8	STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2019-20) SEVENTEENTH LOK SABHA

EIGHTH REPORT

DEMAND FOR GRANTS (2020-21) REPORT

LOK SABHA SECRETARIAT

NEW DELHI

March, 2020/ Phalguna, 1941-42 (Saka)

CC&F.No 8

DRAFT REPORT

STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS
(2019-20)

(SEVENTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2020-21)

Presented to Lok Sabha on 20 March 2020

Laid in Rajya Sabha on 20 March 2020

LOK SABHA SECRETARIAT

NEW DELHI

March, 2018/ Phalguna, 1941-42 (Saka)

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

Smt. 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	Shri Arun Singh$
29	Vacant
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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 Seventh Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2020-21.

The Committee examined the Demands for Grants (2020-21) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which were laid in Lok Sabha and Rajya Sabha on 11 February, 2020.

The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 28 February, 2020.

The Report was considered and adopted by the Committee at their sitting held on 18 March, 2020.

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;
18 March, 2020
28 Phalguna, 1941-42 (Saka)

Kanimozhi Karunanidhi
Chairperson
Standing Committee on
Chemicals and Fertilizers

PART-I

CHAPTER – I

INTRODUCTION

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 (2020-21) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 11 February, 2020. Rs. 333.58 crore is the Budget Estimate (BE) of Demand No. 7 pertaining to Department of Pharmaceuticals. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2020-21. The Observations/Recommendations of the Committee have been given in a separate chapter at the end of the Report. The Committee expects the Department to take all necessary steps for proper and timely utilization of funds ensuring completion of the various plans and projects in a time bound manner. The Committee also expects 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

OVERVIEW ON INDIAN PHARMACEUTICALS INDUSTRY

The history of modern Indian pharmaceutical industry dates back to the early Twentieth century, when heightened nationalism gave rise to greater interest in science. The foundation of two firms, which are still in existence today, marks the start of the modern pharmaceutical industry. One is Bengal Chemical and Pharmaceutical Work (BCPW) Ltd. (present Bengal Chemicals and Pharmaceuticals Ltd.) set up in Kolkata by Acharya PC Ray in 1901. The other is Alembic Chemical Works Company Ltd. in Vadodara by Prof. T K Gajjar, Prof. Kotibhaskar and B D Amin in 1907. Both the companies began an important shift from traditional methods to a more scientific approach to the discovery, development and manufacture of pharmaceuticals employing indigenous technology, skill and raw materials.

India's pharmaceutical industry has gradually evolved from almost nonexistent to a world leader in the production of high quality generic drugs. India has garnered a worldwide reputation for producing high quality, low cost generic drugs. The surge in production has been driven by legislative reforms, the growth in contract manufacturing and outsourcing, value added foreign acquisitions and joint ventures, India's mastery of reverse engineering of patented drug molecules, and India's efforts to comply with its World Trade Organization (WTO) Trade Related Intellectual Property Agreement (TRIPS) obligations.

The total size of the industry (drugs & medical devices) is around USD 43 Billion and it is currently having a growth rate of 7-8 % in drugs sector and 15-16 % in medical device sector. Total exports (drugs and medical devices) are to the tune of USD 20.15 billion with drugs contributing around 90 % of the total exports. Imports form around USD 10.4 billion of which medical devices from around 52 %. Pharma sector is currently contributing to around 1.72% (USD 47.28 billion in 2018-19) of the country's GDP. It is expected that the sector can contribute between USD 85 to 100 billion to Indian Economy by 2024. The Annual Turnover of Pharma Industry during last five years is as following:-

Year	Annual Turnover (in Rs. crore)
2014-15	1,65,202
2015-16	1,85,388
2016-17	2,19,755
2017-18	2,26,423
2018-19	2,58,534

Though pharmaceuticals is identified as one of the champion sectors which contributes substantially to manufacturing GDP in the country, there is an urgent need to pay attention to certain issues which if not handled can adversely affect the competitiveness of the sector in the years to come. Some of the major challenges identified are as follows:-

(i) <u>API/Bulk drugs: Issue of Drug Security</u>: API/Bulk drugs and intermediates form 63% of India's total pharma imports. Even production of some of the NLEM formulations is dependent on imported APIs and intermediates. India imports bulk drugs and intermediates largely on economic considerations. China with a share of 67.6 % is the major source for API. India, being one of the largest manufacturers of medicines and exporting these to over 200 countries, dependence on a single source for import of API is a matter of concern as any disruption in the supplies could jeopardize the pharma sector and affect supplies of medicines both for domestic use and exports.

(ii) <u>Medical Devices: Huge burden of imports and regulatory issues</u>: India imports almost 85% of all its medical device needs. India largely imports high technology medical equipment's and electronics which constitute 66 % of the country's import basket.

(iii) <u>Pharma MSMEs-Poor status of WHO GMP Compliance and concern about competitiveness</u>: The WHO-GMP certificate is a mandatory requirement in most global markets for companies to be able to sell their medicines. It is difficult for the pharma MSMEs to establish and operate World class quality manufacturing and testing facilities on their own due to huge financial and technical investment involved. It is roughly estimated that 80% of the pharma MSMEs in the country are not WHO GMP compliant. Upgrading to such standards require investment to the tune of Rs.5-10 Crore per unit as per the feedback from the stakeholders.

(iv) <u>Research & Development and Skilling in Pharma Sector</u>: Pharmaceutical industry is a knowledge intensive industry and needs continuous development of new Chemical/ biological entities, updating/improvement in the processes, develop new drug delivery systems etc. to remain competitive. To sustain its edge in domestic and export markets, Pharma industry has to invest continuously in R& D. Besides, academia-Industry linkage has been identified as a basic requirement for translating research into development (commercialization) and Innovation.

2.2 On being asked about the specific achievements of the Department in promoting growth and development of Pharmaceuticals in the country during the last 05 years and what achievements are envisaged for next 5 years, the Department in its written replies stated as under:

> " In order to promote the growth and development of pharmaceuticals in the country, the Department of Pharmaceuticals has prepared a Scheme for Development of Pharmaceutical Industry with the objective to ensure drug security in

the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry with the following sub-schemes:-

(i) Under the Scheme "Assistance to Bulk Drug Industry for Common facility Centre" financial assistance is provided for creation of common facilities under any upcoming Bulk Drug Park promoted by State Government/State Corporations.

(ii) Under the Scheme "Assistance to Medical Device Industry for Common facility Centre" financial assistance is provided for creation of common facilities under any upcoming Medical Device Park promoted by State Government/State Corporations.

(iii) Under the Scheme Assistance to Pharmaceuticals Industry for Common Facilities financial assistance is provided for creation of common facilities in any pharma cluster.

(iv) Department has a prepared a scheme viz. Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) to facilitate pharma MSMEs 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. Under the scheme, 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 above mentioned umbrella scheme is envisioned to tackle the major challenges faced by the Indian Pharma industry viz. Issue of Drug Security raising out of import of APIs, Medical Devices; poor status of WHO GMP Compliance and poor Status of R&D and drug discovery.

It is proposed to promote and finance 6 Bulk Drug (API) Parks and 6 Medical Devices Parks promoted by State Governments by 2024-25 to reduce the country's huge import dependence, ensuring drug security and sustained availability of medical devices in the country. The government will also support Pharma MSMEs in their technology up gradation by promoting pharma units in existing 10 pharma clusters by 2024-25. It is proposed to support 4500 Pharma SMEs for Assistance for technological up-gradation so as to meet WHO GMP standards."

2.3 Further the Department of Pharmaceuticals in written replies stated their role and responsibilities including social responsibilities of the Department with regard to matters pertaining to affordable drugs and medical devices which is as under:

"An unique aspect of drug prices is that if patients are unable to afford the drug, they could face worse quality of life or face certain death. Accordingly, National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) has the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharma industry, thereby meeting the goals of employment and shared economic well-being for all. In pursuance to the NPPP-2012, the Drugs (Prices Control) Order, 2013 (DPCO-2013) was made to regulate the prices of medicines. National Pharmaceutical Pricing Authority (NPPA), an attached office of the department, implements the provisions of DPCO.

Additionally, Department of Pharmaceuticals has launched a Scheme "Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)" with the objective of making quality generic medicines available at affordable prices to all. Under this scheme, dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are opened to sell affordable generic medicines of good quality to the public.

A medicine under PMBJP is priced on the principle that its price should be less than 50% of the average price of the top three brands of that particular medicine. Therefore, the price of PMBJP medicines is cheaper at least by 50% and in some cases by 80% to 90%, of the market price of branded medicines. In the current financial year, PMBJP has achieved sales of Rs. 363 crore (at MRP) as on 14.02.2020. This translates to an estimated savings of Rs. 2500 crore to the common man of the country.

As on 17.02.2020, 6141 PMBJP Kendras are functional across the country. 697 districts of the country have been already covered and the target is to cover all districts by 31st March, 2020. The Government of India has requested the State Governments to provide space in government hospitals for the opening of Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs). Continuous efforts are being made by requesting concerned District Magistrates to expedite the opening of PMBJKs in uncovered districts. The Bureau of Pharma Public Sector Undertakings of India (BPPI), the implementing agency for this scheme is continuously pursuing the matter with all the State Governments.

The product basket of PMBJP comprises of 900 drugs and 154 surgicals. To ensure easy availability of the menstrual health services to all women across India, “Janaushadhi Suvidha” sanitary pads are now made available for sale @ Rs 1.00 per pad since 27th August, 2019 in more than 5800 “Pradhan Mantri Bhartiya Janaushadhi Kendras” across the country. More than 60.25 lakh pads have been sold @ Rs. 1.00 per pad since 27th August, 2019."

2.4 The Department in their written reply stated the Import and export data of pharmaceutical industry during the last five years which is as following:-

Year	Import of Pharmaceutical Products (in Rs. crore)	Export of Pharmaceutical Products (in Rs. crore)
2014-15	53568.14	98787.94
2015-16	56760.09	114774.12
2016-17	56923.73	117743.66
2017-18	61767.29	108469.19
2018-19	76303.53	140961.31

It is expected that the growth of export of pharmaceutical products will continue to increase during next five years.

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2.5 Further when the Committee asked about the total amount of foreign exchange incurred on the import of Active Pharmaceutical Ingredients (API) during the last 5 years and steps that have been taken or proposed to be taken by the Department to enhance domestic production of API, the Department in their written reply stated as under:

"The Import of Active Pharmaceutical Ingredients (API) and drug intermediates during the last five years is worth Rs. 103572.90 crore. It is proposed to finance common infrastructure facilities in 6 Bulk Drug (API) Parks in collaboration with State Governments so as to reduce the country’s import dependence on critical Active Pharmaceutical Ingredients (API) and intermediates. The API/bulk drug Parks will reduce the overhead expenditure and provide common facilities at one place."

2.6 During oral evidence the Secretary Department of Pharmaceuticals submitted the constraints the Pharmaceutical industry face due to import of API from China which is as follows:

"……we are unfortunately dependent on China for 58 types of API, KSM and intermediates. Of these, at present we do not have any problem because we have stocks as far as API as well as the finished goods and they can last for another three to four months. We in our Department formed a Standing Committee of Inter-Ministerial Experts and they are meeting every day and keeping a watch on what is happening in China. Because most of our APIs are coming from China, there are not many other sources also. Development of other sources takes time also. The Committee is reviewing the situation. Importers and manufacturers are also a part of this Committee. This is again on the basis of whatever information the importers and manufacturers are getting from their suppliers. We are not very sure whether this information is authentic or not. We are in contact with the Embassy. We have been told that excluding Hubei, in all other Provinces the production has started. The production of 30 to 40 has started. That means, the imports will start coming. But we have to keep our fingers crossed. At present we have not taken any decision whether we should ban experts of that or not. That is because on whatever drugs we give the world, they also do not have any other source…."

2.7 During oral evidence when the Committee asked about the preparedness of the Department in case of outburst of Corona virus like situation in the country as it has happened in China the Secretary Department of Pharmaceuticals submitted as follows:

"We have done two or three things. Firstly, there are some manufacturers or companies who are manufacturing APIs. Most of the people are importing them from China. We have instructed the State Governments and CDSCO when they come for increasing their production capacity. Even before the Corona virus broke up, they had increased their capacity by 50 per cent. This will help them and permission will be given to them automatically and they need not come for environment clearance. They can also change the product mix. We have received some complaints that some States are not implementing it. The Secretary, Environment is going to take a look into these things. If they come for any kind of permission, the State Government or the CDSCO should give them permission immediately. This is one instruction which we have given so that if APIs are not coming from China, they can manufacture them here.

Second thing which we have told is that, there are any other sources through which APIs are available. Four APIs are available in Italy and two or three countries.

