8	STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2024-25) EIGHTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS

(2025-25)

EIGHTH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

March, 2025/ Phalguna, 1946 (Saka)

CC&F.No. 188

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(EIGHTEENTH LOK SABHA)

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DEMANDS FOR GRANTS

(2025-26)

Presented to Lok Sabha on ……March, 2025

Laid in Rajya Sabha on …… March, 2025

LOK SABHA SECRETARIAT

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CONTENTS

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2024-25)

Shri Azad Kirti Jha - Chairperson

MEMBERS

2. Shri Brijmohan Agrawal
3. Shri Ajay Bhatt
4. Shri Robert Bruce C.
5. Shri Bharatsinhji Shankarji Dabhi
6. Smt. Kriti Devi Debbarman
7. Dr. Kalyan Vaijinathrao Kale
8. Shri Malvinder Singh Kang
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12. Dr. Sambit Patra
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15. Shri Eatala Rajender
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17. Shri Daggumalla Prasada Rao
18. Shri Tharaniventhan M.S.
19. Shri Nalin Soren
20. Dr. Ricky Andrew J. Syngkon
21. Shri Shivmangal Singh Tomar

RAJYA SABHA

22. Shri Subhash Barala
23. Shri Subhash Chandra Bose Pilli
24. Dr. Anbumani Ramadoss
25. Shri Sanjay Raut
26. Shri Meda Raghunadha Reddy
27. Dr. Kalpana Saini
28. Shri Arun Singh
29. Shri Akhilesh Prasad Singh
30. Shri Tejveer Singh
31. Vacant*

*Vacant *Vice* Nomination of Shri Niranjan Bishi, MP (Rajya Sabha) has changed *vide* Rajya Sabha Bulletin-Prt II, Para No. 64908 dated 21.11.2024.

SECRETARIAT

1.	Smt. Maya Lingi	-	Joint Secretary
2.	Ms. Miranda Ingudam	-	Director
3.	Shri Kulvinder Singh	-	Deputy Secretary
4.	Ms. Neelam Bhave	-	Committee Officer

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals & Fertilizers (2024-25) having been authorized by the Committee do present on their behalf this Eighth Report (Eighteenth Lok Sabha) on 'Demands for Grants (2025-26)' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

2. The Committee considered the Demands for Grants (2025-26) pertaining to the Department of Pharmaceuticals for the Financial Year 2025-26 which were laid on the Table of the House on 11th February, 2023. Thereafter, the Committee took evidence of the representatives of the Department of Pharmaceuticals on 25th February, 2025. The Committee considered and adopted the Report at their sitting held on 18th March, 2025.

3. The Committee wish to express their thanks to the Officers of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers for tendering evidence and placing before the Committee all the requisite information sought for in connection with the examination of the subject.

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

5. For ease of reference and convenience, the Observations/ Recommendations of the Committee have been printed in bold letters in the body of the Report.

New Delhi;
18 March, 2025
27 Phalguan, 1946(Saka)

Azad Kirti Jha
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

REPORT

PART- I

I. INTRODUCTORY

The Indian Pharmaceutical industry is the world's third largest by volume and the 14th largest by value. The total annual turnover of pharmaceuticals was Rs. 4,17,345 crore for financial (FY) 2023-24 and has grown at an average of 10.08 percent over the last five years. In FY 2023-24, the total value of pharmaceuticals exported was Rs.2,19,439 crore while that of pharmaceuticals imports was Rs.58,440 crore.

The Indian pharmaceutical industry is a significant global player. India is globally the largest supplier of generic drugs, accounting for about 20 percent of the global supply. It manufactures about 60,000 generic brands, across 60 therapeutic categories. Access to affordable treatment for HIV from India is one of the great success stories in modern medicine. Because of low price coupled with quality, Indian medicines are preferred worldwide, thereby earning the country the epithet "Pharmacy of the World".

The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has under its jurisdiction the Pharmaceutical Sector and implements a number of Schemes and flagship programmes.

2. The Department has the mandate to deal with the following broad subject matters:-

(i) Drugs and Pharmaceuticals, excluding those specifically allotted to other Departments.
(ii) Medical Devices Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.
(iii) Promotion of co-ordination of basic, applied and other research in areas related to the pharmaceuticals sector.
(iv) Development of infrastructure, manpower and skills for the pharmaceuticals sector and management of related information.
(v) Education and training including high-end research and grant of fellowships in India and abroad, ex-change of information and technical guidance on all matters relating to pharmaceutical sector.
(vi) Promotion of public-partnership in pharmaceutical related areas.
(vii) International co-operation in pharmaceuticals research, including work related to international conferences in related areas in India and abroad.
(viii) Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
(ix) Technical support for dealing with national hazards in pharmaceutical sector.

(x) All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.
(xi) All matters relating to National Institutes of Pharmaceuticals Education and Research.
(xii) Planning, development and control of and assistance to all industries dealt with by the Department.
(xiii) Bengal Chemicals and Pharmaceuticals Limited.
(xiv) Hindustan Antibiotic Limited.
(xv) Karnataka Antibiotics and Pharmaceuticals Limited.
(xvi) Indian Drugs and Pharmaceuticals Limited; and
(xvii) Rajasthan Drugs and Pharmacuticals Limited.

3. The vision of the Department is to promote Indian Pharmaceuticals 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 Pharmaceutical Sector;
- Make in India in critical APIs and medical devices;
- Industry expansion, skilling, Research and Development and innovation;
- Stable and effective price regulation; and
- Generic medicines by expanding the Pradhan Mantri Bhartiya Janaushadhi Pariyojana Scheme

4. The Department has 14 Divisions to carry out various mandated functions and responsibilities and five (05) Central Public Sector undertakings (CPSUs) under its administrative control is as follows:

(i) Indian Drugs & Pharmaceutical Ltd. (IDPL), Gurugram, Haryana,

(ii) Hindustan Antibiotics Ltd. Pimpri, Pune, Maharashtra,

(iii) Karnataka Antibiotics & Pharmaceuticals Limited, Bengaluru, Karnataka,

(iv) Bengal Chemicals & Pharmaceuticals Ltd, Kolkata, West Bengal, and

(v) Rajasthan Drugs and Pharmaceuticals Limited, Jaipur, Rajasthan

5. The Department has seven Central Sector Schemes, viz. (a) National Institute of Pharmaceutical Education & Research (NIPER) (b) Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP) (c) Development of Pharmaceutical Industry (d) Production Linked Incentive (PLI) (e) Consumer Awareness Publicity and Price Monitoring (f) Promotion of Research and Innovation in Pharma Med-Tech (PRIP) (g) Strengthening of Medical Device Industry (SMDI).

6. The Department of Pharmaceuticals presented their detailed Demands for Grants (Demand No. 7) for the financial year 2025-26 to Parliament on **11th February, 2025**. The Budget Estimate of the Department showing Revenue and Capital expenditure for the year 2025-26 is as under:-

(Rs. In crore)

Section	**2025-26 (BE)**
Revenue	5,26,71,600
Capital	15,600
Total	5,26,87,200

II. PROPOSED AND APPROVED FINANCIAL OUTLAYS OF THE DEPARTMENT OF PHARMACEUTICALS (DoP) FOR THE FINANCIAL YEAR 2025-26

7. The details with regard to the proposed amount for each scheme of the Department of Pharmaceuticals for the year 2025-26 and the amount actually approved by the Ministry of Finance (MoF) was sought. In response, the Department furnished the detailed information in a tabular form as under:-

(Rs. In crore)

Sl. No.	**Name of Scheme**	**BE 2025-26 (Proposed)**	**BE 2025-26 (Approved)**
1	**National Institutes of Pharmaceutical Education and Research (NIPERs)**	383.70	200.07
2	**Jan Aushadhi Scheme**	353.50	353.50
3	**Development of Pharmaceutical Industry**		
	Pharmaceuticals Promotion Development Scheme (PPDS)	5.00	5.00
	Cluster Development	60.00	50.00
	Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	282.00	100.00
	Promotion of Bulk Drug Parks	1900.00	1460.00
4.	**Production Linked Incentive (PLI)**		
	Production Linked Incentive (PLI) Scheme for Promotion	40.00	40.00

			(Rs. In crore)
Sl. No.	**Name of Scheme**	**BE 2025-26 (Proposed)**	**BE 2025-26 (Approved)**
	of Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs		
	Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	150.00	104.93
	Production Linked Incentive Scheme for Pharmaceuticals	2600.00	2300.00
5.	**Consumer Awareness Publicity and Price**	6.00	6.00
6.	**Monitoring Promotion of Research and Innovation in Pharma Med-Tech (PRIP)**	780.00	245.00
7.	**Strengthening of Medical Device Industry (SMDI)**		
	Promotion of Medical Device Parks	125.00	125.00
	Common Facilities for Medical Device Clusters	60.00	60.00
	Capacity Building and Skill Development in Medical Devices Sector	60.00	60.00
	Marginal Investment Scheme for Reducing Import Dependence	60.00	60.00
	Medical Device Clinical Studies Support Scheme	50.00	50.00
	Medical Device Promotion Scheme	5.00	5.00
	Grand Total	**6920.20**	**5268.72**

III. BUDGETARY ALLOCATION *VIS-A-VIS* UTILISATION DURING 2022-23, 2023-24, and 2025-26

8. As regards the Budget Estimates (BE) & Revised Estimates (RE) for the year 2022-23, 2023-24, 2024-25 and 2025-26 of the Department of Pharmaceuticals and the actual utilization of funds thereof, the following information has been furnished to the Committee:—

				(Rs. in crore)
FY	**BE**	**RE**	**Actuals**	**% against RE**
2022-23	2244.15	2268.54	2050.08	90.37
2023-24	3160.06	2697.96	2432.45	90.15
2024-25	4089.95	3387.96	2168.29 (as on 11.03.25)	63.99 (as on 11.03.25)
2025-26	6920.20	5268.72		

9. On being asked to furnish reasons for increasing trend in the BE 2022-23, 2023-24, 2024-25 and 2025-26, the Department stated that some of the new schemes launched by the Department during the period namely Development of Pharmaceutical Industry, Production Linked Schemes (PLIs) and Strengthening of Medical Device Industry (SMDI) and due to provisions being made in the BE for the respective years resulted in enhancement of budgetary allocation for the schemes under the Department.

10. The Committee desired to know that the additional activities the Department propose to undertake in the ensuing Financial Year, in this regard the Department stated that in the FY 2024-25 an umbrella scheme, namely Strengthening of Medical Device Industry (SMDI) got approved during RE stage 2024-25 with token amount provided in the budget. The proposed scheme will start getting implemented in FY 2025-26 for attaining the goals envisaged for each of the scheme during the period.

10 A. On being pointed out that the BE of the Department for the Year 2023-24 was Rs 3160.06 crore which was reduced to Rs. 2697.96 Crore in RE Stage. Similarly for the Year 2025-26, the BE of Rs. 4089.95 Crore was reduced to Rs. 3387.96 Crore in RE stage. The Department stated in their reply that the expected release under some schemes could not be made due to lesser demand in infrastructure schemes because of issues in tendering process, environmental clearances etc, non-fulfillment of targeted achievements to claim incentives etc. These were the primary reasons for which the budget had to be reduced at RE stage during FY 2023-24 and FY 2024-25.

11. The Committee further pointed out that the actual expenditure of the Department is less than the already reduced RE for three consecutive years i.e. 2022-23, 2023-24 and 2024-25. On being sought reason for the same, the Department in their written reply submitted that the Pharma Industry is a growing industry and the targets are based on projections, which at times do not fructify on ground due to various reasons primarily related to infrastructure development for the projects due to various clearances required to be obtained in the time bound manner. Despite, these impediments due to constant monitoring of the scheme by the Department at micro level, 90.37% of RE in FY 2022-23

and 90.15% of RE in FY 2023-24, was utilized. As regards, FY 2024-25, the actual figures for expenditure would only be known on completion of the FY 2024-25 on 31st March, 2025.

12. The Committee also noted that fund utilized by the Department was 90.37 percent, 90.15 percent and 71.79 percent respectively for the years 2022-23, 2023-34 and 2024-25. In this regard, on being asked whether the Department has initiated any steps to keep their utilization trend on higher side in the current financial year, the Department stated that the fund utilizations during the past two financial years (FY 2022-23 and FY 2023-24) was 90.37% and 90.15% respectively. As regards expenditure during FY 2024-25, the expenditure details are for the current date whereas actual expenditure would only be known on 31st March, 2025, to assess the fund utilization against the allocated funds.

13. On being asked about the specific procedural and financial reforms the Department of Pharmaceutical had incorporated/proposed for enhancing effective budget utilization under various Major Budget Heads (MH) of their various Schemes/Programmes during the last three years and the current financial year 2025-26 the Department submitted that the details are as under:

IV. SCHEME WISE ANALYSIS OF BUDGET UTILIZATION AND TARGETS

A. Jan Aushadhi Scheme : Department has set targets for opening of new stores and expansion of product basket. The effective utilization of funds is ensured through regular monitoring of the scheme by the implementing agency - PMBI and the department.

During 2022-23, Rs. 100.00 Crore was projected at BE stage for PMBJP. However, Rs. 72.50 Crore was allotted at BE stage. The amount was increased to Rs. 100.00 Crore at RE stage. The Department released the allotted amount, i.e., Rs. 100.00 crores to PMBI for implementation of the scheme during the F.Y. 22-23 and utilization has been 100%.

During 2023-24, Rs. 115.00 Crore was projected at BE stage for PMBJP and same was allocated. The amount was decreased to Rs. 110.00 crore at RE stage. The Department released the allotted amount, i.e., Rs. 110.00 crore to PMBI for implementation of PMBJP and achieving the target to open 10,000 Kendras and for enhancing the product basket upto 2000 medicines and 300 surgicals. As such, 100 % of the RE has been utilized during the F.Y. 2023-24.

During 2024-25, Rs. 284.50 Crore was projected at BE stage for PMBJP and same was allocated during BE-2024-25 and RE-2024-25. The budget provision of Rs. 284.50 Crores was allocated under PMBJP Scheme with a view to have 20,000 Jan AushadhiKendras at the end of FY 2024-25. However, after review, target of JAKs has been reduced to 15,000 for the F.Y. 2024-25. As on 20.02.2025, Department has released Rs. 182.73 crore to PMBI and target to open 15,000 have already been achieved. PMBI will be able to utilize Rs.182.73 crore and the rest of an amount of Rs. 101.77 crore has been surrendered.

An amount of Rs. 353.50 crore has been allocated in BE- 2025-26, for implementation of the scheme.

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP)

The Committee have been informed that to make quality generic medicines available at affordable prices to all, Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals. Under this scheme, dedicated outlets known as Jan Aushadi Kendra (JAKs) are opened across the country to provide medicines at 50%-80% cheaper rates than branded medicines. A total of 14,589 JAKs have been opened across the country till 31.12.2024.

14. On being asked about to furnish the State-wise list of Jan Aushadi Kendras (JAKs), the Department submitted that Under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), a total of 15,000 Jan AushadhiKendras (JAKs) have been opened till 31.01.2025 across the country. State/UT wise number of JAKs opened is as under: -

S. No	State/UT	Total number of JAKs opened
1	Andaman & Nicobar	9
2	Andhra Pradesh	278
3	Arunachal Pradesh	34
4	Assam	170
5	Bihar	800
6	Chandigarh	11
7	Chhattisgarh	270
8	Delhi	492
9	Goa	15
10	Gujarat	757
11	Haryana	406
12	Himachal Pradesh	72
13	Jammu and Kashmir	317
14	Jharkhand	148
15	Karnataka	1,417
16	Kerala	1,525
17	Ladakh	2
18	Lakshadweep	1
19	Madhya Pradesh	542
20	Maharashtra	711
21	Manipur	56
22	Meghalaya	25
23	Mizoram	15
24	Nagaland	22
25	Odisha	682

26	Puducherry	33
27	Punjab	491
28	Rajasthan	481
29	Sikkim	12
30	Tamil Nadu	1,357
31	Telangana	199
32	Dadra and Nagar Haveli and Daman and Diu	39
33	Tripura	29
34	Uttar Pradesh	2,644
35	Uttarakhand	311
36	West Bengal	627
Grand Total		**15,000**

www.janaushadhi.gov.in/locate-kendra

15. On being asked on the number of Jan Aushadi Kendras (JAKs) have been opened during the last three years and also during the current financial year, the Department submitted that a total of 7,443 Jan Aushadi Kendras **(**JAKs) have been opened across the country during the last three financial year and also during current financial year till 31.01.2025. Financial Year wise details are as under:-

S. No.	Financial Year	No. of JAKs opened
1	2021-22	1,053
2	2022-23	694
3	2023-24	1,957
4	2025-25 (As on 31.01.2025)	3,739
Total		**7,443**

16. During oral evidence the representative of the Department further apprised the Committee regarding Jan Aushadhi Kendras as follows:

" Sir, a decision was taken to open 25 thousand Jan Aushadhi Kendras in the country. The first decision was to increase them from 10 thousand in the next two years, it was changed to say that every year you add 5 thousand, because these are to be opened by entrepreneurs. The target for this year, which was earlier 20 thousand, was reduced to 15 thousand, which we have already achieved in the month of January. Which is this budget, this support is for incentives, to give support to the entrepreneurs based on the medicines they sell, based on their sales, like sir said that their margins are low. Jan Aushadhi Kendra has 20% margin on every medicine, Jan Aushadhi Kendra operator has 20% margin. In addition, there is an incentive scheme for this. If he buys medicines worth one lakh rupees from the government every month, he gets 10 thousand rupees."

17. When asked about the criteria for opening of a Jan Aushadi Kendra (JAKs), the Department submitted that any individual holding a D. Pharm. or B. Pharm. qualification, either personally or through an individual or organization employing person of such qualification as a pharmacist for obtaining a drug license from the concerned State Licensing Authority, is eligible to open a Jan Aushadhi Kendra. The following are the requirements for applying to open a kendra:

a) Minimum space of 120 square feet;
b) Registration of pharmacist with the State Pharmacy Council concerned; and

Submission of suitable certificate/proof issued by the authority concerned, along with an undertaking, in respect of applicants belonging to the *divyangjan*, Scheduled Caste or Scheduled Tribe category.

18. On being asked whether JAKs have also been opened in rural and remote areas of the country the Department submitted that in coordination with the Ministry of Cooperation, JAKs are being opened in identified Primary Agricultural Credit Societies (PACS) and other cooperative societies across the country in rural and remote areas. Till 31.01.2025, 719 Kendras have been opened in PACS and other cooperative societies.

19. When asked about the quality of generic medicines stated to be made available at JAKs has ever been reviewed the Department replied that PMBI procures medicines only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers for ensuring the quality of the products. Apart from this, each batch of drug is tested at laboratories accredited by 'National Accreditation Board for Testing and Calibration Laboratories' (NABL) and only after passing the quality tests, the medicines are dispatched to PMBJP Kendras. PMBI also does routine quality audit of the facilities of vendors and carries out public outreach & campaigns throughout India to do away with the false perception about poor quality of generic medicines and emphasize that the quality of Jan Aushadhi generic medicines are as good as branded ones.

20. The Committee desire to know that whether the Government has developed any mechanism to make the common man aware about the generic medicine the Department submitted that to spread awareness about the scheme, the Pharmaceuticals and Medical Devices Bureau of India, the scheme implementing agency, regularly undertakes several activities including the following measures:

a) Issuance of advertisements in various modes, such as the print media, radio, TV, mobile application, cinema, hoardings, branding of bus queue shelters and buses, auto wrapping and TV screens at Common Service Centres;
b) Outreach through social media platforms, such as Facebook, X, Instagram and YouTube; and
c) *Celebration of Jan Aushadhi Diwas* on the 7th of March every year.

21. On being asked whether the Government has promoted the use of generic medicine thorough the Jan Aushadhi Kendras under PMBJP Scheme to provide affordable medicines to common man. The Department submitted that in order to promote the scheme, the Department of Pharmaceuticals and Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency of the scheme periodically requests the States/UTs to create awareness about the scheme and to open JAKs in government premises.

PMBI also spreads awareness about the scheme through advertisements in Print Media, Radio, TV & Cinema, Mobile Applications, Common Service Centers (CSCs) as well as through Outdoor publicity like Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping, etc. In addition, public is educated about the benefits of Jan Aushadhi generic medicines and the scheme through various social media platforms regularly. Further, Jan Aushadhi Diwas is celebrated every year on 7th March for further dissemination and spreading awareness about the scheme.

PMBI also maintains a mobile application namely “Janaushadhi Sugam”, which is an important facility for the general public by providing a digital platform by virtue of which they can avail a host of user-friendly services like - locate nearby PMBJK (direction guided through Google Maps), search Janaushadhi medicines, telephone numbers, etc.

22. On being asked as on date whether any application(s) for opening of a JAK is pending with the Department. The Department submitted that PMBI continuously receives online applications for opening of new Jan Aushadhi Kendras (JAKs) every month, ensuring a steady expansion of the network across the country. However, due to documentation deficiencies or non-compliance with eligibility criteria, some applications remain under review. Such applicants are promptly informed and guided to complete the required paperwork to facilitate establishment of new JAKs. In the last year, 4,590 new Jan Aushadhi Kendras have been opened across the country. As on 20.02.2025, 561 applications are under process with PMBI. Details of the applications are as under:-

a)	Documents awaited from applicant	-	325
b)	Under review with field officer	-	17
c)	Under process at Head Office	-	219

23. When asked to state that any complaint(s) regarding the quality of medicines has ever been received in any of JAK. The Department submitted that as per PMBI, all batches of Jan Aushadhi medicines are tested on receipt at warehouses for the standard parameters. Only after 100% quality testing, the medicines are supplied at Jan Aushadhi Kendras. Complaints of various nature are received on CPGRAM portal of Govt, of India, as well as, through email by PMBI. Depending upon the nature of complaint suitable action is taken by PMBI, also informing the complainant about the action taken.

