21	**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS** **(2020-21)** **SEVENTEENTH LOK SABHA**

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS

(2021-22)

TWENTY-FIRST REPORT

LOK SABHA SECRETARIAT

NEW DELHI

March, 2021/ Phalguna, 1942 (Saka)

CC&F.No.21

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CHEMICALS AND FERTILIZERS

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Presented to Lok Sabha on 17 March 2021

Laid in Rajya Sabha on 17 March 2021

LOK SABHA SECRETARIAT

NEW DELHI

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2020-21)

Smt. Kanimozhi Karunanidhi - Chairperson

MEMBERS

LOK SABHA

2 Shri Maulana Badruddin Ajmal
3 Shri Deepak Baij
4 Shri Ramakant Bhargava
5 Shri Prataprao Govindrao Patil Chikhalikar
6 Shri Rajeshbhai Naranbhai Chudasama,
7 Shri Ramesh Chandappa Jigajinagi
8 Shri Pakauri Lal
9 Shri Kripanath Mallah
10 Shri Satyadev Pachauri
11 Smt Aparupa Poddar
12 Dr. M.K.Vishnu Prasad
13 Shri Atul Kumar Singh alias Atul Rai
14 Shri Arun Kumar Sagar
15 Shri M. Selvaraj
16 Shri Pradeep Kumar Singh
17 Shri Uday Pratap Singh
18 Shri Indra Hang Subba
19 Shri Er. Bishweswar Tudu
20 Shri Prabhubhai Nagarbhai Vasava
21 Dr. Sanjeev Kumar Singari#

RAJYA SABHA

22 Shri G.C.Chandrashekhar
23 Dr. Anil Jain
24 Shri Ahmad Ashfaque Karim
25 Shri M.V. Shreyams Kumar
26 Shri Jaiprakash Nishad
27 Shri Anthiyur P. Selvarasu
28 Shri Arun Singh$
29 Shri A.D. Singh
30 Shri Vijay Pal Singh Tomar
31 Shri K. Vanlalvena

SECRETARIAT

1. Shri Manoj K. Arora - OSD (LSS)
2. Sh. N.K. Jha - Director
3. Shri C. Kalyanasundaram - Additional Director
4. Ms Sonia Sankhla - Assistant Executive Officer

$Re-nominated to the Committee w.e.f. 23.12.2020.

#Nominated to the Committee w.e.f 28.12.2020 vice Shri Nandigam Suresh.

INTRODUCTION

I, the Chairperson (Acting), Standing Committee on Chemicals and Fertilizers (2020-21) having been authorised by the Committee [as per Rule 277(3) of Procedure and Conduct of Business in Lok Sabha] to present the Report on their behalf, present this Twenty-First Report (Seventeenth Lok Sabha) on 'Demands For Grants (2021-22)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Committee examined the Demands For Grants (2021-22) pertaining to the Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers which were laid in Lok Sabha and Rajya Sabha on 9 February 2021.

3. The Committee took evidence of the representatives of the Ministry on Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 19 February, 2021.

4. The Report was considered and adopted by the Committee at their sitting held on 15.03.2021.

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

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

7. 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;
15 March, 2021
24 Phalguna 1942 (Saka)

Uday Pratap Singh
Chairperson (Acting)
Standing Committee on
Chemicals and Fertilizers

CHAPTER – I
INTRODUCTION

Mandate of Department of Pharmaceuticals

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 Vision and Mission

The Department has vision to promote Indian pharma as the global leader for quality medicines and to ensure availability, accessibility and affordability of drugs and medical devices in the country. The Mission is as follows:

- Investment for Make in India in pharma sector,
- Make in India in critical APIs and medical devices,
- Industry expansion, skilling, R&D and innovation,
- Stable and effective price regulation and
- Generic medicines by expanding Janaushadhi scheme

1.3 Allocation of Work

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. Planning, development and control of, and assistance to, all industries dealt with by the Department
10. Technical support for dealing with national hazards in pharmaceutical sector.

1.4 Attached Office

All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.

1.5 Autonomous Institute

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

1.6 Public Sector Undertakings

The Department has 5 Central Public Section undertakings under its Administrative control, they are:

(i) Indian Drugs & Pharmaceuticals Ltd. (IDPL), Gurgaon, Haryana,
(ii) Hindustan Antibiotics Ltd, Pimpri, Pune, Maharashtra,
(iii) Karnataka Antibiotics & Pharmaceuticals Limited, Bangalore,Karnataka,
(iv) Bengal Chemicals & Pharmaceuticals Ltd, Kolkata, West Bengal and
(v) Rajasthan Drugs and Pharmaceuticals Limited, Jaipur, Rajasthan

1.7 Registered Society

Bureau of Pharma PSUs of India (BPPI) - set up on 1st December, 2008 by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, with the objective to have focused and empowered structure to implement the Jan Aushadhi Scheme launched by Department of Pharmaceuticals.

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1.8 The work of the Department has been mainly divided into Pricing, Policy, Scheme, NIPER, PSU & Medical Device Divisions. National Pharmaceuticals Pricing Authority (NPPA) is an attached office of the Department.

1.9 The detailed Demands for Grants (2021-22) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 9th February, 2021. Rs. 470.41 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 2021-22. The Observations/Recommendations of the Committee have been given in a separate chapter at the end of the Report. The Committee expect the Department to take all necessary steps for proper and timely utilization of funds ensuring completion of the various plans and projects in a time bound manner. The Committee also expect the Department to act on the recommendations of the Committee expeditiously and furnish action taken replies to the observations/recommendations made in the Report within three months from the date of presentation of this Report.

CHAPTER-II

INDIAN PHARMACEUTICALS INDUSTRY – AN OVERVIEW

A. Origin, growth and development of pharmaceutical industry

2.1 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 to 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 in 1901. The other is Alembic Chemical Works Company Ltd. in Vadodara 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. Our country's pharmaceutical industry has gradually evolved from being almost non-existent to a world leader in the production of high quality generic drugs. Our country 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 add contributed by foreign acquisitions and joint ventures, our country's mastery of reverse engineering of patented drug molecules and its efforts to comply with its World Trade Organization (WTO) Trade Related Intellectual Property Agreement (TRIPS) obligations.

2.2 The Indian pharmaceutical industry is the world's 3rd largest by volume and 14th largest in terms of value**.** Total Annual Turnover of Pharmaceuticals is Rs. 2,89,998 crore for the year 2019-2020. Total exports of pharmaceuticals are to the tune of Rs. 1,46,260 crore for the year and total Imports of pharmaceuticals are to the tune of Rs. 42,943 crore.

2.3 Our country has the highest number of US FDA approved plants outside the US. Our country is a global leader in the supply of DPT, BCG, and Measles vaccines. India accounts for 60 percent of global vaccine production, contributing 40 to 70 percent of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine.

2.4 Moreover, our country is the largest provider of generic drugs globally. As per Pharmexcil, the global Generic market in 2019 is estimated at $ 360 billion. The domestic Generic market size in 2019 was $20.87 Billion. India has exported Generics during 2019 worth around $ 15.63 billion. India's share of generics in the global exports is around 4.6%.

2.5 Access to affordable HIV treatment from India is one of the greatest success stories in medicine. India is one of the biggest suppliers of low-cost vaccines in the world. Because of the low price and high quality, Indian medicines are preferred worldwide, thereby rightly making the country the ‘pharmacy’ of the world. Pharma sector is currently contributing to around 1.72% of the country’s GDP.

2.6 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.

B. Annual turnover, Import and Export data of Pharmaceutical Industry

2.7 As per Department written reply the data of total annual turnover, Import and export data of pharmaceutical industry during the last five years are as following: -

Year	Annual Turnover (in Rs. Crore)	Import of Pharmaceutical Products (in Rs. crore)	Export of Pharmaceutical Products (in Rs. crore)
2016-17	225958.17	31,384.84	1,11,817.16
2017-18	229713.08	32,795.69	1,10,195.00
2018-19	263524.01	41,110.32	1,32,585.03
2019-20	289997.67	42,942.67	1,46,259.85
2020-21	255318.30 (April-2020 to Jan-2021)	37,351.76 (April- November, 2020)	1,33,527.10 (April- November, 2020)

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

C. Achievements in Growth and Development of Pharmaceuticals Industry

2.7 The Committee also asked about the specific achievements of the Department in promoting growth and development of Pharmaceuticals industry in the country during the last five years and achievements that are envisaged for next five years, the Department in their written reply sated 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. The achievements in respect of the sub-schemes are as follows:-

(i) **"Pharmaceutical Promotion and Development Scheme":** This Scheme was launched for promotion of pharmaceutical industry. under this scheme various seminars and workshops have been organized during last 5 years. The Department has organized 5 editions of India Pharma and India Medical Device event under this Scheme during last 5 years. The Department intends to organize more workshops/seminars and conduct studies beneficial for Pharmaceutical Sector.

(ii) **Assistance to Pharmaceutical Industry for Common Facilities (API-CF):** During the last 5 years, Department has approved the proposal of Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC) to install Common Effluent Treatment Plant at Alathur, Chennai, Tamil Nadu. Besides this 4 proposals have been approved "in-principle" for financial assistance. The Department intends to approve 10 proposals received from Pharma Clusters for Financial Assistance under this Scheme.

(iii) Scheme for Promotion of Bulk Drug Parks (erstwhile known as Assistance to Bulk Drug Industry for Common Facility Centre:
The total size of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25). For next 5 years, Department is in process of evaluating the proposals received from 13 States/UTs under the scheme "Promotion of Bulk Drug Parks". The Department will shortlist 3 proposals and will accord in-principle approval to them.

(iv) Assistance to Medical Device Industry for Common Facility Centre:
During the last 5 years, Department has proposed the scheme "Assistance to Medical Device Industry for Common Facility Centre" and has revised the same to "Promotion of Medical Devices Parks" on 20.03.2020. The guidelines of the scheme has been released on 27.07.2020. For next five years, Department is in process of evaluating the proposals received from 16 States/UTs under the scheme "Promotion of Medical Devices Parks". 04 selected States/UTs will be provided final approval for giving financial assistance for development of Common Infrastructure Facilities in their upcoming medical device parks.

(v) Production Linked Incentive scheme (PLI) for Pharmaceuticals: The Union Cabinet in its meeting on 11.11.2020 approved yet another Production Linked Incentive scheme (PLI) for Pharmaceuticals. The outlay of the scheme is Rs 15,000 crore and following three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme is proposed to be from FY 2021 to 2028-29

a) **Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key starting materials (KSMs) / Drug Intermediaries and Active Pharmaceutical Ingredients (APIs) in the country :** With an objective to attain self-reliance and reduce import dependence in these critical Bulk Drugs - Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country, the Department of Pharmaceuticals had launched a Production Linked Incentive (PLI) Scheme for promotion of their domestic manufacturing by setting up greenfield plants with minimum domestic value addition in four different Target Segments (In Two Fermentation Based - at least 90% and in the Two Chemical Synthesis Based – at least 70%) with a total outlay of Rs.6,940 cr. for the period 2020-21 to 2029-30. The setting up of these plants will make the country self-reliant to a large extent in respect of Bulk drugs and lead to large investment and employment generation in the domestic sector.

b) **Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices:** With an objective to boost domestic manufacturing, attract large investments in the Medical Device Sector, the Department of Pharmaceuticals had launched a Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices to ensure a level playing field for the domestic manufacturers of medical devices, with a total financial outlay of Rs.3,420 cr. for the period 2020-21 to 2027-28.

D. Major Challenge

2.8 The Department in its written note submitted that the major challenge identified is the issue of Drug Security associated with API/Bulk Drugs. In this regard the Department stated that the 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.

2.9 In this regard, the Committee observed that during the early 90s, India was self-reliant in manufacturing Active Pharmaceutical Ingredients (APIs). However, with the rise of China as a producer of API, it captured the Indian market with cheaper products and it eventually led to high economies of scale for China. China created a low-cost API manufacturing industry. The industry was backed by the low cost of capital followed by aggressive government funding models, tax incentives. Their cost of operation is one-fourth of India's cost. Even the cost of finance in China is 6-7 per cent against India's 13-14 per cent. In this context, the Committee asked about the reasons which led Indian Pharmaceuticals Industry's sudden dependence on imported Active Pharmaceutical Ingredients (APIs) even though the country was self-reliant in bulk drug production before 1990s. Agreeing with the Committees observations the Department in its written reply stated as follows:

> "India pioneered bulk drug manufacturing in the 1980s. However, during 90s the domestic production of bulk drugs decreased because it became cheaper to import than to manufacture locally. The worst hit was the Indian fermentation based bulk drug Industry facing severe competition from overseas players mainly from China. Local production slowly stopped when China started exporting these bulk drugs at very low prices in India. The cost of production of these bulk drugs was low in China due to multiplicity of factors including economies of scale, availability of subsidized utilities such as electricity, steam, brine, effluent treatment etc"

2.10 The Committee also asked the Department to provide details about any policy that favourably distinguish between Pharma companies which manufacture drugs from domestically produced critical Key Starting Materials(KSMs)/Drug Intermediates (DI) and Active Pharmaceutical Ingredients (APIs) in comparison to those companies which manufacture drugs by importing API/KSM/DI from other countries and if not, can the Department incorporate such positive distinction to give impetus to domestic producers of API/KSM/DI. To this query of the Committee, the department in their written reply stated as below:-

> "Department does not have any such policy in place. However,the Department has issued guidelines dated 30.12.2020 for implementation of Public Procurement (Preference to Make in India) Order dated 16.09.2020 issued by Department for Promotion of Industry and Internal Trade, to Pharmaceuticals Sector. The guidelines classify the suppliers for providing preference in public procurement based on their minimum local content for pharmaceuticals formulations. The minimum local content fixed for class-I local supplier is 80% and class-II local supplier is 50%. The suppliers having minimum local content less than 50% shall be non-local supplier and will not be preferred for public procurement. The 'Local content' means the amount of value added in India which shall be the total value of the item procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent."

2.11 The Committee further asked about the definition of a pharmaceutical manufacturer according to the policy of the Department and the benefits that are extended to those manufacturers who manufacture drugs with indigenous know how and domestic raw materials by the Department. In this regard, the Department furnished its written reply as under:-

"As per para 2 (n) of the DPCO, 2013, manufacturer is defined as "…any person who manufactures or imports or markets drugs for distribution or sale in the country." Further, Para 32 of DPCO provides that the provisions of the order shall not apply to:

" (i) a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial marketing in the country.

(ii) a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970 (39 of 1970) (process patent) for a period of five years from the date of the commencement of its commercial production in the country.

(iii) a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India."

The benefits extended to Pharmaceuticals manufacturers are as follows:

(i) As per the Order dated 16.09.2020, only 'Class-I local supplier' and 'Class-II local supplier' shall be eligible to bid in procurement undertaken by procuring entities with estimated value of procurement less than Rs. 200 crore, in accordance with Rule 161 (iv) of GFR, 2017

(ii) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices.

(iii) Production Linked Incentive (PLI) Scheme for promotion of domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs."

E. Specific Problems Faced by the Domestic Pharmaceutical Industry

2.12 Further, when the Committee asked about the details of any study or assessment that the Department has conducted to find out the specific problems faced by the domestic pharmaceutical industry, the Department in a written reply stated :-

> "The Department of Pharmaceuticals 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 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. In 2020, the Committee under chairmanship of Dr Eswara Reddy identified APIs with high degree of import dependence. A Report 'Catalysing the Pharma- Medtech Innovation Ecosystem in India' was prepared by the Department in September 2020 with intensive inputs from Industry and other stakeholders". The Department of Pharmaceuticals has recently launched the following two sub- schemes for promoting domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs viz.(i) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India and (ii) Scheme for Promotion of Bulk Drug Parks."

F. Responsibilities of the Department on the availability of quality and affordable drugs and medical devices

2.13 On being asked to furnish a note on the roles and responsibilities of the Department of Pharmaceuticals with regard to the availability of quality and affordable drugs and medical devices for all diseases/ailments in the country, the Department in its written reply stated, "One of the main missions of Department of Pharmaceuticals is to ensure availability of quality drugs at reasonable prices as per the Pharma Policy. To accomplish this mission, the Department has consistently been taking proactive actions as given below:

(i) Jan Aushadhi Scheme (PMBJP): Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), a flagship scheme of Government of India ensures availability of Quality Generic Medicines to the citizens of the country at an affordable price.. Under this scheme, dedicated outlets known as *Pradhan Mantri Bhartiya Janaushadhi Kendras* (PMBJK) are opened all over the country to provide generic medicines to the masses. A medicine under PMBJP is priced on the principle of a maximum of 50% of the average price of top three branded medicines. Therefore, the price of Jan Aushadhi Medicines is cheaper at least by 50% and in some cases, by 80% to 90% of the market price of branded medicines. The medicines listed in the product list of PMBJP are procured only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers for ensuring the quality of the products. Apart from this, each batch of drug is tested at laboratories accredited by the 'National Accreditation Board for Testing and Calibration Laboratories' (NABL). Only after passing the quality tests, the medicines are dispatched to PMBJP Kendras.

(ii) National Pharmaceutical Pricing Authority (NPPA): For pricing of drugs and to ensure their availability and accessibility at affordable prices, NPPA was established in 1997as an independent Regulator in the form of an attached office of the Department of Pharmaceuticals. As per Para 21 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013), the National Pharmaceutical Pricing Authority (NPPA) is mandated to monitor the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation. The manufacturers are required to furnish the information in a prescribed Form to the Authority. Further, any manufacturer intending to discontinue any scheduled formulation from the market has to issue a public notice and also intimate the Authority at least six months prior to the intended date of discontinuation. In public interest, the manufacturer can be directed to continue with required level of production or import for a period not exceeding one year. The issue of quality of Drugs comes under the purview of Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare."

CHAPTER-III

ANALYSIS OF DEMANDS FOR GRANTS (2021-2022) [Demand No.7]

3.1 For the year 2021-22, Gross Budgetary allocation is of Rs. 470.41 crore against the proposed outlay of Rs.2600.52 crore, out of which Rs. 31.53 crore is towards Centre's Expenditure (Non-Scheme) relating to Secretariat General Services for both Department of Pharmaceuticals and NPPA (against proposed Budget Estimates for Centre's Expenditure of Rs. 35.98 crore). Budgetary allocation for Central Sector Schemes is Rs. 429.76 crore (against proposed Budget Estimates of Rs.2564.48crore) and Rs.9.12crore for Assistance to PSUs (loan) (against proposed Budget Estimates of Rs. 0.06 crore).