If they want to import those APIs from those countries, then we have again instructed the CDSCO that they should not delay in giving them import licence and they should immediately give the import licence to the manufacturers or the importers. This is our second instruction.

As far as manufacturing or increasing the capacity is concerned, unfortunately, technically it cannot be done because it requires two to three years to put up a plant and we have listed out 21 plants which were operating in 2005. These plants have been closed down because of strict competition from China. Even if these plants are to be reactivated, it will take a minimum of one and a half years. So, the best thing is to watch and see what we can do. Unfortunately, the whole world is depending upon us for some API formulations and even APIs. That is also a worrying situation. But we are observing the situation and then take a decision in the best interest of the nation and we will do our best. But the situation in China is improving. That is a sign of good hope. I am saying on the basis of information which I have received. We are not very sure of it."

2.8 On being asked about the whether the Department has conducted any study to find out the specific problems faced by the domestic pharmaceutical industry and the steps taken/ proposed to be taken, the Department in its written reply stated as under:

"Department has not conducted any specific study. However, Department of Pharmaceutical sponsors various seminars/workshops which are aimed to discuss various challenges/problems faced by the Industry. Reports of these seminars/workshops are received by the Department. The Department of Pharmaceuticals has constituted a Forum of Pharma Associations on 14th August, 2019 for hearing the specific problems and issues faced by the domestic pharmaceutical industry. The suggestions/ views/ comments are invited from Pharma Industry Associations from time to time. The Pharma/Medical Device Associations also have the opportunity to raise their various concerns before the Hon'ble Minister of Chemicals & Fertilizers during the annual event organized by Department of Pharmaceuticals, namely, Indian Pharma and India Medical Device.

Department of Pharmaceuticals has also constituted an Inter-Departmental Committee (IDC) on 9th January, 2019 to institutionalize a robust mechanism to ensure economy, efficiency, effectiveness and transparency in the arena of

Pharmaceutical research. The Department has also constituted a Task Force on API under the Chairmanship of the Minister of State (Chemicals & Fertilizers) on 18.04.2018 to formulate a roadmap for the enhanced production of Active Pharmaceutical Ingredients (APIs) in the country."

CHAPTER-III

DEMAND FOR GRANTS (2020-21) - DEMAND NO. 7

Department has received Gross Budgetary allocation of Rs. 338.58 crore for the year 2020-21, out of which Rs. 27.40 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. 28.98 crore and Rs. 299.00 crore for Central Sector Scheme against proposed Budget Estimates of Rs. 665.01crore and Rs. 7.18 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 2020-21 and scheme wise break-up of outlays approved, is given below: -

(Rs in crore)

			2019-20			2020-21	
	Revenue Section	**Major Head**	**BE**	**RE**	**Actual as on 17.01.2020**	**BE**	
						Proposed	**Approved**
1	Secretariat Economic Services	3451	14.15	14.67	10.44	15.41	15.50
2	National Pharmaceuticals Pricing Authority (NPPA)	2852	12.00	11.48	8.33	13.57	11.90
3	National Institute of Pharmaceutical Education and Research (NIPERs)	2552+2852	150.00	160.00	138.10	450.0	202.45
4	Development of Pharmaceuticals Industry	2552+2852	8.30	3.49	2.69	144.01	42.05
5	Jan Aushadhi Scheme	2552	42.00	35.51	35.51	67.00	50.00
6	Consumer Awareness, Publicity and Price Monitoring (CAPPM)	2852	4.00	4.00	1.74	4.00	4.50
	Write Off/ Waiver of losses in respect of Pharmaceuticals HAL		--	--	--	--	--
	Total Revenue Section		**230.45**	**229.15**	**196.81**	**693.99**	**326.40**
			2019-20			**2020-21**	
7	**Capital Section**	**Major Head**	**BE**	**RE**	**Actual as on 17.01.2020**	**BE**	
	(Assistance to PSUs)	6857				**Proposed**	**Approved**
	Indian Drugs & Pharmaceuticals Ltd. (IDPL)		0.01	4.28	--	0.01	0.01
	Hindustan Antibiotics Ltd.		0.01	280.16	116.30	0.01	4.74

	(HAL)						
	Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)		0.01	0.01	--	0.01	0.01
	Bengal Immunity Ltd. (BIL)		0.01	0.01	--	0.01	0.01
	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)		5.01	48.71	48.70	0.01	2.40
	Smith Stanistreet Pharmaceuticals Ltd (SSPL)		0.01	0.01	--	0.01	0.01
	Total (Loan to PSUs)		**5.06**	**333.18**	***165.00**	**0.06**	**7.18**
	Grand Total		**235.51**	**562.33**	**361.81**	**694.05**	**333.58**

*Rs. 160.00 crore under 1st Batch of Supplementary Demand for Grants FY 2019-20 for Public Sector Undertakings to make payment of employee's liabilities of unpaid salary/VRS.

3.2 As per Demand For Grants (2020-21) for Department of Pharmaceuticals, the total BE for the year 2020-21 is only Rs 333.58 crore in comparison to RE of Rs 562.33 crore for 2019-2020. When asked about the reasons for reduced allocation at BE stage for the year 2020-21, the Department in their written reply stated as under:-

"On 17.7.2019 Cabinet had approved an amount of Rs. 330.35 crore. This amount was included in our proposal of RE of Rs. 562.33 crore for providing budgetary support as loan for meeting employee liabilities for unpaid salary and VRS in respect of 3 Pharma PSUs i.e IDPL, HAL and RDPL. This amount is included in RE of Rs. 562.33 crore for making provision for meeting pending Salaries/VRS. The Department had proposed Rs. 694.05 crore for the year 2020-21 against which Rs. 333.58 crore has been allocated by Ministry of Finance. Budget allocation by Ministry of Finance depends on priorities of that Ministry and fiscal policies of the Government. Department of Pharmaceuticals has no role in this matter. No comments/reasons have been elaborated for the reduction of budget by the Ministry of Finance. "

3.3 The Proposed Budget estimate made by the Department of Pharmaceuticals for the year 2020-21 was Rs 694.05 crore but the Approved BE is less than half the amount proposed that is Rs 333.58 crore. When it was asked how the Department proposes to manage the successful implementation of various development programmes/ schemes in the wake of reduced/ inadequate allocation of funds for 2020-21, the Department in their written reply stated as under:

"The total fund allocated for the Department fall short of the urgent fund requirement projected by this Department for carrying out its laid down mandate with regard to the Schemes National Institutes of Pharmaceuticals Education and Research (NIPER) and Development of Pharmaceuticals Industry. A substantial cut in the fund will adversely affect the following schemes being implemented by the Department as detailed below:

(i) National Institutes of Pharmaceuticals Education and Research: An amount of Rs. 450.00 crore was sought for the Scheme of NIPERs by the Department. However, an amount of Rs. 202.45 crore only has been allocated, which will definitely affect the implementation of the various activities of the NIPERs. The construction of campuses of NIPERs at Guwahati and Ahmedabad, which was approved by Expenditure Finance Committee (EFC) in March, 2018, may not be able to be completed with reduced allocation of funds. The Department is in the process of preparing fresh EFC proposal for the existing and newly proposed NIPERs seeking sufficient funds for construction of their campuses, equipping the laboratories as well as other administrative and academic expenses. It will seek funds as proposed/ approved under the fresh EFC.

(ii) Development of Pharmaceuticals Industry: The allocated fund is not sufficient for the scheme "Development of Pharmaceutical Industry". The additional funds will be sought at the stage of first supplementary/R.E. stage.

<u>Scheme wise position for other two schemes are detailed as under:</u>

(iii) Jan Aushadhi Scheme: The Bureau of Pharma PSUs of India (BPPI) which is the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), is increasing self-sufficiency and reducing dependence on grants provided by Department of Pharmaceuticals (DoP) as envisaged in the guidelines for the scheme. In F.Y. 2019-20, BPPI received a grant of Rs 35.50 crore and successfully managed its operation. BPPI is planning to open 1000 new stores in F.Y. 2020-21 & can run its operation within Rs. 50 crore grants to be provided by Department of Pharmaceuticals.

(iv) Consumer Awareness Publicity and Price Monitoring (CAPPM): The proposed BE 2020-21 was Rs.17.58 crore and approved BE 2020-21 is Rs. 16.40 crore. NPPA will be able to fulfil its mandate through this allocation.

As regards to Pharma Public Sector Undertakings, the funds allocated under the Capital Head (Assistance to PSUs) are not sufficient for settlement of pending salaries and giving VRS to employees of PSUs before their closure/ strategic sale as per the cabinet decisions. The department proposes to meet the expenditure from proceeds of sale of surplus land of PSUs."

3.4 During oral evidence, the Committee asked the representatives of the Department, how they will manage this year due to reduced budgetary allocation to the Department. In this regard the Secretary, Pharmaceuticals replied as follows:

"I know that it is a difficult thing. We need money. We will request the Government that they should consider our proposal and sanction some grant in the supplementary stage. I made presentation to all the concerned people. Let us see what happens. But we will be asking for additional amount during supplementary demands."

3.5 Department of Pharmaceuticals had demanded Rs. 630.70 crore under 1st Batch of Supplementary Demand for Grants 2019-20 and Rs. 533.41 crore sought under 2nd and Final Batch of Supplementary Demand for Grants 2019-20 detailed as under:

(Rs in Crores)

Supplementary Grants 2019-20	Pending Employees Liabilities for PSU (HAL, IDPL and RDPL)		NIPER		Others		**Grand Total**	
	Demanded	Actual Released	Demanded	Actual Released	Demanded	Actual Released	**Demanded**	**Actual Released**
First Batch	330.35	116.30 released to HAL and 43.70 to RDPL	300.00	10.00 token supplementary after re-appropriation (matching savings from Jan Aushadhi Scheme and Development of Pharmaceuticals Industry respectively under MH 2852)	0.35 for RDPL	--	**630.70**	**160.00**
Second and Final Batch	485.90= 296.01 for HAL + 19.54 for RDPL+ 170.35 (remaining out of 330.35)	--	30.00= 8.50 for payment of arrear + 15.00 for NIPER Ahemdabad + 6.50 for payment of salary	--	7.50 for Assistance to Medical Device Industry and 0.01 for new minor head 789 and 796 for SC/ST Area Sub Plan	--	**533.41**	--

3.6 On being asked about the reasons for variation in Supplementary Grants demanded by the Department and the actual amount released by the Ministry of Finance in the first batch of Supplementary Grants, 2019-20, the Department in their written reply stated as under:

> "The Department had demanded of Rs. 630.70 crore under 1st Batch of Supplementary Demand for Grants 2019-20 according to requirement of DoP. However, Ministry of Finance has approved Rs. 160.00 core under 1st batch of Supplementary Demand for Grants FY 2019-20 to PSUs of DoP to make payment of employees' liabilities of unpaid salary/VRS. No comments/reasons have been communicated for the reduction of amount by the Ministry of Finance."

3.7 The Committee further asked about the time by which the second batch of Supplementary Grants for the year 2019-20 is expected to be released by Ministry of Finance and the reasons for delay in this regard, the Department stated that the work relating to release of Supplementary Grants comes under the purview of Ministry of Finance. Department of Pharmaceuticals has no role in this regard.

3.8 Thereafter, the Committee also asked the alternative measures that are proposed to be taken by the Department if the second and final batch of supplementary grants fall short of the demanded amount of Rs. 533.41 crore, the Department in their written reply stated as under:

> "In case the proposed demand by the Department during Second and Final Batch of Supplementary Grants FY 2019-20 are not approved by Ministry of Finance then the additional funds would be demanded in 1st Batch of Supplementary Demand for Grant FY 2020-21."

CHAPTER-IV

ANALYSIS OF DEMANDS FOR GRANTS

MAJOR HEAD-[2552(NORTH EAST REGION) AND 2852(INDUSTRIES)]

I. 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 Kendra's. As a result of several steps taken by the Government and efforts made by the Government, 6141 PMBJP Kendras are functional in 36 States/UTs of the country Government as on 17.02.2020. During the years 2018-19 and 2019-20 the outlays of PMBJP Scheme into outcome are as under: -

Financial Year	PMBJP Kendras opened (No.)	Sales at MRP Value in (Rs. Crore)
2018-19	1863	315.70
2019-20 (as on 20.1.2020)	975	327.43

4.2 Year wise fund allocation and the expenditure incurred under Jan Aushadhi Scheme (PMBJP) for the last three years is given as under:

(Rs. in crore)

Name of Scheme	2017-18			2018-19			2019-20			2020-21
	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
Jan Aushadi Scheme	74.62	74.62	47.64	84.00	42.51	42.50	42.00	35.51	35.51*	50.00

***As on 17.01.2020**

4.3 On being asked about the reasons for reduction of budgetary allocation from Rs. 42 crore at BE stage to Rs. 35.51 crore at RE stage of 2019-20 despite of the fact that the number of PMBJP Kendras significantly increased during the year, the Department in their written reply stated as under:

"Ministry of Finance vide its OM No. 2 (20)-B(P&A) dated 4.01.2020 has increased the total allocation of NIPERs to Rs. 160.00 crore in RE 2019-20 from BE provision of Rs. 150.00 crore. To meet the increased allocation for NIPERs, amount of Rs.

