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

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS

(2024-25)

FIFTH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

December, 2024/ Agrahayana, 1946 (Saka)

CC&F.No. 185

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CHEMICALS AND FERTILIZERS

(2024-25)

(EIGHTEENTH LOK SABHA)

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Presented to Lok Sabha on ……November, 2024

Laid in Rajya Sabha on …… November, 2024

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NEW DELHI

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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
9. Shri Babu Singh Kushwaha
10. Shri Utkarsh Verma Madhur
11. Shri Praveen Patel
12. Dr. Sambit Patra
13. Shri Balram Naik Porika
14. Shri Sachithanantham R.
15. Shri Eatala Rajender
16. Shri Rajesh Ranjan
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.

INTRODUCTION

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

2. The Committee considered the Demands for Grants (2024-25) pertaining to the Department of Pharmaceuticals for the Financial Year 2024-25 which were laid on the Table of the House on 2nd August, 2024. Thereafter, the Committee took evidence of the representatives of the Department of Pharmaceuticals on 13th November, 2024. The Committee considered and adopted the Report at their sitting held on 12th December, 2024.

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;
…. December, 2024
….. Agrahayana, 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 of production and plays a significant role globally. India is a global leader in the supply of DPT, BCG and Measles vaccines and one of the largest suppliers of low-cost vaccines in the world. This has earned it the sobriquet the 'pharmacy of the world'. Indian Pharmaceutical Industries is currently valued at $50 Billion and is expected to reach $130 Billion by 2030. Indian medicines reach 200+ Countries, contributing to availability of affordable quality medicines, wellness products, bulk drugs and intermediates. The Indian Pharmaceutical Industries played a very significant role in supply of drugs during COVID pandemic. India produces more than 500 APIs and 60,000 generic drugs across 60 therapeutic categories. 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.

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

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

4. The Department has 15 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 six Central Sector Schemes, viz. (a) Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP) (b) National Institute of Pharmaceutical Education & Research (NIPER) (c) Development of Pharmaceutical Industry (Strengthening of Pharmaceutical Industry) (d) Consumer Awareness, Publicity and Price Monitoring (CAPPM) (e) Production Linked Incentive (PLI) Schemes (f) Promotion of Research and Innovation in Pharma MedTech Sector.

6. The Department of Pharmaceuticals presented their detailed Demands for Grants (Demand No. 7) for the financial year 2024-25 to Parliament on **2nd August, 2024**. The Budget Estimate of the Department showing Revenue and Capital expenditure for the year 2024-25 is as under:-

(Rs. In crore)

Section	**2024-25 (BE)**
Revenue	4088.69
Capital	1.26
Total	4089.95

II. PROPOSED AND APPROVED FINANCIAL OUTLAYS OF THE DEPARTMENT OF PHARMACEUTICALS (DoP) FOR THE FINANCIAL YEAR 2024-25

7. The details with regard to the proposed amount for each scheme of the Department of Pharmaceuticals for the year 2024-25 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 2024-25 (Proposed)**	**BE 2024-25 (Approved)**
1	National Institutes of Pharmaceutical Education and Research (NIPERs)	242.00	242.00
2	Jan Aushadhi Scheme	284.50	284.50
3	Development of Pharmaceutical Industry		
	Pharmaceuticals Promotion Development Scheme (PPDS)	5.00	5.00
	Cluster Development	54.00	50.00
	Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	5.00	5.00
	Promotion of Bulk Drug Parks	1352.00	1000.00
	Promotion of Medical Device Parks	156.89	150.00
	Human Resource Development in Medical Devices Sector (HRD)	98.00	50.00
	Assistance to Medical Device Cluster for Common Facilities (AMD-CF)	191.00	40.00
4	Production Linked Incentive (PLI)		
	Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs	58.00	58.00
	Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	85.00	85.00
	Production Linked Incentive Scheme for Pharmaceuticals	2000.00	2000.00

			(Rs. In crore)
Sl. No.	**Name of Scheme**	**BE 2024-25 (Proposed)**	**BE 2024-25 (Approved)**
5	Consumer Awareness Publicity and Price Monitoring	6.00	4.00
6	Promotion of Research and Innovation in Pharma Med-Tech (PRIP)	150.00	75.00

III. BUDGETARY ALLOCATION *VIS-A-VIS* UTILISATION DURING 2021-22, 2022-23, and 2023-24

8. As regards the Budget Estimates (BE) & Revised Estimates (RE) for the year 2021-22, 2022-23, 2023-24 and 2024-25 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**
2021-22	470.41	823.11	774.94	94.14
2022-23	2244.15	2268.54	2050.08	90.37
2023-24	3160.06	2697.96	2432.45	90.15
2024-25	4089.95	-	1363.55 (as on 31.10.2024)	

9. On being asked to furnish reasons for consistently upward revision in BE *viz* from Rs. 470.41 crore in BE (2021-22) to Rs. 2244.15 crore in BE (2022-23) and further to Rs. 3160.06 crore in BE (2023-24) and further to Rs. 4089.95 crore in the year 2024-25, the Department stated that three new PLI schemes were introduced in 2021-22 for a period of 5/6 years with a combined outlay of Rs. 25,360 crore. The Budgetary provisions were started from 2022-23 onwards, which increased the BE figures of the Department. Similarly, some new Schemes of Development of Pharmaceuticals & Medical Device Industries were also approved during this period and due to BE provision for these new Schemes, the budget of the Department increased from 2022-23 onwards in comparison to 2021-22.

10. On being pointed out that the RE(2023-24) of the Department of Pharmaceutical drastically reduced to Rs. 2697.96 crore from Rs. 3160.06 crore in BE(2023-24), the Department stated 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. and therefore, the budget was reduced at RE stage.

11. It was further pointed out that the actual expenditure of the Department was less than the RE for the three consecutive years i.e. 2021-22, 2022-23 and 2023-24. On being

sought reasons for the same, the Department in their written reply submitted that in the Schemes on Infrastructure *viz* Bulk Drug Parks, Medical Device Parks and Cluster Development Schemes, the release of funds depends upon the actual expenditure on the capital projects by the State level agencies, which further depends upon the tendering processes and mandatory clearances from regulatory bodies and addition of their share of funds. Similarly, in the PLI Schemes, the actual release of incentives depends upon the fulfillment of Scheme Guidelines and sanction provisions. The Department has reviewed the functioning of the Schemes of Medical Devices and has formulated a new Umbrella Scheme in 2024-25 for Strengthening of Medical Device Industry for more focused approach and efficient utilization of funds.

12. An amount of Rs.4089.95 crore was sought by the Department as BE for the year 2024-25 and an amount of Rs. 17.87 crore was stated to be the actual expenditure as on 31.07.2024. On being asked whether the allocated amount of Rs. 4089.95 crore would be fully utilized by the end of the current financial year and if so, the details and the reasons thereto. In their written reply, the Department submitted that the pace of expenditure in the Department picks up from 3rd Quarter onwards because of the nature of Schemes. The Budget of three PLI schemes (Rs. 2,143 crores) is more than 52% of the total BE of the Department and the releases are made from 3rd Quarter onwards after the finalization of the Annual Accounts of the companies. The expenditure has accordingly picked up and it is Rs. 1,363.55 crores (33.34% of the BE) at the end of Oct' 24.

13. The fund utilized by the Department was 94.14 percent, 90.37 percent, 90.15 percent for the year 2021-22, 2022-23 and 2023-24 respectively. 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 too, the Department stated that the expenditure up to Oct'24 was Rs. 1,363.55 crore (33.34% of BE) and it will pick up in the subsequent months when the PLI beneficiary Companies will be raising claims for incentives. The releases under the Pharmaceuticals and Medical Device Schemes will be made on the basis of demand from the grantees and sanctioning of new proposals. Grants to NIPERs will also be released on quarterly basis upon the pace of expenditures.

IV. PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP)

14. **W**ith the objective of making quality generic medicines available at affordable prices to all citizens, especially the poor and the deprived sections, the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by Department of Pharmaceuticals. Under the Scheme, dedicated outlets known as Jan Aushadhi Kendras (JAKs) are opened to provide quality generic medicines at affordable prices. As on 31.07.2024, 13,113 JAKs have been opened across the Country providing quality generic medicines at affordable prices to all.

15. On being asked on the number of Jan Aushadhi Kendras (JAKs) opened during the last three years and also during the current financial year, the Department submitted that under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), total 6574 Jan Aushadhi Kendras have been opened across the Country during the last three financial years including current financial year. The details are as under: -

Sl. No.	Financial Year	Number of PMBJP Kendras opened	
		Yearly Addition	Cumulative
1.	2021-22	1053	8610
2.	2022-23	694	9304
3.	2023-24	1957	11261
4.	2024-25 (As on 31.10.2024)	2870	14131
		6574	

16. When asked about the criteria for opening of a Jan Aushadhi Kendras (JAKs) the Department submitted that under the Pradhan Mantri Bhartiya JanaushadhiPariyojana (PMBJP), any individual having D.Pharma/B. Pharma degree holder himself or any individual/organization who has employed D. Pharma/B. Pharma degree holder for getting drug license from State Government concerned are eligible to open Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK). Following are the requirements for applying to open PMBJK: -

i. Minimum 120 sq. ft. space duly supported by proper documents.
ii. Registration details of the pharmacist with State Pharmacy Council.
iii. Applicants under category of women entrepreneurs, divyang, SC and ST have to submit suitable certificate/proof from respective authorities along with undertaking.
iv. Applicant can apply online through the website - janaushadhi.gov.in for opening of PMBJK. On receipt of the application in PMBI head office, in principle approval is given subject to fulfilment of all required documents along with application. The applicant has to obtain drug license in the name of PMBJK from the concerned drug authority and must be submitted to PMBI head office. Based on the same, final approval letter is given to applicant to make the PMBJK operational, as per the guidelines.

17. On being asked whether JAKs have been opened in rural and remote areas of the Country, the Department submitted that Pradhan Mantri Bhartiya Pariyojana (PMBJP) has partnered with the Cooperative Sector to maximize benefits of PMBJP Kendras in interior parts of the Country. Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency of PMBJP has entered into an agreement for setting up of Jan Aushadhi Kendras in Primary Agricultural Cooperative Credit Society (PACs). This is focused to pass the benefits of PMBJP to both consumers and entrepreneurs who want to start their own business. Till 31st October 2024, 4400+ PACS from 647 Districts have applied & 2695 PACS given initial approval letter, of which 676 Jan Aushadhi Kendras

have been opened in PACS. Also, more than 1000 applicants of PACS have been given online training.

18. When asked about the quality of generic medicines and their reviews, the Department submitted 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). Only after passing the quality tests, the medicines are dispatched to PMBJP Kendras. PMBI also does routine quality audit of the facilities of vendors. PMBI also carries out public outreach & campaigns throughout India to do away the false perception about poor quality of generic medicines and emphasizes that the quality of Jan Aushadhi generic medicines is as good as branded medicines.

