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**STANDING COMMITTEE ON
CHEMICALS & FERTILIZERS**

(2021-22)

SEVENTEENTH LOK SABHA

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

DEMANDS FOR GRANTS

(2022-23)



DRAFT REPORT

**LOK SABHA SECRETARIAT
NEW DELHI**

March, 2022/ Phalguna, 1943 (Saka)

THIRTY FOURTH REPORT
STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS
(2021-22)

(SEVENTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS
(2022-23)

Presented to Lok Sabha on 21 March 2022

Laid in Rajya Sabha on 21 March 2022



LOK SABHA SECRETARIAT
NEW DELHI

March, 2022/ Phalguna, 1943 (Saka)

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**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2021-22)**

Smt. Kanimozhi Karunanidhi - Chairperson

**MEMBERS
LOK SABHA**

2. Shri Dibyendu Adhikari
3. Maulana Badruddin Ajmal
4. Shri Deepak Baij
5. Shri Ramakant Bhargava
6. Shri Prataprao Patil Chikhlikar
7. Shri Rajeshbhai Naranbhai Chudasama
8. Shri Sanjay Shamrao Dhotre
9. Shri Ramesh Chandappa Jigajinagi
10. Shri Kripanath Mallah
11. Shri Vasava Parbhubhai Nagarbhai
12. Shri Satyadev Pachauri
13. Smt Aparupa Poddar (Afrin Ali)
14. Dr. M.K.Vishnu Prasad
15. Shri Arun Kumar Sagar
16. Shri M. Selvaraj
17. Dr. Sanjeev Kumar Singari
18. Shri Atul Kumar Singh
19. Shri Pradeep Kumar Singh
20. Shri Uday Pratap Singh
21. Shri Indra Hang Subba

RAJYA SABHA

22. Shri Ayodhya Rami Reddy Alla
23. Shri G.C.Chandrashekhar
24. Dr. Anil Jain
25. Shri M.V. Shreyams Kumar
26. Shri Jaiprakash Nishad
27. Shri Anthiyur P. Selvarasu
28. Shri Arun Singh
29. Shri Vijay Pal Singh Tomar
30. Shri K. Vanlalvena
31. Vacant

SECRETARIAT

- | | | |
|------------------------------|---|---------------------|
| 1. Shri Vinod Kumar Tripahti | - | Joint Secretary |
| 2. Shri N.K. Jha | - | Director |
| 3. Shri C. Kalyanasundaram | - | Additional Director |
| 4. Ms. Sonia Sankhla | - | Executive Officer |

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2021-22) having been authorised by the Committee to submit the Report on their behalf, present this Thirty Fourth Report (Seventeenth Lok Sabha) on 'Demands for Grants (2022-23)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Committee examined the Demands for Grants (2022-23) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which was laid in Lok Sabha and Rajya Sabha on 8th February, 2022.

3. The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 25th February, 2022.

4. The Report was considered and adopted by the Committee at their sitting held on 16th March, 2022.

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 written information and for placing their views before the Committee.

6. The Committee also place on record their appreciation for the 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;
16 March, 2022
25 Phalguna, 1943 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

REPORT

CHAPTER – I

INTRODUCTORY

Indian Pharmaceutical Industry- An Overview

1.1 Indian pharmaceutical industry is known for its generic medicines and low-cost vaccines globally. Transformed over the years as a vibrant sector, presently Indian Pharma ranks third in pharmaceutical production by volume. In the last nine years, Indian Pharma sector has grown steadily by CAGR of 9.43%. Pharma sector has been consistently earning trade surplus. During 2020-21, total pharma export was ₹180555 Crore (USD 24.35 Bn) against the total pharma import of ₹49436 Crore (USD 6.66 Bn), thereby generating trade surplus of USD 17.68 Bn. Till end September 2021, total pharma export has been ₹ 87864 Crore (USD 11.88 Bn) as against total import of ₹ 33636 Crore (USD 4.66 Bn), thereby generating a trade surplus of ₹ 54228 Crore (USD 7.22 Bn). Major segments of Indian Pharmaceutical Industry include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics.

Indian pharmaceutical industry also plays significant role globally. India has the highest number of United States Food and Drug Administration (USFDA) compliant Pharma plants outside of USA. There are 500 API manufacturers contributing about 8% in the global API Industry. India is the largest supplier of generic medicines with 20% share in the global supply by manufacturing 60000 different generic brands across 60 therapeutic categories. 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”.

Item/Year	Output (₹ in Crore)	Growth Rate
2015-16	3,03,352	16.56
2016-17	3,21,472	5.97
2017-18	3,28,677	2.24
2018-19	3,98,852	21.35
2019-20	3,89,094	-2.45
2020-21*	4,27,109	9.77

*Estimated based on trend growth rate (CAGR) of output at 9.77% achieved during 2013-14 to 2019-20.

1.2 **Major Credentials Of Pharma Industry**

- (i) India provides generic medicines to more than 180 countries
- (ii) 8 out of 20 Global Generic companies are from India
- (iii) Over 55% Exports to Highly Regulated Markets
- (iv) 90% of WHO Pre-Qualified APIs are sourced from India
- (v) 65-70% of WHO's vaccine requirements are sourced from India
- (vi) No. of USFDA approved sites: 741 (as of August 2021)
- (vii) No. of ANDA Market Authorizations secured by Indian companies: 4,346 (as on December 2020)

Department of Pharmaceuticals

1.3 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.

Vision & Mission

1.4 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.

Mandate of the Department

1.5 The following works have been allocated to the Department of Pharmaceuticals:

- (i) Drugs and Pharmaceuticals and Medical Devices, excluding those specifically allotted to other departments
- (ii) Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceutical sector
- (iii) All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring

- (iv) All matters relating to National Institutes of Pharmaceutical Education and Research
- (v) Foreign Direct Investment (FDI) in Pharmaceutical Sector
- (vi) International co-operation in pharmaceutical research, including work related to international conferences in related areas in India and abroad

1.6 **Organizations under the Department**

- National Pharmaceutical Pricing Authority (NPPA), an attached Office
- 7 National Institutes of Pharmaceutical Education and Research (NIPERs)
 - (i) NIPER, Mohali, Punjab (ii) NIPER, Hyderabad, Telangana
 - (iii) NIPER, Ahmedabad, Gujarat (iv) NIPER, Kolkata, West Bengal
 - (v) NIPER, Guwahati, Assam (vi) NIPER, Raebareli, Uttar Pradesh
 - (vii) NIPER, Hajipur, Bihar
- 5 Public Sector Undertakings-
 - (i) Indian Drugs & Pharmaceuticals Ltd (IDPL)
 - (ii) Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)
 - (iii) Hindustan Antibiotics Ltd. (HAL)
 - (iv) Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)
 - (v) Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL)
- Pharmaceuticals & Medical Devices Bureau of India (PMBI)

1.7 **Central Sector Schemes of the Department**

- National Institute of Pharmaceutical Education and Research (NIPER)
- Scheme for Strengthening of Pharmaceutical Industry
 - a) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
 - b) Assistance to Pharmaceutical Industry for Common Facilities (API- CF)
 - c) Pharmaceutical and Medical Devices Promotion and Development Scheme (PMPDS)
- Umbrella Scheme: Development of Pharmaceutical Industry
 - (A) Production Linked Incentive (PLI) Schemes

- (i) PLI scheme for promotion of domestic manufacturing of critical KSMs/DIs/ APIs
 - (ii) PLI scheme for promoting Domestic Manufacturing of Medical Devices
 - (iii) PLI scheme for Pharmaceuticals
- (B) Promotion of Parks Schemes
- (i) Promotion of Bulk Drug Parks
 - (ii) Promotion of Medical Devices Parks
- Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)
 - Consumer Awareness, Publicity and Price Monitoring (CAPPM)

1.8 Department Plans for 2022-23

- Strengthening of NIPERs with infrastructure
- Selection of 3 States under Bulk Drugs Park Scheme (Rs.3000 Cr outlay).
- Selection of beneficiaries under the sub schemes of PTUAS / API-CF of the scheme of SPI.
- Monitoring of implementation of three PLI schemes and Medical Devices Park scheme.
 - Monitoring the increase of the domestic manufacturing capacity of high end medical devices such as Linear Accelerator (LINAC) , CT Scan, MRI X-Ray, Cath Lab, Positron Emission Tomography (PET) Systems, Single Photon Emission Tomography (SPECT), Mammography, C-Arm, etc under PLI scheme
 - Monitoring the production of Bulk Drugs, for which, there are upto 80% dependency. These critical bulk drugs include Para Amino Phenol, Atorvastatin, Sulfadiazine, Levofloxacin, Olmesartan, Lopinavir, Acyclovir, Vitamin B6, Valsartan, Losartan, etc.
- **National Medical Devices Policy, 2022:** To create the ecosystem for the sunrise sector of Medical Devices sector to scale new heights in the coming years
- Bringing out the Policy to catalyse R&D and Innovation in Pharma Medtech
- **Reducing Compliance burden of MedTech Sector:** Large scale compliance burden reduction exercise with the vision to improve the ease of doing business in the sector.

- **Support for manufacturing of raw materials for domestic vaccine production**

1.9 The detailed Demands for Grants (2022-23) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 08 February, 2022. A Budget Estimate (BE) of Rs. 2244.15 Crore has been made to the Department of Pharmaceuticals under Demand No. 7. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2022-23. 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

EXAMINATION OF DEMANDS FOR GRANTS (2022-23) [DEMAND No. 7]

Proposed and Approved Budget Estimate Allocations (2022-23)

2.1 Department of Pharmaceuticals proposed a total outlay of Rs. 10383.26 Crore for the year 2022-23. Gross budgetary allocation of Rs.2244.15 Crore has been made for the Department for the year. From this Rs. 36.35 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. 43.97 Crore). The Budgetary allocation for Central Sector Schemes is Rs. 2202.50 Crore (against proposed Budget Estimates of Rs. 2313.02 Crore) and Rs. 5.30 for Assistance to PSUs (loan) (against proposed Budget Estimates of Rs. 8026.78 Crore). A statement showing Scheme/Non-scheme details of proposed and approved outlays as Gross Budgetary Support (GBS) for the year 2022-23 for is given below:

(Rs. In Crore)		
Name of Scheme/ Non-Scheme	BE 2022-2023 Proposed	BE 2022-23 Approved
(1) Secretariat Economic Services MH 3451 (Non-Scheme)	20.40	18.56
(2) National Pharmaceutical Pricing Authority (NPPA) MH 2852	23.05	17.79
Total Non-Scheme	43.45	36.35
(3) National Institutes of Pharmaceutical Education and Research (NIPERs) MH 2552	74.00	35.00
National Institutes of Pharmaceutical Education and Research (NIPERs) MH 2852	366.00	360
Total NIPERs (MH 2552 + MH 2852)	440.00	395.00
(4) Jan Aushadhi Scheme MH 2552	3.00	7.20
Jan Aushadhi Scheme MH 2852	97.00	65.30
Total Jan Aushashi (MH 2552+ MH 2852)	100.00	72.50
(5) Development of Pharmaceutical Industry MH 2852		
5.1 Pharmaceuticals Promotion Development Scheme (PPDS)	2.00	2.00
5.2 Cluster Development (APICF)	36.00	36.00
5.3 Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	100.00	<u>62.00</u>

(Rs. In Crore)		
Name of Scheme/ Non-Scheme	BE 2022-2023 Proposed	BE 2022-23 Approved
5.4 Assistance to Bulk Drug Industry for Common Facilitation Center	900.00	900.00
5.5 Assistance to Medical Device Industry for Common Facilitation Center	120.00	120.00
5.6 Research and Development in Pharma Sector	0.01	0.01
5.7 Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Durg Intermediates and APIs	390.00	390.00
5.8 Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	216.00	216.00
5.9 Production Linked Incentive Scheme for Pharmaceuticals	3.00	3.00
Total DPI MH 2852	1767.01	1728.99
DPI North East Region MH 2552	0.01	0.01
Total DPI (MH 2852 + MH 2552)	1767.02	1729.00
(6) Consumer Awareness Publicity and Price Monitoring		
Assistance to Project Monitoring Resources Units (PMRUs)	5.00	5.00
Advertising and Publicity for CAPPMs	1.00	1.00
Total CAPPM (MH 2852)	6.00	6.00
(7) Assistance to PSUs		
Indian Drugs and Pharmaceuticals Ltd (IDPL)	6988.50	4.00
Hindustan Antibiotics Ltd (HAL)	1038.24	1.26
Bengal Chemicals & Pharmaceuticals (BCPL)	0.01	0.01
Bengal Immunity Ltd (BIL)	0.01	0.01
Rajasthan Drugs and Pharmaceuticals Ltd (RDPL)	0.01	0.01
Smith Stanistreet Pharmaceuticals Ltd (SSPL)	0.01	0.01
Capital Section Total (MH 6857)	8026.78	5.30
Grand Total	10383.26	2244.15

- MH 3451 - Major Head for Secretariat Economic Services (non-scheme).
 MH 2852 - Major Head for NPPA, NIPERs, Jan Aushadhi Schemes, Development of Pharmaceutical Industry (DPI), CAPPM.
 MH 2552 - Major Head for North East Region - NIPERs, Jan Aushadhi Schemes, DPI.
 MH 6857 - Major Head for Assistance to PSUs Scheme.

2.2 On examination of the above stated Gross and Scheme-wise Proposed and approved Budget Estimate (BE) allocations for the ensuing year 2022-23, the Committee observed that Gross Budget allocation for the Department is Rs. 2244.15 Crore which is nearly 4.6 times less than the amount proposed by the Department of Pharmaceuticals and asked for reasons for the same. Further the Committee enquired whether the actual allocation is sufficient to effectively implement the Schemes /Programmes of the Department during 2022-23. In this regards Department of Pharmaceutical furnished following information:

"**NIPER:** Rs.440.00 Crore were sought in BE 2022-23 for the scheme of NIPERs. Department of Expenditure has allocated Rs.395.00 Crore in BE 2022-23. The fund allocated by Department of Expenditure will be utilized for construction of NIPER campuses at Raebareli, Ahmedabad, Kolkata, Hyderabad and Hajipur and also for purchase of equipments/meeting recurring expenditure of the Institute.

Development of Pharmaceuticals Industry:

Name of the Scheme	(Rs in Crore)	
	BE 2022-2023 Proposed	BE 2022-23 Approved
Pharmaceuticals Promotion Development Scheme (PPDS)	2.00	2.00
Cluster Development (APICF)	36.00	36.00
Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	100.00	61.98
Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs	390.00	390.00
Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	216.00	216.00

Except for PTUAS, fund approved for other above mentioned schemes as per the proposal. The schemes guidelines of PTUAS have recently been revised as per EFC approval. If there is shortage of fund during implementation, the additional fund will be sought at the time Supplementary Demands for Grants.

Jan Aushadhi Scheme: Department has proposed an amount of Rs. 100.00 Crore as BE- 2022-23 for PMBJP. The target for the year is to open 1,000 new Kendras and enhance the product basket up to 1,800 medicines and 280 surgical. However, an amount of Rs. 72.50 Crore only have been allotted under BE 2022-23. Less allocation of funds will hamper effective implementation of the scheme. The Department will seek additional funds from the Ministry of Finance at RE stage.

Promotion of Bulk Drug Park: An amount of Rs. 900 Crore has been allocated under the scheme for Promotion of Bulk Drug Parks in BE 2022-23. This amount will be used to give first installment of Rs 300 Crore each to the 3 selected states for creation of Common Infrastructure Facilities (CIFs) as grant-in-aid.

NPPA: Against proposed outlay of Rs 29.06 Crore, an allocation of Rs. 23.79 Crore has been made for NPPA. This will have an impact on strengthening and effective implementation of the Scheme. The department will seek additional funds from Ministry of Finance at the RE stage.

PSU Section: PSU Division proposed for Rs. 8026.78 Crore for meeting various outstanding liabilities like secured liabilities of various banks and other unsecured liabilities in respect of IDPL and HAL as the same was not covered under the budgetary support of Rs. 330.35 Crore provided in 2019 as per recommendation of the Cabinet.

However, against the proposed amount, only Rs.5.30 Crore, the minimum amount needed for meeting contingent expenditure, court cases etc. has been provided in BE 2022-23."

2.3 The Committee also observed that the Budget allocation for the ensuing year 2022-23 has increased approx. 2.7 times from Rs 823.11 Crore at Revised Estimate (RE) stage in 2021-22 to Rs 2244.15 Crore at BE stage for the year 2022-23. In this regard the Committee asked the Department whether the enhanced fund allocated for the Department at approved BE stage for the ensuing year 2022-23 is sufficient to fulfill its mandate, the Department in its written reply furnished scheme-wise details which is as follows:

"NIPER: Additional funds at RE stage will be sought to expedite construction of campuses of NIPERs.

