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STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2019-20)

SEVENTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2019-20)

FOURTH REPORT

सत्यमेव जयते

LOK SABHA SECRETARIAT

NEW DELHI

December, 2019/ Agrahayana, 1941 (Saka)

CC&F.No.4

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(SEVENTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2019-20)

Presented to Lok Sabha on 12 December 2019

Laid in Rajya Sabha on 12 December 2019

LOK SABHA SECRETARIAT
NEW DELHI

December, 2019/ Agrahayana, 1941 (Saka)

CONTENTS

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2019-20)

Ms. Kanimozhi Karunanidhi - Chairperson

MEMBERS
LOK SABHA

2	Shri Maulana Badruddin Ajmal
3	Shri Ramakant Bhargava
4	Shri Prataprao Govindrao Patil Chikhalikar
5	Shri Rajeshbhai Naranbhai Chudasama,
6	Shri Ramesh Chandappa Jigajinagi
7	Shri Kripanath Mallah
8	Shri Satyadev Pachauri
9	Smt Aparupa Poddar
10	Shri Arun Kumar Sagar
11	Shri M. Selvaraj
12	Shri Pradeep Kumar Singh
13	Shri Uday Pratap Singh
14	Shri Nandigam Suresh
15	Shri Er. Bishweswar Tudu
16	Shri H. Vasanthakumar
17	Shri Prabhubhai Nagarbhai Vasava
18	Dr. Vishnu Prasad M.K.
19	Shri Deepak Baij
20	Dr. Manoj Rajoria
21	Vacant

RAJYA SABHA

22	Shri Ranjib Biswal
23	Shri G.C.Chandrashekhar
24	Dr. Anil Jain
25	Shri Ahmad Ashfaque Karim
26	Shri Amar Singh
27	Shri Vijay Pal Singh Tomar
28	Vacant
29	Vacant
30	Vacant
31	Vacant

SECRETARIAT

1.	Shri Manoj K. Arora	-	Officer on Special Duty
2.	Shri A.K. Srivastava	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Ms Sonia Sankhla	-	Assistant Committee Officer

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2019-20) having been authorised by the Committee to present the Report on their behalf, present this Fourth Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2019-20.

The Committee examined the Demands for Grants (2019-20) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which were laid in Lok Sabha and Rajya Sabha on 16 July 2019.

The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 22 October, 2019.

The Report was considered and adopted by the Committee at their sitting held on 10 December 2019.

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.

For facility of reference and convenience, the Observations/ Recommendations of the Committee have been printed in bold letters at the end of the Report.

New Delhi;
10 December, 2019
19 Agrahayana, 1941 (Saka)

Kanimozhi Karunanidhi
Chairperson
Standing Committee on
Chemicals and Fertilizers

PART-I

CHAPTER – I

INTRODUCTORY

The Department of Pharmaceuticals was created on 1st July, 2008 under the Ministry of Chemicals & Fertilizers 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 The 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.
4. Development of infrastructure, manpower and skills for the pharmaceutical sector and management of related information.
5. 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.
6. Promotion of public – private – partnership in pharmaceutical related areas.
7. International co-operation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
8. Inter-sectorial coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
9. Technical support for dealing with national hazards in pharmaceutical sector.
10. All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.
11. All matters relating to National Institutes of Pharmaceutical Education and Research.

12. Planning, development and control of, and assistance to, all industries dealt with by the Department.

13. Bengal Chemicals and Pharmaceuticals Limited.

14. Hindustan Antibiotics Limited.

15. Indian Drugs and Pharmaceuticals Limited.

16. Karnataka Antibiotics and Pharmaceuticals Limited.

17. Rajasthan Drugs and Pharmaceuticals Limited.

1.3 The work of the Department has been mainly divided into Pricing, Policy-I, Policy-II, NIPER, PSU & Medical Devices Divisions. National Pharmaceutical Pricing Authority (NPPA) is an attached office of the Department.

1.4 **The detailed Demands for Grants (2019-20) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 1st February, 2019. Since the Departmentally Related Standing Committees were not constituted, the Rule 331G of Rules of Procedure and Conduct of Business in Lok Sabha was suspended. Therefore a Motion was moved in Lok Sabha on 11.07.2019 to enable Lok Sabha to pass the Demands for Grants in respect of Union Budget for the year 2019-20 without referring them to DRSCs. However, Hon'ble Speaker observed in the House that the Demands for Grants would stand referred to the concerned Departmentally Related Standing Committees after they have been constituted for examination and report to the House. The demand shows a budgetary support of Rs. 235.51 crore. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2019-20. The Observations/Recommendations of the Committee have been 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 nd projects in a time bound manner. The Committee also expect the Department to act on the recommendations of the Committee expeditiously and furnish action taken replies to the observations/recommendations made in the Report within three months from the date of presentation of this Report.**

CHAPTER-II

DEMAND FOR GRANTS 2019-20

Demand No.7- Department of Pharmaceuticals

Department has received Gross Budgetary allocation of Rs. 235.51 crore for the year 2019-20, out of which Rs. 26.15 crore is towards Centre's Expenditure (Non-Scheme) relating to Secretariat General Services for Department of Pharmaceuticals and NPPA against proposed Budget Estimates for Centre's Expenditure is Rs. 32.62 crore and Rs. 204.30 crore for Central Sector Scheme against proposed Budget Estimates of Rs. 366.05crore and Rs. 5.06 crore for Assistance to PSUs (loan) against proposed Budget Estimates of Rs. 0.06 crore. A statement showing scheme-wise details of outlays, Gross Budgetary Support (GBS) for the year 2019-20 and scheme wise break-up of outlays approved, is given below: -

(Rs. In crore)

Sl. No.	Schemes/Non-Scheme	Major Head	BE 2019-20 (Proposed)	BE 2019-20 (Approved)	Actual expenditure as on 30.9.2019
	Central Expenditure (Non-Scheme)				
1	Secretariat Economic Services	3451	15.96	14.15	6.63
2	National Pharmaceuticals Pricing Authority (NPPA)	2852	16.66	12.00	5.38
	Total of Non Scheme		**32.62**	**26.15**	**12.01**
	Central Sector Scheme				
3	North East Region - National Institute of Pharmaceutical Education and Research (NIPER)	2552	75.00	36.40	34.00
	National Institute of Pharmaceutical Education and Research (NIPERs)	2852	175.00	113.60	62.44
	Total NIPERs (MH 2552+ MH 2852)		**250.00**	**150.00**	**96.44**
4	**Development of Pharmaceuticals Industry**	2552	0.01	0.01	
	Development of Pharmaceuticals Industry	2852			
	Pharmaceutical Promotion & Development Scheme(PPDS)		2.00	2.00	0.21
	Cluster Development Programme for Pharma Sector (CDP-PS) renamed as Assistance to Pharma Industry for Common Facilities(APICF)		10.00	6.23	2.23

					(Rs. In crore)
Sl. No.	**Schemes/Non-Scheme**	**Major Head**	**BE 2019-20 (Proposed)**	**BE 2019-20 (Approved)**	**Actual expenditure as on 30.9.2019**
	Pharmaceuticals Technology Upgradation Assistance Scheme(PTUAS)		0.02	0.02	
	Assistance to Bulk Drug Industry for Common Facilitation Center		50.00	0.02	
	Assistance to Medical Device Industry for Common Facilitation Center		0.02	0.02	
	Total Development of Pharmaceuticals Industry MH2852 + MH 2552		62.05	8.30	2.44
5	**Jan Aushadhi (PMBJP)**	2552	0.01	0.01	-
		2852	49.99	41.99	11.50
	Total Jan Aushadhi (PMBJP) (MH 2552 + MH 2852)		**50.00**	**42.00**	**11.50**
6	**Consumer Awareness, Publicity and Price Monitoring (CAPPM)**	2852			
	Assistance to Project Monitoring Price Monitoring Resource Units (PMRUs)		2.00	2.00	0.76
	Advertising and Publicity for CAPPM		2.00	2.00	-
	Total CAPPM MH 2852		**4.00**	**4.00**	**0.76**
7	**Assistance to PSUs (Loans to PSUs)**	6857			
	Indian Drugs & Pharmaceuticals Ltd. (IDPL)		0.01	0.01	
	Hindustan Antibiotics Ltd. (HAL)		0.01	0.01	
	Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)		0.01	0.01	
	Bengal Immunity Ltd. (BIL)		0.01	0.01	
	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)		0.01	*5.01	5.00
	Smith Stanistreet Pharmaceuticals Ltd (SSPL)		0.01	0.01	
	Total (Loan to PSUs)		**0.06**	**5.06**	**5.00**
	Grand Total		**398.73**	**235.51**	**128.15**

*Rs. 5.00 crore was released to RDPL from Contingency Fund of India, as per the direction of Hon'ble High Court of Rajasthan. Accordingly, Scheme-wise allocation has been revised.

2.2 On being asked about the reasons for difference in proposed BE (2019-20) that is Rs. 398.73 crore and approved BE (2019-20) that is only Rs.235.51 crore and also whether the financial allocation under BE 2019-20 is adequate to achieve the targets fixed by the Ministry/Department for major central sector schemes, the Department in its written reply stated, "For the current financial year 2019-20, Department had proposed an outlay of Rs. 398.73 crore which included Centre's expenditure (Non-schemes) of Rs. 32.62 crore and Rs 366.05 crore for the Central Sector Schemes. However, only Rs 235.51 crore was allocated for this Department by Ministry of Finance compelling the Department to spread thinner allocation amongst its schemes totaling to Rs 204.30 crore for its Central Sector Schemes. The scheme wise allocation of this provision of Rs 235.51 crore has been determined by the Department based on inter-se scheme wise priorities and within the reduced allocation of Rs 235.51 crore made available. This financial allocation under BE 2019-20 falls far short of the fund requirements projected by this Department for carrying out its laid out mandate. The reduction in outlay would have an adverse impact on the implementation of the various schemes and will not be sufficient to achieve the targets fixed by the Ministry/Department for its major central sector schemes (except CAPPM) for reasons detailed as under:

(1) National Institute of Pharmaceutical Education and Research (NIPERs):

Department of Pharma proposed Rs.250 crore for seven NIPERs in BE 2019-20. However, Ministry of Finance has allocated Rs 150 crore in BE 2019-20 to NIPERs. The financial allocation is not adequate to achieve the targets. Therefore, Department has sent a request to Ministry of Finance to allocate Rs 300 crore as approved in EFC (Rs 25 crore in GIA- General) urgently to fill up the regular posts of faculty and non-faculty in six NIPERs and Rs 275 crore for purchase of equipments and machineries for six NIPERs and completion of the construction of NIPER Guwahati campus and starting of construction of NIPER Ahmedabad campus.

(2) Development of Pharmaceutical Industry:

The Department has proposed outlay of Rs. 62.05 crore in respect of the umbrella scheme against which only Rs. 8.30 crore has been approved.The sub-schemes included under this Umbrella scheme are upcoming and new schemes of the Department which need increased allocation of fund for their progress. Proposals have been received in the Department under both the new sub-schemes 'Assistance to Medical Device Industry for Common Facilitation Centres' and 'Assistance to Bulk Drug Industry for Common Facilitation Center'.

Under the new sub-scheme 'Assistance to Medical Device Industry for common facilitation centres', financial assistance to the tune of Rs. 25 crore or 70% of the CFC whichever is less is to be provided for creation of common facilities under any upcoming Medical Device Park promoted by State Government/State corporations. Under this scheme, several proposals seeking financial assistance have been received in the Department and in-principle approval has been given to

Andhra Pradesh Medtech Zone Ltd (AMTZ) on 05/02/19. Thus the allocated fund of Rs 2 lakh in the current financial year for this sub-scheme will not be adequate and it has been decided to seek an amount of Rs 25 crores at the RE stage.