10.00 crore needed to be re-appropriated from other Scheme under Revenue Section for which an amount of Rs. 6.49 crore was identified from the Jan Aushadhi Scheme for re-appropriation to NIPERs. Accordingly, the budgetary allocation was proposed to be reduced from Rs. 42.00 crore at BE stage to Rs. 35.51 crore at RE stage for FY 2019-20."

4.4 The Department in their written reply stated the basis for opening Jan Aushadhi Kendra in a state/ UT/ district, which is as under:

"The opening of Jan Aushadhi Kendras at any particular location depends upon the applications received from eligible applicants from that area. Bureau of Pharma PSUs of India ensures that a minimum distance would be maintained between two stores in order to ensure commercial viability to kendras. In processing applications, priority is always given to unserved areas."

4.5 Further the Committee asked about the specific targets that have been set by the Department with respect to opening Jan Aushadhi Kendras in rural, remote areas and urban fringes, the Department in their written reply stated as under:

"There is no specific location-wise plan for the opening of Pradhan Mantri Bhartiya Janaushadhi Kendras in the country. Bureau of Pharma PSUs of India, the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) has adopted a franchise-like model in which opening of PMBJP Kendra depends upon the eligible applications received from the particular areas. BPPI has targeted to cover all districts of the country by 31st March 2020.As on 17.02.2020, 6141 Pradhan Mantri Bhartiya Janaushadhi Kendras are opened in the country. Out of this, 524 PMBJP Kendras are functional in 117 aspirational districts which are considered relatively backward. Progress likely to be made by 31stMarch 2024 as envisaged in the Vision Plan-

1. Coverage: Target is to open a total of 10000 Kendras by 31st March 2024.
2. Basket of Medicines: The present product basket consists of more than 900 drugs and 154 surgicals. Target is set to enhance it up to 2000 drugs and 300 surgicals, so that all essential medicines covering therapeutic groups like - Anti Diabetics, Cardiovascular Drugs, Anti-Cancer, Analgesics & Antipyretics, Anti Allergic, Gastro-Intestinal Agents, Vitamins, Minerals & Food supplements, Tropical Medicines, etc. get included.

3. Storage & Logistics: Establishment of an effective IT-enabled logistics and supply-chain system for ensuring real-time distribution of medicines at all outlets to avoid stock outs. BPPI has four warehouses at present at Gurugram, Chennai, Bengaluru & Guwahati. Further, the plan is to open two more warehouses; one each in Western and Central India."

4.6 The Committee pointed that during 2018-19, value of medicine sold through PMBJP Kendras was Rs. 315.70 crore with 5056 Kendras across the country. During 2019-20, the number of Kendras was increased to 6031. However, value of sales was Rs. 327.43 crore as on 20.01.2020. In this regard, the Department in their written reply stated the reasons for lower value of sales through PMBJP given as under:

"Sale turnover of BPPI in F.Y-2019-20 (up to 31st Jan 2020) as compared to the same period of F.Y. 2019-20 has shown a growth of 47.67% while growth in a number of Kendras is 22.20%. Thus, growth in sales is much greater than growth in a number of Kendras. Further, the Department is taking various steps to increase the popularity of its medicines and sales. It involves active use of all forms of media, seminars, padayatra etc. It has placed various types of advertisements in Print Media, Radio, TV, Cinema and Outdoor publicity like Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping. In addition to this, the Department is also educating the public about the usages of Jan Aushadhi generic medicines through social media platforms like Facebook, Twitter, Instagram, YouTube, etc. regularly."

4.7 Further the Committee also asked about the steps that are being taken to open PMBJP Kendras in 34 uncovered districts in the country and the progress that has been made in this regard so far, the Department in their written reply stated as under:

"Hon'ble Minister of Chemicals & Fertilizers has written letters to Hon'ble Chief Ministers of various states about salient features of the scheme and requested them to open Janaushadhi Kendras. In a similar way, Secretary, Department of Pharmaceuticals has also written request letters to Chief Secretaries of various states. Further, Joint Secretary, Department of Pharmaceuticals has written letters to Principal Secretaries (Health & Family Welfare) of all states requesting them to provide rent-free space for opening Janaushadhi Kendras at government hospitals. BPPI has written letters to Principal Secretary (Health & Family Welfare) requesting to provide rent free space in every Primary Health Centre (PHC) and Government Hospitals for opening PMBJP kendra. Letters were also written to District

Magistrates of the uncovered districts of the State to expedite the opening of PMBJP kendras. BPPI has released newspaper advertisements and social media advertisements in these districts for inviting applications for the opening of PMBJP kendras. BPPI's Marketing Officers are also organizing various workshops and seminars to encourage private entrepreneurs/NGOs/Civil Society Organizations and unemployed pharmacists for opening PMBJP Kendras. As on 17.02.2020, 6141 Pradhan Mantri Bhartiya Janaushadhi Kendras are functional across the country. PMBJP has already covered 697 districts of the country. Efforts are being made to cover all uncovered districts by 31st March, 2020."

4.8 On being asked about the views of the Governing Council and Executive Council of Bureau of Pharma PSUs on the complimentary role of Pharma PSUs in implementing PMBJP scheme without any significant contribution to the basket of medicine for PMBJP and what specific steps that have been taken/proposed to be taken to procure drug/medicines/medical devices from Pharma PSUs under Pharmaceutical Promotion Policy of the Department, the Department in their written reply state as under:

"BPPI was established as a Bureau for promoting sales of medicines manufactured by pharma PSUs. Gradually, it was assigned the role of implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana. Its mandate is to provide quality & affordable generic medicines to masses at large through Janaushadhi Kendras. For keeping the price of medicines at minimum, open tender process is followed for the procurement of medicines where any eligible manufacturers can participate and bid. Price discovered through this process is generally significantly lower than the price quoted by PSUs. Thus, BPPI preferred to purchase from other companies where it got lower prices. However, in case, where no bids are received or prices are higher than that of PSUs, BPPI procures from PSUs."

MAJOR HEAD-2552(North East Region) and 2852(Industries)

II. <u>Development of Pharmaceutical Industry:</u>

4.9 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.

4.10 Year wise fund allocation and the expenditure incurred under scheme Development of Pharmaceutical Industry for the last three years is given as under:

(Rs. in crore)

Name of Scheme	**2017-18**			**2018-19**			**2019-20**			**2020-21**
	BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
Development of Pharmaceutical Industry	17.03	12.03	1.82	12.97	4.00	2.82	8.30	3.49	2.69*	42.05

*** As on 20.01.2020**

4.11 On being asked about the reasons for under utilization of funds during 2017-18, 2018-19 and 2019-20, the Department in their written reply stated as under:

"Despite the best efforts made by the Government, the sub scheme 'Assistance to Pharma Industry for Common Facilities' under the umbrella scheme "Development of Pharmaceutical Industry" did not receive a good response in 2017-18, 2018-2019 and 2019-2020. For the sub-scheme "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) only token amount was sanctioned.

So far as Pharmaceuticals Promotion and Development Scheme (PPDS) is concerned, the Department is providing financial assistance on the merit of the application received from various Institutions/Organizations/NGOs etc. In the Financial Year 2019-2020, Rs. 76.85 lakh has already been sanctioned against the R.E. of Rs. 1.19 crore."

4.12 A statement showing the extent to which the Department of Pharmaceuticals has been able to convert the outlays for the sub schemes into commensurate outcomes during the years 2018-19 and 2019-20; the proposed and approved BE for the year 2020-21 as furnished by the Department in a written reply is given below:-

(Rs In crores)

S. No.	Scheme (s)	2018-19			2019-20			2020-21	
		RE	Actual Exp.	Outcome (Actual Exp/RE) in %	RE	Actual Exp.	Outcome (Actual Exp/RE) in %	BE Proposed	BE Approved
1.	Assistance to Pharmaceutical Industry for Common Facilities	2.93	2.30	78.5	2.24	2.23	99.55	12.00	12.00
2.	Assistance to Bulk Drug Industry for Common Facility Centre	0.02	NIL	NIL	0.02	Nil	Nil	100.00	21.52
3.	Assistance to Medical Device Industry for Common Facility Centre	0.02	Nil	Nil	0.02	Nil	Nil	30.00	7.50
4.	Pharmaceutical Promotion and Development Scheme (PPDS)	1.00	0.52	52	1.19	0.72	60.50	2.00	1.00
5.	Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)	0.02	Nil	Nil	0.02	Nil	Nil	--	0.02

4.13 An amount of Rs. 144.01 crore was sought from the Ministry of Finance for the implementation of Umbrella Scheme of “Development of Pharmaceuticals Industry” during 2020-21 but only Rs. 42.05 crore has been provided to the Department. Therefore, the Committee asked how the Department proposes to implement the Scheme effectively in the absence of the requisite budgetary allocation particularly sub-schemes of Assistance to Bulk Drug Industry for Common Facility Centre and Assistance to Medical Device Industry for Common Facility Centre, the Department stated in their written reply stated that to implement these sub-schemes effectively, additional funds will be sought at First supplementary/R.E. stage in FY 2020-21.

4.14 Further the Committee asked whether the Department took up the matter at highest level with the Ministry of Finance to impress upon that Ministry about the importance of each sub scheme and the response of that Ministry, the Department in their written reply stated as under:

"A D.O. letter from Hon'ble Minister (C&F) to Hon'ble Minister of Finance was sent. Secretary (Pharma) also wrote to Secretary (Expenditure) for increasing the budgetary allocation of the sub-schemes "Assistance to Bulk Drug Industry for Common Facility Centre" and "Assistance to Medical Device Industry for Common Facility Centre on 23.12.2019.Thereafter another DO letter was issued on 31.01.2020 from Secretary (Pharma) to Secretary (Expenditure) requesting for allocation of Rs. 847.00 crore in addition to approved budget of Rs. 333.58 crore to implement the vision plan. However, no positive response has been received so far from D/o Expenditure."

4.15 The Committee pointed out that in principle approvals have been given for four proposals each under "Assistance to Bulk Drug Industry for Common Facility Centre" and "Assistance to Medical Device Industry for Common Facility Centre". Therefore the Department was asked about the action that are proposed to be taken for the setting up of Common Facility Centres under these two sub-schemes in those states and also about the issue of constraint of funds by the Department, the Department in their written reply stated as under:

"Under the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre", the proposals received from State Governments of Andhra Pradesh, Telangana, Tamil Nadu and Kerala have been given 'in-principle' approval. Also, the proposal of Andhra Pradesh has been given final approval for financial assistance of Rs. 25 crore under this sub scheme. The other three proposals will also be considered for final approval after receipt of Detailed Project Reports (DPRs). Vide letters dated 31.01.2020, State Governments of Telangana, Tamil Nadu and Kerala have been reminded to send DPR at the earliest.

As regards the sub-scheme "Assistance to Bulk Drug Industry for Common Facility Centre", the proposals received from State Governments of Andhra Pradesh, Telangana, Himachal Pradesh and Assam have been given 'in-principle' approval. However, State Government of Assam has stated that it will not be financially viable for them to establish a Bulk Drug Park in their State. The remaining three proposals will be considered for final approval after receipt of Detailed Project Reports (DPRs). Vide letters dated 09.01.2020, State Governments of Andhra Pradesh, Himachal Pradesh and Telangana have been reminded to send DPR at the earliest. The Department will keep on pursuing with the Ministry of Finance for allocation of more funds."

4.16 As per Annual Report of the Department it is stated that the Department has made efforts in promoting Domestic API/Bulk drugs production under a sub-scheme 'Assistance to Bulk Drug Industry for Common Facility Centre' as part of the Department's umbrella scheme namely 'Scheme for Development of Pharmaceutical Industry'. Under this sub-scheme, financial assistance would be provided 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.

4.17 Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) is only on paper since its inception and only token budgetary allocation is being made year after year. There is also inordinate delay in identifying Public Sector Financial Institution (PSFI) which would implement this important sub-scheme. The Committee asked about the exact reasons for Department's inability to implement this scheme and corrective measures that are being taken in this regard, the Department in their written reply as under:

> "The sub-scheme remained a non-starter as no Public Sector Financial Institution (PSFI) came on board as implementing agency. In the meantime, discussions were held with different stakeholders and a number of suggestions were received from industry associations. In the light of the suggestions, it was felt that the sub-scheme required some changes in the guidelines including the selection of PSFI. The guidelines have been revised accordingly."