24. On being asked how to many Jan Aushadi Kendra’s (JAKs) are opened in the rural and tribal areas across the country and whether any incentives proposed to be given to the

owners of JAKs specially those belonging to SC/ST and Tribal communities. The Department submitted that under Pradhan Mantri Bhartiya Janaushadhi Pariyojana, a total 15,057 Jan Aushadhi Kendras (JAKs) have been opened till 28.2.2025 across the country. Out of these, the details regarding whether a JAK is located in urban or rural area are available in respect of 11,998 JAKs, out of which 5,907 (49.2%) are located in rural areas, which include areas with significant concentration of tribal population. State- and Union-territory-wise break-up is at Annex I.

All Jan Aushadhi Kendra owners are eligible for incentive at the rate of 20% of the monthly purchases made by them, subject to a monthly ceiling of ₹20,000 and meeting certain conditions such as maintaining stock of specified medicines. In addition, a one-time incentive of ₹2 lakh is provided to outlets opened in the North-Eastern States, Himalayan areas, Island territories and aspirational districts or those opened by women entrepreneurs, ex-servicemen, *divyangjan* and members of the Scheduled Castes and Scheduled Tribes, as support towards furniture, computers, refrigerators and other fixtures.

25. On being asked whether some suppliers of JAKs have been removed or blacklisted due to non-compliance of quality standards. The Department submitted that as per inputs provided by the Pharmaceuticals and Medical Devices Bureau of India, the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana, during the last five years, M/s ANG Lifescience India Limited and M/s Ridley Life Science Private Limited were blacklisted due to non-supply against purchase orders and non-compliance with quality standards.

26. On being asked whether some cases have been reported where individuals not having license to sell medicines are running medical shops and providing medicines without proper knowledge of drugs. Whether there have been instances where expired medicines have been or being sold in medical shops, especially in those areas where people are lesser educated or illiterate. The Department submitted that as per information provided by the Ministry of Health and Family Welfare, the sale and distribution of drugs in the country is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945. The regulatory control over the manufacture, sale and distribution of drugs in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments.

As per section 18(c) of the said Act, no person can sell or distribute drugs without obtaining license under the provision of the Act. Wherever, such contraventions are noticed, the State drug official stake action, such as seizure of the goods, prosecutions etc. The Act provides stringent punishment with imprisonment up to five years and with fine. The details

of such cases of sale drugs without license and also expired medicine being sold in medical shop are maintained by the State Drug Departments.

B. Consumer Awareness, Publicity and Price Monitoring (CAPPM)

Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has following two Components:

Assistance to Price Monitoring and Resource Units (PMRUs) in State/UTs :

A. Under the scheme Price Monitoring and Resource Units (PMRUs) are set up in the State/ UT and they function under the direct supervision of respective State Drug Controllers SDCs). PMRUs are fully funded by NPPA under CAPPM scheme for establishment and recurring expenses as per the PMRU guidelines.

B. **Advertisement and publicity for CAPPM**: To create general awareness about the functioning of NPPA, availability of medicines, prices of medicines etc.

Consumer Awareness, Publicity and Price Monitoring (CAPPM**):** Details are as under:

[In crore ₹]

FY	**BE**	**RE**	**Actual Expenditure**
2022-23	6.00	3.75	2.20
2023-24	5.00	3.00	2.95
2024-25	4.00	4.50	2.47 (upto 20.02.2025)
2025-26	6.00		

The following are the proposed/suggested Reforms for Enhancing Proper Budget Utilization:

(i) Advance Planning & Fund Disbursement: Ensure early approval and timely release of funds to avoid delays.
(ii) Fixing Quarterly Targets: Set clear expenditure targets to prevent last-minute spending rush.
(iii) Regular Review Mechanism: Conduct monthly/quarterly financial monitoring meetings to assess fund utilization and address bottlenecks.
(iv) Performance-Based Budgeting: Link fund allocation with actual progress and expenditure trends to avoid overestimation.

27. On being asked as to how many Price Monitoring and Resource Units (PMRUs) have been set up till date. The Department submitted in their reply that till date (20th February, 2025), Price Monitoring and Resource Unit (PMRU) have been set up in the following 31 States/ UTs:

S. No.	**Name of State/ UT**	**Date of establishment**
1	Gujarat	16.02.2019
2	Odisha	19.02.2019

S. No.	Name of State/ UT	Date of establishment
3	Rajasthan	07.03.2019
4	Uttar Pradesh	19.07.2019
5	Haryana	20.03.2019
6	Kerala	03.01.2019
7	Punjab	06.05.2019
8	Nagaland	29.05.2019
9	Tripura	25.06.2019
10	Andhra Pradesh	12.08.2020
11	Karnataka	12.08.2020
12	Madhya Pradesh	12.11.2020
13	Maharashtra	17.09.2020
14	Jammu & Kashmir	31.03.2020
15	Telangana	25.08.2020
16	Goa	22.10.2020
17	Mizoram	22.01.2020
18	West Bengal	25.10.2021
19	Chhattisgarh	24.03.2021
20	Jharkhand	18.06.2021
21	Puducherry	29.10.2021
22	Bihar	18.06.2022
23	Himachal Pradesh	22.03.2022
24	Ladakh	02.02.2022
25	Uttarakhand	29.07.2022
26	Assam	08.07.2023
27	Arunachal Pradesh	03.02.2023

S. No.	Name of State/ UT	Date of establishment
28	Chandigarh	27.03.2023
29	Dadra and Nagar Haveli and Daman and Diu	06.12.2023
30	Meghalaya	01.02.2023
31	Lakshadweep	25.01.2024

28. Asked to state the function and mandate of PMRUs and how many PMRUs have been set up till date and what the department has to say regarding their functioning, it was replied that . PMRUs are the key collaborating partners of NPPA with information gathering mechanism at the grass root level. They are expected to create public awareness so that benefits of the Drug Price Control Orders (DPCOs) trickle down to the consumers. Also, PMRUs are expected to provide necessary technical assistance to the State Drug Controllers and NPPA. The functions of the PMRUs are as under:

a) Market availability survey on selected essential drugs and medical devices on a weekly basis.

b) Purchase of samples of medicines from the retail market as per instruction of NPPA and analysis of the same for violation, if any under the DPCO 2013 and sending reports to NPPA.

c) Monitoring the notified prices of medicines

d) To conduct training, seminars and workshops at the State and District level to create general awareness about the availability of medicines, prices of medicines, ceiling prices of medicines fixed by the Government, precaution to be taken while purchasing medicines etc.

29. The Committee desired to know as to how the Department and NPPA monitors the functioning of PMRUs, when was stated that the PMRUs function under the direct supervision of respective State Drug Controllers (SDCs) as are fully funded by NPPA under CAPPM shceme for establishment and recurring expenses as per the PMRU guidelines, the Department submitted that the PMRU are fully funded by NPPA for establishment and recurring expenses. The recurring funds to PMRUs are to be utilized for salaries to PMRU staff, activities of PMRUs and for conducting training, seminars and workshops at the State and District levels to create general awareness about the availability of medicines, prices of medicines, ceiling prices of medicines fixed by the Government, precaution to be taken while purchasing medicines.

The system of monitoring and control over the performance of the CAPPM schemes by NPPA is as below:

a) An Online Integrated Pharmaceutical Database Management System 2.0 (IPDMS) has been developed by NPPA which has a dedicated PMRU module. PMRUs upload their reports, analysis, and other information on the PMRU module. Various

reports are submitted on IPDMS on weekly/ monthly/ yearly basis. At the Central level, there is a MIS report mechanism to oversee and monitor performance through IPDMS on various parameters.

b) Periodic review of the performance of the PMRUs by the senior officials of NPPA.

c) All the PMRUs make payments through Expenditure Advance Transfer (EAT) Module of Public Financial Management System (PFMS) with the approval of State Officers who oversee day to day affairs of PMRU.

30. On being asked about the role of State Drug Controllers (SDCs) in the supervision of Price Monitoring and Resource Units (PMRUs) in their respective States/UTs. The Department replied that at the state level, the progress of the Scheme is monitored by the Authorities concerned viz. Governing Body and Executive Committee at the State/UT level. Functioning of the PMRUs is monitored under the direct supervision of respective State Drugs Controllers. (Reply Q 15 LoP)

31. Asked about the extent the PMRUs have been able to achieve their objectives and what are the present constraints faced by PMRUs and what suggestions would the Department as well as NPPA would like to offer on making the functioning of PMRUs more effective the Department submitted that the PMRUs established in the states/ UTs have been able to achieve the objectives as mandated under the scheme. The activities required to be carried out by the PMRUs, as enumerated in the CAPPM guidelines are broadly classified as: -

a) Market Survey i.e., Market-based data collection on availability, compilation and analysis of report in respect of selected scheduled/non-scheduled formulations
b) Information, Education, and communication (IEC) activities
c) Monitoring of price movement of scheduled/non-scheduled formulations and collection/ purchase of test samples of medicines, if required

The details of the activities carried out by the PMRUs during last 3 years is as under:

2022-23		
1	No. of Weekly surveys	30
2	No. of IEC activities	170
3	No. of samples purchased and overcharging reported	270
2023-24		
1	No. of Weekly surveys	52
2	No. of IEC activities	321
3	No. of samples purchased and overcharging reported	2,000
2024-25 (up to 21.02.2025)		
1	No. of Weekly surveys	45
2	No. of IEC activities	252
3	No. of samples purchased and overcharging reported	1,588

32. Asked to state whether the Department and NPPA has ever reviewed the functioning of PMRUs. The Department submitted that the functioning of the PMRUs is monitored/ reviewed by NPPA on a regular basis at various levels, viz., Chairman, Member Secretary, Adviser, Director etc. Monthly webinars are also held with the PMRUs on various topics to sensitize them with the activities to be carried out by them. In addition field visits by officers of NPPA on time to time basis are also done.

33. Asked about the budget outlay for PMRUs and how the allocated amount is disbursed/utilized for setting up of PMRUs in various States, the Department replied that**:**

(Amount in crore ₹)

Object Head	**2022-23**			**2023-24**			**2024-25 (Up to 20.02.2025)**			**2025-26**
B) Consumer Awareness Publicity and Price Monitoring (CAPPM))	**BE**	**RE**	**Actually spent**	**BE**	**RE**	**Actually spent**	**BE**	**RE**	**Actually spent**	**BE**
(i) Grants-In-Aid General for Assistance to PMRUs	5.00	2.75	1.75	4.00	2.60	2.58	3.00	3.50	2.36	5.00
(ii) Advertising & Publicity	1.00	1.00	0.45	1.00	0.40	0.37	1.00	1.00	0.11	1.00
(B) Total (i) + (ii)	**6.00**	**3.75**	**2.20**	**5.00**	**3.00**	**2.95**	**4.00**	**4.50**	**2.47**	**6.00**

The allocated fund is disbursed to PMRUs as per PMRU guidelines. For setting up of PMRUs one time non -recurring grants is given to different categories of PMRUs. For recurring expenditure, the scale of expenditure has been fixed under different category, which ranges from Rs. 42 lakh per annum to Rs. 55 lakh per annum. Transactions/Payments against CAPPM is made through Expenditure Advance Transfer (EAT) Module of Public Finance Management System (PFMS) by State PMRU. Further, 25% of recurring funds is disbursed in one time after the submission of Utilization certificate of 75 % of allotted fund to PMRU as per the O.M. dated 09.03.2022 by DoE regarding Revised procedure for flow of funds under Central Sector Schemes.

34. On being asked about the training seminars and workshops have been conducted by PMRUs at the State Level and District Level to create general awareness about the availability of medicines, prices etc. The Department replied that The IEC activities as mandated under PMRU guidelines consists of undertaking training, seminar and workshop at State and Districts level for consumer awareness and publicity. These events are aimed for increasing awareness among people about role of NPPA in making the drugs affordable and available for all; promotion and use of Pharma SahiDaam App & IPDMS 2.0, monitoring of prices of medicines through PMRUs, etc. These activities are carried out by the PMRUs at hospitals, colleges, and other public places.

The details of IEC activities conducted during last three years across States/UTs are as follows:

	2022-23	**2023-24**	**2024-25(up to 21.02.2025)**
Number of IEC activities carried out by PMEUs	170	321	252

35. The Committee desire to know what is the criteria/guidelines prescribed by the National Pharmaceutical Pricing Authority (NPPA) for determining and deciding prices of essential and lifesaving drugs used for treatment of cancer, diabetes, heart/kidney diseases and whether the prices of essential and lifesaving drugs and have increased manifold. The Department submitted that currently, the prices of drugs in the country are regulated as per the principles laid down in the National Pharmaceutical Pricing Policy, 2012 (NPPP,2012) which is operationalised through the Drug (Prices Control) Order, 2013 (DPCO,2013).The National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling prices of scheduled medicines notified as Schedule-I of the DPCO, 2013 by the Department of Pharmaceuticals. The National List of Essential Medicines (NLEM) published by the Ministry of Health and Family Welfare is incorporated as the Schedule -I of the DPCO. Presently, NLEM, 2022 is notified as Schedule-I of DPCO,2013 *vide* notification dated 11.11.2022.

The medicines under Schedule I of DPCO 2013 as per NLEM are mentioned according to their therapeutic category. Currently, there are 29 therapeutic groups in Schedule-I of DPCO,2013, The said schedule includes anti-cancer formulations (including immunosuppressive and palliative care medicines) incorporated in its section 7, anti-diabetic medicines incorporated in section 18.3.1, cardiovascular medicines incorporated in section 10 and diuretics incorporated in section 15. Fixation and refixation of prices under NLEM, 2022 has led to an average reduction of about 16.89% in prices, resulting in estimated annual savings of about ₹3,788 crore to patients.

As on 6.3.2025, ceiling prices of 928 scheduled formulations across various therapeutic categories were in effect. These include 131 anti-cancer, 11 anti-diabetic, 65

cardiovascular, 1 haemodialysis solution and 10 diuretics scheduled formulations. The ceiling prices fixed by NPPA are applicable to all manufacturers and marketers selling the formulation, whether generic or branded, who are required to sell the same within the ceiling price fixed by the NPPA and applicable GST and annual revision based on WPI.

In addition to the above, the retail price of a "new drug" as defined in DPCO, 2013 is fixed by NPPA for existing manufacturers of scheduled formulations, and such manufacturers and the marketers of new drug are required to sell the same within the ceiling price fixed by the NPPA and applicable GST and annual revision based on WPI. NPPA has notified over 3,200 retail prices across various therapeutic category.

For non-scheduled formulations (branded or generic), the manufacturers may not increase the maximum retail price of such formulations by more than 10% per annum.

36. On being asked whether Pharma Companies such as Sun Pharma, Arvindo, Dr. Reddy's and Cipla are making huge profits by selling medicines at high prices, the Department submitted that our does not maintain the data on profitability and revenue of companies. The ceiling prices of scheduled medicines and retail prices of new drugs are fixed by NPPA and not by companies. NPPA fixes the same in accordance with provisions of DPCO, 2013 as per market-based data by, *inter alia*, taking the simple average of prices to retailers of all brands and generic version of the medicine that have a market share of more than or equal to 1% of the total market turnover on the basis of the moving annual turnover of a specified medicine. The ceiling/retail price is derived by adding 16% margin on the simple average prices to retailers for the specified medicine. The objective is to put in place a regulatory framework for pricing of drugs with a view to ensure the availability of required medicines – "essential medicines" – at reasonable prices while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well-being for all. Based on these objectives, it was the considered decision of the Government to move away from the earlier regime that provided for the control of the profits of companies.

37. On being asked whether medicines and drugs produced by these companies are beyond the reach of the Common people and whether these Companies have with their own marketing and distribution system have managed to control the prices of medicines. The Department submitted that NPPA fixes the ceiling prices of scheduled medicines, that is, the medicines specified in the said Schedule. The prices fixed by NPPA are applicable to all manufacturers/marketers selling the specified formulations, whether generic or branded. Manufacturers/marketers of scheduled medicines (branded or generic) are required to sell the same within the ceiling price fixed by the NPPA and applicable GST and annual revision on the basis of WPI. The average price reduction due to refixation of

prices under NLEM, 2022 is about 17%, leading to annual savings of approximately ₹3,788 crore to patients.

NPPA also fixes the retail prices of new drugs as defined in DPCO, 2013 for existing manufacturers of scheduled formulations. Retail price of over 3,100 new drugs under DPCO, 2013 till 13.2.2025 have been fixed.

For non-scheduled formulations (branded or generic), the manufacturers may not increase the maximum retail price of such formulations by more than 10% per annum.

38. During oral evidence the representative of the Department further apprised the Committee regarding NAPPA as follows:-

"Sir, I will just take a minute to broadly reiterate or bring out the regulatory framework that exists as of today. NPPA is mandated to implement the drug price control order. Now, the field is divided into two parts. One is scheduled drugs and another is non-scheduled drugs. Scheduled drugs are the drugs basically which figure in the National List of Essential Medicines, which is issued by the Department of Health and Family Welfare. The list is adapted by the Department of Pharmaceuticals and included as a schedule to the DBCO. So, it is the responsibility of the NPPA to fix the ceiling prices of these drugs that are included in the schedule. Right now, as of now, there are 388 drugs which are included which come about under 1,000-odd formulations. So, NPPA is mandated to fix the ceiling prices of these formulations across the industry. So, nobody can sell these drugs, these medicines beyond the ceiling price. They can sell it below the ceiling price and they are giving an annual increase based on the Wholesale Price Index. This is so as far as the scheduled drugs are concerned.

There are non-scheduled drugs constitute about 80 per cent of the entire universe of the drugs. There, NPPA do not fix the ceiling price. The companies are free to fix the ceiling price, but the regulation comes by way of annual increase. They cannot increase the drug prices by more than 10 per cent. So, that is what NPPA enforces as far as the non-scheduled drugs are concerned. There is a third element. It is a new drug, which is defined under the DBCO. A new drug is a drug which is manufactured by an existing customer by a combination of a scheduled and non-scheduled or two scheduled drugs. The idea was that no manufacturer should take advantage of manufacturing a combined drug and take it out of the

schedule and free to fix his own price. So, in those cases, the individual manufacturer has come to the NPPA for fixation of the price."

39. On being asked about the nexus exist between big pharma companies and corporate hospital and Big pharma companies sell their branded medicines to corporate hospitals at cheap rates and doctors in these hospitals prescribe medicines of big companies which the patients are forced to purchase at higher prices. Both corporate hospitals and big pharma companies therefore make huge profits. In this regard, the Department submitted that no such report has been brought to the notice of the Department. All manufactures and marketers are required to sell their scheduled formulations and new drugs within the ceiling/retail prices fixed by NPPA.

On being asked whether some cases of medicines being sold in the market at 10% higher than its manufacturing cost have come to the notice of the Department, whether any action has been taken by the Department in this regard against the violators and what the penalties imposed on them, the Department submitted that DPCO,2013 has been issued pursuant to the National Pharmaceutical Pricing Policy,2012, which follows the principle of market-based pricing as against cost-based pricing under DPCO,1995. However, as per the provisions of paragraph 20 of DPCO, 2013, the manufacturers of non-scheduled formulations are not allowed to increase the MRP of such formulations by more than 10% of maximum retail price during the preceding 12 months. Till 6.3.2025, 307cases were observed of violation of paragraph 20 of DPCO, 2013.

C. NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPERs)

40. The First National Institute of Pharmaceutical Education and Research (NIPER) was set up in the year 1998 at SAS Nagar (Mohali), Punjab - (as an institution of national importance vide NIPER Act, 1998. After amendment of the Act in the year 2007 six more NIPERs were set up at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli.

The main objectives of setting up of NIPERs were stated to include:

i. Nurture and promote quality and excellence in pharmaceutical education and research;
ii. Run integrated, master's, & doctoral courses and research in pharmaceutical education;
iii. Develop a multi-disciplinary approach in carrying out research and training of pharmaceutical manpower; and
iv. Act as nucleus for interaction between academic and industry by undertaking sponsored and funded research as well as consultancy projects.

Since inception, more than 10960 students have passed out from these NIPERs which are working with industry, R&D and academic intuitions. As per the National Institutional Ranking Framework (NIRF 2024) of the Ministry of Education, under the 'Pharmacy' category, six NIPERs are amongst the top thirty pharmacy Institute in the country with NIPER Hyderabad securing 2nd position. As part of academia-industry exchange, NIPERs have signed about 314 MOUs with Industries and other academic institutions. More than 441patents have been filed. About 8,208 research papers published in various reputed journals by the seven working NIPERs.

Of the six new NIPERs, construction of campuses of NIPERs at Guwahati & Ahmedabad has been completed and the permanent campus has been dedicated to the Nation on 12.01.2024 & 30.9.23 respectively by Hon'ble Minister for Chemicals & Fertilizers. Construction of (~75%) building of NIPER-Raebareli, (~35%) building of NIPER-Hyderabad, 50% building of NIPER-Kolkata and 50% building of NIPER-Hajipur is completed.