19. On being asked whether any application(s) for opening of a JAKs was pending with the Department and the timelines the pending applications would be disposed off and also whether any complaint was pending, the Department submitted that there are 3188 pending applications for opening of Jan Aushadhi Kendras with PMBI at different stages, of which 2692 applications have been given in-principle approval and 496 applications are under review. Pharmaceuticals & Medical Devices Bureau of India (PMBI) has a Store Complaint & Facilitation cell (e-mail ID- complaints@janaushadhi.gov.in) to analyse and resolve the queries of the customers as well as entrepreneurs. A toll-free helpline number 18001808080 is also being operated with 06 (Six) telecallers to address the queries of the customers, Jan Aushadhi Kendra owners and applicants etc. The Department further informed that complaints/ grievances received through other portals like RTI, CPGRAM are being addressed by PMBI regularly in a timely manner. There are strict quality control mechanisms in place to ensure compliance of standards and no major quality issue has arisen so far.

20. On being specifically asked about the 3188 applications received for opening of JAKs out of which 2692 applications were given in principle approval and 496 applications are stated to be under review, the Department submitted that the process of receiving applications for opening new Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) and issuing In-Principle Approvals is continuous and ongoing. 'In-principle' approvals are issued in a standard time frame of 15 days as per normal practice and are subject to the submission of all the required documents by the applicants.

In the current Financial Year, as of 31 October 2024, the Pharmaceuticals and Medical Devices Bureau of India (PMBI) had received a cumulative of 3,188 applications for the opening of PMBJKs at different locations nationwide. Out of these, 2,692 applications have already been given In-Principle Approvals. Out of the previously reported pendency of 496, after review, in respect of 20 applications In-Principle Approvals have been issued by PMBI's Head Office till 14 November, 2024. The remaining 476 applications are progressing through various stages of review, including field verification, document validation, and registration fee confirmation.

Details of 476 applications include 61 applications that are awaiting field officer verification of the proposed location, and to ensure compliance with PMBI's distance policy. Another subset of 286 applications remains on hold, as PMBI awaits a complete and legible set of essential documents, including clear scanned copies of Aadhaar Card, PAN Card, No Objection Certificate (for applicants from government premises), Space Allocation Letter, and other requisite materials. In some instances, delays have resulted from applicants not providing accurate addresses for the proposed Kendras. 135 applications are at 2nd stage of approval in Head Quarters where the deficient documents have now been provided and fee verification is under process.

Following the completion of these verification, applications will be given final approval from the designated signing authorities and agreement in each case will be signed, store code will be generated, computer software will be installed & training will be given to the Kendra owner. Subsequently, medicines/devices will be supplied by PMBI at each Kendra.

Therefore, once the documentation and necessary steps are completed, approvals will be granted on an ongoing basis, and no fixed time frame can be given for final approval of all 496 applications. In all, 2870 Kendras have been opened in this Financial Year i.e. approx. 500 Kendras per month on an average.

21. When asked to state that the mechanism to inspect the JAK retail outlets and whether there were lot of malpractices in these shops, the Department submitted that there are more than 14,000 Jan Aushadhi Kendras (JAK's) located in 773 Districts. These are operated and run by private entrepreneurs with their own funds and establishment. Pharmaceuticals & Medical Devices Bureau of India (PMBI) supplies medicines to these JAKs on demand through its channel of distributors and warehouses. It is up to the JAK owner to decide the quantity and variety of the medicines depending upon his/her location, needs, and frequency of the patients. It is his/her responsibility to manage these Kendras in a financially sustainable manner and make decisions to meet the needs of patients. However, to ensure sufficient availability of medicines, a system of stocking mandate has been introduced for 200 medicines, which are fast moving and there is a system of rewarding the entrepreneur with an incentive of Rs. 20,000/- per month.

There are 42 Marketing Officers of PMBI deputed in different States / UTs to handle any complaints of malpractice. Show Cause Notices are issued for violating Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) norms. It may lead to a warning or cancellation in case of any confirmed malpractices. Sometimes there are complaints received from customers about the non-availability of certain medicines or devices, which are attended to promptly by providing the medicines from the nearest distributor or warehouse. There are no major complaints received or malpractices detected, given that there are more than 14,000 JAKs and an equally large number of customers visiting these Kendras daily.

There is a designated toll-free number 18001808080 and e-mail ID complaints@janaushadhi.gov.in for any complaint from customers for easy redressal. Besides this, the complaints received from Government Portal like RTI, and

CPGRAM are also redressed promptly.

22. On being asked about status of opening 14,000 Jan Aushadhi Kendras in the entire Country and the quantum of target achieved so far, the Department submitted that a total of 14,131 Jan Aushadhi Kendras (JAKs) have been opened in the Country till 31.10.2024 and targets have been set to open 15000 JAKs by March 2025, 20000 by March 2026 and 25,000 by March 2027.

23. On being asked whether there was any plan to open Jan Aushadhi Kendras to cover rural population and what is the action plan by the Department to encourage promotion of the Scheme, the Department stated that for rural coverage, Pradhan Mantri Bhartiya Pariyojana (PMBJP) has partnered with the Cooperative sector to maximize the benefits of Kendras in interior parts of the country. Accordingly, Jan Aushadhi Kendras are being set up in Primary Agricultural Cooperative Credit Society (PACS). This was focused on passing the benefits of PMBJP to both consumers and entrepreneurs who want to start their businesses.

Till 31st October 2024, 4400+ PACS from 647 Districts have applied and 2695 PACS have been given initial approval letters and 676 Jan Aushadhi Kendras have been opened in PACS. Also, more than 1000 PACS applicants have been given online training.

The awareness about the salient features of the *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* is spread through various types of advertisements such as Print Media, Radio, TV, Outdoor publicity like Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping, etc. and through TV Screens at Common Service Centers (CSCs) for rural coverage. In addition, the public is educated regularly about *Jan Aushadhi* generic medicines through social media platforms like Facebook, Twitter, Instagram, YouTube, etc.

24. On being asked whether Jan Aushadhi was making medicines such as Benzylpenicillin, Atropine, Streptomycin injection, which are very important drug-resistant for tuberculosis and medicines which are used to cure mental ailments and whether there was a 50 per cent increase in production, the Department submitted that under Jan Aushadhi initiative, medicines are procured from reputed manufacturers and does not manufacture any medicines on its own. Only the Atropine Sulphate injection was procured as per demand and supplied to selected JAKs. The Benzylpenicillin and Streptomycin injection are not part of PMBJP product basket and are not procured. Similarly, tuberculosis medicines are also not part of PMBJP product basket as there was a separate TB Programme of Ministry of Health & Family Welfare to provide free medicines for TB patients under TB Eradication Plan.

25. On being asked the extant mechanism to check the medicines available at Jan Aushadhi centers for poor people and also to ensure that the medicines are not duplicate or ‘expired’ and the steps the Department has taken to obviate scope for such a irregularities in Jan Aushadi Centres, the Department submitted that the "Janaushadhi

Sugam" mobile application serves as a vital resource for the general public, offering a user-friendly digital platform that provides a range of convenient services at their fingertips. Through this App, users can easily locate nearby Janaushadhi Kendras (JAKs) with directions powered by Google Maps, search for Janaushadhi medicines, and compare the prices of generic versus branded medicines, highlighting potential savings in MRP.

All the medicines supplied under Jan Aushadhi scheme are procured from reputed WHO-GMP certified manufacturers only. After procurement these medicines are subjected to independent quality testing in NABL-accredited laboratories. Only after obtaining a standard quality certification for all medicines and products, these are supplied to distributors and Jan Aushadhi Kendras (JAKs). There has been no instance of any duplicate medicines ever reported.

For expired medicines the JAKs have to ensure that these are not sold to customers. PMBI does not supply those medicines which have short life of 03 months or less.

26. The Department had received 3128 applications for opening Jan Aushadhi Kendras, out of which 496 applications are incomplete. On being asked to specify the time lines by which these 496 applications are likely to be approved, the Department stated that the process of receiving applications for opening new Jan Aushadhi Kendras (JAKs) and issuing In-Principle Approvals is continuous and ongoing. 'In-principle' approvals are issued in a standard time frame of 15 days as per normal practice and are subject to the submission of all the required documents by the applicants.

In the current Financial Year, as of 31 October 2024, the Pharmaceuticals and Medical Devices Bureau of India (PMBI) had received a cumulative of 3,188 applications for opening of JAKs at different locations nationwide. Out of these, 2,692 applications have already been given In-Principle approvals. Out of the previously reported pendency of 496, 20 applications have received In-Principle Approval till 14 November, 2024. The remaining 476 applications are progressing through various stages of review, including field verification, document validation, and registration fee confirmation.

Under 476 applications, 61 applications are awaiting field officer verification of the proposed location, and to ensure compliance with PMBI's distance policy. Another subset of 286 applications remain on hold, as PMBI awaits a complete and legible set of essential documents, including clear scanned copies of Aadhaar Card, PAN Card, No Objection Certificate (for applicants from government premises), Space Allocation Letter, and other requisite materials. In some instances, delays have resulted from side of the applicants by not providing accurate addresses for the proposed Kendras.135 applications are at 2nd stage of approval in Head Quarters where the deficient documents have now been received, and fee verification is under process.

Once the documentation and necessary steps are completed, approvals will be granted on an ongoing basis, and no fixed time frame can be given for final approval of all 496 applications. In all, 2870 Kendras have been opened in this Financial Year i.e. approx. 500 Kendras per month on an avSerage.

27. On being asked whether there was a large price difference between good brand of medicine and a generic medicine and whether there is a price control mechanism that is aligned to the medicine, the Department stated that under PMBJP, a medicine is priced on the principle of a maximum of 50% of the average price of the top three branded medicines. The price of Jan Aushadhi Medicines, surgical devices and nutraceutical products are cheaper by at least by 50% and in some cases, by 80% of the market price of branded medicines available in the market.

28. On being asked whether the Department has come up with a plan to open booths/vending machines for sanitary pads, which can be installed in and around institutions, where girls/women can avail this facility, the Department stated that under PMBJP, sanitary pads at Rs. 1/- per pad are sold through its network of more than 14000 Jan Aushadhi Kendras functional across the country. At present, there is no plan for dispensing of sanitary pads through booths/vending machines.

29. To a specific query whether the Government of Telangana has successfully made available sanitary napkins in schools for girls students and whether this Scheme can be implemented across the Country, it was submitted that the matter does not pertain to Jan Aushadhi. It was further stated that the matter may be referred to Ministry of Women & Child Development or Ministry of Health & Family Welfare to offer comments about Telangana State as the question is about making available sanitary napkins to school girls/students. There are 195 Jan Aushadhi Kendras in Telangana which sell Janaushadhi "Suvidha" Sanitary Napkins at subsidized price of Rs. 1/- per pad.

30. Asked as to what steps are being taken by the Department to popularize Ayurveda System of treatment and why the Country was still at two per cent and lagging behind in the implementation of Ayurveda System of treatment among general masses, it was submitted that comments have been sought and are awaited from Ministry of AYUSH.

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

31. 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.

Component A (under PRIP Scheme): Strengthening of research infrastructure by establishment of 7 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

In accordance with Scheme guidelines, NIPER's proposal for the setting up of their CoEs has since been approved by with their respective BoG. The Scheme guidelines also mandates setting up of Steering Committee for Component A which was constituted under the chairpersonship of Secretary, Pharmaceuticals on 01.01.2024. The Steering Committee in its 1st meeting held in March 2024 approved Rs 700 Cr for setting up of CoEs over a period of 5 years with an allocation of Rs 243 Crore for FY 2024-25.

