. The Committee, feel that the new scheme will help the pharma industry to concentrate on the core issue of manufacturing of bulk drugs as the common facilities will be available in the pharma bulk drug parks. The Committee, therefore, recommend that the Scheme for Financing Common Facility Centres (CFCs) at 3 bulk drugs/API Parks may be started immediately and completed in a fixed time frame as in-principle approval of the Department of Expenditure has been received for implementing the Scheme.

The Committee also recommend that the Department may explore to start the Bulk Drug Parks in the campus of Pharma PSUs where the benefit of Infrastructure and expertise of the Pharma PSUs can be harnessed and the resources available this can be utilised to the maximum in order to make Indian Bulk Drug Industry a global leader in Bulk Drug production. The Committee would like to be informed of the action taken in this regard.

## RECOMMENDATION NO.2

### ANNUAL PLAN AND EXPENDITURE

The Committee note that for the Annual Plan 2017-18, the Department of Pharmaceuticals proposed an outlay of Rs.1373.35 crore but only Rs.195.71 crore was approved by the Ministry of Finance for BE 2017-18. Hence there is very meagre allocation to NIPERs. NIPERs have been allocated an amount of Rs.100 crore only against the proposed amount of Rs.1171.36 crore.

The Committee are of the view that the meagre allocation of funds to NIPERs will hamper the construction activities of NIPER Guwahati and NIPER Ahmedabad and it will also affect the operationalization of new NIPERs. Besides this allocations for NPPA and assistance to PSUs is also less. The Committee, feel that severe cut in outlay schemes would have an adverse impact on the implementation of projects and scheme. The Committee are dismayed to note that approved allocation falls far short of the urgent fund requirements projected by the Department for carrying out its laid down mandate and its vision for development of Indian Pharmaceutical Industry. The Committee, therefore, recommend that the Department should take up the issue of fund allocation with the Ministry of Finance and impress upon them to allocate funds as per the Demands and requirements of the Department of Pharmaceuticals so that the project like NIPER are completed timely. The Committee, would like to be informed of the action taken in this regard.

## RECOMMENDATION NO.3

### BUDGETARY ALLOCATION FOR THE YEAR 2017-18

The Committee note that RE 2016-17 was Rs.211.40 crore and BE 2017-18 is Rs.247.74 crore. The Committee also observe that Rs.74.62 crore has been allocated for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and the same will be used in the effective implementation of PMBJP and opening of more Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) across the country. The Committee also note that The Department has prepared an umbrella Scheme for Development of Pharma Industry wherein schemes like Schemes for Assistance to Bulk Drugs Industry for Common Facilitation Centre, Assistance to Medical Device for Common Facilitation Centre, Cluster Development are proposed to be taken up for promoting the growth of Pharma & Medical device industry. Besides, the Pharmaceuticals Technology Up

gradation Assistance Scheme (PTUAS) and Pharmaceuticals Promotion Development Scheme (PPDS) are also proposed to be continued to facilitate growth of the industry. The proposal is presently under consideration with Ministry of Finance and after its appraisal and approval, the Department will seek additional funds.

The Committee, therefore, desires the Department to strongly take up the matter with the Ministry of Finance and to impress upon them for sanction of additional funds for the projects as these projects will help the Pharma Industries to achieve the goal of 'Make In India' and will also lead to reduction in imports and increase in Exports of the Pharma products and generate more employment and foreign exchange and also help the pharma sector to play a leading role in the global market.

#### **RECOMMENDATION NO.4**

##### **PROMOTION OF MEDICAL DEVICES INDUSTRY**

The Committee note that Medical device industry is a multi-product industry, producing wide range of products. India is growing as a key market for Medical Devices and Diagnostics. Indian Medical Device industry depends on imports up to an extent of almost 70%. Most hi-tech innovative products and technology originate from a well-developed eco-system and innovation cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports.