4.18 During oral evidence the Committee raised their concern that 80 per cent of our MSMEs are not eligible for the WHO-GMP certificates and the fund which has been allocated for Technology Up-gradation and Assistance scheme is only around Rs.2 lakh, how do you propose to implement the scheme, the Secretary of the Department replied as follows:

> "Now, we are getting the details from the State Governments as to which are the manufacturers who are not WHO-GMP. But we have done a survey. They are qualified as per our law. But WHO-GMP requires additional funding, which comes to Rs. 5 to Rs. 10 crore per unit. MSMEs cannot afford to take loan also. So, we had this scheme. Unfortunately, we could not implement it. We had to revise it. Now, we have gone for a very ambitious scheme in the sense that in the next five years we want to cover all the MSMEs. We should provide them interest subvention so that they can become WHO-GMP compliant. This will only help our country in the sense that our exports will go up."

4.19 Further the Secretary also submitted following about this scheme:

"We are revamping the scheme. We have issued the EFC also. We have proposed that the Government of India should pay the interest. Then, they can take the loan, and convert their units into WHO-GMP compliant and they will be able to repay the loans also. Naturally, their sales will go up. In India the quality of medicines will improve and even exports would go up. They would be eligible to give these medicines to big companies. Generally big companies outsource manufacturing. So, it is very important that we implement this scheme. As per our estimates, if we can spend around Rs. 500 to Rs. 600 crore, all these units can be converted into WHO-GMP compliant. We can do this."

MAJOR HEAD-2852 (Industries)

III. <u>National Pharmaceutical Pricing Authority (NPPA)</u>

4.20 The National Pharmaceutical Pricing Authority (NPPA),was established through a Government of India resolution dated 29th august , 1997 as an independent body of experts for price control of essential and life saving medicines. NPPA is an attached office of the Department of pharmaceuticals and implements the National Pharmaceuticals Pricing Policy 2012 and the Drugs (Prices Control) Orders as amended from time to time which were issued by the Department.

NPPA fixes ceiling price to all Drugs notified under Schedule-I of the DPCO, 2013 and monitors annual price increase for these medicines. It has, so far, fixed ceiling prices of 860 scheduled formulations and retail prices for 1189 new drugs. By invoking powers under Para 19 of DPCO, 2013, it has regulated prices of 106 anti-diabetic and cardio vascular drugs, stents and knee implants in public interest.

In February 2019, NPPA Launched a Pilot for price regulation of 42 anti-cancer drugs as proof of concept for Trade Margin rationalization of non-scheduled drugs. So far, 526 brands have reported saving up to 90%, amounting to Rs. 984 crore per annum. It is estimated that NPPA has affected a saving of almost Rs.12,447 crore to the consumers since its constitution.

For effective monitoring of DPCO in the country, such as monitoring of notified prices of medicines, detection of violation of the provisions of DPCO, pricing compliance and ensuring availability of medicines, cooperation and involvement of State Drug Controllers (SDCs) is important. In view of that, NPPA has decided to setup Price Monitoring and Resource Units PMRUs), as registered societies under the Societies Registration Act in all the 37 states/UTs to support NPPA and respective State Drug Controllers. As of now, 10 PMRUs have been set up in the states of Kerala, Odisha, Gujarat, Rajasthan, Punjab, Haryana, Nagaland, Tripura, Uttar Pradesh and Andhra Pradesh.

4.21 Fund allocation and utilization by NPPA from 2017-18 to 2020-21 is given as under:

(Rs. in crore)

Name of Scheme	2017-18			2018-19			2019-20			2020-21
	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
NPPA	15.00	14.42	9.53	11.50	12.94	9.45	12.0	11.48	8.33*	11.90

***As on 17.01.2020**

4.22 On being asked about the reasons for underutilization of funds by National Pharmaceutical Pricing Authority (NPPA) during the years 2017-18, 2018-19 and 2019-20, the Department in their written gave following year-wise explanations stated as under:

" **Reasons for underutilization of funds for 2017-18:**

(i) BE for the year 2017-18 was Rs. 11.00 crore towards Establishment Expenditure, which was reduced to Rs. 10.42 crore at RE stage. Actual expenditure during the year was of Rs. 9.53 crore. Further, Rs. 0.68 crore was surrendered. Underutilization of Rs. 0.79 crore (Rs. 11.00 – Rs. 9.53 – Rs. 0.68) in relation to BE was mainly in salary, medical, travel expenses Heads as number of posts remained vacant despite regular follow up with the Department/DoPT. Further, funds could not be utilized under CAPPM Scheme as the 15-digit Head 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 underutilization of funds for 2018-19:

(i) As per the detailed Demand for Grants for the year 2018-19, BE was of Rs. 11.50 crores for Establishment and Rs.4.00 crore for CAPPM Scheme. At RE stage, proposed shifting of the office from YMCA building to LIC building and anticipating consequent additional expenditure on Rent and other office expenses, the Budget provision in RE 2018-19 under Office Expenses was increased to Rs. 3.00 crore from Rs.1.21 crore. But the proposal to shift office of NPPA from the existing Building YMCA Culture Centre to LIC Building could not be materialized as the space offered was not sufficient as per the requirement of the NPPA. So the enhanced budget provision under RE could not be utilized.

(ii) Further, under utilization of fund under Establishment Head was mainly on account of non- utilization of funds in salary, medical, travel expenses Heads as number of posts remain vacant during the year despite follow up with the Department/DoPT.

Reasons for underutilization of funds for 2019-20:

(i) The BE 2019-20 is Rs.12.00 crore for Estt.(NPPA) and expected expenditure during the year is Rs.11.02 crore and savings for surrender is Rs.0.98 crore. The savings is mostly under Object Heads – Salary, Wages, Rent, Rates & Taxes, Travel Expenses (Foreign) & Domestic and Professional Services. The reasons for these savings include non-filling up of 17 sanctioned vacant posts, proposal for additional office space could not be materialized and economy and austerity in expenditure.

(ii) The BE for CAPPM Scheme is Rs.4.00 crore and it is expected that it will be fully utilized."

4.23 The Committee thereafter asked about the rationale for allocation of Rs. 11.90 crore to NPPA when it was not able to spend the revised estimates during previous years, the Department in their written reply stated that:

"The Budget provisions for the year 2020-21 of Rs. 11.90 crore for Establishment (NPPA) is fully justified as funds for the current financial year (2019-20) to the extent of 76.21% (Rs.914.52 lakh) have been utilized by 18.2.2020 and it is expected that an expenditure of Rs.11.02 crore will be incurred by 31.3.2020."

4.24 The Department further stated the measures that are proposed to be taken by NPPA to utilize the allocated funds efficiently and effectively which are stated as under:

"NPPA has taken several measures to utilize the allocated funds efficiently and effectively as mentioned below:

a) Recently, as decided in the meeting with the Principal Scientific Adviser to the Government of India on 6.11.2019, a proposal in the form of Cabinet Note has been sent to DoP on 24th December, 2019 for strengthening of NPPA by creating three (3) Joint Secretary level posts.

b) The proposal for creation of additional thirty-four (34) posts below Joint Secretary level under Group A stands submitted to Department of Expenditure

(DoE) through Department of Pharmaceuticals (DoP) for obtaining necessary approval from as per decision taken in SFC meeting held in DoP.

c) NPPA has undertaken the process of engagement of 19 outsourced persons on contract basis through open tender. However, only 13 could qualify and got engaged. The process to engage more persons is already on.

d) Financial and Administrative approvals have been obtained from DoP for hiring of additional space in the YMCA building. MoU is being worked out with YMCA for hiring of additional space in the same building. Simultaneously, CPWD and NBCC have been asked to give estimates for renovation.

e) For modification and extension of the CAPPM Scheme in line with the Vision Plan of the Department of Pharmaceuticals for setting up of PMRUs in all 37 States/ UTs, the approval has been obtained. Third Party Evaluation of the Scheme is under process.

f) To expedite the activities under the component 'Advertisement and Publicity' under the Scheme, 14 DAVP empanelled multimedia agencies have been empanelled with NPPA after following the process of open tender.

g) NPPA, in coordination with the State PMRUs, have organized consultative seminars in the States of Rajasthan, Uttar Pradesh, Kerala and Gujarat on 'Availability, Accessibility and Affordability of Medicines for all' to create awareness among general public. Further such Seminars are being planned.

h) A training programme for PMRU Staff is scheduled to be organized in Delhi in the month of March, 2020.

NPPA has undertaken an outdoor publicity campaign on 'reduction in the prices of anti-cancer drugs, knee implants, heart stents and general medicines' through various means, including hoardings, LEDs screens, airing of Radio Jingles, Newspaper Advertisement and screening short tele-film (TVC) in cinema halls, etc. throughout the country."

4.25 The Department further stated following the priorities of NPPA with respect to price control of scheduled as well as non-scheduled drugs and medical devices during the year 2020-21:

a) Pricing of formulations as per NLEM 2020 to be released by Ministry of Health and Family Welfare (MoHFW).

b) Assist in framing Pricing Policy based on Trade Margin Rationalization (TMR), which was earlier implemented to anti-cancer drugs as a proof of concept, on non-scheduled drugs and medical devices to extend the benefit of TMR.
c) Creation of integrated database for Pharmaceuticals and Medical Devices through CDAC.
d) Ministry of Health and Family Welfare has notified all Medical Devices with effect from 01.04.2020 ensuring price regulation for these in a phased manner.
e) Providing inputs for different policy decisions."

4.26 Specific new steps/programmes that are proposed to be initiated during 2020-21 to achieve the goals of NPPA are as under:

a. Setting up of PMRUs in 6 more States/ UTs.
b. Rolling out more Information, Education and Communication (IEC) Campaigns to create awareness among common people.
c. Contribution to formulation of a Policy based on Trade Margin Rationalization (TMR) approach.
d. Fixing of Ceiling price for Drugs under new NLEM."

4.27 During the oral evidence Chairperson National Pharmaceutical Pricing Authority (NPPA) briefed the Committee about the contours and the limitations of the Present National Pharmaceutical Pricing Policy 2012, stated as under:

"I would like to submit that there is a National Pharmaceutical Pricing Policy, 2012, which gives the contours of pricing of medicines. As you would appreciate that there is a basic contradiction between the interest of industry and interest of consumers. So, this pricing policy has set the parameters of regulation for the pharma segment, and they have said that only drugs that are placed under the NLEM by the Ministry of Health and Family Welfare shall be placed under the schedule of the Drug Pricing Control Order, 2013.

As of now, they comprise 19-20 per cent of the total pharma segment, and for them NPPA gives a price cap based on market averages. We also see that annual price increase cannot be more than the wholesale price index, which is usually in the range of 4 per cent or so. But for the remaining non-scheduled drugs, which is almost 80 per cent, they are free to log at whatever price they want as per the market dynamics and for those the NPPA only regulates that annual price increase shall not be more than 10 per cent.

I would like to submit this issue of trade margin rationalization, which has been under consideration at the highest levels of the Government. Accordingly, when we launched the pilot on anti-cancer drugs in February 2019, we were given the go-ahead to conduct a pilot and give its study on how it impacts margins. As Secretary has just shared, we brought only 30 anti-cancer drugs – actually the molecules were 42 – but when we brought the margins in control and we limited the margins at 43 per cent as the price to stockists, we got a whooping savings of Rs. 984 crore only for these 42 molecules, which translated into 526 formulations and savings were up to 90 per cent. However, NPPA has submitted its report. We have also had stakeholder consultations. This is as the policy stands of now."

4.28 During the evidence with the representatives of the Department of Pharmaceuticals, the Committee raised their concern over the huge profit margin earn by the big Hospitals on the sale of medicines in their premises.

MAJOR HEAD-[2852 (Industries)]

IV. Consumer Awareness Publicity and Price Monitoring (CAPPM)

4.29 Under the Central Sector Scheme of NPPA, viz., 'Consumer Awareness, Publicity and Price Monitoring' (CAPPM), Price Monitoring and Resource Units (PMRUs) are the societies registered under the Societies Registration Act having its own Memorandum of Association/ Bye laws. The primary function of PMRUs is to assist NPPA in price monitoring, detection of violation of the provisions of DPCO, pricing compliance, ensuring availability of medicines and consumer awareness. They are also responsible for collection, compilation and analysis of market-based data of scheduled as well as non-scheduled formulations. Till now PMRUs have been set up eleven States (Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh , Andhra Pradesh and Mizoram).