32. On being asked as to what extent NIPERs have been able to achieve its stated objectives, the Department submitted that since inception, total number of 10,810 students (10,159- M Pharma/ MBA; 651- PhD) have passed out from these NIPERs who are working with the industry, R&D and academic institutions. As part of academia-industry exchange, NIPERs have signed about 303 MOUs with industries and other academic institutions till September 30, 2024. More than 425 patents have been filed till September 30, 2024. Since inception, about 8,048 research papers published in various reputed journals by the seven working NIPERs till September 30, 2024.

33. The Department further stated that as per National Institutional Ranking Framework (NIRF) of the Ministry of Education, under the 'Pharmacy' category, NIPERs have remained amongst the top pharmacy institutes in the Country. According to the 2024 NIRF,

the NIPER Hyderabad has achieved the 2nd rank in the 'Pharmacy' category. Out of the seven NIPERs, five have been ranked in the top 15 as per NIRF.

The center wise details of achievements of NIPERs are as under:

NIPER	Students passed out (since Inception)	Number of MoU signed	Number of Patents filled	Number of Research Papers Published	NIRF Ranking 2024
Mohali	4890	44	237	3367	9th
Ahmedabad	1215	37	35	1009	15th
Guwahati	844	37	36	756	12th
Hyderabad	1844	87	58	1374	2nd
Hajipur	678	27	12	390	33rd
Kolkata	740	42	13	540	24th
Raebareli	749	29	34	612	14th
Total	**10960**	**303**	**425**	**8048**	

34. When asked to elaborate the concept of CoEs and also to clarify whether the mandate of NIPER & CoEs won't overlap with that of NIPERs, the Department stated as under:

A. 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.

B. PRIP Scheme was approved by the cabinet in July, 2023. The Component A of the PRIP Scheme mandates setting up of CoEs at NIPERs. The Steering Committee in its 1st meeting held in March, 2024 approved Rs. 700 core for setting up of CoEs over a period of 5 years, under Component A at respective NIPERs. These CoEs are as follow:

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

C. 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.

35. On being asked about the decision to establish 07 more centres of NIPERs, the Department stated that NIPERs were set up in the year 1998 *vide* NIPER Act, 1998 and for CoEs the Steering Committee in its first meeting held in March, 2024 approved Rs.700 crore for setting up of CoEs over a period of 05 years with an allocation of Rs.243 crore for the financial year 2024-25. The Department further submitted that:

A. Government of India has established National Institute of Pharmaceutical Education & Research (NIPER) as an Institute of National Importance. These were established with the mandate to nurturing and promoting quality and excellence in pharmaceutical education and research. Under NIPER Act, 1998, NIPER Mohali had established at Mohali, Punjab. Further 6 (six) more NIPERs were set up at Ahmedabad, Guwahati, Hyderabad, Hajipur, Kolkata and Raebareli in 2007-2008. These NIPERs are given grants under NIPER scheme.

B. CoEs are being set up under Component A of "Promotion of Research & Innovation in Pharma-MedTech Sector" (PRIP) Scheme, to further strengthen NIPERs. The scheme was notified on 17th August 2023 for a period of five years (23-24 to 27-28) and guidelines were issued in October, 2023. The Scheme guidelines also mandate setting up of Steering Committee for Component A which was constituted under the chairpersonship of Secretary, Pharmaceuticals on 01.01.2024. The Steering Committee in its 1st meeting held in March, 2024 approved Rs. 700 core for setting up of CoEs over a period of 5 years with allocation of Rs.243 crore for FY 24-25.

36. When enquired about the plan of the Department for utilizing the allocated amount of Rs. 243 crore and setting up of CoEs for the next 05 years and also the CoEs which are likely to be set up each year, it was submitted that:

A. The allocation of Rs 243.03 crores for the year 2024-25 is proposed for creation of requisite infrastructure including capital and equipment as well as

for meeting other operational requirements of the CoEs. Accordingly, in the overall allocation of Rs. 243.03 crore, Rs. 39.53 crores is for General Head and Rs 203.50 crores for Capital Head. Further bifurcation is as under:

(Amount in crores)

NIPER	GIA Capital	GIA- General	Total
Mohali	43	7	50
Ahmedabad	40	9.20	49.2
Hyderabad	24	7.30	31.3
Hajipur	12	3.80	15.8
Raebareli	50	5.10	55.1
Guwahati	19.50	5.17	24.67
Kolkata	15	1.96	16.96
Total	**203.50**	**39.53**	**243.03**

B. Seven Centers of Excellence are being established at the respective National Institutes of Pharmaceutical Education and Research (NIPERs) Under PRIP Scheme with the overall budget outlay of 700 Crore over a period of 5 years. These CoEs are as follow:

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

37. The BE, RE and actual expenditure of NIPER for the year 2021-22 to 2024-25 were stated to be as under:

(Rs. In crore)

Year	BE	RE	Actual
2021-22	234.34	372.00	372.00
2022-23	395.00	451.13	451.13
2023-24	550.00	228.80	228.80

2024-25	242.00	-	-

38. On enhancement of BE (2021-22) of Rs 234.34 Crore to Rs.372.00 Crore and BE (2022-23) of Rs.395.00 crore to Rs.451.13 crore at RE stage but drastic reduction of BE (2023-24) of Rs.550.00 crore to Rs.228.80 crore, the Department submitted that in EFC meeting held on 24.09.2021, EFC approved Rs.1500 crore for 7 existing NIPERs including construction of 6 NIPERs, out of which Rs. 823.13 crore was released up to FY 2022-2023 (Rs 372 cr. 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% utilized.

39. When asked about the drastic cut of almost 50% of BE (2024-25) which has been proposed at Rs.242.00 crore as compared to BE (2023-24) which was Rs.550.00 crore, the Department submitted that based on the expenditure pattern of previous year and in accordance with the EFC ceiling, the BE 2024-25 has been kept at Rs 242 crore.

40. On the number of long term and short term courses which are being offered by NIPERs, the Department submitted that NIPERs are currently providing Long term and Short term courses. Long Term courses include MS/M.Tech/M.Pharm/PhD in various departments (16) and MBA* (*at NIPER Mohali, NIPER Ahmedabad & NIPER Hyderabad). There are 37 Short term courses provided at NIPERs based on industry and pharmaceutical sector requirement.

41. When asked to state as to how many students have been enrolled in NIPERs in different courses, the Department stated as under:

S.No	NIPERs	MS/MBA/M.Tech/M.Pharm	Ph.D	Total
1	Mohali	5188	716	5904
2	Guwahati	1187	200	1387
3	Ahmedabad	1582	197	1779
4	Hyderabad	2176	316	2492
5	Hajipur	835	86	921
6	Kolkata	934	106	1040
7	Raebareli	926	109	1035

42. On being asked about the information regarding the students enrolled, declared successful for each of the Centre for the last three years, the Department stated as under:

NIPER	Total Students Enrolled		Passed out
Mohali	2021-2022	328	267
	2022-2023	346	279
	2023-2024	384	315

Ahmedabad	2021-2022	185	111
	2022-2023	204	153
	2023-2024	235	157
Guwahati	2021-2022	128	100
	2022-2023	159	120
	2023-2024	172	143
Hyderabad	2021-2022	192	186
	2022-2023	224	192
	2023-2024	228	182
Hajipur	2021-2022	54	68
	2022-2023	85	74
	2023-2024	110	93
Kolkata	2021-2022	64	49
	2022-2023	103	75
	2023-2024	118	90
Raebareli	2021-2022	74	74
	2022-2023	93	90
	2023-2024	122	119

43. When asked to state the difference between the number of students enrolled and declared successful, the Department furnished centre-wise information, as under:

NIPER	Enrolled (Since inception)	Passed Out (Since Inception)	Difference
Mohali	5904	4890	1014
Guwahati	1387	844	543
Ahmedabad	1779	1215	564
Hyderabad	2492	1844	648
Hajipur	921	678	243
Kolkata	1040	740	300
Raebareli	1035	749	286

44. To the specific query whether NIPERs also provide placement services to its students, the Department informed that all NIPER provides placement services to its students. The placement details during last three years is as under:

S.No.	NIPER	Placement Average % (Last three years)

1	Mohali	79.54
2	Ahmedabad	96.33
3	Guwahati	100
4	Hyderabad	100
5	Hajipur	82.08
6	Kolkata	86.44
7.	Raebareli	90.67

45. The Committee then desired to know the present status of the construction of building of NIPERs, the Department submitted that NIPER Mohali, Ahmedabad and Guwahati has own campus. The new campus of NIPER Ahmedabad was dedicated to the nation on 30.9.2023 and new campus of NIPER Guwahati was dedicated to the nation on 12.1.2024.

The present status of construction of other four NIPERs are as tabulated below:

Construction of Regular Campus as on 03.10.2024					
S.No	**NIPER**	**% Completion Status**	**Date of Initiation**	**Estimated date of Completion**	**Cost (crore)**
1	Hajipur	38%	19.02.2023	01.04.2025	66.06
2	Hyderabad	25%	01.02.2024	01.07.2025	83.5
3	Kolkata	43%	19.04.2023	30.06.2025	78.56
4	Raebareli	70%	18.03.2023	31.03.2025	77.69

46. On being asked whether NIPER is giving reservation to SC/ST/OBC students for admission in its different courses as per Government of India rules and NIPERs also give concession in fees to SC/ST/OBC students, the Department submitted that NIPERs are giving reservation to SC/ST/OBC students for admission in its different courses as per Government of India rules and also giving concession in Fees to SC/ST students.

47. On being asked to state the present status of the construction on campus of NIPERs as follows, the Department stated that NIPER Mohali, Ahmedabad and Guwahati has their own campus. The new campus of NIPER at Ahmedabad was dedicated to the nation on 30.9.23 and new campus of NIPER at Guwahati was dedicated to the nation on 12.1.24. The Department further informed that the present status of construction of other four NIPERs which are tabulated as under:

NIPER	**Date when Construction Started**	**Dates when construction completed**	**Target Date**	**Cost overrun due to delay**	**Steps taken to expedite the construction, if any**

Hyderabad	01-02-2024	Ongoing	01-07-2025	-	NIPER Hyderabad is monitoring the construction activities by appointing a construction monitoring committee, having weekly meetings, visit to construction sites at regular intervals etc.
Hajipur	19-02-2023	Ongoing	01-04-2025	-	Fort nightly meeting for Regular monitoring of work for timely completion of work with zonal CPWD officials .
Kolkata	19/04/2023	Ongoing	30-06-2025	-	Fort nightly meeting for regular monitoring of work for timely completion of work with CPWD, Kolkata.
Raebareli	18-03-2023	Ongoing	31-03-2025	-	Fortnightly meeting for regular monitoring of work for timely completion of work with CPWD zonal officers.

48. To a specific query whether NIPER, Hajipur was set up in 2007 but only a total number of 572 students have passed out so far in the last 17 years and also whether they are not getting the right number of students or are there fewer seats, the Department submitted that a total Number of 572 students have passed out since the inception of the Institute (2007) till the academic year 2023-24. All the sanctioned seats of NIPER Hajipur were filled every year except a few reserved seats or seats vacated due to cancellation of admission. The number of student's intake for each NIPER is approved by the Standing Committee under the Chairmanship of Secretary, DOP based on the considerations such as the infrastructure/streams/number of faculties at the respective NIPERs. Accordingly, the following intake of students were approved during the last five years.