Similarly, under the other new sub-scheme 'Assistance to Bulk Drug Industry for Common Facilitation Center' the maximum limit for the Grant-In-Aid would be Rs 100 crore per Bulk Drug Park CFC or 70% of the project cost of CFC whichever is less. The department would be providing financial assistance of Rs. 70 crore (maximum) for one Bulk Drug Park in 4 installments. In the year 2019-20, it is expected that the Department would release Rs. 21 crore (30% of Rs. 70 crore) as the first installment.

Under the Cluster Development Programme for Pharma Sector (CDP-PS) (renamed as 'Assistance to Pharma Industry for Common Facilities (APICF))as sub-scheme, an existing scheme, in the year 2019-20 an amount of Rs. 4 crore is to be released to Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC) and it is expected that the Department would release Rs. 6 crore (30% of Rs. 20 crore) as the first installment of new proposed CFC.

As regard to the other existing sub-scheme 'Pharmaceuticals Promotion & Development Scheme (PPDS)' the outlay approved (Rs 2 crore) is sufficient to fulfill the requirement of the Pharmaceuticals Promotion & Development Scheme (PPDS).

Therefore, the fund approved for the Umbrella scheme 'Development of Pharmaceutical Industry' for 2019-20 (Rs 8.23 crore) will not be adequate to fulfill the requirement of the scheme even though there is flexibility in the utilization of funds among the sub-schemes.

(3) Jan Aushadhi (PMBJP):

The final outlay approved by Ministry of Finance for Department of Pharmaceuticals (DoP) may not be sufficient to fulfill the requirement of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP).

(4) Consumer Awareness, Publicity and Price Monitoring (CAPPM):

Financial allocation under BE 2019-20 is adequate to achieve the targets fixed. Utilization of fund shall be ensured by taking timely action.

CHAPTER-III

SCHEMES OF THE DEPARTMENT

(A) JAN AUSHADHI SCHEME (PMBJP)

Department of Pharmaceuticals runs a scheme called 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' (PMBJP) under which quality generic medicines are sold to the public at very affordable prices through dedicated retail outlets called Janaushadhi Kendras. Government has fixed a target to cover all 723 districts of the country by 31st March, 2020. The endeavor of the Government is

(i) to open new PMBJKs in henceforth unserved geographical locations and to increase product basket of PMBJP to 1000 medicines and 200 surgical products.

(ii) To ensure availability of all medicines and surgical items and consumables, demanded out of the product basket.

(iii) To spread awareness among doctors and public at large about quality and effectiveness of generic medicines.

3.2 As a result of several steps taken by the Government and efforts made by the Government, 5463 PMBJP Kendra's are functional in 35 States/UTs of the country Government as on 25.07.2019 during the years 2016-17, 2017-18 and 2018-19 the outlays of PMBJP Scheme into outcome are as under:-

Financial Year	PMBJP Kendra's opened (No.)	Sales at MRP Value in (Rs. Crore)
2016-17	965	32.66
2017-18	3229	140.84
2018-19	5100	315.70

3.3 Under Jan Aushadhi (PMBJP) scheme for the year 2019-20 the Financial target is Rs. 42 crore and the Physical target is given in table below:

Sl.No.	Particulars	Current Status	Target
1.	District Covered	675	723
2.	Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJAK)	5300	6500
3.	Product Basket		
	i) Medicine	900	1200
	ii) Surgicals	154	200
4.	Warehouse	3	4

3.4 Year wise plan activities along with expenditure incurred under Jan Aushadhi Scheme (PMBJP) vis-à-vis BE and RE for last three years and BE for 2019-20 is given as under:

(Rs. In crore)

Name of Scheme	**2016-17**			**2017-18**			**2018-19**			**2019-20**
	BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
Jan Aushadhi Scheme	35.00	49.74	49.75	74.62	74.62	47.64	84.00	42.51	42.50	42.00

3.5 On being asked about the reasons for the allocation of only Rs.42.00 crore under Jan Aushadhi Scheme for the current year 2019-20 and the actual fund required for the scheme to fulfill scheme objectives, the Department in its reply stated as under:

"In para 5.2 of Standing Finance Committee Memorandum dated 05.10.2017 duly concurred by Financial Advisor, Ministry of Chemicals & Fertilizers, it is mentioned that the scheme would run on a self-sustaining business model, and not to be dependent on government subsidies or assistance beyond the initial support.

This is the guiding principle of operations of BPPI which implements the Jan Aushadhi Scheme. BPPI continuously strives to increase its revenue and decrease its operating cost so that it can sustain its operation through internal resources. In F.Y- 2019-20, BPPI will be needing approximately Rs 245.00 Cr for running its operations. Out of these, it can generate Rs 202.50 Cr from its operations. Balance Rs 42.50 Cr is required as grant from the Department of Pharmaceuticals.

Though BPPI is demanding less grant, it doesn't mean that it is downsizing its operations. In F.Y 2019-20, BPPI is planning to open 1000 new Janaushadhi Kendra's with total 6000 Kendra's pan India. BPPI is continuously reducing its indirect expenses like administrative cost, human resources cost, logistics cost etc. For example, human resource cost was 10.19% of BPPI's revenue in F.Y 2016-17 which was reduced to 4.58% in F.Y 2017-18 and 2.09% in F.Y 2018-19. Thus, as envisaged in SFC memorandum, BPPI is increasing self-sustainability and decreasing its dependence on grant provided by the government. Therefore, even with reduced grant, BPPI can sustain its present level of operations for F.Y 2019-20."

3.6 About the system of monitoring and control over the performance of the Jan Aushadhi (PMBJP), the Department in its preliminary material on Demand for Grants 2019-20, stated as under:

" Performance of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is regularly reviewed by the Department of Pharmaceuticals. Various decisions have been taken and implemented for improving the performance of the scheme. For example, a bottleneck in logistics and supply chain was observed, where, it was decided to implement end-to-end supply chain system where drugs are directly delivered to stores from the Central/Regional warehouses instead of routing these through Clearing & Forwarding (C&F) agents and distributors. Further, it was also noticed that store owners were not getting regular financial incentives. As a result, mandatory requirement of sales through centralized software was omitted and backlog of due incentives was cleared. Disbursement of due incentives to PMBJK owners is being done regularly now."

3.7 During oral evidence of the representatives of the Department of Pharmaceuticals on Demands for Grants, 2019-20, when the Committee enquired whether BPPI is purchasing medicines under the PMBJP from PSUs under the Department, Chief Executive Officer of BPPI informed the Committee as under:-

"Hon. Chairperson and hon. Members, the purchase of BPPI is done through open tender. The purpose is to encourage competition so that we can get world class products at affordable prices. Our criterion is that only WHO-GMP certified companies can participate in the open bidding; through the process of open bidding, we finalise the rates. We get rates which are much less only because of open competition and the companies have to compete with each other so that they can supply medicines to us. the BPPI adds its margins like administrative and other costs are arrives at an MRP to sell the products. They come at a lesser cost because our administrative and other expenditure are very less. We do not have to spend on marketing and other promotional activities. It does not mean that our products are inferior. Secondly, we also place orders on PSUs. Last year, we procured drugs from IDPL, Karnataka Antibiotics, and Kerala Drugs and Cosmetics".

3.8 When the Committee further enquired about the cost of medicines they purchased from IDPL, CEO & BPPI further stated:

"It is about Rs. 1 crore. The problem is that the cost of medicines from PSUs is high. They are quoting much higher in the open bidding. Secondly, our purpose is to provide medicines at affordable prices. If we procure at higher prices, it will kill our basic purpose".

3.9 During oral evidence the Committee asked about the setting up of PMBJP Kendras in tribal, hilly or remote areas. The Secretary of the Department furnished the following reply:-

"For example, it is impossible for a tribal in mountains or hilly areas to go to a district headquarter where our Kendras are there. So, we have requested the State Governments if they can allot a PHC without any rent and also with free electricity to a person, we will allow him to sell other goods also so that it becomes viable. If it is done, we will be more than happy to start a Kendra. If we increase the number of centres without making it sure that the person who runs it, he earns something, it will not be a proper thing. Then he will start selling branded medicines which we do not want. We are hearing some complaints in this regard and we have taken action also. We are evaluating and monitoring them. In the mountains and hilly areas, the tribals have to walk a lot and have to travel by spending money. So, we have requested the State Governments if they can provide PHCs there and give this pharmacy to a Scheduled Caste or Scheduled Tribe person or a handicap person, we have a scheme in which he can earn Rs.10000 to Rs.15000 per month".

3.10 Further, when the Committee asked about the details of the evaluation studies/review of the Jan Aushadhi (PMBJP), the Department in its preliminary material on Demand for Grants 2019-20 stated as under:

> "The Department of Pharmaceuticals reviews performance of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) on regular basis. Various decisions have also been taken as a result of such reviews and implemented for improving the performance of the scheme. Also NITI Aayog has submitted a report on PMBJP Scheme and the same is under consideration."

3.11 The Committee also asked about the Mid-term appraisal of Jan Aushadhi (PMBJP) scheme and corrective measures taken, the Department in its preliminary material on Demand for Grants 2019-20 stated as under:

> "In the course of implementing the Jan Aushadhi (PMBJP) Scheme, corrective measures were taken and it was suitably modified to overcome practical difficulties. In this regard, an amendment in the incentive being given to private entrepreneurs of PMBJP was effected. The amendment was discussed in the meeting held on 13.09.2018 at 11:00 AM under the Chairmanship of Hon'ble Minister of State (Chemicals & Fertilizers) to review the progress of PMBJP. As per latest amendment, the incentives is given @ 15% of monthly purchase subject to a ceiling of Rs. 10,000/- per month upto a total limit of Rs. 2.5 lakhs. Earlier it was given on "Sale of medicines, surgicals and consumables"."

(B) DEVELOPMENT OF PHARMACEUTICAL INDUSTRY

3.12 The Department has an umbrella scheme namely 'Scheme for Development of Pharmaceutical Industry'. Its objective is to increase the efficiency and competitiveness of domestic pharmaceutical industry so as to enable them to play a lead role in the global market and to ensure accessibility, availability and affordability of quality pharmaceuticals of mass consumption. This scheme is a Central Sector Scheme (CSS) with a total financial outlay of Rs. 480 crore for a three year period starting from 2017-18 to 2019-20 and comprises of the following five sub-schemes**:**

(a) Cluster Development Programme for Pharma Sector (CDP-PS) (renamed as Assistance to Pharmaceutical Industry for Common Facilities);
(b) Assistance to Bulk Drug Industry for Common Facility Centre;
(c) Assistance to Medical Device Industry for Common Facility Centre;
(d) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS); and
(e) Pharmaceutical Promotion and Development Scheme.

It is expected that the implementation of the scheme would facilitate the growth of domestic pharmaceutical industry to play a lead role in the global market and ensure the availability of good quality pharmaceuticals of mass consumption thereby assuring drug security in the country. This scheme would also help the Pharmaceutical industry including Bulk Drug and Medical Device Industry to cut down their production cost and also to upgrade their plants to WHO-GMP standards enabling Indian Pharmaceutical Industry to be globally competitive. This would also help patients in getting quality medicines at affordable price.