41. On enhancement of BE 2021-22 of NIPER was Rs.234.39 crore which was revised upward to Rs. 373.00 crore. The BE 2022-23 was again revised upward Rs.395.00 crore and further enhanced to Rs.451.13 crore at RE stage. The BE was again revised upward to Rs.550.00 crore during the year 2023-24. But was drastically reduced to Rs.228.80 crore and again revised upward to Rs. 242.00 crore as BE 2024-2025. The Department submitted that EFC approved Rs 1,500 crore for 7 existing NIPERs including construction of 6 NIPERs, out of which Rs. 823.13 crore was released upto FY 2022-2023 (Rs 372 crore in FY 2021-22 and Rs 451.13 crore in FY 2022-23). BE 2023-24 of Rs 550 crore was in accordance with EFC ceiling including capital grant for construction of the NIPERs. However, due to slow pace of expenditure, the estimates were revised to Rs.228.80 crore at RE stage which was 100% utilised and in accordance with the EFC ceiling the BE 2024-25 has been kept at Rs.242 Cr and it has been revised to Rs.248 at RE Stage as per the requirement of NIPER.

42. On being pointed out that about 75%, 35% and 50% construction work of NIPER Raebareli, Hyderabad and Kolkata is stated to have been completed and the Committee desired to know when will the remaining work would be completed. The Department in their reply submitted as under :

Current Status of Construction of Regular Campus as on 31.12.2024			
S.No	**NIPER**	**% Completion Status**	**Target date of Completion**
1	Hajipur	57%	31.07.2025
2	Hyderabad	35%	31.07.2025
3	Kolkata	61%	31.07.2025
4	Raebareli	75%	31.03.2025

43. The Committee desire to know that the construction work at NIPER Hajipur is only 50% completed whereas 50% of the construction work is yet to be completed. The

Department submitted that as on 31.12.2024, 57% of the construction work at NIPER Hajipur has been completed. The Target date of completion of construction of NIPER Hajipur is 31.07.2025. RCC work completed up to top floor in Girls Hostel. RCC work completed up to 4th Floor in Administrative building. Shuttering and reinforcement work for top floor roof slab in administrative and academic building. Brick work at ground floor, first floor and second floor is in progress.

44. On being asked about the main objective of NIPER are inter-alia stated to be to nurture and promote quality and excellence in pharmaceutical, education and research. The Deparment stated that NIPERs are autonomous institutes of national importance, which have been established by an Act passed in Parliament in 1998. Presently, NIPERs at Mohali, Ahmedabad, Guwahati, Hyderabad, Kolkata, Raebareli and Hajipur are functioning under the aegis of the Department. As per the National Institutional Ranking Framework (NIRF) of the Ministry of Education, under the 'Pharmacy' category, six NIPERs are amongst the top thirty pharmacy Institute in the country. Since inception, more than 10,974 students have passed out from these NIPERs which are working with industry, R&D and academic intuitions.

As part of academia-industry exchange, NIPERs have signed about 317 MOUs with Industries and other academic institutions. More than 442 patents have been filed. About 8,262 research papers published in various reputed journals by the seven working NIPERs. (as on 31.01.2025).

Centre wise achievement of NIPERs were stated to be as follows;-

S.NO	NIPER	Research Papers Published	Patents	MoUs
1	**Ahmedabad**	1,025	35	38
2	**Guwahati**	793	36	41
3	**Hajipur**	411	13	29
4	**Hyderabad**	1,401	61	88
5	**Kolkata**	565	14	42
6	**Mohali**	3,441	244	46
7	**Raebareli**	626	39	33
	Total	**8,262**	**442**	**317**

data as on 31.01.2025

45. On being asked about the information regarding students have been passed out from the NIPERs since inception. The Department stated as under **:**

S.NO	NIPER	Student Enrolled (Since Inception)	Students Passed out (Since Inception)
1	Ahmedabad	1,754	1,217
2	Guwahati	1,362	863
3	Hajipur	945	662
4	Hyderabad	2,491	1,852
5	Kolkata	1,040	742
6	Mohali	5,905	4,890
7	Raebareli	1,037	748
	Total	**14,534**	**10,974**

The difference between the number of students enrolled and those who have graduated from NIPER can be attributed to factors such as health issues, selection for government jobs, further studies at other institutions in India and abroad, as well as ongoing postgraduate programs (students currently pursuing their studies). Additionally, the tenure for PhD students has not yet been completed.

46. When asked to state as to how many MoUs have NIPER signed with industries and academic institutions. The Department submitted that as part of academia-industry exchange, NIPERs have signed about 317 MOUs with Industries and other academic institutions. NIPER wise MOUs signed are as follows:-

S.NO	NIPER	MoUs Signed
1	Ahmedabad	38
2	Guwahati	41
3	Hajipur	29
4	Hyderabad	88
5	Mohali	46
6	Kolkata	42
7	Raebareli	33
	Total	**317***

as on 31.01.2025

47. To a specific query whether construction of two NIPERs have completed and were dedicated to the Nation in 2023 and 2024. The Department submitted that Construction of campuses of NIPERs at Ahmedabad and Guwahati had been completed and the permanent campus had dedicated to the Nation on 30.9.2023 & 12.01.2024 respectively by Hon'ble HMCF.

48. On being asked about the percentage of the 'building construction' completed for NIPER-Raebareli and NIPER-Hyderabad. The Department submitted that as on 31.12.2024, 75% of the construction work of NIPER Raebareli and 35% of the construction of NIPER Hyderabad has been completed.

Details of construction of NIPER Hyderabad and Raebareli	
Hyderabad	**Raebareli**
(i)Boundary Wall: Main gate block work and boundary wall east side jungle clearance completed. Plastering for main gate cabins is in progress **(ii)Boys Hostel:** 2nd Floor Slab reinforcement in progress. 2nd floor Slab casting is in progress **(iii)Girls Hostel:** North block 3rd floor columns, south block 2nd floor slab	**(i)Type IV Quarters** –Flooring is in progress **(ii)Academic Building (Block B and Block C) -** Flooring work in progress. **(iii)Boys Hostel-** Internal painting work in progress **(iv)Sub Station-** AAC block work in progress

reinforcement work in progress. Terrace slab shuttering (Upper portion) and 2nd floor slab casting (lower casting) is in progress **(iv)R&D Block:** First floor slab casting (southern side) completed. Rest portion reinforcement work in progress. 1st floor column reinforcement (north side) and slab shuttering (southern side) is in progress **(v)ESS:** Electrical trench work in progress. **(vi)NCRDBD:** Slab casting completed. 1st Floor column reinforcement is in progress.	**(v)Canteen Block-** wall work in progress **(vi)Boundary Wall**- Boundary wall work behind Type IV Quarters is in progress. Boundary wall foundation work behind Administrative Block is in progress. **(vii)External Development work-** sewer line work, RCC drain work, laying of water supply line and sub base preparation for road work in progress.

49. The Committee desired to know what plans do we have for research and education in the pharmaceutical sector in the future, especially in fake medicines, lack of drug inspections, and the shortage of drug inspectors and what specific plans and actions are being taken by the Department. The Department submitted that they have set up seven National Institutes of Pharmaceutical Education and Research (NIPERs) as institutes of National Importance to nurture and promote quality and excellence in pharmaceutical education and research. These institutes impart postgraduate and doctoral education; conduct high-end research in various pharma and meditech specializations; and promote industry-academia interactions and collaborations. Masters Programs are being run in areas like regulatory affairs and regulatory toxicology at many NIPERs. In response to the shortage of drug inspectors, there is a focussed effort to train more students in regulations for adherence to drug safety standards.

50. Asked to state what is the present status of NIPER in Tamil Nadu State, and has any fund been allocated for it, the Department submitted that in the year 2021, the Department of Pharmaceuticals had submitted a proposal to the Expenditure Finance Committee (EFC) for strengthening of the existing seven NIPERs and establishing of five new NIPERs, including one in Tamil Nadu. In the EFC meeting, the Department of Expenditure recommended to first prioritise the strengthening and infrastructure development of the existing seven NIPERs. Consequently, the proposed establishment of new NIPERs did not receive budgetary support.

51. The Committee desired to know what are the other aspects of the development of NIPER besides research and education. The rapid growth in medical field is incresing, what are the future plans for its advancement. The Department submitted that beyond research and education, NIPER is actively involved in various initiatives aimed at advancing the medical and healthcare sector. The institutes is dedicated to supporting India's Atmanirbhar Bharat vision by promoting innovation and self-reliance in medical technology, ensuring the development of affordable, accessible, and cutting-edge healthcare solutions for the nation.

In light of the rapid growth in the medical field, NIPERs have—

(a) *launched specialised programmes:* New courses and research initiatives have been introduced to address emerging areas in medical sciences, aligning with the evolving needs of the healthcare sector, including medical devices. A Centre of Excellence for medical devices has been established at NIPER Ahmedabad;
(b) *established a diagnostic device testing andvalidation facility:* As a futuristic approach, NIPER aims to set up a state-of-the-art facility for testing and validating diagnostic devices. This initiative will offer startups and young innovators access to essential resources for evaluating their prototypes and products; and
(c) *promoted sustainability:* Initiatives aimed at promoting eco-friendly practices in drug development processes are underway, reflecting a commitment to sustainable development. All students are trained in computer based, *in silico* methods so that experiments with chemicals are minimised due to Insilco optimisation.

Further, under the Promotion of Research and Innovation in Pharma-MedTech sector Scheme(PRIP), the Department has set up a Centre of Excellence (CoE) at each of the seven NIPERs, with budget outlay of ₹700 crore over the period from FY 2023-24 to FY2027-28. These CoEs are for medical devices (at NIPER Ahmedabad), bulk drugs (at NIPER Hyderabad), phytopharmaceuticals (at NIPER Guwahati), anti-viral and anti-bacterial drug discovery and development (at NIPER Mohali), biological therapeutics (at NIPER Hajipur) and novel drug delivery system (at NIPER Raebareli). These CoEs aim to foster advanced research and innovation, contributing to self-reliance in pharmaceuticals and medical technology.

D. Promotion of Research and Innovation in Pharma MedTech Sector (PRIP)

The Committee have been informed that the Cabinet approved PRIP (Promotion of Research and Innovation in Pharma MedTech Sector) scheme with a budget outlay of Rs. 5000 crores over a period of 5 years (2023-24 to 2027-28). The objective of the scheme is to transform Indian Pharma and MediTech sector encourage movement of the sector from cost based growth to innovation-based growth by strengthening the research infrastructure in the country. The aim of the scheme is to promote industry-academia linkage for R&D in priority areas and to inculcate the culture of quality research and nurture

our pool of scientists. This will lead to sustained global competitive advantage and contribute to quality employment generation in the country.

The scheme has two components-

Component A: Strengthening of research infrastructure by establishment of seven Centres of Excellence (CoEs) at NIPERS. **The 7 CoEs are as follows-**

S. No	NIPER	Specialization Area of CoE
1	Mohali	Anti-Viral and Anti-Bacterial Drug Discovery and Development
2	Ahmedabad	Medical Devices
3	Hyderabad	Bulk Drugs
4	Kolkata	Flow Chemistry and Continuous Manufacturing
5	Raebareli	Novel Drug Delivery System
6	Guwahati	Phytopharmaceuticals
7	Hajipur	Biological Therapeutics

Component B: Promoting research in pharmaceutical sector by encouraging research in six priority areas like New chemical/biological Entities, Complex generics including biosimilars, medical devices, stem cell therapy, orphan drugs, Drugs against Anti-microbial resistance etc., wherein financial assistance will be provided for the Industries, MSMEs, SMEs, Startups for both In-house research and research in collaboration with Govt. institutes. The financial outlay of this component is Rs 4250Cr. The Component-B is further divided into 3 categories based on the kind and level of research:

a) **Category – B I** – Nine established pharma companies may be selected under this category who are willing to carry out research in six priority areas in collaboration with Govt. institute of national repute. Under this category Rs 125 Cr or 35% of the projects cost, whichever is lower, will be provided to the projects from TRL 1 to reach TRL 9.

b) **Category B II** – In order to expedite the market launch and commercialization of products/technologies in the six priority areas having high commercial potential or societal impact, financial assistance will be provided to 30 projects at TRL5/6 to reach TRL 8/9. Rs 100 Cr or 35% of the projects cost, whichever is lower, will be provided to the selected beneficiaries under this category.

c) **Category – B III**- Under this category, financial support of up to ₹1 Cr will be provided to around 125 research projects from start-ups/ SMEs/ MSMEs having potential or having made sufficient headway in the research in six priority areas which have clear potential to translate into commercial product/technology.

52. The Committee desired to know that how to many Centre of Excellence (CoEs) are being established under the PRIP Scheme and also to clarify whether the mandate of NIPER & CoEs won't overlap with that of NIPERs, the Department stated that Seven Centre of Excellence (CoEs) are being established under the Scheme which are as follows:

S. No	NIPER	Specialization Area of CoE
1	Mohali	Anti-Viral and Anti-Bacterial Drug Discovery and Development
2	Ahmedabad	Medical Devices
3	Hyderabad	Bulk Drugs
4	Kolkata	Flow Chemistry and Continuous Manufacturing
5	Raebareli	Novel Drug Delivery System
6	Guwahati	Phytopharmaceuticals
7	Hajipur	Biological Therapeutics

53. These CoEs will function as hubs for research and development, providing state-of-the-art testing and certification facilities while offering targeted capacity-building programs designed to empower both industry professionals and students. Additionally, the CoEs will contribute to reducing import dependence, establish incubation facilities for startups, and facilitate skill development training programs. They will also serve as skilling hubs to address existing gaps in industry capacity development.

The mandate of NIPERs focuses on nurturing and promoting quality and excellence in pharmaceutical education and research, developing a multi-disciplinary approach to education and research, and, acting as a nucleus for interaction between academia and industry, which aligns closely with those of CoEs under PRIP Scheme and would complement each other. While both entities share the goal of enhancing research capabilities and educational standards, the CoEs will specifically focus on developing state-of-the-art infrastructure in targeted research areas and greater industry-academia engagement. They will facilitate better utilization of existing skilled resources, provide improved exposure to professionals and students and act as skilling hubs to address existing gaps in industry capacity development.

54. Asked about the budget outlay for PRIP, the Department submitted that the overall approval for the scheme would be Rs. 5,000 crore segregated in the following manner:

(in crore ₹)

I. **Component A (Setting up of CoEs)**	**700**		
II. Component B			
Description	**Category – B I**	**Category – B II**	**Category – B III**

No. of projects to be selected	**9**	**30**	**125**
Funding	@35% or Rs 125 crore whichever is minimum/ participant over a period of 5 years	@35% or Rs100 crore whichever is minimum/ participant over a period of 5 years	Rs. 1 crore over a period of 5 years on milestone basis
Eligible R&D fund over 5 yrs	**1,125**	**3,000**	**125**
Total funding for 5 years for component B	4,250		
Total outlay for I & II	4,950		
Administrative cost	50		
Total outlay of the scheme	**5,000**		

55. On being asked as to what extent the PRIP Scheme would help segment the Indian Pharma and MediTech Sectors and how does the scheme aim to contribute to employment generation in the Country. The Department further stated that As innovation drives two-thirds of global pharmaceutical opportunities, the PRIP scheme aims to bolster the Indian Pharma and MedTech sectors by fostering research and innovation within the industry. By encouraging private investment with a strong focus on healthcare, the scheme will help establish a world-class research ecosystem at NIPERs through the creation of Centres of Excellence (CoEs) and the development of a skilled talent pool. Additionally, it will facilitate the launch of commercially viable products, thereby accelerating the growth of the Indian pharmaceutical sector and contributing to employment generation.

56. When enquired about the plan of the Department for utilizing the allocated amount of Rs.5000 crores for setting up of CoEs for the next 05 years and how many CoEs are likely to be set up each year. The Department further submitted that under the PRIP Scheme, a total financial outlay of ₹5,000 crorehas been allocated for two components. Under one of these Components, i.e., Component A, seven CoEs one at each NIPERs have been established with an outlay of INR 700 crore. This allocation would be released towards duration of the scheme (2023-28).

57. The Committee then desired to know as how to many established Pharma companies have been selected under category B-1 of PRIP as on date and what is the Selection Procedure, how many established pharma companies have been provided Rs.125 crore or 35% of the project cost for Projects from (Technology Readiness Levels) TRL 1 to reach TRL 9 and how many projects have been provided the financial assistance of Rs. 100 crore or 35% of the project cost at TRL 5/6 to reach TRL 8/9, the Department

stated that Consulting firm has been on boarded for implementation of the scheme. The call for application is planned in April 2025.

E. Development of Pharmaceuticals Industry:

58. The Committee have been informed that with an objective to strengthen the existing infrastructure facilities and in order to make India a global leader in the Pharma Sector, the Department of Pharmaceuticals released the guidelines for the scheme "Strengthening of Pharmaceutical Industry" (SPI), with a total financial outlay of Rs. 500 Cr. for the period from Financial Year 2021-22 to Financial Year 2025-26 on 11.3.2022. The scheme addresses the rising demand in terms of support required to existing Pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability. The objectives of the scheme "Strengthening of Pharmaceutical Industry" (SPI) are to strengthen the existing infrastructure facilities in order to make India a global leader in the Pharma Sector.

- This Scheme is a Central Sector Scheme and comprises the following sub-schemes:

a. Assistance to Pharmaceutical Industry for Common Facilities (API-CF)

b. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

c. Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

Under the new sub scheme Assistance to Pharmaceutical Industry for Common Facilities (API-CF) of Strengthening of Pharmaceutical Industry (SPI) Scheme, application window was opened from 1st August- 7th October, 2022 for inviting applications for project proposals. Out of 20 applications received under the Scheme, 07 were shortlisted, out of which, 06 projects have been given 'Final approval' (04 projects in 2022-23 and 02 projects in 2023-24) and 01 project has been given 'in-principle approval (in 2023-24) by Scheme Steering Committee (SSC). Further, one new project has been accorded Final approval by the SSC in 2024-25.

59. The Committee desire to know about the details of 20 applications received under the scheme and how many applications have been disposed and pending as on date. The Department submitted that 20 applications received through API-CF sub-scheme portal in F.Y.2022. Out of these 20 applications, 07 applicants were shortlisted. Out of which, 6 applicants have been given 'Final approval' under the API-CF sub scheme and 01 applicant (PUNDRUG, Mohali) given "in-principle" approval has been cancelled due to non-compliance of conditions for granting Final approval.

Further, in F.Y. 2024-25, one more project (Inducare Phase II, Pune, Maharashtra) has been given 'Final approval' and another project Himachal Pradesh Testing Lab Limited (HPTLL), Solan-H.P. has been approved for granting "in-principle" approval. Presently, there are no applications under API-CF sub scheme which are pending for approval.

60. On being asked the reasons why only 07 were shortlisted, out of which, 06 projects have been given 'Final approval' (04 projects in 2022-23 and 02 projects in 2023-24) and 01 project has been given 'in-principle approval (in 2023-24) by Scheme Steering Committee (SSC). The Department submitted that It may be mentioned that the Financial Outlay of the API-CF sub scheme is Rs. 178.40 crore, out of which Rs. 20.15 crore (including PMC charges) has been spent on old projects which have been completed.

As of now, seven (7) have been given ' Final approval' (with committed Grant-in-aid of Rs. 124.32 crore). Further, one project (PUNDRUG, Mohali) given "in-principle" approval earlier (with Grant-in-aid of Rs. 7.00 crore) has been cancelled due to non-compliance of conditions for granting Final approval. One project (HTTL, Solan-HP) has been approved for granting "in-principle" approval (with approved Grant-in-aid of Rs. 20.47 crore). The details of projects under API-CF are as under :

S. No.	Name of SPV	Project	Place	Approved Project Cost	Approved Grant-in-aid
(A) Expenditure incurred on Old Projects (including PMC charges) under API-CF is **Rs. 20.15 crore** **Funds available for further releases :** **Rs. 178.40 crore - Rs. 20.15 crore = Rs. 158.25 crore**					
Projects under Execution/ Ongoing Projects					
1.	Devbhumi Pharmaceutical Testing and Training Foundation	Testing Laboratory	Haridwar, Uttarakhand	Rs. 23.68 crore	Rs. 20.00 crore
2.	Welzo Research and Development Pvt. Ltd.	Research & Development and Testing Laboratory	Baddi, Himachal Pradesh	Rs. 29.90 crore	Rs. 19.53 crore
3.	Jeedimetla Effluent Treatment Ltd.	Common Effluent Treatment Plant (CETP)	Hyderabad, Telangana	Rs. 29.17 crore	Rs. 20.00 crore
4.	Tindivanam Pharma Park Association	Common Effluent Treatment Plant (CETP)	Viluppuram, Tamil Nadu	Rs. 39.51 crore	Rs. 15.88 crore
5.	Tirupati Research & Development Pvt. Ltd. (TREND)	Common Facility Centre for Research & Development and Testing & Training facility	Tirupati, Andhra Pradesh	Rs. 29.90 crore	Rs. 20.00 crore
6.	Telangana Lifesciences	Centre of Excellence on	Hyderabad, Telangana	Rs. 26.02 crore	Rs. 18.87 crore

	Foundation (Earlier Hyderabad Pharmacity Limited)	Antimicrobial Resistance (AMRCoE)			
7.	Inducare Pharma Research Foundation (Phase II)	Testing Laboratories	Jejuri, Pune, Maharashtra	Rs. 14.37 crore	Rs. 7.18 crore
(B) Total				**Rs. 184.80 crore**	**Rs. 121.46 crore**
(C) Expenditure to be incurred on Ongoing projects (including PMC charges) under API-CF is Rs. 124.32 crore					
(D) Total committed expenditure is (A) + (C) = 20.15 + 124.32= Rs. 144.47 crore					
(E) Balance fund available for new projects = Rs. 178.40- (D) = Rs. 33.93 crore					
Projects under consideration out of available balance funds					
8.	Himachal Pradesh Testing Lab Limited (approved in SSC meeting)	Research organisation cum centre for excellence	Solan, Himachal Pradesh	Rs. 23.92 crore	Rs. 20.00 crore
(F) Expenditure to be incurred on upcoming projects (including PMC charges) under API-CF as at Sl. No. 8					**Rs. 20.47 crore**
(G)Balance left as on 20.02.2025 = (E) – (F) = 33.93-20.47 = Rs. 13.46 crore					

It may be further mentioned that out of the total budget of Rs. 178.40 crore of API-CF scheme, an amount of Rs. 164.94 crore has been/ would be spent on the projects (completed/under execution/ consideration). Further, one project (PUNDRUG, Mohali) given "in-principle" approval earlier (with grant-in-aid of Rs. 7.00 crore) has been cancelled due to non-compliance of conditions for granting Final approval. Hence, Deptt. could consider only 08 new projects under API-CF Scheme till date, in view of financial outlay/ available budget under the Scheme.