Development of Pharmaceuticals Industry:

The details of RE 2021-22 and BE 2022-23 of following schemes is given in table:

(Rs in Crore)

Name of the Scheme	RE 2021-22	BE 2022-23
Pharmaceuticals Promotion Development Scheme (PPDS)	2.00	2.00
Cluster Development (APICF)	15.61	36.00
Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	0.01	62.00
Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Durg Intermediates and APIs	2.79	390.00
Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	3.31	216.00

The enhanced amount allocated in BE 2022-23 as compared to RE 2021-22 is sufficient to fulfil the scheme mandates.

Jan Aushadhi Scheme: Under PMBJP Rs. 72.50 Crore have been allocated against the request of Rs. 100 Crore for B.E. 2022-23. The funds are not sufficient and less allocation of funds will hamper effective implementation of the scheme. The Department will seek additional funds from the Ministry of Finance at RE stage.

NPPA: Budget allocation for ensuing year 2022-23 for NPPA is Rs. 23.79 Crore, which is higher than the RE 2021-22 (Rs. 18.51 Crore), but less than the proposed outlay for next year. This will have an impact on strengthening and effective implementation of the Scheme. The department will seek additional funds from Ministry of Finance at the RE stage."

2.4 On being asked about the Strategy of the Department for Effective Fund utilization of Rs. 2202.50 Crore allocated at BE stage for the year 2022-23 for achieving the mandate of the Central Sector Schemes, the Department in its written reply furnished the following scheme-wise details:

"NIPER: Department has selected CPWD for construction of campuses of NIPERs at Kolkata, Raebareli and Hajipur. Regular follow up at the Institute and the Department level will be done for effective utilization of funds.

Development of Pharmaceuticals Industry:

The fund allocated under the schemes will be fully utilized during FY 2022-23 as follows:

PPDS: 5 studies have been approved in FY 2021-22. Part instalments are to be released in FY 2022-23. New studies will be considered in FY 2022-23. Various events, seminars, conferences are to be organized. Annual India Pharma/Medical Device Event is to be organized during FY 2022-23.

APICF: Part funds are to be released to already approved projects of IPRF and KIDC. 2 projects which have been granted in-principle approval are under consideration for final approval. The projects will be considered for final approval in FY 2022-23 and funds will be released to them. Consultancy Fees are also to be released to PDIL and NPCCL.

PTUAS: The schemes guidelines of PTUAS have recently been revised as per EFC approval. Eligible applications will be considered in FY 22-23.

PLI Scheme for Bulk Drugs: Incentives are to be released to the approved applicants on sales of eligible products under the scheme.

PLI Scheme for Medical Devices: Incentives are to be released to the approved applicants on sales of eligible products under the scheme.

Jan Aushadhi Scheme: Department has given targets to the implementing agency, Pharmaceuticals & Medical Devices Bureau of India (PMBI) for opening of stores, expansion of product basket etc. The effective utilization of funds is ensured by regular monitoring of the scheme by PMBI. Further, the performance of the scheme is regularly reviewed by the Executive Council and Governing Council of PMBI. Moreover, periodic meetings are held at the level of the Secretary of the Department, as well as at the level of Minister of Chemicals & Fertilizers to review the performance and to ensure fulfilment of its mandate.

Promotion of Bulk Drug Park: An amount of Rs. 900 Crore has been allocated under the scheme for Promotion of Bulk Drug Parks in BE 2022-23. This amount will be used to give first instalment of Rs 300 Crore each to the 3 selected states for creation of Common Infrastructure Facilities (CIFs) as grant-in-aid. The Scheme Steering Committee (SSC) under the scheme will monitor the implementation of the scheme and the subsequent instalments will be released after obtaining Utilization Certificate from the State Implementing Agency against utilization of the first instalment.

NPPA: The implementation of the scheme is monitored at the level of NPPA. Further, weekly meetings are held at the level of Secretary of the department to review the progress and ensure fulfillment of various physical and financial targets. "

Scheme-wise Physical and Financial Targets (2022-23)

2. 5 On being asked about the Scheme-wise physical and financial targets set for all Central Sector Schemes by the Department for the year 2022-23, the Department in its written reply stated as under:

"NIPER Physical Target 2022-23:

Name of NIPER	Construction	Research Paper Publication	Patents to be filed	Student intake
Ahmedabad	100%	220	14	205
Hajipur	30%	90	2	110
Hyderabad	30%	200	9	215
Guwahati	100%	140	8	185
Raebareli	30%	115	6	135
Kolkata	30%	115	3	110
Mohali	-	220	13	340
Total		1100	55	1300

NIPERs Financial Target 2022-23:

Department of Expenditure has allocated Rs.395.00Crore in BE 2022-23. The same will be utilized for up-gradation of existing 7 NIPERs.

Development of Pharmaceuticals Industry: Under PPDS, no physical and financial targets have been fixed so far, due to the evolving COVID situation, as most of the conferences are being organized virtually. However, based on the trend in the previous years, it is expected that about 15-20 Conferences / Seminars / Workshops and 7-10 studies will be conducted during FY 2022-23.

Under APICF, already two projects have been granted in-principle approval and are under consideration for final approval. The projects will be considered for final approval in FY 2022-23 and funds will be released to them. As per New Guidelines five projects will be approved in financial year 2022-23

PTUAS: The schemes guidelines of PTUAS are being revised as per EFC approval. Once approved, eligible applications will be considered in FY 22-23.

PLI Scheme for Bulk Drugs: Physical and financial outlay of the scheme are already fixed and year wise release of Incentives are to be released to the approved applicants on sales of eligible products under the scheme. So far, Total 49 applicants have been approved. Notice for 3rd round of application window has been issued with last date as 31.3.2022.

PLI Scheme for Medical Devices: Physical and financial outlay of the scheme are already fixed and year wise release of Incentives are to be released to the approved applicants on sales of eligible products under the scheme. Total 21 applications have been approved.

Assistance to Medical Device Industry for Common Facilitation Center:

Physical Target- Creation of Common Infrastructure Facility in 4 Medical Device Parks as per the physical deliverables in the DPRs as approved by the SSC. **Financial Target-** Financial release will consist of grant by DoP and

proportionate contribution by the State Implementing Agency and Release of Rs. 120 Crore to 4 Medical Device Parks States as second instalment.

Jan Aushadhi Scheme: The target for the year 2022-23 is to open new 1000 Kendras and enhance the product basket upto 1,800 medicines and 280 surgicals. Further, a sale target of Rs. 775 Crore has also been prescribed.

Promotion of Bulk Drug Park: Physical Target- Creation of Common Infrastructure Facility in 3 Bulk Drug Parks, as per the physical deliverables in the DPRs as approved by the SSC. **Financial Target-** Financial release will consist of release of grant by DoP and proportionate contribution by the State Implementing Agency and Release of Rs. 900 Crore by DoP to 3 States as first installment of grant-in-aid.

NPPA: NPPA implements Consumer Awareness Publicity and Price Monitoring (CAPP) scheme, which has two components. The first is opening of Price Monitoring Resource Units (PMRUs) in the States / UTs. PMRUs have already been set up in 22 States / UTs and two (2) more PMRUs are about to be set up during FY 2021-22. During FY 2022-23, there is target to set up six (6) new PMRUs. These PMRUs are the key contributing partners of NPPA with information gathering mechanism envisaged at grass root levels and creating public awareness, so that benefits of Drugs Prices Control Order (DPCO) (revised from time to time) trickle down to grass root levels. The second component of the scheme is to carry out the advertising and publicity campaigns as well as organizing training workshops and seminars so as to make public aware about the recent decisions / actions in particular and activities of NPPA in general. The physical and financial targets are as under:

(Rs. in Crore)

Name of the Scheme	BE 2022-23	Physical Targets	Financial Targets
Consumer Awareness Publicity and Price Monitoring (CAPP)			
Assistance to Project Monitoring Resource Units (PMRUs) Grants-in-Aid	5.00	To set up six (6) new PMRUs in States / UTs	5.00
Advertising & Publicity of CAPPs	1.00	Carry out advertising and publicity campaigns through outdoor publicity (Hoardings, LED screens etc.), print media (Newspapers, Magazines, Pamphlets etc.), electronic media (Radio jingles, Telefilms etc.) and social media (Twitter, Facebook etc.) as well as organizing training workshops and seminars on various topics / areas of functioning of NPPA.	1.00

2.6 **Research and Development In Pharma Sector:**

Under Major Head 2852, only a token allocation of Rs. 1 Lakh has been made for “Research and Development in Pharma Sector”. During oral evidence of the representatives of Department of Pharmaceuticals on Demands for Grants 2022-23, the Committee observed that the Government has to put in much more finances into research and Development in the Pharma Sector and specifically in the medical devices industry. In this regard, the Secretary, Department of Pharmaceutical informed the Committee as follows”:

“We also, as a Department, believe that to take pharmaceutical to the next level of development and to increase the value of this sector in the global market, we have to focus more on research and development. We have come out with a policy after a lot of deliberations. It is at the discussion stage....This is the policy for catalysing R&D and innovation in pharmaceutical and medical sector. A draft Cabinet note has already been circulated. We have received extensive comments, both from industry as well as the Departments. We would like to finalise it.”

CHAPTER-III

BUDGET UTILIZATION TREND (2019-20 to 2021-22)

3.1 The details of the Budget Estimates (B.E.), Revised Estimates (R.E.) and Actual Expenditure incurred by the Department of Pharmaceuticals on various scheme/non-scheme heads during the financial period 2019-20 to 2021-22 and B.E. allocation for the Financial Year 2022-23 are given below:

(Rs. In Crore)											
		2019-20			2020-21			2021-22			2022-23
	Revenue Section	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual as on 11.02.2022	BE
1	Secretariat Economic Services	14.15	14.67	13.69	15.50	14.45	14.40	16.73	15.98	13.73	18.56
2	National Pharmaceuticals Pricing Authority (NPPA)	12.00	11.48	10.61	11.90	12.90	12.74	14.80	14.01	12.39	17.79
3	National Institute of Pharmaceutical Education and Research (NIPERs)	150.00	160.00	160.01	202.45	333.83	333.83	234.34	372.00	230.34	395.00
4	Development of Pharmaceuticals Industry	8.30	3.49	3.29	42.05	34.05	20.44	124.42	200.00	56.73	1729.00
5	Jan Aushadhi Scheme	42.00	35.51	35.51	50.00	65.00	65.00	65.00	68.50	56.30	72.50
6	Consumer Awareness, Publicity and Price Monitoring (CAPPM)	4.00	4.00	3.99	4.50	3.00	2.60	6.00	4.50	1.89	6.00
	Write Off/ Waiver of losses in respect of Pharmaceutical In respect of IDPL (Rs. 889.50 Crore and BCPL (193.71 cr)	--	--		--						
7	Capital Section										
	(Assistance to PSUs)										
	Indian Drugs & Pharmaceuticals Ltd. (IDPL)	0.01	4.28	4.28	0.01	2.23	2.23	2.00	2.00	2.00	4.00
	Hindustan Antibiotics Ltd. (HAL)	0.01	280.16	280.16	4.74	2.52	2.52	4.09	122.09	122.09	1.26
	Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)	0.01	0.01	0.00	0.01	0.01	0.00	0.01	0.01	0.00	0.01
	Bengal Immunity Ltd. (BIL)	0.01	0.01	0.00	0.01	0.01	0.00	0.01	0.01	0.00	0.01
	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)	5.01	48.71	48.71	2.40	2.40	2.40	3.00	24.00	21.00	0.01
	Smith Stanistreet Pharmaceuticals Ltd (SSPL)	0.01	0.01	0.00	0.01	0.01	0.00	0.01	0.01	0.00	0.01
	Total (Loan to PSUs)	5.06	#333.18	333.15	7.18	7.18	7.15	9.12	\$148.12	139.70	5.30

(Rs. In Crore)											
	2019-20			2020-21			2021-22			2022-23	
Revenue Section	BE	RE	Actual	BE	RE	Actual	BE	RE	Actual as on 11.02.2022	BE	
Grand Total	235.51	562.33	560.25	333.58	470.41	456.16	470.41	823.11	516.47	2244.15	

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 permitted 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 Crore 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). However, funds amounting to Rs.328.12 Crore was granted by M/o Finance which were released to 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.

During the year 2020-21: Ministry of Finance vide its OM No. 2(20)/-B(P&A)/2019 dated 04.01.2020 had increased the total allocation of Department to Rs. 470.41 Crore against of BE of Rs. 333.58 core for Department of Pharmaceuticals. The surplus of Rs. 136.83 core was allocated to NIPER (Rs. 121.83 Crore) and Janaushadhi Scheme (Rs. 15.00 Crore). The minimum allocation for NIPERs had been indicated as Rs. 300.00 and Rs. 65 Crore for Jan Aushadhi.

3.2 In view of the above stated Budget Estimates (BE), Revised Estimates (RE) and actual utilization during 2021-22, the Committee observed that the Gross Budget Utilization during the financial year 2021-22 at RE stage is increased to Rs. 823.11 Crore from Rs. 470.41 Crore at BE stage, however the actual utilization as on 11.02.2022 is only Rs. 516.47 Crore which is even less than the BE allocation. On being asked about the cogent reasons for under utilization of funds after adequate allocation of funds at RE stage, the Department gave following justification one by one for all the Central Sector Schemes under its jurisdiction:

"NIPERs: Rs.100.00Crore has been allocated through 2nd Supplementary Demands for Grants 2021-22. The same are being released to NIPERs for construction of campuses. Further, Rs.37.36 Crore may be made available through 3rd and final Supplementary Demands for Grants 2021-22 after approval of Parliament and the same will be released to NIPERs for their strengthening/up-gradation, as required.

Development of Pharmaceuticals Industry: The details of BE 2021-22, RE 2021-22 and Actual (as on 11.2.2022) is given below:

(Rs in Crore)

Name of the Scheme	RE 2021-22	RE 2021-22	Actual (as on 11.2.2022)
Pharmaceuticals Promotion Development Scheme (PPDS)	2.00	2.00	1.01
Cluster Development (APICF)	18.00	15.61	1.51
Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	0.01	0.01	-
Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Durg Intermediates and APIs	2.79	2.79	0.22
Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	2.36	3.31	2.125

PPDS: 5 studies have been approved in FY 2021-22. Part instalments are to be released in FY 2021-22. Few events, seminars, conferences are to be organized. It is expected that entire RE will be utilized till 31st March, 2021.

APICF: Final Instalment to Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC), 2nd instalment to Inducare Pharmaceuticals and Research Foundation (IPRF) and 3rd instalment are to be released to Kala Amb Infrastructure Development Company (KIDC). Consultancy Fees are to be released to PDIL and NPCCL.

PTUAS: Only token amount allocated.

PLI Scheme for Bulk Drugs: Consultancy fee is to be released to PMA. Payment was withheld as the funds are to be released from Professional Services Head. Now the Professional Services Head has been created and fund has been re-appropriated. It is expected that entire RE will be utilized till 31st March, 2021.

PLI Scheme for Medical Devices: Consultancy fee is to be released to PMA. Payment was withheld as the funds are to be released from Professional Services Head. Now the Professional Services Head has been created and fund has been re-appropriated. It is expected that entire RE will be utilized till 31st March, 2021.

Jan Aushadhi Scheme: During 2021-22, Rs. 80.00 Crore was projected at BE stage for PMBJP. However, an amount of Rs. 65.00 Crore only was allotted at BE stage and Rs. 68.50 Crore at RE Stage. The Department has already released Rs. 56.30 Crore to PMBI for implementation of PMBJP as per projection. The process for release of remaining funds is already underway. The department will also take it up with the Ministry of Finance for seeking remaining funds at the stage of 3rd supplementary.

Promotion of Bulk Drug Park: A total number of 13 proposals have been received under the scheme for Promotion of Bulk Drugs Parks. As per the scheme guidelines, three (3) States are to be selected for providing financial assistance for common infrastructure facility through a competition method based on the best quotes for charges of various utilities, land rate, fiscal incentives by States, land registration charges etc. During the evaluation of the proposals, the Project Management Agency (PMA) identified certain issues w.r.t the above proposed charges quoted by the States thereby presenting an anomalous situation which was not conducive to the assessment of comparative merits.

In view of the issues highlighted, an advisory Committee has been constituted with CEO NITI Aayog, Secretary DoP and representatives of DPIIT & Department of Expenditure to advise DoP on the qualitative application of the scheme guidelines to the proposals. In its first meeting held on 03.09.2021, the Committee advised the Department to apply a set of qualitative filters to the proposals received under Bulk Drug parks. Accordingly, some additional information has been collected from the States which is being processed for the same to be presented to the Advisory Committee for further action."