The Committee also note that the Department has a proposal for Scheme for Development of Common Facilitation Centres under the Umbrella Scheme for Development of Pharmaceuticals Industry. This sub-scheme proposes for Financing Common Facility Centres (CFCs) at Medical Device Parks in the country at a total cost of Rs.250 crores.

The Committee, are of the view that Developing Indigenous Medical Device Industry is of paramount importance and fits in realizing the 'Make in India' goal of the Government and it will also reduce the dependence on import of medical devices. For this world class quality manufacturing facilities with high level of productivity with innovative capabilities cannot be established and opened by medical devices manufacturing units on their own due to financial constraints. The Committee been informed that Government of India does not establish pharma parks but is only providing common facilities at Medical Device Parks thus it is imperative that it may be impressed upon State Governments/ Union Territories to set up Pharma Parks in their States/Union Territories so that the money allocated under the scheme of Common Facilities is optimally utilised. The Committee, therefore, recommend that

the proposal of development of common facility centres at medical device park in the country may be planned and initiated and the matter of early allocation of funds for implementation of this important scheme may please be taken up with the Ministry of Finance at the earliest. The Committee, would like to be informed of the action taken by the Department in this regard.

#### RECOMMENDATION NO.5

The Committee note that Regarding disinvestment, closure etc., a Committee under Vice Chairman, NITI Aayog after careful scrutiny and analysis of 74 loss making/ sick/ non-performing CPSEs, whose operations are of non-strategic nature, advised for revival/ sale/ closure/ management contract/ strategic disinvestment, as applicable in each case. The Committee also note that Minister of Finance, Minister of Road Transport & Highways and Minister of Chemicals & Fertilizers comprehensively examined the status of all Pharmaceutical Companies in the public sector and noted that all PSUs except KAPL are sick or incipient sick. IDPL, BCPL and HAL were declared sick and formally referred to BIFR since 1992, 1993 and 1997 respectively. The earlier revival/rehabilitation packages of IDPL, HAL & BCPL have failed to achieve desired results. The production activities in RDPL too have stopped after fire in the plant in October, 2016. HAL and RDPL are not in a position to even pay the salaries to their employees. All these companies possess substantial land assets. The Government has decided on 28.12.2016 to sell that much of surplus land of Indian Drugs & Pharmaceuticals Limited (IDPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL) Hindustan Antibiotics Limited (HAL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL) to Government agencies as would be required to clear their outstanding liabilities, implement Voluntary Retirement Scheme(VRS)/Voluntary Separation Scheme (VSS) to pave way for their closure, manage the remaining land in accordance with guidelines of Department of Investment and Public Assets Management/ Department of Public Enterprises and if need be, vest it in a Special Purpose Vehicle (SPV). The Government has decided that after liabilities have been met, balance sheet cleansed and VRS/VSS effected, IDPL and RDPL be closed & HAL and BCPL sold strategically.

The Committee are deeply pained to note that the Government has decided to sell surplus land of IDPL, RDPL, HAL and BCPL that after liabilities have been met, balance sheet cleansed and VRS/VSS effected IDPL and RDPL be closed and HAL and BCPL be sold strategically. The Committee, feel that the main objective of setting up Pharma PSUs were not to earn profits but to encourage indigenous production of