4.30 Year wise fund allocation and expenditure incurred under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme for the last three years is given as under:

(Rs.in crore)

Name of Scheme	2017-18			2018-19			2019-20			2020-21
	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
Consumer Awareness through print, electronic and other media (renamed as Consumer Awareness, Publicity and Price Monitoring	--	--	--	4.00	4.00	2.98	4.00	4.00	1.74*	4.50

***As on 17.01.2020**

4.31 Performance of this scheme during the last two years was not up to the mark. Actual expenditure was less than RE during both the years. The Committee asked about the rationale for making a higher allocation of Rs. 4.50 crore for this Scheme during 2020-21, the Department in their written reply stated as under:

" 2018-19: The 15-digit digital code (Account Head) as was compulsorily required by Pay and Accounts Office (DoP) for release of funds under PFMS for both the components of the CAPPM Scheme. This could be obtained in 2018-19. The concentrated efforts were made for setting up of PMRUs in different States. As a result, PMRUs in four States viz. Kerala, Gujarat, Odisha and Rajasthan were set up. The funds of Rs. 1,14,17,185/- got disbursed to the four States viz. Kerala, Gujarat, Odisha and Rajasthan as per PMRUs guidelines. In the meantime, due to application of Model Code of Conduct (MCC) before the Lok Sabha elections 2019, the process of setting up of PMRUs in other States got delayed. It is pertinent to mention that the process of setting up of PMRUs largely depends upon the willingness, enthusiasm and cooperation from the respective state Government and their State Drug Controller/ Food and Drug Administrators. NPPA continued its efforts by following the States vigorously.

The funds under the 2nd Component of the CAPPM Scheme, i.e. 'Advertising and Publicity' of the CAPPM scheme could not be utilized due to following reasons:

a. Delay of advertisements due to application of Model Code of Conduct (MCC) before General Assembly Elections 2019.

b. Non-receipt of bills of Rs. 34,85,547/- of Radio Jingle from DAVP by March end.

2019-20: As per the Scheme, 10 PMRUs have been setup in different States. NPPA has already utilised Rs. 2.32 crore approx. during the F.Y 2019-20 (upto 18.2.20) out of the budget allocation of Rs. 4.00 crore under the two components of CAPPM Scheme, viz., (i) Grant in Aid to PMRUs (Rs. 1.73 crore out of Rs. 2.00 crore) and (ii) Advertising and Publicity (Rs. 0.59 crore out of Rs. 2.00 crore). The matter of release of remaining fund is under process."

4.32 During the oral evidence the NPPA Chairperson further clarified on the utilization of Rs 4.00 crore made under CAPPM during RE 2019-20 which is as under:

"Rs. 2 crore is for setting up of PMRUs. We are going to set up 12 PMRUs. Already money has been given for 11 PMRUs. So, Rs. 2 crore is for PMRU and for publicity it is Rs. 2 crore. For this Rs. 2 crore, we had an open tender. That is because last time we had an issue as to which company we should give, etc. So, we had an open tender. We have empanelled DAVP-empanelled agencies. In Delhi alone, there was an issue because of elections at that time. It could not be done due to that. We have done that on LED screens, on bus stands, newspaper advertisements, radio jingles, metro stations, etc. We are also making films. So, all this has been done. The amount is very small. We would like to get more. We would be grateful if more amount is allotted."

4.33 Further the Department in their written reply stated the manner in which the higher allocation of Rs. 4.50 crore is proposed to be spent during 2020-21, given as under:

"As per the vision plan of Department of Pharmaceuticals (DoP) the PMRUs are now to be set up in all the 37 States/ UTs. The Scheme is, therefore, being modified to match the Vision Plan. During the year 2020-21, the number of PMRUs is to be increased to 16 from 10 in 2019-20. The IEC activities will also increase during 2020-21. Accordingly, the allocation of Rs.4.50 crore under CAPPM Scheme is justified."

4.34 During the oral evidence the NPPA, Chairperson submitted before the Committee that the hands of NPPA have got strengthened with Price Monitoring Resource Units (PMRUs) functioning in 11 states given as under:

> "…NPPA has also now got 11 Prime Monitoring Resource Units about which I have briefed in the last meeting. In 11 States we have these agencies. They are slowly being manned and trained and operationalized. But at least we have a structure there in 11 States. This strengthens the hand of the NPPA…."

MAJOR HEAD-[2552 (North East Region) and 2852 (Industries)]

V. National Institute of Pharmaceutical Education and Research (NIPER)

4.35 Indian Pharma Industry has been a global leader in Generic drugs. In order to acquire leadership position in drug discovery and development and to continue to excel in the formulations, Government recognized that human resources / talent pool is very critical. National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar (Mohali) was set up as a registered society under the Societies Registration Act 1860. Subsequently the Institute was given statutory recognition by an act of Parliament, NIPER Act, 1998 and was declared as an Institute of National Importance.

During 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institutes. Subsequently, NIPER at Madurai was approved in the year 2012. During 2015-16, Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh, Maharashtra and Rajasthan.

Objectives are (a) to act as nucleus for interaction between academic and industry by encouraging exchange of scientist and other technical staff between the Institute and the industry and by undertaking sponsored and funded research as well as consultancy projects by the Institute, (b) to nurture and promote quality and excellence in pharmaceutical education and research, and (c) to concentrate on courses leading to master's degree, doctoral and post-doctoral courses and research in pharmaceutical education.

NIPER-Mohali has regular faculty posts and non-faculty posts. Department of Expenditure has created 156 faculty and 150 non-faculty posts in six NIPERs viz. Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli in January 2019.

4.36 Year wise fund allocation and expenditure incurred under NIPER Scheme for the last three years is given as under:

(Rs. in crore)

Name of Scheme	2017-18			2018-19			2019-20			2020-21
	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
NIPERs	127.73	151.66	180.77	135.0	135.0	135.0	150.0	160.00	138.10*	202.45

***As on 17.01.2020**

4.37 Rs. 202.45 crore has been allocated at BE stage against the proposed requirement of Rs. 450.00 crore for NIPERs. The Committee asked how the Department will manage infrastructural, technical and human resource requirement of all the NIPERs during the year 2020-21 with the reduced allocation and what steps are proposed to be taken thereon, the Department in their written reply stated as under:

> " While the Department had sought Rs. 450.00 crore for NIPERs, the Ministry of Finance has allocated only Rs. 202.45 crore, which will definitely affect the implementation of the various activities of the NIPERs. This will certainly delay the construction of campuses. The Department is in process of preparing fresh Expenditure Finance Committee (EFC) proposal for the existing and newly proposed NIPERs seeking sufficient funds for construction of their campuses, equipping the laboratories as well as other administrative and academic expenses. It will seek funds as proposed/ approved under the fresh EFC. Further, the Department will seek additional funds for NIPERs through 1st Supplementary Demands for Grants for FY 2020-21."

4.38 The Department had made additional Demand of Rs 300 crore for NIPERs during 2019-20 but only Rs.10 crore was added at RE stage as token supplementary fund after re-appropriation from matching savings from MH 2852 Development of Pharmaceuticals and Jan Aushadhi Scheme to make the total allocation to Rs 160 crore from Rs. 150 crore at BE stage in 2019-20. The Committee asked the extent to which the developmental activities of various NIPERs were affected due to curtailment of funds, the Department in their written reply stated as under:

> "The additional fund of Rs. 300.00 crore (Rs. 275 crore for CCA + Rs. 25 crore under Grants in Aid-General) was sought during the 2019-20 from the funds approved by EFC in March, 2018 for construction of campuses of NIPERs at Guwahati and Ahmedabad, purchase of equipment, salary of newly appointed regular faculty/administrative staff and meeting other recurring expenditure, etc. Out of Rs. 10 crore additional funds allocated in BE, Rs. 5 crore is proposed to be

allocated to NIPER Guwahati for construction activities and remaining Rs. 5 crore will be allocated among other NIPERs to meet the salary expenses of newly recruited faculty/ administrative staff. The activity for the purchase of equipment for NIPERs would per force be deferred till approval of the fresh EFC proposal beyond March, 2020."

4.39 Department provided NIPER-wise details of progress made in creation of building and technical infrastructure during 2019-20. The Committee asked whether the allocated fund is fully utilized by each NIPER as only Rs. 138.10 crore has been utilized as on 17.01.2020, the Department in their written reply stated as under:

"The Expenditure Finance Committee (EFC) in its meeting held on 26.03.2018 recommended for continuation and strengthening of the existing six NIPERs, namely, Ahmedabad, Guwahati, Hyderabad, Hajipur, Kolkata and Raebareli during the period 2017-18 to 2019-20 at a total cost of Rs. 959.53 cr. The Committee approved construction of campuses of only two NIPERs, viz., NIPER at Ahmedabad and Guwahati The construction of campus of NIPER Guwahati has since been completed almost 90%. Further, the tender for NIPER Ahmedabad has been issued, party selected and work order issued by PMC. A token amount of Rs. 1.5 crore has also been released to NIPER Ahmedabad to start the construction of the campus. In case of other four existing NIPERs, the decision to set up campuses was deferred by EFC. It, however, allocated Rs 465 crore for equipping the laboratories of these six existing NIPERs. The EFC also recommended that setting up of the proposed four new NIPERs at Madurai and in the states of Maharashtra, Chhattisgarh and Rajasthan be deferred. It suggested that the same may be reviewed in the year 2020 by the Department during the Fifteenth Finance Commission period (2020-25). The Department is in process of preparing fresh Expenditure Finance Committee (EFC) proposal for the existing and these newly proposed NIPERs."

MAJOR HEAD-(6857)

VI. <u>Assistance to PSUs (Loan to PSUs)</u>

4.40 The Department has five Central Public Sector Undertakings under its administrative control viz. (a) Indian Drugs& Pharmaceuticals Ltd. (IDPL) (b) Hindustan Antibiotics Ltd (c) Karnataka Antibiotics & Pharmaceuticals Limited (d) Bengal Chemicals & Pharmaceuticals Ltd and (e) Rajasthan Drugs and Pharmaceuticals Limited.

4.41 Year wise fund allocation and the expenditure incurred under scheme Assistance to PSUs for the last three years is given as under:

(Rs. in crore)

Name of Scheme	2017-18			2018-19			2019-20			2020-21
	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
Assistance to PSUs	0.06	0.06	0.00	0.06	7.00	10.95*	5.06	333.18	165.00	7.18

*Rs. 160.00 crore under 1st Batch of Supplementary Demand for Grants FY 2019-20 for Public Sector Undertakings to make payment of employee's liabilities of unpaid salary/VRS.

4.42 The Department in their written reply furnished physical and financial performance of each of their public sector undertakings for the last three financial years which is given as under:

"Physical and Financial Performance of PSUs during the last 3 years:

I. Bengal Chemicals & Pharmaceuticals Ltd.

(Rs. in Crore)

S. No.		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

II. Hindustan Antibiotics Ltd.

(Rs. in Crore)

S. No.		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	208.32 *	-71.10
4.	Earnings (After Tax)	-78.24	208.32 *	-71.10
5.	Net Profit/Loss	-78.24	208.32 *	-71.10

* The said Net Profit is the result of an extra-ordinary item of income, viz, waiver by Govt. of India of its plan & non-plan of Rs. 186.96 crores and the interest thereon of Rs. 89.94 crores, totally Rs. 276.90 Crores.

III. Indian Drugs and Pharmaceuticals Ltd.

(Rs. in Crore)

S. No.		2016-17	2017-18	2018-19
1.	Net Worth	-7,302.79	-7,464.66	-7,626.58
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

IV. Rajasthan Drugs and Pharmaceuticals Ltd.

(Rs. in Crore)

S. No.		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

V. Karnataka Antibiotics & Pharmaceuticals Ltd.(KAPL)

(Rs. in Crore)

S No.		2016-17	2017-18	2018-19
1.	Production	405.51	366.82	388.63
2.	Sales Turnover	386.27	353.83	360.36
3.	Operating Profit	43.35	20.59	22.75
4.	Net Profit	30.33	14.55	15.82

Note: The details for the financial year 2019-20 would be available only after closing of the financial year."

4.43 The present status of closure/ strategic sale/ disinvestment of each of the Public Sector Undertakings furnished by the Department in their written reply as under:

"(i) The Union Cabinet in its meeting held on 28.12.2016 has decided for the closure of Indian Drugs & Pharmaceuticals Ltd. (IDPL) & Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL) and strategic sale of Hindustan Antibiotics Ltd. (HAL) & Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) after settling their liabilities from the sale of their surplus land to government agencies.

(ii) The Union Cabinet in its meeting held on 17.07.2019, has inter-alia, approved modification of its earlier decision dated 28.12.2016 of sale of surplus land of PSUs to Government Agency and instead permitted the sale of land as per revised DPE Guidelines dated 14.06.2018, which includes sale of land to other entities. It also approved constitution of a Committee of Ministers for taking all decisions pertaining to closure/ strategic sale of the PSUs. Further, it approved budgetary support as loan to the tune of Rs

330.35 cr. for meeting the employees' liabilities (unpaid salary – Rs. 158.35 cr. + VRS Rs. 172.00 cr.) as per following break-up:

IDPL	Rs. 6.50 cr.
RDPL	Rs. 43.70 cr.
HAL	Rs. 280.15 cr.