3.2 A statement showing scheme-wise details of outlays, Gross Budgetary Support (GBS) for the year 2021-22 and scheme wise break-up of outlays proposed and approved, is given below:

				(Rs. In crore)
Sl. No.	**Schemes/Non-Scheme**	**M.H.**	**BE 2021-22 (Proposed)**	**BE 2021-22 (Approved)**
	Central Expenditure (Non-Scheme)			
1	Secretariat Economic Services	3451	16.12	16.73
2	National Pharmaceuticals Pricing Authority (NPPA)	2852	19.86	14.80
	Total of Non Scheme		**35.98**	**31.53**
	Center Sector Scheme			
3	North East Region - National Institute of Pharmaceutical Education and Research (NIPER)	2552	39.00	34.70
	National Institute of Pharmaceutical Education and Research (NIPERs)	2852	1181.0	199.64
	Total NIPERs (MH 2552+ MH 2852)		**1220.00**	**234.34**
4	**Development of Pharmaceuticals Industry**	2552	0.01	0.01
	Development of Pharmaceuticals Industry	2852		
	Pharmaceutical Promotion & Development Scheme(PPDS)		10.00	2.00

(Rs. In crore)				
Sl. No.	**Schemes/Non-Scheme**	**M.H.**	**BE 2021-22 (Proposed)**	**BE 2021-22 (Approved)**
	Creation of IPR Facilitation Centre			
	Scheme for Kala Azar and Anti TB agents			
	Cluster Development		36.00	18.00
	Pharmaceuticals Technology Upgradation Assistance Scheme(PTUAS)		185.00	0.01
	Setting up of Venture Fund for drug design, discovery & innovation in Pharma Sector			
	Setting up of Pharma Promotion Council			
	Setting up of Medical Device Promotion Council			
	Pharmaceutical Export Promotion Scheme (PEPS)			
	Critical Assistance for WHO Pre-qualification			
	Assistance to Bulk Drug Industry for Common Facilitation Centre		900.00	36.24
	Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical KSMs/Drug Intermediates and APIs		2.79	2.79
	Assistance to Medical Device Industry for Common Facilitation Centre		120.00	60.00
	Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical device		2.36	2.36
	Production linked Incentive (PLI) scheme for Pharmaceuticals			3.00
	Research and Development in			0.01

				(Rs. In crore)
Sl. No.	**Schemes/Non-Scheme**	**M.H.**	**BE 2021-22 (Proposed)**	**BE 2021-22 (Approved)**
	Pharma Sector			
	Total Development of Pharmaceuticals Industry (MH2852 + MH 2552)		**1256.16**	**124.42**
5	**Jan Aushadhi Scheme**	2552	75.30	3.0
		2852	4.70	62.00
	Total Jan Aushadhi Scheme (MH 2552 + MH 2852)		**80.00**	**65.00**
6	**Consumer Awareness, Publicity and Price Monitoring (CAPPM)**	2852	6.32	5.00
	Assistance to Project Monitoring Price Monitoring Resource Units (PMRUs)		2.00	1.00
	Advertising and Publicity for CAPPM		**8.32**	**6.00**
	Total CAPPM MH 2852			
7	**Assistance to PSUs (Loans to PSUs)**	6857		
	Indian Drugs & Pharmaceuticals Ltd. (IDPL)		0.01	2.00
	Hindustan Antibiotics Ltd. (HAL)		0.01	4.09
	Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)		0.01	0.01
	Bengal Immunity Ltd. (BIL)		0.01	0.01
	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)		0.01	3.00
	Smith Stanistreet Pharmaceuticals Ltd (SSPL)		0.01	0.01
	Total (Loan to PSUs)		0.06	**9.12**
	Grand Total		**2600.52**	**470.41**

3.3 Above statement shows that the Budget Estimate (BE) proposed by the Department of Pharmaceuticals for the year 2021-22 was Rs. 2600.52 crore but the approved BE is only Rs. 470.41 crores. In view of the above, the Committee asked the Department about the adequacy of this allocated fund at BE stage for 2021-22 and in case of inadequacy, the Department was asked to mention the challenges foreseen by it due to the reduced/ inadequate allocation of funds for

2021-22. In this regard, the Department in its written reply stated,"The total fund allocated for 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’ 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 (NIPER) : The funds approved in BE 2021-22 are not sufficient to fulfill the mandate of the Scheme. A consolidated EFC Note for upgradation of existing seven NIPERs at Mohali, Ahmedabad, Hyderabad, Guwahati, Kolkata, Raebareli & Hajipur and setting up of proposed five NIPERs at Nagpur (Maharashtra), Madurai (Tamil Nadu), Jhalawar (Rajasthan), Raipur (Chhattisgarh) and Bengaluru (Karnataka) with estimated cost of Rs. 4,300 crore for the period 2021-22 to 2025-26 has been sent to the Department of Expenditure for achieving the objectives of the scheme. The Department will be seeking funds at the stage of RE 2021-22 on approval of EFC.

(ii) Development of Pharmaceuticals Industry: The allocated fund is not sufficient for the sub-schemes of Umbrella Scheme “Development of Pharmaceutical Industry” as detailed below:-

Promotion of Medical Devices Parks (earlier known as Assistance to Medical Device Industry for Common Facilitation Center):

The guidelines of the scheme “Promotion of Medical Devices Parks” were released on 27.07.2020. A total number of 16 proposals have been received which are under evaluation. The Department will accord 'in-principle' approval to 4 States/UTs under the scheme. The 4 States/UTs will submit a detailed project report within 180 days of date of issuance of in- principle approval letter. As per scheme guidelines, the Department has to release first instalment of 30% of the total financial assistance of Rs. 100 crore at the time of final approval of the project by the Scheme Steering Committee. Since the final approval may be accorded in the FY 2021-22, there will be need of Rs. 120 crore (Rs. 30 crore each for 4 parks).

The Department had demanded Rs. 120 crore for BE 2021-22, however, only Rs. 36.24 crore has been allocated. This fund will not be adequate to meet the requirements under the scheme “Promotion of Medical Devices Parks”. Additional amount will be sought at Supplementary Demands for Grants/RE stage

Promotion of Bulk Drug Parks (earlier known as Assistance to Bulk Drug Industry for Common Facilitation Center): The guidelines of the scheme “Promotion of Bulk Drug Parks” were released on 27.07.2020. A total number of 13 proposals have been received which are under evaluation. The Department will soon accord 'in-principle' approval to 3 States/UTs under the scheme. The 3 States/UTs will submit a detailed project report within 180 days of date of issuance of in-principle approval letter. As per scheme guidelines, the Department has to release first installment of 30% of the total financial assistance of Rs. 1000 crore at the time of final approval of the project by the Scheme Steering Committee. Since the final approval may be accorded in the FY 2021-22, there will be need of Rs. 900 crore (Rs. 300 crore each for 3 parks). The Department had demanded Rs. 900 crore for BE 2021-22, however, only Rs. 60 crore has been allocated. This fund will not be adequate to meet the requirements under the scheme “Promotion of Bulk Drug Parks”. Additional amount will be sought at Supplementary Demands for Grants/RE stage

The amount allocated in BE 2021-22 for other sub-schemes of DPI i.e Pharmaceutical Promotion & Development Scheme (PPDS), Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS), Assistance to Pharmaceutical Industry for Common Facilities (APICF) is also not sufficient. Additional amount will be sought at Supplementary Demands for Grants/RE stage

(iii) Jan Aushadhi Scheme: The funds approved in BE 2021-22 may not be sufficient to fulfill the mandate of the Scheme. The additional funds will be sought at the stage of first supplementary/R.E. stage.

(iv) Consumer Awareness Publicity and Price Monitoring (CAPPM). The proposed BE 2021-22 was Rs.8.32 crore and approved BE 2021-22 is Rs. 6.00 crore. NPPA will be able to fulfil its mandate through this allocation. If additional funds are required, it will be sought at 1st Batch of Supplementary Demand for Grants FY 2021-22/RE stage."

3.4 In continuation, the Committee asked the Department about the reasons conveyed by the Ministry of Finance for reduced allocation of funds for BE 2021-22 and the steps that are being taken by the Department of Pharmaceuticals to impress at the highest level with the Ministry of Finance to allocate the funds necessary for implementation of its Schemes/programmes at BE stage itself for proper planning and implementation of its Schemes/programmes. The Department stated in writing as below:

"The Department had proposed Rs. 2600.52 crore for the BE 2021-22 against which Rs. 470.41 crore has been allocated by Ministry of Finance. No comments/reasons have been furnished for the reduction of budget by the Ministry of Finance. On receipt of lower allocation, a DO letter by Secretary (Pharma) to Secretary (Expenditure) was instantly issued on 08.01.2021. Thereafter, a letter to Hon'ble Finance Minister from Hon'ble Minister of Chemicals and Fertilizers has also been issued on 20.01.2021 requesting for increased allocation to ensure smooth implementation of new sub-schemes. "

3.5 On being asked about the reasons for huge variation in the proposed Budget Estimates (BE) of Rs. 1256.16 crore and the allocated fund of only Rs. 124.42 crore at BE stage by the Ministry of Finance for the Central Sector Schemes of Development of Pharmaceuticals Industry (MH2852 + MH 2552) of the Department of Pharmaceuticals, the Department in a written reply stated:-

"While the Department had sought Rs. 1256.16 crore for Development of Pharmaceuticals Industry, the Ministry of Finance has allocated only Rs. 124.42 crore for the DPI Scheme. Budget allocation by MoF depends on priorities of that Ministry and fiscal policies of the Government. Department of Pharmaceuticals has projected its requirement in its proposals and is not aware of the reasons for the reduced allocation. "

3.6 During oral evidence of the representatives of the Department of Pharmaceuticals, when the Committee enquired how the Department proposes to bridge the gap between the proposed budget estimate of Rs.2,600 crores and the BE allocation of only Rs.470 Crore, the Secretary, Department of Pharmaceuticals replied as under:-

"Coming to 2021-22, we asked for a very large amount Seven NIPERs are approved. The one in Mohali has its own campus. The campus at Ahmedabad and Guwahati are being built. The other four NIPERs are working in rented premises. So, we have Expenditure Finance Committee memo proposal for Rs.4,300 crore which covers not only these four existing NIPERs, to give them their own campus, but also the other NIPERs including the one at Madurai which have been announced. That is the EFC memo of Rs.4,300 crore which we have now posed to the Finance Ministry. They have asked us to rationalise. We have rationalised it and we have posed it. If they provide, which they have not obviously in the Budget estimates, and gets approved during the next financial year, I hope that in the RE we may ask for some more money against our requirement of Rs.4,300 crore. For NIPER, as of today, in Budget 2021-22 we have only Rs.234 crore.

Regarding the other shortfall or what we did not get approved is the Bulk Drug Park and the Medical Devices Park. If we are able to approve the Bulk Drug Park in this year, the States will submit the DPR. They are supposed to start construction. We have to provide 30 per cent of the financial support, which will be Rs.300 crore per Bulk Drug Park; for three parks it comes to Rs.900 crore. This has not been provided for in the Budget estimates, possibly because we are still in the process of doing the approvals. As Rajesh ji mentioned, if we are able to get the DPRs from the States, we have to select only three States, then we will have to go for the RE. Otherwise, we will not be able to help. Similar is the case with Medical Devices Park. Madam, Rs.400 crore is the overall provision, out of which if we approve the four Parks and get the DPRs, and the State Governments start the work, we will have to give 30 per cent, that is Rs.120 crore, to each of them. This is the breakup of Rs.2,600 crore.

Madam, as you are aware, two of the PSUs, IDPL and RDPL, are under closure and the other three are under strategic sale. We make provision for providing loan to discharge their liabilities. If the Government provides the Budget, we can discharge the liabilities otherwise we cannot. NIPER, we are trying to make functional but I think the main challenge is to get the financial approvals. We will try it".

BUDGET UTILIZATION PATTERN

3.7 The following table depicts the budget utilization pattern of the Department of Pharmaceuticals during the last three years from 2018-19 to 2020-21:-

Year-wise Gross Budget Allocation	Budget Estimate (BE)	Revised Estimate (RE)	Actual	Percentage Utilization
2018-19	261.53	527.64	525.31	99.55
2019-20	235.51	562.33	560.25	99.63
2020-21	333.58	470.41	298.46 (as on 15.01.2021)	63.44

3.8 Above table shows that out of Rs.470.41 allocated at RE stage during 2020-21, only 63.44 % of funds have been utilized as on 15/01/2021. In this regard, Department was asked about the utilization of the rest of the RE allocation before March 2021 and provide scheme wise details, the Department in its written reply stated as under:

"Ministry of Finance had communicated the RE ceiling of Rs. 470.41 crore as against the BE of Rs 333.58 core for Department of Pharmaceuticals. The surplus of Rs. 136.82 core has been allocated to NIPER (Rs. 121.82 crore) and Janaushadhi Scheme (Rs. 15.00 crore) respectively and the same has accordingly been sought in 2^{nd} and Final Batch of Supplementary Demand for Grants FY 2020-21. This amount will be released/utilized on receipt of Presidential Assent on Second Batch of Supplementary."

3.9 During oral evidence, the Committee pointed out that only Rs.302 Crore has been utilized during 2020-21 out of RE allocation of Rs.333.58 crore and in this regard, the Secretary, Department of Pharmaceuticals clarified as under:-

"Regarding utilisation, against Rs.333 crore for the current year, the establishment part is Rs.27.40 crore. That, we will completely utilise. That will not be a problem. Regarding the schematic allocation, it is Rs.299 crore. There, we have received a RE of Rs.435 crore. Against Rs.299 crore, we have spent Rs.273.32 crore. That is, we have spent 91 per cent. The remaining RE, once it is authorised, we will be spending. We have taken the RE mainly in NIPERs. This is given as grant. But it is for construction, equipment purchase and filling up of posts. So, in NIPERs, originally in the BE, we had Rs.202.45 crore. The concerned officer not here but Dr. Shashi Bala is here; we are doing construction in two places, that is, in Guwahati and in Ahmedabad. Strengthening of equipment is in all the seven NIPERs. So, against Rs.202 crore, we have already spent Rs.208 crore. Thanks to the RE; we will try to complete it. I am pretty sure that we will be able to complete it.

Regarding the shortfall, it is possible in the cluster programme. That is why I have mentioned that in Chennai we had one which we were not able to spent. But after speaking to the State Government, they have given us that pollution clearance. We will be able to spend it.

There is one more release to one medical devices park in Andhra Pradesh. For that one, we have asked for a site visit. NIPER Hyderabad has done the site visit. We will be able to release that money. So, I am hopeful, Madam, that this year we will complete hundred per cent against RE. That is our planning."

SCHEMEWISE BUDGET UTILIZATION PATTERN FROM (2018-19 to 2020-2021)

A. SCHEMES FOR DEVELOPMENT OF PHARMA INDUSTRY (MH 2852+ MH2552)

3.10 The Department has an Umbrella Scheme namely 'Scheme for Development of Pharmaceutical Industry'. Its objective is to increase 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 and availability of quality pharmaceuticals for mass consumption. This Scheme is a Central Sector Scheme and comprises the following seven sub-schemes:

a) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India
b) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices
c) Promotion of Bulk Drug Parks
d) Promotion of Medical Device Parks
e) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
f) Assistance to Pharmaceutical Industry for Common Facilities (API-CF)
g) Pharmaceutical Promotion and Development Scheme (PPDS)

3.11 Year wise BE, RE and actual expenditure incurred under scheme Development of Pharmaceutical Industry for the last three years and BE allocation for the year 2021-22 is given as under:

(Rs. in crores)

Name of Scheme	**2018-19**			**2019-20**			**2020-21**			**2021-22**
	BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
Development of Pharmaceutical Industry	12.97	4.00	2.82	8.30	3.49	3.29	42.05	34.05	11.26*	124.4

*** As on 15.01.2021**

3.12 On being asked about the specific reasons for utilization of only Rs.11.26 crore as on 15.01.2021 against the allocation of Rs. 34.05 crore at RE stage during the current year 2020-21,the Department in its written reply stated as under:

"It is expected that the rest of the funds will be utilized before 31st March 2021 as justified below:

						(Rs. In crore)
Sl. No.	**Development of Pharmaceuticals Sub-schemes**	**BE**	**RE**	**Actual Exp. As on 15.02.21**	**(Actual Exp/RE) in % as on 15.2.21**	**Justification**
1.	Pharmaceutical Promotion and Development Scheme (PPDS)	1.00	0.50	0.26	52	Proposals are under consideration. It is expected that remaining fund will be released by March 2021.
2.	Assistance to Pharmaceuticals Industry for Common Facilitation Center(previous known as Cluster Development)	12.00	7.23	0.22	3.04	4 proposals are under consideration for final approval. It is expected that after approval the remaining fund will be released for the projects.
3.	Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)	0.02	0.01	Nil	Nil	Only token amount allocated
4.	Assistance to Bulk Drug Industry for Common Facilitation Center	21.52	1.69	1.68	99.40	Already utilized
5	Assistance to Medical Device Industry for Common Facilitation Center	7.50	21.05	7.49	34.84	A proposal seeking permission for re-appropriation of Rs. 13.55 Cr. to "Assistance to Medical Device Industry for Common Facilitation Center" on the basis of matching savings within Revenue section of the

(Rs. In crore)						
Sl. No.	**Development of Pharmaceuticals Sub-schemes**	**BE**	**RE**	**Actual Exp. As on 15.02.21**	**(Actual Exp/RE) in % as on 15.2.21**	**Justification**
						grant was sent for inclusion in 2nd final supplementary demand for grant,Dec.2020.Majority of the savings was identified from another sub-scheme of DPI i.e. “Assistance to Bulk Drug Industry for Common Facilitation Center”.However, it was observed that in the 2nd Supplementary the permission was granted inadvertently to “Assistance to Bulk Drug Industry for Common Facilitation Center”.Written note has been sent to Department of Economic Affairs(DEA) for the correction and the matter is also being taken up for rectification with the senior officers of DEA telephonically consistently.
6.	PLI Scheme for promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug	-	1.55	1.55	100	Fully utilized

(Rs. In crore)						
Sl. No.	**Development of Pharmaceuticals Sub-schemes**	**BE**	**RE**	**Actual Exp. As on 15.02.21**	**(Actual Exp/RE) in % as on 15.2.21**	**Justification**
	Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India					
7.	PLI Scheme for Promoting Domestic Manufacturing of Medical Devices	-	2.00	1.77	88.50	

3.13 Further on being asked about the recommendation-wise progress on status of implementation of the recommendations made in the third Party Evaluation report on the umbrella scheme 'Development of Pharmaceutical Industry' by the Centre for Global Development and Research Pvt. Ltd., the Department in its written reply stated, "Progress on status of implementation of the recommendations made in the third Party Evaluation report on the umbrella scheme Development of Pharmaceutical Industry by the Centre for Global Development and Research Private Ltd. is as follows:

Sl. No.	**Recommendation of third party evaluation report**	**Reply of Department**
Pharmaceutical Promotion and Development Scheme (PPDS)		
i.	Increasing the extent of coverage of the target groups considering the number and spread of target groups, DoP to have its own database of manufacturers, retailers and other stakeholders	The Department is exploring ways create its own database manufacturer retailers and other stakeholders.
ii.	To develop an institution such as 'Bureau of Pharma Development',	A Pharma Bureau has been set-up in this regard which shall take care of development of intervention strategies and program.
iii	To design programme for mass communication and skill development.	The Department through NGOs/organizations/associations organizes various workshops, trainings

		etc pertaining to pharmaceutical industries.
Assistance to Pharmaceutical Industry for Common Facilities (API-CF)		
i.	Need for better coordination between SPV, PMC and the department to set up a section 8 company under DoP to take up the responsibility for installation and operation of Pharmaceutical Industry Specific CETP	As per scheme guidelines, the Project Management Consultant (PMC) is a bridge between the Department and SPV which act as catalyst in expeditious implementation of the scheme. The Department has appointed M/s National Projects Construction Corporation Limited(NPCC).
ii	To continue the scheme	The Department has sent EFC Memo to DoE on 10.2.201 for continuation of the scheme.
Promotion of Bulk Drug Parks (Earlier known as Assistance to Bulk Drug for Common Facilitation Center)		
I	The third Party Evaluation report on the umbrella scheme 'Development of Pharmaceutical Industry' by the Centre for Global Development and Research Pvt. Ltd., was considered before finalization of the guidelines of the scheme "Promotion of Bulk Drug Parks". According to the recommendations of the report, the Department has engaged a Project Management Agency (PMA) for implementation of the scheme "Promotion of Bulk Drug Parks"	
Promotion of Medical Devices Parks (Earlier known as Assistance to Medical Device Industry for Common Facilitation Center)"		
I	The third Party Evaluation report on the umbrella scheme 'Development of Pharmaceutical Industry' by the Centre for Global Development and Research Pvt.Ltd., was considered before finalization of the guidelines of the scheme "Promotion of Medical Devices Parks". According to the recommendations of the report, the Department has engaged a Project Management Agency (PMA) for implementation of the scheme "Promotion of Medical Devices Parks	

3.14 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 2019-20 & 2020-21is given under: -

(Rs in crores)

S.No.	Scheme (s)	2019-20			2020-21			
		RE	Actual Exp.	Outcome (Actual Exp/RE)	BE	RE	Actual Exp.	Outcome (Actual Exp/RE)

				in %				in % *
1.	Pharmaceutical Promotion and Development Scheme (PPDS)	1.19	1.06	89.08	1.00	0.50	0.23	46
2.	Assistance to Pharmaceuticals Industry for Common Facilitation Center(previous known as Cluster Development)	2.23	2.23	100.00	12.00	7.23	0.22	3.04
3.	Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)	0.02	Nil	Nil	0.02	0.01	Nil	Nil
4.	Assistance to Bulk Drug Industry for Common Facilitation Center	0.02	Nil	Nil	21.52	1.69	-	-
5	Assistance to Medical Device Industry for Common Facilitation Center	0.02	Nil	Nil	7.50	21.05	7.49	34.84
6.	PLI Scheme for promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India	New sub-scheme Approved in 2020.				1.55	1.55	100
7.	PLI Scheme for Promoting Domestic Manufacturing of Medical Devices	New sub-scheme. Approved in 2020.				2.00	1.77	88.5

***Full utilization of RE is expected by March 2021.**

In view of above figures, sub-scheme wise analysis of Budget utilization during the year 2019-20 and 2020-21 is as follows:

a) <u>Pharmaceutical Promotion and Development Scheme (PPDS)</u>

3.15 The Scheme aims at promotion, development and export promotion in Pharmaceutical sector by extending financial support for conducting seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector. Under PPDS, the Department of Pharmaceuticals on its own or through financial support by way of Grant-in-aid to the Institutions, organizations, Voluntary organizations or Non-Government Organizations as mentioned in Rule 228 of GFR 2017:-

i. Conduct Training/knowledge improvement programs/activities on issues/subjects relevant to growth of pharmaceutical industry. An indicative list of subject is as under: - a. Quality Management System/Quality Improvement Program b. Handling USFDA notice c. Success Story Presentation-Pharmaceutical Entrepreneur d. Government regulations/guidelines for clinical trials in India versus USA, EU etc. e. Waste Management.
ii. Organize Summits, Conventions, Exhibitions, Pharmacy weeks, meetings etc. in India and abroad and produce promotional materials like films, displays etc.
iii. Conduct research studies, sector reports etc.
iv. Purchase books, quality standards, pharmacopoeias, magazines, directories, software for developing information data banks, developing e-learning modules etc.
v. Give awards to achievers in pharmaceutical industry.
vi. For creating awareness and publicity of important activities related to Pharmaceutical/ Medical Device and related sector.
vii. For any other activity not covered under above categories which may be decided by the Department of Pharmaceuticals from time to time.