bulk drugs and life saving drugs and formulations and to support various health programmes of the Government. The Committee observe that Pharma PSUs supply generic medicines all over the country. It is also observed that BCPL has made a stellar performance during the last two years. While in the year 2014-15 its MOU Assessment was good and Corporate Governance was fair, it became excellent both in respect of MOU Assessment and Corporate Governance during the year 2015-16. The Committee also observe that BCPL is planning to start Anti-Snake Venom Project (ASVS) project as the product is not available in the country at the moment in required quantity as both Government sector units namely BCPL and Central Research Institute (CRI), Kasuali have stopped production of ASVS for the last 10 years. Due to non availability of fund and also due to project cost escalation the project could not be commissioned. The Committee feel that the Department is not taking the matter seriously inspite of the fact that 2 lakh people are suffering from snake bite every year. The Committee, therefore recommend that BCPL may not be closed by strategically selling and instead be supported in its special cause especially when it is on the path of regaining its old glory. The Committee, further observe that funds to be allocated to Pharma PSUs had been consistently delayed due to the lackadaisical approach of the Department to impress upon the Ministry of Finance of the urgent need for funds to complete the projects resulting in untimely closure of IDPL and RDPL plants and strategic sale of BCPL and HAL. The Committee therefore recommend that even if there is any little scope for running the PSUs in PPP mode or other mode the Department should consider this and instead of closing the IDPL and RDPL and option of strategic sales of BCPL and HAL, all may be fully revived. The Committee, would like to be informed of the action taken in this regard.

#### **RECOMMENDATION NO.6**

##### **PRADHAN MANTRI BHARTIYA JANAUSHADI PARIYOJANA**

The committee note that for effective implementation of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) key areas of significance were identified and major changes in PMBJP were made by waiving application fee. An amount of Rs. 2.5 lakhs shall be extended to NGOs/agencies/individuals for establishing PMBJK in government premises like hospitals/ medical colleges/Railways/Sate Transport/ Co-operation/ Municipalities/ Post offices etc. where space is provided free of cost by Government to operating agency. Trade margins have been revised from 16% to 20% for Retailers and from 8% to 10% for Distributors.

The Committee also note that 802 JAS have been opened till 22.2.2017. The Committee also note that attainment of target of opening 3000 JAS appears to be difficult as on date and that the success of this initiative largely depends on other agencies such as Ministry of Health & Family Welfare, different State Governments, active co-operation of Hon. Members of Parliament, Hon. Members of different Legislative Assemblies, IMA, Hospitals run by Private Groups and Charitable Institutions, NGOs, Practicing Doctors, etc. State Governments are having their own schemes like free distribution of medicines. Non-prescription of Generic Medicines by the doctors is another critical factor.

The Committee are perturbed to note that in spite of Committee's repeated recommendations for quick implementation of the scheme initiated in 2008, the scheme has not been fully implemented throughout the country. In view of this Committee once again recommend that the Department should take up the issue on war footing level to overcome the hurdles by involving other agencies such as Ministry of Health & Family Welfare, different State Governments, IMA, Hospitals run by Private Groups and Charitable Institutions, NGOs, Practicing Doctors, etc. for compulsory prescription of generic medicines by doctors and also keeping the supply chain in preparedness so that the requirements are met fully without any delay and also to overcome the requirement of Pharmacists to man the PMBJK and try to achieve the targets of opening 3000 number of PMBJK within the specified time. The Committee would like to be informed of the action taken in this regard.

#### **RECOMMENDATION NO.7**

##### **NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)**

The Committee note that National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers 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 formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

The Committee also note that NPPA has initiated about 1493 cases of overcharging as on 31<sup>st</sup> December, 2016 (1285 cases under DPCO 1995 and 208 cases under DPCO 2013), where demand notices have been issued to



pharmaceuticals companies. The demanded amount works out to Rs. 5037.64 crore (Rs.4956.48 crore under DPCO 1995 and Rs.81.16 crore under DPCO 2013) for sale of medicine at prices higher than that fixed by NPPA /Government. However only an amount of Rs. 640.16 crore (Rs 536.81 crore under DPCO 1995 and Rs.103.35 crore under DPCO 2013) has been recovered on 31<sup>st</sup> December, 2016 from pharmaceutical companies. This includes an amount of Rs. 215 crore deposited by pharmaceutical companies in response to the verdict of the Supreme Court delivered on 20<sup>th</sup> July, 2016. Out of the balance outstanding amount of Rs. 4359.93 crore, Rs. 3460.32 crore is still locked up in litigation. The Committee, feel that time and money are wasted in legal disputes and every year the outstanding amount locked in litigation increases causing great loss to the exchequer, The Committee feel that had the One Time Settlement proposal been approved, by the Ministry of Finance almost all the outstanding amount would have been recovered and there would have been no litigation charges also. The Committee, therefore recommend that the Department should strongly take up the issue with the Ministry of Finance about the advantages of One Time Settlement as it will not only help in the early settlement of the outstanding amount but also save the expenditure incurred on the litigation. The Committee desire to be apprised of the detailed action taken in this regard.