Course	**Batch**	**Approved student intake**	**Student admitted**	**Student graduated**
Masters (2 year course)	2019-21	48	48	48
	2020-22	51	51	51
	2021-23	71	71	71
	2022-24	91	91	91
	2023-25	114	114	pursuing
	2024-26	60	54	pursuing

49. When pointed out specifically that though the NIPER, Hajipur has a good placement record, one-fourth of the students are not being able to complete their course, the

Department submitted that the significant component of students not competing their course is account by the students who are still pursuing their masters (as may be seen from the table above i.e. Question 1 batch of 2023-24 and 2024-26). It is further seen from the same table that all student admitted in earlier years have completed their course and graduated. Further, the placement results of NIPER Hajipur has improved in the last three years after the establishment of Training and Placement Cell (TPC) in November 2021. Steps are being taken to strengthen the placement activities, and improving Industry-academia collaborations. The placement record of NIPER Hajipur is as under:

Batch	Total Graduated	Total Placed	Placed in Industry, JRF/project fellow	Opted Higher studies	% Placed
2017-19	32	26	21	4	81.26
2018-20	36	13	9	4	36.11
2019-21	48	34	18	16	72.72
2020-22	51	43	32	16	84.31
2021-23	71	63	36	27	88.73
2022-24	91	80	65	15	88.01

50. Asked to indicate the likely deadline by the Department for setting up of COEs at NIPERs in the State /UTs, it was submitted that the Department has approved the proposals for setting up and operation of CoEs in all seven NIPERs with an overall budget outlay of Rs 700 Cr over a period of 5 years. The foundation stone laying ceremony for the CoEs at NIPER Mohali, NIPER Ahmedabad, NIPER Guwahati and NIPER Hyderabad by Hon'ble Prime Minister was held virtually on 29.10.2024.

51. During oral evidence the representative of the Department apprised the Committee regarding NIPERs as follows:

> "Sir, we have seven NIPERs which are imparting education and research activity to students and industry. These seven NIPERs are located in Mohali, Ahmedabad, Hyderabad, Hajipur, 13.11.2024 AN STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS 6 Guwahati, Raebareli and Kolkata. These are all institutes of national importance. The first NIPER which was at Mohali was set up in 1998. Others are of recent vintage, all approved in 2007-08. Two of them have their campus ready and shifted to their own campus. For remaining five, the construction is ongoing and will be completed by 2025. These NIPERs are doing very well academically. In the NIRF published by Ministry of Education, two NIPERs are in top 10 and five are in top 50. So, they are really good as academic institutions. We have introduced certain amendment s to the original NIPER Act through which NIPER-Mohali was set up. By NIPER Amendment Act 2020-21, we have rationalized the BoG structure and given powers to standing committee to lay down uniform policy across NIPERs. The NIPER Council has been set up and meetings have taken place. BoG of all the seven NIPERs was constituted in 2020-21 and it

has a three-year tenure. In Financial Year 2024-25, Rs. 242 crores were allocated to NIPERs and we have utilized Rs.134 crores from that. NIPERs have filed 425 patents and have published more than 8,000 research papers till date."

VI. Strengthening of Pharmaceutical Industry

52. 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 has released the Guidelines for the scheme "**Strengthening of Pharmaceutical Industry" (SPI),** with a total financial outlay of Rs. 500 Cr for the period from FY 21-22 to FY 25-26 on 11.3.2022. It was further stated that the Scheme will address 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 Department elaborated that 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) Cluster Development/Assistance to Pharmaceutical Industry for Common Facilities
(b) Pharmaceutical Technology Upgradation Assistance Scheme
(c) Pharmaceuticals Promotion and Development Scheme/Pharmaceutical & Medical Devices Promotion and Development Scheme

(a) **Cluster Development/Assistance to Pharmaceutical Industry for Common Facilities** to strengthen the existing pharmaceutical clusters' capacity for their sustained growth by creating common facilities. This will not only improve the quality but also ensure the sustainable growth of clusters.

(b) **Pharmaceutical Technology Upgradation Assistance Scheme** to facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards (WHO-GMP or Schedule-M), interest subvention or capital subsidy on their capital loans will be provided, which will further facilitate the growth in volumes as well as in quality; and

(c) **Pharmaceuticals Promotion and Development Scheme/Pharmaceutical & Medical Devices Promotion and Development Scheme** to facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry.

- The above three sub-schemes are already approved in the Department of Pharmaceuticals as part of scheme for 'Development of Pharmaceutical Industries' (DPI). Now, the DoP has combined the above schemes into a single scheme namely 'Strengthening of Pharmaceutical Industry (SPI)' with modification in the scheme guidelines, after stakeholder consultations for effective intervention.

- It is expected that the units supported under this scheme will act as Demonstration Firms for the pharma clusters and MSMEs Pharma Industries, to develop on quality and technology upgradation fronts.

- SIDBI has been appointed as the Project Management Consultant (PMC) for the SPI scheme.

In the earlier scheme known as Cluster Development Programme for Pharma Sector (CDP-PS) and further renamed as Assistance to Pharmaceutical Industry for Common Facilities (API-CF) three (03) Projects were completed during 2020-21 to 2022-23 viz. **(i)** Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC) viz. setting up Common Effluent Treatment Plant (CETP) at Alathur, Tamil Nadu with total cost of project of Rs. 11.02 crores., **(ii)** Kala Amb Infrastructure Development Company (KIDC) viz. setting up Common Effluent Treatment Plant (CETP) at Kala Amb Tehsil Nahan, District Sirmaur, Himachal Pradesh with total cost of project of Rs. 7.20 crores and **(iii)**Inducare Pharmaceuticals and Research Foundation (IPRF) viz. setting up Common Facilities Centre at Pune, Maharashtra with total cost of project of Rs. 31.44 crores.

54. Under the new sub-scheme assistance to Pharmceutical industry for common facilities (API-CF) of strengthening of Pharmaceutical industry (SPI) Scheme, application window was opened for inviting applications for project purposes. 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 (PUNDRUG) has been given 'in-principle approval (in 2023-24) by Scheme Steering Committee (SSC). Subsequently, application window was again opened in March, 2024 and two applications were received, out of which one application (Inducare-Phase II) has been given Final approval and one application (Brahma Kamal) is under consideration.

55. The Department furnished the details of List of applications received under APICF which are as under:

Sl.No.	Name of the applicant	Location	No of units in the cluster	Date of application	Amount (Rs. in Cr)
1. **Research and Development Lab**					
1	Welzo Research and Devt. P.Ltd. (Shri Venkata Subba Rao, md@criuslife.com, Green Enviro Co, Sano Cito Therapeutics)	Malpur, Baddi, Himachal	400	29-09-2022	19.53

2	SPV to be set up (Shri Bharat Bhushan, Shri Shailesh Siraya)	Bommasandra indl area, Bangalore, Karnataka	50	30-09-2022	19.88
3	Hyderabad Pharma Infrastructure and Technologies (**Govt** – Director Life Sciences Shri Shakti Nagappan)	Jeedimetla, Hyderabad, Telangaana	320	30-09-2022	20.00
4	SPV to be set-up (Ramachandra Reddy, Glory Pharmachem India, Senergies Remedies, AP Drugs, SLR Pharma)	Gaajulamadyam, Chittor, AP	20	30-09-2022	14.00
5	Uni Scientific Research And Research analytical foundation (Shri Sanjay Sikara, Ashok Windlass)	Pharmacity 2, Charba, Dehradun, Uttarakhand	98	30-09-2022	18.00
	Sub Total				**91.41**
2.	**Testing Laboratory for Pharma Products**				
6	SPV to be set up (Shri Krishna Kumar, Nanoceut, Life Care formulations, E Srinivasan)	Puducherry	60	29-09-2022	**20.00**
7	SPV to be set up (Jagdeep Singh, parexpharma@hotmail.com)	Mohali, Punjab	100	30-09-2022	7.45
8	SPV to be setup (Jincla Healthcare, Apco Pharma, Malinds Health care, Shri Bhupender Rawat)	Birpur Area, Roorkee Road, Haridwar Uttarakhand	70	30-09-2022	18.00
	Sub Total				**45.45**
3.	**Effluent Treatment Plants**				
9	Jeedimetla Effuent Treatment Ltd. (Shir Bakka Reddy , pbreddy@jetltd.org)	Jeedimetla, Telangana	250	17-09-2022	19.94
10	Sirmour Green Environ Ltd. (Shri Jitender , jitender.singh@relaxpharmaceuticals.in)	Himachal Pradesh	102	17-09-2022	9.42
11	Mohali Green Environment Pvt. Ltd. (Shri Ashwani Vig, mgepl12@gmail.com)	Derabassi, Mohali, Punjab	80	17-09-2022	2.00

12	SPV to be set up (Shri Jayaseelan, Sethupathy, V Veeramani,)	SIPCOT Industrial Park, Tindivanam T N	60	23-09-2022	20.00
13	Visakha Pharma City Ltd (Shri Lal Krishna, Visakaha pharma, Ajay)	Visakhapatnam, AP	100	28-09-2022	20.00
	Sub Total				**71.36**
4.	**Logistics Centres**				
14	SPV to be setup (Shri Lal Krishna, Visakaha pharma, Ajay)	Visakhapatnam, AP	100	28-09-2022	20.00
	Sub Total				**20.00**
5.	**Training Centres**				
15	Bulk Drug Manufacturers Association (Shri R K Agrawal, Shri Srinivasa Raju)	Hyderabad, Telangana	320	23-09-2022	11.39
16	SPV to be setup (Shri Lal Krishna, Visakahapharma, Ajay)	Visakhapatnam, AP	100	28-09-2022	9.80
17	Hyderabad Pharma City Ltd, ((**Govt** – Director Life Sciences Shri Shakti Nagappan)	Genome Valley, Hyderabad, Telangana	320	07-10-2022	20.00
	Sub Total				**41.19**
6.	**Others**				
18	SPV to be set up (Rajender Tulsiyan, Talbros Formulations, Feezochem Formulations, Shri Bhupender Rawat) - All five activities as per scheme	US Nagar Dist. Rudrapur, UK	70	30-09-2022	18.00
19	SPV to be setup (Shri Lal Krishna, Visakaha pharma, Ajay) - Cogeneration plant	Visakhapatnam, AP	100	28-09-2022	20.00
20	Gujarat Indl Devt. Corpn. (M. Thennarasan, IAS) - Water Supply pipeline	Jambusar, Gujarat	94	28-09-2022	50.00
	Sub Total				**88.00**
	GRAND TOTAL				**357.41**

56. On being asked the reasons why only 07 applications were short listed out of which 06 projects were given 'Final approval' and 01 project were given 'in-principle' approval by

the Scheme Steering Committee, the Department submitted that the Financial Outlay of the API-CF sub scheme is Rs. 178.40 crores, out of which Rs. 20.15 crores (including PMC charges) has been spent on old projects which have been completed.The Department further stated that as of now, seven (07) projects have received Final approval, one (01) project has been given “in-principle” approval and two (02) project is under consideration.