3.16 To the query of the Committee on under utilization of the allocated funds under Pharmaceutical Promotion and Development Scheme (PPDS) during the year 2019-20 and 2020-21 and the steps that are being taken to fully and effectively utilize the funds allocated so as to encourage the Ministry of Finance to allocate the requisite amount of funds for the scheme, the Department in its written reply stated as beow:

> "During financial year 2020-21, due to corona virus pandemic, the Department has received fewer proposals for organizing webinars/seminars under PPDS." On further being asked to enumerate the challenges being faced by the Department in execution of this scheme and steps that are being taken by the Department to resolve them, the Department in its written reply stated, "Web based events and conference are being approved under the PPDS due to pandemic linked challenges."

b) Assistance to Pharmaceuticals Industry for Common Facilitation Center (previous known as Cluster Development)

3.17 This sub-scheme is implemented in a Public Private Partnership (PPP) mode. Financial assistance under this scheme is provided for creation of Common Facilities, such as Common Testing Centre, Training Centre, R&D Centre, Central Effluent Treatment Plan (CETP), Common Logistic Centre, etc. to a Special Purpose Vehicles(SPVs) set up for the purpose. Maximum limit for the grant-in-aid under this scheme is Rs 20.00 crore per cluster or 70% of the cost of projects whichever is less. A total of Rs 12.00 crore has been sanctioned for the year 2020-21. At present one project of Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC) to set up Common Effluent Treatment Plan (CETP) at Alathur, Tamil Nadu is under process. The total cost of the project is Rs 10,59,90,000/-. The project is expected to be completed by January, 2021. Four other proposals have been given 'in principle approval'.

3.18 Under Assistance to Pharmaceuticals Industry for Common Facilitation Centre (previous known as Cluster Development) actual expenditure incurred is only Rs. 0.22 crore against the approved RE of Rs. 7.23 crore, that is utilization is only 3.04 percent. The Committee asked the Department justification for this abysmal performance of the scheme and corrective measures that are being taken by the Department to ensure timely utilization of funds under the scheme. In reply, Department in writing as follows:-

> "During 2020-21, three new proposals have been received in the year 2020-21 from Bulk Drug Manufacturers Association (BDMA), M/s Sirmour Green Environ Ltd. (SGEL), Paonta Sahib, Himachal Pradesh, M/s Kala Amb Infrastructure Development Company (KDIC) and Sirmaur, Himachal Pradesh, which have been given in-principle approval in the month of September and October 2020. The applicants have submitted the Detailed Projects Reports which are being examined by the Project Management Agency (PMC) which has been appointed on 8.1.2021. Since the funds are released after final approval of the projects, there is lesser release of

fund. It is expected that these projects will be approved and remaining fund will be released by 31st March, 2021. The matter is being regularly reviewed at senior levels in the department."

3.19 Even though the utilization percentage of funds under the Scheme is very poor, the Department demanded an amount of Rs. 36.00 crore for the Scheme during 2021-22. In this regard the Committee sought the justification for the same particularly keeping in view the abysmal performance of the Scheme so far. The Department in its written reply stated, "Since four proposals were given in principle approval, it was expected that the same will be given final approval and 1st and 2nd instalment of fund will be required to be released during 2021-22. Hence Rs 36.00 crore was sought for 2021-22."

3.20 On being asked about the adequacy of the fund of Rs.18 crore allocated by the Ministry of Finance for the scheme during 2021-22, the Department in a written reply clarified, "As the final approval in individual cases was delayed, the requirement of amount of Rs. 18 cr. may be sufficient as of now. In case additional funds are required, the projections will be made at RE stage."

3.21 Further the Committee asked about the concrete steps that are proposed to be taken by the Department to fully utilize the allocated amount for the effective implementation of the Scheme, the Department in its written reply stated as under:

> "The Department has appointed M/s National Projects Construction Corporation Limited (NPCC) as the Project Management Consultant (PMC) which acts as a bridge between the Department and SPV and helps in expeditious implementation of the scheme. The four proposals which have been given in principle approval are being assessed by PMC."

c) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

3.22 The objective of the sub-scheme is to facilitate Small and Medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to World Health Organization (WHO)/Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets. Assistance in the form of interest subvention against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private sector will be provided to 900 Pharma SMEs of proven track record. The Scheme will be implemented through a Public Sector Financial Institution (PSFI) to be identified by the Government by inviting Expression of Interest. A total of Rs. 144 crore has been earmarked for the scheme. The upper limit of interest subvention on loans for technology/infrastructure upgradation shall be restricted to 6% per annum for a period of three years on reducing balance basis. The maximum loan eligible for this purpose will be Rs. 4 Crore, availed by the concerned SME.

3.23 Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) was approved by SFC in 2016. During 2019-20 and 2020-21, only a token allocation of Rs.1 lakh was provided for the Scheme. So, the Scheme remained a non-starter. Even though the Department had demanded Rs.185.00 crore for the Scheme, again only a token allocation of Rs.1 lakh has been made by the Ministry of Finance for 2021-22.

3.24 In this view of above observation, the Committee sought reasons for on paper existence of this important Scheme meant for technology upgradation of pharmaceutical industry, the Department in its written reply stated, "Non-receipt of applications for financial assistance was the reason the scheme could not move ahead. The Department has revamped the PTUAS scheme and approached the EFC for approval from 2021-22 to 2025-26."

3.25 The Committee also brought the attention of the Department to the recommendations made in the third party evaluation of Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS). The Department furnished the following action taken replies on the recommendations:

Sl.No.	**Recommendation of third party evaluation report**	**Reply of Department**
i.	The number of factories that need to be WHO-GMP compliant is much higher than 250, which is the target of this scheme.	The Department is proposing to provide assistance to 900 Micro, Small and Medium Enterprises (MSME) in the EFC Memo which has been sent to DoE on 10.2.2021.
ii.	To scientifically survey enough number of factories for willingness to invest under different conditions.	The Department intends to conduct studies to collect details.
iii.	By making export as criteria for scheme, the possibilities of upgradation of the sector are minimised. Instead, it should focus on raising the level of production process and quality norms in the MSME sector. By doing	The Department intends to conduct studies to collect details.

	this the overall level of quality of products and process would be elevated leading to inherent strength of the sector that would be capable of exploiting international market.	
iv.	It seems there is no clarity about the objective of the scheme. There should be enough brain storming to set ONE LINER objective for this scheme.	The objective of the Scheme is to facilitate Micro, Small and Medium Pharma Enterprises (SMEs) of a proven track record to migrate from Schedule-M to World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards to enable them to manufacture pharmaceutical products to the globally accepted standards of quality, safety and efficacy thereby increasing their global competitiveness and market share.
v.	It would be pragmatic to treat the PTUAS scheme in different light going beyond export and other outcomes. The scheme can be opened for MSME instead of SME sector.	The recommendation has been accepted and it has been proposed to provide assistance to Micro, Small and Medium Enterprises (MSME) for upgrading their plant and machinery to WHO-GMP or higher standards.
vi.	The eligibility norms are too stringent. The more units in the country are WHO-GMP certified the better would it be and therefore, the scheme objectives and eligibility should be set on such lines.	The Department has revised the EFC Note based on recommendation made in the report and Final EFC memo has been sent to the Department of Expenditure.
vii.	It is recommended that the Sub-scheme of 'Pharmaceutical Technology Upgradation Assistance Scheme' (PTUAS) must be started	The PTUAS is an existing scheme and revised EFC Note has been sent to DoE on 10.2.2021.

	as soon as possible with liberal terms and conditions and broad objective of transforming quality of production in MSME sector.		

3.26 This Scheme is implemented through a Public Sector Financial Institution (PSFI) to be identified by the Government. On being asked about the reasons for delays in identification of PSFI and concrete steps that are being taken by the Department in this regard, the Department in its written reply sated, "The scheme was approved for 2016-17 to 2019-20, but it had lukewarm response. Further, the department has sent a proposal to EFC for continuation of the scheme. After approval of the EFC, steps will be taken to identify the PSFI."

d) Assistance to Bulk Drug Industry for Common Facilitation Center

3.27 Under this scheme, only a token allocation of Rs.2.00 lakh was made for the Scheme during 2019-20. Rs. 21.52 crore was allocated at BE stage of 2020-21 which got reduced to only Rs. 1.69 crore at RE stage but no expenditure has so far been made under the Scheme during 2020-21. In this backdrop, the Department had sought Rs.900.00 crore for the implementation of the Scheme during 2021-22 but the Ministry of Finance has allocated only Rs.36.24 crore at BE stage.

3.28 In view of the above, the Committee asked about the reasons for non utilisation of funds under the Scheme during 2020-21 and justifications for claim of higher allocation of funds when Department is unable to utilize the allocated funds and concrete steps that are proposed to be taken for the successful utilization of Rs.36.24 crore allocated for the Scheme during 2021-22. The Department in its written reply sated:

> **"**The guidelines of the scheme “Promotion of Bulk Drug Parks” (Earlier know as Assistance to Bulk Drug Industry for Common Facilitation Center) were released on 27.07.2020. A total number of 13 proposals have been received which are under evaluation. The Department will soon accord 'in-principle' approval to 3 States/UTs under the scheme. The 3 States/UTs will submit a detailed project report within 180 days of date of issuance of in-principle approval letter. As per scheme guidelines, the Department has to release first installment of 30% of the total financial assistance of Rs. 1000 crore at the time of final approval of the project by the Scheme Steering Committee. Since the final approval may be accorded in the FY 2021-22, there will be need of Rs. 900 crore (Rs. 300 crore each for 3 parks). The Policy Section has demanded Rs. 900 crore for BE 2021-22, however, only Rs. 36.24 crore has been allocated. This fund will not be adequate to meet the requirements under the scheme “Promotion of Bulk Drug Parks."

e) Assistance to Medical Device Industry for Common Facilitation Center

3.29 In Financial Year 2020-21, the Union Cabinet has revised the scheme “Assistance to Medical Device Industry for Common Facility Centre” to “Promotion of Medical Devices Parks” with a total financial outlay of Rs. 400 crore. The Department has rolled out the scheme “Promotion of Medical Devices Parks” with the objective of creation of world class infrastructure facilities in order to make Indian medical device industry a global leader. The medical device parks approved under the scheme will provide common testing and laboratory facilities/centre at one place reducing the manufacturing cost significantly and will help in creating a robust ecosystem for medical device manufacturing in the country. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025. Financial assistance to a selected Medical Device Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Medical Device Park would be limited to ₹ 100 crore.

3.30 Under this Scheme an allocation of Rs.7.50 crore was made at BE stage of 2020-21 and the same was increased to Rs. 21.05 crore but the Department is able to spend only Rs 7.49 crore so far. In this regard, the Committee asked about the reasons for low utilisation of funds under the Scheme and the steps being taken to utilize the allocated funds before 31 March, 2021. The Department in its written reply stated as under:

> "The Department has approved financial assistance of Rs. 25 crore to Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh under the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre" for creation of common facility centre for superconducting magnetic coils testing & research facility. Initially, fund of Rs. 7.50 crore was available at BE 2020-21. The Department has released first instalment of Rs. 7.49 crore for the project on 11.09.2020. Additional funds of Rs.13.55 crore have been kept in RE 2020-21 under this sub-scheme. However, the funds are to be released/utilized after issuance Re-appropriation order which will be issued after receipt of Presidential Assent Second and Final Batch of Supplementary Demand For Grants FY 2020-21. The fund of Rs. 1.12 crore will be released to the Project Management Agency of the scheme "Promotion of Medical Devices Parks" as fee. The rest of the fund will be released to Andhra Pradesh Medtech Zone Ltd (AMTZ) as subsequent instalments of grant-in-aid as approved under the scheme "Assistance to Medical Device Industry for Common Facility Centre".

3.31 The Department had demanded Rs.120 crore for the implementation of the Scheme during 2021-22 but the Ministry of Finance has allocated only Rs.60 crore at BE stage. In this regard, on being asked about the adequacy of the BE allocation and the steps that are contemplated for effective utilisation of the allocation and the measures that are proposed for the allocation of the requisite amount of funds at RE stage, the Department in its written reply stated as follows:-

> "The scheme "Promotion of Medical Devices Parks" (earlier known as Assistance to Medical Device Industry for Common Facility Centre) is at the initial stage of implementation. As per scheme guidelines, the Department has to release first instalment of 30% of the total financial

assistance of Rs. 100 crore at the time of final approval of the project. Since the final approval may be accorded in the FY 2021-22, the Department has projected a need of Rs. 120 crore (Rs. 30 crore each for 4 parks) for FY 2021-22. However, only Rs. 60 crore has been allocated under BE 2021-22. Viewing the progress of the scheme, the requirement of funds will be proposed at RE stage."

3.32 Under the scheme, in-principle approval was given to the projects of Andhra Pradesh, Telangana, Kerala and Tamil Nadu. However, final approval for providing assistance of Rs. 25 crore was given to the proposal received from Andhra Pradesh only. In this regard, when the Committee asked about the status of other projects during 2021-22, the Department in its written reply stated as under:

"In-principle approvals were given to the proposals of Andhra Pradesh, Kerala, Tamil Nadu and Telangana under the sub-scheme “Assistance to Medical Device Industry for Common Facility Centre”. However, the proposal of Andhra Pradesh Medtech Zone Ltd was first taken up. The Scheme Steering Committee after due consideration gave its final approval to the proposal of AMTZ. The approval was conveyed vide letter dated 24.02.2020.The scheme was revised to “Promotion of Medical Devices Parks” by the Government of India on 20th March 2020. The guidelines of the revised scheme were issued on 27.07.2020. After the revision of the scheme, the fresh proposals have been received from the State Governments of Kerala, Tamil Nadu and Telangana in accordance with the revised guidelines of the scheme. A total number of 16 proposals have been received. All the proposals are being evaluated for giving in-principle approval."

f) <u>New Production Linked Incentive (PLI) schemes</u>

3.33 Under Umbrella Scheme of DoP “Development of Pharmaceuticals Industry” two new sub-schemes i.e (a) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device” and (b) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country have been approved by Cabinet in its meeting dated 20.3.2020 with a total outlay of Rs. 3420 crores and Rs. 6940 crores respectively. However the fund sought for these two sub-scheme under 1st batch of Supplementary Demand for Grants 2020-21 from Ministry of Finance is only Rs. 2.00 crores for Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device and Rs. 1.55 crores for Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical

Key Starting Materials (KSM)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country.

3.34 The Committee sought reasons for seeking only Rs. 2.00 crore and Rs. 1.55 crore under the first batch of Supplementary Grants (2020-21) during the year 2020-21 and only token allocations of Rs. 2.36 crore and Rs. 2.79 crore have been made at BE stage for 2021-22 for both these ambitious schemes when the Cabinet has approved a total outlay of Rs. 3420 crore from FY 2020-21 to FY 2027-28 and Rs. 6940 crore from FY 2020-21 to FY 2029-30 for Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device and Production Linked Incentive (PLI) Scheme, respectively and also the steps that are being taken during 2020-21 to implement the Schemes in an effective and efficient manner. In this regard, the Department in its written reply stated as follows:

> "As per scheme guidelines of PLI scheme for Bulk Drugs, the gestation period for fermentation-based products is up to 2022-23 and chemical synthesis-based product, the gestation period is up to 2021-22. As per scheme guidelines of PLI scheme for Medical Devices, the incentive to the applicants under four target segments will be applicable from FY 2022-23. As such, funds for disbursal of incentives to selected applicants are not required. Accordingly, the fee of Project Management Agency (PMA) will only be paid during 2020-21 and 2021-22 for which Rs 2.00 crore and Rs 1.55 crore was sought. The detailed action plan has been indicated in the scheme Guidelines issued on 29.10.2020. The last date of receipt of applications was 30th November, 2020. All the applications, after being appraised by PMC, will be placed for approval of Empowered Committee by 28th February, 2021."

3.35 Further on being asked about the response from the Pharmaceutical sector for the Production Linked Incentive (PLI) Scheme for Bulk Drugs and PLI Scheme for Medical Devices and steps that are being taken by the Department towards to the response of the pharmaceutical sector, the Department in a written reply stated as below:

> "In total 215 applications have been received for the 4 Target Segments for the PLI schemes for Bulk Drugs and 28 applications for the 4 Target Segments for the PLI Scheme for Medical Devices. Meetings of Empowered Committed have been held under the chairmanship of CEO, NITI Aayog. Five applications under PLI scheme for Bulk Drugs and nine applications under PLI scheme for Medical Devices have been approved till 15th February, 2021."

3.36 On being asked about the salient features of the new Production linked Incentive (PLI) scheme for Pharmaceuticals including its financial outlay and the time period for its implementation, the Department furnished the following reply in writing :

"The Union Cabinet in its meeting on 11.11.2020 approved yet another Production Linked Incentive scheme for Pharmaceuticals with the objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains.

The salient features of proposed new PLI are that the following three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales:

(a) Category 1

Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.; Complex excipients; Phyto-pharmaceuticals; Other drugs as approved.

(b) **Category 2**

Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates.

(c) **Category 3 (Drugs not covered under Category 1 and Category 2)**

Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs; In vitro diagnostic devices; Other drugs as approved; Other drugs not manufactured in India.

The outlay of the scheme is Rs 15,000 crore and above three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme is proposed to be from FY 2021 to 2028-29."