New Delhi  
17 March 2017  
26 Phalguna 1938(Saka)

Anandrao Adsul  
Chairperson  
Standing Committee on  
Chemicals and Fertilizers

## MINISTRY OF CHEMICALS AND FERTILISERS

DEMAND NO. 8

## Department of Pharmaceuticals

(In ₹ crores)

	Actual 2015-2016			Budget 2016-2017			Revised 2016-2017			Budget 2017-2018		
	Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
<b>Gross</b>	188.41	24.25	212.66	211.30	0.10	211.40	211.30	0.10	211.40	247.68	0.06	247.74
<i>Recoveries</i>	...	...	...	...	...	...	...	...	...	...	...	...
<i>Receipts</i>	...	...	...	...	...	...	...	...	...	...	...	...
<b>Net</b>	188.41	24.25	212.66	211.30	0.10	211.40	211.30	0.10	211.40	247.68	0.06	247.74
A. The Budget allocations, net of recoveries, are given below:												
<b>CENTRE'S EXPENDITURE</b>												
<b>Establishment Expenditure of the Centre</b>												
1. Secretariat	9.84	...	9.84	12.66	...	12.66	12.66	...	12.66	13.30	...	13.30
2. National Pharmaceutical Pricing Authority	10.00	...	10.00	16.66	...	16.66	13.16	...	13.16	15.00	...	15.00
<b>Total-Establishment Expenditure of the Centre</b>	<b>19.84</b>	...	<b>19.84</b>	<b>29.32</b>	...	<b>29.32</b>	<b>25.82</b>	...	<b>25.82</b>	<b>28.30</b>	...	<b>28.30</b>
<b>Central Sector Schemes/Projects</b>												
3. National Institutes of Pharmaceutical Education and Research (NIPERs)	142.91	...	142.91	127.48	...	127.48	127.48	...	127.48	127.73	...	127.73
4. Jan Aushadhi Scheme	16.91	...	16.91	35.00	...	35.00	49.75	...	49.75	74.62	...	74.62
5. Development of Pharmaceutical Industry	8.75	...	8.75	19.50	...	19.50	8.25	...	8.25	17.03	...	17.03
<b>Total-Central Sector Schemes/Projects</b>	<b>168.57</b>	...	<b>168.57</b>	<b>181.98</b>	...	<b>181.98</b>	<b>185.48</b>	...	<b>185.48</b>	<b>219.38</b>	...	<b>219.38</b>
<b>Other Central Sector Expenditure</b>												
<b>Public Sector Undertakings</b>												
6. Assistance to PSUs	...	24.25	24.25	...	0.10	0.10	...	0.10	0.10	...	0.06	0.06
<b>Grand Total</b>	<b>188.41</b>	<b>24.25</b>	<b>212.66</b>	<b>211.30</b>	<b>0.10</b>	<b>211.40</b>	<b>211.30</b>	<b>0.10</b>	<b>211.40</b>	<b>247.68</b>	<b>0.06</b>	<b>247.74</b>
B. Developmental Heads												
<b>Economic Services</b>												
1. Industries	178.57	...	178.57	179.12	...	179.12	172.37	...	172.37	202.86	...	202.86
2. Secretariat-Economic Services	9.84	...	9.84	12.66	...	12.66	12.66	...	12.66	13.30	...	13.30
3. Loans for Chemical and Pharmaceutical Industries	...	24.25	24.25	...	0.10	0.10	...	0.10	0.10	...	0.06	0.06