(iii) Department of Pharmaceuticals holds regular meetings with NBCC (Land Management Agency), MSTC (Auctioning Agency), MDs of the PSUs and other appropriate Departments for quickening the closure/strategic sale of the Government PSUs. The work relating to valuation of both movable and immovable property is in progress, based on which necessary follow-up action shall be taken.

(iv) Against the total sanction of Rs.280.15 crore to HAL by the Cabinet on 17.07.2019, Department released Rs.116.30 crore to HAL on 30.12.2019 towards VRS/pending salaries of HAL. Further, an amount of Rs.43.70 crore has been released to RDPL for unpaid salaries/VRS.

(v) The Hon'ble High Court, Kolkata has set aside the decision of strategic sale of BCPL. An appeal has been filed in the matter before the Division Bench of the Court, which is yet to be listed for final hearing.

(vi) CCEA in its meeting held on 01.11.2017 had accorded 'in principle' approval for strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL). The Department has not supported the decision of strategic disinvestment of KAPL, as the company is profit making and has been assigned the responsibility of being the sole manufacturer of Oxytocin for domestic consumption. The matter has been taken up with the NITI Aayog/Ministry of Finance for re-consideration of the decision on 01.11.2017 and on 17.06.2019.

(vii) M/o Health and Family Welfare (MoH&FW) has issued notification on 27.07.2018 prohibiting private sector companies from manufacture of Oxytocin. The said notification was quashed by High Court of Delhi on 14.12.2018. An appeal has been filed in the matter by MoH&FW at the Hon'ble Supreme Court indicating *inter-alia* that the decision of disinvestment will not materialize if the Govt's scheme of manufacturing Oxytocin through public sector receives a confirmation of the higher court. The Hon'ble Supreme Court vide judgement dated 22.08.2019 has decided that the matter be decided by a larger bench."

4.44 Further during the study visit of the Committee at Bengaluru, in a informal discussion held with representatives of Department of Pharmaceuticals and KAPL on the matter related to the present status of Strategic Disinvestment of KAPL and issues related to production of Oxytocin, the department submitted as under:

"The matter is presently sub judice and the decision of disinvestment of KAPL is presently put on hold. As recommended by the Committee, the matter of strategic disinvestment of KAPL has been taken up at the level of Minster of Chemicals & Fertilizers with the Minister of Finance and Vice chairman, NITI Aayog. The last reminder in the matter was sent on 17.06.2019."

4.45 On measures taken to pursue Karnataka Government to buy shares of KAPL the Department submitted as under:

"The Secretary, Pharmaceuticals had visited Bengaluru and discussed the matter with Chief Secretary and other officials of Government of Karnataka. The Government of Karnataka intimated the Department on 01.03.2019 about its inability to pick-up Government of India equity in the company."

4.46 The Department also briefed the Committee about the extension of Pharmaceuticals Purchase Policy of Government to purchase medicines from Pharmaceuticals PSUs, the Department submitted as under:

"The Cabinet on 20.11.2019 has approved extension of Pharmaceuticals Purchase Policy (PPP) till final closure/strategic sale of Pharma PSUs. All state/Central Governments/Departments/procuring agencies have been informed in this regard by the Department of Pharmaceuticals on 04.12.2019."

4.47 The Committee asked about the progress made in regard to payment of pending salary dues, VRS dues etc. to each of the sick/ closed PSUs under the Department, the Department in their written reply stated as under:

"During the financial year 2018-19, Rs. 2.00 crore were released during the month of October, 2018 to RDPL towards part payment of pending salary. Rs. 5.00 crore were released during the month of March, 2019 to HAL to meet the pending salary dues and other critical expenditure. During the year 2019-20, Rs. 5.00 crore were released during the month of May, 2019 based on the Hon'ble High Court of Rajasthan at Jaipur. A sum of Rs. 43.70 were released to RDPL during the month of

December, 2019 as loan towards payment of employees' liabilities of unpaid salary and VRS as approved by the Cabinet in its meeting on 17.07.2019 and Rs. 116.30 crore were released HAL during the month of December, 2019 towards part payment of pending salary/VRS. In pursuant there to, 99 employees of RDPL and 250 employees of HAL have been given VRS.

Further, the balance amount of Rs. 163.85 crore is expected to be released to HAL towards payment of salaries/VRS as per the Cabinet Decision dated 17.07.2019 after the approval of second batch of supplementary demand for grants 2019-20 to be approved by Ministry of Finance. Further, In respect of IDPL, the sum of Rs. 4.28 crores shall be released towards VRS in 2019-20."

RECOMMENDATIONS/OBSERVATIONS

RECOMMENDATION NO. 1: NEED FOR ENHANCEMENT OF BUDGETARY ALLOCATION

The Committee note that 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. The total size of Indian drugs and medical devices industry is around USD 43 Billion and it is currently having a growth rate of 7-8 % in drugs sector and 15-16 % in medical device sector. Total exports of drugs and medical devices are to the tune of USD 20.15 billion with drugs contributing around 90% of the total exports. Imports around USD 10.4 billion of which medical devices constitute around 52 %. Pharma sector is currently contributing US$ 47.28 billion which is around 1.72% of country's GDP. It is expected that the sector can contribute between USD 85 to 100 billion to Indian Economy by 2024. However, the Committee are concerned to note that there are certain issues viz. dependence on import of API mostly from China, import of more than 50% of medical devices needs of the country, non-compliance of WHO GMP standards by most of the drug manufacturers in the country, etc. which have to be immediately addressed by the Government for continuous march as a frontline drug manufacturing country. The Committee note that the Department of Pharmaceuticals has initiated a few schemes for setting up of Common Facility Centres for Pharmaceutical industry, Bulk drug (API) industry and medical devices so as to promote the holistic growth of the Pharma sector in the country particularly to

reduce the import of bulk drugs and medical devices. There is also an ambitious scheme for technology upgradation of 4500 pharma SMEs to make them comply with WHO GMP standards. In this regard, the Committee are constrained to note the inadequate budgetary allocation of only Rs. 333.58 crore as against the demand of Rs.694.05 crore made by the Department. Notwithstanding huge responsibilities of the Department to ensure quality medicines at affordable prices to the entire population of the country, budgetary allocation is hardly sufficient to fulfill this huge responsibility. The Committee also 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. Since it is very much necessary to make adequate level of budgetary support to the Department to enable it achieve the goals before it particularly to enable the poor and deprived sections of the society to have basic access to affordable quality medicines. The Committee further note that during the year 2019-20 the Department could utilise only 64.34 per cent of the total allocated budget i.e. Rs. 361.81 crore (as on 17.01.2020) out of Rs. 562.33 crore available at revised estimate stage. The Committee are dismayed to note the under utilization of funds by the Department, which reflects poorly on their planning and scheme implementation capabilities. Therefore, the Committee feel that on one hand the Department has to work hard effectively towards utilization of allocated funds and on the other hand there is need to enhance the budget allocation commensurate with the social mandate of the Department . The Department shall 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 of Finance for necessary action at its level.

RECOMMENDATION NO. 2 : PROMOTION OF BULK DRUG /API INDUSTRY IN THE COUNTRY

The Committee are concerned to note that Active Pharmaceuticals Ingredients (API)/Bulk drugs and intermediates form 63% of India's total pharma imports. Even production of some of the NLEM formulations is dependent on imported APIs and intermediates. India imports bulk drugs and intermediates largely on economic considerations as imports are cheaper than domestic production. China with a share of 67.6 % is the major source of API for the country. India, being one of the largest manufacturers of medicines and exporting to over 200 countries, dependence on a single source for import of API is a matter of concern as any disruption in the supplies could jeopardize the entire pharma sector and affect supplies of medicines both for domestic use and exports. The Committee note that the Department has constituted a Task Force on API under the Chairmanship of the Minister of State (Chemicals & Fertilizers) on 18.04.2018 to formulate a roadmap for the enhanced production of Active Pharmaceutical Ingredients (APIs) in the country. The Committee also note that Department has taken some steps viz instructions issued to the State Governments to increase the API production capacity, timely permission by State Governments and Central Drugs Standard Control Organization (CDSCO) for setting up of API Plants and diversifying import of API from countries like Italy etc. rather than relying solely on China. The Department has also planned to revive 21 API plants which were operating in 2005 and were closed down because of stiff competition from China but the revival process likely to take one and a half year. The Committee further note that the Department has made efforts in promoting Domestic API/Bulk drugs production under a sub-scheme 'Assistance to Bulk Drug Industry for Common Facility Centre' as part of the Department's umbrella scheme namely 'Scheme for Development of Pharmaceutical Industry'. Under this sub-

scheme, financial assistance would be provided 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. This sub-scheme has received only an allocation of Rs 21.52 crore at BE stage of 2020-21 against the proposed fund requirement of Rs.100.00 crore. The Department has stated that the proposals received from State Governments of Andhra Pradesh, Telangana, Himachal Pradesh and Assam have been given 'in-principle' approval. However, State Government of Assam has stated that it will not be financially viable for them to establish a Bulk Drug Park in their State. The remaining three proposals will be considered for final approval after receipt of Detailed Project Reports (DPRs) and the respective State Governments have been reminded to send Detailed Project Report at the earliest. In this regard, the Committee are dismayed to note that there is no concrete effort to reverse the trend of over-dependence on imports for the API. The Scheme of Assistance to Bulk Drug Industry for Common Facility Centre was launched only during 2017-18, but the setting up of Bulk drug parks in four states under the Scheme is only at approval stage even after two years of implementation of the Scheme. It is also a matter of concern that only Rs. 21.52 crore has been allocated for the Scheme against the requirement of Rs. 100 crore. Since it is high time specially in view of spread of corona virus from China the Government pays due attention for the promotion of bulk drug industry in the country, the Committee strongly recommend that swift action should be taken to establish the proposed Bulk drug parks in four states and the feasibility of setting up these parks in other states should also be examined in a time bound manner so as to create a strong bulk drug/API manufacturing base in the country instead on relying on a foreign country

on this critical sector. Immediate steps should also be initiated for revival of 21 API plants which were closed due to competition from China. The Committee is also concerned about this approach to give grants to the States to implement some kind of a cluster approach. The Committee would like the Department to examine if such a cluster approach of boosting industrial activity has resulted in any concrete benefit in any other sector. The Committee would also like the Department to examine if a new approach involving concrete benefits in the form of say, subsidized finance, free industrial land, assured buy back contracts, etc. can be formulated so that it becomes economically viable for the pharmaceutical units to procure API locally. Since this is a critical sector for the economic and physical well-being of the country, the Committee would like the Department to seriously examine the issue of creating tariff barriers so that it becomes attractive to produce API in the country. This may be taken up with Ministry of Commerce and Ministry of Finance at the highest level.

RECOMMENDATION NO. 3: TECHNOLOGICAL UPGRADATION OF PHARMACEUTICAL INDUSTRY

The Committee note that the World Health Organization- Good Manufacturing Practices (WHO-GMP) certificate is a mandatory requirement in most global markets for companies to be able to sell their medicines. It is difficult for the pharmaceutical Micro Small and Medium Enterprises (MSMEs) to establish and operate world class quality manufacturing and testing facilities on their own due to huge financial and technical investment involved. It is roughly estimated that 80% of the pharmaceutical MSMEs in the country are not WHO GMP compliant. Upgrading to such standards require investment to the tune of Rs.5-10 crore per unit as per the feedback from the stakeholders. The Committee observe that the Department has launched a scheme

viz. Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) to facilitate pharmaceutical MSMEs 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. Under the scheme, 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 pharmaceutical MSMEs of proven track record.(Ref: P5 Para 2.2). The country requires Rs. 500 crore to Rs. 600 crore to convert the Pharma units in the country into WHO-GMP compliant. However the Committee are dismayed to note that the Department has been getting only a token allocation of Rs. 2 lakh for the scheme since 2018-19 including 2020-21 at BE stage which is a miniscule amount to start this important scheme for improving the standards of vast number of pharmaceutical MSMEs in the country and scheme has been a non-starter as no Public Sector Financial Institution(PSFI) has come on board to implement this scheme. After discussing with various stake holders, guidelines of this scheme have been revised by the Department including the selection of PSFI. The Committee would like the Department to appreciate the fact that technology upgradation to the level of WHO-GMP compliance will not happen unless the pharmaceutical SMEs are physically and financially assisted. The Committee would simultaneously want the Department to appreciate that WHO-GMP compliance not only helps the exporting pharmaceutical units but also enhances the quality of drugs available for domestic consumption. Therefore, the Committee would like the Ministry to formulate a concrete scheme involving real assistance to the SMEs for making them WHO-GMP compliant. Even if the scheme provides assistance to a few units each year (in view of paucity of funds), it should extend substantial assistance to the units beyond

encouragement and guidance. The Committee in this regard recommend that swift action should be taken by the Department to implement the scheme in a time bound manner. For this to take place, the Committee strongly recommend that the Finance Ministry should enhance the budgetary allocation for this scheme so that the Department can implement this scheme for technology up-gradation of the pharmaceutical MSMEs. The Department shall 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 Finance Ministry for necessary action at its level. In case of funding difficulties, the Department may consider to create a Special purpose Vehicle (SPV) in partnership with Private Pharmaceutical Industry who are dependent on the MSMEs sector to produce their pharmaceutical products so that a specific investment fund may be created for the technological up-gradation of Pharma MSMEs.