2nd Batch of Supplementary Demands For Grants for Financial Year 2021-22 and Its Impact on Major Central Sector Schemes of the Department

3.3 The Department has sought cash supplementary of Rs. 400 Crore for NIPERs and token supplementary of Rs. 0.08 Crore for re-appropriation/opening of new object head "Professional Services" under various sub-schemes of "Development of Pharmaceuticals Industry" under Second Batch of Supplementary Demand for Grants for 2021-22 and details are as under: -

		(Rs. In Crore)
Proposed 2nd Batch of Supplementary for Demand for Grants FY 2021-22		Reason
Revenue		
MH 2852 National Institutes of Pharmaceutical Education & Research (NIPERs)	400.00	For the purpose of construction of campuses, purchase of equipment of various NIPERs.
Development of Pharmaceuticals Industry MH 2852		Reason
(i) Pharmaceuticals Promotion Development Scheme (PPDS)	0.01	For opening of a new object head "Professional Services"
(ii) Cluster Development	0.01	For opening a new object head "Professional Services" and Re-appropriation of Rs. 1.00 Crore from GIA-General object head to proposed "Professional Services"
(iii) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	0.02	For opening of a new object head "Professional Services".
(iv) Assistance to Bulk Drug Industry for Common Facilitation Center	0.01	For opening a new object head "Professional Services" and Re-appropriation of Rs. 2.25Crore from GIA-General object head to proposed "Professional Services"
(v) Assistance to Medical Device Industry for Common Facilitation Center	0.01	For opening a new object head "Professional Services" and Re-appropriation of Rs. 33.99Crore from GIA-General object head of "Assistance to Bulk Drug Industry for Common Facilitation Center" to proposed "Professional Services" object head (Rs. 0.8968 Crore) and GIA-General object head (Rs. 33.0932 Crore)
(vi) Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Durg Intermediates and APIs	0.01	For opening a new object head "Professional Services" and Re-appropriation of Rs. 2.57Crore from GIA-General object head to proposed "Professional Services" object head.
(vii) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device		For opening a new object head "Professional Services" and Re-appropriation of Rs. 0.2350 Crore from GIA-General object head to proposed "Professional Services" object head.
(viii) Production Linked Incentive Scheme for Pharmaceuticals		For opening of a new object head "Professional Services"

3.4 The Committee observed that during 2021-22, for 2nd Batch of Supplementary Demand for Grants Ministry of Finance has approved total cash supplementary of only Rs.100 Crore for NIPERs which is less than proposed cash Supplementary Grant of Rs 400.00 Crore sought by the Department. In this regard the Committee asked about the reasons for the shortfall in 2nd Batch of Supplementary Demand for Grants by Ministry of Finance and its specific impact on construction of campuses, purchase of equipment of various NIPERs during the year 2021-22, the Department furnished following reply:

"As funds approved by Expenditure Finance Committee (EFC) in March, 2018 were not fully allocated, including the balance the Department had sought Rs.400.00Crore through 2nd Batch of Supplementary Demand for Grants 2021-22 for expediting construction of campuses of NIPERs and strengthening of their laboratories. However, the Department of Expenditure has allocated Rs. 100.00Crore only in 2nd Supplementary Demands for Grants for the said activities. Moreover, Department of Expenditure has allocated Rs.395.00Crore in BE 2022-23 for NIPERs. Out of which, more than 50% fund is earmarked for construction of campus/procurement of equipment for FY2022-23. Department is in process of start of construction of permanent campus at NIPER Kolkata, Hajipur, Raebareli and Hyderabad and construction of campus of NIPER Ahmedabad is going on at full swing. Additional funds at RE stage will be sought to complete the same."

3.5 Further, it is observed that out of token supplementary of Rs. 0.08 Crore sought for re-appropriation/opening of new object head "Professional Services" under various sub-schemes of "Development of Pharmaceuticals Industry" under Second Batch of Supplementary Demand for Grants for 2021-22. The Committee asked how much is proposed for Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device and Production Linked Incentive Scheme for Pharmaceuticals and reasons for no token allocation made for these two Schemes, the Department in its written reply stated as under:

"Department was requested to open "Professional Services" Head under PLI Scheme for Medical Devices and re-appropriate Rs 0.2350 cr from GIA General to Professional Services Head during 2nd batch of supplementary Demand for Grants vide letter dated 5.11.2021. The same was permitted by MoF. But due to lack of requisition/proposals in the sub-scheme i.e Production Linked Incentive Scheme for Pharmaceuticals, no fund was allocated under the said sub-scheme. In the FY 2022-23, Rs. 2.50 Crore has been allocated under "Professional Services" and Rs. 0.50 Crore under GIA-General for PLI scheme for Pharmaceuticals."

3.6 The Committee also asked about the aims and objective for opening the new object head "Professional Services" under various sub-schemes of "Development of Pharmaceuticals Industry" , the Department in its written reply stated as under:

"Development of Pharmaceuticals Industry (Scheme Section):

PPDS: Funds are released to the agencies for conducting studies. The same are required to be released from Professional Services Head.

APICF, PTUAS, PLI Scheme for Bulk Drugs and PLI Scheme for Medical Devices: For releasing consultancy fee to PMA, Professional Services Head has been created.

Promotion of Bulk Drug Park: The object head "Professional Services" has been created to make payments to the Project Management Agency for hiring the services for implementation of the scheme."

SCHEMEWISE FINANCIAL AND PHYSICAL OUTCOMES DURING 2019-20 TO 2021-22

A. National Institutes of Pharmaceutical Education and Research (NIPERs) - MH 2552 + MH 2852

3.7 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, the 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.

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.

3.8 On the basis of Output and Outcome framework following are the commensurate outcomes in respect of NIPERs from 2019-20 to 2021-22.

Indicators	2019-20		2020-21		2021-22	
	Targets	Achievements	Targets	Achievements	Targets	Achievements
Financial Out lay	Rs.150.00 cr.	Rs.160.01cr.	Rs.202.45cr.	Rs.333.82cr.	Rs.372.00 cr.	Rs.204.34cr.
No. of Experts in Pharmaceuticals and R&D	550	593#	750	676#	1100	750#

Number of NIPERs in which Construction of campuses and laboratory facilities has commenced	Two (i) NIPER Guwahati (ii) NIPER Ahmedabad	(i) More than 80% construction of NIPER-Guwahati campus has been completed (ii) Tender for construction of NIPER-Ahmedabad Campus finalized.	Two (i) NIPER Guwahati (ii) NIPER Ahmedabad	(i) More than 95% construction of NIPER-Guwahati campus has been completed (ii) Construction of NIPER-Ahmedabad campus has been started.	Two (i) NIPER Guwahati (ii) NIPER Ahmedabad (iii) To start construction of NIPER Hyderabad/Kolkata/Raebareilly/Hajipur	(i) Construction of NIPER Guwahati completed (ii) More than 10% construction of NIPER-Ahmedabad campus has been completed
No. of Research publications	600	598	750	622	900	455
No. of Patents filed/granted	25	23	35	46	45	13

#Student passed out* Till 31.12.2021

3.9 From the above tabular data it is also evident that number of Research publications of NIPERs is on decline in comparison to the target set for the year 2019-20, 2020-21 and 2021-22. On being asked about the reasons and steps that are being taken to improve the performance of NIPERs, the Department stated following written reply:

"Department of Expenditure has created 156 faculty post for 6 NIPERs in February, 2019. Framing of their RRs and actual filling took some time and as of now about nearly 70% posts have been filled while, remaining are under process. Due to absence of regular faculty, there has been a shortfall in achieving the targets. Further, as the educational institutes could not function to their full capacity due to covid lock downs/ restrictions, there has been a slight decline. The matter has been also deliberated regularly at the Institute/ Board and department level, and all NIPERs have been directed to achieve the vision target fixed for publishing of research papers. As of 15th February, 2022, 602 research papers have been published by NIPERs."

3.10 The Committee noted that as on date only 10% of the NIPER-Ahmedabad campus has been completed. In this regard the Committee asked about the reasons for slow progress in construction of campus and total fund that is needed for construction of the campus and by which year the campus will be completed. In this regard, the Department in its written reply stated as follows:

"Nearly 20% of construction has been completed. Work is going on at war footing and it is expected that the construction of the campus will be completed during FY 2022-23. EFC has approved Rs.103.88Crore for construction of campus. The slow progress is on account of less allocation of funds by Ministry of Finance and also due to COVID related issues."

3. 11 The Committee also noted that 20.55 acres of land that has been given to NIPER Kolkata for Campus building at BCPL Kolkata. In this regard, the Committee asked about the adequacy of this land and in general asked about existence of any policy of the Department to provide basic uniform land allotment to all NIPERs as they are Institutes of National Importance, the Department furnished following written reply:

"NIPER, Kolkata has requested the Department for providing a minimum of 20 acres of land for construction of regular campus. The provision of land to NIPER, Kolkata is as per their request and BCPL also identified that much of land as surplus."

3.12 During the oral evidence of the representatives of the Department of Pharmaceuticals on Demands for Grants 2022-23, when the Chairperson asked about the status of five new NIPERs along with budgetary constraints in this regard, the Secretary, Department of Pharmaceuticals stated as below:

"Madam, you had asked us to also highlight any budgetary constraints. As you are aware, we have seven functional NIPERs. All of them also do not have buildings and infrastructure plus five new NIPERs have been agreed to. So, we asked for Rs. 4,300 Crore for the next five year period under EFC. This was our proposal. However, in the EFC, in the current year because of the COVID-19 related expenditure, etc., we were only given the approval for Rs. 1,500 Crore plus. The EFC has said that Rs. 1,500 Crore should be used for the existing NIPERs. They said that you can consider the other NIPERs some time later. We are not supported at this stage. We have now proposed to our Minister that since these are already approved and the States are also interested, we have to look at other ways of finding resources for these NIPERs. He has given the green signal that although EFC is not able to provide in the current year, let us look at something like a Centrally-sponsored Scheme or something where we can take this forward or do it in a modular approach. So, we are trying to work out how to get it done."

3.13 Further a representative of the Department while highlighting the performance and challenges before NIPERs, stated as under:

"Basically, these NIPERs impart postgraduate and doctorate education, and also conduct research in various specializations in pharma and medical devices sector. The Ministry of Education ranks all educational institutions in the country, and under the 'Pharmacy' category as per the latest ranking three NIPERs are in the top 10, namely, Mohali, Hyderabad and Ahmedabad, and other two NIPERs are in the top 20, namely, Raebareli and Guwahati. This ranking is of all the public and private institutions. So, more than 350 institutions had participated in this ranking, and five NIPERs are in the top 20 list.

Initially, there were some hiccups in their establishment, campus and creation of posts, but now posts at all the NIPERs have been sanctioned, recruitment rules have been framed and posts have been filled up as per requirement. The construction of the campus at Guwahati has been about 95 per cent completed, and the Committee has already seen the NIPER, Guwahati

campus. The construction of the campus at Ahmedabad has been about 30 per cent completed, and the EFC has recently given permission to construct campus of other four NIPERs. We have already nominated CPWD to construct the campus, and we have also got some additional funds. So, we are hopeful that the campuses of remaining four NIPERs will be completed in the next financial year.

As regards challenges for NIPERs, it includes financial allocation. Actually, we had gone to EFC seeking a fund of about Rs. 4,300 Crore for a period of five years, but what we have got is only Rs. 1,500 Crore for the existing NIPERs. The Rs 1500 crore that has been received for seven exiting NIPERs. We want to set-up five more NIPERs, for them we are trying for alternate sources, through which we can set-up these NIPERs. These NIPERs are in Madurai, Bangalore, Chhattisgarh, Rajasthan and Maharashtra. Recently, NIPERs have taken some initiatives, to which I would like to draw your attention.”

3.14 On being asked about the initiatives taken by the Department to utilize funds under National Research Foundation (NRF), the Secretary of the Department stated that "Sir, in that we had submitted a proposal for Rs 1,000 crore. In that we were looking to take research programme, NIPERs may not be covered under this scheme. We wanted to create Center of Excellence. In that we were given the reply that NRF guidelines are still in process.

3.15 During the oral evidence on Demands for Grants 2022-23 the Committee also observed that private pharma companies have resources to fund research and development whereas pharma MSMEs lack such resources at their disposal . In this regard the Committee suggested that can the Department of Pharmaceuticals think of linking NIPERs research programmes with the research and development demands of the Pharma MSME industry.

3.16 On the above suggestion of the Committee, the Secretary, Department of Pharmaceuticals during the oral evidence gave following inputs:

"....NIPERs are somewhat insulated. They do not have so much of public visibility. Therefore, the work that they are doing does not get reflected to the industry. So, we have started more interaction with the industry. As our JS mentioned, we have worked on the Common Research Programme. They identify four problems which are important for our country. What are the diseases from which most people are affected? What are those therapies where we need to work more? As the hon. Member also said, how can we be helpful to the MSME sector? If there are 25 faculty in one NIPER, then one company may have 2,000 scientists also. So, we have to prioritize and so, we are working on it. When we have this presentation, we would like to share our approach with the Committee and take the guidance. So, officers of NIPERs and our two directors are also taking note."

B. Umbrella Scheme Development of Pharmaceutical Industry- MH 2852

3.17 The Department has an umbrella scheme namely '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, availability and affordability of quality pharmaceuticals for mass consumption. This Scheme is a Central Sector Scheme and comprises the following 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) Promotion of Bulk Drug Parks
- (c) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices
- (d) Promotion of Medical Device Parks
- (e) Production Linked Incentive (PLI) Scheme for Pharmaceuticals
- (f) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
- (g) Assistance to Pharmaceutical Industry for Common Facilities (APICF)
- (h) Pharmaceutical Promotion and Development Scheme (PPDS)

Expenditure Finance Committee (EFC) has recommended to de-link sub-schemes (f) to (h) from the Umbrella scheme and implement them as a separate scheme.

3.18 In continuation of the above stated recommendation of EFC, a representative of the Department of Pharmaceuticals during oral evidence on Demands for Grants 2022-23, also submitted before the Committee that for increasing the drug security in the country the Department is implementing a particular scheme called Scheme for strengthening the Pharmaceutical Industry. It has three sub-schemes viz (i) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS); (ii) Assistance to Pharmaceutical Industry for Common Facilities (APICF) and (iii) Pharmaceutical and Medical Devices Promotion and Development Scheme (PMPDS).

3.19 In this regard, the representative of the Department of Pharmaceutical gave a brief overview on the status of these three sub-schemes which is as under:

"In the EFC meeting held in September, last year, these three schemes have been given Rs.500 crore for five years, starting from this financial year. We have done extensive stakeholders' consultation before arriving at the scheme guidelines, which are being accordingly revised and put up for the approval of the Hon. Minister.

As indicated by the Committee last time, we are appointing professional PMC – Project Management Consultant – so that these projects can be executed in a systemic, professional and transparent manner without any delay.

This is Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS), which is focusing on the MSMEs, SMEs in the pharma and medical sector to upgrade standards both quality and technical to WHO-Good Manufacturing Practices so that they would be able to produce a world-class high quality drugs and also become globally competitive. We are planning to support Schedule-M and WHO-GMP certification so that they are eligible to export to other countries. As per the information available, out of 6,700 plus SMEs available in both Pharma and APIs, only 2,006 are certified. So, we have a large basket which is to be supported. We are also planning to co-opt the schemes available with MSME Ministry as well so that they are able to support. There is some hike in the budget. So, we want to co-opt with them also. For this financial year, we have budgetary provision of Rs.62 crore. We are planning to have a series of meeting so that we cover enough units.

Then, we have Assistance to Pharmaceutical Industry for Common Facilities (API-CF), which provides assistance to create common facilities such as CETPs, training and R&D centres. This is a continuing schemes; already a project has been commissioned and two more projects are in the pipeline.

We have new scheme guidelines based on the indications from the EFC, which are being finalised. About API-CF scheme, we have given CETP plant in Tamil Nadu, which has been commissioned and started functioning. We have released to a large extent; remaining finance would be released after checking the bills, etc.

These are the two projects under the same scheme – one is in Himachal Pradesh. This is also CETP, where we have almost released 60 per cent; second one is in Pune where it is for testing labs. We are reviewing regularly. We have ordered equipment. Once they arrive, we will release the remaining amount.

This is the third scheme of the sub-scheme. This will cover Pharmaceutical Promotion Development Scheme. It is mostly for facilitating small studies, research and conducting conferences and webinars. We are also finalising new studies. We are planning to have a number of studies supported. In the current financial year, we have already supported five studies, both short term and long term, which are critical and important and which would give us enough inputs for effective policy making decision. This has been done by notification; we have selected through technical committee.”

3.20 Further, with regard to the PPDS scheme the Secretary, Department of Pharmaceutical also stated that earlier the studies conducted under the scheme were ad-hoc and now the Department had collected the requirements of study from all the Departments/Organisations/Industry and is now conducting studies in a systematic way.