3.13 The physical and financial targets projected for the year 2019-20 for the sub-schemes under the umbrella scheme of Development of Pharmaceutical Industry are given below:

(a) Cluster Development Programme for Pharma Sector (CDP-PS) renamed as Assistance to Pharmaceutical Industry for Common facilities (APICF): The Financial target is Rs 10 crore. In the year 2019-20, an amount of Rs. 4 crore to be released to Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC) and it is expected that the department would release Rs. 6 crore (30% of Rs. 20 crore) as the first installment of new proposed CFC. The Physical Target is completion of Common facilities in one pharma cluster Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC).

(b) Assistance to Bulk Drug Industry for Common Facility Centre (BDCFC): The Financial target is Rs. 21 crore. The maximum limit for the grant in aid under this category would be Rs. 100 Crore per Bulk Drug Park CFC or 70% of the project cost of CFC whichever is less. The department would be providing financial assistance of Rs. 70 crore (maximum) for one Bulk Drug Park in 4 installments. In the year 2019-20, it is expected that the department would release Rs. 21 crore (30% of Rs. 70 crore) as the first installment. The Physical Target is commencement of implementation for creation of Common Facilities in one Bulk drug park.

(c) Assistance to Medical Device Industry for Common Facility Centre: Department of Pharmaceuticals vide letter dated 05.02.2019 has given in-principle approval to Andhra Pradesh Medtech Zone ltd (AMTZ) for financial assistance of up-to Rs.25 crores under the sub-scheme “Assistance to Medical Device Industry for Common Facility Centre”. Apart from this, proposals seeking financial assistance have also been received from HLL Medipark Limited, Kerala State Industrial Development Corporation and State Government of Telangana. Also letter of expression for setting up of Medical Device Park in Uttrakhand has been received from Government of Uttrakhand. The State Government has been requested to submit the detailed proposal. To deal with the current proposals, the Department would need Rs.25 Crores in the current Financial Year. Also, letter expressing interest received from Uttarakhand and the state has been asked to submit its detailed proposal.

(d) Pharmaceuticals Promotion & Development Scheme (PPDS): The Financial target is Rs. 2 crore. The Physical target is to provide the financial assistance to the Institutions, Organisations, Voluntary Organisations or Non-Government Organizations as mentioned in Rule 206 of GFR 2005 for promotions, development and export promotion in pharmaceutical sector. Also, letters expressing interest received from Uttarakhand and have asked them to submit proposal.

(e) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) is yet to be launched.

3.14 Year wise plan activities along with expenditure incurred under scheme Development of Pharmaceutical Industry(MH-2852)vis-à-vis BE and RE for last three years is given as under:

(Rs. In crore)

Name of Scheme	**2016-17**			**2017-18**			**2018-19**			**2019-20**
	BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
Development of Pharmaceutical Industry	19.44	8.25	7.62	17.03	12.03	1.82	12.97	4.00	2.82	8.30

3.15 On being asked about the reasons for underutilization of funds of during 2017-18 and 2018-19, the Department in its preliminary material on Demands for Grants 2019-20 stated as under:

"This umbrella scheme constitutes of two existing schemes 'Cluster Development Programme for Pharma Sector (CDP-PS) (renamed as Assistance to Pharma Industry for Common Facilities (APICF)) and Pharmaceuticals Promotion & Development Scheme (PPDS) and three new schemes namely Assistance to Bulk Drug Industry for Common Facility Centre, Assistance to Medical Device Industry for Common Facility Centre and Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS).

In spite of the best efforts made by the government, the Cluster Development Programme for Pharma Sector (CDP-PS) (renamed as Assistance to Pharma Industry for Common Facilities (APICF)) scheme did not receive good response in 2016-17 and 2017-18. Therefore funds allocated for this scheme remained unutilized. The Scheme has now been renamed as 'Assistance to Pharma Industry for Common Facilities(APICF)' and has been included under the new umbrella Scheme 'Development of Pharmaceutical Industry'.

For the sub-scheme Pharmaceuticals Promotion & Development Scheme (PPDS), during 2017-18, the total budget allocation in BE& RE was Rs. 2.00 crore. During 2017-18, Department of Pharmaceuticals received more than 100 proposals from various Associations/Organizations for financial assistance for conducting Conference/Seminars/Workshops under PPDS. After consideration of these proposals, Department found that only 35 Conference/Seminars/Workshops were as per guidelines of PPDS. Hence, Rs. 1.00 crore could only be utilized under PPDS.

For PPDS, during the financial year 2018-19, Rs. 2.00 crore was allocated under BE. Due to limited number of proposals received, BE 2018-19 was reduced to Rs. 1.00 crore under RE and the actual expenditure was Rs. 52.00 lakh to different institutions for organizing 13 events/seminars which fall under PPDS guidelines. The remaining amount i.e Rs. 1.48 crore was surrendered due to receipts of less proposals.

The other three sub-schemes being new schemes, only token amount were provided at BE and RE stage."

DETAILS ON SUB-SCHEMES:

(a) Cluster Development Programme for pharma Sector-Assistance to Pharmaceutical Industry for Common Facilities:

3.16 The Scheme Cluster Development Programme for Pharma Sector (CDP-PS) (renamed as Assistance to Pharma Industry for Common Facilities (APICF)) was announced on 17.06.2015. This is an existing and approved scheme of the Department (Cluster Development Programme for Pharma Sector(CDP-PS)) now being subsumed under theumbrella scheme. Under the Scheme, financial assistance would be provided for creation of common facilities in any pharma clusters including Bulk Drug, Medical Device, Ayurvedic, Unani and Cosmetics Units. Some of the indicative activities under the Common facilities include Common Testing Facilities, Training Centre, R&D Centers, Effluent Treatment Plant and Common Logistics Centre. The Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant-in-aid to be released to a Special Purpose Vehicles (SPVs) set up for the purpose. A total of Rs. 30 crore has been earmarked for the scheme including Rs. 10 crore which was allocated in 2017-18. Maximum limit for the grant in aid under this category would be Rs 20.00 crore per cluster or 70% of the cost of project whichever is less.

The Projects & Development India Limited (PDIL), a Public Sector Company under the administrative control of Ministry of Chemicals and Fertilizers was appointed as the Project Management Consultant (PMC) to implement the Scheme. In the first phase, the PMC called for the Expression of Interest (EOI) and six EOIs were received which were considered by the Scheme Steering Committee (SSC). Only one EOI that of M/s. Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC), Alathur, Distt. Kanchipuram, Tamilnadu was found eligible and Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC) was declared as the SPV for the scheme.

PDIL had further called for 3 more EOIs and also relaxed the eligibility criteria by including the Cosmetic, Unani and Ayurveda Units along with Allopathic Pharma companies to be considered as eligible Pharma Units. However, no response was received from the industry. The Cluster Development Programme for Pharma Sector (CDP-PS) has not taken off as expected despite the best efforts of the government.

Seeing the industries' poor response and lack of interest, the department has modified the scheme and renamed it as Assistance to Pharmaceutical Industry for Common Facilities (APICF) on April, 2018. The modified scheme is receiving positive responses from the industry.

3.17 About the findings of internal evaluation of scheme Assistance to Pharmaceutical Industry for Common Facility and follow up steps that are being taken, the Department in its written reply stated as under:

> "An internal evaluation of the Scheme was done by the Department in 2017. In the evaluation, the scheme was found to be useful. The evaluation report suggested to curtail the limit of 10 units in pharma cluster to 5-6 units and to increase the grant from Rs. 20 crore to Rs. 40 crore. Similarly, an increase in the amount of maximum grant per cluster from Rs. 20 crore to Rs. 40 crore would also not serve any purpose since even in the proposals received, the present amount of Rs. 20 crore seemed sufficient. We have accepted recommendation reduce the number of units from 10 to minimum 3."

3.18 During oral evidence, when the Committee enquired would it be commercially feasible if the common facility has only three units, Secretary of the Department stated,

> "The facilities can be used by companies which are not members of the SPV. So, normally it is difficult for ten companies to come together and form an SPV. As we were not receiving enough proposals the conditions have been relaxed". He had further stated, "We have talked to various stakeholders. One problem is that of land. So, land is one problem. The second problem is, as far as research facilities are concerned, many people are not ready to share their secrets. So, we have to take a complete review of this scheme and then see what we can do. We are going for a third-party evaluation. We have implemented one project in Chennai. So, we will go for the review of the scheme".

3.19 The Committee asked about the specific modification that have been brought about under the renamed scheme Assistance to Pharmaceutical Industry for Common Facilities and also about the budget that has been allocated for the same during 2018-19 and 2019-20, the Department in its written reply stated as under:

> "Some of the major modifications done in the Scheme are as following:
>
> - The condition that an SPV is a clear legal entity (Cooperative Society, Registered Society, Trust or a Company) with members located within a radius of 10-15 km with in proposed cluster was removed.
>
> - Limit of minimum 10 Pharma units to form an SPV has been reduced to 3 Pharma units which may also include Bulk drug and medical device units.
>
> - A new clause stating "Where only State Government or an agency of State Government is applicant without private participation, the SPV formation

may not be insisted upon, instead they should just create an Escrow/TRA account so that funds are utilized only for the project purpose" is added.

- Establishment of project specific Trust and Retention Account (TRA), with Schedule Commercial Banks by the SPV was changed to Establishment of project specific Current Account with Schedule Commercial Banks by the SPV to transfer funds from the department.

- Budget Allocated for the Scheme 'Assistance to Pharmaceutical Industry for Common Facilities' are as under:

FY 2018-19	2019-20
Rs. 10.89 Crore	6.22 Crore

3.20 Regarding the response from the industry for the modified scheme, the Department in its written reply stated as under:

"For the modified scheme proposals from Indumati Pharma Pvt. Ltd (Pune), Maharashtra, Marathwada Pharma Cluster (Aurangabad), Maharashtra, Himachal Drug Manufacturers Association (Baddi), Himachal Pradesh and M.P. Small Scale Drug Manufactures Association (Indore), Madhya Pradesh have been received. In-principle approval was given to Indumati Pharma Private Limited, Pune."

(b) Assistance to Bulk Drug Industry for Common Facility Centre and Assistance to Medical Device Industry for Common Facility Centre:

3.21 Two new Schemes viz (1) Assistance to Bulk Drug Industry for Common Facility Centre (2) Assistance to Medical Device Industry for Common facility Center have been launched and these are in their initial stages of their implementation. The performance of these two schemes is being closely monitored by the Scheme Steering Committee (SSC) as per the scheme guidelines. Evaluation of these two schemes will be done in due course.

3.22 Regarding the salient features of the scheme Assistance to Bulk Drug Industry for Common Facility Centre and its difference from Assistance to Pharma Industry for Common Facilities, the Department in its written reply stated as under:

"The scheme for 'Assistance to Bulk Drug Industry for Common Facilities' aims at providing financial assistance for creation of common facilities in any upcoming Bulk Drug Park promoted by State Governments/State Corporations. The Scheme would be implemented through a one-time grant-in-aid to be released to a State Implementing Agency (SIA) set up for the purpose. Some of the indicative activities under the Common facilities include Effluent Treatment Plants, Captive Power Plants, Steam and Cooling systems, Incubation facilities, Common logistic facilities, Advance common testing Centre, Regulatory awareness facilitation Centre and Emergency Response Centre. A total of Rs. 200 Crore has been earmarked for the scheme. The maximum limit for the grant in aid under this category would be Rs. 100 Crore per Bulk Drug Park CFC or 70% of the project cost of CFC whichever is less.