B. JAN AUSHADHI SCHEME (PMBJP) MAJOR HEAD-[2552(NORTH EAST REGION) AND 2852(INDUSTRIES)]

3.37 Despite the country being one of the leading exporters of generic medicines to the world, the majority of Indians lack sufficient access to affordable medicines. The branded (Generic) medicines are sold at significantly higher prices than their un-branded generic equivalents, though are identical in the therapeutic value. With an objective of making quality generic medicines available at affordable prices to all especially for the poor and the deprived ones, Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department in the year 2008. Under this scheme, dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJK) are opened all over the country to provide generic medicines to the masses. Implementing Agency Bureau of Pharma Public Sector Undertakings of India (BPPI) was set up on 1st December, 2008 by the Department with a major objective to have focused and empowered structure to implement the Jan Aushadhi Campaign. The Governing Council of the Bureau in its 34th meeting held on 26.02.2020 decided to change its name from 'Bureau of Pharma PSUs of India (BPPI)' to 'Pharmaceuticals & Medical Devices Bureau of India (PMBI). Jan Aushadhi Scheme has been approved for continuation with the financial outlay of Rs. 490 crore for the period 2020-2021 to 2024-2025. The target was to cover all districts of the country by the end of Financial Year 2020-2021 which has been achieved. It has also been decided to open 10500 PMBJP Kendras in all over the country by March, 2025.

3.38 Year wise BE, RE and actual expenditure incurred under Jan Aushadhi Scheme (PMBJP) for the last three years and BE allocation for the year 2021-22 is given below:

(Rs. in crore)

Name of Scheme	**2018-19**			**2019-20**			**2020-21**			**2021-22**
	BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
Jan Aushadi Scheme	84.00	42.51	42.50	42.00	35.51	35.51	50.00	65.00	50.00*	65.00

***As on 15.01.2021**

3.39 The Department has got Rs. 65.00 crore at BE stage for 2021-22 as against Department's demand for Rs. 80.00 crore. The Committee asked about the adequacy of the fund allocated and impact of shortage of fund on the implementation of this ambitious scheme of the Department. The Department in its written reply stated as follows**:**

> "The non-allocation of funds sought by the Department will affect implementation of the Scheme. However, BPPI is being advised to explore means to reduce dependence on grants provided by the Department and generate sufficient revenue to expand their operations."

3.40 On Being asked about the details of physical and financial targets set to be achieved under this scheme during the year 2021-22, the Department in its written reply stated as under**:**

Particulars	**Target for the year 2020-21**	**Achievements till 31-01-2021**	**Target for the year 2021-22**
Districts to be covered by opening PMBJKs	All	All	All
Total No. of PMBJKs	7300	7259	8300
Product Basket a) Medicines b) Surgicals	 1400 220	 1449 204	 1600 260
Warehouses	4	3	4
Estimated Sales (Rs. in cr.)	500	527	625

3.41 Further on being asked about the specific targets that have been set by the Department with respect to opening Jan Aushadi Kendras in urban fringes, rural, remote areas, hilly areas and island territory during 2021-22, the Department in its written reply stated as under:

> "Pradhan Mantri Bhartiya Janaushadhi Kendras are being opened all across 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 areas. In processing applications, priority is always given to unserved areas. BPPI has already covered all aspirational districts of the country. Further, additional grant of up to Rs 2.00 lacs is provided to entrepreneur for setting up kendras in aspirational districts, Himalayan states, island territory & N-E states."

3.42 The Committee also asked the Department about any special policy to open Jan Aushadhi Kendras in urban fringes, rural, remote areas, hilly areas and island territory even in case of non receipt of any applicant to open such kendras from these areas. In this regard, the Department stated in its written reply as follows:

> "BPPI has policy to give special grant to women entrepreneurs, divyang, SC, ST (category based) & area-based grant to any entrepreneur running Janaushadhi stores in aspirational districts as notified by the NITI Aayog& in North-Eastern States, Himalayan States & Island Territory. An amount of up to Rs. 2.00 lakh in addition to normal incentives as

applicable is to be given to above mentioned entrepreneurs as mentioned below-

(i) Rs. 1.50 lakh reimbursement of furniture and fixtures
(ii) Rs. 0.50 lakh as reimbursement for computer, internet, printer, scanner, etc.

This will be one-time grant for opening of new JAK against submission of original bill and restricted up to actual expenditure incurred. These provisions are made to attract entrepreneurs to open Janaushadhi Kendras at above areas.

Earlier areas from which applications were not received for opening of kendras and belonged to un-served districts, one general pharma shop was approved to keep medicines of Janaushadhi and were entitled to sales-based incentive as given to other Janaushadhi Kendra. Total 32 kendras have been opened under this category. Now, out of these 32 stores, 10 are already covered by opening dedicated outlet."

3.43 Year-wise Progress made in opening functional PMBJP kendras is mentioned below in the table:

Financial Year	**Yearly Addition**	**Cumulative**	**Sales at MRP Value in Crores**
2014-15	14	86	7.29
2015-16	154	240	12.16
2016-17	720	960	32.66
2017-18	2233	3193	140.84
2018-19	1863	5056	315.70
2019-20	1250	6306	433.60
2020-21 (as on 05.01.2021)	712	7018	473.70

3.44 Above table shows that 2233 new Jan Aushadi Kendras were opened during the year 2017-18, 1863 new kendras were opened during 2018-19, during the year 2019-20 this figure came down to 1250 kendras and in 2020-21 it further came down to 712 kendras only. In this regard, the Committee asked about the prominent reasons for this gradual reduction in opening new Kendras during the last four years and suggested ways to convert this downward trend into upward trend in the coming years. The Department in its written reply stated as below:

"In year 2020-21, 1475 new kendras are opened (up to 12th February 2021) & 434 kendras, who were found violating guidelines of Janaushadhi were closed. Thus, net addition is 1041 which is more than the target of 1000 for the year.

However, increase in number of kendras requires corresponding strengthening of related infrastructure which can support the increased operations. Further, impact in commercial viability of existing kendras is also being considered while granting new approvals. Thus, a distance policy is observed while granting approvals to new kendras. A minimum distance of 1.00 km is maintained between two kendras in seven metro cities & districts having population 10 lakhs & more. In other districts, it is 1.5 km.

Further, BPPI is increasing its warehouse and logistics network. One new warehouse is under construction at Surat and seven new distributors are appointed across the country. BPPI is expected to open 7500 stores in FY 2020-21 and 10,000 outlets by FY 2023-24."

3.45 During 2018-19 and 2019-20, value of medicine sold through 5056 and 6306 PMBJP Kendras was Rs. 315.70 crore and Rs. 433.60 crore respectively and during 2020-21, value of medicine sold through 7018 PMBJP Kendras increased to Rs. 473.70 crore. When asked whether the Department is satisfied with the increase in volume of sales corresponding to the increase in number of kendras during the last three years and the steps that are being taken to popularize PMBJP among people, the Department in its written reply stated as follows:

"Sale turnover of BPPI in F.Y-2020-21 (up to 31st Jan 2021) is Rs 527 Crore as compared to Rs. 348 Crore during the same period of F.Y. 2019-20. The turnover has, thus, shown a growth of 51% while growth in number of kendras is 19.35% (from 6082 to 7259 up to 31st Jan 2021). Thus, growth in sales is much greater than the growth in number of kendras. In fact, BPPI is well set to achieve sales turnover of more than Rs 625 Crore which is the target for FY- 2021-22, one year earlier.

Further, BPPI 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, BPPI also educating the public about the usages of Jan Aushadhi generic medicines through social media platforms like Facebook, Twitter, Instagram, YouTube, etc. on daily basis. Janaushadhi Week is also celebrated every year in first week of March in which various activities are organized to create awareness among masses."

3.46 On being asked about the response towards the scheme after introduction of enhanced normal incentives and additional incentives for women, divyang, SC &ST entrepreneurs, the Department in its written reply stated, "In FY 2020-21, total 1475 new kendras are opened, out of which 434 kendras (30%) are eligible for additional grant up to Rs 2.00 lakhs. Thus, the change in scheme is well responded by the entrepreneurs."

3.47 The Committee also asked about the recommendation wise status of implementation of the third party evaluation report on “Improving Effectiveness of Jan Aushadhi (JA) Stores” submitted by NITI Aayog in January 2019, the Department in its written reply stated as :-

“The scheme was evaluated by NITI Aayog during the period of June-September 2018. The evaluation study was commissioned by NITI Aayog and carried out jointly by BML Munjal University, Gurugram and BEN Consulting, Singapore. The evaluation study report was submitted in January 2019 under the title “Improving Effectiveness of Jan Aushadhi (JA) Stores” with the following recommendations to improve the effectiveness of the Scheme:

a) Government hospitals are best place to be a prime growth driver, preferably operated by a private operator.
b) Private Jan Aushadhi stores, through large in number, vary widely in performance; the stores must be rewarded or graded based on their performance; each store should undergo assessment through a structured Performance Score Card.
c) The subsidy now being given to private Jan Aushadhi stores is serving little purpose and can be diverted to provide funds for increasing awareness spend; there is a case for increasing the margin allowed on sales to the retail JA stores from 20% to 30%
d) There is an urgent need to step up awareness through allocation of higher budget for brand spend directed at doctors and patients.
e) Supply chain scale-up needs to be in accordance with the need of a 5000-strong network; action plan identified focusing on predictive demand forecasting, widening participation of bidders, bringing in quality as a gating item, simplification of MSME reservation method, among others.
f) Stricter quality criteria and monitoring thereof can raise the bar, which will help in building confidence of target customers.

g) There is a need to upgrade capability and strengthen the monitoring role of BPPI, including its corporatization.

Some of the issues highlighted in the report are being addressed as follow-

(i) Market Reach Expansion: BPPI has taken various steps to ensure market expansion. State Health departments and associated government authorities have been requested to open Jan Aushadhi Stores in various government hospitals and associated premises. Further Stores have been also categorized as mentioned in the report and focusing on A and B category stores. Eligibility criteria for opening of store have been also revised. To ensure recognition in masses, social media platform is being used on daily basis and various types of awareness about PMBJP and its products are being spread through various social media platforms. Government is also adopting an integrated approach for spreading awareness about PMBJP. Promotion workshops are also organized across India with stores owners, doctors and various important dignitaries.

(ii) Increase in trade margin to kendras: This proposal was evaluated and found that in place of increase in trade margin to 30%, it is better to increase sales-based incentive to the kendras. This is revised to up to Rs 15,000/- p.m. &Rs 5.00 total from Rs 10,000/- &Rs 2.50 lacs earlier.

(iii) Supply Chain Management: Supply chain has been also revamped and a Central warehouse at Gurugram with regional warehouses at Chennai & Guwahati are functional with robust IT system based on SAP for demand forecasting & acceptance of orders on real time basis. WHO-GDP complaint facilities have been created to cater the requirement of PMBJKs.

(iv) Quality Criteria Management: The issue has been taken up and BPPI is procuring medicines from companies/plants which are WHO-GMP certified. Further, Quality Standard Operating Procedures have been also developed to ensure better quality of products. To enhance the Quality Assurance, BPPI do periodically inspection of the manufacturing site(s) as per the tender terms and condition."

3.48 During oral evidence of the representatives of the Department of Pharmaceuticals on Demands for Grants, 2021-22, the Hon’ble Chairperson and members of the Committee, raised several questions about the implementation of PMBJP viz. awareness among people about generic medicines, incentives to entrepreneurs, setting up of PMBJP kendras at block level, sensitizing medical practitioners about prescribing generic medicines, etc. In this regard, the Secretary, DoP replied as follows:-

“I will, therefore, come to the Jan Aushadhi Kendra. I would like to thank the hon. Members and hon. Chairperson for appreciating the scheme. Certainly, it is a very satisfying work for the Department also to do. Madam, we started in 2008. By 2014, I think there were about 80 stores in the country. Today we are having 7,290. Next year, for which we have sought the budget of Rs.65 crore, we hope to reach 8,500. So, there has been growth in the number of stores. That is true. Secondly, we also managed to cover every District. Now, because it is obvious that there is a lot of demand for the services of Jan Aushadhi Kendras, we are trying to identify those Blocks that are not covered. That is because a District may have four or five stores but they may all be in the District Headquarters. So, we are trying now to go to the Blocks. In the latest advertisement issued for receiving applications, they have identified Blocks that we want applications in these particular Blocks. We have done that.

There was a suggestion that we should ask for more money for Jan Aushadhi Kendra. We had in fact asked for Rs.80 Crore this year and we have been given Rs.65 Crore. If we use the amount, I am hopeful that we will get more. However, the entire Jan Aushadhi Pariyojana is designed on a self-financing model. The Pariyojana procures generic medicines in bulk and they get it lower price. They purchase the medicines at 50 per cent or 80 per cent discounted price compared to whatever is the market price and provide the medicines to the Kendras, allowing them a small margin. That is how it is sold at a cheap price. It is a self-financing model like a business.

However, they require support for two things. One is for creating awareness so that, as Madam rightly said, people know that there is an option of generic medicine. Secondly, they require money to support the entrepreneurs so that they are incentivized and encouraged to come into this business. As Madam correctly pointed out, entrepreneurs feel that they will not be able to compete with the other commercial stores. For that reason, we provide three types of support.

The first one is that we provide infrastructure support of Rs. 2 lakh to set up the shop, out of which Rs. 1.5 lakh is for the shop and remaining amount of Rs. 50,000 is for the IT system. If the entrepreneur belongs to women category, Divyang, SC or ST or whoever wants to set up the shop in Himalayan States, North East region or island territories, gets this support. This helps them to overcome the initial capital investment.

The second support we provide is this 15 per cent. The entrepreneur can take the margin. In addition, they can also get 15 per cent to enable them to cross over the initial time of building the business reputation. So, it is given for three and a half years or so upto 5 lakhs.

The third support that we are trying to give is through our awareness programmes. There are various media awareness programmes and local awareness programmes. I am happy to inform the august Committee that from 1st to 7th March, we will have Jan Aushadhi Week. This is an annual event enforcing the messaging through repetition. We try to engage with doctors, youngsters, pharmacy students, schools etc. We engage with the communities also. This year, we will be reaching out to the old age homes and senior citizens in their homes to educate them that generic drugs are good. But I think there is also a big role for the medical profession in this, and therefore, the Health Ministry has been repeatedly writing to the State Governments asking them to sensitize the doctors to prescribe in the generic forms, because doctors tend to prescribe in the brand name. There is a whole reason for that, as all of you are aware. So, there is a tendency to prescribe in the brand name. So, an awareness to prescribe in the generic names is an uphill task because there are so many interests at work. But we are trying through the Health Ministry and every bit of awareness helps in that. Without that, we will continue not to be able to fully exploit the potential of generic medicines. The Hon'ble Ministers and Prime Minister also speak of generic medicines during this week-long celebration. Another point is that the Government is not providing working capital for the purchase of medicines. It is providing only Rs. 60 crore against the purchase of Rs. 600 crore per year. They also take care that when they expand, they should expand in a sustainable manner. But the points made by the hon. Chairperson and the hon. Members are very well taken. When we prepare both our media plan as well as our operation plan for 2021-22, we will take special care to look into this and incorporate it in our planning".

3.49 Further when the Committee asked who is looking after the activity of Jan Aushadhi Kendras at the State and district levels, a representative of the Department stated as under:-

"Sir, at the State level, we have marketing officers. They look after the events of the Jan Aushadhi at the State level. Sir, at the district level, we do not have any officers. It is taken care at the State level. We have a robust IT technology that takes care of it. Every storage is given a code and a login ID. Every event of the store, the requirement of medicines, supply, despatch, billing, everything is available on that system".

CHAPTER-IV

ATTACHED OFFICE AND AUTONOMOUS INSTITUTIONS

A. NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA) [MAJOR HEAD-2852 (INDUSTRIES)]

The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals was constituted by the Government of India vide resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia, includes fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines. The Government notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995.

4.2 Year wise BE, RE and actual expenditure incurred by the NPPA during last three years and BE allocation for the year 2021-22 is given as under:

(Rs. in crore)

Name of Scheme	2018-19			2019-20			2020-21			2021-22
	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
NPPA	11.50	12.94	9.45	12.00	11.48	10.61	11.90	12.90	9.94*	14.80

***As on 15.01.2021**

4.3 On perusal of the above table, the Committee asked about the reasons for underutilization of funds by National Pharmaceutical Pricing Authority (NPPA) during the years 2018-19, 2019-20 and 2020-21. The Department in its written reply stated, "The reasons for under-utilization of funds include proposed shifting of NPPA having been delayed leading to less expenditure on rent, office expenses, etc. Further, numbers of posts remaining vacant led to less expenditure on salaries, travel expenses, etc."

4.4 On being asked about the reasons for increased allocation of Rs.14.80 crore at BE stage of 2021-22 despite of the fact that NPPA was unable to utilize the funds fully during the last three financial years, the Department in its written reply stated, "The reasons for increased allocation include additional expenditure on rent for the additional office space hired in the year 2020-21 in the YMCA Building in which NPPA office is located and to meet expenditure on CADC Project for automation of NPPA."

4.5 The Committee also asked about the measures that are proposed to be taken by NPPA to utilize the allocated funds fully and efficiently. In this regard, the Department in a written reply, "All requisite measures are being taken by NPPA to utilize the allocated funds fully and efficiently. Further, provision of official space for NPPA is being explored by the Department with Ministry of Urban Development under Central Vista."

4.6 When the Committee asked about the priorities of NPPA with respect to price control of scheduled as well as non scheduled drugs and medical devices during the year 2021-22, the Department in its written reply stated as under:

"(a) NPPA fixes the ceiling price of scheduled medicines specified in the first schedule of the Drugs (Prices Control) Order, 2013 (DPCO) in accordance with the provisions of the DPCO. All manufactures of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. It also fixes the retail price of 'new drugs' on application in Form-I being filed by the companies.

(b) Under Para 18 (i) of DPCO 2013, ceiling price are to be revised as and when the National List of Essential Medicines (NLEM) is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price, whichever is earlier. The ceiling price of the scheduled medicine is to be done during 2021-22 either immediately after the expiry of 5 years from the date of fixing of previous ceiling price under DPCO, 2013 or based on notification of NLEM, which is under revision.

(c) Taking the pilot on Trade Margin Rationalization (TMR) on anti-cancer drugs ahead.

(d) Creation of database & price monitoring in respect of 28 Medical Devices."

4.7 The Committee further asked about the specific new steps/programmes which are proposed to be initiated during 2021-22 to achieve the goals of NPPA. In its written reply, the Department stated as follows:

"NPPA has signed an MoU with CDAC for development and implementation of a cloud based advanced Integrated Pharmaceuticals Database Management System ver. 2 (IPDMS 2.0) with an object to ensure more efficient, transparent and time bound functioning through complete office automation. The project will be implemented during 2021-22 and is envisaged to optimize synergies in operations as it would enable paperless functioning within the organization and also facilitate the stakeholders to connect with NPPA without the need of visiting the Office. In addition, NPPA will continue with the registration and consolidation of PMRUs under the Consumer Awareness, Publicity and Price Monitoring (CAPPM) scheme in other States/UTs to increase its outreach and presence to achieve the goals of NPPA."

4.8 During Oral Evidence, the Committee brought to the attention of the representatives of the impact of higher prices of medicines on poor people, and enquired about the steps being taken thereon by the Department and NPPA. In this regard, the Chairperson, NPPA made the following submission before the Committee:-

> "Hon. Chairperson and the hon. Members, it is a matter of great grief to hear from one of the hon. Member Dr. Singari that there were six suicides that can be attributed to the high prices of medicines. When we look at the data, we are aware that more than 50 per cent of expenditure on health is out of pocket in India. We know that this out-of-pocket expenditure on health is the main reason for dragging families below poverty line in India. It creates a vicious circle where poverty impacts livelihood, healthcare system etc. But to hear from the hon. Member that he has personally witnessed six cases where lack of availability of medicines led people to suicides is very depressive. It is for this purpose that the NPPA always strives. We try and work in the interest of the consumers to the best of our abilities within the regulation framework that is given to us. I would most humbly like to reiterate that as of now, the ceiling price is being extended only to 17.2 per cent of the total pharma. The rest are in the non-schedule segment. They are without the ceiling price and we are able to calibrate it up to 10 per cent increase of MRP per annum. So, there is that limitation of regulation to a certain extent and there are policy options open there".