3.21 A statement showing the extent to which the Department of Pharmaceuticals has been able to convert the financial outlays for different sub-schemes under umbrella Scheme 'Development of Pharmaceutical Industry' into commensurate outcomes during the years 2019-20, 2020-21 & 2021-22 is as follows:-

(Rs in Crore)										
S. No	Scheme (s)	2019-20			2020-21			2021-22		
		RE	Actual Exp.	Outcome (Actual Exp/RE) in %	RE	Actual Exp.	Outcome (Actual Exp/RE) in %	RE	Actual Exp.	Outcome (Actual Exp/RE) in %
1.	Pharmaceuticals Promotion Development Schemes	1.19	1.06	89.08	0.50	0.50	100	2.00	0.01*	0.5
2.	Pharmaceuticals Technology Upgradation Assistance Scheme	0.02	Nil	Nil	0.01	Nil	Nil	0.01	Nil	Nil
3.	Cluster Development	2.24	2.23	99.55	7.50	7.22	96.26	15.61	1.51	15.1
4	Assistance to Bulk Drug for Common Facilitation Center	0.02	-	-	1.69	1.68	99.40	36.24	0.00	-
5	Assistance to Medical Device for Common Facilitation Center	0.02	-	-	21.05	7.49	35.58	137.02	8.62	6.29
6	Research and Development in Pharma Sector	-	-	-	-	-	-	0.01	-	-
7	PLI Scheme for Promotion of Domestic Manufacturing of Critical KSMs/ Drug Intermediates and APIs	New sub-scheme. Approved in 2020.			1.55	1.55	100	2.79	0.22	7.89
8	PLI Scheme for Promoting Domestic Manufacturing for Medical Device	New sub-scheme. Approved in 2020			2.00	2.00	100	3.31	2.13	64.20
9	Production Linked Incentive scheme Pharmaceuticals	-			-	-	-	3.00	1.24	

* As on 30.12.2021

3.22 Sub-scheme-wise analysis of financial outlays and outcomes under the umbrella scheme Development of Pharmaceutical Industry is mentioned below:-:

a) Pharmaceuticals and Medical Devices Promotion Development Schemes (PMPDS)

3.23 The aim of this sub-scheme is promotion, development and export promotion in Pharmaceutical sector by extending financial support for conducting seminars, conferences, exhibitions, conducting studies/ consultancies etc. The new scheme guidelines are being finalized, reflecting financial outlay of the sub-scheme.

3.24 The Committee asked about the reason for utilization of only Rs. 0.01 Crore as on 30.12.2021 under Pharmaceutical Promotion and Development Scheme (PPDS) during the current financial year 2021-22 and steps that are being taken to utilize the allocated funds fully, the Department in its written reply stated as under:

(Rs in Crore)			
Name of the Scheme	BE 2021-22	RE 2021-22	Actual (as on 11.2.2022)
Pharmaceuticals Promotion Development Scheme (PPDS)	2.00	2.00	1.01

5 studies have been approved in FY 2021-22. Part instalments are to be released in FY 2021-22. Few events, seminars, conferences are to be organized. It is expected that entire RE will be utilized till 31st March, 2021."

3.25 On being asked to enumerate the challenges that are being faced by the Department in execution of this scheme and steps that are being taken by the Department to resolve them, the Department gave following reply:

"As such, no challenges are faced in execution of the scheme. The EFC in its meeting held on 24.9.2021 recommended that the sub-schemes of the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), Assistance to Pharmaceutical Industry for Common Facilities (API-CF) and Pharmaceutical Promotion and Development Scheme (PPDS) may be continued as a separate scheme with an outlay of Rs 500 Crore for the period of FY 2021-22 to FY 2025-26. Accordingly, the scheme guidelines for these sub-schemes are being finalized along with financial outlay of the sub-schemes, wherein it is proposed to have a Project Management Consultant for expeditious implementation of the projects in a systematic, professional and transparent manner."

b) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

3.26 The aim of this sub-scheme is to facilitate Pharma Small and Medium Enterprises (SMEs) to upgrade their plant and machinery to World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards, so as to enable them to make world-class high-quality drugs and become globally competitive and markets leaders.

Need for the Scheme:

- a. To support pharma MSMEs for quality / Technology upgradation - Schedule-M / WHO-GMP certification, to enable them become eligible to export to USA and Europe, by supporting for replacement/up-gradation/of the present plant and machinery.

- b. As per available information, out of 6790 SMEs in manufacturing Pharma and API drugs, only 2006 are WHO GMP certified and more than 4500 remain outside WHO-GMP.
- c. PTUAS will motivate many units in SME sector to upgrade themselves for an internationally compliant manufacturing process.

3.27 The Department stated that in view of Non-receipt of applications for financial assistance, only token amount was allocated during FYs 2019-20, 2020-21 & 2021-22.

3.28 On being asked about the challenges that are being faced by the Department in execution of this scheme and steps that are being taken by the Department to resolve them, the Department gave following reply:

"Non-receipt of applications for financial assistance was the challenge in the execution of the scheme. In view of the same, scheme was revamped and Department submitted EFC for approval. The EFC in its meeting held on 24.9.2021 recommended that the sub-schemes of the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), Assistance to Pharmaceutical Industry for Common Facilities (API-CF) and Pharmaceutical Promotion and Development Scheme (PPDS) may be continued as a separate scheme with an outlay of Rs 500 Crore for the period of FY 2021-22 to FY 2025-26. Accordingly, the scheme guidelines for these sub-schemes are being finalized along with financial outlay of the sub-schemes, wherein it is proposed to have a Project Management Consultant for expeditious implementation of the projects in a systematic, professional and transparent manner."

3.29 Further the Committee also asked about the budgetary allocation for the Scheme during 2022-23 and how the same is proposed to be utilised, the Department replied as under:

"BE 2022-23 for PTUAS is Rs 62.00 Crore. The scheme guidelines are being revised as per EFC approval wherein it is proposed to have a Project Management Consultant for expeditious implementation of the projects in a systematic, professional and transparent manner. It is expected that the scheme guidelines will be approved shortly and the application window will be opened soon. The fund will be released to the approved applicant."

c) Assistance to Pharmaceuticals Industry for Common Facilitation Center (previously known as Cluster Development)

3.30 This sub-scheme is implemented in a Public Private Partnership (PPP) mode. Financial assistance under this sub-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.

3.31 Under Assistance to Pharmaceuticals Industry for Common Facilitation Center (previously known as Cluster Development) actual expenditure incurred is only Rs.1.51 Crore against the approved RE of Rs. 15.61 Crore, that is only 15.1 percent funds has been utilized. In this regard the Committee asked about the justification for abysmal performance of the scheme and corrective measures that are being taken by the Department to ensure timely utilization of funds under the scheme, The Department in its written reply stated as below:

"Funds to the approved projects are released in installments as per terms of payment mentioned in the scheme guidelines. Since IPRF did not complete the target for release of 2nd installment, no amount was released to them. Only an amount of Rs 1.51 cr was released to KIDC as 2nd installment. Now release of 2nd installment of Rs 6.51 cr to IPRF is under process. 3rd installment will also be released to KIDC by March 2022. Consultancy Fee to PDIL and NPCCL will also be released by March 31, 2022."

3.32 Regarding the present status of implementation of the projects that have got in-principle approval, the Department submitted following status:

- i. Proposal of Jeedimetla Effluent Treatment Limited (JETL) for Common Effluent Treatment plant of project cost of Rs. 29.91 Cr is under consideration for final approval.
- ii. Proposal of Bulk Drug Manufacturers Association (India) to set up "Advanced Analytical Testing Facility and Training Center" at Jeedimetla, Hyderabad has been rejected.
- iii. Proposal of Sirmour Green Environ Ltd. (SGEL) to set up a Common Effluent Treatment Plant (CETP) at Industrial area Gondpur, Tehsil Paonta Sahib, disttSirmaur Himachal Pradeshise under consideration for final approval.
- iv. Proposal of Inducare Pharmaceuticals and Research Foundation (IPRF) for creation of Common Facility Centre at Pune, Maharashtra has been given final approval. 1st installment has already been released.
- v. Proposal of Kala Amb Infrastructure Development Company to set up a Common Effluent Treatment Plant (CETP) at Industrial area Kala amb Tehsil Nahan, disttSirmaur Himachal Pradesh has been given final approval. 2 installments have already been released."

d) Promotion of Bulk Drug Parks (Assistance to Bulk Drug Industry for Common Facilitation Center)

3.33 The Objective of the scheme is to promote 3 Bulk Drug Parks by providing Grant-in-Aid for creation of World class Common Infrastructure facilities (CIF).Financial assistance of Rs. 1000 Crore per Park or 70% of the cost of the CIF, whichever is less. 90% for NER and Hill States.Total project outlay is Rs. 3000 Crore. Duration of the

Scheme is 2020-21 to 2024-25. Estimated expenditure during current year is Rs. 2.25 crore.

3.34 When the Committee further asked the Department to state the reasons for non utilisation of funds Rs. 36.24 Crore at RE stage under the Scheme during 2021-22 and steps that are being taken for the utilization of Rs.36.24 Crore allocated for the Scheme during 2021-22, the Department gave the following reply:

" 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. Since the selection of 3 States is under process, the amount of Rs 36.24 Crore could not be fully utilized. Further, the amount required under this scheme for the first instalment would be Rs 900 Crore which has been allocated in BE 2022-23."

3.35 Further the Department stated that the allocation for 2022-23 under the Scheme at BE stage is Rs. 900 Crore that has been allocated under the scheme for Promotion of Bulk Drug Parks in BE 2022-23. This amount will be used to give first instalment of Rs 300 Crore each to the 3 selected states for creation of Common Infrastructure Facilities (CIFs) as grant-in-aid.

e) Promotion of Medical Devices Parks (Assistance to Medical Device Industry for Common Facilitation Center)

3.36 The objective of the scheme is to promote 4 Medical Device Parks by providing Grant-in-Aid for creation of Common Infrastructure facilities (CIF). Total financial outlay of Rs.400 Crore. Duration of the Scheme is 2020-21 to 2024-25. Financial assistance is Rs. 100 Crore per Park or 70% of the cost of the CIF, whichever is less. The assistance would be 90% for NER and Hill States.

3.37 Under the sub-scheme "Promotion of Medical Devices Parks" for creation of Common Infrastructure Facilities Rs. 120 Crore is provisioned in BE 2022-23 which will be utilized to provide the 2nd grant to the 4 selected States.

3.38 Under this Scheme the Department is able to spend only Rs. 8.62 Crore out of allocated amount of Rs. 137.02 Crore at RE stage of 2021-22. The Committee asked about the reasons for under-utilization of funds, the Department stated as under:

"In RE 2021-22, Rs. 137.02 Crore is provisioned under the scheme "Promotion of Medical Devices Parks". So far, Rs. 7.50 Crore has been released as second installment to Andhra Pradesh Medtech Zone Ltd (AMTZ), Rs. 1.12 Crore has been released to IFCI Ltd, the Project Management Agency of the Scheme as fee and the first installment of Rs.12 Crore & Rs.30 Crore has been released to States of Uttar Pradesh & Tamil Nadu respectively under the scheme "Promotion of Medical Devices Parks". Hence, Rs. 50.62 Crore has been released so far.

Remaining amount shall be released to AMTZ as third installment (Rs 7.5 Crore), IFCI Ltd as service fee, first installment of Rs 30 Crore each to the States of Himachal Pradesh and Madhya Pradesh. Also, part of first installment of Rs 18 Crore shall be released to State of Uttar Pradesh."

3.39 On being asked about the justification for non-utilization of Rs. 13.58 Crore for the sub-scheme Assistance to Medical Device Industry for Common Facilitation Centre during 2020-21, the Department stated as follows:

" Out of BE Rs.7.50 Cr in the **FY 2020-21**, Rs.7.49Cr was utilized under the sub-scheme Assistance to Medical Device Industry for Common Facilitation Centre only, as 1st GIA to AMTZ.

In RE Stage, Rs. 21.05 Crore was allocated to Assistance to Medical Device Industry for Common Facilitation Centre and the same was sought under Second Batch of Supplementary Demand for Grants FY 2020-21. But at the vetting time the same could not be verified as the names of the two sub-scheme being similar, it was misinterpreted between Assistance to Bulk Drug Industry for Common Facilitation centre and Assistance to Medical Device for Common Facilitation centre. And MoF gave permission for re-appropriation in the same sub-scheme i.e Assistance to Bulk Drug Industry for Common Facilitation centre instead of Assistance to Medical Device for Common Facilitation Center."

C. New Production Linked Incentive (PLI) Schemes

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:

3.40 The scheme provides for financial incentives to manufacturers selected under the scheme for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). The scheme provides for incentives on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940 Crore and the tenure of the scheme is from FY 2020-2021 to 2029-30.

3.41 Under this Scheme the Department is able to spend only Rs. 0.22 Crore out of allocated amount of Rs. 2.79 Crore at RE stage of 2021-22 which is only Rs. 7.89 percent of the allocated RE amount. When the Committee asked about the reasons for the same, the Department stated, "the amount available in RE 2021-22 is for releasing consultancy fee to PMA. No fee was released to PMA in view of awaiting opening of Professional Services head. The fund will be utilized by 31st March 2022."

3.42 On being asked about the response from the Pharmaceutical sector for the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of

critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs), the Department stated that "Very good response has been received from the pharmaceutical sector. Total 239 applications were received in Round 1 and Round II. 49 applicants have been approved with committed investment of Rs 3,685.38 Crore"

3.43 Further the allocation for the sub- Scheme at BE stage of 2022-23 is Rs.390 Crore. Regarding utilization of this allocation, the Department stated in a written reply, "Incentives are to be released to the approved applicants on sales of eligible products under the scheme. 49 applicants have been approved under the scheme. A total of 8 plants have been commissioned till date."

3.44 A representative of the Department of Pharmaceutical explained about the features of the Scheme during oral evidence on Demands for Grants 2022-23, as below:

"The first PLI scheme is for key starting materials, drug intermediaries, active pharmaceutical ingredients, which we commonly call bulk drugs. These are precursor to the formulations. We are already exporting some of the bulk drugs to other countries but we are dependent on imports also. We analysed some critical APIs where the dependency is more than 80 per cent. Then, we arrived at some 53 APIs out of which we have created a scheme for 41 eligible products. We have put an incentive there. We have two types of manufacturing. One is on fermentation basis and another is chemical synthesis based. We have given more incentive for the fermentation-based products because it involves much more support both on the gestation and technical side. Accordingly, we have given the incentives. These products have been notified. For 41 products, that we have notified both in round-1 and round-2, we have selected 49 applications. Out of 49, 8 have already been commissioned and they have started manufacturing. The remaining 12 will also be commissioned in March itself. I just want to apprise the Committee that despite the 41 eligible products notified, we **did not get full applications for 10 products**. So, we got a third round also which we are planning to complete. Last date is 13th March. We are in touch with the industries to tell them that these products are important so that it will reduce our import dependency and we will also become self-reliant."

3.45 In regard to the above, the Committee observed that the Department should look into the reasons of not getting enough applications and try to resolve the matter. In reply, the Secretary Department of Pharmaceutical furnished the following clarification:

"Regarding the API which Madam has mentioned, out of 41 for 33, we found bidders and as I said, some have also started production. In eight where we have not got bidders, most of them are fermentation based. Out of those eight, the list was prepared at that time, now, when we are talking to the industry as to why they are not able to apply, etc, the industry is of the opinion that a few of these APIs do not have much market any more. They mention neomycin, gentamycin, etc. For the others, in fermentation, the technology is difficult, large scale is

required and costs are high. As mentioned by the hon. Member also, other countries are providing very high level of support in power cost, water cost and perhaps the environmental costs may be much lower in other places. We do not know about it. But in India, we depend on the States to provide those kinds of incentives. However, some private players have shown interest. We also tried to analyse, as Madam has mentioned, the reason why people are not coming forward for these eight. We found that one was lack of market, second is concerns about cost competitiveness and the third is the investment and scale requirements. We have now talked to some industries to come forward. I may share that it is possible that three or four may still be left out. Then we will go to the Cabinet to drop these and take other products because the list is approved by the Cabinet. I do not want to go to Cabinet unless I have explored all possible options”.

(ii) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device:

3.46 The domestic medical devices industry faces challenges related to considerable cost of manufacturing disability, among other things, on account of lack of adequate infrastructure, domestic supply chain and logistics, high cost of finance, inadequate availability of quality power, limited design capabilities and low investments on R&D and skill development. With a view to address these challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies, a scheme called “Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices” was approved by the Government of India on 20.03.2020. The guidelines for implementation of the scheme were issued on 29.10.2020. The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of ₹ 3,420 Crore. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five years.

3.47 During 2021-22 under this scheme RE is Rs. 3.31 Crore, and actual expenditure is Rs. 2.13 Crore which is only 64.20 percent utilization. On being asked about the reason for the variation in RE and actual expenditure, the Department stated that " BE 2021-22 is Rs 2.36 Crore, RE 2021-22 is Rs 3.31 Crore and Actual expenditure till date is Rs 2.13 Crore. Fixed Quarterly fee of Rs 50,00,000/- for quarters ending December 2021 and March 2022 are to be released to PMA. RE 2021-22 will be utilized completely by March 2022."

3.48 Further the allocation for the sub- Scheme at BE stage of 2022-23 is Rs.216 Crore. In regard to the utilization of the same, Department stated, “Incentives are to be released to the approved applicants on sales of eligible products under the scheme. 21 applicants have been approved under the scheme.”