However, Department may consider any future project under API-CF scheme against the available balance fund of Rs. 13.46 crore subject to feasibility, viability and also in view of scheme tenure ending in Financial Year 2025-26.

61. On being asked whether the norms for approval of applications are very rigid/strict resulting in approval of fewer applications. The Department stated that the applications received through APICF portal are scrutinized by Project Management Consultant (PMC) / SIDBI w.r.t. requisite documents like Detailed Project Report, etc. in consultation with Technical Committee constituted for the purpose, for comments on feasibility/financial viability etc. w.r.t. Scheme guidelines. Further, preference is given to those proposals which will utilize / leverage for scaling up production & financing of common cluster facility.

PMC after scrutiny of the applications submits appraisal report with recommendations to the Department for approval by the Department. Further, the actual applications considered for approval under the Scheme is based on feasibility, total outlay and balance budget available under the Scheme.

62. On being asked the reasons about 265 registrations have been made under the Scheme, with 128 successful applicants. 78 applicants have been approved by the Scheme Steering Committee (SSC), the Department submitted that as on19.02.2025, about 301 registrations have been made under the scheme, with 149 successful applicants. 103 applicants have been approved by the Scheme Steering Committee.

The pharma units who have registered themselves through RPTUAS Portal needs to submit the 'Gap Analysis' Report* and updated KYC for successfully submitting their application under the Scheme. However, many phama units though registered have not yet finalized their 'Gap Analysis' Report and Project Cost for applying under the Scheme. Department / PMC is continuously assisting the registered pharma units through webinars for converting them into successful applicants.

(* Gap analysis- the expenditure required to fill the gap between the existing capacity of the pharma units and the required infrastructure facility for getting the Revised Schedule M / WHO GMP certification)

63. The Committee desire to know how to many proposals under the scheme have been rejected, put on hold etc. by the SSC constituted by the Department of Pharmaceuticals and how many successful applicants have been recorded under the RPTUAS scheme as of January 24.01.2025. The Department submitted that only one proposal viz. Narmada Organics has been rejected by the Scheme Steering Committee due to ineligibility of the applicant in terms of minimum average annual turnover for the last three years as per Scheme guidelines.

As on 24.01.2025, 129 successful applicants have been recorded under the RPTUAS Scheme.

F. <u>Scheme for Strengthening of Medical Device Industry</u>

In order to provide support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion, a new scheme "Strengthening of Medical Device Industry" with five sub-schemes has been launched by Union Minister of Chemicals & Fertilizers and Health & Family Welfare on 8.11.2024 with financial outlay of Rs. 500 crores. Objective of the sub-schemes under the scheme are as follows:

i. Common Facilities for Medical Device Clusters
ii. Marginal Investment Scheme for Reducing Import Dependence

iii. Capacity Building and Skill Development in Medical Device Sector
iv. Medical Device Clinical Studies Support Scheme
v. Medical Device Promotion Scheme

64. On being asked about the criteria for selection of Universities/Institutes under the scheme, the Department submitted that the criteria for the selection under the scheme "Capacity Building and Skill Development in Medical Device Sector Scheme" are as under:-

For Component A, the criteria for selection of institutions is listed below:

1. Availability of Faculties in Institution.
2. Proposed course curriculum in accordance with NEP 2020 and DoP guidelines and Industry demanded learning outcomes.
3. Available/ Provisional Industry and Research Collaboration of Institute in Medical Devices Sector.
4. Available/ Provisional Research Ecosystem in Institute for Medical Devices and related Sector (components of Medical Devices).
5. Linkage Developed with Industry for Skill Training (Summer/Winter Training) as per standards of Sector Skill Councils operating in Medical Devices Sector under Ministry of Skill Development and Entrepreneurship.
6. Placement Strategy proposed and past placement track record.
7. Past workshops/ trainings done by the institution in Medical Devices Sector.

For Component B, the criteria of selection of institutions is as listed below:

1. Affiliation of proposed program with a NCVET approved awarding Body or provision of approval for any new proposed program.
2. Demand for the proposed program by Industry.
3. Availability of the certified Trainers by NCVET approved awarding body.
4. Availability of infrastructure with applicant institution, required to deliver the program (as per NCVET approved awarding body guidelines).
5. Past placement track record of institution.
6. Past workshops/ trainings done by the institution in Medical Devices Sector.
7. Capacity to conduct customized training according to industrial demand/ market demand.
8. Proximity of applicant institution to Medical Device industrial area for industrial visit and in-house training.
9. Industry collaboration available with the institute in Medical Devices Sector.

65. On being asked how to many Central Government Universities/Institutes have been provided financial support or proposed to be provided during the current financial year. The Department further stated that under the sub-scheme "Capacity Building and Skill Development in Medical Device Sector Scheme", in-principle approval has been granted to 13 proposals for Component-A-Support for running post graduate courses (MS/MTech/ PG-Diploma) in Medical Devices in existing institutes and 5 proposals for Component B: Capacity development in Medical

Devices - design, production and testing through diploma, certificate and short term courses, in January, 2025 to provide financial assistance under the scheme.

66. When asked whether the Department has taken any steps to popularize its scheme, the Department submitted that the Life Sciences Sector Skill Development Council (LSSSDC), the Project Management Agency (PMA) of the scheme and the Department have taken several steps to popularize the scheme through print and social media outreach, targeted awareness campaigns (Workshops and Webinars), collaboration with academic bodies, comprehensive guidelines on its website, and active engagement with stakeholders. These initiatives aim to raise awareness and encourage participation among educational institutions and industry.

67. On being asked how much amount has been gainfully utilized so far out of the allocated amount of Rs. 500 crore, the Department submitted that scheme for Strengthening Medical Device Industry was launched on 8.11.2024, with a financial outlay of Rs. 500 crore for the period from 2024-25 to 2026-27 with a view to provide support in critical areas of the medical device industry, under the following five sub-schemes:

(1) Common Facilities for Medical Devices Clusters;
(2) Marginal Investment Scheme for Reducing Import Dependence;
(3) Capacity Building and Skill Development for Medical Devices;
(4) Medical Device Clinical Studies Support Scheme; and
(5) Medical Device Promotion Scheme.

Till date, no funds have been utilized under the scheme.

68. On being asked how to many proposals are pending before the Steering as on date and by what time they are likely to be approved. The Department submitted that the Department of Pharmaceuticals (DoP) had invited applications from eligible applicants on 23 Dec, 2024 for the three (3) sub-schemes under the Scheme for Strengthening of Medical Device Industry (SMDI) through Life Sciences Sector Skill Development Council, the Project Management Agency (PMA) appointed by DoP, for these sub schemes. On the last day of application submission i.e. 31.01.2025, a total of 131 applications were received, with 48 applications for the Marginal Investment Scheme for Reducing Import Dependence, 63 applications for the Medical Device Clinical Studies Support Scheme, and 20 applications for the Capacity Building And Skill Development For Medical Devices (Component B). After scrutiny, the application would be placed before the Scheme Steering Committee for consideration within the current financial year.

69. The Committee desire to know that what are the achievements under this Scheme so far and the details of problems/bottlenecks, the Department submitted that scheme for Strengthening Medical Device Industry was launched on 8.11.2024. Under the sub-scheme “Capacity Building and Skill Development in the Medical Device Sector,” in-

principle approval was granted in January, 2025 for 13 proposals under Component-A to support the running of postgraduate courses (MS/MTech/PG-Diploma) in medical devices at existing institutes and 5 proposals for Component-B, aimed at capacity development in design, production, and testing in the medical device sector through diploma certificate and short-term courses.

Under the sub-scheme "Common Facilities for Medical Device Clusters," in-principle approval was granted in December, 2024 and January, 2025 for 4 proposals to set up common facilities and 6 proposals to establish testing facilities. Furthermore, applications for the schemes (i) Marginal Investment for Reducing Import Dependence, (ii) Clinical Studies Support Scheme, and (iii) Capacity Building (only for Component-B) were called through an online portal by January 31, 2025. Proposals have been received which are currently under initial scrutiny by the Project Management Agency (PMA).

At present, there are no bottlenecks hindering the progress of these initiatives.

70. On being asked as to how many common infrastructure facilities financial assistance has been provided so far and also for establishment/strengthening of testing facilities. The Department stated that under the sub-scheme, in-principle approval has been given to 4 proposals to set up common facilities and 6 proposals to establish testing facilities in the month of December, 2024 and January, 2025. The first instalment to the selected applicants are likely to be released by March 2025.In-principle approval has been given to the following applicants-

For Common Facilities

S. No	Applicant Name
1	Tamil Nadu Advance Manufacturing Centre of Excellence (TAMCOE), Chennai
2	Centre for Medical Mold and Dies, Vishakhapatnam
3	International Centre for Medical Glass and Engineering Image Dept., Vishakhapatnam
4	Telangana Life Sciences Foundation, Hyderabad

For Testing Facilities

S. No.	Applicant Name
1	Shri ChitraTirunal Institute for Medical Sciences Technology, Trivandrum
2	AMTZ Medi Valley Incubation Council, Vishakhapatnam
3	Gesco Healthcare Private Limited, Chennai
4	Testing Centre for Microfabrication and Medical Devices Now - Centre for Cellular & Molecular Platforms[C-CAMP], Bengaluru
5	QVC Certification Services Pvt. Ltd., Ambala
6	OSEL Devices Pvt. Ltd., Greater Noida

71. When asked how many proposals have been received under the Scheme. The Department submitted that the break-up of proposals received under the sub-scheme "Common Facilities for Medical Device Clusters" for 2 components viz. Assistance for Common Facilities (CF) and Assistance for Testing Facilities (TF) is detailed below: -

(a) Assistance for Common Facilities (CF)			
S. No.	**Name of applicant**	**State**	**District**
1	Telangana Life Sciences Foundation	Telangana	Hyderabad
2	Medicolab Nexus	Madhya Pradesh	Indore
3	Centre for Medical Mould and Devices	Andhra Pradesh	Visakhapatnam
4	Medlife Technologies	Gujarat	Ahmedabad
5	Jalore India Medical Park Private Limited	Maharashtra	Mumbai
6	International Centre for Medical Glass and Engineering Image Dept.	Andhra Pradesh	Visakhapatnam
7	Tamil Nadu Smart and Advanced Manufacturing Centre	Tamil Nadu	Chennai
8	Tamil Nadu Advance Manufacturing Centre of Excellence	Tamil Nadu	Chennai

(b) Assistance for Testing Facilities (TF)			
S. No.	**Name of applicant**	**State**	**District**
1	Biovantis Healthcare Private Limited	Himachal Pradesh	Kangra
2	Bombay Test House Private Limited	Maharashtra	Thane
3	Osel Devices Private Limited	Uttar Pradesh	Greater Noida
4	Gesco Healthcare Private Limited	Tamil Nadu	Chennai
5	Medical City	Karnataka	Bengaluru
6	Shri ChitraTirunal Institute for Medical Sciences Technology	Kerala	Thiruvananthapuram
7	DSR PharmcaeuticalEquipments Testing Lab	Uttar Pradesh	Gautam Buddha Nagar
8	Testing Centre for Microfabrication and Medical Devices	Karnataka	Bengaluru
9	Consilience consultants	Karnataka	Bengaluru
10	Rathinam Medical Device Cluster Testing Center**	Tamil Nadu	Coimbatore
11.	AIC AMTZ Medi Valley Incubation Council	Andhra Pradesh	Visakhapatnam
12	QVC Certification Services Private Limited	Haryana	Ambala

72. On being asked the criteria for evaluation of the proposals so received and by what time the proposal are likely to be approved, the Department submitted that a Technical Committee has been constituted for the sub-scheme "Common Facilities for Medical Device Clusters," consisting of representatives from key organizations, including CDSCO (Central Drugs Standard Control Organization), DGHS (Directorate General of Health Services), SGSMIT, and IIT Delhi. The selection of beneficiaries for this initiative has been carried out based on scrutiny by the Project Management Agency (PMA) and recommendations of the Technical Committee after a comprehensive appraisal of the DPRs received considering the suitability of the proposal for the medical device sector, capability of the applicant and business model etc. In principle approval has been granted by the Scheme Steering Committee (SSC). Final approval is likely to be granted within FY 2024-25 to applicants meeting the conditionalities of in-principle approval.

73. When enquired about the allocated amount of Rs. 500 crore for the scheme has been utilized so far and whether any annual target has been fixed. The Department submitted that the new scheme has been launched in November, 2024. The in-principle approval has been given to the proposals received under the scheme in December, 2024 and January, 2025. The first instalment to the selected applicants are likely to be released by March 2025, after verification of all documents as per criteria of the scheme guidelines.

74. On being asked whether the whole allocated fund of Rs. 500 crore would be optimally utilized during the year 2025-26, the Department stated that the total financial outlay of the scheme is Rs. 500 crore for 3 years i.e. Financial Year 2024-25 to 2026-27. It is expected that maximum allocation of fund is likely to be utilised by financial year 2025-26.

G. Promotion of Medical Device Parks

75. The Department of Pharmaceuticals has engaged IFCI as Project Management Agency (PMA) to oversee the implementation of the scheme for promoting Medical Device Parks. This ensures support of a professional agency in implementation of the scheme. In addition, the Department reviews progress on regular basis and advises State Implementing Agencies (SIAs) to expedite fund utilization and physical progress. On several occasions, the Department has communicated directly with senior state officials, to address the slow pace of development in the Medical Device Parks, urging them to accelerate both physical progress and fund utilization. Furthermore, regular review meetings have been conducted to ensure continuous monitoring and resolve any issues impeding successful implementation of the scheme.

The Scheme Pharmaceutical Technology Upgradation Assistance **(PTUAS)** has been revised and renamed as ‘Revamped Pharmaceuticals Technology Upgradation Scheme’ (RPTUAS) on 11.03.2024 with a view to better uptake and to help upgrade the technological capabilities of our pharmaceutical industry to ensure its alignment with the global standards.

RPTUAS scheme guidelines have been further modified on 17thSeptember, 2024 based on the representations received from various Industry Associations to boost participation in the scheme.

The modifications in the RPTUAS guidelines includes (i) increase in the maximum amount of incentive to Pharma units from Rs. 1 crore to Rs. 2 crore, (ii) increase in the maximum amount of 1stand 2ndinstalment from Rs. 50 lakh each to Rs. 1 crore each and (iii) incorporating the expenditure incurred on 'Production Equipment' in the list of Eligible Activities.

It has been informed that under the Scheme, financial assistance is provided for creation of Common Infrastructure Facilities (CIF) in the selected medical device Park promoted by State Government/State Corporation. The total financial outlay of the scheme is Rs. 400 crore and the tenure of the Scheme is from 2020-21 to 2024-25. The financial assistance by the centre is subject to a maximum limit of Rs.100 crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States),whichever is less.

The Medical Device Park projects selected under the Scheme are being implemented by a State Implementing Agency (SIA). The proposals under the scheme were approved by the Scheme Steering Committee (SSC) constituted by Department of Pharmaceuticals (DoP). A Project Management Agency (PMA) assists DoP for effective implementation of the Scheme.

76. On being asked how much financial assistance has been provided to medical device parks in North Eastern States and Hilly States. The Department submitted that under, the scheme "Promotion of Medical Device Parks" financial assistance is provided to selected Medical Device Park @ 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance is 90% of the project cost. Maximum assistance under the scheme for one Medical Device Park is limited to Rs.100 crore. Under the scheme, Madhya Pradesh,TamilNadu, Uttar Pradesh and hilly state Himachal Pradesh were selected for providing grant-in- aid for creation of common infrastructure facilities in the Medical Device Park.

An amount of Rs. 30 crore was released to State Implementing Agency of Himachal Pradesh as first instalment in 2021-2022. Recently, Himachal Pradesh, has withdrawn from the scheme and informed that it will take up the work from its own funds.

77. On being asked how many States have received final approval for creating common infrastructure facilities in their medical device parks as on date, the Department stated that Madhya Pradesh, Tamil Nadu, Uttar Pradesh and Himachal Pradesh were given final approval for creation of common infrastructure facilities in the Medical Device Park. The state of Himachal Pradesh has withdrawn from the scheme and informed that it will take up the work from its own funds.

78. When asked about the Composition of the Scheme Steering Committee and details of the Project Management Agency (PMA). The Department submitted that the

composition of the Scheme Steering Committee (SSC) of the Scheme Promotion of Medical Device Parks is as under:

Secretary, D/o Pharmaceuticals	Chairperson
Financial Advisor, D/o Pharmaceuticals	Member
Joint Secretary, M/o Environment, Forest & Climate Change	Member
Joint Secretary, M/o Health and Family Welfare	Member
Joint Secretary, Department for Promotion of Industry and Internal Trade	Member
Drugs Controller General of India, Central Drugs Standard Control Organisation	Member
Joint Secretary, D/o Pharmaceuticals	Convenor

The Department of Pharmaceuticals has proactively engaged IFCI as the Project Management Agency (PMA) to oversee the implementation of the Medical Device Parks scheme. The PMA regularly visits the development sites in each state and prepares monthly review reports to track the activities being undertaken. Additionally, the PMA monitors the tenders being published, and sees that the project progresses efficiently and as planned.

79. On being asked proposals are stated to have been received for 16 States after evaluation the proposals of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh have been granted final approval for creation of common infrastructure facilities in medical device parks under the scheme. The Department submitted the proposals received from 16 states under the scheme, were evaluated based on the selection criteria given in the scheme guidelines. After evaluation of the proposals, Govt. of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh were conveyed final approval for creation of Common Infrastructure Facilities (CIF), in the proposed medical device parks, in these four states.

First instalment of Rs 30 crore was released to each of the four selected states in the financial year 2021-2022. Recently, the state of Himachal Pradesh has withdrawn from the scheme and informed that it will take up the work from its own funds. They are in process to return the Grant-in-aid of ₹ 30 crore along with the accrued interest since the release of the first instalment under the scheme.

80. During oral evidence the representative of the Department apprised the Committee regarding Medical Device Park as follows:

> "Sir, we had invited 16 proposals. The provision was only for about four parks. He was on a contractual basis. States gave proposals, where it was felt that viability, feasibility would be the best, it was kept accordingly. There were to be 16 medical device parks, there were to be four and out of that Himachal Pradesh withdrew on its own after the sanctions."

The representative further stated that:

"Sir, three Medical Device Parks are coming up in Greater Noida, Ujjain and Kancheepuram. In all three of these coming financial years, they are expected to become operational. If we see the progress in the screen, in 90 hectares, they have already allotted land to about 140 units. Civil works are almost complete. Equipment in various stages of completion. Some have come and some tender is under process and two-four have to float. In all probability, these three will become functional. The total expected investment in the projects that have been filed so far, 3300 crore rupees have been projected by the units and thereare opportunities for 20 thousand jobs. So, this is the status on the Medical Device Parks."

81. When enquired about the First instalment of Rs. 30 crore have been released to each of the Four (4) selected States in the Financial Year 2021-22. The Department submitted that Till January, 2025 the first instalment has been fully exhausted by the states. Now, all the three selected states (Himachal Pradesh has withdrawn from the scheme) have requested for 2nd instalment. The breakup of the same is as below:

Selected States	Central Grant Released	Central Grant Utilized
Tamil Nadu	30.00	30.00
Uttar Pradesh	30.00	30.00
Madhya Pradesh	30.00	30.00
Total	**90.00**	**90.00**

H. Promotion of Bulk Drug Parks

The Scheme for Promotion of Bulk Drug Parks was approved by the Government of India on 20th March 2020 and notified on 21st July 2020. The tenure of the Scheme is from FY 2020-2021 to FY 2025-2026.The objective of the Scheme is to promote setting up of bulk drug parks in the country for providing easy access to world class common infrastructure facilities to bulk drug units located in the parks to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry.

Under the Scheme for Promotion of Bulk Drug Parks, the Department had received proposals from 13 states. After evaluation, proposals of Gujarat, Himachal Pradesh and Andhra Pradesh were approved.

Under the Scheme, financial assistance is being provided for creation of Common Infrastructure Facilities (CIF) viz.-

a. Central Effluent Treatment Plant(s) (CETP)
b. Solid waste management
c. Storm water drains network
d. Common Solvent Storage System, Solvent recovery and distillation plant

e. Common Warehouse
f. Dedicated power sub-station and distribution system with the necessary transformers at factory gate
g. Raw, Potable and Demineralized Water
h. Steam generation and distribution system
i. Common cooling system and distribution network
j. Common logistics
k. Advanced laboratory testing Centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers
l. Emergency Response Centre
m. Safety/ Hazardous operations audits centre and
n. Centre of Excellence etc.