4.9 During oral evidence, the Committee also pointed out that the price of medicines is quite high in private hospitals and the patients do not get the benefits when they go to private hospitals in spite of capping of the prices of those medicines/drugs. In this regard, the Secretary, Department of Pharmaceuticals informed the Committee during evidence as below:-

> "You are right that the hospitals are not treated as retailers by the system. They are operating under the Clinical Establishments Rules where they apply, etc. So, using the system that we have at the moment for fixing prices, at times, it may be challenging to regulate the prices charged by the hospital from the patient as a part of the overall treatment charges. So, there is another methodology called a trade margin rationalisation. We are

examining that also where we can take into account these kinds of alternative channels of sale of drugs than through a retailer. Of course, the retail shop in the hospital is a retailer. … Therefore, they are acting as distributors or stockists. Therefore, we are trying to look at the new methodology or an alternate methodology called trade margin rationalization. We are having stakeholder consultation with industry and with other departments whether we can move forward in this direction. This will probably give us a little more leverage in ensuring that prices can be regulated in a more rational manner. That is what we are trying. Certainly, this may be helpful".

4.10 The Committee also asked about the NPPA's role if any in controlling the price of COVID-19 vaccines and that of drugs/ medicines in treatment of this disease and if not provide reasons for the same. In this regard, the Department in a written reply stated as below:

"NPPA fixes the ceiling prices of formulations which are included in Schedule-I of DPCO 2013, which includes National List of Essential Medicines (NLEM) issued by the Ministry of Health and Family Welfare. Further, as per DPCO 2013, any vaccine included in Universal Immunisation Programme (UIP) is deemed to be scheduled formulation and accordingly its price can be fixed. The vaccines approved for COVID-19 treatment is neither included in NLEM nor in UIP. Also, the same have been approved for emergency use. Accordingly, the price of COVID-19 vaccine has not been fixed yet by NPPA. Presently, all procurement of vaccines has been made by MoHFW."

4.11 On being asked about the steps that have been taken by NPPA as the drug price regulator of the country to ensure strict compliance of Drugs Prices Control Order,2013 (DPCO) amid this pandemic situation in the country, the Department stated in writing as under:

"In order to ensure availability and accessibility of medicines at affordable prices during the COVID-19 pandemic, NPPA played an active role and undertook necessary measures to ensure continued availability of life saving essential medicines throughout the country. NPPA fine-tuned its interventions during the COVID pandemic to strike at profiteering tendencies by manufacturers/marketers in public interest. It monitored export/ import trends to ensure domestic availability of key drugs and Medical Devices. NPPA, in coordination with CDSCO, developed a comprehensive database for COVID & COVID plus (55+97) drugs as a measure of preventive preparedness for fighting COVID-19. NPPA took steps to enhance numbers of manufacturing units of Hydroxychloroquine and other drugs. NPPA, in public interest, capped the price of Liquid Medical Oxygen (LMO) and the Oxygen Inhalation (Medicinal gas) for six months. It also revised the ceiling price of Heparin upward for a period of six month to ensure its continued availability during the pandemic. In order to ensure availability of N95 mask at affordable prices in the Country, NPPA issued an Advisory, which led to reduction of its prices significantly up to 67%. The Authority also set up a ‘Control Room’ which handled complaints of shortages, black marketing etc. of various life- saving drugs.

4.12 When enquired about the challenges that NPPA face in the implementation of the DPCO in all states and Union Territories, the Department in its reply stated, "The challenges include availability of manpower, establishing state-level presence through PMRUs and implementing a computerized system for enhanced efficiency, so as to bring synergies across its various functions."

Consumer Awareness Publicity and Price Monitoring (CAPPM) Major Head-[2852 (Industries)]

4.13 Under the Central Sector Scheme of NPPA, viz., ‘Consumer Awareness, Publicity and Price Monitoring’ (CAPPM), Price Monitoring and Resource Units (PMRUs) are being set up in the States/ Union Territories. These 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. Year wise BE, RE and actual expenditure incurred under this scheme for the last three years is mentioned below in this table:

(Rs. in crore)

Name of Scheme	2018-19			2019-20			2020-21			2021-22
	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual	BE
Consumer Awareness, Publicity and Price Monitoring	4.00	4.00	2.98	4.00	4.00	3.99	4.50	3.00	1.78*	6.00

***As on 15.01.2021**

4.14 On being asked about the reasons for lowering of fund allocation from Rs. 4.5 crore at BE stage to Rs.3 crore at RE stage during 2020-21 and the specific reasons for lower utilization of funds during 2020-21 as only Rs1.78 crore has been spent as on 15.01.2021. The Committee also asked NPPA whether it will fully utilize the funds by 31 March, 2021. In this regard, the Department stated in a written reply as under:

“CAPPM scheme has two components, vis., (i) Grants in aid to Price Monitoring and Resource Unit (PMRU) and (ii) Advertisement & Publicity. Year wise BE, RE and actual expenditure incurred under this scheme for the last three years is mentioned below in this table:

(Rs. in crore)

Name of component	**2018-19**			**2019-20**			**2020-21**			**2021-22**
	BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
Price Monitoring &Resource Unit (PMRU)	2.00	2.00	1.14	2.00	2.00	2.00	2.50	2.50	1.78* (71%)	5.00
Advertisement & Publicity	2.00	2.00	1.84	2.00	2.00	1.99	2.00	0.50	0.10 (20%)	1.00
Total	4.00	4.00	2.94	4.00	4.00	3.99	4.50	3.00	63%	6.00

A sum of Rs. 1.50 crore was surrendered against Advertising and Publicity component leaving total Revised Budget for the Scheme as Rs. 3.00 crore. Under the first component (Assistance to PMRUs), it is expected that total funds will be utilized up to end of the F.Y. 2020-21. As regard the 2nd Component (Advertising and Publicity) the budget has been revised from Rs.2.00 crore to Rs. 0.50 crore. Further, an amount of Rs 1.00 Crore has been re-appropriated for CDAC project."

4.15 During oral evidence, when the Committee enquired about the adequacy of budgetary allocation for advertisement and publicity, the Chairperson, NPPA replied, “Last year, as I submitted, we had undertaken a campaign within the limit of Rs.2 crore. It is not too big a money. But whatever we were sanctioned, we undertook that. This year, we have been advised to undertake through social media. We are doing that. We will try and upscale this also”.

4.16 On being asked about the status of recommendation wise progress made in regard to their implementation of the third party evaluation done by Tariff Commission, Department of Industrial Policy & Promotion, Ministry of Commerce & Industry for CAPPM scheme, the Department furnished the following information:-

"Third Party Evaluation of the ‘Consumer Awareness Publicity and Price Monitoring (CAPPM) Scheme of NPPA was carried out by an independent body, i.e., Tariff Commission, Ministry of Commerce and Industry and it submitted the report on 20.03.2020. The main recommendations and action taken thereon are indicated in the following table:

S. No.	Recommendations	Action Taken
1	Slow pace of expenditure	The funds in respect of both of the components of the Scheme were fully utilized during the year 2019-20.
2	Functioning of 10 PMRUs	With the consistent and rigorous efforts, twelve (12) PMRUs were set up in the States viz. Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram and Jammu & Kashmir by 31st March 2020.
3	To set up at least one PMRU in East and Central Region	PMRUs have been set up in Odisha (East) and Madhya Pradesh (Central). However, it has to be noted that the setting up of PMRU largely depends upon the interest shown by the particular State. Vigorous efforts are being made to set up PMRUs in all the regions of the country.
4	Conducting Conferences/ Workshops/ Seminars at State and National level	Seminars/ Conferences and workshops were conducted in States as well at National level during the year 2019-20. Also, various IEC activities were carried out on “Reduction in the prices of Anti-Cancer drugs, Heart Stents, Knee Implants and General Medicines” across the country through putting of Hoardings/ LED screens, airing of radio Jingles, print media and creation of Short Telefilm (TVC). Monthly Webinar series of India@75 have been launched.

4.17 On being asked about the details of States/UTs where PMRUs have been set up so far, including the extent to which these PMRUs are effective in their own functioning as well as effective in monitoring drug price regulation, the Department in its written reply stated as under:

"Up to F.Y. 2020-21 there is a target to set up PMRUs in the 18 (Eighteen) States (cumulatively). With continuous and vigorous efforts, PMRUs have been set up in the 17 (Seventeen) States, viz., Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa and Madhya Pradesh. The process of setting up 18th PMRU is at advance stage and will be completed in current financial year.

Out of the total seventeen (17) PMRUs, the PMRUs in the state of Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa and Madhya Pradesh are newly set up. The PMRUs in other 12 (Twelve) States are fully functional. They are functioning, in co-ordination with NPPA, towards attainment of objectives, including, monitoring drug price regulation, ensuring availability of medicines, conducting IEC activities and organizing seminar/ webinar etc. The PMRUs are sending regular reports of their activities to NPPA."

4.18 Further the Committee asked about the details of States/UTs where PMRUs have not yet been set up alongwith the reasons therefor and about the time frame within which PMRUs are being set up in these state/UT. The Department in its written reply stated as below:

"As per NPPA/ DoP's Vision Plan, there is a target to set up PMRUs in all the States/ UTs by the F.Y. 2023-24. For the FY 2021-22, there is the target to set-up PMRUs in another six State/UTs.The PMRUs in the States of Bihar, Tamil Nadu, West Bengal, Assam, Chhattisgarh, Delhi, Jharkhand, Andaman & Nicobar Islands, Arunachal Pradesh, Chandigarh, Dadra &Nagar Haveli and Daman & Diu, Himachal Pradesh, Lakshadweep, Manipur, Meghalaya, Puducherry, Sikkim, Uttarakhand and Laddakh are yet to be set-up."

4.19 When the Committee also sought the reasons for downward revision of budgetary allocation from Rs. 2 crore to Rs. 50 lakh from BE stage to RE stage during 2020-21and also non spending of any budgetary allocation for advertisement and publicity during 2020-21 under advertisement and publicity component of this Consumer Awareness, Publicity and Price Monitoring Scheme (CAPPM), the Department in its written reply stated as follows:

"Under the component of Advertising and Publicity, the budget was revised from Rs.2.00 crore to Rs. 0.50 crore. An amount of Rs 1.00 Crore has been re-appropriated for CDAC project. Vigorous efforts were made by NPPA to launch comprehensive IEC campaign under the Advertising and Publicity component of the scheme. The components of the media plan are currently under review and hence expenditure of Rs 0.19 crore has been made."

4.20 The Committee further asked about the reasons for reduced allocation of Rs.1 crore for advertisement and publicity during 2021-22 and whether this reduced allocation of Rs.1.00 crore is sufficient to cater to the advertisement and publicity needs of CAPPM scheme, the Department in its written reply stated as under:

> **"**The funds were sought to the tune of Rs.2.00 crore for Advertising & Publicity in BE 2021-22. However, only Rs.1.00 crore has been allocated. In case of any additional need as per the progress of the activities, the additional funds would be sought at Supplementary/ RE stage."

B. NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPER) [MAJOR HEAD-2552 (NORTH EAST REGION) AND 2852 (INDUSTRIES)]

4.21 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 and given statutory recognition by an act of Parliament, NIPER Act, 1998 and was declared as an Institute of National Importance.

4.22 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. Another NIPER is proposed to be set up at Bengaluru, Karnataka.

4.23 Year wise BE, RE and actual expenditure incurred under NIPER Scheme during last three years and BE allocation for the year 2021-22 is given as under:

Name of Scheme	**2018-19**			**2019-20**			**2020-21**			**2021-22**
	BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
NIPERs	135.00	35.00	35.00	150.00	60.00	160.01	202.45	333.83	208.50*	234.34

(Rs. in crore)

***As on 15.01.2021**

4.24 On being asked about the reasons for increase in budgetary allocation from Rs.202.45 crore (BE) to Rs.333.83 crore (RE) during 2020-21, the Department in its written reply stated as below:

> "The Department aggressively sought the funds approved by the EFC in March 2018 for construction of campuses of NIPERs at Ahmedabad and Guwahati and equipping of laboratories in all NIPERs, but were not fully allocated/ released. The additional allocation at RE 2020-21 was on these counts and for payment of salaries of recently filled up faculty/administrative posts created with approval of the Ministry of Finance in the year 2019."

4.25 Further the Committee sought reasons for low utilization of funds to the tune of only Rs. 208.50 crores as on 15.01.2021 against the allocated amount of Rs. 333.83 crore at RE stage and NIPERS will be able to utilize the rest of the amount before 31 March, 2021. The Department in its written reply stated in this regard as under:

> "An amount of Rs. 202.45 crore has been allocated for the scheme of NIPERs in BE 2020-21. The Department has fully utilized the same along with additional Rs. 9.55 crore received under Supplementary Demands for Grants 2020-21, which has been released to NIPER, Mohali for payment of arrears of 7th Central Pay Commission. The additional funds being made available at RE 2020-21 (Rs. 121.83 crore) would be utilized for construction of campuses at NIPERs at Guwahati and Ahmedabad (Rs. 41 crore), purchase of equipment by six existing NIPERs (Rs. 71 crore) and payment of salary of newly recruited faculty / staff (Rs. 9.83 crore). The Department has already bifurcated the additional funds amongst various NIPERs and advised them to take steps to ensure utilization of the same during the current financial year. NIPERs have a Common Purchase Committee (CPC) for purchase of high end equipments. The Committee, after considering the requisitions of individual NIPERs, has already made its recommendations for purchase of equipment's by the individual NIPERs. Similar tying up has been done by the NIPERs concerned with contractors for utilization of the additional funds allocated for construction of campuses. The Department will be monitoring at its level so as to ensure that funds are fully utilized as and when they are made available."

4.26 When the Committee asked about the reasons for allocating only Rs. 234.34 crore at BE stage in 2021-22 against the proposed BE of Rs1220.00 crore whereas NIPER scheme utilization pattern shown in the above table is increasing year after year, the Department in its written reply stated, "While the Ministry of Finance will be in better position to explain the reasons of reduced allocation, one of the reasons can be the limits prescribed under the Medium Term Expenditure Framework (MTEF)."

4.27 The Committee also asked about the extent to which the reduced allocation of Rs. 234.34 crore at BE stage for the year 2021-22 as against the proposal of the Department for Rs.1220 crore for NIPERS during 2021-22 will affect the infrastructure and other development programmes of NIPERS as well as the research and development potential of these institutes and steps that are being taken by the Department of Pharmaceuticals. In this regard, the Department in its written reply stated as under:

> "The reduced allocation would adversely affect construction of campuses, setting up of laboratories and Centres of Excellence at NIPERs and would resultantly adversely impact the research and development potential of these institutes. A proposal for up-gradation and establishment of existing seven NIPERs as well as setting up of new five NIPERs with estimated cost of Rs. 4,300 crore sent to the Department of Expenditure in June, 2020 was returned by the Ministry of Finance indicating that the continuing schemes needs to be appraised and approved further for the period of 2021-22 to 2025-26 after 15th Finance Commission recommendations are accepted and resource position of public exchequer is clear. In pursuant to Department of Expenditure's instructions issued dated 8th December, 2020, a proposal has been sent again to the Department of Expenditure in the revised format for consideration by the EFC."

4.28 On being asked about the strategy being contemplated by the Department to persuade the Ministry of Finance to allocate the proposed amount of funds for NIPERs, the Department in conveyed in writing as below:

> "The matter will be taken up at higher level with the Ministry of Finance. Further, the Department will be seeking help of NITI Aayog and other Ministries/ departments concerned to persuade the Ministry of Finance to allocate the amount sought. It will also try to expedite the appraisal by EFC and subsequent release of funds."

4.29 The Committee also asked NIPER-wise details of progress made in creation of building and technical infrastructure during 2020-21 and about the complete utilization of funds by each NIPER as only Rs. 208.50 crores has been utilized as on 15.01.2020**.** In this regard**,** the Department furnished the following details:

> "Details of progress made in creation of building and Technical infrastructure are as under**:-**

S. No.	Name of NIPER	Details of progress made in creation of building
1.	NIPER, Guwahati	More than 90% construction of NIPER-Guwahati campus has been completed.
2.	NIPER, Ahmedabad	Construction of NIPER-Ahmedabad campus has started.

The amount of Budget Estimates and Status of Budget Expenditure for the Year 2020-21 is as under:

Release of funds during 2020-21			**(Rs. in crore)**
Sl. No.	**NIPER**	**BE 2020-21**	**Expenditure**
1	Ahmedabad	36.50	36.50
2	Guwahati	34.45	34.45
3	Hajipur	15.00	15.00
4	Hyderabad	30.50	30.50
5	Kolkata	23.00	23.00
6	Raebareli	22.00	22.00
7	Mohali	41.00	47.05
	Total	**202.45**	**208.50***

**** includes Rs. 9.55 crore received through Supplementary Demands for Grants 2020-21.Out of this an amount of Rs.45.00 cr. was utilized by NIPERs for creation of technical infrastructure (purchase of equipment for laboratories) during 2020-21.***

4.30 The Committee asked about the construction status of campus for NIPER-Guwahati, the Department stated that more than 90% construction of NIPER-Guwahati campus has been completed. It is likely to be completed by end of March, 2021. In regard to a query of the Committee about the construction of NIPER Ahmedabad which has been started in 2020-21 and steps that are being taken by the Department to expedite the campus construction process in a time bound manner, the Department stated in a written reply, "The construction activities of the campus are being monitored by the Building and Works Committee and the Board of Governors (BoG) of the Institute. The Department also monitors the various issues, including construction activities at regular review meetings held at the level of senior officers and Hon'ble Minsters."

4.31 The Department in its Preliminary Material on DFG, 2021-22 has stated that Rs. 121.83 crore has been allocated to NIPERs, which has been sought under the second and final batch of supplementary Demands for Grants during Financial Year 2020-21 which will be utilized for construction of campus of NIPER Guwahati and Ahmedabad. In this regard, when the Committee enquired whether the fund has actually been received from the Ministry of Finance, the Department in its written reply stated as follows:-

> "The allocation of Rs. 121.83 crore approved in RE 2020-21 has not yet been received from the Ministry of Finance. The proposal has been sent to the Ministry of Finance for seeking funds in the final batch of Supplementary Demands for Grants during FY 2020-21. The same would be provided after approval of the Parliament."

4.32 Further the Committee also asked about the steps that are being taken by the Department to start the construction of own campus for the other five NIPERs and if so, please provide details thereof, NIPER-wise and the fund requirement for the construction of own campus for each of the NIPER and steps that are being taken to mobilize the same, the Department replied as given below:

> "Out of the other five existing NIPERs at Mohali, Kolkata, Hyderabad, Raebareli and Hajipur, the NIPER at Mohali already has a well-developed full-fledged campus. The remaining four NIPERs have been allotted land by the State Governments free of cost. The Department also intends to transfer surplus land of PSUs under its aegis for setting of campuses of these institutes – 50 acres of surplus land of IDPL Hyderabad (under closure) for setting up campus of NIPER Hyderabad and 20 acres of surplus land of BCPL (under strategic sale) for setting up campus of NIPER at Kolkata. On deferment of the proposal for construction of campuses of these four NIPERs in March, 2018, the Department tried to get the funds through Higher Education Funding Agency (HEFA), which did not materialize. The Department has again sent a consolidated proposal for consideration of EFC, which include funds for construction of campuses of these institutes. About Rs. 612 crore have been indicated as projected requirement for construction of campuses of these four NIPERs."