(iii) Production Linked Incentive (PLI) Scheme for Pharmaceuticals

3.49 The Union Cabinet in its meeting on 11.11.2020 approved 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.

3.50 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) 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.

Small Industries Development Bank of India (SIDBI) has been selected as Project Management Agency (PMA) for PLI Scheme for Pharmaceuticals through open bidding and for selection of applicants under the scheme, vide OM dated 01.11.2021, a Selection Committee has been constituted under the Chairpersonship of Secretary, DoP. After scrutiny of proposals received, 11 applicants under Group A, 9 applicants Under Group 'B' and 35 applicants under Group 'C' category have been selected. Under this scheme Rs. 1.24 Crore have been released as service fee to SIDBI, the Project Management Agency. The remaining amount of Rs 1.76 Crore has been surrendered since the same is not required during FY 2021-22.

D. Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) /Jan Aushadhi Scheme - MH 2552+ MH 2852

3.51 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 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. The first Jan Aushadhi Kendra was opened on 25.11.2008 at Amritsar, Punjab. The scheme didn't take off and by 31.03.2014, only 80 stores were functioning. In 2015, Committee of Secretaries set up by Hon'ble Prime Minister to deliberate on health related issues had recommended that "Jan Aushadhi Kendras" should be expanded.

Accordingly, franchisee like model was adopted and an intensive media campaign in national and regional newspapers inviting individual entrepreneurs to apply for establishing and running PMBJP Kendra was undertaken. In response, the applications received were scrutinized and eligible applicants were assisted with drug license and other infrastructure facilities to open the Kendras. The gate was opened for private participation in procurement as well as sale of medicines.

The target of opening 3000 Kendras was achieved in December 2017. Further, revised target of total 6000 outlets was achieved in March, 2020. As on 31.12.2021, 8640 Janaushadhi Kendras are functional across the country. Product basket of PMBJP comprises 1451 drugs and 240 surgical equipment. PMBJP has decided to include AYUSH products, specifically 75 Ayurvedic drugs in the product basket of the Pariyojana. An e-tender has been prepared by PMBI for procurement of the same.

3.52 The physical and financial outlay and outcomes for the last three years, viz., 2019-20, 2020-21 and 2021-22 of the PMBJP Scheme are as under:-

FY	Physical Outlays (Number of Kendras)	Physical Outcomes (Number of Kendras)	Financial Outlays (In Rs. Crore)	Financial Outcomes (in Rs. Crore)	Product Basket Outlay (Medicine, Surgicals)	Product Basket Outcomes	Sale Target Outlays	Sale Target Outcomes	No. of Ware-houses Outlays	No. of Ware-houses Outcomes
2019-20	6300	6306	42.00	35.51	-	802 155	-	433.61	-	4
2020-21	7300	7557	65.00	65.00	1400 220	1449 204	500	665.83	4	3

2021-22	8300	8683 (As on 15.02.2022)	68.50	56.30 (As on 15.02.2022)	1600 240	1451 240	625	751.42	5	3*
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* One more Warehouse will be opened during 2021-22.

3.53 Further the Committee 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 2022-23

"The target for the year 2022-23 is to open 1,000 Kendras and enhance the product basket up to 1800 medicines and 280 surgical. In order to popularize the Scheme and expand opening of Kendras in the aspirational districts, Himalayan, Island territories and the North-Eastern States, a new incentive plan has been launched. Such Kendras now get a one-time grant of ₹ 2 lakh in addition to normal incentives, as under:

- i. ₹ 1.50 lakh reimbursement of furniture and fixtures.
- ii. ₹ 0.50 lakh as reimbursement for computer, internet, printer, scanner etc.

Under PMBJP, all 739 districts of the country have already been covered. However, PMBI has released various newspaper advertisements for inviting applications for opening of PMBJKs in July, 2021 for opening of PMBJKs in 265 districts of the different States where coverage is less."

3.54 On being asked 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, the Department in its written reply stated as under:

"One time grant is given for opening of Kendras in the aspirational districts, Himalayan, Island territories and North-Eastern States. Special attention is also being accorded to districts having less coverage and applications invited from such areas separately."

3.55 During oral evidence on Demands for Grants 2022-23, the Chairperson observed that entrepreneurs face difficulties to come forward to set up Jan Aushadhi outlets as it is not very profitable because they are not allowed to keep branded products. Sometimes, people do not understand what is generic medicines and they want exactly what the doctors prescribes. In this regard, the Secretary, Department of Pharmaceuticals responded as follows:

"Madam, I will try to respond in two, three measures which are possible and are being taken because this is of interest. People have shown interest towards Jan Aushadhi Kendras. Madam, we have been steadily growing. So, there is interest.

Large number of shops are there in UP, Karnataka, Kerala, Tamil Nadu. Tamil Nadu may be third in terms of number of shops. They have got lots of shops. More shops are possible. We have two ways in which we can increase. From time to time, we are writing to the State Government to open the shops in the government hospital or community health centre because there are a lot of footfalls and the shop will become viable because many people come and mostly belonging to middle class and lower middle class come to our government facilities and they will get the benefit of cheaper drugs also. That is one we keep writing. That is one opportunity. Some States have opened a lot of Jan Aushadhi Kendras in the government premises, some States have not done it. That is one opportunity.

Secondly, the shop has to be viable. After all, we provide 15 per cent incentive only till he reaches Rs.5 lakh. After that the entrepreneur has to be viable on his own. Therefore, what we are now doing is instead of everybody coming and keeping the shop in the same District head quarter, we advertised for those Districts where the number of shops is less than five. We are trying to now write to the District Magistrates. The CEO already wrote to the District Magistrates to identify entrepreneurs if there are less than five shops in his/her District, and we will be ready to give more shops. However, when we approve the shops, we do look at the viability. We do not want the shop to fail because he is an entrepreneur and he will put in his money. So, as a partner we have to ensure that the shop is successful. So, we look at viability. Then he must have a pharmacist registration and he has to obtain the drug licence from the State Drug Controller. As mentioned, we should try to do more Aspirational Districts because that additional Rs.2 lakh incentive is available. If we have women, divyang, SC/ST entrepreneur also additional incentive is available. Where it is not viable, we can help in that way. So, we are very much open. We want that this should be enhanced. Earlier, Committee at some time also said that there should be one for every 10,000 people. That is not viable. One for about three to four lakh people may be viable. These are 8,000 shops whereas the total number of retailers in India is nine lakh. Plus, here we only do the sale of generic medicines. Therefore, we should target in a way that every shop is viable. So we are very much open, Madam, we will be very happy if we get names also or locations. We will personally follow up.”

CHAPTER-IV

PUBLIC SECTOR UNDERTAKINGS

4.1 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 & Pharmaceutical Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL).

Timeline of Cabinet Decision on Closer/Revival of Pharma PSUs

4.2 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 might comprehensively examine the status of all pharmaceutical companies in the public sector and suggest the future course of action. After detailed deliberations, the decisions of the meeting held in December 2016 and later are as follows:

- Cabinet decision on 28.12.2016
 - Sale of surplus land to meet outstanding liabilities and then
 - Closure of IDPL & BCPL
 - Strategic disinvestment of BCPL & HAL
- CCEA decision on 01.11.2017
 - Strategic disinvestment of 100% GOI equity in KAPL.
- Cabinet decision on 17.07.2019 :
 - Sale of land as per revised DPE's guidelines dated 14.06.2018
 - Providing budgetary support of Rs 330.35 Crore for meeting the employees' liabilities
 - Constitution of a Committee of Ministers (CoM) for taking all decisions pertaining to closure/ strategic sale including the sale of assets and clearance of outstanding liabilities.
- Committee of Ministers (CoM) meeting held on 27.05.2021, the decisions of the meeting and status are as follows:

SI.No.	COM decision of 27.05.21	Status of Implementation
1	Budgetary support of Rs. 139 Crore- Rs. 118.00 Crore for HAL and Rs.	Sanction of Rs.139 Crore received in the first supplementary of 2021-22 and

	21.00 Crore for RDPL, as loan at supplementary budget of 2021-22 to clear pending employees' dues.	Rs.21 Crore to RDPL and Rs.118 Crore to HAL released on 28.10.2021 for clearing pending employees' dues & interest payment to EFFO
2	Return of 833.38 acres of leasehold land of IDPL at Rishikesh including 1.01 acres of freehold land, to the Government of Uttarakhand and to pay the agreed electricity dues of Rs. 46.39Crore of UPCL from sale proceeds of assets at other locations.	The lease of the land expired on 27.11.2021. The matter has been taken up with the State Government for the early return of the land.
3	Transfer of 50 acres of land out of IDPL plant Site-I, Hyderabad to NIPER, Hyderabad for setting up Regular Campus at Reserve price of Rs. 889.50 Crore, making book adjustment against Government of India Loan to IDPL/notional grant of NIPER, Hyderabad.	The Government has waived off Gol loan of IDPL amounting Rs.889.50 Crore through book adjustment and the land has been formally handed over to NIPER, Hyderabad. IDPL is providing necessary support in getting the land transferred under the relevant revenue record.
4	Transfer of 20.55 acres of land of BCPL at Panihati, Kolkata to NIPER Kolkata for setting up Regular Campus at Reserve Price of Rs. 345.24 Crore and waiver of all Government of India Loan to BCPL of Rs. 193.71 Crore along with accrued interest.	The Government has waived off Gol loan of BCPL amounting to Rs.193.71 Crore through book adjustment. Physical verification of the land has been done and Conveyance Deed prepared. The process of registration of the transfer has been started.
5	Sale of 3.5 acres of surplus land of HAL to EPFO.	3.5 acres of HAL land sold to EPFO at Rs.42 Crore.
6	Third Party Evaluation of assets of PSUs to discover realistic floor price of the assets of PSUs	A Committee has been constituted under the Chairmanship of Secretary (P) on 25.11.2021 with members from DIPAM & Department for selection of independent asset valuer for separate valuation of assets of Pharma PSUs. As recommended by the Committee, Request for Proposal (RFP) is being issued for engagement of Independent Asset valuers.

Assistance to PSUs (Loan) Scheme - MH 6857

4.3 While considering the Proposed and Approved Budget Estimate Allocations (2022-23) under Assistance to PSUs (loan) Scheme MH 6857 the Committee asked about the reasons for huge variation of Rs. 8021.48 Crore, as the proposed BE is Rs. 8026.78 Crore and the allocated fund is only Rs. 5.30 Crore at BE stage by the Ministry of Finance for the year 2022-23 and also sought reasons for seeking huge allocation in respect of IDPL and HAL, the Department of Pharmaceuticals in their written reply clarified as under:

"PSU Division proposed for Rs. 8026.78 Crore for meeting various outstanding liabilities like secured liabilities of various banks and other unsecured liabilities in respect of IDPL and HAL as the same was not covered under the budgetary support of Rs. 330.35 Crore provided in 2019 as per recommendation of the Cabinet. However, against the proposed amount, only Rs.5.30 Crore, the minimum amount needed for meeting contingent expenditure, court cases etc. has been provided in BE 2022-23."

4.4 When the Committee asked about the reasons for the Department's proposal for seeking funds under Assistance to PSUs (loan) Scheme, after the Cabinet decision on 28.12.2016 and later on 17.07.2019 on Pharma PSUs loans that the expenditure on the closed/loss making PSUs is to be met from the sale of land of Pharma PSUs to government agencies and other entities as per Department of Public Enterprises (DPE's) guidelines dated 14.06.2018 for meeting the employee's liabilities (Salary/VRS), the Department of Pharmaceuticals furnished the following written reply:

"As decided by the Cabinet, first pending liabilities including employee's liabilities are required to be cleared and cleansed the balance sheet of the pharma PSUs before closure or strategic disinvestment. Pending sale of land of the PSUs, and since operation of RDPL and IDPL has been closed and HAL is a loss making PSU, budgetary support has been sought to meet the pending salary and retiral dues of the employees including VRS."

4.5 When the Committee further asked that the Department has proposed an amount of Rs. 6988.50 Crore for Indian Drugs and Pharmaceuticals Ltd (IDPL) and Rs. 1038.24 Crore for Hindustan Antibiotics Ltd (HAL) however the allocated amount at BE stage for 2022-23 is only Rs. 4.00 Crore and Rs. 1.26 Crore respectively. The Committee asked for reasons for the variation in proposed and approved allocation and its impact on payment of pending salaries/VRS of regular employees/payment to EPFO and other claims of the employees, the Department of Pharmaceuticals in their written reply stated as under:

"PSU Division has proposed funds as sought by IDPL (Rs. 6988.50 Crore) and HAL (Rs. 1038.24 Crore) for meeting various liabilities like outstanding liabilities of various banks, financial institutions and unsecured liabilities. The pending employees dues (serving/retired/VRS) of IDPL, HAL and RDPL have been

settled by providing budgetary support as loans in FY 2019-20, 2020-21 & 2021-22 and EPFO interest payment of HAL employees (Rs. 76 Crore) released in 2021-22. The minimum amount needed for meeting contingent expenditure, court cases etc. has been provided for HAL and IDPL in BE 2022-23."

4.6 On further seeking the rationale for only token allocation of Rs. 0.01 Crore for Bengal Chemicals & Pharmaceuticals (BCPL) and Rajasthan Drugs and Pharmaceuticals Ltd (RDPL) at BE stage for the year 2022-23, the Department in their written reply gave following justification:

"BCPL has no employees dues/other liabilities and no funds has been sought by the company. As regards RDPL, fund has been released for clearing the pending retiral dues of employees as per Cabinet decisions dt. 17.07.2019/CoM dt. 27.05.2021. Further, a proposal from State Govt. of Rajasthan has been received requesting the transfer of RDPL to the state which is under consideration of the Government. As such, no fund has been sought for RDPL in BE- 2022-23."

4.7 Further the Department of Pharmaceuticals stated the following present status of functioning/closure/strategic sale/revival of IDPL, RDPL, HAL and BCPL including clearance of salary and other payment dues to employees:

" Indian Drugs & Pharmaceutical Limited (IDPL) - Revival Package

The Rehabilitation Scheme approved by Board for Industrial and Financial Reconstruction (BIFR) in the year 1994 failed as full funds could not be released as envisaged, capital restructuring not done; banks did not provide adequate working capital requirements; working capital funds were diverted to meet fixed expenses of subsidiary units and land could not be sold. BIFR ordered winding-up of the company in December, 2003. As per directions of the Appellate Authority for Industrial Financial Reconstruction (AAIFR), a Road Map for revival of the Company was prepared. The same was placed before the Cabinet Committee on Economic Affairs (CCEA) and referred to a Group of Minister (GoM), which in its meeting held on 11.10.2007 advised that IDPL's revival plan should be based on public interest goals and ensure the viability of the Company. Subsequent thereto, IDPL appointed M/s E&Y as Consultant to carry out the feasibility study. On the basis of its report, a revised up-dated Debt Restructuring Plan was prepared. The matter was subsequently considered by a Committee consisting of three senior Ministers and based on their recommendations, the Union Cabinet decided on 28.12.2016 to close the company after meeting all its liabilities from proceeds of sale of surplus land to Government agencies.

Present Status

- (i) IDPL Plant at Rishikesh is to be returned back to the State Government of Uttarakhand and necessary action for return back is underway.

- (ii) CoM had inter-alia approved Transfer of 50 acres of land out of IDPL plant site-I, Hyderabad to NIPER, Hyderabad for setting up regular campus at Reserve price of Rs. 889.50 Crore making book adjustment against Govt. of India loan to IDPL/notional grant to NIPER, Hyderabad. Accordingly, Necessary orders to this affect has been issued by the Department vide order dt. 14.12.2021.
- (iii) Follow up action of closure activities of IDPL plant at Hyderabad & Gurgaon and its subsidiaries is underway.
- (iv) As per direction of Committee of Ministers (CoM), in its meeting dt. 27.05.2021, Department has taken steps for floating Request for Proposal (RFP) for independent valuation of assets of freehold land of IDPL at Hyderabad & Gurgaon to arrive at realistic floor price before sale of land.

Releases made to IDPL:-

- (a) As per Cabinet decision dt. 17.07.2019 RS. 6.50 Crore released in FY 2019-20 and 2020-21 as loan for meeting employees liabilities/VRS
- (b) Rs. 70 lakh released as loan for meeting VRS dues of ODCL employees
- (c) Rs. 1.30 Crore released as loan for returning the retained amount of Ex-employees of IDPL Rishkesh& Chennai plants on vacation from the company's quarters.

Rajasthan Drugs & Pharmaceuticals Limited (RDPL)- Revival Package

The production of the company stopped after fire at its plant in October, 2016. The company proposed a revival plan to start the production. However, based on recommendation of the three senior Ministers, the Union Cabinet on 28.12.2016 decided to close the company after meeting up all its liabilities from sale of surplus land to Government agencies."

Present Status

The proposal of transfer of RDPL to State Government of Rajasthan is under active consideration in the Department.