The financial assistance by the Central Govt. is subject to a maximum limit of Rs.1000 Crore per park or 70% of the project cost of Common Infrastructure Facilities (CIF) (90% in case of Northeastern States and Hilly States i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), whichever is less. The fund allocated for the scheme is Rs. 3000 crores and Rs. 1000 crores grant has been approved for each of the selected State, i.e. Gujarat, Himachal Pradesh and Andhra Pradesh. Construction activities are in progress in all 3 selected parks

82. On being asked as to what extent the scheme for promotion of Bulk Drug Parks have been able to achieve its objectives, the Department submitted that the Government of India approved the scheme for "Promotion of Bulk Drug Parks", with an objective to create a world class Common Infrastructure Facility (CIF) and Testing Centers.

In this regard, development of Common Infrastructure Facilities (CIF) have started in all the 3 approved bulk drug parks. Out of the 3 approved States, in 2 States (Gujarat &Himachal Pradesh), the development of the Bulk Drug park is behind schedule, owing to delay in Environment Clearance and in the State of Andhra Pradesh, the development of the park got delayed, owing to change in location of Bulk Drug Park.

Based on the request received from the approved States, the Scheme for promotion of Bulk Drug Parks has been extended till FY 2025-26. All the 3 approved Bulk Drug Parks have submitted revised timelines up to March 2026, for commissioning of Bulk Drug Parks.

83. On being asked give year-wise achievements of the scheme since the inception of the scheme in the year 2020 including the current financial year. The Department stated Year-wise achievement of the Scheme, since FY 2020-21 is as follows:

Financial Year 2020-21:

Scheme was notified in July 2020 and proposals were received from 13 states viz. (i) Uttar Pradesh (ii) Tamil Nadu (iii) Telangana (iv) Karnataka (v) Maharashtra (vi) Gujarat (vii) Madhya Pradesh (viii) Rajasthan (ix) Punjab (x) Haryana (xi) Himachal Pradesh (xii) Andhra Pradesh and (xiii) Odisha.

Further, certain additional details such as GST subvention and Interest rate subvention, were sought from the State Governments.

Financial Year 2021-22:

Based on additional information submitted by the State Governments, evaluation took place till September 2021. Owing to low rates quoted by the States for Utility and Land Lease charges and geographical dispersion, an Advisory Committee, comprising of CEO NITI Aayog, Secretary, Department of Pharmaceuticals (DoP), Secretary DPIIT and representative from Department of Expenditure (Jont Secretary level), was formed with the approval of Hon'ble Minister of Chemicals and Fertilizers dated 26/07/2021, to assist the Department in the selection process.

Financial Year 2022-23:

Under the above-mentioned Advisory Committee, three meetings were conducted, wherein qualitative evaluation, based on parameters such as Availability of Power and Water Infrastructure, State GSDP, Availability of pharma clusters, Environmental issues, etc., was carried out for final selection.

Based on recommendation of the Advisory Committee, Scheme Steering Committee (SSC) held a meeting on 04/07/2022, during which in-principal approval was given to 3 states (Andhra Pradesh, Himachal Pradesh and Gujarat), for setting up Bulk Drugs Parks and Madhya Pradesh was kept on waitlist.

Later, as per Scheme Guidelines, States were given 45 days for submission of DPR. Based on DPR submission and evaluation, the following states have been selected and 01st Installment has been released:

Approved States	Approval Date	Release Date of 1st Instalment of Central Grant	Central Grant-in-aid released (Rs. Crore)
Gujarat	08/10/2022	14/10/2022	300
Himachal Pradesh (HP)	11/10/2022	20/02/2023	225
Andhra Pradesh (AP)	07/12/2023 (New Location - Nakkapalli) 07/11/2022 (Old Location – Kakinada)	13/03/2023	225

Financial Year 2023-24:

Gujarat Bulk Drug Park received Environmental Clearance (EC) on 26thFebruary 2024. Further, owing to issue of Partial de-notification of 769.65 acres of SEZ land (out of the total 2,000 acres, approved for the BD park), AP Bulk Drug park submitted a proposal for

a new location for BD park on 12th October 2023. Based on the request of State Government, approval for new location of AP BD Park at Nakkapalli was conveyed by SSC on 7thDecember 2023. Further, Andhra Pradesh BD Park received amended Environmental Clearance (EC) on 15thMarch 2024.

Financial Year 2024-25:

As of January 2025, in Gujarat Bulk Drug Park, construction work of Boundary walls and approach Roads is completed. Construction work of Internal Roads, Drainage system, internal water supply and Effluent Treatment Plant (ETP) lines is under progress. CIF Utility tenders for Common Effluent Treatment Plant, Solvent Recovery and Treatment Storage & Disposal Facilities awarded and work is under progress. Tender for Common Sewerage Treatment Plant (CSTP), Centre of Excellence and parking has been released. Further, bids for utility tender of Common Steam Supply have been reinvited, owing to nil response received earlier.

In Andhra Pradesh Bulk Drug Park, tender awarded for Roads, Power, water and other utility buildings. Contractor has started the site clearance work (removal of vegetation and jungle clearance) and embankment work. Tender for Common Effluent Treatment Plant (CETP), Steam Generation and solvent recovery is under preparation.

In case of Bulk Drug Park in Himachal Pradesh, the State Implementation Agency (SIA) has submitted an application to Ministry of Environment, Forest and Climate Change (MoEF&CC), for grant of Environmental Clearance. In this regard, a presentation to Ministry of Environment Forest & Climate Change (MoEF&CC) was made on 30th January 2025 and the approval for grant of Environment Clearance is awaited.

84. On being asked the details of utilization of Rs. 3,000 crore allocated for the scheme. The Department stated that a total of Rs. 750 crore have been released to the three approved states, towards first installment (Gujarat – 300 crore, Himachal Pradsh – 225 crore, Andhra Pradesh -225 crore) in FY 2022-23.

Fund Released and Utilized (In crore ₹)						
State	**Approved CIF Cost**	**Central Grant Released**	**State Fund Released**	**Fund Utilized in FY 2023-24**	**Fund utilized in FY 2024-25 (till Jan 2025)**	**Total fund utilized since inception**
Gujarat	1,457.01	300.00	137.10	31.48	220.15	**251.63**
Himachal Pradesh	1,118.46	225.00	35.54	20.93	26.30	**47.23**
Andhra Pradesh	1,438.89	225.00	132.30	-	46.36	**46.36**
Total	**4,014.36**	**750.00**	**304.94**	**52.41**	**292.81**	**345.22**

85. The Committee desire to know how many Parks have been given the grant-in-aid of Rs. 1,000 crore per Park or 70% of the project cost of Common Infrastructure Facilities (CIF) as on date the Department submitted that total 3 Parks in the States of Gujarat, Andhra Pradesh and Himachal Pradesh have been selected under the Scheme for Promotion of Bulk Drug Park.

86. When asked to state that the Department has received proposal from 13 States under the scheme but proposals of three states only have been selected. The Department submitted that as per clause 4.3 of the Scheme Guidelines, a maximum of 3 Bulk Drug Parks can be supported under the Scheme for Promotion of Bulk Drug Park.

87. As regards the present status of construction of Bulk Drug Parks in the States of Gujarat, Himachal Pradesh and Andhra Pradesh. The Department submitted that as on January 2025, the status of Bulk Drug Parks is as under:-

In Gujarat Bulk Drug Park, construction work of Boundary walls and approach Roads is completed. Construction work of Internal Roads, Drainage system, internal water supply and Effluent Treatment Plant (ETP) lines is under progress. CIF Utility tenders for Common Effluent Treatment Plant, Solvent Recovery and Treatment Storage & Disposal Facilities awarded and work is under progress. Tender for Common Sewerage Treatment Plant (CSTP), Centre of Excellence and parking has been released. Further, bids for utility tender of Common Steam Supply have been reinvited, owing to nil response received earlier.

In Andhra Pradesh Bulk Drug Park, tender awarded for Roads, Power, water and other utility buildings. Contractor has started the site clearance work (removal of vegetation and jungle clearance) and embankment work. Tender for CETP, Steam Generation and solvent recovery is under preparation.

In case of Bulk Drug Park in Himachal Pradesh, the State Implementation Agency (SIA) has submitted an application to Ministry of Environment, Forest and Climate Change (MoEF&CC), for grant of Environmental Clearance. In this regard, a presentation to MoEF&CC made on 30thJanuary 2025 and the approval for grant of Environment Clearance is awaited.

88. On being asked about the present status of utilization of first installment released to the three States so far. The Department submitted that:

		Fund Released and utilized till 31stJanuary 2025 (In crore ₹)					
State	**Approved CIF Cost**	**Central Grant Released**	**Central Grant Utilized**	**State Fund Released**	**State Fund Utilized**	**Total Fund Utilized till 31st January 2025**	**Target Utilization amount for availing 2nd Installment (75% utilization of 1st Installment) (In crore ₹)**
Gujarat	1,457.01	300.00	227.68	137.10	23.95	251.63	327.83
Himachal Pradesh	1,118.46	225.00	45.54	35.54	1.69	47.23	195.40
Andhra Pradesh	1,438.89	225.00	24.05	132.30	22.31	46.36	267.98

Total	**4,014.36**	**750.00**	**297.27**	**304.94**	**47.95**	**345.22**	**791.21**

89. To a specific query of the Committee that the Scheme is being implemented through the State Implementing Agencies then how the Department is monitoring the progress of establishment of Bulk Drug Parks, the Department submitted as follows:

A format has been prepared to capture the physical and financial progress of the bulk drug park and the same has been shared with State Implementing Agencies (SIA). On submission of the Monthly Progress Report (MPR), the same is reviewed by the Department to understand the progress and bottlenecks, if any.

Also, the Department has regular interaction with the State Implementing Agencies (SIA) through e-mails, phone calls and online meetings, regarding progress of the project and understanding and resolving the implementation concerns, if any.

Further, the Department conducts Monthly Review Meetings, under the Chairpersonship of Joint Secretary Level, to monitor the physical and financial progress of the Bulk Drug park.

During the above interactions, Department extends support to SIAs in expediting regulatory approvals, in coordination with concerned Ministry.

Department / PMA undertakes periodic site visits to approved Bulk Drug Park sites to review physical and financial progress on project site.

90. When asked about the expected employment generation in each of the Bulk Drug Park. The Department submitted that expected employment generation in Bulk Drug Parks, as submitted in DPR, by the approved States, is as mentioned below:

Gujarat – 67,000.
Andhra Pradesh – 54,307.
Himachal Pradesh – 17,500.

91. When specifically asked that by what time, the three Bulk Drug Parks are likely to be set up and functional, the Department further submitted that all the three approved BD Parks have submitted revised timeline up to March 2026, towards commissioning of Bulk Drug Park.

92. When asked to state that whether any target date has also been fixed for the establishment of three Bulk Drug Parks. If so, the details thereof and steps, if any, taken to complete the process within the target date so fixed. The Department submitted that all the three approved Bulk Drug Parks have submitted revised timeline up to March 2026,

towards commissioning of Bulk Drug Park and accordingly, the tenure of the Scheme for Bulk Drug Park has been extended till March, 2026.

Department undertakes periodic reviews of the Bulk Drug parks, with the representatives of the State Government, to ensure the following:

(a) Necessary regulatory approvals and clearances required for the Park
(b) Release and award of tenders of approved CIF projects
(c) Project execution within the Scheme tenure
(d) Fund Utilisation
(e) Invite applications from prospective stakeholders

Further, Department has issued DO Letters to Additional Chief Secretary/ Principal Secretary of the States, apprising about the progress in Bulk Drug Parks, requesting to expedite the physical progress of the park.

94. On being asked about the comprehensive present status report of Bulk Drug Parks being set up at Bharuch and Nakkapali and what is the estimated investment in these Bulk Drug Parks. The Department submitted that the Scheme for Promotion of Bulk Drug Parks was approved in 2020 to facilitate setting up of three bulk drug parks in the country, with the objective of bringing down the cost of manufacturing of bulk drugs by creation of world-class common infrastructure facilities (CIF). The financial assistance by the Centre is subject to a maximum limit of ₹1,000 crore per park, or 70% of the project cost of CIF (90% in the case of North-Eastern and Himalayan States).

Under the scheme Bulk Drugs Parks have been approved in Bharuch (Gujarat), Nakkapalli (Andhra Pradesh) and Una (Himachal Pradesh) districts. The total project costs for the Gujarat, Andhra Pradesh and Himachal Pradesh Bulk Drugs Parks are ₹2,507.02 crore, ₹1,876.66 crore and ₹1,923 crore. The respective approved CIF costs are ₹1,457.01 crore, ₹1,438.89 crore and ₹1,118.46 crore.

In Gujarat Bulk DrugsPark, Bharuch, construction work of boundary walls and approach roads has been completed. Construction work of internal roads, drainage system, internal water supply and effluent treatment plant (ETP) lines is in progress. Common infrastructure facilities (CIF) utility tenders for ETP, solvent recovery and treatment storage and disposal facilities have been awarded and work is in progress. Tender for common sewerage treatment plant (CSTP), centre of excellence and parking is under evaluation. Further, bids for utility tender of common steam supply have been reinvited following lack of response to the invitation for bids issued earlier. Till 28.2.2025, ₹307 crore have been utilised.

In Andhra Pradesh Bulk Drugs Park, Nakkapalli, tender has been awarded for roads and power, water and other utility buildings. The contractor has started site clearance and embankment works. The tender for ETP, steam generation and solvent recovery is under preparation. Till 31.1.2025, ₹46.36 crore have been utilised.

For the Himachal Pradesh Bulk Drugs Park, Una, approval was accorded by the Government of India in October 2022. Himachal Pradesh Bulk Drug Park Infrastructure Limited (HPBDPIL) under the State Department of Industry is the implementing agency. The timeline for execution of the projects is August 2024 to March 2026.Government of India has approved a grant of ₹ 1,000 crore to support CIF development, with the remaining to be funded by the State Government. First instalment of ₹ 225 crore was released to HPBDPIL on 20.2.2023. The State agency has made a presentation to the Ministry of Environment, Forests and Climate Change on 29th and 30th January 2025 for obtaining environment clearance, and the Expert Appraisal Committee (EAC) has given its observations to the State representatives and deferred grant of environment clearance, while recommending that the sub-committee shall conduct a site visit for further appraisal. Tenders worth ₹53.10 crore have been awarded, for water tank, tube wells, pumping station, pipeline to administrative block and water sustainability system, and 90% of the awarded work has been completed.Tenders for the remaining CIF units are under the process of preparation and approval.

The status of utilisation of funds for the three parks, as on 28.2.2025, is as under:

State	Approved CIF Cost	Central Grant Released	Central Grant Utilized	State Fund Released	State Fund Utilized	Total Fund Utilized till 28th February 2025	Target Utilization amount for availing 2nd Installment (75% utilization of 1st Installment) (Rs. Crore)
Gujarat (status as on 28.2.2025)	1457.01	300.00	227.68	137.10	79.32	307	327.83
Himachal Pradesh (status as on 28.2.2025)	1118.46	225.00	46.54	35.54	1.69	48.23	195.40
Andhra Pradesh (status as on 31.1.2025)	1438.89	225.00	24.05	132.30	22.31	46.36	267.98
Total	4014.36	750.00	298.27	304.94	103.32	401.59	791.21

95. During oral evidence the representative of the Department further apprised the Committee regarding Bulk Drug Parks as follows;-

" Sir, all three were approved. Bharuch and Nakkapalli will be started in the coming year. The work is in advanced stage and is expected to be operational by 2026. Himachal is also at the stage of environmental approval. There is a massive investment of Rs 5500 crore and 2200 hectares of land. About 600 bulk drugs units will be set up. They have all kinds of features. The state governments have supported the schemes on their behalf. This will lead to substantial expansion I the ecosystem of Bulk Drugs."

G. Production Linked Incentive (PLI) Scheme

96. On being asked about the tenure of PLI Scheme the Department submitted that it is from year 2020-21 to 2029-30 with the total financial outlay of Rs. 6,940 crore. The Department submitted that in total, 249 applications were received in four rounds of application window. 48 green field projects for 33 bulk drugs have been approved with a total committed investment of Rs. 3,938 Crores. Against the investment committed, selected applicants have already made an actual investment worth Rs 4,253.92 crores and generated employment for 4,473 individuals, as per the December 2024 Quarterly Review Report. As of February 2025, the selected applicants have commissioned a total of 34 projects for 25 bulk drugs, resulting in cumulative capacity creation of 55,361 MT per annum. Remaining 14 projects are under development. Under the scheme cumulative sales worth Rs 1,556.04 crore, including export sales worth Rs 412.12 crore has been made till December 2024.

The scheme has resulted in capacity creation for bulk drugs which were hitherto imported in the country. The scheme has further resulted in strengthening of fermentation technology manufacturing capability by commissioning of projects such as – Penicillin G, Clavulanic Acid, Prednisolone etc.

97. When asked about the percentage of allocated amount of Rs. 6,940 crore have been utilized so far and how the rest of the allocation is proposed to be utilized by the year 2029-2030, the Department submitted that under the PLI scheme for Bulk Drugs, FY 2022-23 was the first year of performance for Chemical Synthesis products and FY 2023-24 was the first year of performance for Fermentation based products. As of February 2025, an incentive amount of Rs 20.32 crore have been disbursed to applicants, out of total financial allocation of Rs 6,940 crore. The bulk drug projects are gradually scaled up because of consistency of quality and stability requirements. Further, fourteen more projects are under construction and expected to be commissioned in FY 2025-26. It is expected that as the projects mature, there would be increase in sales and proportionately more incentive is expected to be disbursed in the future.

98. On being asked about the details of 41 identified products categorized into four target segments. How this categorization has helped in successfully influencing the PLI scheme, the Department submitted that the list of 41 notified bulk drugs under the PLI scheme for Bulk Drugs are as follows:

Target Segment	Sr. No.	Name of KSM/DI/API
I. Key Fermentation based KSMs / Drug Intermediates	1	Penicillin G
	2	7-ACA
	3	Erythromycin Thiocynate (TIOC)
	4	Clavulanic Acid
II. Fermentation based niche KSMs / Drug Intermediates / APIs	5	Neomycin
	6	Gentamycin
	7	Betamethasone
	8	Dexamethasone
	9	Prednisolone
	10	Rifampicin
	11	Vitamin B1
	12	Clindamycin Base
	13	Streptomycin
	14	Tetracycline
III. Key Chemical Synthesis based KSMs / Drug Intermediates	15	1,1 Cyclohexane Diacetic Acid (CDA)
	16	2-Methyl-5Nitro-Imidazole (2-MNI)
	17	Dicyandiamide (DCDA)
	18	Para amino phenol
IV. Other Chemical Synthesis based KSMs / Drug Intermediates / APIs	19	Meropenem
	20	Atorvastatin
	21	Olmesartan
	22	Valsartan
	23	Losartan
	24	Levofloxacin
	25	Sulfadiazine
	26	Ciprofloxacin
	27	Ofloxacin
	28	Norfloxacin
	29	Artesunate
	30	Telmisartan
	31	Aspirin
	32	Diclofenac Sodium
	33	Levetiracetam
	34	Carbidopa
	35	Ritonavir
	36	Lopinavir
	37	Acyclovir
	38	Carbamazepine
	39	Oxcarbazepine
	40	Vitamin B6
	41	Levodopa

The bulk drugs have been notified under the scheme in two Categories i.e. Fermentation based products and Chemical synthesis based products. The gestation period for setting up of greenfield project under the scheme for Fermentation based product was two years and Chemical synthesis was one year. The Category wise incentive rate under the scheme is as follows:

Category	**Incentive period**	**Incentive rate**
Fermentation based	2023-24 to 2028-29	20% for first 4 years, 15% for fifth year and 5% for sixth year
Chemical synthesis	2022-23 to 2027-28	10%

The categorization has helped in optimizing resource allocation under the scheme. Higher incentive rate has been fixed for technologically challenging fermentation-based manufacturing.

99. When enquired about how the PLI scheme is functioning. The Department submitted that under the PLI scheme for Bulk Drugs applicants have made an actual investment of Rs 4,253.92 crore against the committed investment of Rs 3,938.57 crore and sales worth Rs.1,556.04 crore have been made including export sales worth Rs.412.42 crore, as of December 2025. Total 34 projects have been commissioned for 25 bulk drugs. The scheme has resulted in capacity creation for bulk drugs which were hitherto imported in the country. The scheme has further resulted in strengthening of fermentation technology manufacturing capability by commissioning of projects such as – Penicillin G, Clavulanic Acid, Prednisolone etc.

The overall scheme has been affected by Covid, as projects were delayed because of it. Being greenfield projects, the projects have faced other challenges in form of delays in land acquisition, environmental clearance, drug licensing approvals etc. In some cases, the projects have suffered delays on account of technology availability.

100. When asked about out of 249 applications received under the scheme 48 projects have been approved and how many more projects are proposed to be approved in the current Financial Year and also in the ensuring Financial Year 2025-26, the Department submitted that in four rounds of application window, 48 projects were approved for 33 products. As of February 2025, there is no proposal for opening the application window in near future.

101. On being asked as how many applications are lying pending in the Department and at what level alos by what time the pending applications are likely to be disposed of. The

Department stated that as of February 2025, no applications are pending with the Department for approval or for disposal.

102. When asked to state that whether the PLI Scheme is generating employment as per expectations of the Department. In this regard the Department submitted that under the PLI scheme for Bulk Drugs, there is no specific employment target under the scheme. However, it is anticipated that 9,600 jobs will be created during the scheme's tenure. As per the Quarterly Review Report of December 2024, 4,473 jobs have been generated by the selected applicants.