4.33 The Department in its reply to a query of the Committee about the adequacy of funds to NIPERS stated in the Preliminary Material on DFG, 2021-22 that the faculty of NIPERs has been directed to earn at least 1/3rd of their salary to reduce dependency on Government Grants. When the Committee further enquired, whether this decision of the Department shall not repel the best talented faculty from joining NIPERs as they are not providing attractive salary packages instead asking to earn a part of salary on their own and also wanted to know about other research/academic institution that has followed such a model of salary structure for the faculty and benefitted from the same, the Department in its written reply stated as under:

> "While the Government is mandated to provide funds for construction of campuses, setting up well equipped laboratories, the Institutes need to strive to be self-reliant for meeting at least part of their operational expenses. The generation of resources will be through fees from students, testing fee from equipments, projects, consultancies etc. by the faculty. This is a goal which the NIPERs would be able to achieve once the basic infrastructure like permanent building, labs etc. are created and regular faculties are in place. NIPERs being institute of national importance are in position to generate funds through consultancies for industry, conducting various on-line skill development courses, courses for industry executives, conducting national/international conferences/ symposiums/ workshops, getting project funding from various sources, commercialization of patents, drug discovery etc. It is not that salary of individual faculty will depend on the revenue generated by him/ her, but it is a goal set up for the Institutes *per se*, which has been set in consultation with NIPER Directors and Chairmen of the Board of Governors."

4.34 On being asked to state the details of monitoring and control over the performance of NIPERS, the Department in its Preliminary Material on DFG, 2021-22 has stated that the Department has initiated process for amendment of the NIPER Act for setting up of a NIPER Council under the Hon'ble Minister of Chemicals & Fertilizers and few other changes. In this regard, when further asked about the details of the proposed amendments to the NIPER Act, the Department stated in writing as below:-

> "In order to further equip the NIPERs and strengthen their education and research capabilities in Pharma and medical devices sectors, the Cabinet has since approved specific changes in the NIPER Act due to passage of time and changed circumstances. This includes rationalization of the strength of Board of Governors (BoG) of individual NIPERs from its existing unwieldy size of 23 members to about 12 members; extend the mandate of NIPERs to include undergraduate, integrated courses and other short-term courses; setting up of a NIPER Council under the chairmanship of the Minister in charge of the Department of the Pharmaceuticals, which would co-ordinate the activities of all NIPERs, advise them on issues relating to duration of the courses, lay down policy, examine development plans, examine the annual budget estimates of each Institute, recommend the Central Government regarding allocation of funds and advise the Visitor (Hon'ble President of India) in respect of any function to be performed by him under the Act. An enabling provision has also been made requiring the Institute to carry out such directions as may be issued from time to time by the Central Government for efficient

administration of the Act. The amendments bill will now be introduced in the Parliament."

4.35 Further the Committee asked about the initiatives that have been taken by the Department with respect to setting up of new NIPERs at Tamil Nadu (Madurai), Chhattisgarh, Maharashtra and Rajasthan and that any time frame has been set by the Ministry for the setting up of these new NIPERs. In this regard, the Department furnished the following reply:

"The proposal sent to the Department of Expenditure for setting up of new NIPERs at Tamil Nadu (Madurai) and in the states of Chhattisgarh, Maharashtra and Rajasthan was deferred by the EFC in its meeting held on 26.03.2018 with a recommendation that the same may be reviewed and appropriately considered while allocations of funds are made under the Fifteenth Finance Commission for the period 2020-25. A consolidated proposal was sent to Department of Expenditure on 11.06.2020 for setting up these four NIPERs and another NIPER at Bengaluru, Karnataka, which was returned by the Ministry of Finance to submit the same after 15th Finance Commission recommendations are accepted and resource position of public exchequer is clear. A proposal has again been sent to the Department of Expenditure on 12.02.2021 for consideration by EFC. Subsequent to EFC approval, further action will be taken for setting up of these NIPERs. An amount of Rs. 310 cr for each NIPER has been sought for setting up these Institutes."

4.36 Year wise BE, RE and actual expenditure incurred under North East Region-NIPER Scheme during last four years is given as under:

(Rs. In crore)

	Budget Estimates (BE) year-wise	**Provision for North East Region**			**B.E. for North East Region as % of total B.E. of the Department**
Year		**BE**	**RE**	**Actual**	
2017-18 (Revenue)	247.74	31.52	52.02	52.00	12.72
2018-19 (Revenue)	261.53	33.52	33.52	33.50	12.81
2019-20 (Revenue)	235.51	36.42	41.42	41.40	15.46
2020-21 (Revenue)	333.58	33.46	79.26	33.45*	10.03

***Actual expenditure as on 15.01.2021**

4.37 When the Department was asked about the physical and financial targets for the year 2021-22 under NER-NIPER scheme, it stated as under:

"The details of physical and financial targets for the year 2021-22 under NER-NIPER, Guwahati are as under:-

Physical		**Target**
Construction activities		Construction of residential quarters for faculty and Non-faculty
Research papers to be published		100
Patents to be filed		6
Financial		**Target**
GIA-CCA	17.00 crore	To achieve 100% utilization of funds available under BE 2021-22.
GIA-Gen	17.70 crore	

4.38 The BE allocation for the year 2021-22 is Rs. 34.70 crores against proposed amount of Rs. 39.00 crores. The Department has utilized only

Rs. 33.45 crores out of RE allocation of Rs. 79.26 crores during the year 2020-21. These figures show that Department has not been able to utilize higher fund allocation made during RE 2020-21 due to which BE for the year 2021-22 has been reduced keeping in mind Department's utilization capacity. In this regard the Department has been asked to justify such utilization trends for North East Region-NIPER scheme. In its written reply, the Department has given following justification:

"The allocation of Rs. 34.45 crore made for NIPER, Guwahati under BE 2020-21 has been fully utilized till 15.01.2021. However, the additional allocation made under RE 2020-21 has been sought in the Final batch of Supplementary Demands for Grants 2020-21 and would be provided after approval by the Parliament. The same would be utilized for completion of construction of NIPER, Guwahati campus. The funds allocated as per the Budget Estimates under the NIPER scheme have been fully utilized. The additional funds allotted at RE stage will be utilized by the end of financial year."

CHAPTER-V

PUBLIC SECTOR UNDERTAKINGS
ASSISTANCE TO PSUs (LOAN TO PSUs) MAJOR HEAD-(6857)

There are five Public Sector Undertakings (PSUs) under the aegis of the Department, namely, Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL), Indian Drugs & Pharmaceuticals Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL).

5.2 The Cabinet in April 2016, while considering a proposal for sale of part of surplus and vacant land of Hindustan Antibiotics Limited (HAL) for meeting its liabilities directed that the Minister of Finance, Minister of Road Transport, Highways & Shipping and Minister of Chemicals & Fertilizers may comprehensively examine the status of all pharmaceutical companies in the public sector and suggest the future course of action. After detailed deliberations, the Ministers recommended in December 2016 that:

i.) Only that much of surplus land of Hindustan Antibiotics Limited (HAL), Indian Drugs & Pharmaceuticals Limited (IDPL), Rajasthan Drugs & Pharmaceuticals (RDPL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL) as would be required to meet the liabilities be sold through open competitive bidding to Government agencies and the outstanding liabilities be cleared from the sale proceeds. Voluntary Separation Scheme/Voluntary Retirement Scheme also be implemented in these PSUs to pave way for their closure. Remaining part of the land should be managed in accordance with guidelines of Department of Investment and Public Asset Management (DIPAM) and Department of Public Enterprises (DPE) in this regard and if need be, vested in a SPV created for this purpose.

ii.) After liabilities have been met, balance sheet cleansed and the Voluntary Separation Scheme/Voluntary Retirement Scheme effected, the Department to close IDPL & RDPL and HAL & BCPL be put up for strategic sale.

iii.) While taking a decision to close the PSUs, the Department may also explore the possibility of hiving off the subsidiary companies of HAL and IDPL for private participation, wherever found viable.

The Cabinet considered the recommendations of the Ministers' and approved the same in its meeting held on 28.12.2016.

5.3 The Department/ PSUs had the tenders issued for sale of surplus land of the PSUs, but no bids were received, the bidding being restricted to the government agencies as per the Cabinet's decision. As the land could not be sold, the liabilities of the PSUs could not be met and no progress made in respect of their closure/ strategic sale. The matter was again placed before the Cabinet, which in its meeting held on 17.07.2019 decided to:

(i) Modifying the earlier decision dated 28.12.2016 of sale of land of PSUs to government agencies and instead permitting the sale of land as per revised DPE's guidelines dated 14.06.2018.

(ii) Providing 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:

a. IDPL – Rs. 6.50 cr.

b. RDPL – Rs. 43.70 cr.

c. HAL – Rs. 280.15 cr.

(iii) Constitution of a Committee of Ministers for taking all decisions pertaining to closure/ strategic sale of the four Public Sector Undertakings, including the sale of assets and clearance of outstanding liabilities.

Summary of Central Public Sector Units of the Department of Pharmaceuticals

(As on December 2020)

	HAL	**IDPL**	**RDPL**	**BCPL**	**KAPL**
Established in	1954	05/04/1961	02/11/1978	1981	1981
Classification	Sick	Schedule-B, Sick PSU(In the process of closure)	CPSE-Under Closure	Sick (now Profit making)	Miniratna "C"
Net worth (in cr.)	-606.20	-7785.84 crore	21.32 crore	-53.68	216.53
Turnover (in cr.)	63.97	0.15 crore	NIL	55.50	366.67
Operating profit/loss (in cr.)	-19.47 (loss before Interest, Depreciation)	-160 crore	-12.60 crore	22.30	27.50
Liabilities (in cr.)	1053.08	7860.65 crore	75.29 crore	208.92	95.37
Referred to BIFR	1997	Referred to BIFR on 25.05.1992 BIFR declared IDPL Sick on 12.08.1992	No	1992	No
Total land	263.57 acres	Gurgaon: 89.79 acres (Freehold) Hyderabad: 891.95 acres (Freehold) Rishikesh: 833.878 acres (Leasehold) Total: 1815.618 acres (Excluding Subsidiary Unit)	37856 Sq.Mtr.	72.89 acre	40 Acres & 8 Guntas
Leasehold	NIL	833.878 acres	NIL	1.10 acre	-
Freehold	263.57 acres	981.74 acres	37856 Sq. Mtr.	71.79 acre	40 Acres & 8

					Guntas

5.4 On being asked about PSU-wise details on present status of functioning/closure/sale of HAL, IDPL, RDPL, and BCPL including clearance of salary and other payment dues to employees, the Department in its written reply stated as under:

	Name of CPSE	Salary dues (Rs. Crore)	Other payment dues (Rs. Crore)	Closure/ Sale	Whether Functional
1	Indian Drugs & Pharmaceuticals Ltd. (IDPL)	-	2.23	Under the process of closure	-
2	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)	-	20.46	Under the process of closure	-
3	Hindustan Antibiotics Ltd. (HAL)	-	162.60		Functioning
4	Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)	-	-		Functioning
5	Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL)	-	-		Functioning

5.5 On being asked about the Memorandum of Understanding(MOU) Assessment rating of all the five PSUs for the last 10 years from 2010-11 to 2020-21, the Department in a written reply furnished the information given below:-

"Memorandum of Understanding (MoU) is signed between Department and the PSUs to set progressive targets and assess performance. In view of two PSUs, namely IDPL and RDPL being under process of closure, the MOU assessment rating in respect of HAL, KAPL and BCPL is given as under.:-

Year	KAPL	BCPL	HAL
2010-11	Excellent	-	None
2011-12	Very Good	-	None
2012-13	Very Good	-	Poor

2013-14	Very Good	-	Poor
2014-15	Good	Good	Fair
2015-16	Very Good	Excellent	Poor
2016-17	Very Good	Very Good	Good
2017-18	Fair	-	Good
2018-19	Fair	-	Poor
2019-20	Very Good	-	Under Evaluation
2020-21	Under Evaluation	-	Under Evaluation

As shown above, MOU has not been signed with BCPL since 2017-18 as the company was sick and accordingly, DPE was requested to exempt signing of MoU. Further, BCPL was not rated by DPE before 2014-15 due to its poor performance and non-finalization of Annual Accounts within stipulated time. However, the Department is again approaching DPE for signing of MoU in respect of BCPL as the Company has made turnaround earning profits since last 3-4 years.

5.6 Year wise BE, RE and actual expenditure incurred under scheme Assistance to PSUs for the last three years and BE allocation for the year 2021-22 is given as under:

(Rs. in crores)

(Assistance to PSUs)	**2018-19**			**2019-20**			**2020-21**			**2021-22**
	BE	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**
Indian Drugs & Pharmaceuticals Ltd. (IDPL)	0.01	0.00	0.00	0.01	4.28	4.28	0.01	2.23	2.23	2.00
Hindustan Antibiotics Ltd. (HAL)	0.01	5.00	5.00	0.01	280.16	280.16	4.74	2.52	2.52	4.09
Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)	0.01	0.00	0.00	0.01	0.01		0.01	0.01	-	0.01
Bengal Immunity Ltd. (BIL)	0.01	0.00	0.00	0.01	0.01		0.01	0.01	-	0.01
Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)	0.01	2.00	***5.95	5.01	48.71	48.71	2.40	2.40	2.40	3.00
Smith Stanistreet Pharmaceuticals Ltd (SSPL)	0.01	0.00	0.00	0.01	0.01		0.01	0.01	-	0.01
Total (Loan to PSUs)	**0.06**	**7.00**	**10.95**	**5.06**	**#333.18**	**333.15**	**7.18**	**7.18**	**7.15**	**9.12**

*** Rs. 3.95 crore grant under 3rd Batch of Supplementary Demand for Grants (Technical) for the FY 2018-19.

#During the year 2019-20, the Cabinet on 17.07.2019 approved for modifying the earlier decision dated 28.12.2016, for sale of land to Govt. agencies and instead permit sale of land of PSUs as per revised DPE's guidelines dated 14.06.2018, which includes sale of land to other entities, for providing budgetary support of Rs. 330.35 crores as loan to the Pharma PSUs for meeting the employees' liabilities (Salary/VRS) (IDPL – Rs. 6.50 crore, HAL – Rs. 280.15 crore, RDPL – Rs. 43.70 crore). Funds amounting to Rs.328.12 cr was granted by M/o Finance which were released HAL (Rs. 280.15 crore), RDPL(Rs. 43.70 crore) and IDPL(only Rs. 4.27 crore out of Rs. 6.50 crore as less fund was made available). Thereafter the BE allocation of Rs.5.01 cr was also released to RDPL for meeting pending salaries of RDPL employees as per Hon'ble Court direction.

5.7 Under Assistance to PSU scheme of the Department during the year 2020-21 Rs.7.18 crore was allocated at both BE and RE stage but the actual utilization is Rs. 4.92 crore. On being asked about the reasons for non utilization of funds by IDPL to the tune of Rs. 2.23 crore, the Department in its written reply stated, "Another amount of Rs. 2.23 crore is under process of release to IDPL with which utilization of fund under the assistance to PSUs will be almost 100% (except the token amount of Rs.3 lakh)."

5.8 When the Committee asked about the details on progress made in regard to payment of pending salary dues, VRS dues etc. for PSUs under the Department in tabular format, the Department in its written reply stated as under:

"The details of pending payments in respect of employees

(Rs. in crores)

Name of PSU	**Pending salary**		**VRS**		**Other Dues pending**	**Remarks**
	Employee	**Amount**	**Employee**	**Amount**		
HAL	-	-	380 (Nos)	-	162.60*	* employees dues of LTC + Medical + CL/SL
IDPL	-	-	11 (Nos)	-	2.23	-
RDPL	-	-	25 (Nos)	2.90	17.56*	Gratuity, EL etc.
Total				2.90	182.39	

Out of 128 employees, 99 availed VRS, 25 employees prayed to court, 4 (3 suspended, 1 expired) and their VRS fund approx 2.90 crores kept aside.

5.9 Further, the Committee asked about the reasons for seeking only Rs. 0.06 crore from the Ministry of Finance under “Assistance to PSUs” in Demands for Grants 2021-22, whereas under 1st and 2nd phase of Supplementary Demands for Grants 2020-21, additional fund of Rs. 8688.60 crore and Rs. 9046.06 crore was sought by the Department on cash outgo basis, the Department in its written reply stated as under:

> "The Department sought Rs. 8688.60 crore under 1st Supplementary and Rs. 9046.06 crore under 2nd Supplementary for PSUs. As the requirement of fund for PSUs has already been sought under Supplementary Demand for Grant and presuming sanction, no fund has been sought for BE 2021-22."

5.10 On being asked about the release of additional funds of Rs.8688.60 crore and Rs.9046 crore under 1st and 2nd phases of supplementary Demands for Grants, 2020-21 by the Ministry of Finance the Department in its written note stated, "No additional funds has been released under 1stSupplementary. Department has also pursued with M/o Finance for Rs.9046 crore under 2ndSupplementary demand for grant"

5.11 The Committee also asked about the progress on repayment of Rs. 9046.06 crore which include Rs. 7860.65 crore for IDPL, Rs. 1117.27 crore for HAL and Rs. 75.29 crore for RDPL through sale proceeds of surplus, the Department in its written reply stated as under:

> "In view of non-bidders for PSU land by government agencies**,** the Cabinet approved on 17.07.2019 (i) modification of the earlier decision dated 28.12.2016 of sale of land of PSUs to government agencies and instead permitting the sale of land as per revised DPE’s guidelines dated 14.06.2018; and (ii) Constitution of a Committee of Ministers for taking all decisions pertaining to closure/ strategic sale of the four Public Sector Undertakings, including the sale of assets and clearance of outstanding liabilities.
>
> The Committee of Ministers was constituted on 09.09.2019 to take decision regarding sale of surplus land of PSUs as per DPE’s guidelines dt.14.06.2018. Valuation of the land (9.35 acres) in respect of RDPL has been done by NBCC. In respect of HAL, valuation of the surplus land (87.70 acres) was done by NBCC. Accordingly, the Department has sought convenient date for holding meeting by the Committee of Ministers."

5.12 The Department in its Annual Report, 2020-21 has stated that the Cabinet Committee on Economic Affairs (CCEA) in its meeting held on 1.11.2017 has ‘in principle’ approved strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru. In this regard, the Committee asked about the Department’s view on the strategic disinvestment of this profit making Mini Ratna Category 'C' Public Sector Undertaking and measures that were taken to persuade CCEA to drop the proposal of strategic disinvestment of KAPL, the Department provided the following steps taken by it:

> "CCEA has decided on 1.11.2017 for 100 % strategic disinvestment of an all along profit making pharma Mini Ratna PSU, namely, the Karnataka Antibiotics & Pharmaceuticals Limited (KAPL). However, Hon’ble Minister (C&F), Vide D.O. dated 03.07.2020 and 23.12.2020, requested NITI Aayog for reconsideration of the decision of disinvestment of KAPL including Hindustan Antibiotics Limited (HAL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL). The Department is following up with NITI Aayog for reconsideration of disinvestment/ feasibility of merger through in-depth examination by the Aayog itself or by awarding a comprehensive study to an independent agency on priority."

5.13 Further during oral evidence before the Committee held on 19.02.2021, the Secretary, Department of Pharmaceuticals while explaining the position of the Government with regard to closure of loss making PSUs and strategic sale/disinvestment of profit making PSUs stated as under:

> "When the decision was taken in 2016, none of them were making profits. It was also a decision that these were not strategic sectors at that time, and, therefore, it was discussed that it should be sold. It will continue to function but we will make a strategic disinvestment. After COVID we have taken up with the NITI Aayog to study whether the three of them, which are currently working, should be merged or continued as a strategic sector. However, you would have noted in the Budget announcements of disinvestment that pharmaceutical has not been included as a strategic sector. Yesterday also there was a meeting in which I made this representation that whether we should reconsider this. The view of the Finance Ministry is that there is a very strong private pharmaceutical industry which is very vibrant, and capable of meeting the needs of the country. Therefore, it is not required to continue these in the public sector. That was the view. That is where we stand."

5.14 The Committee asked about the factors that have led to the turnaround of sick PSU- Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) to emerge as a profit making PSU and enquired whether similar efforts by other loss making PSUs viz. Hindustan Antibiotics Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL) can help in their turn around, the Department furnished the following written reply:

> "Bengal Chemicals and Pharmaceuticals Limited (BCPL), under the guidance of its Administrative Ministry, took up a number steps such as centralization of Procurement System, Accounting System and HRM Record Maintenance System. With the above actions, BCPL has been able to reduce procurement cost substantially and to stop financial leakages. BCPL is now a profit-making company.
>
> As per decision of the Cabinet dated 28.12.2016, IDPL is under closure.
>
> HAL has adopted similar measures as BCPL for management improvement and cost effectiveness. In addition, HAL has also taken the following measures.
>
> (i) Downsizing the manpower by offering VRS to the employees
> (ii) Diversification of Products,
> (iii) Reducing the costs wherever possible."