RECOMMENDATION NO 4: PROMOTION OF ADVANCED RESEARCH IN DRUGS AND MEDICAL DEVICES FIELDS

The Committee note that Pharmaceutical industry is a knowledge intensive industry and needs continuous development of new Chemical/ biological entities, updating/improvement in the processes, develop new drug delivery systems etc. to remain competitive. To sustain its edge in domestic and export markets, Pharma industry has to invest continuously in R& D. Besides, academia-Industry linkage has been identified as a basic requirement for translating research into development (commercialization) and Innovation. The Committee note that the Department of Pharmaceuticals has also constituted an Inter-Departmental Committee (IDC) on 9th January, 2019 to institutionalize a robust mechanism to ensure economy, efficiency, effectiveness and transparency in the arena of Pharmaceutical research.

Since it is very much necessary to have a strong Research and Development base in the country to remain competitive at the global level and to meet the medicines needs of this huge country, the Committee would like to recommend that the Department should take concrete steps for promoting advance research in drugs and medical devices fields in collaboration with National Institute of Pharmaceutical Education and Research (NIPER), Public Sector Undertakings like BCPL and KAPL and private research laboratories. In this regard the Committee strongly recommend that the Department shall request the Ministry of Finance to make separate budgetary allocation for Research and Development segment for pharmaceuticals sector.

RECOMMENDATION NO 5 : ASSISTANCE TO MEDICAL DEVICES INDUSTRY

The Committee note that the country imports almost 85% of all its medical device needs. The country largely imports high technology medical equipments and electronics which constitute 66 % of the country's import basket. The Committee note that for the year 2020-21 the Department had proposed an amount of Rs 30.00 crore under the sub-scheme 'Assistance to Medical Device Industry for Common Facility Centre' but the Finance Ministry has allocated only Rs 7.50 crore. The Committee note that in principle approvals have been given for four proposals under this sub-scheme. The Department stated that under this sub-scheme, the proposals received from State Governments of Andhra Pradesh, Telangana, Tamil Nadu and Kerala have been given 'in-principle' approval. Also, the proposal of Andhra Pradesh has been given final approval for financial assistance of Rs. 25 crore. The other three proposals will also be considered for final approval after receipt of Detailed Project Reports (DPRs) for which the concerned State Governments have been reminded by

the Department. The Committee feel that the setting up of common facility for Medical Device Industry would play major role in promotion of medical device industry in the country. Therefore, the Committee strongly recommend that the Department should take concrete steps in coordination with State/UT Government concerned to implement this sub scheme effectively. The steps to be taken by the Department should involve a dedicated infrastructure with free or nearly free land, easy access to low cost finances and technological assistance as without these basic ingredients, it is not possible to motivate any entrepreneur to set up new business in a sector where imports have a lower cost in general. The Department should also pursue with the Ministry of Finance to increase budgetary allocation for this scheme keeping in mind the priority of medical devices industry for the health sector. The Department shall 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 Finance Ministry for necessary action at its level.

RECOMMENDATION NO 6 : PRADHAN MANTRI BHARTIYA JANAUSHADI PARIYOJANA (PMBJP)

The Committee note that the Department of Pharmaceuticals has launched a Scheme called "Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)" with the objective of making quality generic medicines available at affordable prices to all. Presently 6141 PMBJP Kendras are functional across the country and out of this, 524 PMBJP Kendras are functional in 117 aspirational districts which are considered relatively backward 697 districts of the country have been already covered and the target has been fixed to cover all districts by 31st March, 2020. The Government of India has requested the State Governments to provide space in government hospitals for the opening of Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs). As on

date the product basket of PMBJP comprises of 900 drugs and 154 surgicals. Further, the Committee are pleased to note that the Bureau of Pharma PSUs of India (BPPI) which is the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), is increasing self-sufficiency and reducing dependence on grants provided by Department of Pharmaceuticals (DoP) as envisaged in the guidelines of the scheme. Under the Vision Plan of BPPI the target is to open 1000 more Kendras by 31st March 2024, to enhance basket of medicines up to 2000 drugs and 300 surgicals, and establishment of an effective IT-enabled logistics and supply-chain system for ensuring real-time distribution of medicines at all outlets to avoid stock outs. Since PMBJP Kendras can play a vital role in providing quality medicines at affordable prices, the Committee recommend the following:-

(i) Concrete steps should be taken to open more number of PMBJP Kendras in all Tehsil sub district of the country with particular emphasis on opening PMBJP Kendras in the rural, hilly and remote areas of the country.

(ii) Initiative should be made to open PMBJP Kendras in Primary Health Centres and Government hospitals across the country and for this purpose State/UT Governments should be impressed upon at the highest level to provide free space at PHCs and Government hospitals to open PMBJP Kendras in their premises.

(iii) Presently there are four warehouses of BPPI at Gurgaon, Chennai, Bengaluru and Guwahati. Two more are likely to be opened each in Western and Central India. Since the absence of warehouse in each state may result in longer time for delivery of drugs to PMBJP Kendras, the Committee recommend that warehouses may be opened in each

state for timely distribution and delivery of medicines to PMBJP Kendras.

(iv) The feasibility of providing financial assistance to PMBJP Kendras to provide basic infrastructure support to them viz. refrigerators etc. for storing the medicines safely in them may be examined for implementation.

(v) The Public Sector Enterprises under the Department viz. KAPL and BCPL may be given equal opportunity to sell their products for PMBJP scheme so as to enable their successful running with profit and at the same time ensuring procurement of quality medicines under the scheme.

(vi) The Department should also examine a better way to compensate the *Jan Aushadhi* store owners where their compensation could be based on the number of medicines sold rather than percentage of the value which is already extremely low.

RECOMMENDATION NO 7: SCHEME FOR DEVELOPMENT OF PHARMACEUTICAL INDUSTRY

The Committee note that 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. The Department admitted that despite the best efforts made by the Government, the sub scheme 'Assistance to Pharma Industry for Common Facilities' under the umbrella scheme "Development of Pharmaceutical Industry" did not receive a good response in 2017-18, 2018-2019 and 2019-2020. For the sub-scheme "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) only token amount was sanctioned during the period. The Department has now received proposals from the State Governments for setting up Common Facility Centres under these two sub-schemes and in-principle approvals have also been given for setting up of these Centres. Since the Department requires budgetary allocation for implementation of these sub-schemes, the Department had sought an amount of Rs. 144.01 crore from the Ministry of Finance for the implementation of Umbrella Scheme of "Development of Pharmaceuticals Industry" during 2020-21 but only Rs. 42.05 crore has been provided to the Department.

The Committee note that during the last 3 year that is 2017-18, 2018-19 and 2019-20 the Department has been allocated 12.03 crore, 4.00 crore & 3.49 crore respectively as Revised Estimate allocation. Out of this the percentage utilisation was only 15.18%, 70.25% and 77.07% respectively. Though the percentage utilisation has increased over a period of time but the Department is unable to utilise

100% allocation. The Committee also note that for the year 2020-21 the Department has been allocated Rs. 42.05 crore against their demand of Rs.144.01 crore. Though the allocation has increased substantially by Rs. 38.56 crore as compared to last year Revised Estimate figures, but the Department has asked for more allocation that is Rs. 144.01 crore for implementation of the umbrella scheme of Development of Pharma Industries. The Committee hope that the Department would be able utilise their initial allocation and ask for more allocation in the Supplementary Demand For Grants (2020-21) by reflecting their good physical and financial progress.

RECOMMENDATION NO 8: NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATIONAL AND RESEARCH (NIPER)

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. The Department had made additional demand of Rs 300.00 crore for NIPERs during 2019-20 but only Rs.10.00 crore was added at RE stage as token supplementary fund after re-appropriation from matching savings from another scheme to make the total allocation to Rs 160 crore from Rs. 150.00 crore at BE stage in 2019-20. (Ref: Para 3.4 table/NIPER column) The Committee note that an amount of Rs. 450.00 crore was sought for the Scheme of NIPERs by the Department for the year 2020-21. However, the Department submitted that only Rs. 202.45 crore has been allocated, which will affect the implementation of t he various activities of the NIPERs particularly the construction of campuses for NIPERs. In this regard, the

Committee note that the Expenditure Finance Committee (EFC) in its meeting held on 26.03.2018 recommended for continuation and strengthening of the existing six NIPERs, namely, Ahmedabad, Guwahati, Hyderabad, Hajipur, Kolkata and Raebareli during the period 2017-18 to 2019-20 at a total cost of Rs. 959.53 crore. However, the construction of 90% of campus of NIPER, Guwahati has only been achieved during the period. EFC also allocated Rs. 465 crore for equipping the laboratories of the six existing NIPERs. The EFC also recommended that setting up of the proposed four new NIPERs at Madurai and in the states of Maharashtra, Chhattisgarh and Rajasthan be deferred. It suggested that the same may be reviewed in the year 2020 by the Department during the Fifteenth Finance Commission period (2020-25).(Ref: Para 5.19). The Department is in the process of preparing a fresh EFC proposal for the existing and newly proposed NIPERs seeking sufficient funds for construction of their campuses, equipping the laboratories as well as other administrative and academic expenses. It will seek funds as proposed/ approved under the fresh EFC. The Committee are dismayed to note that the proposal for the purchase of equipment for NIPERs has been deferred till the approval of the fresh EFC proposal beyond March, 2020.(Ref: Para 5.18 last line). The Committee note that the NIPERs have been set up as Institutes of National Importance but the inordinate delay in allocation of requisite amount of fund since their inception is ruining the purpose for which these Institutes were set up. The Committee therefore strongly recommend that the Government look into this matter on priority basis and make adequate budget allocations for these institutes to construct building infrastructure, upgrade their laboratories and appoint regular staff and faculty.

RECOMMENDATION NO 9: NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

The Committee note that the National Pharmaceutical Pricing Authority (NPPA), was established through a Government of India resolution dated 29th August , 1997 as an independent body of experts for price control of essential and life saving medicines. NPPA is an attached office of the Department of pharmaceuticals and implements the National Pharmaceuticals Pricing Policy 2012 and the Drugs (Prices Control) Orders as amended from time to time which were issued by the Department. The Committee note that National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) has the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharma industry, thereby meeting the goals of employment and shared economic well-being for all. In pursuance to the NPPP-2012, the Drugs (Prices Control) Order, 2013 (DPCO-2013) was made to regulate the prices of medicines. In this regard, the Committee note that the NPPA regulates 19 to 20 percent of drugs prices based on market averages. But for the remaining non scheduled drugs which are almost 80 percent, companies are free to fix price as per market dynamics and their annual price cannot increase more than 10 percent. The Committee therefore strongly recommend that ambit of scheduled drugs should be increased so that NPPA can control the prices of more drugs. The Committee also recommend that NPPA should monitor effectively to ensure that the annual price increase shall not increase more than 10% and strict action should be taken against those drug manufacturing companies which increase the price of medicines beyond 10%. National Pharmaceutical Pricing Authority capped the Trade Margin of all the non-scheduled formulations of select 30 Anti-Cancer drugs (42 molecules) as

recommended by Expert Committee of Ministry of Health & Family Welfare, under the 'Trade margin Rationalization Approach' and as a result, a the total 526 brands of these medicines have shown reduction in MRP. The Committee while appreciating the policy of Trade Margin Rationalization (TMR) as a forward step in the direction of making branded medicines affordable to poor and deprived patients, recommend that the Department in coordination with NPPA should extend the benefits of TMR to more non-scheduled drugs and medical devices and the action taken in this regard should be conveyed to the Committee. The Committee note that while the NPPA regulates the prices of drugs which are sold at the retail level, there appears to be no regulation of pricing at which the hospitals charge the patients. It has been observed that large hospitals are able to "extract" significantly higher discounts from the pharmaceutical companies but the end user, that is the patient, is billed at the retail price. It is also seen that many hospitals use only those medicines on which an unusually high MRP is printed so that the billing to the patients becomes more profitable. Therefore, the Committee recommend that NPPA should separately examine this aspect within the overall regulatory framework of drug pricing so that the patients being treated in the hospitals are not charged excessively for the medicines. The Committee also observed that as a routine practice, the hospitals bill the patients who are in ICU or in a state of unconsciousness, for drugs which are never actually administered. The patients as well as the family members have no means to verify whether the billed drugs were actually administered or not. The Committee understand that this issue may not be falling directly within the purview of the Department but the Committee would like the Department to refer this matter to the Ministry of Health and Family Welfare for necessary action at their end.