103. On being asked whether any steps have been taken to make available medical devices to the deaf and dumb children at nominal prices or free of cost to the economically weaker section of the society particularly in rural and remote areas of the Country. The Department submitted that prices of those medical devices that are included in NLEM are controlled under DPCO, 2013. As the devices for deaf and dumb children are not included in the NLEM, 2022, their ceiling prices are not fixed by NPPA. Further, relief to the persons with disabilities is a State subject by virtue of entry '9' of the State List of the Constitution of India. However, the Central Government supplements the efforts of the State Governments for empowerment of persons with disabilities. The Department of Empowerment of Persons with Disabilities (DEPwD) has the certain major provisions/schemes to encourage the persons with disabilities including the deaf and dumb students. DEPwD is implementing Scheme of 'Assistance to Disabled Persons for Purchase/Fitting of Aids/Appliances (ADIP)' under which funds are released to various Implementing Agencies for distribution of aids and assistive devices to eligible persons with disabilities including deaf and dumb, boys and girls throughout the country.

104. On being asked when a company conducts research and development to manufacture a product like a stent in the future does this process get evaluated or verified by the Department. The Department submitted that as per the information provided by the Department of Health and Family Welfare as follows: -

(a) Licenses to manufacture or import a medical device are issued under the Medical Devices Rules, 2017, after thorough scrutiny and demonstration of conformance to quality management system for manufacturing of the medical devices.
(b) As per the said rules, the applicant has to submit the application and technical documents such as product specifications, device design and manufacturing process information, essential principles checklist, verification and validation data, biocompatibility data and sterilisation validation data. Further, the Central Drugs Standard Control Organisation (CDSCO)carries out inspection of the manufacturing site with respect to the quality management system followed by the applicant entity.

(c) The manufacturer is required to comply with the condition of the licence, including the quality management system.
(d) Laboratories for testing medical devices in the country are notified by CDSCO.
(e) In case of report of any quality issue, serious adverse event, death or any other report, the matter is investigated and, based on the facts found, appropriate action is taken under the Drugs and Cosmetic Act, 1940 and the Medical Devices Rules, 2017 against the manufacturer.

For the reporting of adverse events and subsequently evaluating the same, the Ministry of Health and Family Welfare has established the Materiovigilance Programme of India (MvPI)at the Indian Pharmacopeia Commission. No signal related to use of cardiac stents has been detected under MvPI.

105. On being inquired about the reasons for variation of the prices of stents (such as 60,000, 80,000, 1.5 lakh, 2 lakh) are available in market the Department submitted that the Department of Health and Family Welfare incorporated coronary stents [Bare Metal Stents (BMS) and Drug Eluting Stents (DES)], which include metallic DES and Bioresorbable Vascular Scaffold (BVS) / Biodegradable stents, into NLEM, 2015 on 19.7.2016. Following this, coronary stents were included in Schedule I to DPCO, 2013 on 21.12.2016. NPPA initially fixed and notified ceiling prices for coronary stents on 13.2.2017 at ₹7,260 for BMS and ₹29,600 for DES, including metallic DES and BVS/Biodegradable stents.

On 12.2.2018, NPPA revised the ceiling prices of coronary stents to ₹7,660 for BMS and ₹27,890 for DES, including metallic DES and BVS/Biodegradable stents. Subsequently, the ceiling prices were revised every year based on the annual WPI.

The ceiling prices of coronary stents fixed from time to time over the period from 2017 onwards are as below:

Particulars	Drug Eluting Stent (in ₹)	Bare Metal Stent (in ₹)
Ceiling prices fixed on 13.2.2017	29,600	7,260
Ceiling prices w.e.f. 1.4.2017	30,180	7,400
Ceiling prices re-fixed on 12.2.2018	27,890	7,660
Ceiling prices w.e.f. 1.4.2018	28,849	7,923
Ceiling prices w.e.f. 1.4.2019	30,080	8,261
Ceiling prices w.e.f. 1.4.2020	30,647	8,417
Ceiling prices w.e.f. 1.4.2021	30,811	8,462
Ceiling prices w.e.f. 1.4.2022	34,128	9,373
Ceiling prices w.e.f. 1.4.2023	38,265.07	10,509.20
Ceiling prices w.e.f. 1.4.2024	38,267.18	10,509.79

All manufacturers/marketers are required to sell coronary stents within the ceiling price (plus applicable Goods and Service Tax) fixed by NPPA.However, manufacturers/marketers are at liberty to sell at a price below the ceiling price too and may do so based on their respective business considerations.

106. On being asked when a stent is inserted in the heart whether there is a risk of thrombosis and how does a Loan License relate to ensuring the quality and safety of such medical devices like stents. The Department submitted under the Drugs and Cosmetics Act, 1940, CDSCO is responsible for the approval of drugs, conduct of clinical trials, laying down the standards for drugs, control over the quality of imported drugs and coordination of the activities of State Drug Control Organisations. CDSCO has been requested to directly send to the Secretariat of the Parliamentary Standing Committee the information sought.

107. The Committee desire to know whether it is a fact that cardiac stents are being implanted in patients without obtaining proper consent or procedures from the patients or their families. A news report in Gujarat mentioned that two patients died after Dr Khyati Hospital allegedly performed angioplasty to benefit from the Government scheme. The Department submitted that data related to implantation of cardiac stents and consent etc. are not maintained.

As per information provided by MH&FW, in the said matter, it is informed that the incident relating to the death of patients at Khyati Hospital, Ahmedabad took place on 11.11.2024. As a result, an FIR has been filed against Khyati Hospital, Ahmedabad on 12.11.2024 for culpable homicide, cheating and conspiracy. The case has been filed against the doctors, management and owners of Khyati Hospital. All the concerned doctors and cardiologists have been suspended from the scheme and the license of these doctors has also been suspended by the Gujarat Medical Council.

New guidelines were issued for organizing medical camps for hospitals listed under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana Mukhyamantri Amritan (ABPMJAY-MA), which include mandatory prior information of the camp to the District Health Officer, mandatory presence of a medical officer from the government side, and no new enrolment of any kind in the camp.

In addition, a national level workshop was organised by the National Health Authority (NHA) for all the States/UTs implementing AB-PMJAY to check the misuse and irregularities under the scheme and necessary guidelines have also been issued. Also, various steps have been taken by the State Health Agency (SHA) Gujarat to prevent such incidents in future.

108. On being asked whether in reply to a Question asked in Delhi Legislative Assembly, it was replied that in the past two years around 100 patients who get heart stent implants done in Delhi Government-Rajiv Gandhi Super Speciality Hospital died at the facility post surgery and in reply the Government stated that in the last two years, 218 patients have succumbed in the Cardiology Department of which 101 were those patients who had undergone stent implantation and angiography procedure. The Department submitted that the Department of Health and Family Welfare has not offered any comments in the matter as the same pertains to the Government of National Capital Territory of Delhi.

109. On being asked whether Cardiac stents ranging from Thirty Thousand to two lakh rupees and even more are available in the market and there are no guidelines for the patients to exercise an informed choice of the stents to be implanted. The Department submitted that NPPA fixed and notified ceiling prices for coronary stents. Presently, the ceiling prices for coronary stents are ₹10,509.79 for Bare Metal Stents (BMS) and ₹38,267.18 for Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS) / Biodegradable Stents. All manufactures/marketers are required to sell coronary stents within the ceiling price fixed by NPPA.

H. Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device

104. On being asked under PLIMD financial incentive has been given to how many companies @5% on incremental sales of Medical Devices manufactured in India during the previous financial year and also in the current Financial Year 2025-2026. The Department stated that till date, the financial incentive of Rs. 48.85 crore has been approved and disbursed to six (6) applicants under the Scheme. The details are as follows-

S. No.	Applicant Name	Incentive Amount Approved (In Rs. Crore)	Amount Disbursed (In Rs. Crore)
1	Panacea Medical Technologies Pvt. Ltd.	3.10	3.10
2	Wipro GE Healthcare Private Limited	8.00	8.00
3	Nipro India Corporation Private Limited	3.61	3.61
4	Meril Life Sciences Private Limited	6.14	6.14
5	Siemens Healthcare Private Limited	8.00	6.40*
6	Philips Global Business Services LLP	8.00	8.00
	Philips Global Business Services LLP	17.00	13.60*
	TOTAL	53.85	48.85

*Disbursed 80% of the approved incentive based on Management Certified Financial Statements, as per the approved Standard Operating Procedure (SoP). Disbursement of remaining 20% will be done after submission of audited financial statements with statutory auditor's certificate and reconciliation with annual regulatory return filings.

105. On being specifically asked to state as to how the outlay of Rs. 3,420 crore for PLIMD is proposed to be optimally utilized. The Department submitted that under the PLI scheme for Medical Devices, FY 2022-23 was the first year of performance. As on January 2025, the incentive amount of Rs 48.85 crore has been disbursed to applicants. Further, Rs 85.00crore is expected to be disbursed in FY 2024-25.

Due to delay in commissioning of the projects on account of Covid-19 outbreak and delay in regulatory approvals, the incentive allocated for 2022-23 could not be fully utilized. Regular follow up is being done with the applicants for early commissioning of projects under implementation. Through Project Development Cell, support is being provided to facilitate early regulatory approvals. To attract more applicants for development of additional medical devices, Round V was opened in 2024 and six applications have been approved. This will also help in further utilization of the outlay.

106. On being asked about the percentage of the allocated outlay of Rs.3,420 crore has been utilized as on date and how, the Department submitted that under the PLI scheme for Medical Devices, FY 2022-23 was the first year of performance. As on January 2025, incentive amount of Rs 48.85 crore has been disbursed to applicants, out of total financial allocation of Rs 3,420 crore.

107. On being asked whether the Department is hopeful of utilizing the entire outlay of Rs.3,420 crore by the year 2027-28 i.e. when the tenure of the scheme would end, the Department submitted that under the PLI scheme for Medical Devices, FY 2026-27 is the last year of performance and last year for incentive disbursement year is FY FY 2027-28. Total 77 applications were received (42 - Category A + 35 - Category B) in five rounds of application windows 32 applications have been approved (19 –Category –A and 13-Category –B) with committed investment of Rs. 1,356.94 crore and expected employment generation of around 8,437 persons. Incentive amount of Rs. 2,819 crore is expected to be utilized, provided the applicants meet the performance thresholds. As of December 2024, total 19 (18 – Category-A and 1 - category-B) projects have been commissioned for 46 products, out of 154 approved products (44 – Category-A and 110 – Category-B).

108. On being asked what the Department has to say on the functions of the scheme PLIMD and what has been the experience of the Department regarding the implementation of the scheme since the year 2020, the Department submitted that the scheme has received a very good response from the industry and a total of 77 applications were received in five rounds of application window, against which a maximum of 32 applications (19 –Category –A and 13-Category –B) have been approved. The committed investment by the selected applicants is Rs 1,356.94 crore, against which an investment of Rs

1,107.19 crore has been grounded till December, 2024. As per December 2024 Quarterly Review Report , the sales made under the scheme is Rs.9,117.07 crore, which includes export sales worth of Rs.4,398.34 crore. 19 Projects have been commissioned for 46 unique, high end medical devices such as CT scan, MRI machines, LINAC, Rotational Cobalt Machine, Stent, Heart Occluder & Heart Valves, which were previously imported, are now being manufactured in India.

109. On being asked whether in rural areas the Medical Devices are not available and even small scanning machines are also not available in rural areas for analysis of pregnant women, what action the Department has taken in this regards. The Department submitted that as per information provided by the Ministry of Health and Family Welfare, the National Health Policy, 2017 recommends free drugs and diagnostics in public hospitals and aims to improve the quality of diagnosis and treatment. Under the National Health Mission (NHM), the Ministry provides financial and technical support to the States/UTs to strengthen their healthcare system for the provision of accessible, affordable and quality healthcare to all the people. The Ministry focuses on the availability of drugs and diagnostics at all levels of healthcare as recommended in the National Essential Diagnostic List (NEDL) and Free Diagnostic Service Initiative (FDSI). Availability of diagnostics leads to a reduction in out-of-pocket expenditure of the patients.

The Ministry of Health and Family Welfare had launched the FDSI programme under the National Health Mission in 2015 to provide accessible and affordable pathological and radiological diagnostics services closer to the community, which in turn reduces the out-of-pocket expenditure.

110. When asked to state whether the Department has any suggestions to offer for better implementation and improving the overall functioning of the PLIMD. The Department submitted that the commencement of projects under Category-A of the scheme had been delayed due to COVID-19 and pending regulatory approvals such as manufacturing licences. The revision in Scheduled Commercial Operation Date (SCOD), by the Empowered Committee, in respect of these applicants was made because of delays in launching of Greenfield Projects due to COVID-19 and pending regulatory approvals such as manufacturing licences. Further, thirteen Category-B applicants with 110 products have their approval in the month of February and August 2023 and September 2024. The projects of these applicants are under implementation with production expected to commence from FY 2024-25 onwards.

In view of the delay in the commissioning of Category –A applicant projects and on account of approvals granted in FY 2023-24 and FY 2024-25 for Category-B applicants, the incentive allocated for 2022-23 could not be fully utilized despite the investments being made by the applicants. This unclaimed incentive, as per the existing scheme Guidelines, cannot be carried over and could remain unutilized. Due to the delay in the scheduled commercial operation of projects owing to COVID-19, and regulatory approvals proposal

has been submitted to DPIIT for extension of tenure of the scheme by one year from FY 2026-27 to FY 2027-28 (last year of eligible production).

111. On being asked what is the response of the medical devices manufactures towards PLIMD. In view of the Department how the scheme can be made more lucrative for medical devices manufacturers, the Department submitted that the scheme has received a very good response from the industry and a total of 77 applications were received in five rounds of application window, against which 32 applications (19 –Category –A and 13-Category –B) have been approved for 154 products.

During the implementation of the scheme, it was observed that Threshold Minimum Incremental Sales of Manufactured Goods year on year was found to be very high for Category-A applicants. Accordingly, the Department amended the scheme guidelines with the approval of Empowered Group of Secretaries (EGoS) and a "Category B" was introduced with reduced Threshold Minimum Incremental Sales of Manufactured Goods for eligibility to claim for incentive. Thereafter, applications window for Category B applicants was opened and in response, 35 applications have been received out of which 13 applications have been approved. Necessary facilitation is being given to the applicants in setting up of Green Field projects for regulatory approvals through the Project Development Cell in the Department .

112. When asked to state whether any complaint/suggestions has been received from the medical devices manufacturers. The Department submitted that based on Industry consultations, it was observed that Threshold Minimum Incremental Sales of Manufactured Goods to be achieved on year on year basis to become eligible for incentives was found to be very high for Category–A applicants and Gestation Period for setting up of Green-field plants in one year was insufficient.

As per the above observation, the Department amended the scheme guidelines with the approval of EGoS and a "Category B" was introduced in the scheme with reduced Threshold Minimum Incremental Sales of Manufactured Goods for incentive claim eligibility. Accordingly, applications window for Category B applicants was opened and in response, 35 applications were received out of which 13 applications have been approved.

As Gestation Period for setting up of Green-field plants in one year was found to be insufficient, the competent authority i.e. Empowered Committee after review on case to case basis approved extension of Scheduled Commercial Operation Date (SCOD) for the delayed projects. The Department is supporting the applicants in resolution of all issues related to commissioning of projects through the Project Development Cell (PDC) mechanism. The Department has helped in resolution of various issues such as facilitating land allotment, manufacturing licenses, Environmental Clearance and other issues in commissioning of the Projects under PLI scheme for Medical Devices.

113. When asked to state Whether PLIMD is generating the 'employment' as expected. The Department stated that as per December, 2024 Quarterly Review Report, employment of 5,483 persons has been generated against the overall expected employment of 8,437 persons upto March, 2027.

I. Production Linked Incentive for Pharmaceuticals (PLI Pharma)

114. On being asked as to what extent the PLI for Pharmaceuticals has been able to achieve its objectives. The Department submitted that the objective of the scheme is 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.

A total of 278 applications were received by the closing date of 31.08.2021 against which a maximum of 55 applicants have been selected which includes five applicants of In-vitro Diagnostics (IVD) devices. The sales made by the approved applicants till December 2024 Quarterly Review Report is worth Rs 2,34,569 crore which includes exports worth Rs 1,49,420 crore.

115. The Committee desire to know how PLI for Pharmaceuticals has enhanced Country's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification. The Department stated that as per Quarterly Review Report of December 2024, the actual investment made by the applicants are Rs. 34,771 crore against the committed investment of Rs.17,275 crore. The cumulative sales made under the scheme is worth Rs 2,34,569 crore, including export sales worth of Rs 1,49,420 crore.

High-value drugs such as Bio-Pharmaceuticals, Complex generics, patented drugs/Off-Patented drugs (expiring during the scheme duration), auto-immune drugs, anti-cancer drugs, anti-diabetic drugs, cardiovascular drugs, anti-retroviral drugs, Orphan drugs and In Vitro Diagnostic devices etc. are getting manufactured under the scheme.

116. On being asked how to many applicants have been provided financial incentives since inception of the Scheme and what is the outcome. The Department submitted that as on 23.02.2025, total incentive worth Rs 3,589.28 crore has been disbursed to applicants for performance year FY 2022-23 and FY 2023-24. Applicant wise financial incentive disbursed is as under:

(In crore ₹)

S. No.	Applicant Name	Claim Disbursed for performance year 2022-23	Claim Disbursed for performance year 2023-24*
1	Aurobindo Pharma Limited	172.16	230.79
2	Cipla Limited	118.89	127.5
3	Dr. Reddy's Laboratories Limited	330.00	150.00
4	Glenmark Pharmaceuticals Limited	151.88	
5	Intas Pharmaceuticals Limited	149.96	
6	Lupin Limited	62.89	150.00

7	Sun Pharmaceutical Industries Limited	330.00	150.00
8	Torrent Pharmaceuticals Limited	57.31	62.56
9	Zydus Lifesciences Limited	146.99	150.00
10	Alembic Pharmaceuticals Limited	63.87	37.50
11	Biocon Limited	82.50	37.50
12	Biological E Limited	77.59	37.50
13	Emcure Pharmaceuticals Limited	18.94	21.37
14	Macleods Pharmaceuticals Limited	82.50	37.50
15	MSN Laboratories Private Limited	82.50	37.50
16	Natco Pharma Limited	5.88	5.55
17	Strides Pharma Science Limited	21.18	22.50
18	AartiPharmalabs Limited	14.80	
19	Aragen Life Sciences Limited	4.09	
20	BDR Pharmaceuticals International Private Limited	13.51	7.50
21	Concord Biotech Limited	14.81	7.50
22	Malladi Drugs & Pharmaceuticals Limited	10.00	12.37
23	Nosch Labs Private Limited	14.62	7.50
24	Panacea Biotec Limited	2.65	12.37
25	Sai Life Sciences Limited	16.50	
26	Sri Krishna Pharmaceuticals Limited	16.50	
27	Steril-Gene Life Sciences Private Limited	0.89	
28	SymbiotecPharmalab Private Limited	10.89	7.50
29	Umedica Laboratories Private Limited	5.54	5.80
30	Venus Remedies Limited	10.00	
31	Symed Labs Limited	10.00	7.50
32	Poly Medicure Limited (IVD)	0.81	1.06
33	Abhilash Life Sciences LLP	4.51	
34	Aurore Life Sciences Private Limited	16.50	7.50
35	Bal Pharma Limited	9.90	4.50
36	Biophore India Pharmaceuticals Private Limited	3.74	4.84
37	Milan Laboratories India Private Limited	4.54	
38	Neogen Chemicals Limited	16.50	

39	Optimus Drugs Private Limited	16.50	
40	Psychotropics India Limited	0.36	1.27
41	Vandana Life Sciences Private Limited	5.53	
42	Agappe Diagnostics Limited (IVD)	1.88	5.23
43	Transasia Bio-Medicals Limited (IVD)	0.00	
44	Sigachi Industries Limited	0.00	
45	Amneal Pharmaceuticals Private Limited	41.10	
46	Mylan Laboratories Limited	0.00	
47	Premier Medical Corporation Private Limited (IVD)	6.36	11.00
Total		2,228.07	1,361.21

*Incentive claims of Rs 143.542 crore are under examination and expected to disbursed by end of February 2025. Further incentive of Rs.515.84 crore is expected to be disbursed by the end of FY 2024-25.