5.15 Further the Committee also asked about the reasons for not referring the matter of sickness of Rajasthan Drugs & Pharmaceuticals Limited (RDPL) by the department of Pharmaceuticals to Board for Industrial & Financial Reconstruction (BIFR)/National Company Law Tribunal (NCLT) for scrutiny in detail the financial conditions/ management output/ business revival and to take appropriate action thereon, the Department in its written reply stated, "RDPL was not functioning since October, 2016. Further, as per decision of the Cabinet dated 28.12.2016, RDPL is under the process of closure. All employees have been offered VRS. The company is, therefore, not referred to BIFR."

5.16 The Committee also asked whether the Department of Pharmaceuticals has ever proposed reforms at administrative/ management level like professionalization of Board of pharma PSUs, lateral entry of pharma business experts, promotion of Corporate Governance practices etc. alongwith the financial package for revival/turnaround of the pharma PSUs at the initial stage of their showing signs of sickness and if not , provide reasons for inaction on this front. In this regard, the Department provided the following clarification in writing:

"BCPL and KAPL are profit making PSUs whereas the other two PSUs, namely, RDPL and IDPL are under closure as per decision of the Cabinet. HAL is a loss-making company not able to meet expense for salary/dues of its employees. However, with a number of initiatives taken, such as downsizing manpower through VRS scheme, product diversification and cost cutting measures, HAL has been able to improve sales turnovers over the last few years, though still making losses. Financial packages were also given to HAL, particularly to meet wages, salaries and other critical expenses of immediate nature. M/o Finance approved waiver of Govt. of India loans and interest amounting of Rs. 307.23 crore in respect of HAL. Funds of Rs. 100 crore as loan was released to HAL during 2016-17 to meet wages, salaries and other critical expenses of immediate nature. Rs.280.15 crore was granted to HAL during the year 2019-20 for the purpose of paying unpaid salary and effecting VRS for willing employees."

5.17 On being asked about the efforts the Department is putting to ensure compliance of Corporate Governance norms/guidelines by the PSUs, the Department in its written reply stated, "All the Pharma PSUs follow the prescribed guidelines of Department of Public Enterprises (DPE). HAL, BCPL and KAPL also report their Corporate Governance initiatives to the Department (except RDPL & IDPL which are under closure as per Cabinet decision dated 28.12.2016)."

5.18 The Committee also asked about the details of quantum of funds allocated and utilized under Corporate Social Responsibility (CSR) and the CSR works taken up and completed by each of the profit making PSUs under the Department during the last three years, the Department in its written reply stated as under:

"Only one PSU, namely KAPL is spending under Corporate Social Responsibility (CSR) and the details are as under: -

Financial Year	**Rs. In Lakhs**	**CSR activity**
2019-20	63	• Free Medicines during natural calamity in Karnataka Maharashtra & Kerala
2018-19	63	• Free Medicines during natural calamity in Karnataka & Kerala. • Supply of Machineries for Human Milk Bank to Government Hospital Karnataka
2017-18	64	• Health related activities in Karnataka

		• Clean Ganga Project

5.19 When the Committee asked about the contributions made by profit making PSUs under the Department to the Government Exchequer by way of dividend etc during each of the last three years, the Department in its written reply stated as under:

> "Only KAPL has contributed by way of dividend to the Government. The details are as under.

(Rs. In Lakhs)

Particulars	2019-20	2018-19	2017-18
Central Govt. (Dividend)	223.49	175.60	159.64
State Govt. (Dividend)	154.23	121.18	110.16

Observations / Recommendations

Recommendation No. 1: Need for Enhanced Budgetary Allocation.

The Committee note that the Department of Pharmaceuticals has vision to promote Indian pharmaceutical sector as the global leader for quality medicines and to ensure availability, accessibility and affordability of drugs and medical devices in the country. However, the Committee are dismayed to note that the Gross Budgetary allocation for the year 2021-22 is Rs. 470.41 Crore against the proposed outlay of Rs.2600.52 Crore which is only one sixth of the outlay proposed by the Department. Out of Rs 470.41 Crore allocated to the Department, Rs. 31.53 Crore is towards the administrative expenditures for both the Department of Pharmaceuticals and National Pharmaceuticals Pricing Authority (NPPA) against proposed Budget Estimate of Rs. 35.98 Crore. Budgetary allocation for Central Sector Schemes is Rs. 429.76 Crore against proposed Budget Estimates of Rs.2564.48 Crore. According to the Department of Pharmaceuticals, total funds allocated will fall short of the urgent fund requirements projected by the Department for carrying out its laid down mandate and will adversely affect the central sector schemes being implemented by the Department viz. Development of Pharmaceuticals Industry and National Institutes of Pharmaceuticals Education and Research (NIPER). In this regard, the Committee note that the Department has been allocated Rs. 234.34 crore against its requirement of Rs. 1220 crore for NIPERs and only Rs. 124.42 crore against the proposal of the Department of Pharmaceuticals for a budgetary allocation of Rs. 1256.16 core for the implementation of important umbrella scheme of the Department for the development of Pharmaceuticals industry during 2021-22. Going by the pace at which this umbrella scheme with important sub schemes for the holistic development of the Pharmaceutical Industry is being implemented by the Department, it is not surprising to the committee that the Ministry of Finance has curtailed the allocation drastically. Since it is very much essential to develop state of the art common facilities, to provide funds for technology upgradation, to offer production linked incentives etc to the pharma industry including

bulk drug and medical devices industries, the committee strongly recommend that the Department should take serious and concrete efforts for the implementation of all the sub schemes of the umbrella scheme in a time bound manner particularly to examine the proposals under various sub schemes expeditiously and to accord approval in a time bound manner so as to enable the Ministry of Finance allocate the requisite amount of funds for the implementation of various sub schemes under the umbrella scheme. It is also necessary to make realistic budgetary proposals on actual need basis. As far as fund allocation to NIPERs is concerned, the Committee take a serious view of non allocation of requisite amount of funds by the Ministry of Finance for the infrastructural development of NIPERS even after a decade of their existence due to which these institutes are unable to attain their full potential. Since the subject matter pertaining to the Department of Pharmaceuticals is concerned with the drug security of the country, the Committee urge upon the Ministry of Finance to examine the budget proposals of the Department of Pharmaceuticals very carefully and the make adequate allocation of funds for the implementation of various Schemes and programmes of the Department. Since the allocation made at BE is very less to cope the fund requirements of various schemes which are at the advanced stages of proposal approval and fund release, the Department of Pharmaceuticals should prepare fresh proposals for fund release at RE stage of 2021-22 and the same should be submitted to Ministry of Finance for the allocation of necessary funds at RE stage. A copy of this recommendation may also be sent to Ministry of Finance for its compliance.

<u>Recommendation No. 2 Major issue of drug security associated with overdependence on imported API/Bulk Drugs</u>

The Committee note that pharmaceuticals has been identified as one of the champion sectors, which forms around 1.72 percent of the country's GDP but there is an urgent need to pay attention to major issue of drug security associated with overdependence on imported API/Bulk Drugs which if not handled can adversely affect the competitiveness of the domestic pharmaceutical sector in the years to come. In this regard, the

Department of Pharmaceuticals has informed that the Active Pharmaceutical Ingredients (API)/Bulk drugs and intermediates form 63% of India's total pharma imports. Even production of some of the National List of Essential Medicines (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 serious concern as any disruption in the supplies could jeopardize the pharma sector and affect the supplies of medicines both for domestic use and exports. In this regard, the Committee observed that during the early 90s, India was self-reliant in manufacturing APIs. However, with the rise of China as a producer of API, it captured the Indian market with its low-cost API manufacturing industry. The worst hit was the Indian fermentation based bulk drug Industry facing severe competition from overseas players mainly from China. Local production slowly stopped when China started exporting these bulk drugs at very low prices in India. The cost of production of these bulk drugs was low in China due to multiplicity of factors including low cost of capital followed by aggressive government funding models, tax incentives, availability of subsidized utilities such as electricity, steam, brine, effluent treatment etc. In order to negate imports, the Department has issued guidelines dated 30.12.2020 for implementation of Public Procurement (Preference to Make in India) Order dated 16.09.2020 issued by Department for Promotion of Industry and Internal Trade, to Pharmaceuticals Sector which classify the suppliers for providing preference in public procurement based on their minimum local content for pharmaceuticals formulations. In 2020, the Committee under chairmanship of Dr Eswara Reddy identified APIs with high degree of import dependence. Further, a Production linked incentive scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country has been launched by the Government. The committee is also given to understand that Department has no policy to favourably distinguish between Pharma companies which manufacture drugs from domestically produced critical

Key Starting Materials(KSMs)/Drug Intermediates (DI) and Active Pharmaceutical Ingredients (APIs) in comparison to those companies which manufacture drugs by importing API/KSM/DI from other countries. Since it is very much necessary to stop the dumping of cheap raw material in the country by China, there is a need to curtail this trend and therefore, the Committee recommend that the following measures should be taken:-

(i) NITI Ayog and the Department of Pharmaceuticals to make an indepth study of various concessions being provided by China to its bulk drug industry and to initiate immediate appropriate measures in a war footing manner for the creation of a very strong API/bulk drug/KSM industry in the country as a viable competitor and alternative source country for API/bulk drug/KSMs

(ii) Need to provide manufacturing support infrastructure viz. subsidized utilities such as electricity, water, steam, brine, effluent treatment plant etc and help create economies of scale for fermentation based bulk drug Industry clusters.

(ii) Reclassify suppliers into three categories Class-I with 100 percent local content, Class-II 80 percent local content and Class-III with 60 percent local content and provide progressive incentives like zero duty on 100 percent local content suppliers and rationally increase duty on other two category of suppliers for both public and private procurements done in Pharmaceutical sectors.

(iv) Enhance the budget allocation for the scheme Promotion of Bulk Drugs during RE stage for the year 2021-22 to make effective stride in establishing 3 Bulk Drug Parks in the country and expand the scheme to establish more Bulk Drug parks in future.

(v) Department of Pharmaceuticals to frame a comprehensive incentive policy for domestic bulk drugs producers.

This recommendation may also be sent to NITI Ayog for Action Taken Reply by both the Department of Pharmaceuticals and NITI Ayog.

Recommendation No.3 Assistance to Pharmaceuticals Industry for common facilitation centre.

The Committee are concerned to note the very slow progress is being made under the sub scheme of "Assistance to Pharmaceuticals Industry for common Facilitation center". This sub scheme earlier known as cluster Development has been rechristened after a dint of unsuccessful implementation. Grant-in-aid of Rs. 20 crore per cluster or 70% of the cost of the project whichever is less is granted under this sub scheme. During 2019-20, only Rs. 2.23 crore was spent on this scheme. During 2020-21, Rs, 12 crore allocated at BE stage was reduced to Rs. 7.23 crore at RE stage due to the inability of the Department to spend but the actual utilization was only Rs. 22 lakh. Under the sub scheme, one proposal from Chennai has already been approved. During 2020-21, there new proposals have been given in-principle approval in the months of September and October, 2020 but the same are under examination of PMC and as a result, no funds have so far been utilized under this sub-scheme. Such a slow approach on the part of the Department has resulted in on-paper existence of sub schemes under the umbrella scheme. While deprecating such lackadaisical approach of the Department towards this important scheme, the committee strongly recommend to expedite the process of final approval of the projects so as to demand the funds required from the Ministry of Finance at RE stage. Progress made in this regard should be intimated to the Committee.

Recommendation No. 4 Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)

The Committee are dismayed to note that the important sub scheme of Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) remains a non-starter since its approval in 2016. Only a token allocation of Rs. 1 lakh was provided for the sub scheme for the financial years 2019-20 and 2020-21. Even though the Department had demanded Rs. 185 crore for the sub scheme, again only a token allocation of Rs. 1 lakh has been made by the Ministry of Finance for 2020-21. This clearly shows the lack of

faith in Department's credentials to implement this important scheme which aims to facilitate small and medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to WHO GMP standards so as to enable them to participate and compete in global markets. As per the sub scheme, assistance in the form of interest subvention against the sanctioned loan by any scheduled commercial bank/financial institution, both in public and private sector will be provided to 900 Pharma SMEs of proven track record. The scheme is to be implemented by a Public Sector Financial Institution (PSFI). But everything remains on paper without any concrete action to implement the scheme. Non receipt of applications for financial assistance was the reason given by the Department for the non-moving of the scheme ahead. In this regard, the recommendations made in third party evaluation viz. need for enough brain storming to set one liner objective for the Scheme, need for implementation with liberal terms and conditions and opening of the scheme to MSME sector instead of SME sector are worth for consideration. It is a matter of serious concern that the Department could not appoint Public sector Financial Institution (PSFI) during the last 4 years of implementation of the scheme. Since it is very much necessary to raise the standards of Pharma production units to that of WHO GMP standards in order to medicines/drugs of highest standards to the people of the country and also for the export purpose, the Committee strongly recommend that the Department should take prompt steps for the early Expenditure Finance Committee approval of the scheme for implementation of the sub scheme from 2021-22 to 2025-26. PSFI should be appointed immediately after the EFC approval and prompt steps should be taken for the successful implementation the schemes from 2021-22 onwards. The Progress made in this regard should be intimated to this committee within 3 months.

<u>Recommendation No. 5 Promotion of Medical Devices Parks</u>

The Committee are constrained to note that another sub-scheme named "Assistance to Medical Device Industry for Common Facility Centre" was also not properly implemented by the Department and the same has

been revised by the Union Cabinet During 2020-21. The sub-scheme has been renamed as "Promotion of Medical Devices Parks" with a total financial outlay of Rs. 400 crore. The objective of the sub-scheme is creation of world class infrastructure facilities in order to make Indian medical device industry a global leader. The tenure of the scheme is from 2020-2021 to 2024-2025. Maximum assistance under the scheme for one Medical Device Park would be limited to ₹ 100 crore. Under this Scheme an allocation of Rs.7.50 crore was made at BE stage of 2020-21 and the same was increased to Rs. 21.05 crore but the Department is able to spend only Rs 7.49 crore so far. In this background, the Department had demanded Rs.120 crore for the implementation of the Scheme during 2021-22 but the Ministry of Finance has allocated only Rs.60 crore at BE stage. The Committee note that in-principle approvals were given to the proposals received from Andhra Pradesh, Kerala, Tamil Nadu and Telangana. Subsequently the proposal of Andhra Pradesh was first taken up. After revision of the scheme by the Union Cabinet, the guidelines of the revised scheme were issued on 27.07.2020. After the revision of the scheme, 16 proposals have been received in accordance with the revised guidelines of the scheme. All the proposals are being evaluated for giving in-principle approval. Taking into consideration the importance of common laboratory and testing facilities in reducing the production cost of medical devices, the Committee recommend that the Department should take earnest steps for granting expeditious approvals to the eligible proposals under the Scheme during 2021-22 and financial assistance should also be provided to them according to the Scheme guidelines in a time bound manner. In case of necessity of further funds for the implementation of the Scheme during 2021-22, concrete proposals for allocation of the same at RE stage should be made to the Ministry of Finance. The Committee hope that the Department would act fast in coordination with State Implementing Agency (SIA), would expedite the approval procedures and disburse the funds allocated at BE 2021-22, so as to enable the Ministry of Finance consider favourably the allocation of further funds at RE stage. The progress made in this regard may be intimated to the Committee.

Recommendation No. 6 Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device

The Committee note that under the Umbrella Scheme of "Development of Pharmaceuticals Industry", a new sub-scheme "Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device" has been approved by the Union Cabinet in its meeting dated 20.3.2020 with a total outlay of Rs. 3420 Crore. However, only Rs.2.00 Crore was sought under the first batch of Supplementary Demands for Grants 2020-21 from Ministry of Finance for implementation of the sub-scheme during the year and only an allocation of Rs. 2.36 Crore has been made at BE stage for 2021-22. In regard to the reasons for less allocation of fund for the sub-scheme, the Committee note that as per scheme guidelines, the incentive to the applicants under four target segments will be applicable from 2022-23 onwards only and as such the funds for disbursal of incentives to selected applicants are not required. Accordingly, the fee of Project Management Agency (PMA) will only be paid during 2020-21 and 2021-22. The Committee further note that 28 applications for four Target Segments of the Scheme were received and out of them nine applications have been approved till 15th February, 2021. As the country is largely dependent on imports for meeting its medical devices requirements, the Committee recommend that due attention should be paid by the Department for the timely implementation of this sub-scheme in letter and spirit. The progress made in this regard may be intimated to the Committee.

Recommendation No. 7 Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country

The Committee note that a new sub scheme "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country" has been approved by the Union Cabinet in its meeting held on 20.3.2020

with a total outlay of Rs. 6940 Crore under Umbrella Scheme of "Development of Pharmaceuticals Industry". However, only Rs. 1.55 crore was sought for this sub-scheme under 1st batch of Supplementary Demand for Grants 2020-21 from Ministry of Finance. Moreover, only a token allocation of Rs. 2.79 crore has been made at BE stage for 2021-22 for this Scheme. According to the Department of Pharmaceuticals, as per scheme guidelines of PLI scheme for Bulk Drugs, the gestation period for fermentation-based products is up to 2022-23 and up to 2021-22 for chemical synthesis-based products. As such, funds for disbursal of incentives to selected applicants are not required. Accordingly, the fee of Project Management Agency (PMA) will only be paid during 2020-21 and 2021-22. The Committee note that a total 215 applications have been received for the four Target Segments of the PLI scheme for Bulk Drugs. Out of it only five applications have been approved till 15th February, 2021 by the Empowered Committee under the chairmanship of CEO, NITI Aayog. In this regard, the Committee feel that outrightly rejecting vast majority of applications may not be conducive for the development of a strong bulk drug industry in the country. The Committee, therefore, recommend that the prospective entrepreneurs, who are eager to set up API/bulk drug/KSMs industry in the country, whose applications have been rejected may be given a chance to resubmit their applications after fulfilling the requirements of Scheme guidelines so as to encourage setting up of required number of bulk drug manufacturing units in the country. The Committee also recommend that the Department should act swiftly for the effective and total implementation of this vital scheme aimed at safeguarding drug security of the country. The Committee should be apprised of the progress made in implementation of the Scheme.

<u>Recommendation No. 8 Assistance to Bulk Drug Industry for Common Facilitation Center</u>

The Committee are also constrained to note the on paper existence of another sub scheme "Assistance to Bulk Drug Industry for Common Facilitation Center" under the umbrella scheme of "Development of

Pharmaceutical Industry". The sub scheme has now been renamed as "Promotion of Bulk Drug Parks". The guidelines of the sub-scheme were released on 27.07.2020. Only a token allocation of Rs.2.00 lakh was made for the Scheme during 2019-20. Rs. 21.52 crore was allocated at BE stage of 2020-21 which got reduced to only Rs. 1.69 crore at RE stage but no expenditure has so far been made under the Scheme during 2020-21. In this backdrop, the Department had sought Rs.900.00 crore for the implementation of the Scheme during 2021-22 but the Ministry of Finance has allocated only Rs.36.24 crore at BE stage. In this regard, Department of Pharmaceuticals clarified that a total number of 13 proposals have been received which are under evaluation. The Department will soon accord 'in-principle' approval to three States/UTs under the scheme. Those three States/UTs will submit a detailed project report within 180 days of date of issuance of in-principle approval letter. As per scheme guidelines, the Department has to release first installment of 30% of the total financial assistance of Rs. 1000 crore at the time of final approval of the project by the Scheme Steering Committee. Since the final approval may be accorded during 2021-22, there will be need of Rs. 900 crore (Rs. 300 crore each for 3 parks). As there is an urgent need to create a very strong bulk drug industry in the country to meet the bulk drugs requirements of the country, the Committee recommend that definite time limits may be set for issuing in-principle and final approvals by the Department of Pharmaceuticals. Moreover, the concerned States may be requested to submit the detailed project reports within three months (90 days) rather than six months (180 days) so as to facilitate early implementation of the Scheme. Department of Pharmaceuticals should initiate prompt steps as recommended above for according final approvals to three parks well before projecting the requirement of Rs.900 Crore for RE 2021-22 allocation so as to enable the Ministry of Finance allocate the same at RE stage.