Releases made to RDPL:-

- i. Rs. 43.70 Crore approved by Cabinet on 17.07.2019 released as loan in FY 2019-20 to meet employees unpaid salary/VRS liabilities.
- ii. Rs. 21.00 Crore approved by CoM released in 2021-22 for payment of Leave Encashment, Gratuity and other perk & allowances of RDPL retired employees.

Hindustan Antibiotics Limited (HAL)- Revival Package

A revival package of Rs. 137.59 Crore was sanctioned in the year 2007. Further, the Government waived off loan and interest amounting to Rs. 118.26 Crore. However the revival plan could not succeed. The company submitted Second Rehabilitation plan in the year 2014. The Cabinet in its meeting held on

21.12.2016 decided to waive Government of India's loans and interest amounting to Rs. 307.23 Crore (Principal - Rs.186.96 Crore and Interest - Rs.120.27), deferment of various dues amounting to Rs. 128.68 Crores and sanctioned Rs. 100 Crore for payment of salary, wages and critical expenses. Subsequently, based on recommendation of the three senior Ministers, the Union Cabinet on 28.12.2016 decided to strategically sell the company after meeting up all its liabilities from sale of surplus land to Government agencies.

Releases made to HAL:-

- i. HAL (87.70 acres), 3.5 acres of land of HAL has been sold to EPFO at negotiated price of Rs. 42 Crore.
- ii. The balance surplus land is to be undertaken for sale after independent valuation, as per direction of Committee of Ministers (CoM), in its meeting dt. 27.05.2021. Department has taken steps for floating Request for Proposal (RFP) for independent valuation of total land of HAL to arrive at realistic floor price before sale of balance surplus land.

Present Status

- (a) Rs. 280.15 Crore (Rs. 134.35 Crore – employees dues + Rs. 145.80 Crore – VRS) approved by Cabinet on 17.07.2019 was released in FY 2019-20.
- (b) Rs. 118.00 Crore approved by CoM was released in FY 2021-22. - Rs. 76.00 Crore for payment to EPFO (interest amount), Rs. 42.00 Crore for payment of Medical claims, Gratuity, Leave encashment, LTC claim of HAL retired employees/VR employees.

Bengal Chemicals and Pharmaceuticals Limited (BCPL)- Revival Package

Government sanctioned a Revival Package of Rs.440.60 Crore in the financial year 2006-07 consisting of Rs 233.41 Crore towards waivers of loans and interest on past loans as on 31-03-2005 and Rs. 207.19 Crore towards infusion of funds. Government sanctioned a Revival Package of Rs.440.60 Crore in the financial year 2006-07 consisting of Rs 233.41 Crore towards waivers of loans and interest on past loans as on 31-03-2005 and Rs. 207.19 Crore towards infusion of funds.

Present Status

Committee of Ministers (CoM), in its meeting dt. 27.05.2021 had inter-alia approved transfer of 20.55 acres of land of BCPL at Panihati, Kolkata to NIPER Kolkata for setting up regular campus at reserve price of Rs. 345.24 Crore and waiver off all Govt. of India loan to BCPL of Rs. 193.71 Crore along with accrued interest. Accordingly, necessary orders to this effect has been issued by the Department vide order dt.14.12.2021. The issue of strategic sale is sub-judice in Hon'ble High Court of Calcutta. Steps are being taken by the Department for early disposal of case."

4.8 A representative of Department of Pharmaceutical informed the Committee about PSUs under the Department during oral evidence on Demands for Grants, 2022-23 as under:

“Our Department has five PSUs- Indian Drugs and Pharmaceuticals Limited, Rajasthan Drugs and Pharmaceuticals Limited, Hindustan Antibiotics Limited, Karnataka Antibiotics and Pharmaceuticals Limited, and Bengal Chemicals and Pharmaceuticals Limited. Over the last five years or so, the Government has taken a number of decisions at different points of time. I will take you through the different decisions taken so far. In December, 2016, based on the recommendations of a Group of Ministers, a decision was taken with regard to four PSUs, namely IDPL, RDPL, HAL, and BCPL. It was decided that we should first go for sale of surplus land or assets to clear all the outstanding liabilities and then close two PSUs, namely, IDPL and RDPL, and go for strategic disinvestment of two other PSUs, that is, BCPL and HAL. Then in 2019, since by that time there was a new guideline from DPE about sale of assets, the decision was slightly adjusted so as to follow this new guideline of 2018. The Cabinet recommended for a budgetary support of Rs. 330.35 Crore to clear all pending salaries etc. A committee of ministers was also constituted to take all decisions pertaining to closure or strategic sale of PSUs including clearance of outstanding liabilities. As you know, KAPL is a joint company. Government of India holds shares of up to 59 per cent and Karnataka Government through KSIIDC holds 41 per cent. The CCEA decided in 2017 that the Government of India should sell its 100 per cent shares. There was a meeting of committee of ministers in May, 2021 and a number of decisions were taken. In the next slide, we will give a brief update of the decisions and what we have done so far.

First, a budgetary support of Rs. 139 Crore was recommended to clear the retired employees’ dues of RDPL and HAL. Accordingly, we have also got the money in First Supplementary Demand for Grants 2021-22 and we have also released the money to clear the dues of retired employees. Second, there was the return of 833.38 acres of leasehold land of IDPL at Rishikesh. IDPL has lands at three locations – Gurugram, Hyderabad, and Rishikesh. The land at Rishikesh is leasehold land. As per DPE guideline, we have to return the leasehold land to the respective State Government. The third decision was regarding the transfer of 50 acres of land of IDPL from the plant site of Hyderabad to NIPER. The valuation was Rs. 889.5 Crore. The Government of India has waived off the loan of IDPL through book adjustment. The transfer process is on and the registration process has been initiated. The fourth decision is regarding the transfer of 20.55 acres of surplus land of BCPL to NIPER. This process is on and the Government has also waived off BCPL’s loan of Rs. 193.71 Crore through book adjustment. Regarding HAL, there was a decision to sell 3.5 acres of surplus land to EPFO. This land has been sold to EPFO and we have got Rs. 42 Crore at negotiated price. The fifth decision was regarding the selling of assets of PSU. The committee recommended that we should go for third party evaluation so that we can discover the realistic floor price of assets and go for bidding of land. For that, we have constituted a committee under the chairmanship of Secretary, and representatives from DIPAM. The Committee has approved the RFP. So, we are in the process of floating the RFP.”

4.9 Further the Secretary Department of Pharmaceuticals during the oral evidence also clarified the new initiatives introduced in HAL for its revival and KAPL success in getting benefits of Production Linked Incentives (PLI) scheme which is stated below:

"Honorable Member asked about PSUs. HAL had attempted revival twice. For the second time, the strategic sale has been decided in 2016. We have provided it. Now we are looking for sale partner but for that the Government of India has brought new guidelines. We're going to work under it. Strategic sale also means a kind of revival that we make the company more strong and strong by bringing a private investment. Here is MD of HAL. She has already started the work of introducing new products at HAL. They have launched many new products in the context of COVID. She has also strengthened the marketing arm of HAL. It is not that it is dormant state. All the efforts are being done. KAPL applied in PLI so we have taken KAPL in PLI."

4.10 Regarding 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 submitted following information:

"As per decision of the Union Cabinet, RDPL and IDPL are under closure and the information for remaining three PSUs are given below:

KAPL

KAPL signs Memorandum of Understanding (MoU) with Department of Pharmaceuticals every year. The MoU ratings for the last 10 years are as follows:

Year	Rating
2010-11	Excellent
2011-12	Very Good
2012-13	Very Good
2013-14	Good
2014-15	Very Good
2015-16	Very Good
2016-17	Very Good
2017-18	Poor
2018-19	Good
2019-20	Very Good
2020-21	Good

BCPL : The assessment ratings for the last ten years are as follows:

Year	Rating
2020-21	NA#

2019-20	NA\$
2018-19	NA\$
2017-18	NA\$
2016-17	Very Good
2015-16	Excellent
2014-15	Good
2013-14	Poor
2012-13	Poor
2011-12	Poor
2010-11	Poor

:- As per instructions of DPE, BCPL has submitted all the requisite information on DPE's online MoU Portal. The signing of MoU is pending at the end of Govt.

§ :- Due to the Cabinet Decision dated 28th December, 2016 regarding Strategic Sale of BCPL. The Administrative Ministry vide letter under F.No.53017/10/2017-PSU(Pt) dt.28th June, 2017 made representation to DPE for granting exemption to BCPL for signing MoU.

HAL : The assessment ratings are as follows:

Year	Rating
2020-21	Good
2019-20	Fair
2018-19	Poor
2017-18	Good
2016-17	Good
2015-16	Poor

Assistance to PSU (loan) Budget Utilization (2021-22)

4.11 The actual utilization as on 04.01.2022 for IDPL, HAL and RDPL is Rs. 0.70 Crore, Rs. 118.00 Crore and Rs. 21.00 Crore respectively against the allocated amount of Rs. 2.00 Crore, Rs. 122.09 Crore and Rs. 24.00 Crore at RE stage during the year 2021-22. In this regard, when the Committee asked whether the Department will be able to utilize the funds fully by the end of the financial year 2021-22, the Department in their written reply stated as below:

"Yes. Rs.118 cr to HAL and Rs.21 cr to RDPL allocated in 1st Supplementary Demands for Grants 2021-22 has already been released vide sanction orders dt.28.10.2021. Against Rs. 9.12 cr allocated in BE-2021-22, Rs.6.09 cr has already been utilized. It is proposed to re-appropriate Rs. 3.00 Crore from RDPL to IDPL after receiving re-appropriation orders. Balance Rs. 3 lakh (Rs. 1 lakh

each in respect of BCPL, BIL & SSPL) is proposed to be surrendered being token amount."

First Batch of Supplementary Demands For Grants (2021-2022) and Its Impact on Assistance to PSU Scheme

4.12 During the Financial Year (2021-22), the proposed 1st batch of Supplementary Demand for Grant is as under:

(Rs. In Crore)		
	Proposal under 1st Batch of Supplementary Demand for Grants FY 2021-22	
	Revenue	Capital
Bengal Chemicals and Pharmaceuticals MH 2852	193.71	
Indian Drugs and Pharmaceuticals Ltd MH 2852	889.50	
Hindustan Antibiotics Ltd (HAL) MH6857		118.00
Rajasthan Drugs and Pharmaceuticals Ltd (RDPL) MH 6857		21.00
Total	1083.21	139.00

4.13 Ministry of Finance has approved total cash supplementary of Rs. 1222.21 Crore in the 1st Batch of Supplementary Demand for Grants FY 2021-22. Out of which, Rs. 1083.21 Crore was allocated under Revenue Section for waiver of Loan of Indian Drugs and Pharmaceuticals Limited (IDPL) that is Rs. 889.50 Crore against transfer of 50 acres of land out of IDPL Plant Site-I, Hyderabad to National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad and (ii) Waiver of Government of India Loan that is Rs. 107.49 Crore and accrued interest of Rs. 86.22 Crore of Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) against transfer of 20.55 acres of land at reserve price of 345.24 Crore to National Institute of Pharmaceutical Education and Research (NIPER), Kolkata. Out of Rs.139 Crore under Capital Section MH 2852 – Rs.118.00 Crore for HAL and Rs. 21.00 Crore for RDPL, as loan at Supplementary budget of 2021-22 to clear pending employees' dues.

4.14 In this regard the Committee asked about the status of utilization of Supplementary Grant sought by the Department with respect to Capital Expenditure of Rs 118.00 Crore for HAL and Rs. 21.00 Crore for RDPL during the year 2021-22, the Department in their written reply stated as under:

- “(i) Rs. 118.00 Crore sanctioned in the First Supplementary Demands for grants of 2021-22 was released as loan to HAL vide DoP sanction order dated 28.10.2021. Rs. 76.00 Crore for payment to EPFO (interest amount) and Rs. 42.00 Crore for payment of Medical claims, Gratuity, Leave encashment, LTC claim of HAL retired employees/VR employees.

- (ii) Rs. 21.00 Crore sanctioned in the First Supplementary Demands for grants of 2021-22 as loan was released to RDPL vide DoP sanction order dt.28.10.2021 for payment of Leave Encashment, Gratuity and other perk & allowances of RDPL retired employees."

4.15 Further, the Committee asked information regarding future expansion projects of profit making BCPL and how 20.55 acres of land transfer to NIPER Kolkata will impact the surplus land pool required for future projects of BCPL, the Department in their written reply stated that "BCPL has identified the said 20.55 acres of land at Panihati, Kolkata as surplus for sale. Further, the expansion plan such as setting up of the Anti Snake Venom Serum Plant (ASVS) is proposed at Maniktala. Thus, transfer of land of 20.55 acre at Panihati, Kolkata to NIPER, Kolkata will not impact future expansion plan."

OBSERVATIONS/RECOMMENDATIONS

Recommendation No. 1 : Budgetary allocation for the Department of Pharmaceuticals

The Committee note that a gross budgetary allocation of Rs.2244.15 Crore has been made for the Department of Pharmaceuticals at Budget Estimate (BE) stage of 2022-23 against the outlay of Rs.10383.25 Crore proposed by the Department for the year. In comparison, the Gross Budgetary allocation for the year 2021-22 was Rs. 470.41 Crore against the proposed outlay of Rs.2600.52 Crore which was only 18% of the outlay proposed by the Department and this time it has increased to 21.6%. Even though the actual allocation for the year 2022-23 is very less when compared to the demand of the Department, the major chunk of this allocation has been made for Central Sector Schemes of the Department. Against the proposal of Rs.2313.02 Crore, an allocation of Rs. 2202.50 Crore has been made for the Central Sector Schemes of the Department. For the Heads relating to the “Development of Pharmaceutical Industry”, Rs.1729.00 Crore has been allocated against the demand of Rs.1767.02 Crore of the Department. Under the Capital Section of “Assistance to PSUs” , the Department demanded Rs.8026.78 Crore but only an allocation of Rs.5.30 Crore has been made at the BE stage of 2022-23. Since the demand for grants of the Department for implementing its developmental schemes has almost been fully met by the budgetary allocation, the Committee feel that the ball is now in the court of the Department. Unlike previous years, this year the hands of the Department have been strengthened with the requisite amount of budgetary allocation by the Ministry of Finance. Now the Department has to prove its mettle

through effective implementation of all its development schemes. In this regard, the Committee recommend that an annual action plan with monthly achievable targets should be chalked out by the Department in respect of all the developmental schemes for which requisite amount of budgetary allocation has been made under Major Heads 2852 and 2552 and concrete steps should be taken for achieving targets under each of the developmental Schemes for timely and resourceful utilization of budgetary allocations made for the year. An effective monitoring of implementation of each of the development Schemes should be made at highest level in the Department and it should be ensured that the targets fixed for each of the Schemes are achieved in a time bound manner during the year 2022-23 through the full utilization of budgetary allocation. Progress made in this regard should be intimated to the Committee.

Recommendation No. 2 : Construction of campuses for National Institute of Pharmaceutical Education and Research(NIPER)

The Committee note that an allocation of Rs.395.00 Crore has been made for NIPERS (in MH 2552 + 2852) against the proposal of the Department for Rs.440.00 Crore for 2022-23. The fund allocated by the Ministry of Finance will be utilized for construction of NIPER Campuses at Raebareli, Ahmedabad, Kolkata, Hyderabad and Hajipur and also for purchase of equipments/meeting recurring expenditures of the institutes. As far as construction of NIPER campuses is concerned, the Department proposes to complete 100% of construction in respect of Ahmedabad NIPER and 30% of construction in respect of Hajipur, Hyderabad, Raebarelli and Kolkata NIPERS. Recently, the Committee visited NIPERS at Guwahati and Kolkata. While construction of permanent campus for

Guwahati was almost complete, the Kolkata NIPER was functioning in small rented premise which is not commensurate with the status of 'Institution of National Importance'. The Committee, therefore, feel that it is a matter of utmost importance that the state of the art permanent campuses for Hajipur, Hyderabad, Raebarelli and Kolkata NIPERS is created in a time bound manner so as to enable them to function in the true spirit of 'Institutions of National Importance'. The Committee, therefore, strongly recommend that the construction of permanent campuses for these four NIPERs should be completed within two years. Department, now proposed to complete 30% percent of construction during 2022-23 with the budgetary funds allocated for the purpose. Instead the Department may plan to complete 50% of construction of all the four NIPERs during 2022-23 and rest of the construction may be completed during 2023-24. In case of requirement of more funds for construction of these four NIPERs namely Hajipur, Hyderabad, Raebarelli and Kolkata additional demand may be made at RE /supplementary demands during 2022-23. This recommendation of the Committee may also be sent to the Ministry of Finance for its consideration. The Action taken in this regard should be intimated to the Committee.