The details of projects under API-CF is 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 crores**					
Projects under Execution/ Ongoing Projects					
1.	Devbhumi Pharmaceutical Testing and Training Foundation	Testing Laboratory	Haridwar, Uttarakhand	Rs. 23.68 Crores	Rs. 20.00 Crores
2.	Welzo Research and Development Pvt. Ltd.	Research & Development and Testing Laboratory	Baddi, Himachal Pradesh	Rs. 29.90 Crores	Rs. 19.53 Crores
3.	Jeedimetla Effluent Treatment Ltd.	Common Effluent Treatment Plant (CETP)	Hyderabad, Telangana	Rs. 29.17 Crores	Rs. 20.00 Crores
4.	Tindivanam Pharma Park Association	Common Effluent Treatment Plant (CETP)	Viluppuram, Tamil Nadu	Rs. 31.76 Crores	Rs. 15.88 Crores
5.	Tirupati Research & Development Pvt. Ltd. (TREND)	Common Facility Centre for Research & Development and Testing & Training facility	Tirupati, Andhra Pradesh	Rs. 29.90 Crores	Rs. 20.00 Crores
6.	Telangana Lifesciences Foundation (Earlier Hyderabad Pharmacity Limited)	Centre of Excellence on Antimicrobial Resistance (AMRCoE)	Hyderabad, Telangana	Rs. 26.02 Crores	Rs. 18.87 Crores

7.	Inducare Pharma Research Foundation (Phase II)	Testing Laboratories	Jejuri, Pune, Maharashtra	Rs. 14.37 crores	Rs. 7.18 crores
(B) Total				**Rs. 184.80 crores**	**Rs. 121.46**
(C) Expenditure to be incurred on Ongoing Projects (including PMC charges) under API-CF is Rs. 124.32 crores					
(D) Total commited Expenditure is (A) + (C)= 20.15+ 124.32= Rs. 144.47 crores.					
(E) Balance Fund available for new projects - Rs. 178.40- (D) = Rs. 33.93 crores					
Projects under consideration out of available balance fund					
1.	Pundrug Research Foundation (In-principle approval given)	Research and Testing Laboratory	Mohali, Punjab	Rs. 10.00 crores	Rs. 7.00 crores
2.	Brahma Kamal Biomed Foundation	Common Testing Facility, R&D centre and Logistic Centre	Sitarganj, Uttarakhand	Rs. 27.50 crores	Rs. 20.00 crores
(F) Total				Rs. 37.50 crores	Rs. 27.00 crores
Total expenditure expected (including PMC charges)					Rs. 27.63 crores

57. The Department further submitted that out of the total budget of Rs. 178.40 crores of API-CF scheme, an amount of Rs. 172.10 crores (on completed/ongoing/under consideration projects) would be spent. Hence, due to financial outlay/ budget constraints of the API-CF scheme, only 09 projects have been considered under the scheme.

III Scheme for Promotion of Bulk Drug Parks

The scheme "Promotion of Bulk Drug Parks" was approved on 20th March, 2020 for providing easy access to world class common infrastructure facilities to bulk drug units located in the parks. The total financial outlay of the scheme is Rs. 3000 crore for the Scheme tenure from FY 2020-2021 to FY 2024-2025.The grant-in-aid given under the scheme has a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern states and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh), the maximum limit of financial assistance would be Rs 1000 crore or 90% of the project cost, whichever is less. The Department had

received proposals from 13 states. After evaluation, proposals of Gujarat, Himachal Pradesh and Andhra Pradesh were selected. Establishment of Bulk Drug Parks have been approved in the States of Gujarat on 08.10.2022, Himachal Pradesh on 11.10.2022 and Andhra Pradesh initially on 07.11.2022 (Kakinada) and to new location on 07.12.2023 (Nakkapalli). The Scheme is being implemented through the State Implementing Agencies (SIAs) of all the three States. First instalment has been released to the three States in F.Y. 2022-23 - Rs.300 crore released to Gujarat on 14.10.2022, Rs.225 crore released to H.P. on 20.02.2023 and Rs. 225 crore released to Andhra Pradesh on 13.03.2023. Expected Employment Generation is around 1,00,000 persons in the three selected Bulk Drug Parks. Scheme Steering Committee (SSC) meeting held under the chair of Secretary (Pharma) on 09.07.2024, approved the extension of tenure by one year from F.Y. 2024-25 to F.Y. 2025-26 for completing and implementation of the Bulk Drug Parks in the States.

58. The total financial outlay of the Scheme was Rs.3000 crore and the scheme tenure was from the year 2020-2021 to 2024-25. The scheme was stated to be approved on 20.03.2020 for providing easy access to world class common infrastructure facilities to drug units located in Parks. In this regard, the Department submitted that development of Common Infrastructure Facilities (CIF) have started in all the 3 approved bulk drug parks. Out of the approved States, in 02 States the development of the BD park is behind schedule, owing to delay in Environment Clearance and in one State, 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 by SSC in the review meeting dated 09th July 2024. Also, the request for approval for extension of unutilized Budget under the 'Scheme of Promotion of Bulk Drug Parks' till F.Y. 2025-26 has also been forwarded to Department of Expenditure, Ministry of Finance vide OM dated 25.10.2024. All the 03 approved BD Parks have submitted revised timelines up to March 2026 for commissioning of Bulk Drug Parks.

59. On being asked whether the Department intend to extend their Scheme further as the yaer 2024-25 was the last year of the Scheme, the Department submitted that based on the request received from the approved States i.e. Gujarat, Himachal and Andhra Pradesh, the Scheme of promotion of Bulk Drug Parks has been extended till FY 2025-26 by SSC in the review meeting dated 09th July 2024.

60. On being asked to give year-wise achievements of the scheme since the inception of the scheme in the year 2020, the Department submitted year-wise achievement of the Scheme since FY 2020-21 as follows:

1) FY 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. After evaluation as per the scheme

guidelines, the proposals of Andhra Pradesh, Gujarat and Himachal Pradesh were selected in October-November 2022 and further additional information such as GST subvention and Interest rate subvention details were sought from the proposers.

2) FY 2021-22: Based on additional information submitted, evaluation took place till Sept 2021. Owing to low rates quoted by the States for Utility and Land Lease charges and geographical dispersion, an **Advisory Committee** comprising CEO NITI Aayog, Secretary DoP, Secretary DPIIT and representative from Department of Expenditure (JS level) was formed with the approval of Hon'ble Minister (C&F) dated 26/07/2021 to assist the Department in the selection process.

3) FY 2022-23: Under the above mentioned Advisory Committee, three meetings were conducted, where in 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-principle 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 States were given 45 days for submission of DPR as per Scheme Guidelines. 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)	07/11/2022	13/03/2023	225

4) FY 2023-24: Gujarat BD Park received Environmental Clearance (EC) on 26th February 2024. Further, owing to issue of Partial de-notification of 769.65 acres of SEZ land (out of the total 2000 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 07th December 2023. Further, Andhra Pradesh BD Park received amended Environmental Clearance (EC) on 15th March 2024.

5) FY 2024-25: Till October 2024, Gujarat has started construction of Boundary walls, Roads, Drainage system, internal water supply, ETP lines. AP Bulk Drug Park has awarded a tender for Roads, Power, water and other utility buildings. In reference to EC approval of HP Bulk Drug Park, they have received approval of Term of Reference (ToR) and public hearing is planned on 20th November 2024.

61. When asked to give details of utilization of Rs.3000 crore allocated for the Scheme, the Department submitted that Govt. of India has released total Rs. 750 crore to all three approved States as first installment (Gujarat – 300, HP – 225, AP -225) in FY 2022-23.

Fund Released and Utilized (Rs. crore)						
State	**Approved CIF Cost**	**Central Grant Released**	**State Fund Released**	**Fund Utilized in FY 2023-24**	**Fund utilized in FY 2024-25 (till Oct 2024)**	**Total fund utilized since inception**
Gujarat	1457.01	300.00	137.10	31.48	119.12	150.60
Himachal Pradesh	1118.46	225.00	35.54	20.93	24.98	45.91
Andhra Pradesh	1438.89	225.00	132.30	-	2.30	2.30
Total	**4014.36**	**750.00**	**304.94**	**52.41**	**146.40**	**198.81**

62. On being specifically asked to state as to how many Parks the grant-in-aid of Rs.1000 crore for Park or 70% of the project cost of CIF has been granted, it was submitted that total 03 Parks in the States of Gujarat, Andhra Pradesh and Himachal Pradesh have been selected under the Scheme for Promotion of Bulk Drug Park.

63. When asked to state that the Department has received proposals 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, maximum 03 Bulk Drug Parks will be supported under the Scheme.

64. As regards the present status of the construction of Bulk Drug Parks in the State of Gujarat, Himachal Pradesh and Andhra Pradesh, the Department submitted the following information:

Gujarat: Construction work of Boundary walls, Roads, Drainage system, internal water supply, Effluent Collection pipeline, is in progress, upto October 2024.

Andhra Pradesh: A tender has been awarded for Roads, Power, water and other utility buildings and contractor has been on-boarded.

Himachal Pradesh: Approval received for Terms for Reference (ToR) towards Environment Clearance (EC). The public hearing has been scheduled by HP BD park on 20th November 2024.

65. When specifically asked about the present status of utilization of first installment released to the three States so far, the Department furnished the following:

		Fund Released and utilized till October 2024 (Rs. Crore)					
State	Approved CIF Cost	Central Grant Released	Central Grant Utilized	State Fund Released	State Fund Utilized	Total Fund Utilized till Oct 2024	Target Utilization amount for availing 2nd Installment (75% utilization of 1st Installment) (Rs. Crore)
Gujarat	1457.01	300.00	150.60	137.10	-	150.60	327.83
Himachal Pradesh	1118.46	225.00	40.11	35.54	5.80	45.91	195.40
Andhra Pradesh	1438.89	225.00	2.30	132.30	-	2.30	267.98
Total	**4014.36**	**750.00**	**193.01**	**304.94**	**5.80**	**198.81**	**791.21**

66. 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.

67. When asked about the expected employment generation in each of the Bulk Drug Park, it was submitted that **e**xpected 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.

68. When specifically asked that by what time, the three Bulk Drug Parks are likely to be set up and functional, it was submitted that all the 03 approved Bulk Drug Parks have submitted revised timeline up to March 2026, towards commissioning of Bulk Drug Park.

69. 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 03 approved Bulk Drug Parks have submitted revised timeline up to March 2026, towards commissioning of Bulk Drug Park.

70. The Department has approved the extension of tenure of the Scheme just by one year for completing and implementation of the Bulk Drug Parks in the States and desired to know whether short tenure of one year would be sufficient enough for the establishment of Bulk Dry Parks, the Department submitted that post extension of Scheme Tenure, all three Bulk Drug Parks have submitted that by March 2026 commissioning of BD parks will take place. Owing to its hilly terrain, Himachal Pradesh may take some additional time towards operationalization of Bulk Drug Park.

71. The BE, RE and Actual expenditure in respect of Bulk Drug Parks was stated to be as follows:

(Rs. In Crore)

Year	BE	RE	Actual
2021-22	36.24	2.25	2.25
2022-23	900.00	900.00	301.50

2023-24	900.00	900.00	2.25

In the above statement, the actual expenditure for FY 2022-23 is Rs 751.50 crore against the mentioned expenditure of Rs 300.50 crore.

72. The BE (2021-22) for Rs. 36.24 Crore was drastically reduced to Rs. 2.25 crore only. On being asked the reasons for the same, the Department submitted that in FY 2021-22, proposals received from 13 States were under evaluation. Further, owing to low rates quoted by the States, for Utility and Land Lease charges and other selection parameters, it took more than the expected time towards evaluation and selection of the Bulk Drug Parks. Accordingly, a revised RE was submitted for FY 2021-22.