Recommendation No. 9 Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

The Committee note that Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals in the year 2008 with an objective of making quality generic medicines available at affordable prices to all especially for the poor and the deprived ones. Under this scheme, dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJK) are opened all over the country to provide generic medicines to the masses. The Scheme has been approved for continuation with the financial outlay of Rs. 490 crore for the period 2020-2021 to 2024-2025. The Committee note that PMBJP is designed to function on a self-financing model like a business. Budgetary support is provided to the Scheme mainly for promotion and for providing incentives to the entrepreneurs. An amount of Rs.65 Crore has been allocated at BE stage for 2021-22 against the propososal of the Department for Rs.80 Crore. In regard to the better implementation of the Scheme, the Committee recommend the following:-

(i) Although a total of 7259 PMBJP kendras have been opened as on 31 January, 2021 and all the districts in the country have been covered, the Department should take necessary steps for opening PMBJP kendras in every block at each district in the country.

(ii) Presently three warehouses are functioning at Gurgoan, Chennai and Guwahati. Fourth warehouse is under construction in Surat. The Department should consider opening a few more warehouses particularly in those regions of the country where there is no PMBJP warehouse.

(iii) Requisite number of distributors should be appointed in each State according to the size and number of PMBJP Kendras of the State.

(iv) Entrepreneurs who set up kendras under the Scheme should be provided more incentives and the budgetary

allocation in this regard may be increased for successful running of the Scheme

(v) Awareness Programmes about the features of the Scheme should be increased and should aimed at reaching poor people including those living in slums and other economically deprived areas. Budgetary allocation in this regard may be increased commensurately.

(vi) Marketing Officers who is responsible for smooth implementation of the Scheme at State and district levels should be appointed in each State/Union Territory and effective steps should be taken for monitoring the functioning of each and every BMBJP Kendra at district level.

(vii) The Government/Department should forgo the self financing model for opening Janaushadhi Kendras in North East, hilly and island areas of the country. Instead the Department should open government funded Janaushadhi Kendras in North East states, hilly areas and island territory and allot them to Women, Divyang, SC, ST.

Recommendation No. 10 National Pharmaceutical Pricing Authority (NPPA)

The Committee note that the National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals is entrusted with the responsibilities of fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. However, the Committee are concerned to note that NPPA fixes ceiling prices of only scheduled formulations which constitutes only about 17.2 per cent of the total formulations. The rest of 82.8 per cent of medicines are in the non-scheduled segment and the NPPA does not fixes ceiling price of those

medicines/drugs. However, their price increase is permitted only up to 10 per cent of MRP per annum. So, there is a limitation of regulatory powers of NPPA in fixing and monitoring of prices of non-scheduled drug formulations. Since the expenditure on medicines constitutes more than 50 per cent of expenditure on health, it is very much affecting poor families who struggle to cope with the high cost of medicines for treatment of any disease. The Committee feel that there is immediate need to increase the percentage of regulation of medicines from 17.2 percent to at least 50 percent within a year by incorporating suitable policy changes in this regard. Moreover, the Committee also feel that there is a need to regulate the prices of medicines charged by private hospitals from the patients as a part of the overall treatment charges. In view of the above, the Committee recommend the following:-

(i) There is a need for introducing policy changes in the National Pharmaceutical Pricing Policy, 2012 and Drug Price Control Order (DPCO) wherein NPPA should be given autonomy to regulate the base prices of at least 50 percent of all drugs sold in the domestic market, to expand NPPA price regulation function in an effective way beyond the scheduled drugs mentioned in the National List of Essential Medicine (NLEM);

(ii) Apart from fixing the prices of scheduled drugs, NPPA should also fix the ceiling prices of all non-scheduled drug formulations which are prescribed more often by medical practitioners for treating many of the common ailments;

(iii) Department of Pharmaceuticals and NPPA should examine critically whether it is necessary to permit 10% increase of MRP of non-scheduled drugs per annum particularly when the prices of raw materials, etc does not increase and appropriate steps should be initiated on the basis of outcome of the such critical examination;

(iv) Also examine the rationalization of fixation of Maximum Retail Price (MRP), as MRP itself is fixed on the higher side and

subsequent 10 percent increase in price per annum makes the cost of drugs unaffordable for the common people; and

(v) Department of Pharmaceuticals and NPPA should also examine the issues pertaining to high prices of medicines charged by private hospitals.

Recommendation No. 11 Consumer Awareness, Publicity and Price Monitoring (CAPPM)

The Committee note that there are two components Under the Central Sector Scheme of NPPA, viz., 'Consumer Awareness, Publicity and Price Monitoring' (CAPPM). First component is setting up of Price Monitoring and Resource Units (PMRUs) in the States/ Union Territories. 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. The second component is advertisement and publicity. During the year 2020-21 Rs. 4.5 crore was allocated at BE stage and the same was reduced to Rs.3 crore at RE stage. However, only Rs.1.78 crore has been spent as on 15.01.2021. Under the first component (Assistance to PMRUs), it is expected that total funds will be utilized up to end of the F.Y. 2020-21. As regard the 2nd Component (Advertising and Publicity) the budget has been revised from Rs. 2.00 crore to Rs. 0.50 crore. The Committee note that the mobile application 'Pharma Sahi Daam' launched by NPPA is non-functional that defeats the very purpose of launching the application. A budgetary allocation (BE) of Rs.6 crore has been made for 2021-22. Out of this, Rs.5Crore has been allocated to PMRUs and Rs.1 crore for Advertisement and publicity. The Committee also note that in order to increase the effectiveness and outreach of NPPA, 17 PMRUs have been set up in States of Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa and Madhya Pradesh. However as submitted by the Department

PMRUs in only 12 States are fully functional as PMRUs in the states of Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa and Madhya Pradesh are newly set up. The Committee feel that PMRUs are functioning as crucial link between the States and NPPA as they monitor drug price regulation, ensure availability of medicines, conduct IEC activities and organize seminar/ webinar etc. and hence they should be set up in all States in a time bound manner. Moreover, the activities of NPPA in the area of advertisement and publicity are needed to be strengthened. In view of the above, the Committee recommend the following:-

(i) Concerted efforts should be made by the Department of Pharmaceuticals (DoP) and NPPA to set up functional PMRUs in all the States and Union Territories latest by 2023-24 as projected under the Vision Plan of NPPA. In case of non-cooperation of any State/UT Government, the matter should be taken up at the highest level with those Governments. Alternatively, DoP and NPPA may explore the possibilities of setting up of PMRUs by the Union Government itself. If needed the increase of budgetary allocation for the purpose may be considered.

(ii) Continuous monitoring by NPPA on proper functioning of PMRUs particularly with regard to price monitoring, detection of violation of the provisions of DPCO, pricing compliance and ensuring availability of medicines to the people.

(iii) Awareness and publicity through print, electronic and social media about the pricing of scheduled and non scheduled drugs, availability of affordable and quality generic medicines as alternatives to branded medicines, robust grievance redressal mechanism in respect of overcharging, ensure proper functioning of Pharma Sahi Daam app etc. and ehance the budgetary allocation for the same as the present allocation of Rs.1 crore is inadequate.

Recommendation No. 12 National Institute of Pharmaceutical Education and Research (NIPER)

The Committee note that National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar (Mohali) was set up as a registered society under the Societies Registration Act, 1860 and 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. Another NIPER is proposed to be set up at Bengaluru, Karnataka. With respect to the budgetary allocation made for the NIPERs for the ensuing year 2021-22, the Committee note that the Department has been allocated only Rs. 234.34 crore against its requirement of Rs. 1220 crore for NIPERs during 2020-21. Under NIPER scheme fund utilization pattern is 100 percent during the year 2018-19, 2019-20 and likely to be fully utilized during the year 2020-21 as well. One of the physical targets of the Department is to create own campus with permanent buildings for all the existing NIPERs as well as for the newly proposed NIPERS. In this regard, a proposal for up-gradation and establishment of existing seven NIPERs as well as setting up of new five NIPERs at an estimated cost of Rs. 4,300 crore sent to the Department of Expenditure in June, 2020 was returned by the Ministry of Finance indicating that the continuing schemes needs to be appraised and approved further for the period of 2021-22 to 2025-26 after 15th Finance Commission recommendations are accepted and resource position of public exchequer is clear. In pursuant to the Department of Expenditure's instructions issued dated 8th December, 2020, a fresh proposal has been sent to that Department in the revised format for consideration by the Expenditure Finance Committee (EFC). The Committee are deeply concerned to note that creation of requisite infrastructure for 6 NIPERs

which were declared as Institutes of National Importance has been delayed by more than a decade. The work of construction of Permanent campus is nearing completion only in respect of Guwahati NIPER and the construction work of campus for Ahmedabad NIPER has been started recently. In this regard, the Committee feel that it is very much necessary to create own campus for NIPERs at Hyderabad, Kolkata, Raebareli and Hajipur so as to enable them function in a full fledged manner in the true spirit of Institute of National Importance. The Committee, therefore, strongly recommend that a definite time schedule should be fixed for construction of own campus with permanent buildings for these NIPERS and accordingly enhanced budgetary allocation should be made for the purpose. The Department should pursue vigorously with the Department of Expenditure for the early EFC approval of the proposals for creation of own campus with permanent buildings for the existing NIPERs and for the setting up of five new NIPERS at Madurai, Jhalawar, Raipur, Nagpur and Bangaluru. Based on the approval, concrete steps should be taken for the construction of permanent campus for the existing NIPERS and the time bound setting up of new NIPERS.

<u>Recommendation No. 13 Setting up of modern laboratories in NIPERS and faculty/staff welfare</u>

Grants in aid to NIPERs include the purchase of equipment by the existing NIPERs and payment of salary to faculty / staff. In this regard, the Committee recommend the following:-

(i) Apart from construction of own campuses for NIPERs, due attention should be paid for setting up modern laboratories with state of the art equipments for imparting pharmaceutical education in a holistic manner and for Research and Development in the field. Requisite amount of budgetary allocations should be made for the purpose. The Committee may be informed about the progress in this regard.

(ii) **The Committee note that NIPERs have been directed to earn at least 1/3rd of their salary to reduce dependency on Government Grants. While it is prudent that the NIPERs need to strive to be self-reliant for meeting at least part of their operational expenses through fees from students, testing fee from equipments, projects, consultancies etc, the Committee are of the view that the interests of faculty and staff should be protected till they reach their full potential and hence recommend that NIPERs should be provided enough budgetary grants so as to meet the salary requirements of faculty and staff till they become self reliant with permanent building and strong laboratory facilities.**

Recommendation No. 14 Disinvestment of Public Sector Undertakings (PSUs)

The Committee note there are five Public Sector Undertakings (PSUs) under the aegis of the Department of Pharmaceuticals. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL) and Hindustan Antibiotics Limited (HAL) are presently functional. While the first two are profit making, the third one is sick. Indian Drugs & Pharmaceuticals Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL) are under closure. In 2016, The Government of India decided for strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru, strategic sale of BCPL and closure of HAL. At that point of time, both BCPL and HAL were loss making but BCPL has turned into profit making PSU as it was able to reduce procurement cost substantially, financial leakages, etc. due to concrete steps taken such as centralization of Procurement System, Accounting System and HRM Record Maintenance System. On Similar lines, HAL has been able to improve sales turnovers over the last few years, though still making losses with a number of initiatives taken, such as downsizing manpower through VRS scheme,

product diversification and cost cutting measures. In the aftermath of COVID 19 pandemic, Minister of Chemicals and Fertilizers had requested NITI Aayog to reconsider the decision of disinvestment of KAPL including Hindustan Antibiotics Limited (HAL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL). The Department is following up this matter with NITI Aayog for reconsideration of disinvestment/ feasibility of merger through in-depth examination by the Aayog itself or by awarding a comprehensive study to an independent agency on priority. Even though there is a strong private pharmaceutical industry, the Committee are of the firm view that it is very much necessary to retain functional public sector pharmaceutical units as the coexistence of both the public and private sector pharmaceutical industry is beneficial to the country particularly to make available quality medicines at affordable prices to all sections of the society including poor and needy. Moreover, the Government is committed to provide drug security at affordable cost for the people of the country. This can be ensured only with the strengthening of Pharmaceutical PSUs because private sector is driven by profit motive and market demand sentiment which does not cater to the needs of the lower middle class, poor and down trodden people for the availability of quality drugs at affordable prices. Keeping in view the wellbeing of the common people the, Committee, therefore, strongly recommend the following:-

(i) The proposal of strategic disinvestment of KAPL, which is a profit making mini ratna PSU, should be dropped.

(ii) The proposal of strategic sale of BCPL which has emerged as a profit making PSU should also be dropped.

(iii) The proposal for closure of HAL should also be dropped and corrective measures should be taken to make it profit making on the lines of BCPL.

(iv) Rather than disinvestment/sale, the Government should consider various measures for successful/profitable running of PSUs including reforms at administrative/ management level like professionalization of Board of Pharma PSUs, promotion of Corporate Governance practices etc. to safeguard the

interest of the common people who are dependent on affordable and quality medicines produced by Pharmaceutical PSUs.

Recommendation No. 15 Indian Drugs & Pharmaceuticals Limited (IDPL)

The Committee note that Indian Drugs & Pharmaceuticals Limited (IDPL) which was set up in 1961, is Schedule-B Sick PSU, referred to Board for Industrial and Financial Reconstruction (BIFR) on 25.05.1992 and BIFR declared IDPL Sick on 12.08.1992, now is in the process of closure having large liabilities of Rs. 7860.65 crore. As per the data provided by the Department, Rs. 4.28 crore was provided as loan assistance to IDPL during 2019-20 for repayment of liabilities. For the year 2020-21, Rs 2.23 crore was allocated and it was reduced to Rs 2.00 crore at RE stage and again Rs.2.00 Crore has been allocated at BE stage for the year 2021-22. The Committee note that IDPL was declared sick way back in 1992 since then the Department/Ministry had been failing to bring it back on profit track which is a matter of deep concern and raises question mark on the capability of the administrators and management of IDPL. However, having being declared sick for almost past 29 years, the liabilities have increased to Rs. 7860.65 crore. The Committee feel that the liabilities would not have increased to this level had the Department chalked out a decent exit plan for this PSU in a time bound manner Hence, the Committee strongly recommend that the Department should clear all the liabilities of IDPL including salary and other dues of the employees within a year as the matter is lingering for quite a long period now.

Recommendation No.16 Rajasthan Drugs & Pharmaceuticals Limited (RDPL)

The Committee note that Rajasthan Drugs & Pharmaceuticals Limited (RDPL) set up in 1978, was declared Sick PSU in October 2016 and now is under the process of closure having liabilities of 75.29 crore. During the years 2019-20 and 2020-21, Rs. 48.71 crore and Rs. 2.40 crore was provided respectively as loan assistance to RDPL for repayment of liabilities. For the year 2021-22 Rs. 3.00 crore has been allocated at BE stage. The Committee

also note that Department of Pharmaceuticals did not refer the matter of sickness of Rajasthan Drugs & Pharmaceuticals Limited (RDPL) to Board for Industrial & Financial Reconstruction (BIFR)/National Company Law Tribunal (NCLT) for detail scrutiny about its financial conditions/ management output/ business revival and to take appropriate action thereon. The Committee feel that since RDPL is incipient sick PSU with net worth of Rs. 21.32 crore and operational loss of only Rs. 12.60 crore there is a scope for turnaround of this PSU into profit making one as it happened in case of BCPL by making innovative and sound business revival plans with help of independent industry experts. Therefore, the Committee strongly recommend the Department to prepare an innovative revival plan for RDPL.

New Delhi;
15 March, 2021
24 Phalguna, 1942 (Saka)

Uday Pratap Singh
Chairperson (Acting)
Standing Committee on
Chemicals and Fertilizers

MINUTES OF THE SITTING OF THE
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2020-21)

The Committee sat on Friday, the 19th February, 2021 from 1400 hrs. to 1415 hrs. in Committee Room No. 3, Extension to Parliament House Annexe Building, New Delhi.

PRESENT
Smt. Kanimozhi Karunanidhi- Chairperson
MEMBERS
LOK SABHA

1 Shri Deepak Baij
2 Shri Ramesh Chandappa Jigajinagi
3 Shri Satyadev Pachauri
4 Shri Arun Kumar Sagar
5 Shri Pradeep Kumar Singh
6 Er. Bishweswar Tudu
7 Dr. Sanjeev Kumar Singari

Rajya Sabha Members

8 Shri G. C. Chandrashekhar
9 Shri Jaiprakash Nishad
10 Shri Arun Singh
11 Shri A. D. Singh
12 Shri Vijay Pal Singh Tomar
13 Shri K. Vanlalvena

SECRETARIAT

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

LIST OF WITNESSES

DEPARTMENT OF PHARMACEUTICALS

1. Ms. S. Aparna, Secretary (Pharma)
2. Shri Rajesh Aggarwal, AS&FA
3. Shri H.K. Hajong, Economic Advisor
4. Ms. Shubra Singh, Chairperson NPPA
5. Shri Sumit Garg, DS (Policy)
6. Ms.Deepika Jain, CCA

<u>Representative list of Other Min./Deptts</u>.:

7. Sh. Sachin Kumar Singh, CEO, BPPI
8. Ms.Nirja Saraf, MD,(HAL, RDPL,BCPL)
9. Ms.Shashi Bala Singh, NIPER Hyderabad
10. Sh. P. Krishna Kumar, Director, NIPER

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 2021-22 of the Department of Pharmaceuticals.

4. Power point presentation was followed by discussion on several aspects of Demands for Grants of the Department for 2021-22. 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. A copy of the verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

MINUTES OF THE FIFTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2020-21)

The Committee sat on Monday, the 15th March, 2021 from 1500 hrs. to 1545 hrs. in Committee Room No.139, Parliament House Annexe, New Delhi.

PRESENT

Shri Uday Pratap Singh, Chairperson (Acting)

MEMBERS

LOK SABHA

2. Shri Ramakant Bhargava
3. Shri Satyadev Pachauri
4. Dr. M.K. Vishnu Prasad
5. Shri Arun Kumar Sagar
6. Shri Pradeep Kumar Singh
7. Shri Indra Hang Subba
8. Shri Prabhubhai Nagarbhai Vasava

RAJYA SABHA

9. Shri G. C. Chandrashekhar
10. Dr. Anil Jain
11. Shri Ahmad Ashfaque Karim
12. Shri Jaiprakash Nishad
13. Shri Arun Singh
14. Shri A.D. Singh
15. Shri Vijay Pal Singh Tomar
16. Shri K. Vanlalvena

SECRETARIAT

1.	Shri Manoj K. Arora	-	OSD (LSS)
2.	Shri N.K Jha	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Shri Panna Lal	-	Under Secretary

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 Report(s):

(i) 'Demands for Grants 2021-22' of the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals);
(ii) 'Demands for Grants 2021-22' of the Ministry of Chemicals and Fertilizers (Department of Fertilizers);
(iii) 'Demands for Grants 2021-22' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals); and
(iv) 'Status of Covid-19 Vaccine Production In India' pertaining to the Department of Pharmaceuticals.

4. After deliberations, the Committee adopted the above four Draft Report(s) unanimously without any change/amendment.

5. The Committee also authorised the Chairperson to make consequential changes, if any, arising out of the factual verification of the Report(s) by the Department of Chemicals and Petrochemicals, Department of Fertilizers and Department of

Pharmaceuticals of the Ministry of Chemicals and Fertilizers and present the same to both the Houses of Parliament.

The Committee then adjourned.