117. When asked about 278 applications are stated to have been received by the closing date of 31.08.2021 and 55 applications have been selected. When asked to give details and the incentives extended to these 55 selected applicants so far and their contribution in enhancing manufacturing capabilities of the Country in Medical Device Sector. In this regard the Department stated that as per Quarterly Review Report of December 2024, the actual investment made by the applicants is worth Rs 34,771 crore against the committed investment of Rs.17,275 crore. The cumulative sales made under the scheme is worth Rs 2,34,569 crore, including export sales worth Rs 1,49,420 crore. Applicant wise financial incentive disbursed are as under:

(In crore ₹)

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8	Torrent Pharmaceuticals Limited	57.31	62.56
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12	Biological E Limited	77.59	37.50
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15	MSN Laboratories Private Limited	82.50	37.50
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17	Strides Pharma Science Limited	21.18	22.50
18	AartiPharmalabs Limited	14.80	
19	Aragen Life Sciences Limited	4.09	
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24	Panacea Biotec Limited	2.65	12.37
25	Sai Life Sciences Limited	16.50	
26	Sri Krishna Pharmaceuticals Limited	16.50	
27	Steril-Gene Life Sciences Private Limited	0.89	
28	SymbiotecPharmalab Private Limited	10.89	7.50
29	Umedica Laboratories Private Limited	5.54	5.80
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31	Symed Labs Limited	10.00	7.50
32	Poly Medicure Limited (IVD)	0.81	1.06
33	Abhilash Life Sciences LLP	4.51	
34	Aurore Life Sciences Private Limited	16.50	7.50
35	Bal Pharma Limited	9.90	4.50
36	Biophore India Pharmaceuticals Private Limited	3.74	4.84
37	Milan Laboratories India Private Limited	4.54	
38	Neogen Chemicals Limited	16.50	
39	Optimus Drugs Private Limited	16.50	
40	Psychotropics India Limited	0.36	1.27
41	Vandana Life Sciences Private Limited	5.53	
42	Agappe Diagnostics Limited (IVD)	1.88	5.23

43	Transasia Bio-Medicals Limited (IVD)	0.00	
44	Sigachi Industries Limited	0.00	
45	Amneal Pharmaceuticals Private Limited	41.10	
46	Mylan Laboratories Limited	0.00	
47	Premier Medical Corporation Private Limited (IVD)	6.36	11.00
Total		2,228.07	1,361.21

*Incentive claims of Rs 143.542 crore are under examination and expected to disbursed by end of February 2025. Further incentive of Rs.515.84 crore is expected to be disbursed by the end of FY 2024-25.

Under the PLI scheme for Pharmaceuticals, 55 applicants were selected which includes 5 applicants of In-Vitro Diagnostics (IVD). Their committed investment worth Rs. 131.09 crore, against which actual investment of Rs. 281.36 crore has been realized as of December 2024. Furthermore, as per December 2024 Quarterly Review Report, sales made by the IVD applicants are worth Rs. 5,126.08 crore, which includes export sales of Rs. 2,236.79 crore.

J. **Spurious Drugs/Adulterated Drugs**

118. When enquired about what steps has been taken by the Department to stop issuing new licenses for manufacturing drugs in order to control the production of fake and poor-quality medicines, the Department submitted that as per information given by the Ministry of Health and Family Welfare, the manufacturing, sale and distribution of drugs in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945. The regulatory control over the manufacture, sale and distribution of drugs in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments.

The Drugs Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government. The manufacturing premises is required to comply with Good Manufacturing Practices (GMP) provided under Schedule “M” of the said rules for the grant of the licence. Further, the GMP requirement have been revised recently to further ensure quality of the drugs manufactured. In addition to the above, manufacturers are required to comply with the conditions of licence granted under the said Act and rules to manufacture any drugs for sale and distribution in the country.

119. On being asked to state that why did the Ministry of Health & Family Welfare ban the export of drugs containing Tapentadoland Carisoprodol, what actions were taken by the CDSCO and the State Regulatory Authority during their audit of Aveo Pharmaceuticals and how many tablets, capsules, and batches of APIs were seized during the audit to prevent further distribution. The Department submitted that the Ministry of Health and Family Welfare has informed that taking cognizance of media reports, the following actions were taken by CDSCO and the said Ministry:

(a) *Audit and inspection:* A joint team from the CDSCO and the State Regulatory Authority conducted a comprehensive audit of M/s. Aveo Pharmaceuticals between 21st and 22nd February 2025. The findings from the audit led to the issuance of a Stop Activity Order, halting all operations at the company's premises.
(b) *Seizure of materials:* Following the audit, the investigation team seized all raw materials, in-process materials, and finished products. Approximately 1.3 crore tablets/capsules and 26 batches of APIs (Active Pharmaceutical Ingredients) of Tapentadol and Carisoprodol were detained to prevent further distribution of these potentially dangerous drugs.
(c) *Stop Production Order:* The Maharashtra FDA issued a Stop Production Order to M/s. Aveo Pharmaceuticals on 22.2.2025, effectively halting the manufacturing of the concerned drug combinations.
(d) *Withdrawal of export NOCs:* Communications have been sent to all State Drugs Control Authorities and Zonal Offices to immediately withdraw Export NOCs and Manufacturing Licenses granted for any combination of Tapentadol and Carisoprodol. The same communication has also been sent to all Customs offices at notified ports to route all consignments of referred products through CDSCO Port offices.
(e) *Seizure of export consignment:* An export consignment of Tapentadol 125 mg + Carisoprodol 100 mg, destined for Ghana, has been put on hold at Mumbai Air Cargo pending further investigation.
(f) *Updating export NOC checklist:* Going forward, CDSCO has updated the Export NOC checklist, to ensure that either the Product Registration Certificate from the importing country’s National Regulatory Agency (NRA) or approval from the Indian Regulatory Authority (CDSCO) is required for all medicines being exported from India.

120. The desire to know what measures has been taken by the Department to spread awareness among the general public, especially in rural and remote areas, about the proper use of medicines. The Department submitted that as per the information provided by the Ministry of Health and Family Welfare, instructions regarding proper use of the medicines are provided on the label of the medicine. Awareness efforts are as follows:

(a) *Health education campaigns for the general public:* The government conducts health education campaigns to raise awareness about preventive healthcare, hygiene and the importance of seeking timely medical attention.
(b) *Training of community health workers:* Community health workers are trained to provide health education and promote preventive healthcare practices in rural areas.

121. On being asked whether department has details regarding action taken against the factories manufacturing spurious drugs by the respective States. The Department submitted that as per information provided by the Ministry of Health and Family Welfare, on receipt of information gathered or based on complaints received, the matter is investigated in coordination with States and appropriate regulatory actions including arrest of the accused and launching of prosecution are taken. As per information received from various States/Union Territories Drugs Controllers, number of drug samples reported Not of Standard Quality/spurious/adulterated and enforcement action taken by the States/UTs Drugs Controller during the last five years is as under:

Year (April to March)	**No. of drugs samples tested**	**No. of drugs samples declared Not of Standard Quality**	**No. of drugs samples declared Spurious/ Adulterated**	**No. of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs**	**No. of persons arrested**
2019-20	81,329	2,497	199	421	220
2020-21	84,874	2,652	263	236	164
2021-22	88,844	2,545	379	592	450
2022-23	96,713	3,053	424	663	263
2023-24	10,6150	2,988	282	604	131

PART - II

OBSERVATIONS/RECOMMENDATIONS

BUDGETARY ALLOCATION *VIS-A-VIS* UTILISATION DURING 2022-23, 2023-24, and 2025-26

1. The Committee note that the BE of the Department for the financial year 2022-23 was Rs.2244.15 crore. The BE was enhanced to Rs.3160.06 crore in the year 2023-24 and the BE was further enhanced to Rs.4089.95 crore and yet further enhanced to Rs.6920.20 crore. As regard the reasons for increasing trend in the BE of the Department, the Committee have been apprised that some of the new schemes launched by the Department during the period namely Development of Pharmaceutical Industry, Production Linked Schemes (PLIs) and Strengthening of Medical Device Industry (SMDI) and due to provisions being made in the BE for the respective years resulted in enhancement of budgetary allocation for the schemes under the Department. The Committee are of the view that with the enhanced demand for allocation of funds and also enhanced allocation of funds it becomes imperative on the part of the Department to optimally utilize the allocated funds. The Committee desire to know that with the introduction/launching of the new schemes, what measures the Department has put in place to successfully run those schemes. The Committee may be apprised accordingly.

2. The Committee note that the BE of the Department for the year 2023-24 was Rs.3160.06 crore which was reduced to 2697.96 crore. Similarly, the BE for the year 2024-25 was Rs.4089.95 crore which was again reduced to Rs.3387.96 crore and BE for the year 2025-26 was Rs.6920.20 crore which has again been reduced to

Rs.5268.7 crore. As regard this reduction in the BE of the Department the Committee have been apprised that expected release under some schemes could not be made due to lesser demand in infrastructure schemes because of issues in tendering process, environmental clearances etc. non-fulfillment of targeted achievements to claim incentives etc. These were the primary reasons for which the budget had to be reduced at RE stage during FY 2023-24 and FY 2024-25. The Committee are of the view that the reasons cited by the Department are well within the administrative control of the Department itself. The Committee, therefore, recommend that the Department should initiate immediate steps to overcome issues related to tendering process, environmental clearances etc. and ensure that such issues does not hinder the Department from higher allocation of funds.

3. The Committee note with concern that the Department sought Rs.6920.20 crore for the financial year 2025-26 but have been allocated an amount of Rs. 5268.7 crore. Thus, the Ministry of Finance has drastically reduced the allocation by Rs.1651.5 crore. In this regard the Committee desire to know how the different schemes/programmes being run by the Department would be affected and to what extent the Department would have to sacrifice its schemes and programmes. The Department has submitted that if need be they would seek funds later to ensure that the schemes/programmes being run by it will be suffer due to paucity of funds, however, the Committee recommends that the Department should analyse the reasons for drastic reduction in its projected BE and initiate steps so as to seek higher allocation of funds in future.

4. As regards the actual expenditure of the Department the Committee note that the actual expenditure of the Department for the year 2022-23 was Rs.2050.08 crore against allocated amount of Rs.2268.54 crore. During the year 2023-24 expenditure was Rs.2432.45 crore against allocated amount of Rs.2697.96 crore. During the year 2024-25 expenditure was Rs.2432.44 crore against allocated amount of Rs.3387.96 crore. Thus, the Department has not been able to utilize the allocated funds to it for the three consecutive years. In this regard the Department has submitted their justification for under utilization of funds that the Pharma Industry is a growing industry and the targets are based on projections, which at times do not fructify on ground due to various reasons primarily related to infrastructure development for the projects due to various clearances required to be obtained in the time bound manner. Despite, these impediments due to constant monitoring of the scheme by the Department at micro level, 90.37% of RE in FY 2022-23 and 90.15% of RE in FY 2023-24, was utilized. As regards, FY 2024-25, the actual figures for expenditure would only be known on completion of the FY 2024-25 on 31st March, 2025. The Committee do appreciate the contention of the Department that targets set by it are based on projections, which at times do not fructify on ground due to various reasons. However, the Committee recommend that the Department should fix the realistic targets after careful analysis of all the aspects. The Committee would like to be apprised of the steps taken by the Department in this regard.

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP)

5. Expansion of Janaushadhi Kendras (JAKs)

The Committee notes that while the Department has reported the establishment of 15,000 Jan Aushadhi Kendras (KAKs) as of 31.01.2025, their

distribution across the country remains uneven, particularly in the Northeastern States and Union Territories. A closer examination of the state-wise data reveals that certain regions have a significantly lower number of JAKs, with only 9 in Andaman & Nicobar, 2 in Ladakh, 1 in Lakshadweep, 56 in Manipur, 25 in Meghalaya, 15 in Mizoram, 22 in Nagaland, 12 in Sikkim and 29 in Tripura. Given the objective of providing affordable medicines to all, the Committee believes that this distribution pattern needs urgent attention.

Furthermore, considering India's large population of over 1.4 billion people, the current total of 15,000 JAKs translates to approximately one Kendra per 93,000 people, which may not be sufficient to meet the healthcare needs, especially in rural and remote areas. The Committee finds that there is no clear assessment of the actual number of JAKs required to adequately serve the population, particularly in underserved regions with geographical challenges. Additionally, the absence of a comprehensive expansion strategy for JAKs in such areas suggests the needs for a more proactive approach by the Department.

In light of these observations, the Committee recommends an immediate and structured expansion of the JAK network, with a special focus on states and UTs where their presence is minimal. The Department should undertake feasibility studies, demand assessments and consultations with stakeholders to determine the optimal number and location of additional Kendras. The Committee urges the Department to formulate a time-bound action plan ensuring that every district has an adequate number of Kendras, taking into account population density, healthcare access and regional challenges.

6. Disclosure of Complaints Regarding Quality of Medicines

The Committee notes the importance of ensuring transparency and accountability in maintaining the quality of medicines supplied through Janaushadhi Kendras (JAKs). While the department has stated that all batches of medicines undergo 100% quality testing before distribution, it has not provided the exact number of complaints received regarding medicines quality through the CPGRAMS portal of the Government of India and emails to the Pharmaceuticals & Medical Devices Bureau of India (PMBI). The Committee believes that sharing such data is essential for public confidence in the Janaushadhi Scheme and for reinforcing the Department's commitment to quality assurance. Instead of a general assurance, the Committee urges the Department to provide concrete information on the number of complaints received, the nature of concerns raised, and the corrective measures undertaken. This will help in addressing public apprehensions and ensuring that necessary actions are taken to uphold medicines quality. The Committee is particularly interested in understanding whether medicines failing quality checks are promptly recalled and whether appropriate measures, including penalties, are imposed on defaulting suppliers.

7. Establishment of Price Monitoring and Resource Units (PMRUs) in All States/UTs

The Committee notes that the Consumer Awareness Publicity and Price Monitoring (CAPPM) Scheme consists of two key components: Assistance to Price Monitoring and Resource Units (PMRUs) in States/UTs and Advertisement and Publicity for CAPPM. While the Department has informed that PMRUs are operational in 31 States/UTs, the Committee observes that five States/UTs—

Andaman & Nicobar Islands, Tamil Nadu, Delhi, Sikkim, and Manipur—are yet to have functional PMRUs. The Committee is concerned that this gap in implementation may affect price monitoring efforts in these regions, which play a crucial role in preventing overpricing and ensuring price transparency in the pharmaceutical sector.

Since PMRUs are fully funded by the National Pharmaceutical Pricing Authority (NPPA) for both establishment and recurring expenses, financial constraints should not be a limiting factor in their setup. The delay in establishing PMRUs in these regions underscores the need for more focused efforts to ensure uniform implementation of the CAPPM Scheme. The Committee emphasizes the importance of ensuring that consumers across all States/UTs have access to a robust price monitoring mechanism that safeguards them from overpricing and market exploitation.

In this regard, the Committee recommends that the Department take expedited measures to establish PMRUs in the remaining five States/UTs at the earliest. A clear timeline for their operationalization should be provided, along with an explanation for the delay and the corrective measures being undertaken. Ensuring consistent implementation of the CAPPM Scheme across all regions will enhance consumer protection and strengthen price regulation in the pharmaceutical sector.

8. <u>Strengthening and Infrastructure Development of Existing NIPERs</u>

The Committee notes that while the Department had submitted a proposal in 2021 for the establishment of new National Institute of Pharmaceutical Education

and Research (NIPER) centres, the Expenditure Finance Committee (EFC) recommended prioritizing the strengthening and infrastructure development of the existing seven NIPERs instead. Consequently, the Department did not receive any budgetary support for setting up a new NIPER centre in Tamil Nadu.

The Committee acknowledges the importance of enhancing the infrastructure of existing NIPERs before expanding the network. However, it is concerned about the lack of clarity regarding the measures taken to upgrade these premier pharmaceutical research institutions. The absence of a concrete plan or timeline detailing the improvements, financial outlays, and expected outcomes raises concerns about potential delays in infrastructure development. Such delays could indefinitely postpone the expansion of NIPERs, thereby limiting access to high-quality pharmaceutical education and research in other regions.

Given these concerns, the Committee recommends that the Department address this matter with urgency. A comprehensive action plan should be prepared, outlining the specific steps taken to enhance infrastructure in the seven existing NIPERs, the timelines and financial allocations earmarked for these improvements, the status of faculty recruitment, research facilities, and industry collaborations under this initiative, and a strategy to secure additional funding to expedite infrastructure strengthening while also facilitating the future establishment of new NIPERs, particularly in Tamil Nadu.

PROMOTION OF RESEARCH AND INNOVATION IN PHARMA MED-TECH SECTOR (PRIP)

9. The Committee note that the cabinet approved PRIP scheme with a budget outlay of Rs.5000 crore over a period of 5 years ranging from 2023-24 to 2027-28. The scheme has two components (i) strengthening of research infrastructure by establishment of 07 Centres of Excellence (CoEs) and (ii) promoting research in pharmaceutical sector by encouraging research in 06 priority areas. The Committee further note that the objectives of the Scheme are laudable, however, the scheme would end in the year 2027-28. As such only a couple of years have been left for the running of the scheme. The Committee desire and recommend that the Department should fully exploit the scheme and make optimal utilization of the Rs. 5000 crore allocated to it. If need be the Department should also seek extension of the scheme beyond 2027-28.

10. Effective Utilization of Funds Under the Strengthening of Pharmaceutical Industry (SPI) Scheme

The Committee note that the Strengthening of Pharmaceutical Industry (SPI) Scheme was launched with a total financial outlay of ₹500 crore for the period 2021-22 to 2025-26. With just one year remaining before the scheme concludes, the Committee is concerned about the effective utilization of the allocated funds and whether the scheme's objectives are being met. Any inefficiency in fund utilization could lead to underperformance, limiting the intended support for the pharmaceutical sector. Given the industry's critical role in ensuring self-reliance and

global competitiveness, delays in implementation could have long-term implications for industry growth and public health.

To ensure the full and effective utilization of the remaining budget in the final financial year (2025-26), the Committee emphasizes the need for a robust mechanism to monitor progress. The Department must take immediate steps to review the scheme's implementation, ensuring that funds are being utilized as planned and delivering tangible outcomes. Identifying and addressing any bottlenecks hindering the scheme's execution is essential. In this regard, the Committee recommends that the Department conduct a detailed review of the SPI scheme, including an account of funds allocated and utilized, as well as its actual impact on the pharmaceutical sector. A comprehensive status report should be prepared, outlining specific projects funded, industry beneficiaries, and measurable improvements resulting from the scheme.

11. The Committee further note that out of the 20 applications received under the strengthening of pharmaceutical scheme, 07 applicants have been shortlisted and just 06 applicants have been given final approval whereas in principal approval granted to one applicant has been cancelled and at present the Department has NIL number of applications. The Committee desire to know whether in principle approval granted to a few applicants is sufficient enough to meet the objectives of the scheme.

PROMOTION OF MEDICAL DEVICE PARK

12. As regards Promotion of Medical Device Parks the Committee have been apprised that the first installment of Rs. 30 crore has been released to each of the

03 States selected in the year 2021-22 for Promotion of Medical Device Parks. The Committee have been further apprised that till January, 2025 the first installment of Rs. 30 crore each has been fully utilized by the 03 States namely Tamil Nadu, Uttar Pradesh and Madhya Pradesh. The Committee desire that the remaining installments may be released at the earliest and the Promotion of Medical Device Parks may be brought to logical conclusion at the earliest.

PROMOTION OF BULK DRUG PARKS

13. The Committee note that the scheme for Promotion of Bulk Drug Parks was approved way back in the year 2020 and the tenure of the Scheme is from the year 2020-21 to 2025-26. The objective of the scheme is stated to be to promote Bulk Drug Parks in the country for providing easy access to world class common infrastructure facility to Bulk Drug Unit located in the Parks to significantly bring down the manufacturing cost of Bulk Drugs and to make our Country self reliant in Bulk Drugs by increasing the competitiveness of the domestic Bulk Drug industry. For this purpose 03 States namely Gujarat, Himachal Pradesh and Andhra Pradesh have been selected and construction activities are stated to be in progress in these 03 States. However, the Committee regret to note that out of the 03 States selected for promotion of Bulk Drug Parks 02 states namely Gujarat and Himachal Pradesh are lagging behind and Development of the Bulk Drug Parks in these States is behind scheduled owing to delay in environmental clearances and change in location of Bulk Drug Parks etc. Under these circumstances the 03 States have submitted revised timeline upto March, 2026 for commissioning of Bulk Drug Parks. The Committee recommend that the Department should work in close cooperation with the State Government of Gujarat and Himachal Pradesh to resolve the issues which

are hindering the development/construction work of Bulk Drug Parks in these States. The Committee also recommend that the issues be resolved expeditiously and vigorously pursued with the State Governments. The Committee also recommend that the Bulk Drug Parks may be given a concrete shape and should be made ready by March, 2026 invariably. The Committee would like to be apprised by the steps taken in this regard by the Department.

14. As regard Promotion of Bulk Drug Parks the Committee have noted with deep concern that for the State of Gujarat, Himachal Pradesh and Andhra Pradesh the Central grant and the State fund released is Rs. 437.10 crore, Rs. 260.54 crore and 357.30 crore respectively however, the total fund utilized till January, 2025 is Rs. 251.63 crore, Rs. 47.23 crore and Rs. 46.36 crore whereas, the target utilization amount for availing second installment is stated to be Rs. 327.83 crore, Rs. 195.40 crore and 267.98 crore. Under these circumstances the 03 States would not be able to avail the second installment of the funds. The Committee deplores the same and such clarification from the Department for slow pace of expenditure by the 03 States. The Committee recommend that immediate attention may be paid for accelerating the pace of funds utilization by the selected States and at the same time analyze the reasons for the same.

PRODUCTION LINKED INCENTIVE SCHEME (PLI Scheme)

15. The Committee note that the tenure of PLI Scheme is from the year 2020-21 to 2029-30 with the total financial outlay of Rs. 69.40 crore and the selected applicants have already made an actual investment of Rs. 4253.92 crore and have also generated employment for 4473 individuals. Further, they have commissioned a

total of 34 projects for 25 Bulk Drugs. The scheme has resulted in capacity creation for Bulk Drugs which were hithereto imported in the Country besides strengthening of fermentation technology manufacturing capability by commissioning of projects. The Committee are of the view that the objectives of the scheme are laudable and the Department has been able to implement the scheme successfully. The Committee recommend that the scheme may be strengthened further and the allocated outlay of Rs. 6940 crore may be optimally utilized till the end of the tenure of the scheme in the year 2029-30. The Committee have also been informed that a national level workshop was organized by the National Health Authority for all the States/UTs to check the misuse and irregularities under the PLI Scheme and necessary guidelines have also been issued. The Committee recommend that adequate action may be initiated so that the guidelines may be implemented in letter and spirit.