On the other hand, under the scheme 'Assistance to Pharma Industry for Common Facilities' financial assistance is provided for creation of identified infrastructure and common facilities. The Scheme would be implemented on a Public Private Partnership (PPP) format through one-time grant-in-aid to be released in various to a Special Purpose Vehicles (SPVs) set up for the purpose. All the Pharmaceuticals units are eligible to from SPV under this scheme and create common facilities.

Availing the common facilities at the Bulk Drug Park will help reduce the cost of production for the bulk drug being produced by the member units of the park and the increased production at the Park will help reduce the dependence on import of Bulk drug."

3.23 On being asked about the effective steps that are being taken to spread awareness about the benefits of the scheme 'Assistance to Bulk Drug Industry for Common Facilities' among entrepreneurs of Pharma Industry and the response of the industry, the Department in its written reply stated as under:

"Department has written to all the states in the country to avail of the benefits of the scheme. Also, Department of Pharmaceuticals organized a full day workshop on the Department's Scheme for Development of Pharmaceuticals Industry on 30.11.2018 at NIPER Hyderabad (Balanagar, Medchal, Malkajgiri, Hyderabad-500037) for awareness generation on the Scheme amongst the Stakeholders. Further, the department made a presentation on schemes in meeting of Forum of Pharma Associations held on 23.08.2019 and suggestions/ views comments were invited from Pharma Industry Associations for further improvement and effective implementation of the scheme. So far, department has received proposals from the state Governments of Andhra Pradesh, Assam, Telangana and Himachal Pradesh. In-principle approval has been given to Assam and Andhra Pradesh. Telangana and Himachal Pradesh have been asked to make presentation of their proposals."

3.24 Similarly, the Committee also asked about the salient features of the scheme Assistance to Medical Device Industry for Common Facility Centre. The Department in its written reply,-

"The main features of the sub-scheme are as under:

(a) Financial assistance to the tune of Rs.25 Crore or 70% of the project cost of CFC whichever is less may be provided for creation of common facilities under any upcoming Medical Device Park promoted by State Government/State Corporations.

(b) The Scheme would be implemented through a one-time grant in-aid to be released to a State Implementing Agency (SIA) set up for the purpose. Some of the indicative activities under the Common facilities include Component Testing

Centre, Electromagnetic interference laboratory, Biomaterial / Biocompatibility testing centre, Medical grade low vacuum moulding, Cabinet moulding injection moulding centers, 2D designing and printing for medical grade products, Sterilization and Toxicity testing centre, Radiation testing centre, etc

(c) The total size of the scheme is proposed as Rs.100 Crores for 2018-2020. The maximum limit for the grant in aid under this category would be Rs. 25 crore per Medical Device Park CFC or 70% of the project cost of CFC whichever is less.

(d) In-principle approval for a project will be accorded by the Scheme Steering Committee (SSC) based on preliminary proposal submitted by the SIA/State Government covering the major features of the proposed project and availability of land. Such in-principle approval will be valid for a period of 6 months from the date of approval. In this time, the proposal should become ready for final approval.

(e) Based on the DPR and the nature of the project, detailed guidelines in respect of implementation of the project and subsequently release of funds by the Department, will be prepared by the SIA and approved by the SSC in the specified manner.

This sub-scheme has been meant to boost manufacturing of medical devices in the country.

3.25 When the Committee asked regarding the justification for allocation of only 0.02 crore has been for these Schemes, the Department in its written reply stated as under:

"Both these being new schemes only token amount has been allocated in Demand for Grants. However, proposals have been received in both these schemes. Since both these sub-schemes are under Umbrella Scheme, funds may be utilized from the other sub-schemes. Additional funds will also be sought at RE stage."

3.26 During oral evidence, the Committee specifically enquired whether the allocation of only Rs. 2 lakh is adequate to implement the important sub-scheme of Assistance to Medical Device Industry for Common Facility Centre", the Secretary of the Department replies as follows:-

"Madam you are very right, as far as medical devices are concerned, the health care facilities are evolving very fast. Now because of National Health Mission, most of the States have come up with various policies and programmes in order to help the poor if they want to go for stent or knee implant or other things. The testing facilities have also improved. So, we require a lot of medical devices. As far as drugs are concerned, we are in a competitive age. There is a huge demand in India of medical devices. So, we have to import them. We are also exporting medical devices worth Rs. 14400 crore but our import is worth Rs. 37800 crore. So, we need to reverse this situation and for that naturally this scheme has come up. But this scheme has not taken up.

Madam, in the last meeting I had told you that in principle approval has been given to four. We will be doing hand-holding with the State Government. The instruments, laboratories and the testing facilities are very expensive. The big people can afford them but MSMEs cannot afford them. If we want to reduce the dependence on imports, we need to give them those facilities. That is why, we would provide the Common User Facility in a pack at one place so that they do not have to go too far off places. In some cases, you may have to go to Mumbai. In this regard, the Government of Andhra Pradesh has done an excellent project. Under this project, they have put up facilities to the extent of Rs. 220 crore and are drawing the support from various Ministries. We are also financing them. They have already got a lot of units and more units will come. Japan is also showing interest in investing in this. So, if you have facilities, people will come. Take, for example, RMI facilities In India. We do not have that kind of facility. At present, we are 100 per cent dependent on China. So that facility is also coming which we are financing. Madam, I agree that we need to concentrate on this scheme. This year we will be making enough provision and we will make it successful".

(c) <u>Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS):</u>

3.27 The objective of this sub-scheme is to facilitate Small and Medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to World Health Organization (WHO)/Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets. Assistance in the form of interest subvention against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private sector will be provided to 250 pharma SMEs of proven track record. The Scheme is implemented through a Public Sector Financial Institution (PSFI) to be identified by the Government. A total of Rs.144 crore has been earmarked for the scheme. The upper limit of interest subvention on loans for technology/infrastructure upgradation shall be restricted to 6% per annum for a period of three years on reducing balance basis. The maximum loan eligible for this purpose will be Rs. 4 crore, availed by the concerned SME.

3.28 On being asked about the reasons for delay in identifying the implementing agency and the steps that are being taken to identify the agency in a time bound manner, the Department stated that an advertisement was given earlier to select a public sector financial institutions as no offers were received, SIDBI is being approached again.

CHAPTER IV

PUBLIC SECTOR UNDERTAKINGS

4.1 There are five Central Public Sector Enterprises (CPSEs) under the administrative control of the Department of Pharmaceuticals. Of the five PSUs, two viz. Indian Drugs & Pharmaceuticals Limited(IDPL) & Hindustan Antibiotics Limited (HAL) are sick. Rajasthan Drugs & Pharmaceuticals Limited (RDPL) has reported losses since 2013-14 and is incipient sick. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are the profit making CPSEs.

4.2 The current financial status of IDPL, RDPL, HAL, BCPL and KAPL is as under:

(I) Financial Performance of IDPL for three years:

(Rs. In crore)

		2016-17	2017-18	2018-19
1.	Net Worth	-7,302.79	-7,464.66	-7,624.18
2.	Turnover (Gross)	74.79	39.16	33.96
3.	Earnings (Before Tax)	-3.91	-16.85	-13.25
4.	Earnings (After Tax)	-3.91	-16.85	-13.25
5.	Net Profit/Loss	-153.38	-164.57	-159.22

(II) Financial Performance of RDPL for three years:

(Rs. In crore)

		2016-17	2017-18	2018-19
1.	Net Worth	-39.53	-54.78	-69.88
2.	Turnover	7.66040	-0.40	-0.14
3.	Earnings (Before Tax)	-14.88	-15.25	-15.10
4.	Earnings (After Tax)	-14.88	-15.25	-15.10
5.	Net Profit/Loss	-14.88	-15.25	-15.10

(III) Financial Performance of HAL for three years:

(Rs. In crore)

		2016-17	2017-18	2018-19
1.	Net Worth	-566.54	-358.60	-430.58
2.	Turnover	10.73	35.21	66.85
3.	Earnings (Before Tax)	-78.24	- 68.58 *	-71.10
4.	Earnings (After Tax)	-78.24	- 68.58 *	-71.10
5.	Net Profit/Loss	-78.24	- 68.58 *	-71.10

* There is a Net Profit of Rs. 208.32 cr. as a result of an extra-ordinary item of income, viz, waiver by Govt. of India of its plan & non-plan loans of Rs. 186.96 crores and the interest therein of Rs. 89.94 crores Totaling Rs. 276.90 Crores minus Operational Loss of Rs.68.58 crores.

(IV) Financial Performance of BCPL for three years:

(Rs. In crores)

		2016-17	**2017-18**	**2018-19**
1.	Net Worth	-102.10	-92.04	-66.78
2.	Turnover	85.36	78.01	100.50
3.	Earnings before pay Gross Margin (PBDIT)	24.05	24.23	32.83
4.	Earnings after pay Gross Margin(PBDIT)	24.05	24.23	32.83
5.	Net Profit	4.51	10.06	25.26

(V) Financial Performance of KAPL for three years:

(Rs. In crores)

	2016-17	**2017-18**	**2018-19**
Production	405.51	366.82	411
Sales Turnover	386.27	353.83	376
Operating Profit	43.35	20.59	16.50
Net Profit	30.33	14.55	19.00

4.3 On 22.10.2019, During oral evidence on Demands For Grants, 2019, the Secretary, Department of Pharmaceuticals in formed the Committee during power point presentation about the Following Cabinet decisions on closure/strategic sale of Public Sector Undertakings:

- Cabinet on 28.12.2016 decided for:
  - Sale of surplus land of HAL, IDPL, RDPL and BCPL to Government agencies.
  - Meeting liabilities from proceeds of surplus land and thereafter IDPL & RDPL be closed and HAL & BCPL sold strategically.

- Cabinet on 17.07.2019 decided for:
  - Modifying the earlier decision and permitting sale of land as per revised DPE's guidelines dated 14.06.2018
  - Providing budgetary support of Rs. 330.35 cr. for meeting the employees liabilities (Unpaid salary + VRS) for IDPL, RDPL & HAL employees.
  - Constitution of a Committee of Ministers for taking all decisions pertaining to closure/ strategic sale including the sale of assets and clearance of outstanding liabilities.

4.4 The Secretary further informed the Committee that follow up action in pursuance of Cabinet decision is being taken. In this regard, when the Committee asked for reasons for closing the PSUs, The Secretary informed the Committee during oral evidence as under:

"Sir, IDPL and HAL, including RDPL, are making huge losses. About the HAL, the decision has been taken to go for a strategic sale which means that its plant and machinery will be sold to a manufacturer through a competitive bid. As far as IDPL and RDPL are concerned, we are supposed to go for a closure which means that we will have to sell off their assets and meet the liabilities."

4.5 The Committee further enquired about the settlement of dues of employees in case of closure of PSUs. The Secretary informed the Committee during evidence as follows:

"Already the Cabinet has taken a decision that they should be paid off. So, we had moved the file to the Finance Ministry. They have asked us to make the necessary provision in the RE and we have already made that provision. We have also requested them to give us a one-time grant so that we can pay the salaries and their other dues even before the RE is approved."