Recommendation No. 3 : Monitoring the Performance of NIPERs

The Committee are concerned to note that NIPERs have only published 602 Research publications as on 15 February, 2022 against the target of 900 Research publications for 2021-22. Similarly, only 13 patents have been filed /granted against the target of 45 for the year. Presently NIPERS at Mohali and Guwahati are functioning in permanent campuses with very good infrastructure facilities but their performance in terms of student intake, research paper publication and

patents filing is not better than other NIPERs which are presently lacking sound infrastructure facilities. For the year 2022-23, for instance Guwahati NIPER has set physical target regarding intake of 185 students, 140 Research Publications and only 8 patents which are less than Hyderabad, Mohali and Ahmedabad NIPERs. In this regard, the Committee expect that the NIPERs with own infrastructure and requisite number of faculties should perform better than others. The Committee, therefore, recommend that the Department of Pharmaceuticals should regularly monitor the performance of NIPERs and ensure that the targets fixed in respect of student intake, research publications and patents are achieved by them without fail. A quarterly review of performance of each NIPER may be made at the Department level and the difficulties being faced by NIPERs in achieving their targets may be addressed to by the Department.

Recommendation No. 4 : Assistance in Research and Development by NIPERs

The Committee also note that NIPERs are presently functioning in an insulated atmosphere without much public visibility and engagements. As per the Department of Pharmaceuticals, a Common Research Programme has been worked out under which most common health problems faced by the people of the country have been identified for common research by NIPERS. Major pharmaceutical companies in private sector have their own R & D facilities but Pharma Medium Small and Micro Enterprises (MSMEs) lack them. Since it is very much necessary for NIPERs to play a catalytic role in pharmaceutical research, the Committee would like to make the following recommendations:-

- i) A time bound programme should be chalked out for Common Research Programme of NIPERS and a few areas of health concerns of the country may be identified for common research by NIPERS
- ii) NIPERs may render research and development assistance to MSMEs and a workable model in this regard may be worked out by Department of Pharmaceuticals in coordination with the NIPERs.

Recommendation No. 5 : Filling up of faculty positions in NIPERs

The Committee note that the Department of Expenditure has created 156 faculty posts for NIPERs in February, 2019. Presently 70% of the faculty positions have been filled up and the remaining are under process. Since the availability of requisite number of faculty is very much essential for the effective performance of NIPERs, the Committee recommend that the process of recruitment of requisite number of faculty for all NIPERs should be a continuous process till the recruitment of all the sanctioned posts of faculties in all NIPERs. Progress made in this regard may be intimated to the Committee.

Recommendation No. 6 : Setting up of five new NIPERs

The Committee are constrained to note that the proposal to set up five new NIPERs in Tamil Nadu (Madurai), Karnataka (Bangalore), Chhattisgarh, Rajasthan and Maharashtra are still on paper without any concrete action to set up them. In this regard, the Committee note that the Department had asked the Expenditure Finance Committee (EFC) to allocate Rs.4300.00 Crore for present seven NIPERs and additional five NIPERs for the next five years. However, EFC has earmarked only Rs.1500.00 Crore for NIPERs with the rider that this allocation should be

utilized only for the existing seven NIPERs. In this regard, the Department of Pharmaceuticals now proposed to explore the alternate ways of funding of these NIPERs. Since the present number of seven NIPERs are hardly sufficient to meet the requirements of the country in the field of Pharmaceutical Education and Research, the Committee strongly recommend that all necessary steps should be taken by the Department of Pharmaceuticals for the early setting up of five new NIPERs. In this regard, a fresh proposal may be submitted to EFC for reconsideration of their decision and the concern expressed by this Committee may be conveyed to them. The Department may also explore alternate ways of funding of these NIPERs including financial contribution by both the Union and the concerned state Governments so that these five NIPERs are also developed and completed in a time bound manner. Progress made in this regard may be conveyed to the Committee.

Recommendation No. 7 : Pradhan Mantri Bhartiya Janaushadhi Pariyojana

(PMBJP)

The Committee note that a Budgetary allocation of Rs. 72.50 Crore has been made for PMBJP against the Department of Pharmaceutical's proposal for Rs. 100.00 Crore for 2022-23. Under this Scheme, a target has been fixed to open new 1000 Kendras and enhance the product basket upto 1,800 medicines and 280 surgicals during the year 2022-23. Further, a sale target of Rs. 775.00 Crore has also been prescribed for the year. As per the Department, the funds allocated at BE stage are not sufficient and less allocation of funds will hamper effective implementation of the scheme. The Scheme aims to make available quality generic medicines at affordable prices to all especially for the poor and the

deprived ones. As on 15.02.2022, 8683 PMBJP outlets have been opened in the country with product basket of 1451 medicines and 240 surgicals. In this regard, the Committee feel that the number of PMBJP outlets in the country are inadequate when compared to nine lakh plus medical shops in the country. Further with regard to the present population of the country i.e. near about 140.52 crore it is noted that one Kendra is catering to approximately 16 lakh population. Hence, there is a need to increase the number of PMBJP outlets in the country and also to increase the product basket of the outlets. The Committee, therefore, recommend that the Department of Pharmaceuticals should impress upon the Ministry of Finance for the allocation of remaining funds (Rs. 27.50 Crore) required for effective implementation at RE stage of 2022-23. This recommendation of the Committee should also be sent to the Ministry of Finance for its implementation.

Recommendation No. 8 : Coverage and product basket of PMBJP

The Committee note that all 739 districts of the country have already been covered under Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP). In order to popularize the Scheme and expand opening of Kendras in the aspirational districts, Himalayan, Island territories and the North-Eastern States, a new incentive plan has been launched. Such Kendras now get a one-time grant of ₹ 2 lakh in addition to normal incentives viz. Rs.1.50 lakh for reimbursement of furniture and fixtures and Rs.0.50 lakh for reimbursement for computer, internet, printer, scanner etc. Pharmaceuticals and Medical Devices Bureau of India (PMBI) has released various newspaper advertisements for inviting applications for opening of PMBJP outlets in July, 2021 for opening of PMBJP outlets in 265

districts of the different States where coverage is less. Since continuous efforts are to be made for expanding coverage of the Scheme so as to achieve its objectives of providing quality generic medicines and medical devices at affordable prices to the people of the country, the Committee would like to make the following recommendations:-

- i) An action plan should be chalked out to open more Jan Aushadi outlets in urban fringes particularly near slum pockets and other urban areas where concentration of poor and below poverty line people is more, semi urban areas, rural areas, remote areas and hilly areas so as to enable the people of these areas get benefited from the Scheme.**
- ii) Additional Incentives which are offered to the entrepreneurs of aspirational districts, Himalayan, Island territories and the North-Eastern States may be offered to all the entrepreneurs who come forward to set PMBJP outlets in any part of the country so as to make it attractive to them.**
- iii) A study/evaluation may be conducted by the Department of Pharmaceuticals and PMBI on the continuous viability of these outlets even after the incentive period including the need for permission to sell other products alongwith Janaushadi medicines and medical devices and necessary follow up action may be taken up according to the outcome of the Study/evaluation.**
- iv) Measures should be taken by the Department along with PMBI and National Pharmaceuticals Pricing Authority (NPPA) to educate the people about the quality, efficacy and affordability of generic medicines**

being sold through PMBJP outlets so as to attract more people towards these outlets.

- v) Department of Pharmaceuticals, NPPA and the Ministry of Health and Family Welfare may make coordinated efforts to make the medical practitioners prescribe quality generic medicines rather than exorbitant branded medicines. This recommendation may also be sent to the Ministry of Health and Family Welfare.

Specific Action Taken Reply may be given with respect to each of the above recommendations.

Recommendation No. 9 : Scheme for strengthening the Pharmaceutical Industry

The Committee note that Expenditure Finance Committee (EFC) has recommended to de-link three sub-schemes viz (i) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS); (ii) Assistance to Pharmaceutical Industry for Common Facilities (APICF) and (iii) Pharmaceutical Promotion and Development Scheme (PPDS) from the Umbrella scheme of Development of Pharmaceutical Industry and implement them as a separate scheme. Accordingly, the Department is implementing a particular scheme called Scheme for strengthening the Pharmaceutical Industry. Above mentioned three Schemes have been included under this new Scheme. According to the Department, EFC has earmarked Rs.500 crore for five years to implement these three schemes. In this regard, the Department has done extensive stakeholders' consultation before arriving at the scheme guidelines, which are being accordingly revised and put up for the approval for the Minister. As recommended by the Committee last

year, the Department is in the process of appointing professional PMC – Project Management Consultant for the implementation of these Schemes in a systemic, professional and transparent manner without any delay. Keeping in view the assured financial allocation for next five years, the Committee is now hopeful that the Department will raise the level of implementation of these sub-schemes so that the Department will be able to achieve the goal of ensuring drug security for the country. In this regard, the Committee recommend that the Department should act swiftly to finalize the revised guidelines for the Scheme with the approval of the Minister and each sub scheme should be implemented from 2022-23 onwards in letter and spirit. Progress made in this regard should be intimated to the Committee.

Recommendation No. 10 : Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

The Committee note that the Department had sought Rs 100.00 Crore for the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) but the approved BE allocation is Rs 62.00 Crore for the year 2022-23. According to the Department, the reason for this difference in proposed and approved BE allocation is the present revision of scheme guidelines of PTUAS as per EFC approval. Once approved, eligible applications will be considered in FY 2022-23. Only token allocation was made to this important Scheme during the financial years 2019-20, 2020-21 and 2021-22. For the first time, the scheme has got the needed financial support of Rs 62.00 Crore at BE stage of 2022-23. The aim of PTUAS is to provide interest subvention to the Pharmaceutical Medium Small and

Micro Enterprises (Pharma MSMEs) to upgrade their standards both in terms of quality and technique to WHO-Good Manufacturing Practices so that the Pharma MSMEs would be able to produce quality drugs and become globally competitive. This Scheme enables upgradation of these enterprises from Schedule M to WHO-GMP standards so that they are eligible to export in global markets and earn foreign exchange. Out of 6790 SMEs in manufacturing bulk and API drugs, only 2006 are WHO-GMP certified and more than 4500 remain outside the purview of WHO-GMP certification. The Committee are constrained to note that this Scheme remained on paper with token allocations during the last three financial years. With the allocation of funds made for 2022-23, it is time for the Department to initiate concrete and time bound efforts to start implementing this Scheme from 2022-23 onwards. The Committee, therefore, strongly recommend:

- i) Guidelines of the scheme should be finalized quickly and the fund allocated for 2022-23 should be fully utilized.**
- ii) Further funds if needed for implementation of the Scheme should demanded at RE stage for 2022-23**
- iii) A definite time frame should be fixed for the upgradation of all MSMEs engaged in pharma sector to WHO GMP standards as their upgradation will benefit the country immensely by providing quality medicines to the people of the country as well as pave way for large scale export of medicines to other countries.**

Recommendation No.11 : Assistance to Pharmaceuticals Industry for Common Facilitation Center (previously known as Cluster Development)

- (i) The Committee note that the scheme Assistance to Pharmaceuticals Industry for Common Facilitation Center Scheme (previously known as Cluster Development) is implemented in a Public Private Partnership (PPP) mode. Financial assistance under this sub-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. For the ensuing year 2022-23, the Department has been allocated an amount of Rs. 36.00 Crore which is 50 percent hike in comparison to RE stage allocation of Rs. 15.61 Crore during 2021-22. However, during 2021-22 the Committee noticed sheer under utilization of funds. The actual utilization as on 11.02.2022 is only 9.6 percent that is Rs. 1.51 Crore out of Rs 15.61 Crore available at Revised Estimates stage with the Department. In this regard, the Committee note the assurance given by the Department that they will release funds to some projects before 31 March, 2022. The details of actual fund utilized under the Scheme on or before 31 March 2022 should be intimated to the Committee. Having noted that some Common Effluent Treatment Plants, Testing laboratory etc. are under approval/implementation stages under the Scheme, the Committee recommend that concrete and time bound steps should be initiated by the Department for the successful completion and commissioning of these projects during 2022-23 and for fully utilizing the funds allocated for the year.

- (ii) The Committee also recommend that the Department should take steps for the expansion of PPP projects under the scheme so as to involve all the States/UTs that have strong presence of private Pharma industries and also the States/UTs which strive to develop pharma industries.

Recommendation No. 12 : Pharmaceutical and Medical Devices Promotion Development Scheme (PMPDS)

- i. The Committee note that the Pharmaceutical and Medical Devices Promotion Development Scheme (PMPDS) aims at promotion, development and export promotion in Pharmaceutical sector by extending financial support for conducting seminars, conferences, exhibitions, conducting studies/ consultancies etc. Presently, the new scheme guidelines are being finalized by the Department. Out of RE allocation of Rs. 2.00 Crore for 2021-22, the Department has utilized only Rs.1.01 Crore as on 11.02.2022. In this regard, the Committee note that 5 studies have been approved in FY 2021-22 and part instalments are to be released for the purpose. Further, few events, seminars, conferences are to be organized and It is expected that entire RE will be utilized till 31st March, 2022. Progress made in regard to utilization of RE allocation during 2021-22 should be furnished to the Committee. For the year 2022-23, the Department has again received an allocation of Rs. 2.00 Crore. According to the Department, earlier studies conducted under the scheme were ad-hoc and now the Department has collected the requirements of study from all the Departments/Organisations/Industry and is now

conducting studies in a systematic way. The Committee feel that the effective implementation of this Scheme will provide a helping hand in promotion and development of the pharma sector in the country and hence the Committee recommend that an annual calendar of events to be organized/studies to be conducted under the Scheme should be chalked out well in advance before the starting of a financial year and concrete steps should be taken for resourceful spending of budgetary allocation made rather than rushing for last quarter spending.

- ii. The Committee also recommend that the Department may consider organizing mega events like Pharma Expo for bringing in various stake holders together for the holistic promotion and development of pharma sector in the country.

RECOMMENDATION NO. 13 : Promotion of Bulk Drug Parks (Assistance to Bulk Drug Industry for Common Facilitation Center)

- i. The Committee note that the objective of this sub scheme is to promote three Bulk Drug Parks by providing Grants-in-Aid for creation of World class Common Infrastructure facilities (CIF). A Financial assistance of Rs. 1000 crore per Park or 70% of the cost of the CIF, whichever is less is provided. The assistance would be 90% for North East Region and Hill States. Total financial outlay for the Scheme is Rs. 3000.00 crore and the duration of its implementation is 2020-21 to 2024-25. The Committee note that this Scheme has not been able to take off since 2019-20. During 2019-20 only a token allocation was made. Later during 2020-21, Rs.1.68 Crore was utilized out of RE allocation of Rs.1.69 Crore for Project Management

Agency. Further during 2021-22, Rs.36.24 Crore at RE stage remained unutilized as the process to select beneficiary states could not be completed. However, it is noted that an amount of Rs.900.00 Crore has been allocated in BE 2022-23. This amount will be used to give first instalment of Rs. 300.00 Crore each to the three selected states for creation of Common Infrastructure Facilities (CIFs) as grant-in-aid. Thirteen states have applied for assistance under the Scheme. Since the Project Management Agency (PMA) has identified certain issues in the proposals received under this scheme during 2021-22, an advisory Committee has been constituted with CEO NITI Aayog, Secretary, DoP and representatives of DPIIT & Department of Expenditure which has advised the Department to apply a set of qualitative filters to the proposals received looking at the higher technology, market and environmental risks emerging in the last year in respect of the Bulk Drug segment. The process in this regard is presently underway in the Department. The country is in urgent need of meeting the requirements of bulk drugs indigenously rather than dependence on other countries. The Committee, therefore, recommend that the process of selection of three beneficiary states should be expedited and the first instalment of Rs.300.00 Crore should be released to the States which are to be selected for implementation of the Scheme so that the undesirable situation of surrender of unutilized budgetary allocation does not recur again.

- ii. The Committee also feel that three bulk drug parks are not adequate to meet the production needs of bulk drugs in the country particularly keeping in view its status of “World Pharmacy”. Since there is vast

potential for export in the pharma sector, the Committee recommend that more Bulk Drug Parks may be set up in all the aspiring states and the Ministry of Finance may be approached for requisite budgetary allocation for the purpose.

RECOMMENDATION NO. 14 : Promotion of Medical Devices Parks (Assistance to Medical Device Industry for Common Facilitation Center)

- i. The Committee note that the objective of the scheme is to promote 4 Medical Device Parks by providing Grants-in-Aid for creation of Common Infrastructure facilities (CIF). Total financial outlay for the Scheme is Rs.400.00 Crore for the period 2020-21 to 2024-25. Financial assistance is Rs.100.00 Crore per Park or 70% of the cost of the CIF, whichever is less. The assistance would be 90% for North Eastern Region and Hill States. The Committee are concerned to note funds allocated for this Scheme during 2020-21 and 2021-22 were not fully utilized. During 2020-21, out of Revised Estimate allocation of Rs.21.05 Crore, only Rs.7.49 Crore was spent. During 2021-22, the Department had spent Rs.50.62 Crore out of allocated amount of Rs. 137.02 Crore at RE stage till the time information was furnished to the Committee. In this regard, the Department has assured the Committee that the remaining amount would be released to the States before the end of the financial year. The details of Actual Expenditure incurred as on 31 March, 2022 may be furnished to the Committee. In this backdrop, Rs.120.00 Crore has been provisioned in BE 2022-23 which the Department will release as the 2nd grant to 4 Medical

Device Parks States with proportionate contribution by the State Implementing Agencies (SIAs). Medical Devices Sector being a sunrise sector of the Indian Economy, creation of state of the art Common Infrastructure Facilities (CIF) in Medical Devices Parks is need of the hour and their creation will attract private investment in Medical devices Industry. The Committee, therefore, strongly recommend that the Department should take necessary steps for the early release of budgetary funds to four Medical Devices Parks being set up in Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh and it should also be monitored by the Department whether the released funds are resourcefully utilized by the concerned states. The progress made in achieving the physical and financial targets set under the scheme should be intimated to the Committee.