RECOMMENDATION NO 10: CONSUMER AWARENESS, PUBLICITY AND PRICE MONITORING SCHEME

The Committee note that the sub-scheme of Consumer Awareness, Publicity and Price Monitoring (CAPPM) has two components viz. Price Monitoring and Consumer Awareness and Publicity. Under the first component, Price Monitoring and Resource Units (PMRUs) are set up in Stats/UTs. The primary function of PMRUs is to assist NPPA in price monitoring, detection of violation of the provisions of DPCO, pricing compliance, ensuring availability of medicines and consumer awareness. They are also responsible for collection, compilation and analysis of market-based data of scheduled as well as non-scheduled formulations. Eleven Price Monitoring and Resource Units (PMRUs) have so far been set up in States of Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh and Mizoram. Six more PMRUs are targeted to be set up during 2020-21 (Ref: Para 4.28 Chapter-IV). The Committee note that during the year 2019-20 Rs 4.00 crore was allocated at both BE and RE stages under this scheme from which Rs. 2.00 crore was for opening PMRUs and another Rs 2.00 crore was for publicity and consumer awareness campaigns. The allocation has been increased slightly to Rs 4.50 crore for 2020-21. However, the Committee observe that during 2019-20, NPPA could utilise only Rs. 2.32 crore approx. till 18.2.2020. Out of which only 0.59 crore was spent on consumer awareness and publicity purpose. This shows that NPPA is unable to utilise even the meagre sum of Rs. 2.00 crore for consumer awareness and publicity. The Committee while taking note that the allocation of Rs. 4.50 crore for the year 2020-21 is quite nominal for both the components *viz.* PMRUs and consumer awareness and publicity purpose have their apprehension that the Department would be able to fully utilize this meagre amount. The Committee is deeply concerned that on the one hand the Government is

committed to provide low cost health services for all citizens, while on the other hand, the pharmaceutical companies continue to charge extremely high prices even for the routine medicines. While the physical 'offerings' by the Government are extremely promising (Jan Aushadhi Yojana, Pradhan Mantri Swasthya Suraksh Yojana, etc.), the consumers have to be educated in an aggressive manner. This requires large volume of funds as these funds will have a huge impact on the well-being of the citizens of the country. The Committee, therefore recommend that the Department should augment their scheme of Consumer Awareness, Publicity and Price Monitoring (CAPPM) by optimum utilisation of funds for both the components i.e. PMRUs and consumer awareness and publicity and thereafter seek for additional allocation in their Supplementary Demand for Grants 2020-21. Further the Committee recommend that Department and NPPA should take active steps to open PMRUs in all 37 States/UTs in a time bound manner so that the hands of NPPA are strengthened and is empowered to monitor the quality and standards of the drugs sold in the market across the country.

RECOMMENDATION NO 11: DISINVESTMENT OF PROFIT MAKING PHARMA PSUS

The Committee are concerned to note that out of five Public Sector Undertakings (PSUs) under the Department of Pharmaceuticals, Karnataka Antibiotics & Pharmaceuticals (KAPL) and Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) are profit making PSUs. The Government has decided for strategic sale of BCPL and strategic disinvestment of 100% Government of India equity in KAPL. As regards BCPL, Hon'ble High Court of Kolkata set aside the decision of its strategic sale. Now an appeal has been made before the Division bench of the Court. The Department of Pharmaceuticals opposed the strategic disinvestment of KAPL as the company is profit making and has been assigned the responsibility of being the sole

manufacturer of Oxytocin for domestic consumption. This matter of sole Oxytocin production rights to KAPL is presently *sub-judice* in the Hon'ble Supreme Court. The Committee are perturbed to note the decision of NITI Aayog to sell/ disinvest these two profit making PSUs of this priority sector which is concerning the health of huge population of this vast country. Entirely leaving drug manufacturing at the hands of private sector may not be a prudent step as these PSUs may provide required quantity of essential medicines at affordable prices at times of needs particularly during epidemic and pandemic outbreak of diseases. The Committee, therefore, strongly recommend that the decision for the strategic sale/ disinvestment of KAPL and BCPL should be revisited by the Government in the public interest. The Committee should be informed of the action taken in this matter. This recommendation of the Committee should also be sent to NITI Aayog for its specific reply within three months.

<u>RECOMMENDATION NO. 12 : SETTLEMENT OF LIABILITIES OF CLOSED PHARMA PSUS</u>

The Committee also note that the Government is in the process of settling the liabilities including payment of dues to employees of closed PSUs under the Department viz Indian Drugs& Pharmaceuticals Ltd. (IDPL), Hindustan Antibiotics Ltd (HAL) and Rajasthan Drugs and Pharmaceuticals Limited (RDPL) through sale of their movable and immovable properties. Since this is a time consuming process, the Government has approved a budgetary support to the tune of Rs. 330.35 crore as loan to these three PSUs for settling pending salaries/ VRS dues of their employees. Out of total sanction of Rs. 230.15 crore to HAL, Department has released only Rs. 116.30 crore to HAL on 30.12.2019. RDPL was provided the entire sanctioned loan of Rs. 43.70 crore. It is understood that IDPL is

yet to be given its sanctioned loan of Rs. 6.50 crore. Since it is very much necessary to settle the salaries/VRS dues of these three closed PSUs, the Committee recommend that the Department should release entire amount of loan sanctioned to HAL and IDPL for the purpose within a definite period of time. The Committee further note that during the year 2020-21 an amount to the tune of Rs. 7.18 crore has been allocated. The Committee have their doubt that this meagre amount of Rs. 7.18 crore would be able to settle pending salaries/VRS dues of the employees of the above mentioned PSUs. The Committee therefore recommend to revisit this allocation to ensure that all employees get their salary/VRS dues in time. The Committee observe that along with the dues of the employees, there are also significant dues of the former business associates of the closed PSUs which may pertain to advance deposits, outstanding payments, etc.

The Committee recommend that the Department should examine these dues also and settle them as per the provisions of the law.

New Delhi;

18 March, 2020 **Kanimozhi Karunanidhi**

28 Phalguna, 1941(Saka) **Chairperson**

Standing Committee on
Chemicals and Fertilizers

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

(2019-20)

The Committee sat on Friday, the 28th February, 2020 from 1130 hrs. to 1330 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT
Smt. Kanimozhi Karunanidhi- Chairperson
MEMBERS
LOK SABHA

2 Shri Satyadev Pachauri

3 Shri Arun Kumar Sagar

4 Shri M. Selvaraj

5 Shri Uday Pratap Singh

6 Shri Deepak Baij

7 Dr. Manoj Rajoria

RAJYA SABHA

8 Shri G.C. Chandrashekhar

9 Shri Anil Jain

10 Shri Vijay Pal Singh Tomar

SECRETARIAT

1.	Shri Manoj Kumar Arora	-	Officer on Special Duty(LSS)
2.	Shri A. K. Srivastava	-	Director
3.	Shri N. Amarthiagan	-	Under Secretary

LIST OF WITNESSES

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

S.No	Name of the Officer/Officials	Designation
1.	Dr. P. D. Vaghela	Secretary

2.	Ms. Alka Tiwari	AS&FA
3.	Sh. Navdeep Rinwa	Joint Secretary
4.	Sh. Rajneesh Tingal	Joint Secretary
5.	Sh. H. K. Hajong	Economic Adviser
6.	Smt. Deepika Jain	CCA
7.	Shri Pawan Kumar	Director (NIPER)

II. REPRESENTATIVES OF NPPA

1.	Smt. Shubra Singh	Chairperson, National Pharmaceuticals Pricing Authority (NPPA)

III ***REPRESENTATIVES OF NIPER***

2.	Dr. Kiran Kalia	Director (NIPER Ahmedabad)
3	Dr. Shashi Bala Singh	Director (NIPER- Hyderabad)
4	Dr. V. Ravichandiran	Director (NIPER-Kolkata and NIPER - Hajipur)
5	Dr. U S N Murty	Director (NIPER-Guwahati)
6	Dr. S J S Flora	Director (NIPER-Rai Bareli and NIPER - Mohali)

IV. REPRESENTATIVES OF PSUS

1	Ms. Nirja Saraf	Managing Director, Hindustan Antibiotics Limited (HAL) and RDPL
2	Mr. Sunil Kumar Kaimal	Managing Director, Karnataka Antibiotics & Pharmaceuticals Limited, (KAPL)
3	Sh. P. M. Chandraiah	Managing Director, Bengal Chemicals and Pharmaceuticals Limited (BCPL)
4	Sh. 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 2020-21 of the Department of Pharmaceuticals.

4. Power point presentation was followed by discussion on several aspects of Demands for Grants of the Department for 2020-21. During the discussion, the Hon'ble Chairperson and Members of the Committee raised queries on several issues and some of the important points discussed were given below:-

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

(ii) Less allocation of funds for the Pharmaceuticals Technology Up-gradation Scheme (PTUAS) and other schemes of the Department.

(iii) Implementation of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' in the country

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

(v) Issues relating to National Institute of Pharmaceuticals Education and Research

(vi) National Pharmaceutical Pricing Authority (NPPA) and functioning and setting up of price Monitoring units..

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 The Committee thereafter took up for consideration and adoption the draft Report on the subject 'The Study of System of Fertilizer Subsidy' pertaining to Department of Fertilizers. After deliberations, the Committee adopted the draft report unanimously without any changes/amendments. The Committee also authorised the Chairperson to finalize and present the report to the Parliament.

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

The Committee then adjourned

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

(2019-20)

The Committee sat on Thursday, the 18 March, 2020 from 1000 hrs. to 1045 hrs. in Committee Room C, Parliament House Annexe, New Delhi.

PRESENT
Ms 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. Shri Uday Pratap Singh
8. Shri H. Vasanthakumar
9. Shri Prabhubhai Nagarbhai Vasava
10. Dr. M. K. Vishnu Prasad
11. Dr. Manoj Rajoria
12. Shri Shriniwas Patil

RAJYA SABHA

13. Shri G. C. Chandrashekhar
14. Dr. Anil Jain
15. Shri Ahmad Ashfaque Karim
16 Shri Vijay Pal Singh Tomar
17. Shri Arun Singh

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 2020-21' (Department of Chemicals and Petrochemicals);
(ii) Draft report on 'Demands for Grants 2020-21' (Department of Fertilizers); and
(iii) Draft report on 'Demands for Grants 2020-21' (Department of Pharmaceuticals);

4. After deliberations, the Committee unanimously adopted Draft Reports pertaining to the Department of Chemicals & Petrochemicals and the Department of Fertilizers without any changes/amendments.

5. The Committee adopted the draft report on Demands for Grants, 2020-21 of the Department of Pharmaceuticals with the following additions to the recommendations:-

<u>Recommendation No.9 National Pharmaceutical Pricing Authority (NPPA):</u>

The Committee note that while the NPPA regulates the prices of drugs which are sold at the retail level, there appears to be no regulation of pricing at which the hospitals charge the patients. It has been observed that large hospitals are able to "extract" significantly higher discounts from the pharmaceutical companies but the end user, that is the patient, is billed at the retail price. It is also seen that many hospitals use only those medicines on which an unusually high MRP is printed so that the billing to the patients becomes more profitable. Therefore, the Committee recommend that NPPA should separately examine this aspect within the overall regulatory framework of drug pricing so that the patients being treated in the hospitals are not charged excessively for the medicines.

The Committee also observed that as a routine practice, the hospitals bill the patients who are in ICU or in a state of unconsciousness, for drugs which are never actually administered. The patient as well as the family members have no means to verify whether the billed drugs were actually administered or not. The Committee understand that this issue may not be falling directly within the purview of the Department but the Committee would like the Department to refer this matter to the Ministry of Health and Family Welfare for necessary action at their end.

<u>Recommendation No:12 Settlement of Liabilities of Closed Pharma PSUS</u>:

> **The Committee observe that along with the dues of the employees, there are also significant dues of the former business associates of the closed PSUs which may pertain to advance deposits, outstanding payments, etc. The Committee recommend that the Department should examine these dues also and settle them as per the provisions of the law.**

6. The Committee then 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.

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