4.6 The Committee also asked about the status of disinvestment of HAL and BCPL as decided by the cabinet, the Department in its written reply stated as under:

"The Cabinet had decided for strategic sale of HAL and BCPL after meeting their liabilities from sale of their surplus land to government agencies. In pursuance of the Cabinet decision, the Department has constituted Evaluation Committees for both the companies on 31.01.2017. Department of Investment and Public Asset Management (DIPAM) has also constituted Inter Ministerial Group (IMG) on 16/17.03.2017. DIPAM has subsequently informed the Department on 14.12.2017 that after sale of land and settlement of liabilities of these PSUs as per the Cabinet decision, the Core Group of Secretaries on Disinvestment (CGD) would be apprised in the matter to give its recommendation to the CCEA on the report of NITI Aayog on the mode and quantum of the strategic disinvestment as also the valuation methodologies. The process can, thus, move ahead only after sale of land of the PSUs. Subsequently, the Cabinet on 17.07.2019 has decided that land of the PSUs be sold as per DPE's guidelines dated 14.06.2018. The Department is taking follow up action for expeditious implementation of the Cabinet decision."

4.7 When the Committee asked about the reasons for sale of BCPL, Secretary, Department of Pharmaceuticals stated as under during oral evidence:-

"We have already taken a decision to go for strategic sale. At present, there is a stay of the High Court. So, the matter stands there".

4.8 The Committee were also informed about the strategic disinvestment of KAPL with the approval of the Cabinet Committee on Economic Affairs on 01.11.2017 based on the recommendation of NITI Aayog. In this regard the Committee were of unanimous view that this profit making PSU may not be disinvested and urged the representatives of the Ministry to convey the views of the Committee to the NITI Aayog.

4.9 In regard to above views of the Committee, the Department stated as under:

"The Department agrees with the views of the Committee regarding disinvestment of KAPL. In this regard, it is submitted that the Department has not supported the proposal to disinvest KAPL at any stage, it being a profit making company since inception; would be the only Central Pharma PSU left after closure/ sale of the other four PSUs; its role in supply of generic medicines under various Government programmes; need to have at least one pharma PSU for supply of essential medicine during time of natural calamities, other exigencies & outbreak of epidemics etc.

In view of the judgement/ order of High Court of Himachal Pradesh, it was subsequently decided to entrust the responsibility to KAPL to be the sole manufacturer and distributor of "Oxytocin" for domestic consumption. M/o H&FW issued notification in this regard on 27.04.2018 prohibiting private sector companies from manufacture of Oxytocin for domestic consumption. The same has, however, been quashed by High Court Delhi vide its order dated 14.12.2018. Matter is presently pending in the Supreme Court.

The matter has been taken up number of times at the level of Minister (Chemicals & Fertilizers) with Minister of Finance and Vice Chairman, NITI Aayog for reconsideration of the decision in view of KAPL being directed to create manufacturing facilities for production of Oxytocin, amongst other reasons.

It has been decided to keep the strategic disinvestment of KAPL on hold till the decision of Court. The Government has informed the Court that the decision of disinvestment will not materialize if the Government's scheme of manufacturing of Oxytocin through Public Sector receives a confirmation of the higher court."

4.10 During the oral evidence of the representatives of the Department of pharmaceuticals, the Committee raised the issue of strategic sale/disinvestment of profit making PSUs viz. BCPL and KAPL, to this Secretary Pharmaceuticals responded as under:

"It is the general policy of PSUs that they should either be disinvested or closed or put on strategic sale. Actually, our department's view was slightly different with regard to BCPL and KAPL……. On KAPL and BCPL, we have our view that these should be continued."

Kommentar [P1]: fd

4.11 Subsequently, another representative of the Department also seconded the views given by the Secretary of the Department which is as under:

"As Secretary Sir has said, KAPL is a different case. For other four PSUs the Department had gone to the Cabinet for their decision. KAPL was all along a profit-making unit. So, we never went for its closure or sale. Actually, the NITI Aayog had set up a Committee to recommend for the sale, closure or disinvestment of all the PSUs. The NITI Aayog had basically categorised all the PSUs in the country. They set different parameters on the basis of which an industry can be categorised as a priority sector or not. Pharma sector they said is not a priority sector. As we have shown in our initial slide, we are the pharmacy of the world. The private pharma sector has grown so much in the country. About 50 per cent of the production is being done by the industry. So, the NITI Aayog felt that even a profit-making pharma unit should be sold strategically.

In the KAPL case, the Department had not gone to the Cabinet. On the basis of recommendations of NITI Aayog, DIPAM has gone to the CCEA and they had made the recommendations. When the comments were sought from the Department, before going to the CCEA and even after CCEA recommendation, we at the level of Minister had always opposed disinvestment of KAPL. Subsequently, KAPL has been assigned the responsibility of being the sole manufacturer and distributor of oxytocin in the country. On the basis of that, the Ministry of Health and Family Welfare had issued a notification and suspended the licence of all the private manufacturers who were producing oxytocin. The private manufacturers had gone to the court and the notification of the Ministry of Health and Family Welfare was quashed. The Ministry has again gone to the court and the matter is before the Supreme Court. The Government has given an undertaking that in case the decision to manufacture oxytocin continues with KAPL, the Government would not go ahead with disinvestment of KAPL. This is the present status. The matter is presently in the court."

CHAPTER-V

STATUTORY BODY - NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPER)

5.1 NIPERs are institutions of national importance which imparts postgraduate and doctorate education and conduct research in various streams of Pharmaceutics. Presently, there are 7 NIPERs at Mohali, Guwahati, Ahmedabad, Hajipur, Raebareli, Kolkata and Hyderabad.

5.2 Further the Department in its written reply also stated that NIPER Mohali was the first Institute set up in the year 1998 and it has its own campus, regular faculty and well equipped labs. Other six NIPERs were set up in the year 2007-08 with mentor institutes. They had only one regular post, that of Director. Other faculty and administrative posts were on contractual basis.

Since then, land for all the NIPERs have been allotted by the State Governments concerned. Posts of Directors in all NIPERs have been filled up. The Board of Governors (BoG) of individual NIPERs have been constituted. Regular faculty and administrative posts created, their recruitment rules finalized and process of filling up initiated. The posts are likely to be filled up by December, 2019.

5.3 The Department in its written reply provided the following details of progress made in creation of building and technical infrastructure during last financial year 2018-19, is as under:

> **"**All NIPERs have been allotted land for construction of their regular campus. As of now, about 90% construction of campus of NIPER Guwahati has been completed. NIPER Ahmedabad has finalized the design of campus and recently issued tender. The construction of campus would commence by January, 2020, subject to provision of additional funds by Ministry of Finance. In case of other NIPERs, though EFC has decided to defer construction till March, 2020, the individual Institutes have been advised to take steps to finalize drawings of their campus so that the construction of campuses can commence immediately on approval of EFC. Department has constituted a Common Purchase Committee of all NIPERs for purchase of high end equipment common to NIPERs so as to have uniform standards and competitive rates. NIPER wise details of funds spent on infrastructure, equipment and construction during FY 2018-19 is as under:

(Rs. In crore)

NIPER	Infrastructure	Equipment's	Construction
Ahmedabad	1.50	1.50	-
Guwahati	0.30	3.70	24.00
Hajipur	0.60	2.85	-
Hyderabad	-	4.00	-
Kolkata	-	5.00	-
Raebareli	1.90	3.10	-
Total	**4.30**	**20.15**	**24.00**

5.4 Year-wise budgetary allocation and actual expenditure incurred by NIPERs since 2016-17 is given below:-

(Rs. In crore)

Name of Scheme	2016-17			2017-18			2018-19			2019-20	
	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE	Actual as on 30.9.2019
NIPERs	127.48	127.48	127.48	127.73	151.66	180.77	135.0	135.0	135.0	150.0	96.44

5.5 Regarding the amount sanctioned by expenditure Finance Committee (EFC) for strengthening of NIPERs, the Department in its written reply stated as under:

> "EFC has recommended continuation and strengthening of the six NIPERs, namely, Guwahati, Gandhinagar, Hyderabad, Hajipur, Kolkata and Raebareli during the period 2017-18 to 2019-20 at a total cost of Rs. 959.53 cr. Out of which EFC has recommended Rs. 103.88 cr. each for construction of regular campuses of NIPERs (Ahmedabad and Guwahati); Rs. 100.00 cr. each for equipping of labs of NIPERs (Ahmedabad, Guwahati and Hyderabad) and @ Rs,55.00 cr. each for (NIPERs, (Hajipur, Kolkata and Raebareli)."

5.6 Further, when the Committee asked that the allocated amount of Rs. 150 crore is sufficient to meet the needs of NIPERs during 2019-20, the Department in its written reply stated as under:

> "Department had sought Rs. 250.00 cr. for seven NIPERs in BE 2019-20. However, Ministry of Finance has allocated Rs 150.00 in BE 2019-20 to NIPERs. The financial allocation is not adequate to achieve the targets. Department has subsequently sent a request to Ministry of Finance to allocate Rs 300.00 crore as approved in EFC (Rs 25.00 cr. in GIA- General) urgently to fill up the regular posts of faculty and non-faculty in six NIPERs and Rs 275.00 cr. for purchase of equipment's and machineries for six NIPERs and completion of the construction of NIPER Guwahati campus and starting of construction of NIPER Ahmedabad campus."

5.7 In this regard, the Secretary, Department of Pharmaceuticals further informed the Committee during oral evidence on Demands for Grants 2019-20 of the Department as follows:-

> "As I told you, we are going to the EFC again that we should be allowed to put up the full-fledged campuses in all the remaining NIPERS. Because if we do not have the campus, then we cannot do the justice to the very mandate which has been given to us".

5.8 When the Committee asked about the response of Ministry of Finance over allocation of the entire amount sanctioned by EFC for NIPERs, the Department in its written reply state as under:

" EFC in its meeting held on 26.03.2018 approved Rs. 959.53 crore for a period 2017-18 to 2019-20. During FY 2017-18, an amount of Rs. 180.77 cr. was released for NIPERs. During FY 2018-19, an amount of Rs. 135.00 cr. was released to NIPERs. In the FY 2019-20, an amount of Rs. 150.00 cr has been allocated. Subsequently, recently, the Department has sent a request to Ministry of Finance to allocate additional Rs 300.00 cr. As mentioned above, the proposal is pending with the Ministry of Finance."

5.9 Further, during the oral evidence of the representatives of Department of Pharmaceuticals, the Secretary of the Department also submitted before the Committee that each NIPERs need approximately Rs. 200 to 250 crore for complete construction of building and world class research laboratories in each campus.

5.10 On being asked about the status of Internal Extra Budgetary Resources (IEBR) of National Institute of Pharmaceutical Education and Research (NIPERs), the Department in its written reply stated as under:

(Rs. In crore)

Head	**Mohali**	**Ahmedabad**	**Raebareli**	**Hajipur**	**Kolkata**	**Hyderabad**	**Guwahati**
Internal Resources	7.35	1.31	0.67	0.64	1.20	2.60	0.93
Others	NIL	NIL	NIL	0.0074	NIL	NIL	0.10
Total	**7.35**	**1.31**	**0.67**	**0.6573**	**1.20**	**2.60**	**1.03**

5.11 With regard to the reasons for low generation of Internal Extra Budgetary Resources (IEBR) by NIPERs particularly Raebareli, Hajipur and Guwahati except for NIPER Mohali and Hyderabad, all other NIPERs generate major part of their internal resources through fees from students and minimal amount from consultancy. Most of the Institutes are lacking infrastructure such as equipment's/machineries. NIPER Raebareli, Hajipur and Guwahati have fewer students as compared to other NIPERs, so the IEBR generated by them is low. Further, these Institutes lack well equipped labs, which is also a source for generation of revenue by other NIPERs.