*(In ₹ crores)*

	Actual 2015-2016			Budget 2016-2017			Revised 2016-2017			Budget 2017-2018		
	Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total	Revenue	Capital	Total
<b>Total-Economic Services</b>	<b>188.41</b>	<b>24.25</b>	<b>212.66</b>	<b>191.78</b>	<b>0.10</b>	<b>191.88</b>	<b>185.03</b>	<b>0.10</b>	<b>185.13</b>	<b>216.16</b>	<b>0.06</b>	<b>216.22</b>
<b>Others</b>												
4. North Eastern Areas	...	...	...	19.52	...	19.52	26.27	...	26.27	31.52	...	31.52
<b>Total-Others</b>	<b>...</b>	<b>...</b>	<b>...</b>	<b>19.52</b>	<b>...</b>	<b>19.52</b>	<b>26.27</b>	<b>...</b>	<b>26.27</b>	<b>31.52</b>	<b>...</b>	<b>31.52</b>
<b>Grand Total</b>	<b>188.41</b>	<b>24.25</b>	<b>212.66</b>	<b>211.30</b>	<b>0.10</b>	<b>211.40</b>	<b>211.30</b>	<b>0.10</b>	<b>211.40</b>	<b>247.68</b>	<b>0.06</b>	<b>247.74</b>

1. **Secretariat:** The provision is for the Salary and Establishment Expenditure of Department of Pharmaceuticals.

2. **National Pharmaceutical Pricing Authority:** The provision is for the Secretariat and Establishment Expenditure of NPPA, Consumer Awareness Programme and providing support to state resource units.

3. **National Institutes of Pharmaceutical Education and Research (NIPERs):** The provision is for the 7 NIPERs which are operational and also for the 4 NIPERs which are proposed.

4. **Jan Aushadhi Scheme:** Under the Jan Aushadhi Scheme opening of 3000 Jan Aushadhi Stores across the country is targeted.

5. **Development of Pharmaceutical Industry:** The scheme for Development of Pharmaceuticals Industry consists of a number of sub scheme such as: Pharmaceuticals Promotion Development Scheme (PPDS), Cluster Development, Critical Assistance for WHO Pre-Qualification for Pharma PSUs, assistance to Bulk Drug Industry for Common Facilitation Centre, and assistance to Medical Device for Common Facilitation Centre etc.

6. **Assistance to PSUs:** These are provisions under loan kept for the 6 Pharmaceuticals Public Sector Undertakings.

**MINUTES OF THE NINTH SITTING OF THE  
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS  
(2016-17)**

The Committee sat on Wednesday, the 22<sup>nd</sup> February, 2017 from 1500 hrs. to 1700 hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

**PRESENT**

**Shri Anandrao Adsul - Chairperson**

**MEMBERS**

**LOK SABHA**

2. Smt. Anju Bala
3. Shri B. N. Chandrappa
4. Smt. Veena Devi
5. Shri K. Ashok Kumar
6. Shri Chhedi Paswan
7. Smt. Kamla Devi Patle
8. Shri S. Rajendran
9. Shri Kotha Prabhakar Reddy
10. Dr. Kulamani Samal
11. Shri Tasleem Uddin
12. Smt Rekha Arun Verma
13. Dr. (Smt.) Ratna De (Nag)

**RAJYA SABHA**

14. Shri Biswajit Daimary
15. Shri Narayan Lal Panchariya
16. Shri Palvai Govardhan Reddy

**SECRETARIAT**

- |    |                       |   |                 |
|----|-----------------------|---|-----------------|
| 1. | Smt. Rashmi Jain      | - | Joint Secretary |
| 2. | Shri A. K. Srivastava | - | Director        |
| 3. | Shri Nishant Mehra    | - | Under Secretary |