16. The Committee are deeply concerned about the tragic incident in a hospital in Ahmedabad, Gujarat, where a patient lost their life due to the insertion of cardiac stents without proper consent or adherence to medical procedures. While it is noted that an FIR has been lodged against the hospital, legal action has been initiated against the doctors, management, and owners, and the concerned medical professionals have been suspended along with their licenses, the Committee emphasizes the need for stricter preventive measures.

The Committee recommend that stringent action continue to be taken in similar cases in the future to ensure accountability. More importantly, the Department, in consultation with the Ministry of Health and Family Welfare, must urgently formulate clear guidelines and protocols to prevent such incidents from

recurring. These guidelines should establish strict procedural safeguards for informed consent, adherence to medical ethics, and monitoring mechanisms to ensure compliance in all healthcare institutions.

17. The Committee have also been informed that a national level workshop was organized by the National Health Authority for all the States/UTs to check the misuse and irregularities under the scheme and necessary guidelines have also been issued. The Committee strongly recommend that the guidelines may be implemented in letter and spirit.

18. The Committee note that the Department has informed them about the ceiling prices for coronary stents fixed and notified by the National Pharmaceutical Pricing Authority (NPPA), which currently stand at ₹10,509.79 for Bare Metal Stents (BMS) and ₹38,267.18 for Drug Eluting Stents (DES), including metallic DES and Bioresorbable Vascular Scaffold (BVS)/Biodegradable Stents. All manufacturers and marketers are required to adhere to these price caps while selling cardiac stents.

However, the Committee are concerned about reports indicating that cardiac stents are still being sold at significantly higher prices in hospitals and the open market, raising serious questions about the enforcement of price controls and potential profiteering by pharmaceutical companies. In light of the recent surge in medicine prices across various categories, including essential life-saving drugs, the Committee is particularly troubled by the possibility that patients are being burdened with excessive costs, despite regulatory price ceilings.

The Committee, therefore, strongly recommend that the Department, in coordination with NPPA, take immediate and effective measures to ensure strict compliance with the prescribed ceiling prices for cardiac stents. A transparent and robust monitoring mechanism must be put in place to track pricing and prevent any overcharging by manufacturers, marketers, and healthcare institutions. Additionally, the Committee urges the Department to conduct a comprehensive review of the pricing trends of critical medical devices and medicines, including cardiac stents, to curb excessive profiteering and ensure that patients have access to these life-saving interventions at genuinely affordable rates.

19. The Committee expresses serious concern over the unchecked rise in prices of medicines that do not fall under the purview of the National List of Essential Medicines (NLEM). While price regulation under the NLEM ensures affordability for essential medicines, a significant number of life-saving and widely prescribed drugs remain outside this regulatory framework, leading to exorbitant pricing. This creates an undue financial burden on the common people, making critical healthcare unaffordable, particularly for lower-income households.

The Committee strongly recommends that the Department of Pharmaceuticals, in coordination with the Central Drugs Standard Control Organization (CDSCO) and the National Pharmaceutical Pricing Authority (NPPA), take immediate steps to expand the scope of the NLEM to include more essential and widely used medicines, particularly those required for chronic diseases, rare disorders, and critical care. The failure to regulate these medicines allows pharmaceutical companies to impose arbitrary pricing, making essential treatments unaffordable for vast sections of the population.

The Committee further urges the Department to undertake a comprehensive review of the NLEM at regular intervals and ensure that the list reflects the evolving healthcare needs of the country. The arbitrary exclusion of essential medicines from price control must be addressed immediately. Any delay in expanding the NLEM would result in continued financial hardship for patients and compromise access to life-saving treatments. The Committee expects urgent action in this regard and seeks a detailed response from the Department at the earliest.

PRODUCTION LINKED INCENTIVE SCHEME FOR PROMOTING DOMESTIC MANUFACTURING FOR MEDICAL DEVICES (PLIMD)

20. As regard the availability of small scanning machine and other Medical Devices in rural areas for examination of pregnant women etc. the Department has submitted that the National Health Policy, 2017 recommends free drugs and diagnostics in public hospitals and aims to improve the quality of diagnosis and treatment. Under the National Health Mission (NHM), the Ministry provides financial and technical support to the States/UTs to strengthen their healthcare system for the provision of accessible, affordable and quality healthcare to all the people. The Ministry focuses on the availability of drugs and diagnostics at all levels of healthcare as recommended in the National Essential Diagnostic List (NEDL) and Free Diagnostic Service Initiative (FDSI). Availability of diagnostics leads to a reduction in out-of-pocket expenditure of the patients. The Ministry of Health and Family Welfare had launched the FDSI programme under the National Health Mission in 2015 to provide accessible and affordable pathological and radiological diagnostics services closer to the community, which in turn reduces the out-of-pocket expenditure. In this regard the Committee desire to know whether the

provisions of National Health Policy, 2017 are good in paper only and whether practically the benefits of the Policy are being delivered to the common man practically also.

21. As regard to PLIMD scheme the Department has submitted that the commencement of projects under Category-A of the scheme were delayed due to COVID-19 and pending regulatory approvals such as manufacturing licences. The revision in Scheduled Commercial Operation Date (SCOD), by the Empowered Committee, in respect of these applicants was made because of delays in launching of Greenfield Projects due to COVID-19 and pending regulatory approvals such as manufacturing licences. Further, thirteen Category-B applicants with 110 products have their approval in the month of February and August 2023 and September 2024. The projects of these applicants are under implementation with production expected to commence from FY 2024-25 onwards.

In view of the delay in the commissioning of Category –A applicant projects and on account of approvals granted in FY 2023-24 and FY 2024-25 for Category-B applicants, the incentive allocated for 2022-23 could not be fully utilized despite the investments being made by the applicants. This unclaimed incentive, as per the existing scheme Guidelines, cannot be carried over and could remain unutilized. Due to the delay in the scheduled commercial operation of projects owing to COVID-19, and regulatory approvals proposal has been submitted to DPIIT for extension of tenure of the scheme by one year from FY 2026-27 to FY 2027-28. In this regard the Committee are of the opinion that a considerable time has been elapsed after COVID-19 and the PLIMD scheme should not be got effected by the aftermath of COVID-19. The Department should initiate steps to overcome the problems posed by the

COVID-19. The Committee would like to be apprised of the steps taken by the Department.

22. <u>Strict Implementation of Drug Regulations to Curb Spurious and Adulterated Medicines</u>

The Committee notes that the manufacturing, sale, and distribution of drugs in India are regulated under the Drugs and Cosmetics Act, 1940, and the Drugs Rules, 1945. The regulatory framework operates through a system of licensing and inspection carried out by the State Licensing Authorities (SLAs) under the respective State Governments. As per recent amendments to the Drugs Rules, 1945, it is now mandatory for a manufacturing establishment to be inspected jointly by Drugs Inspectors of the Central and State Governments before granting a manufacturing license. Additionally, manufacturing premises must adhere to Good Manufacturing Practices (GMP) as outlined in Schedule 'M' of the Rules. These GMP requirements have recently been revised to further strengthen quality control measures. However, it has been noted that the deadline for compliance with the revised Schedule 'M' has been extended until December 31, 2025. The Committee seeks to understand the rationale behind this extension and emphasizes the need for the industry to implement the updated Good Manufacturing Practices at the earliest.

Despite these regulatory provisions, the Committee remains deeply concerned about the persistent issue of spurious and adulterated drugs circulating in the market, posing a serious threat to public health and safety. The Committee

strongly emphasizes that mere amendments to regulations are not enough unless their implementation is strict, uniform, and effectively monitored across all States and Union Territories. There is an urgent need to ensure full compliance with these regulatory provisions, particularly in high-risk regions where counterfeit drugs are prevalent.

In this regard, the Committee strongly recommends that the Drugs and Cosmetics Act, 1940, and the Drugs Rules, 1945, be enforced rigorously across the country to eliminate the menace of spurious and adulterated drugs. The Department of Pharmaceuticals must work in close coordination with the Ministry of Health and Family Welfare to ensure strict monitoring, timely inspections, and swift punitive action against violators. The Committee recommends that the guidelines issued by the Central Drugs Standard Control Organization (CDSCO) on Good Distribution Practices (GDP) released on 4th April 2024 be made legally enforceable. This will strengthen the quality standardsacross the pharmaceutical industry by ensuring proper handling, storage, and tracking of drugs throughout the supply chain. Furthermore, the Committee recommends that the Department should conduct a detailed review of the situation taking into account (i) the number of inspections conducted, (ii) violations detected, (iii) actions taken against non-compliant manufacturers, and (iv) additional measures planned to strengthen enforcement mechanisms.

23. The Committee has been apprised that out of 4,57,910 drug samples tested, as many as 13,735 samples were found not of standard quality, and 1,547 samples were declared spurious or adulterated. Further, 2,516 prosecutions were initiated for

the manufacture, sale, and distribution of spurious/adulterated drugs, leading to the arrest of 1,228 persons during the period 2019-20 to 2023-24.The Committee is deeply perturbed by these figures, which expose the alarming prevalence of spurious and substandard drugs in the market. While the detection of non-standard and spurious drugs is a serious concern in itself, the Committee finds it equally disturbing that the number of prosecutions and arrests is disproportionately low compared to the number of substandard and spurious drug samples identified. This indicates weak enforcement, inadequate punitive action, and possible lapses in regulatory oversight, which ultimately compromise public health and safety.

The Committee is of the firm opinion that mere identification of spurious drugs is not enough—strict legal action must follow, including swift prosecutions, stricter penalties, and immediate shutdowns of non-compliant manufacturers. The current level of enforcement is grossly insufficient, and much stronger efforts are needed by the Department of Pharmaceuticals and the Ministry of Health and Family Welfare to eliminate the production and distribution of counterfeit and adulterated drugs.

In this regard, the Committee recommends that the Department and the Ministry take urgent and concrete steps to: 1. Enhance surveillance and inspections across all manufacturing units, particularly in high-risk regions. 2. Expedite legal proceedings and ensure maximum penalties for those involved in the production and distribution of spurious drugs. 3. Increase inter-agency coordination, including collaboration with law enforcement agencies, to dismantle networks engaged in counterfeit drug production. 4. Strengthen penalties under the Drugs and Cosmetics Act to serve as a deterrent against the manufacture and sale of substandard drugs.

5. Launch a national awareness campaign to educate consumers and healthcare professionals about identifying counterfeit medicines and reporting violations.

The Committee further desires to be apprised of the specific measures taken to strengthen enforcement and regulatory oversight in this regard.

New Delhi;
18 March, 2025
27Phalguna, 1946 (Saka)

Azad Kirti Jha
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

Annexure A.1

Centre wise and year wise details of Students Enrolled and Students passed out from all NIPERs since inception

Annexure A.1														
NIPER	Ahmedabad		Guwahati		Hajipur		Hyderabad		Kolkata		Mohali		Raebareli	
Year Wise	Students Enrolled (Total)	Students Passed out (Total)	Students Enrolled (Total)	Students Passed out (Total)	Students Enrolled (Total)	Students Passed out (Total)	Students Enrolled (Total)	Students Passed out (Total)	Students Enrolled (Total)	Students Passed out (Total)	Students Enrolled (Total)	Students Passed out (Total)	Students Enrolled (Total)	Students Passed out (Total)
1998											47			
1999											40			
2000											46	47		
2001											53	40		
2002											100	46		
2003											119	53		
2004											129	99		
2005											121	117		
2006											148	122		
2007	31				29		41		29		170	117		
2008	36		19		30		47		32		190	141	20	
2009	36	31	27		34	29	57	41	40	29	214	163	28	
2010	67	33	37	19	42	27	75	44	49	32	358	182	30	20
2011	54	35	42	27	48	32	82	56	47	40	336	208	31	28
2012	62	58	41	37	26	41	109	75	37	49	376	322	37	30
2013	38	46	37	38	44	46	121	82	49	47	225	314	38	31
2014	36	56	35	36	40	22	121	109	42	37	262	347	38	37
2015	65	31	30	39	29	41	124	119	39	49	286	216	36	38
2016	84	32	38	35	37	40	133	117	51	42	283	237	35	38
2017	88	62	43	27	42	25	141	120	55	39	280	278	42	41
2018	111	76	69	35	41	31	145	128	28	42	256	268	61	39
2019	124	83	76	40	53	35	167	139	32	46	268	272	68	43
2020	169	103	116	69	57	36	202	140	59	27	271	244	78	56
2021	185	115	150	73	85	44	226	155	90	33	328	257	106	78
2022	201	142	179	115	110	51	229	165	116	49	346	250	139	74
2023	213	151	238	127	133	71	252	183	140	84	384	267	137	88
2024	154	163	185	146	65	91	219	179	105	97	269	283	113	107
Total	1754	1217	1362	863	945	662	2491	1852	1040	742	5905	4890	1037	748

Total Students Enrolled in all NIPERs	14534
Total Students Passed Out all from NIPER	10974

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
(2024-25)

Minutes of the Thirteenth Sitting of the Committee

The Committee sat on Tuesday, the 25th February, 2025 from 1100 hrs. to 1340 hrs. in Committee Room No. 1, EPHA, A Block, New Delhi.

PRESENT

Shri Azad Kirti Jha – Chairperson

MEMBERS

LOK SABHA

2. Shri Brijmohan Agrawal
3. Shri Ajay Bhatt
4. Shri Rober Bruce C.
5. ShriBharatsinhji Shankarji Dabhi
6. Shri Malvinder Singh Kang
7. Shri Babu Singh Kushwaha
8. Dr. Sambit Patra
9. Shri Balram Nair Porika
10. Shri Schithanantham R.
11. Shri Daggumalla Prasada Rao
12. Shri Tharaniventhan M.S.
13. Shri Shivmangal Singh Tomar

RAJYA SABHA

14. Shri Subhash Barala
15. Shri Subhash Chandra Bose Pilli
16. Shri Meda Raghunadha Reddy
17. Dr. Kalpana Saini
18. Shri Tejveer Singh

SECRETARIAT

5. Smt. Suman Arora - Additional Secretary
6. Ms. Miranda Ingudam - Director
7. Shri Kulvinder Singh - Deputy Secretary
8. Ms. Neelam Bhave - Committee Officer

WITNESSES

I Representatives of the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals

1. Shri Amit Agrawal, Secretary
2. Shri Awadhesh Kumar Choudhary, Sr. Economic Adviser
3. Shri P. Krishnamurthy, Chairman, NPPA
4. Shri Manoj Sethi, Joint Secretary (JS&FA)
5. Ms. Gayatri Nair, Economic Adviser (DoP)
6. Shri Santosh Kumar, Chief Controller of Accounts (DoP)
7. Shri Abhishek Kumar Singh, Director (DoP)
8. Shri Hitendra Sahu, Director (DoP)
9. Ms. Vinod Kotwal, Member, Secretary, NPPA
10. Ms. Nirja Saraf, Managing Director, Hindustan Antibiotics Limited (HAL)
11. Shir Ravi Dadhich, CEO (PMBI)

2. At the outset, the Chairperson welcomed the Members of the Committee and the representatives of the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers to the Sitting of the Committee convened to take oral evidence of the Department on 'Demands for Grants (2025-26)'. Their attention was then drawn to Direction 58 of the 'Direction by the Speaker' regarding confidentiality of the proceedings of the Committee. The Committee desired to know that the Department ought an allocation of Rs. 6920.2 crore for the year 2025-26 and an amount of Rs.5224.5 crore has actually been allocated to it. The Committee desired to be apprised of the reasons for the drastic cut in the budget allocation for the Department and the schemes/programmes which would have to be sacrificed due to lesser allocation of funds. The Committee also desired to know about the priorities of the Department during the year 2025-26, whether the Department propose to seek more funds at RE 2025-26 stage and what advance measures are being taken/proposed to speed up the implementation of various Schemes in the current Financial year.

3. The Secretary, DoP accordingly, briefed the Committee through a Power Point Presentation on various aspects related to examination of Demands for Grants viz. the proposed budgetary allocations for the year 2025-26 vis-à-vis funds allocated to the Department overview of the Pharmaceutical Industry; Medical Device Sector; Key

objectives of the Schemes; Making affordable Jan Aushadhi to all; Women inclusivity; PLI Schemes for Pharmaceuticals; Critical bulk drugs produced under Pharma PLI scheme; Bulk Drug Parks Scheme; Strengthening of Pharmaceutical Industry Scheme; PLI Scheme for Medical Devices; Medical Device Parks Schemes; National Pharmaceutical Pricing Policy, 2012; Price regulation under DPCO, 2013; Impact on prices of NLEM and non-NELM drugs; Additional price regulation in some cases; National Institutes of Pharmaceutical Education & Research (NIPERs); Supporting research & innovation; Public Sector Undertakings and Budget Estimates for Financial Year 2025-26.

4. The Secretary, DoP also informed the Committee about the mandate and strategies of the Department of Pharmaceuticals, Central Sector Schemes, challenges and initiatives of National Institute of Pharmaceuticals Education and Research (NIPER), Bulk Drug Park Scheme, PLI Schemes for promoting Medical Devices and Pharmaceuticals, Promotion of Medical Device Parks, Strengthening of Pharmaceutical Industry Scheme etc.

5. Thereafter, Hon'ble Chairperson and Members posed several queries on the subject like (i) the RE for Jan Aushadhi Scheme for the year 2024-25 was Rs.284.50 crore but as on 19.02.2025 just Rs.178.67 crore could be spent as such the Committee desired to know whether the remaining amount of Rs. 105.83 crore would be utilized by the end of the current financial year. (ii) How many Bulk Drug Parks were to be set up; (iii) Status of Bulk Drug Park at Nakkapalli, a comprehensive report on the setting up of three Bulk Drug Park including Nakkapalli; (iv) Reasons for meager expenditure of Rs.0.90 crore being the actual expenditure during the year 2022-23, 2023-24 of the scheme for Promotion of Medical Device Parks; (v) What is Loan Licence and who does give the Loan Licence; (vi) Availability of Medical Devices in rural areas for pregnant women; (vii) Production and assembly of medical devices like linear accelerator and MRI; (vii)The record of fatalities after insertion of cardiac stents; (ix) Ban on sale and distribution of spurious medicines; (x) Vacant posts of drug inspectors in CDSCO; (xi) Whether only 5-10 big pharmaceutical companies are controlling the price of drugs in the country; (xii) Whether it is a fact that until the profit margins of the Pharma Companies are not controlled it would be difficult to control the prices of life saving medicines such as in the case of stents; (xiii) Whether life saving drugs have become out of reach of poor people due to the high cost of these medicines; (xiv) Whether Pharma

Companies such as Sun Pharma, Arvindo, Dr. Reddy's and Cipla are making huge profits by selling medicines at high prices; (xv) Whether medicines and drugs produced by these companies are beyond the reach of the Common people; (xvi) Whether these Companies have with their own marketing and distribution system have managed to control the prices of medicines; (xvii) Whether Cardiac stents ranging from Thirty Thousand to two lakh rupees and even more are available in the market etc. which were responded to by the representatives.

6. On the points requiring details and statistical information which was not readily available, the Chairperson asked the Secretary, DoP to furnish written replies and also to the queries raised by the Members which remained unanswered during the sitting of the Committee, with 2-3 days.

(The witnesses then withdrew)

[A verbatim record of the proceedings was kept on record]

The Committee then adjourned.

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STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2024-25) MINUTES OF THE FOURTEENTH SITTING

The Committee sat on Tuesday, the 18th March, 2025 from 1000 hrs. to 1030 hrs. in Committee **Room 'C', PHA, New Delhi.**

MEMBERS

LOK SABHA

2. Shri Robert Bruce C
3. Smt. Kriti Devi Debbarman
4. Dr. Kalyan Vaijinathrao Kale
5. Shri Babu Singh Kushwaha
6. Shri Utkarsh Verma Madhur
7. Shri Praveen Patel
8. Shri Balram Naik Porika
9. Shri Sachithanantham R.
10. Shri Eatala Rajender
11. Shri Daggumalla Prasada Rao
12. Dr. Ricky Andrew J. Syngkon
13. Shri Shivmangal Singh Tomar

RAJYA SABHA

14. Shri Subhash Barala
15. Shri Subhash Chandra Bose Pilli
16. Shri Meda Raghunadha Reddy
17. Dr. Kalpana Saini
18. Shri Arun Singh

SECRETARIAT

9. Smt. Maya Lingi - Joint Secretary
10. Ms. Miranda Ingudam - Director
11. Shri Kulvinder Singh - Deputy Secretary
12. Shri Nagendra Suman - Deputy Secretary
13. Shri Abhishek Kumar - Deputy Director
14. Ms. Neelam Bhave - Committee Officer

2. At the outset, the Chairperson welcomed the Members to the sitting of the Committee. Thereafter, the Committee took up for consideration, the following Draft

Reports:

(i) XXXX XXXX XXXX XXXX

(ii) XXXX XXXX XXXX XXXX

(iii) Eighth Report on 'Demands for Grants (2025-26)' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

3. Giving an overview of the important Observations/Recommendations contained in the draft Reports, the Chairperson solicited the views/suggestions of the Members.

4. After some deliberations, the draft Reports were adopted by the Committee without any amendment.

5. The Committee then authorized the Chairperson to finalize the Reports and present/lay the Reports in both the Houses of Parliament in light of factual verifications received from the concerned Ministry/Departments.

6. The Committee thereafter decided to undertake a study visit programme during the last week of April 2025.

***The Committee then adjourned*.**