5.12 Steps that are being taken by the Ministry to enhance the Internal Extra Budgetary Resources (IEBR) of all NIPERs, the Department in its written reply stated as under:

" EFC has sanctioned Rs. 103.88 crore each for construction of regular campuses of NIPERs at (Ahmedabad and Guwahati); Rs. 100.00 crore each for equipping of labs of NIPERs at (Ahmedabad, Guwahati and Hyderabad) and @ Rs.55.00 crore each for NIPERs at Hajipur, Kolkata and Raebareli. Department of Expenditure has also approved Regular posts of faculty and other administrative staff in six NIPERs. It is expected that after creation of adequate infrastructure and appointment of regular faculty, NIPERs will generate more resources. Department has sought Rs. 300.00 crore. (out of Rs.960 crore approved by EFC) crore from Department of Expenditure so that adequate infrastructure could be created in each NIPER.

In a meeting held under the chairmanship of Secretary on 19.09.2019, all NIPERs have been directed to ensure that proactive steps be taken for attaining self-sufficiency and generation of part of the operating expenses, as decided earlier by the Steering Committee. It was further decided that the Institutes should take steps to revise the tuition fees annually and as far as feasible recover charges of other facilities provided to the students. It was decided that individual NIPERs should take steps to develop academic industry linkages. Further, they should start short term certification courses for the industry, professional and other stakeholders. NIPERs should also undertake project and consultancies and permit industry to use their high-end equipment on payment of user charges. The Institutes were advised about the need for admission of foreign students for generation of revenue. They were also directed to prepare a vision document on generation of IEBR for presentation before the Hon'ble President of India during the Visitor's Conference to be held in January, 2020. Further, a Committee has been set up to examine the matter and submit its report within one month on different ways of generating IEBR after consulting various stakeholders."

5.13 On being asked about the present status of setting up of new NIPERs at Tamil Nadu (Madurai), Chhattisgarh, Maharashtra and Rajasthan, the Department in its written reply stated as under:

"EFC in its meeting dated 26.03.2018 had decided to defer the setting up of four new NIPERs: at Madurai and in the states of Rajasthan, Chhattisgarh and Maharashtra up to March, 2020, i.e. next Finance Commission period. The Department will take up the matter with Department of Expenditure in due course."

5.14 Regarding NIPER-wise details about financial allocation made for the propose during 2019-20, the Department in its written reply stated that since setting up of new NIPERs was deferred, no financial allocation was made and also stated that no time frame has been set by the Department/Ministry for setting up of these NIPERs.

5.15 Regarding the status of implementation of four new NIPERs proposed at Madurai, Maharashtra, Rajasthan and Chhatisgarh, the Secretary Department of pharmaceuticals during oral evidence stated as under:

"Actually, a decision was taken by the EFC last year that first, we should consolidate the working of the present NIPERs and then, we should go back to the Finance Ministry. We have decided to move for the remaining places also. They have told us that we should first consolidate the present NIPERs till March, 2020."

In this regard, another representative of the Ministry stated during evidence, "So, we will be going back to Finance Commission for these four NIPERs after March 2020".

5.16 Despite all these handicaps, as of now, three NIPERs – Mohali, Hyderabad and Ahmedabad are ranked as number 3, 6 and 9 respectively in the National Institutional Ranking Framework (NIRF) 2019 of the Ministry of Human Resource Development under ‘Pharma’ category. These Institutes have published more than 3500 Research papers and filed more than 200 patents.

NIPER Statutes have liberal provisions for contractual research and providing consultancy and technical services by faculty. With joining of regular faculty, they would be able to take advantage thereof. NITI Aayog has formulated an Output: Outcome based framework and review on quarterly/ annual basis the performance of NIPERs as per the specified indicators.

Expenditure Finance Committee (EFC) has sanctioned substantial amount for equipping of labs, which would help in research & development as well as act as source of revenue generation for NIPERs by providing the facilities to industry.

5.17 The Department in its preliminary material on Demand for Grants 2019-20 provided the details of Patents filed and Research Papers published by NIPERs which is as under:

Sl. No.	**NIPERs**	**Research Papers published**	**Patents filed**
1	Mohali	2386	187
2	Hyderabad	523	12
3	Kolkata	79	0
4	Guwahati	106	2
5	Raebareli	78	0
6	Ahmedabad	280	6
7	Hajipur	4	0
	Total	**3457**	**214**

5.18 The Committee observed that except Mohali, performance of all other NIPERs with regard to research papers published and patents filled is not up to the mark and asked for the reasons as well as concrete steps that are being taken/proposed to be taken in this regard, the Department in its written reply stated as under:

> "The figures provided in the table above are cumulative**.** NIPER-Mohali isfully operational since 1998 whereas other NIPERs became operational from 2007-08 onwards, that too with the help of Mentor Institutes. These new NIPERs are lacking the adequate infrastructure and regular academic and other staff. NIPER-Mohali has regular faculties while other NIPERs are running with the help of contractual faculty. Once regular faculties are appointed in other NIPERs and adequate infrastructure provided to them, the number of publication of Research Papers and filling of Patents will increase."

5.19 Further when the committee asked about NIPER-wise progress made with regard to Filling up of faculty posts, the Department in its written reply stated as under:

"NIPER Mohali has regular sanctioned posts. In other six NIPERs, the faculty posts have been created in January 2019 and the Recruitment Rules of all these posts have been framed with approval of the Competent Authority. NIPER Ahmedabad, Guwahati, Hyderabad, Kolkata and Raebareli have already issued advertisements for filling up of the posts. NIPER Hajipur is in the process of advertising the posts. NIPERs will fill up the posts as per recommendation of NITI Aayog and considering the Students Faculty Ratio 12:1. It is expected that all the posts will be filled by NIPERs by December 2019."

5.20 When the Committee asked about the composition of the Apex Council constituted to ensure coordination across all NIPERs as recommended by NITI Aayog, the Department in its written reply stated as under:

"Apex Council has been constituted under the Chairmanship of Secretary (Pharma) to oversee the common issues of the NIPERs. The composition of the Committee is as under:

i.	Secretary, Department of Pharmaceuticals	- Chairman
ii.	Chairpersons of BoG of all NIPERs	- Members
iii.	Directors of all NIPERs	- Invitees (where needed)
iv.	AS&FA, Department of Pharmaceuticals	- Member
v.	Joint Secretary, NIPER, DoP	- Member – Convener

Suitable amendment in NIPER Act will be made to include Apex Council in the Act under the Chairmanship of Hon'ble Minister (C&F) in line with IITs for implementation of the recommendation of NITI Aayog. The Department is in process of amendment of the NIPER Act."

CHAPTER-VI

INDEPENDENT BODY- NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

6.1 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.

6.2 During the oral evidence of the representatives of the Department of Pharmaceuticals before the Committee on 22.10.2019, the Committee raised the issue of price control of non-schedule drugs which is nearly 82 percent of domestic pharmaceutical market, the Secretary Department of pharmaceuticals stated as under:

> "We fix ceiling only for the essential drugs as notified by NLEM. As far as non-scheduled drugs are concerned, you are very right that the manufacturer can fix the price, but then he cannot increase it beyond 10 per cent per annum. This is what we monitor, but we agree that in non-scheduled drugs also there is a huge margin and we need to work on it. Already, we have received a Report and discussion is going on at various forums, and we will be taking appropriate decision in the times to come. But you are very right that we need to control the prices of non-scheduled drugs also."

6.3 The Chairman of NPPA further clarified in the matter as under:-

> "Actually, the Drug Pricing control Order 1995 existed prior to the Drug Pricing Control Order of 2013. This concept of a ceiling price is based on market averages has come in 2013. By doing that, we are regulating and giving ceiling price to almost 18.6 per cent of the entire pharma industry. But the remaining is the non-scheduled segment for which we have run this trade margin rationalization on anti-Cancer, and we have recommended to the Government that in phases we should also bring price rationalization on this so far unregulated market."

(a) Consumer Awareness Publicity and Price Monitoring (CAPPM)

6.4 CAPPM Scheme is being implemented by NPPA**.** The Scheme has two components, viz., Assistance to Price Monitoring Resource Units (PMRUs) and Advertising and Publicity with BE of Rs. 2.00 crore each.

6.5 Year wise plan activities along with expenditure incurred under Consumer Awareness Publicity and Price Monitoring **(**CAPPM) Scheme vis-à-vis BE and RE for last three years and BE for 2019-20 is given as under:

(Rs.In crore)

Sl. N.	Name of Scheme/ Programme	BE 2016-17	RE 2016-17	Actual Exp 2016-17	BE 2017-18	RE 2017-18	Actual Exp 2017-18	BE 2018-19	RE 2018-19	Actual Exp 2018-19	Prop BE 2019-20
1	Consumer Awareness through print, electronic and other media (renamed as Consumer Awareness, Publicity and Price Monitoring)	5.45	2.87	2.17	4.00	2.00	NIL	4.00	2.98	1.14	4.00
	Total	**5.45**	**2.87**	**2.17**	**4.00**	**2.00**	**Nil**	**4.00**	**2.98**	**1.14**	**4.00**

6.6 On being asked about the underutilization of the allocated funds under this scheme despite of public health welfare objectives of the scheme, the Department in its written reply stated as under

"Reasons for the year 2017-18

i. Under the Scheme named Consumer Awareness & Publicity and Price Monitoring (CAPPM), a sum of Rs.17.10 lakh was released to PMRUs in the financial year 2016-17. However, expenditure during the financial year 2017-18 could not be incurred due to issues in opening of a separate 15 digit numeric Head.

ii. The 15-digit Head was made functional only in March, 2018. Further, the Scheme was revised in March, 2018 due to which no fund could be released during the financial year 2017-18.

Reasons for the year 2018-19

i Under the first component of CAPPM scheme (Grant in Aid General), Government of India has initiated setting up of Price Monitoring and Resource Units (PMRU) at the States/ Union Territories that would provide all necessary support to the State drug Controllers and NPPA to trickle down to benefits of the DPCO, 2013 at the grass root level. PMRUs are societies registered under

Societies Registration Act having their own Memorandum of Association/ Byelaws.

ii In this connection, it may be stated that concerted efforts were made in the F.Y. 2018-19 for setting up of PMRUs in different States. A meeting with of the State Drug Controllers (SDCs)/ Food & Drug Administrators (FDAs) was organized at NPPA in Delhi in January, 2019. Besides this, reiteration was done with the SDCs/ FDAs in the Consultative Committee meeting of CDSCO of DCGI in Delhi. Social media was also used by regular communication and follow up through WhatsApp group of SDCs/ FDAs and information dissemination through twitter handle of NPPA was also used to impress upon the need of setting of PMRUs.

iii With regular and vigorous follow up, PMRUs in four States, viz., Kerala, Gujarat, Odisha and Rajasthan were set up towards the end of the year 2018-19. A sum of Rs. 1.14 crore got disbursed to these four States during the year under first component of the Scheme, i.e., 'Grant in Aid General'.

iv In the meantime, due to application of Model Code of Conduct (MCC) during the process of the Lok Sabha elections in 2019, the process of setting up of PMRUs in other States got delayed. Further, the process of setting up of PMRUs largely depends upon the preparedness and cooperation from the respective State Government and their respective State Drug Controllers/ Food and Drug Administrators.

v By the end of August, 2019 PMRUs in ten States have been registered as per the target set under the scheme for 2019-20 by SFC and also target set under 100 days' Plan of the Government of India. The Committee were further informed that in line with the five years' plan for the period from 2019-20 to 2023-24, the number of PMRUs to be set up during the year 2019-20 is being increased to 12 and in all States/ UTs by 2023-24 by modifying the Scheme.

vi Under the second component of the CAPPM scheme, viz., 'Advertising and Publicity' Rs.1.49 crore at RE stage could not be utilised due to the following reasons:

a. Time taken in the process of getting clearance for release of advertisements in newspapers and short video spot due to application of Model Code of Conduct (MCC) before General Elections 2019.

b. Non-receipt of bills towards Radio Jingles aired during the year through DAVP."