73. The BE (2022-23) and RE (2022-23) for this Scheme stood at Rs 900.00 Crore but the actual expenditure was just Rs 301.50 Crore. Asked to state reasons for underutilization of funds, the Department submitted that final approval was accorded to selected BD Parks in FY 2022-23 and first installment of Grant-in-aid of Rs. 750 crore (to all three approved Parks) was released in FY 2022-23. Owing to non-receipt of EC approval, the States could not start civil construction work of BD park which impacted their fund utilization.

74. The BE (2023-24) and RE (2023-24) was Rs. 900.00 crore but utilization was a miniscule Rs 2.25 Crore. On being asked to furnish a detailed reply, the Department submitted that owing to non-receipt of EC approval, States could not start civil construction which impacted their fund utilization. Gujarat received EC approval in February 2024 and Andhra Pradesh received EC approval in March 2024. EC approval of Himachal Pradesh Bulk Drug Park was awaited. Only post EC approval, States can start CIF development works and make payments against expenditure on civil construction works. These reasons have resulted in less utilization of funds.

75. An amount of Rs.120 crore was stated to have been released to Tamil Nadu, Uttar Pradesh, Himachal Pradesh and Madhya Pradesh till date and till June, 2024 Rs. 92.71 crore was stated to have been utilized. On being asked for reasons for difference between the Central grants released and utilized by the States and the timelines by which the States are likely to utilize the remaining Central Grants, it submitted that during periodic reviews, the Department has regularly advised the representatives of SIAs to expedite fund utilization. Further, Department has issued DO Letters dated 01st May 2024 and 12th June 2024 to Additional Chief Secretary/ Principal Secretary of the States, apprising about the slow progress in Bulk Drug Parks and requesting to speed up the physical progress and fund utilization.

76. The BE 2021-22 for Promotion of Bulk Drug Parks was Rs.36.24 crore. The RE was also Rs.36.24 crore but the actual expenditure was Rs.2.25 crore only. For the year 2022-23, the BE was Rs.900.00 crore and the RE was also Rs.900.00 crore but the actual expenditure was Rs.751.49 crore. The BE 2023-24 was Rs.900.00 crore which was reduced to Rs.85.15 crore but actual expenditure was a meager Rs.2.24 crore only. On

being asked the reasons for the under utilization of funds for three consecutive years, the Department submitted as under:

1. In FY 2021-22, proposals submitted by the 13 State Government towards 'Development of Bulk Drug Parks' were under evaluation. On evaluation of the proposals, it was observed that many States had submitted very low rates towards - Utility and Land Lease charges and other selection parameters, as a part of Selection Parameter, in order to be selected in the scheme. In order to evaluate, Sustainability of low rates quoted by the State Government and financial viability of the Projects, at such low rates, the Advisory Committee was appointed towards evaluation of proposals received from the State. Thereby, it took more than expected time towards evaluation and selection of the BD parks and hence the BE of FY 2021 – 22 could not be spent and a RE was submitted for FY 2021-22.
2. In FY 2022-23, final approval was accorded to BD Parks in the State of Gujarat, Andhra Pradesh and Himachal Pradesh and first installment of Grant-in-aid of Rs. 750 crore (to all three approved Parks) was released in FY 2022-23. Post receipt of approval, the State Government applied for Environment Clearance (EC) approval. Being a Red Category Industry, the approval of EC could not be received by the approved States in FY 2022 – 23 and hence they couldn't start civil construction work of BD park, which impacted their fund utilization of FY 2022 - 23.
3. In FY 2023-24, State Government of Gujarat had initially received approval of Environment Impact Study (EIA). Later, the State Government was asked to relocate the Marine Discharge of the Park and re-submit the EIA report, towards approval of Environment Clearance. Subsequently, Gujarat received EC approval in February 2024. As on date, State Government of Gujarat has awarded CIF tenders amounting to Rs. 486.50 crores and work on construction of Boundary walls, Roads, Drainage system, internal water supply, ETP lines, has started on the site. Further, CIF tenders amounting to Rs. 842.20 crores [Common Steam Supply (Rs.472.5 crores), Common Effluent Treatment Plant (Rs. 150.0 crores), Solvent Recovery (Rs. 119.7 crores) and Treatment Storage & Disposal Facilities (Rs. 100 crores)] has been released, with bid submission by mid December 2024.

4. Owing to the issue of Partial de-notification of 769.65 acres of SEZ land (out of the total 2000 acres, approved for the BD park), State Government of Andhra Pradesh had to re-locate the location of Bulk Drug Park. The proposal for re-location of Bulk Drug Park was submitted in October 2023, which was granted approval by SSC in December 2023. Later, Andhra Pradesh received EC approval in March 2024. State Government of Andhra Pradesh has prepared three tender packages for development of CIF work in the AP Bulk Drug Park, as mentioned below:

Sr No.	Tender Package	Details of Tender	Approx. Cost of Tenders (in Rs. Crores)
1.	Package 1	Civil work for Roads, Drains, Buildings, Utility Corridors on-boarded. Site development work has not been started yet.	875.00
2.	Package 2	Common Effluent Treatment Plant	311.00
3.	Package 3	Steam Generation and Solvent Recovery	250.00

5. Out of the above 03 Tender packages, tender package 1 has been awarded and the Vendor has mobilized men and machinery on the site and has started survey work on the site. Also, the Vendor has started preparation of civil construction drawings. Regarding Tender Package 2 and Package 3, stakeholder consultation with prospective vendors is in progress and the tenders are scheduled for release in December 2024 and January 2025 respectively.

6. EC approval of Himachal Pradesh Bulk Drug park is still awaited, as on date. Only post EC approval, States can start CIF development works and make payments against expenditure on civil construction works. In regard to EC approval, Public Hearing scheduled on 20th November 2024, has been initiated by the State Government. These issues, resulted into lower utilization of funds.

77. The Department has submitted that though the development of Common Infrastructure Facilities (CIF) have started in all the 3 approved bulk drug parks. However, out of the approved States, in 02 States the development of the Bulk Drug park was behind schedule, owing to delay in Environment Clearance and in one State, owing to change inlocation of Bulk Drug Park. Based on the request received from the approved States, the Scheme for promotion of BulkDrug Parks has been extended till Financial Year 2025-26 bySteering Committee for Component in the review meeting dated 9th July, 2024. Also, the request for approval for extension of unutilized Budget under the 'Scheme of Promotion of Bulk Drug Parks' till Financial Year 2025-26 has also been forwarded to Department of Expenditure, Ministry of Finance *vide* OM dated 25.10.2024. All the 03 approved Bulk Drug Parks have submitted revised timelines up to March, 2026 for commissioning of Bulk Drug Parks. The Department submitted that the State Government of Gujarat had initially received approval of Environment Impact Study (EIA). Later, the State Government was asked to relocate the Marine Discharge of the Park and re-submit the EIA report, towards approval of Environment Clearance. Subsequently, Gujarat received EC approval in February 2024. Owing to the same, there has been delay in the implementation of the Bulk Drug Park at Gujarat. The State Government of Gujarat has submitted a revised schedule for implementation of Bulk Drug Park, according to which the park is likely to operationalise by March 2026. Owing to issue of partial de-notification of 769.65 acres of SEZ land (out of the total 2000 acres, approved

for the BD park), AP Bulk Drug park submitted a revised proposal for a new location for BD park on 12th October 2023, which was granted approval on 07th December 2023 by the SSC. Later, Andhra Pradesh BD Park received Environmental Clearance (EC) on 15th March 2024. The State Government of Andhra Pradesh has submitted a revised schedule for implementation of Bulk Drug park, according to which the park is likely to operationalised by March 2026. Andhra Pradesh may take some additional time towards operationalization of BD park, owing to re-location of BD park. The State Government of Himachal Pradesh is yet to receive approval of Environment Clearance for the Bulk Drug Park. The State Government has received approval of Term of Reference (ToR) and public hearing is scheduled on 20th November 2024. Accordingly, Himachal Pradesh may take additional time towards operationalization of BD Park, owing to delay in receipt of Environment Clearance.

78. On being asked whether the Department has initiated any stepor proposed to initiate steps to accelerate the pace of development of Common Infrastructure Facilities in Bulk Drug Parks, the Department submitted that **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 was 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 meetings and other modes such as e-mails, phone calls regarding progress of the project and understanding and resolving the implementation concerns, if any.Further, the Department conducts fortnightly review meetings, to monitor the physical and financial progress of the Bulk Drug parks. 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.

79. To a specific query that in view of the fact that the Scheme for Promotion of Bulk Drug Parks has been extended till the year 2025-26, whether theBulk Drug Parks would be made functional by the year 2025-26 and whether in the opinion of the Department, the Scheme has got enough extension for establishment of BulkDrug Parks or it should have been extended for more time, the Department submitted that whilst Bulk Drug park at Gujarat was likely to be operationalized by March 2026, the Bulk Drug Parks at Andhra Pradesh and Himachal Pradesh, may take some additional time towards operationalization of Bulk Drugs Park.

80. The Committee pointed out that Central Grant released to Gujarat till 80. 80. On being pointed out that Central Grant released to Gujarat till October, 2024 was Rs.300.00 crore, out of which Rs.150.60 crore could be utilized and the State fund released was Rs.137.10 crore, out of which 'Nil' amount could be utilized. Similarly, the Central Grant released to Himachal Pradesh was Rs.225.00 crore, out of which Rs.40.11 crore could be utilized

and the State fund released was Rs.35.54 crore, out of which Rs.5.80 crore could be utilized. The Central Grant released to Andhra Pradesh was Rs.225.00 crore, out of which Rs. 2.30 crore could be utilized and the State fund released was Rs.132.30 crore, out of which 'Nil" amount could be utilized. On being asked the reasons for under utilization of the Central and State grants released to the three States and whether the Department has initiated any steps to accelerate the pace of expenditure by the States, the Department submitted that owing to non-receipt of EC approval, State Government of Gujarat and Himachal Pradesh could not start park development work, which impacted their fund utilization. Gujarat received EC approval in February 2024 and EC approval of Himachal Pradesh Bulk Drug Park is awaited, as on date. Only post EC approval, States can start CIF development works and make payments against expenditure on civil construction works, resulting into lower utilization of funds. Owing to issue of partial de-notification of 769.65 acres of SEZ land (out of the total 2000 acres, approved for the BD park), AP Bulk Drug park submitted a revised proposal for a new location for BD park on 12th October 2023, which was granted approval on 07th December 2023 by the SSC. Later, Andhra Pradesh BD Park received Environmental Clearance (EC) on 15th March 2024. Owing to the above issue, there has been low utilization of funds. During periodic reviews, Department has extended support to SIAs in expediting regulatory approvals, in coordination with concerned Ministry. Further, Department has regularly advised the representatives of SIAs to expedite fund utilization.

81. During oral evidence the representative of the Department apprised the Committee regarding Bulk Drug Parks as follows:

> "Sir, in continuation with the PLI scheme for making India Aatmanirbhar Bharat, three major bulk drug parks are coming up in the State of Himachal Pradesh, Gujarat and Andhra Pradesh. These States were chosen basis an Advisory Committee. The three States have all identified their land and the progress of the bulk drug parks is on. In the two States, tenders have already been awarded, work is on and in Himachal Pradesh, due to the delay in environmental clearance, we are awaiting the environmental clearance this month itself and then work will start. These bulk drug parks will on an average host 100 to 110 units which as Sir mentioned, when we talked about PLI bulk drug scheme, these are green field projects which are difficult to take off due to land availability, construction of common infrastructure. So, this scheme envisages state-of-the-art global standard common infrastructure for these units which can then come and set up their units in these bulk drug parks. The three State

Governments have set up their SIAs which are offering concessions to the units."