**LIST OF WITNESSES**

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

- |    |                        |  |
|----|------------------------|--|
| 1. | Shri Jai Priye Prakash | Secretary                                |
| 2. | Ms. Meenakshi Gupta    | Additional Secretary & Financial Advisor |
| 3. | Shri Sudhansh Pant     | Joint Secretary                          |
| 4. | Shri Rajneesh Tingal   | Joint Secretary                          |
| 5. | Smt. Bandhula Sagar    | CCA                                      |

**II. REPRESENTATIVES OF NPPA**

- |    |                          |   |
|----|--------------------------|---|
| 1. | Shri Bhupendra Singh     | Chairman, National Pharmaceuticals Pricing Authority (NPPA)         |
| 2. | Dr. Sharmila Mary Joseph | Member Secretary, National Pharmaceuticals Pricing Authority (NPPA) |

**III. REPRESENTATIVES OF NIPER**

- |   |                                      |                            |
|---|--------------------------------------|----------------------------|
| 1 | Dr. KiranKalia                       | Director, NIPER, Ahmedabad |
| 2 | Wing Cdr PJP Singh Waraich<br>(Retd) | Registrar, NIPER Mohali    |
| 3 | Dr. V. Ravichandran                  | Director, NIPER, Kolkata   |
| 4 | Dr. U. S. N Murty                    | Director, NIPER, Guwahati  |
| 5 | Dr. S. J. S. Flora                   | Director, NIPER, Raebareli |

**IV. REPRESENTATIVES OF PSUs**

- |    |                       |   |
|----|-----------------------|---|
| 1. | Ms. Nirja Saraf       | MD, Hindustan Antibiotics Limited (HAL)                 |
| 2. | Shri P. M. Chandraiah | MD, Bengal Chemicals and Pharmaceuticals Limited (BCPL) |

2. At the outset, Hon'ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) and other officials 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, a representative of the Department of Pharmaceuticals made power point presentation to the Committee regarding Demands for Grants 2017-18 of the Department of Pharmaceuticals.

4. During the discussion, the Hon'ble Chairperson and Members of the Committee raised queries on several issues such as shortage of funds allocated for various schemes of the Department, Implementation of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana', Strategic sale of HAL and BCPL and closure of IDPL and RDPL, functioning of NIPER, role of NPPA, Cluster Development Programme for Pharma Sector (CDP-PS) and not sanctioning funds for anti snake venom project of BCPL, which were replied to by the Secretary, Department of Pharmaceuticals and other officials.

5. The Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee. They were also asked to provide required information not readily available at the earliest.

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

*The Committee then adjourned.*

**MINUTES****MINUTES OF THE ELEVENTH SITTING OF THE  
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS  
(2016-17)**

The Committee sat on Friday, the 17 March, 2017 from 1500 hrs. to 1530 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

**Shri Anandrao Adsul - Chairperson**

**Members  
Lok Sabha**

2. Shri George Baker
3. Smt. Anju Bala
4. Shri K. Ashok Kumar
5. Shri Chhedi Paswan
6. Shri Kotha Prabhakar Reddy
7. Smt. Rekha Arun Verma
8. Smt. Pankaj Chaudhary

**Rajya Sabha**

9. Shri Biswajit Daimary
10. Shri Narayan Lal Panchariya
11. Shri Palvai Govardhan Reddy

**Secretariat**

- |    |                      |   |                 |
|----|----------------------|---|-----------------|
| 1. | Smt. Rashmi Jain     | - | Joint Secretary |
| 2. | Shri A.K. Srivastava | - | Director        |
| 3. | Shri Nishant Mehra   | - | Under Secretary |

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)      Demands for Grants (2017-18) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)
4. The draft Reports were adopted by the Committee without any amendment.
5. The Committee authorised the Chairman to make consequential changes, if any, arising out of the factual verification of the Reports by the Department of Fertilizers, and Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers and present the same to both the Houses of Parliament.

*The Committee then adjourned.*

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xxxx Matters not related to this Report.