6.7 Further, when the Committee asked about the system of monitoring and control over the performance of the Consumer Awareness Publicity and Price Monitoring (CAPPM), the Department in its preliminary material on Demand for Grants 2019-20, stated as under:

"NPPA is implementing the scheme in coordination with State Drug Controllers of respective States where the PMRUs has been recently registered. The performance of PMRUs is being closely monitored by NPPA under the Scheme guidelines and by Secretary, Department of Pharmaceuticals. The progress of utilization of funds is also being continuously monitored at regular intervals by senior officers of department. Revenue expenditure is monitored at the level of Secretary, Department of Pharma in Co-ordination meetings convened twice a month, as also on a case to case basis. Targeted activities are broken upto into individual timelines of achievements; hurdles identified and pace of expenditure speeded up under various Revenue Schemes. Timely obtaining of requisite Appraisal/Approval from concerned agencies i.e NITI Aayog, Department of Expenditure, convening of EFC meetings etc is speeded up."

6.8 During oral evidence, the Secretary, Department of Pharmaceuticals further informed the Committee as under when the Committee asked about the steps taken to set up PMRUs in all states:-

"We have them in Kerala, Gujarat, Odisha, Rajasthan, Haryana, Nagaland, Tripura, Uttar Pradesh, Punjab and Himachal Pradesh. We have just started this scheme. This is a new scheme. We have started the scheme with first seven States. This year, we have approved ten. The NPPA now has proposed that it should be in all the States. So, we will be asking the Government for this remaining 31 also. We would like to do this in the Union Territories also because they are also full-fledged independent entities".

Kommentar [SS2]: FOLLOWED

RECOMMENDATIONS/OBSERVATIONS

RECOMMENDATION NO. 1

The Committee are constrained to note that only Rs. 235.51 crore could be allocated by the Ministry of Finance out of Rs. 398.05 crore proposed by the Department of Pharmaceuticals for the current financial year 2019-20. The proposed amount of Rs. 398.05 crore included Rs. 366.05 crore for Central Sector Schemes. In view of the curtailed allocation, the Department had to spread thinner allocation amongst its Central Sector Schemes totaling to Rs. 204.30 crore. In this regard, the Committee note the views expressed by the Department that the reduction in outlay would have an adverse impact on the implementation of various Schemes and will not be sufficient to achieve the targets fixed by the Department for its major Central Sector Schemes. As per the details given by the Department, development of National Institute of Pharmaceutical Education and Research (NIPER), implementation of Umbrella Scheme of Development of Pharmaceutical Industry and also the Pradhan Mantri Bhartiya Janaushadi Pariyojana (PMBJP) are likely to be affected due to reduced allocation of funds. Since it is a vital sector concerning health upkeep of the entire population of the country, the Committee strongly recommend that the Ministry of Finance should consider the proposals of the Department for allocation of funds to the various Central Sector Schemes of the Department and allocate requisite amount of funds for the Schemes of the Department at RE stage during 2019-20. The Department should also take up this matter at the highest level with the Ministry of Finance and this recommendation made by the Committee should be conveyed to that Ministry for necessary action at its level.

RECOMMENDATION NO. 2

The Committee appreciate that the guiding Principle of Bureau of Pharma Public Sector Undertakings of India (BPPI) which implements the important scheme of PMBJP to continuously strive to increase its revenue and decrease its operating cost so that it

sustain its operations through internal resources. During 2019-20, BPPI will approximately need Rs. 245 crore for running its operations. Out of this, it is in a position to generate Rs. 202.50 crore from its operations and only Rs. 42.50 crore is required by it as grant from the Government. The Committee while appreciating the efforts of BPPI to be completely self sustainable in the implementation of PMBJP, are of the firm view that the objective of the PMBJP to provide generic medicines at affordable prices to the people should not in any way diluted and therefore recommend that the Government should provide grants to BPPI till it completely attains its self-sustainability. Department should place its demand for additional fund requirements for implementation of PMBJP during 2019-20 with the Ministry of Finance for allocation of funds at RE stage and convey the views expressed by this Committee in this regard.

<u>RECOMMENDATION NO</u>. 3

The Committee are happy to note that 1200 PMBJP Kendras are proposed to be opened during 2019-20. Presently there are 5300 Kendras in 675 districts and target has been fixed for increasing the number of Kendras to 6500 in 723 districts during 2019-20. Likewise product basket of medicines is also proposed to be increased from 900 to 1200 during the year. In this regard, the Committee recommend that concrete steps should be taken to achieve the targets fixed for opening of PMBJP Kendras and to expand the product basket during the year as more Kendras with considerable product basket would benefit more people to get generic medicines at affordable prices. The progress made in this regard may be apprised to the Committee.

<u>RECOMMENDATION NO</u>. 4

The Committee note that the Department has requested the State Governments to allot space in Primary Health Centres with free electricity for opening PMBJP kendras in rural and remote areas including mountainous, hilly and tribal areas. The Committee recommend that sincere efforts should be made by the Department to convince the State

Governments to provide space in PHCs to open PMBJP kendras in rural, remote, hilly and tribal areas. Progress made in this regard should also be conveyed to the Committee.

RECOMMENDATION NO. 5

The Committee note that presently on an average 8 PMBJP Kendras are functioning in a district and this may be increased to 9 kendras in a district by the end of the year. In Committee's view, this number of PMBJP kendras may not be sufficient to meet the lofty ideal of the Scheme to provide quality generic medicines at affordable prices to the people as it would be difficult to people to travel long distances in search of a PMBJP kendra particularly when they are in urgent need of medicines. The Committee, therefore, recommend to open more PMBJP kendras in every district in the country so as to benefit more number of people.

RECOMMENDATION NO. 6

The Committee are concerned to note that the Umbrella Scheme of the Department namely "Scheme for Development of Pharmaceutical Industry" largely remains non-starter due to various issues involving implementation of the Scheme. This is a Central Sector Scheme with a total outlay of Rs. 480 crore for a three year period from 2017-18 to 2019-20. About Rs. 4.64 crore has only been spent during the period from 2017-18 to 2018-19 and an allocation of Rs. 8.29 crore has only been made for 2019-20. This Scheme includes five sub-schemes viz. Assistance to Pharmaceutical Industry for Common Facilities (APICF); Assistance to Bulk Drug Industry for Common Facility Centre; Assistance to Medical Device Industry for Common Facility Centre ; Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS); and Pharmaceutical Promotion and Development Scheme (PPDS). The Committee find that only token allocation of Rs. 1 lakh has been made for the sub-schemes of Pharmaceuticals Technology Upgradation Assistance Scheme, Assistance to Bulk Drug

Industry for Common Facility Centre and Assistance to Medical Device Industry for Common Facility Centre during 2019-20. These schemes are running into third year of their implementation and still only token allocation has been made for 2019-20. Since it is the flagship scheme of the Department aimed at overall development of the Pharmaceutical industry, the Committee recommend the following:-

(i) Immediate and effective steps should be taken by the Department for actual implementation of these schemes from the current financial year onwards. The progress made in this regard should be conveyed to the Committee on each of the sub-scheme.

(ii) Third Party evaluation of all sub-schemes should be conducted and corrective steps should be taken based on the evaluation for flawless implementation of the Schemes. Similarities in the sub-schemes may also be studied for suitable action.

(iii) Fresh proposals have come under the sub-schemes. All these proposals should be scrutinized as per scheme guidelines and timely approvals should be accorded on these proposals. Since budgetary allocation of only Rs. 8.30 crore has been made for the entire umbrella scheme, funds required for implementation of the sub-schemes should be obtained at RE stage during 2019-20. Scheme-wise details of action taken in this regard should be furnished to the Committee within three months.

(iv) Immediate steps should be taken for implementation of the important Sub-scheme "Pharmaceuticals Technology Upgradation Assistance Scheme. The process of selection of a Public Sector Financial Institution to implement the Scheme should be expedited and the progress made in this regard should be conveyed to the Committee in the Action Taken Replies.

RECOMMENDATION NO. 7

The Committee note that there are five Central Public Sector Enterprises (CPSEs) under the administrative control of the Department of Pharmaceuticals. Of the five PSUs, two viz. Indian Drugs & Pharmaceuticals Limited (IDPL) & Hindustan Antibiotics Limited (HAL) are sick, Rajasthan Drugs & Pharmaceuticals Limited (RDPL) has reported losses since 2013-14 and is incipient sick. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are profit making CPSEs. The Committee further note that IDPL, HAL and RDPL are making huge losses and the Government has decided to go for strategic sale of HAL which means its plant and machinery will be sold to a manufacturer through a competitive bid. As far as IDPL and RDPL are concerned, the Government propose to close these PSUs and to sell their assets to meet the liabilities. The Committee are concerned about the settlement of salary and other dues of the employees of these sick PSUs and in this regard, the Committee note that the Department has moved file to the Ministry of Finance to either make necessary provision in RE of 2019-20 or to provide one-time grant before RE so as to pay the salaries and other dues of the employees. The Committee strongly recommend that the Department should take concrete steps to settle the salaries and other dues of the employees of these PSUs by taking up at highest level in the Ministry of Finance to either provide one-time grant or make adequate provision in the RE of 2019-20. The concern expressed by this committee should also be conveyed to the Ministry of Finance. The committee should be apprised of the progress made in this regard within three months of the presentation of this Report.

RECOMMENDATION NO. 8

In regard to other two profit making PSUs, the Committee note that the Government has decided to go for strategic investment of KAPL and strategic sale of BCPL. However, these processes are on hold due to court cases. In this regard, the

Committee note that the Department of Pharmaceuticals has not supported the disinvestment of KAPL at any stage as KAPL is a profit making PSU since its inception and the Department has acknowledged its role in supply of generic medicines under various Government programmes. BCPL is also producer of anti-snake venom which is not produced by other PSUs. It has also brought turnaround in profits during the last three years. In Committee's view, co-existence of public sector and private Sector and the healthy competition between them would result in production of quality medicines at prices affordable to the people. KAPL and BCPL are profit making PSUs and their presence may be necessary for the supply of essential medicines during the time of natural calamities, other exigencies and outbreak of epidemics, etc. Moreover, the presence of PSUs in this sector may provide a level playing field as far as the prices of medicines are concerned. If this sector is entirely left to Private sector, prices of medicines may be fixed by them at their will in the absence of competition from Public Sector enterprises. The Committee, therefore, recommend that the policy decision to disinvest/sale of KAPL and BCPL should be revisited in view of their strategic importance and instead they should be strengthened with modernization, diversification and superior technical know-how so as to enable them remain competitive in this crucial sector. The Committee are of the view that the policy decision of the Government should be based on facts and figures.

RECOMMENDATION NO. 9

The Committee note that there are seven NIPERs at Mohali, Guwahati, Ahmedabad, Hajipur, Raebareli, Kolkata and Hyderabad. Out of these only NIPER-Mohali, which was established in 1998, is fully operational and others which were operational since 2007-08 are functioning only with the help of Mentor Institutes. These new NIPERs are lacking infrastructure and regular academic and other staff. In this regard, the Committee are satisfied to note that in these six NIPERs, the faculty posts have been created in January 2019 and the Recruitment Rules of all these posts have been framed

by the Department. NIPER Ahmedabad, Guwahati, Hyderabad, Kolkata and Raebareli have already issued advertisements for filling up of the posts. NIPER Hajipur is in the process of advertising the posts. It is expected that all the posts will be filled by NIPERs by December 2019. Since more than a decade is over after creation of NIPERs at Guwahati, Ahmedabad, Hyderabad, Kolkata and Raebareli, the Committee recommend that faculty and other posts of these NIPERs should be filled by regular staff before December, 2019 and the Committee should be apprised about the progress made in this regard.