Scheme for Promotion of Medical Device Parks

82. 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) assistsDoP for effective implementation of the Scheme.

Under the scheme, the Department had received proposals from 16 States. 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 in the proposed medical device parks in these four states. First installment of Rs 30 crore was released to each of the four selected states in the financial year 2021-2022. Construction activities are in progress in all 4 selected parks.

83. The BE 2021-22 for Promotion Medical Device Park was Rs.60.00 crore. The RE was enhanced to Rs.137.02 crore and the actual expenditure was Rs.137.02 crore. For the year 2022-23, the BE was Rs.120.00 crore which was reduced to Rs.32.93 crore but the actual expenditure was a meager Rs. 0.90 crore. The BE 2023-24 was Rs.200.00 crore which was reduced to Rs.64.00 crore but actual expenditure was Rs.0.90 crore only. Please explain the reasons for the under utilization of funds for 2022-23 and 2023-24, the Department submitted that in FY 2022-23, from December 2021 to February 2022, final approval was accorded to four Medical Devices Parks i.e., Madhya Pradesh, Uttar Pradesh, Himachal Pradesh and Tamil Nadu. First Central Grant-in-aid was released to all the approved Parks amounting Rs. 120 crores (Rs. 30 crores to each park) from January 2022 to March 2022. Accordingly, complete fund budgeted for FY 2022-23 (BE) was utilized in FY 2022-23. In respect of Medical Device Park at Himachal Pradesh, Environment Clearance could be received only in November 2023. Accordingly, Common Infrastructure Facilities (CIF) tenders were released in last quarter of FY 2023-24 and site development and civil work could start in FY 2024-25. In case of other three States, after receiving environmental clearance, major Civil Tenders were awarded in FY 2023-24 and work started. In the Medical Devices parks, CIF Equipment tenders are of specialized nature, for facilities as follows -

Electra Magnetic Interference (EMI) & Electra Magnetic Compatibility (EMC) centre

(i) Component Testing Centre / ESDM / PCB / Sensor's facility
(ii) Sterilization/ETO/Gamma Centre

(iii) 3D designing and printing for medical grade products

There are limited domestic and international suppliers for these equipment, due to which the procurement process for award of tenders of CIF equipment has taken more time than expected. CIF equipment are in different stages of installation in the three parks and already sufficient expenditure has been incurred in the MD Parks at Uttar Pradesh, Madhya Pradesh and Tamil Nadu. Second installment of funds will be released to these parks by December, 2024.

84. On being asked whether it was a fact that Himachal Pradesh has withdrawn from the Scheme of Medical Device Park and remaining three states i.e. Uttar Pradesh, Madhya Pradesh and TamilNadu had issued tenders but those tenders received no response or only single bid was received, the Department stated that Department of Industries, Government of Himachal Pradesh vide letter dated 07-09-2024 has informed that as per Cabinet decision, the State Government of HP has decided to develop Medical Device Park at Nalagarh from its own funds. Further, they have decided that minimum 25% of the plots will be allotted for Medical Devices and rest of the plots for other general and green industries as per State Government priority. Progress of the Scheme has been regularly reviewed by the Department and States have been encouraged to expedite setting up of facilities. The States were selected under the Park Scheme on the basis of competitive rates quoted by them towards provision of utility services and allotment of land on long lease to manufacturers. Medical Device Park at Himachal Pradesh was facing funding issues from the State Government side. It appears that due to cost overrun it did not remain feasible for the state government to implement the park within the framework of the scheme guidelines of the department and hence it withdrew, despite all support available from the Department and Rs. 30 crores already released to the State. Civil works in all the other three Parks has progressed well and structures for housing equipment for CIF constructed. With regard to Equipment Tenders of CIF units, the State of Madhya Pradesh has awarded Equipment Tenders of 05 CIF units, out of 08 CIF units and few equipment have already been received on site. Further, State of Tamil Nadu has also awarded Equipment Tender of EMI/EMC Center and has received Schedule-I equipment on site and the State of Uttar Pradesh has released Equipment tenders of 02 units.Owing to the requirement of specialized Equipment and limited domestic and international suppliers, the procurement process of CIF Equipment has taken additional time, but as on date, with the help of Technical Partners such as IIT Kanpur, IIT Delhi, Anna University, IIT-Indore and Raja Ramanana Centre for Advanced Technology (RRCAT), State Implementing Agencies (SIAs) are in the process of finalization of outstanding tenders.

Scheme for Assistance to the Medical Devices Clusters for Common Facilities(AMD-CF)

85. The Scheme “Assistance to the Medical Devices Clusters for Common Facilities(AMD-CF)” was approved by the Standing Finance Committee (SFC) in its meeting held on 20.03.2023 with the aim to strengthen Medical Device clusters by providing financial assistance and to strengthen and / or establish more Testing

Laboratories for Medical Devices to improve quality and for sustainable growth of the sector. The total financial outlay of the Scheme was Rs 300 Crore. The period of the Scheme was from financial year 2023-24 to financial year 2025-26.The proposals under the Scheme will be 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. The Scheme has provision to provide financial support for 12 Common Infrastructure facilities and establishment/strengthening of 12 testing facilities. The proposals received under the Scheme are presently under examination.

86. When specifically asked that the period of AMD-CF was from the year 2023-24 to the year 2025-26 and had an outlay of Rs.300 crore and whether any plan has been drawn for this scheme, the Department submitted that under the scheme, Detailed Project Report (DPR) has been called from 6 Applicant for Common facilities and 6 applicants for testing facilities. Appraisal of received DPR by PMA is under process. In this connection, it is submitted that a new scheme "**Strengthening of Medical Device Industry**" with the financial outlay of Rs. 500 crore, consisting of 5 sub-schemes -(a) Common Facilities for Medical Devices Clusters; (b) Marginal Investment Scheme for Reducing Import Dependence; (c) Capacity Building and Skill Development for Medical Devices; (d) Medical Device Clinical Studies Support Scheme; and (e) Medical Device Promotion Scheme is being implemented. This outlay for the new scheme has been taken from the outlay of the two existing schemes- Assistance to Medical Device Clusters for Common Facilities: Rs.300 crore and Human Resource Development Scheme for Medical Device Sector: Rs. 480 crore. The existing two schemes will become part of the new scheme with reduced outlay of Rs. 110 crore for 2024-2025 to 2026-2027 with new name "Common Facilities for Medical Devices Clusters and Capacity Building and Skill Development for Medical Devices with an out lay of Rs. 100 crore for 2024-2025 to 2026-2027.

87. To a specific query on the achievements and constraints faced, the Department submitted that the AMD-CF Scheme is hosted on the web portal and consists of two components: Assistance to Common Facilities (ACF) and Assistance to Testing Facilities (ATF). To promote the scheme, outreach programs were organized in six locations: New Delhi, Ahmedabad, Mumbai, Chennai, Bangalore, and Visakhapatnam. The Scheme Steering Committee (SSC) shortlisted 12 proposals (6 for ACF and 6 for ATF) for the submission of Detailed Project Reports (DPR). 10 applicants (4 for Common Facilities and 6 for Testing Facilities) have already submitted their DPRs, which is under examination by Project Management Agency (PMA), SIDBI. As of now, no major bottlenecks have been encountered. In the initial implementation phase, bottleneck was faced in selection of PMA, for which multiple tenders had to be floated, which caused delay.

88. When asked to give the composition of the Scheme Steering Committee and details of the Project Management Agency (PMA), how PMA has helped/assisted the Department in running the Scheme, the following information was submitted:

The composition of the Scheme Steering Committee (SSC) is as under:

i. Secretary, DoP – Chairperson
ii. Financial Adviser, DoP - Member.
iii. Drug Controller General of India - Member.
iv. Joint Secretary (Medical Devices), DoP - Member.
v. Representative of Ministry of MSME - Member.
vi. Representative of Ministry of MeitY – Member.
vii. Representative of Ministry of DPIIT – Member
viii. Director / Deputy Secretary (Medical Device), DoP – Convener.

Project Management Agency (PMA) for the Scheme is Small Industries Development Bank of India (SIDBI). The PMA reports directly to the SSC and has the following responsibilities as per Para-9 of the scheme guidelines: -

i. Assist SSC in drafting and issuing Expression of Interest (EoI)/ Request for Proposal(RFP) and formulating criteria for evaluation to select the Projects from the Proposals received in response to RFP.
ii. Devise the prescribed application formats and list the supporting documents as well as the appraisal methodology for approval of SSC/ DoP.
iii. Preliminary examination of the proposals, and preparation of evaluation/appraisal reports that shall be placed before the SSC for final selection of proposals.
iv. Sensitization of the Industry/potential beneficiaries on the Scheme and its benefits and also guiding them to apply for benefits under the scheme.
v. Preparing the Draft Agreement for selected beneficiaries for implementation of the scheme as per guidelines.
vi. Developing an online portal to receive the applications, disbursement of incentive and maintain the MIS and data of the applicants with all the details.
vii. Assist the selected beneficiary in the selection of agencies/ experts for various services such as capacity building, business development, technical or engineering support, in developing suitable O&M framework for making the project more effective.
viii. Monitoring the approved projects through physical inspection, monitor implementation schedule based on Quarterly Review Report & submit monthly & quarterly review of the projects report to DoP/SSC for timely disbursement and utilization of the funds.
ix. Provide other need based advisory services to the SPV in effective implementation of the scheme

The Evaluation of the PMA shall be done on the basis of quality and timeliness of appraisal of new projects brought to DoP/SSC for final approval, monitoring for ensuring completion of the projects within the stipulated timelines mentioned in the approved

DPR/Projects. If progress and performance of the PMA is not satisfactory, DoP/SSC reserve the right to remove the PMA at any time during the tenure of the Scheme after serving a notice and considering its reply thereto. The PMA supported the Department in publicity about the Scheme, organizing outreach activities, development of portal for receiving the applications, scrutiny of proposals, conducting meeting of SSC and was presently doing the appraisal of DPRs.

89. When asked about the common infrastructure facilities; financial assistance that has been provided so far along with dates; Establishment/strengthening of testing facilities; List of the beneficiaries ;the Department submitted that under the Scheme, Detailed Project Report (DPR) has been received from 6 Applicant for Common facilities and 6 applicants for testing facilities. Appraisal received from DPR by PMA was under process. Vetting of proposals by Technical Committee constituted by DoP was also under progress. As and when the beneficiaries are finalized, the list will be made available.

90. On being asked to state as to how many proposals have been received under the Scheme, the Department submitted following information:-

"Under the Scheme 10 proposals received which are under process by PMA. List of the proposals is as under: -

Assistance to Common Facilities (ACF)

1. Telangana Life Sciences Foundation, Hyderabad, Telangana.
2. Centre for Medical Mould and Dies, Visakhapatnam, Andhra Pradesh.
3. International Centre for Medical Glass and Engineering Image Deptt.,Visakhapatnam, Andhra Pradesh.
4. Tamil Nadu Advance Manufacturing Centre of Excellence, Chennai, Tamil Nadu.