- ii. The Committee also recommend to examine the necessity of setting up of more Medical Devices Parks in the country and appropriate steps should be initiated there for the setting up of Medical Devices Parks in other States as well.

RECOMMENDATION NO. 15 : Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs)

The Committee note that the scheme provides for financial incentives to manufacturers selected under the scheme for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). The scheme provides for incentives on incremental sales to selected

participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940.00 Crore and its tenure is from FY 2020-2021 to 2029-30. The Committee note that the Department has been allocated an amount of Rs. 390.00 Crore at BE stage for the year 2022-23 in comparison to only Rs 2.79 Crore at RE stage in 2021-22. According to the Department, good response has been received from the pharmaceutical sector. Total 239 applications were received in Round I and Round II. 49 applicants have been approved with committed investment of Rs. 3,685.38 Crore. Out of these 49 applicants, 8 have already commissioned their plants and 13 more are expected to commission their plants by the end of March, 2022. The main objective of this scheme is to reduce dependency on imports for 41 critical APIs. However, the Committee note that out of 41 critical APIs only 33 APIs found their bidders among domestic manufacturers and the response is poor in respect of other 8 APIs as these APIs do not have demand in the market and are fermentation based whose technology is difficult as well as costly which requires greater investment. Further, the private players hesitate to invest in these 8 APIs as their end products are not competitive in global market. In this regard the Committee note that other countries are providing very high level of support in terms of power cost, water cost and the environmental cost. Since it is very much necessary to create a strong manufacturing base for critical Key Starting Materials / Drug Intermediates and Active Pharmaceutical Ingredients so that the country entirely meet the requirements of these materials indigenously both for the domestic medicine needs as well as for exports, the Committee, therefore strongly recommend the following:-

- (i) Department should chalk out an action plan for the time bound and resourceful utilization of budgetary allocation of Rs.390.00 Crore under the Scheme. For that purpose, concrete steps should be taken by the Department for the expeditious commissioning of plants by all the 49 applicants approved under the Scheme and timely start of sales by these plants so that the incentive is disbursed to them in the form of production linked incentives. Progress made in this regard should be intimated to the Committee.**
- (ii) Since fermentation technology is difficult and large scale investment is required, the Department should consider providing high level support to the entrepreneurs who come forward to set up these industries in terms of subsidized power cost, adequate water supply at low cost, single window environmental clearance, lower environmental cost, etc. in coordination with the State/UT Governments so as to attract more investment in this sector.**
- (iii) The Department in consultation with various stake holders should prepare a list of alternate products in place of 8 APIs/KSMs which are no longer necessary because of less demand and seek Cabinet approval for those alternate APIs for inclusion under the Scheme.**
- (iv) As the Fermentation based APIs are based on complex and costly technology, research and development may be encouraged for the invention of cost effective alternate technology for fermentation process. NIPERs may also be engaged in Research and Development in this regard.**

RECOMMENDATION NO. 16 : Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device:

- i. **The Committee note that Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices was approved by the Government of India on 20.03.2020 to address the challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies. The guidelines for implementation of the scheme were issued on 29.10.2020. The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of Rs. 3,420.00 Crore. Under this Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the target segments of the scheme, for a period of five years. The Committee note that for the year 2022-23, the Department has been allocated Rs.216.00 Crore at BE stage which is a marked enhancement in comparison to Rs.3.31 Crore allocated at RE stage during 2021-22. Further, the Department has approved 21 applicants under the scheme. Since it is very much important that all the 21 applicants commission their plants in a time bound manner and start production and sale of medical devices so that they become eligible to get incentive under the Scheme, the Committee, therefore, recommend that concrete steps should be taken by the Department of Pharmaceuticals for timely commissioning of plants by**

these applicants and ensure full utilization of budgetary allocation of Rs.216.00 Crore for the disbursement of incentives to them based on their production and sale of medical devices. A definite responsibility may be fixed on Project Management Agency in this regard. The details of progress made in implementation of the Scheme during 2022-23 should be intimated to the Committee.

- ii. The Committee notes that the incentives provided under the scheme are for incremental sales only and in no way address the major challenges faced by Greenfield projects viz. poor infrastructure, weak domestic supply chain and logistics, high cost of project finance, inadequate power backup, limited design capabilities, low investment in R&D and skill development, etc. Unless these challenges are overcome it is difficult to visualize that the domestic Medical Device Industry can reap the real benefits out of the PLI scheme. Hence, the Committee recommends that the Department may ponder over the ways and means to address these grass root challenges faced by the medical device industry and initiate appropriate steps thereon.

RECOMMENDATION NO. 17 : Production Linked Incentive (PLI) Scheme for Pharmaceuticals

The Committee notes that the Production Linked Incentive scheme for Pharmaceuticals was approved by the Cabinet on 11.11.2020 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 outlay of the scheme is Rs. 15,000.00 Crore and 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. (Ref: Para 3.50) However for the year 2022-23 the Department has received only Rs. 3.00 Crore at BE stage. During 2021-22, out of total RE allocation of Rs. 3.00 Crore, Rs.1.24 Crore have been released as service fee to Small Industries Development Bank of India (SIDBI), the Project Management Agency and the remaining amount of Rs.1.76 Crore has been surrendered. As on date 11 applicants under Group A, 9 applicant's Under Group 'B' and 35 applicants under Group 'C' category have been shortlisted by the Selection Committee of the Department for assistance under the Scheme. Since the implementation of the Scheme in letter and spirit will give a boost to the pharmaceutical sector in the country, the Committee, therefore recommend the following:-

- i) Immediate steps should be taken for the effective implementation of the Scheme from 2022-23 onwards. Particularly, the commissioning of plants by all the 55 approved applicants belonging to all the three categories should be ensured during 2022-23 so as to start disbursing incentives to them.
- ii) Allocation of only Rs.3.00 Crore for 2022-23 out of Rs.15,000.00 Crore earmarked for the Scheme is miniscule. In this regard, the Department should make demand for requisite allocation of fund at RE stage for the disbursement of incentives to applicants who start production and sale during 2022-23.

- iii) Under Category 2 of this Scheme, Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates have been included. Since there is a separate PLI Scheme for APIs/KSMs/DIs, the Department may examine the necessity of Category 2 under this Scheme and take appropriate action thereon.
- iv) The number of applicants approved under all the three categories is less considering the scope of production of pharmaceuticals under these categories. In this regard, the Department may create an enabling ecosystem for the pharmaceutical start-ups and young entrepreneurs through this PLI scheme and upscale the financial and physicals targets under the scheme to make India world leader in production of medicines.

RECOMMENDATION NO. 18 : Research and Development of Pharma Sector and future strategy

- i. The Committee are concerned to note that only a token allocation of Rs.1 lakh has been made for Research and Development in Pharma Sector for the year 2022-23. In this regard, the Committee note that the Department of Pharmaceuticals has come out with a Policy for Catalysing Research and Development and innovation in pharmaceutical and medical sector. A draft Cabinet note has already been circulated. We have received extensive comments, both from industry as well as from the Departments. Now the Policy is under finalization stage. Since it is necessary to take pharma sector to the

next level of development and to increase the value of this sector in the global market, the Committee strongly recommend that this Policy should be finalized at the earliest and necessary steps should be taken up by the Department of Pharmaceuticals to implement the Policy in letter and spirit. Separate budgetary allocation is also ought to be made for Research and Development so as to put in the necessary finances into research and development in pharma sector specifically in the medical devices industry. Department of Pharmaceuticals should impress upon the Ministry of Finance about the necessity of budgetary allocation for research and development in pharma sector. This recommendation of the Committee may also be shared with that Ministry for the purpose.

- ii. The Committee feel that it is important that the Government should come out with clear strategies in terms of manner in which the support should be given to pharma sector for holistically developing the sector in all fronts and to make it a world leader. In this regard, the Committee recommend that the Government should chalk out a long term plan/strategy with the help of best of the policy makers and experts in the field so as to create a world class infrastructure in the country for the all round development of the pharma sector in the country.

RECOMMENDATION NO. 19 : Assistance to PSUs

The Committee are concerned to note that only Rs.5.30 Crore has been allocated under the Head “Assistance to PSUs” against the demand of Rs.8021.48

Cre by the Department of Pharmaceuticals for the year 2022-23. The Department has proposed an amount of Rs. 6988.50 Cre for Indian Drugs and Pharmaceuticals Ltd (IDPL) and Rs. 1038.24 Cre for Hindustan Antibiotics Ltd (HAL) . However the allocated amount at BE stage for 2022-23 is only Rs. 4.00 Cre and Rs. 1.26 Cre for these two PSUs respectively. According to the Department of Pharmaceuticals, PSU Division of the Department has proposed funds as sought by IDPL (Rs. 6988.50 Cre) and HAL (Rs. 1038.24 Cre) for meeting various liabilities like outstanding liabilities of various banks, financial institutions and unsecured liabilities. The pending employees dues (serving/retired/VRS) of IDPL, HAL and Rajasthan Drugs & Pharmaceuticals Limited (RDPL) have been settled by providing budgetary support as loans in FY 2019-20, 2020-21 & 2021-22 and EPFO interest payment of HAL employees (Rs. 76.00 Cre) released in 2021-22. Now, only the minimum amount of Rs.5.30 Cre needed for meeting contingent expenditure, court cases etc. has been provided for HAL and IDPL in BE 2022-23. Further, the Committee note that IDPL plants at various locations have been closed and the IDPL plant at Rishikesh is being returned back to the Government of Uttarakhand. RDPL has also been closed and the proposal to transfer it to the Government of Rajasthan is under active consideration of the Department. Regarding other three PSUs, the Government proposed strategic sale of HAL which is loss making and strategic disinvestment of profit making KAPL and BCPL. Having concerned to note the way in which the affairs relating to the PSUs are being dealt by the Government, the Committee strongly recommend the following:-

- i) **Appropriate steps should be taken for immediately clearing various liabilities of IDPL and HAL like outstanding liabilities of various banks, financial institutions and unsecured liabilities.**
- ii) **The process of transferring the factories of IDPL, Rishikesh and RDPL to the respective State Governments should be completed in a time bound manner.**
- iii) **Efforts should be made to transfer the closed IDPL plants at Gurgaon, Hyderabad, Chennai and other places to the respective State Governments for their continuous operation.**

**New Delhi;
16 March, 2022**
25 Phalgun, 1943 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2021-22)

Minutes of the Fifth Sitting of the Committee

The Committee sat on Friday, the 25th February, 2022 from 1100 hrs. to 1330 hrs. in Committee Room No. 1, Parliament House Annexe Extension Building, New Delhi.

PRESENT

Ms Kanimozhi Karunanidhi- Chairperson

MEMBERS

LOK SABHA

2. Shri Parbhubhai Nagarbhai Vasava
3. Shri Satyadev Pachauri
4. Shri Arun Kumar Sagar
5. Shri M. Selvaraj
6. Dr. Sanjeev Kumar Singari
7. Shri Pradeep Kumar Singh
8. Shri Uday Pratap Singh

RAJYA SABHA

9. Shri Ayodhya Rami Reddy Alla
10. Shri G. C. Chandrashekhar
11. Dr. Anil Jain
12. Shri Arun Singh

SECRETARIAT

1. Shri Nabin Kumar Jha - Director
2. Shri C. Kalyanasundaram - Additional Director
3. Shri Kulvinder Singh - Deputy Secretary
4. Shri Panna Lal - Under Secretary

Witnesses

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

SI No.	Name of Officer	Designation and Department
1.	Ms. S. Aparna	Secretary, Department of Pharmaceuticals
2.	Shri Satendra singh	AS &FA
3.	Shri Rajneesh Tingal	Joint Secretary, Department of Pharmaceuticals
4.	Shri N. Yuvaraj,	Joint Secretary, Department of Pharmaceuticals
5.	Shri H.K. Hajong,	Economic Advisor, Department of Pharmaceuticals

REPRESENTATIVES OF PSU/AUTONOMOUS INSTITUTES

1.	Sh. Kamlesh Kumar Pant	Chairman, National Pharmaceuticals Pricing Authority
2.	Ms. Nirja Saraf	Managing Director, HAL&RDPL, BCPL (Add Charge)
3.	Shri Sunil Kumar Kaimal	Managing Director, KAPL
4.	Shri Ravi Dadhich	CEO (PMBI)
5.	Dr. Shashi Bala Singh	Director (NIPER- Hyderabad)
6.	Prof. Dulal Panda	Director (NIPER) Mohali

2. At the outset, the Chairperson welcomed the Members of the Committee and the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) to the sitting of the Committee which was convened to take oral evidence of the Ministry on 'Demands for Grants 2022-23'. Drawing the attention of the

witnesses to Direction 58 of the 'Directions by the Speaker' regarding confidentiality of the proceedings during deposition before the Parliamentary Committees, the Chairperson asked the Secretary, Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) to give an overview of the actual expenditure for the previous year (2021-22) and Budgetary provisions for the year 2022-23 for various programmes/schemes and the plan of action on the part of the Ministry for optimal utilization of the earmarked funds and maximum achievements in physical targets.

3. The representatives of the Department of Pharmaceuticals through a Power Point Presentation, *inter-alia* explained the present status of Indian Pharmaceuticals Industry and its contributions to global Trade, Export and Import trend, Indian Medical Devices Industry, FDI in Pharmaceuticals, etc.

4. Further, the representatives of the Depart also briefed the Committee on the budget utilization in 2021-22 and BE for the year 2022-23 for the Schemes and programmes of the Department, National Pharmaceuticals Pricing Authority, 7 National Institutes of Pharmaceutical Education and Research, Public Sector Undertakings, Pharmaceuticals and Medical Devices Bureau of India (PMBI).

5. The representatives of the Ministry also responded to various queries raised by the Members regarding utilization of allocations made at RE stage during the year 2021-22, Promotion of research in NIPERs, creating world class infrastructure in Pharmaceuticals clusters, promotion of research and development in Medical Device Sector, Public Private Partnership to promote NIPERs research work, opening of more Jan Aushadhi Kendras , reducing dependence on imported APIs, etc.

6. The Chairperson thanked the Secretary and other representatives of the Ministry for furnishing valuable information on the subject matter and responding to the queries of the Members.

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

The Committee then adjourned.

**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2021-22)**

Minutes of the Sixth Sitting of the Committee

The Committee sat on Wednesday, the 16th March, 2022 from 1500 hrs. to 1545 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

SHRI ARUN SINGH- Chairperson (Acting)

MEMBERS

LOK SABHA

2. Shri Ramakant Bhargava
3. Shri Rajeshbhai Naranbhai Chudasama
4. Shri Ramesh Chandappa Jigajinagi
5. Shri Satyadev Pachauri
6. Smt Aparupa Poddar (Afrin Ali)
7. Dr. M.K.Vishnu Prasad
8. Dr. Sanjeev Kumar Singari
9. Shri Uday Pratap Singh
10. Shri Indra Hang Subba

RAJYA SABHA

11. Shri Ayodhya Rami Reddy Alla
12. Shri G.C.Chandrashekhar
13. Shri Jaiprakash Nishad
14. Shri Vijay Pal Singh Tomar
15. Shri K. Vanlalvena

SECRETARIAT

1. Shri Vinod Kumar Tripathi - Joint Secretary
2. Shri Nabin Kumar Jha - Director
3. Shri C. Kalyanasundaram - Additional Director
4. Shri Kulvinder Singh - Deputy Secretary
5. Shri Panna Lal - Under Secretary

2. Since the Chairperson of the Committee was unable to attend the sitting, the Committee chose Shri Arun Singh, MP to act as Chairperson for the sitting under Rule 258(3) of Rules of Procedure and Conduct of Business in Lok Sabha.

3. Thereafter the acting Chairperson welcomed the Members of the Committee to the sitting which was convened to consider and adopt four draft Reports. The Committee, then, took up for consideration and adoption of the following draft Reports:

- (i) **xxx** **xxx** **xxx**
- (ii) **xxx** **xxx** **xxx**
- (iii) **xxx** **xxx** **xxx**
- (iv) Demands for Grants 2022-23 of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

4. The Committee considered and adopted the Reports unanimously without any amendment.

5. The Committee then authorized the Chairperson to finalise the Reports and present them during the current session of the Parliament.

The Committee then adjourned