RECOMMENDATION NO. 10

The Committee also note that only NIPER at Mohali is functioning from its own premises and all other NIPERs have been allotted land for construction of their regular campus. As of now, about 90% construction of campus of NIPER Guwahati has been completed. NIPER Ahmedabad has finalized the design of campus and recently issued tender. The construction of campus would commence by January, 2020, subject to provision of additional funds by Ministry of Finance. In case of other NIPERs, though Expenditure Finance Committee has decided to defer construction till March, 2020, the individual Institutes have been advised to take steps to finalize drawings of their campus so that the construction of campuses can commence immediately on approval of Expenditure Finance Committee. The Committee are concerned to note that out of seven NIPERs, only NIPER, Mohali is having its own campus. Since NIPERs are institutions of national importance which imparts post graduate and doctorate education and conduct research in various streams of Pharmaceuticals, it is very much necessary that they have state of the art infrastructure and laboratory facilities. The Committee, therefore, recommend that immediate necessary steps should be taken by the Department for the construction of regular campuses for all the six NIPERs within a definite period of time.

RECOMMENDATION NO. 11

The Committee are further concerned to note that the Department had sought Rs. 250.00 crore for seven NIPERs in BE 2019-20. However, Ministry of Finance has allocated only Rs 150.00 crore to NIPERs. This financial allocation is not adequate to achieve the targets. The Committee also note that Expenditure Finance Committee in its meeting held on 26.03.2018 approved Rs. 959.53 crore for the period 2017-18 to 2019-20. However, only Rs. 465.77 crore has been allocated for the period. Recently, the Department has sent a request to Ministry of Finance to allocate additional Rs 300.00 crore including Rs 25.00 crore to urgently fill up the regular posts of faculty and non-faculty in six NIPERs and Rs 275.00 crore for the purchase of equipments and machineries for six NIPERs and completion of the construction of NIPER Guwahati campus and starting of construction of NIPER Ahmedabad campus and the proposal is pending with the Ministry of Finance. Since the fund allocation is very much necessary for full-fledged functioning of these NIPERs, the Committee recommend that the Department should take up this matter of additional requirement of Rs. 300 crore during 2019-20 for NIPERs at highest level with the Ministry of Finance for allocation of the funds at RE stage. This recommendation of the Committee may also be sent to that Ministry for its compliance.

RECOMMENDATION NO. 12

The Committee note that the setting up of four new NIPERs at Madurai, Tamil Nadu and in the states of Rajasthan, Chhattisgarh and Maharashtra has been deferred by Expenditure Finance Committee till March, 2020 so as to consolidate the present NIPERs first. In this regard, the Committee recommend that process of starting of these NIPERs should begin at the right earnest so that these States would also be benefitted of this institution of national importance.

<u>RECOMMENDATION NO</u>. 13

The Committee note that the main functions of NPPA include fixation and revision of prices of scheduled formulations under the Drugs Price Control Order (DPCO), 2013. Hence they are fixing prices of almost 18.6 per cent of the medicines manufactured by entire Pharma industry. Prices of rest of the medicines/drugs which are non-scheduled drugs are not controlled by NPPA. Manufacturer can fix the price but the same cannot be increased by 10 per cent per annum. In Committee's view, prices of non-scheduled drugs which comprises 81.4% of the medicines/ drugs sold in the country should also be controlled by NPPA. In this regard, the committee note the admission made by the Department that there is huge margin between the cost and price of non-scheduled drugs and they need to work on it. Since it is very much necessary to control the prices of non-scheduled drugs, the committee recommend that suitable mechanism should be devised by the Department of Pharmaceuticals and NPPA to control the prices of non-scheduled drugs so as not to pinch the purses of common man.

<u>RECOMMENDATION NO</u>. 14

The Committee note that 'Assistance to Price Monitoring Resource Units (PMRUs)' is one of the component of Consumer Awareness Publicity and Price Monitoring (CAPPM) scheme under which Government of India has initiated setting up of Price Monitoring and Resource Units (PMRU) at the States/Union Territories that would provide all necessary support to the State drug Controllers and National Pharmaceuticals Pricing Authority (NPPA) to trickle down benefits of the Drugs Prices Control Order (DPCO), 2013 at the grass root level. This Scheme is being implemented by NPPA. PMRUs are societies registered under Societies Registration Act having their own Memorandum of Association/ Bye Laws. The Committee note that 10 PMRUs have been established in the states of Kerala, Gujarat, Odisha, Rajasthan, Haryana, Nagaland,

Tripura, Uttar Pradesh, Punjab and Andhra Pradesh. The Department has fixed target for setting up two more PMRUs during 2019-20 and to cover all states/ Union Territories by 2023-24. In this regard, the Committee note that the process of setting up of PMRUs largely depends upon the preparedness and cooperation of the respective State Government and their respective State Drug Controllers/ Food and Drug Administrators. Since PMRUs will be helpful in monitoring prices of drugs at grass root level, the Committee recommend that concrete steps should be taken by the Department for the setting up of PMRUs in all the states/ UTs by 2023-24. In case of non-cooperation by any states/UTs, this matter may be taken at Chief Minister level by stating the benefits of the Scheme.

New Delhi;
10 December, 2019
19 Agrahayana, 1941 (Saka)

Kanimozhi Karunanidhi
Chairperson
Standing Committee on
Chemicals and Fertilizers

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

(2019-20)

The Committee sat on Tuesday, the 22nd October, 2019 from 1430 hrs. to 1630 hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT
Smt. Kanimozhi Karunanidhi- Chairperson

MEMBERS
LOK SABHA

2 Shri Prataprao Patil Chikhalikar
3 Shri Satyadev Pachauri
4 Shri Arun Kumar Sagar
5 Shri M. Selvaraj
6 Shri Pradeep Kumar Singh
7 Er. Bishweswar Tudu
8 Shri Prabhubhai Nagarbhai Vasava
9 Dr. M. K. Vishnu Prasad

RAJYA SABHA

10 Shri G.C. Chandrashekhar
11 Shri Ahmad Ashfaque Karim
12 Shri Vijay Pal Singh Tomar

SECRETARIAT

1.	Shri Manoj Kumar Arora	-	Officer on Special Duty(LSS)
2.	Shri A. K. Srivastava	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director

LIST OF WITNESSES

I. MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

1.	Shri P. D. Vaghela	Secretary
2.	Ms. Alka Tiwari	Additional Secretary & Financial Advisor
3.	Shri Navdeep Rinwa	Joint Secretary
4.	Shri Rajneesh Tingal	Joint Secretary

II. REPRESENTATIVES OF NPPA

1.	Smt. Shubra Singh	Chairperson, National Pharmaceuticals Pricing Authority (NPPA)
2.	Ms Ritu Dhillon	JS&MS (NPPA)

III *REPRESENTATIVES OF NIPER*

1.	Prof. A Raghuram Rao Akkinepally	Director (NIPER Mohali)
2.	Dr. Kiran Kalia	Director (NIPER Ahmedabad)
3.	Dr. Shashi Bala Singh	Director (NIPER- Hyderabad)
4.	Dr. Gayathri V. Patil	Director (NIPER- Hajipur)
5.	Dr. V. Ravichandiran	Director (NIPER-Kolkata)
6.	Dr. U S N Murty	Director (NIPER-Guwahati)
7.	Dr. S J S Flora	Director (NIPER-Rai Bareli)

IV. REPRESENTATIVES OF PSUs

1.	Ms. Nirja Saraf	MD, Hindustan Antibiotics Limited (HAL)
2.	Sh. P. M. Chandraiah	Managing Director, Bengal Chemicals and Pharmaceuticals Limited (BCPL)
3.	Shri Sachin Kumar Singh	CEO, Bureau of Pharma Public Sector Undertakings of India (BPPI)

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, Secretary of the Department of Pharmaceuticals made power point presentation to the Committee regarding Demands for Grants 2019-20 of the Department of Pharmaceuticals.

4. Power point presentation was followed by discussion on several aspects of Demands for Grants of the Department. During the discussion, the Hon'ble Chairperson and Members of the Committee raised queries on several issues such as:-

(i) Budget allocation and utilization of funds by the department;

(ii) Less allocation of funds for the umbrella scheme of Development of Pharmaceuticals Industry and the status of setting up of Common Facility Centre for Bulk Drug Industry, Medical Device Industry and Pharmaceutical Industry as well as implementation of Pharmaceuticals Technology up-gradation scheme;

(iii) Implementation of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' including lack of Jan Aushadhi Kendras in rural areas and efforts being made towards simplification of license procedure to open more Kendras in remote areas;

(iv) Efforts made by Bureau of Pharma Public Sector Undertakings of India (BPPI) towards opening more warehouses in the country and technology upgradation for correct forecasting of drug demand from various Jan Aushadi Kendras and bridging the demand supply gap of generic medicines and medical devices in these Kendras;

(v) Disinvestment of PSUs under the Department particularly the reasons for disinvestments of profit making PSUs viz. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL);

(vi) Functioning and performance of NIPERs in the country including the issues relating to filling up of Vacant faculty positions and administrative posts in various NIPERs and the status of the proposed NIPERs including NIPER, Madurai; and

(viii) Role of NPPA in drugs price control, monitoring as well as functioning of Price Monitoring Resource Units (PMRUs) established in ten states and their expansion in other states /UTs;

5. The Secretary, Department of Pharmaceuticals and other officials responded to the aforesaid issues raised by the Committee.

6. 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.

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

The Committee then adjourned.

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

(2019-20)

The Committee sat on Tuesday, the 10th December, 2019 from 1700 hrs. to 1730 hrs. in Committee Room B, Parliament House Annexe, New Delhi.

PRESENT

Ms Kanimozhi Karunanidhi- Chairperson

MEMBERS

LOK SABHA

2. Shri Ramakant Bhargava
3. Shri Prataprao Patil Chikhalikar
4. Shri Rajeshbhai Naranbhai Chudasama
5. Shri Satyadev Pachauri
6. Shri Pradeep Kumar Singh
7. Shri M. Selvaraj
8. Shri Uday Pratap Singh
9. Shri H. Vasanthakumar
10. Shri Prabhubhai Nagarbhai Vasava
11. Dr. M. K. Vishnu Prasad
12. Shri Deepak Baij
13 Dr. Manoj Rajoria

RAJYA SABHA

14. Shri G. C. Chandrashekhar
15. Shri Ahmad Ashfaque Karim

SECRETARIAT

1. Shri Manoj K. Arora - OSD
2. Shri A. K. Srivastava - Director
3. Shri C. Kalyanasundaram - Additional Director

2. At the outset, the Hon’ble Chairperson welcomed the Members of the Committee.

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

(i) Draft report on 'Demands for Grants 2019-20' (Department of Chemicals and Petrochemicals);

(ii) Draft report on 'Demands for Grants 2019-20' (Department of Pharmaceuticals; and

(iii) Draft report on 'Demands for Grants 2019-20' (Department of Fertilizers.

4. After deliberations the Draft Reports were unanimously adopted by the Committee without any changes/amendments.

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

The Committee then adjourned.