Assistance to Testing Facilities (ATF)

1. Osel Devices Private Limited, Gautam Budh Nagar, Uttar Pradesh.
2. Gesco Healthcare Private Limited, Chennai, Tamil Nadu.
3. Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala.
4. Testing Centre for Microfabrication and Medical Devices Now - Centre for Cellular & Molecular Platforms[C-CAMP], Bangalore, Karnataka.
5. AIC AMTZ Medi Valley Incubation Council, Visakhapatnam, Andhra Pradesh.
6. QVC Certification Services Private Limited, Ambala, Haryana."

91. When asked as to how much from the allocated amount of Rs.300 crore for the Scheme has been utilized so far, the Department replied that no fund has been released/utilized under the scheme till date.

92. When asked whether the whole allocated fund of Rs.300 crore would be optimally utilized by the year 2025-26 it was replied that the utilization of fund will depend upon final approval of the proposals by Scheme Steering Committee (SSC) under the scheme and physical progress of the project.

93. The Department sought 'Nil" funds for years 2021-22 and2022-23. For the year 2023-24, the Department sought 'Nil" funds at BE stage but RE 2023-24 was Rs.33.0025 crore and actual expenditure was Rs.0.00 crore. On being asked to explain, the Department submitted that the SFC approved the Scheme on 29.03.2023 and scheme guidelines were issued on 09.05.2023. Hence, nil fund was sought under the scheme for FY 2021-22 and FY 2022-23. Thereafter, process was initiated for selection of Project Management Agency. However, only after floating the RFP for the third time, the Project Management Agency (PMA) –SIDBI could be selected and MoU signed on 26.10.2023. After development of portal for receiving applications by PMA, the applications window could be opened on 11.01.2024, which was open till 15.03.2024. Outreach activities were also undertaken to sensitize the industry. Under the scheme AMD-CF, 20 applications were received - 8 applications for the sub-scheme Assistance for Common Facilities and 12 applications for the sub-scheme Assistance for Testing Facilities. The first Scheme Steering committee (SSC) meeting was held on 12.04.2024 in which the committee directed PMA-SIDBI to seek pre-feasibility report and financial model of the proposed projects from the applicants. Thereafter, in the next Scheme Steering Committee meeting held on 15th July 2024, it was decided to call Detailed Project Report from 6 applicants for Common Facilities and 6 applicants of Testing Facilities. Applicants took time in submission of DPRs, which have been received from all, but two applicants, which are under process. After evaluation of DPRs and approval of proposals by SSC, funds will be released as per scheme Guidelines. Therefore, no expenditure could be made in FY 2023-24.

Scheme for Human Resource Development in Medical Devices Sector

94. The scheme on 'Human Resource Development in Medical Devices Sector" was approved by the Standing Finance Committee (SFC) in its meeting held on 14.07.2023 with the objective to fill the gap existing in the education and research in medical devices sector and to ensure quality teaching, training and nurturing excellence in Medical Technology education for generating critical mass of trained human resource to meet the requirements of rapidly innovating multidisciplinary areas of Medical Technology and create R&D ecosystem for the sector. The Scheme was approved with an outlay of Rs. 480 cr for a period from 2023-24 to 2025-26.

Under the scheme financial support will be provided to Central Government Universities/Institutes for running multi-disciplinary post-graduate courses(MS/MTech/PG-Diploma) in medical devices and to Central/State Government Universities/ Institutes and Private Institutes for running diploma, certificate and short-term training courses for existing workforce (technicians, regulators) of medical device industry.

The proposals under the scheme will be approved by the Steering Committee (SC) constituted by Department of Pharmaceuticals (DoP). A Project Management Agency (PMA) assists DoP for effective implementation of the Scheme.

95. On being asked whether the Scheme was being implemented by the Department since 14.07.2023 with the objective to fill the gap existing in the education and research in medical devices sector and to ensure the quality teaching and to provide the achievements of the scheme during the previous year and also a gist of problems being faced by the Department in the implementation of the Scheme, the Department submitted that the Scheme was launched by the Department on 14th July 2023, since then the following has been achieved:-

1. Scheme Guidelines were published on 20th Oct 2023.
2. Selection of Project Management Agency (PMA) was done on 26th Dec 2023.
3. The Scheme could not be launched in March 2024 due to implementation of the Model Code of Conduct due to Elections.
4. The MoU with Project Management Agency (PMA) was done on 5th April 2024.
5. 1st Steering Committee meeting was held on 14th Jun 2024.
6. The Application window was open for beneficiaries from 28th Jun 2024 with end date of application on 7th Aug 2024 and the same was published in National Newspapers both Hindi and English.
7. The timelines were extended on 7th Aug 2024 till 14th Aug 2024 on request from many applicants to PMA .
8. The Department received a total of 16 Application from Central Government Universities / Institutes under Component A and 7 Applications under Component B from Private and Central Govt. institutions for financial support.

In this connection, it is submitted that a new scheme “Strengthening of Medical Device Industry” with the financial outlay of Rs. 500 crore, consisting of 5 sub-schemes - (a) Common Facilities for Medical Devices Clusters; (b) Marginal Investment Scheme for Reducing Import Dependence; (c) Capacity Building and Skill Development for Medical Devices; (d) Medical Device Clinical Studies Support Scheme; and (e) Medical Device Promotion Scheme is being implemented. This outlay has been taken from the outlay of the two existing schemes- Assistance to Medical Device Clusters for Common Facilities: Rs. 300 crore and Human Resource Development Scheme for Medical Device Sector: Rs. 480 crore. The existing two schemes will become part of the new scheme with reduced outlay of Rs. 110 crore for 2024-2025 to 2026-2027 with new name “**Common Facilities for Medical Devices Clusters and Capacity Building and Skill Development for Medical Devices** with an outlay of Rs. 100 crore for 2024-2025 to 2026-2027.

96.On being asked about the Scheme, it was submitted that the Department was driving this scheme with high priority and has made MediTech division responsible to run the scheme in alignment with the other Medical Devices schemes to ensure effective

implementation of National Medical Device Polcy 2023. The Department has appointed Life Sciences Sector Skill Development Council (LSSSDC), the sector skill council for Medical Devices sector, as the Project Management Agency (PMA) to ensure the linkage of the Human Resource Development Scheme for Medical Deceive Sector with Industrial needs and to have effective implementation. Since the appointment, LSSSDC, under the guidance of the DoP, has conducted 10 workshops (both physical and virtual) with industry and academia to promote the scheme.

97. On being specifically asked as to how many Central Government Universities/Institutes, financial support has been provided or proposed to be provided during the current financial year, the Department submitted that the Department has received a total of 16 Application from Central Government Universities / Institutes under Component A and 7 Applications under Component B for financial support during the current financial year. The Department is actively reviewing these applications to allocate the funds to selected Applicants.

98. Asked to state the criteria for selection of Universities/Institutes, the Department stated as under:

For **Component A** the Criteria of the selection of institutions is 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 success of Institution.
7. Past workshops/ trainings done by Institutions in Medical Devices Sector.

For **Component B** the Criteria of the selection of institutions is below**:**

1. Affiliation of proposed program with a NCVET approved awarding Body or provision of approval for any new proposed program.
2. Demand establishment of the 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 Institutions in Medical Devices Sector.
7. Feasibility of Customized training according to Industrial demand/ market Demand.
8. Proximity of applicant institution to Medical Device industrial area for Industrial Visit and Inhouse-Training.
9. Available Industry Collaboration of Institute in Medical Devices Sector.

99. When asked to state whether the Department has taken any steps to popularize its scheme, it was submitted that **t**he Department [Project Management Agency (PMA), Secretariat] has undertaken several proactive measures to popularize its Scheme aimed at enhancing education and research in the medical devices sector. These steps are designed to raise awareness among stakeholders, encourage participation from Central Government Universities and Institutes, and ensure that the benefits of the scheme are widely recognized. Below are the Steps Taken to Popularize the Scheme-

1. **Print and Social Media Outreach**: The Department (through Project Management Agency (PMA)) has utilized print and social media platforms to promote the scheme, sharing updates, and important deadlines to reach a wider audience.

2. **Awareness Campaigns**: The Department (through Project Management Agency (PMA)) has launched targeted awareness campaigns to inform educational institutions and I ndustry about the objectives and benefits of the scheme. This includes webinars and workshops that outline the application process and funding opportunities.

3. **Collaboration with Academic Bodies**: The Department has collaborated with various academic bodies and associations to disseminate information about the scheme. This partnership aims to reach a broader audience.

4. **Guidelines and Resources**: Comprehensive guidelines and resource materials have been developed and made available on the Department's official website. These resources provide detailed information on eligibility criteria, application procedures, etc. making it easier for institutions to engage with the scheme.

5. **Engagement with Stakeholders**: The Department (through Project Management Agency (PMA)) has actively engaged with stakeholders, including university administrators, faculty members, and industry representatives, to gather feedback and address any concerns regarding the scheme. This engagement has helped build trust and encourage more institutions to apply.

100. Asked to state as to how much amount has been gainfully utilized so far out of the allocated amount of Rs. 480 crore, it was submitted that Rs. 90 Lacs has been released to PMA as fee for professional services till date.

101. Asked about proposals under the Scheme which have been approved, rejected, put on hold etc. by the Steering Committee(SC) constituted by the Department of Pharmaceuticals, it was submitted that under the Scheme, a total no. of 23 proposals (16 Application from Central Government Universities / Institutes under Component A and 7 Applications under Component B) have been received which are under examination.

102**.** When asked about proposals pending before the Steering Committee as on date and the time by which they are likely to be approved, the Committee were apprised that under the Scheme, a total no. of 23 proposals (16 Application from Central Government Universities / Institutes under Component A and 7 Applications under Component B) have been received which are under examination.

103. The Department sought 'Nil" funds for years 2021-22 and2022-23. For the year 2023-24, the Department sought 'Nil" funds at BE stage but RE 2023-24 was Rs.31.0025 crore and actual expenditure was Rs.0.00 crore. On being asked the reasons, the Department replied that the **"Human Resource Development in the Medical Device Sector"** Scheme was approved by SFC on 14.07.2023 and the Guidelines were approved in October, 2023. Due to imposition of Model Code of Conduct for the General Elections in 2024, the engagement of Project Management Agency (PMA) could be done after receiving approval from the Election Commission. A Memorandum of Understanding (MoU) was signed for engaging PMA in April, 2024. After selection of the Life Sciences Sector Skill Development Council (LSSSDC) as PMA, and onboarding of PMA team, an advertisement was issued in August 2024 inviting applications for various courses to be conducted at different institutions and applications have been received as follows - 16 under component-A and 07 under component -B, which are under process and will soon be finalized. As a result, no funds were utilized during the year 2023-24.

Consumer Awareness, Publicity and Price Monitoring (CAPPM)

104. The Scheme is stated to have the following two components:

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

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

2. The scheme is implemented and monitored at the Central level by NPPA and is executed through PMRUs, which are registered Society in the concerned State/ UT for the 1st component i.e. 'A' above. Activities under the 2nd component i.e. 'B' above are undertaken by NPPA.

3. **Setting up of PMRUs in the State/UT**: 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.

4. Till 2nd August 2024, Price Monitoring and Resource Unit (PMRU) have been set up in the 31 States/ UTs and setting up of PMRUs in the remaining States/UTs is in progress.

Activities of PMRUs:

- Market availability survey on selected essential drugs and medical devices on a weekly basis.
- 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.
- Monitoring the notified prices of medicines
- 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.

105. The Committee desired to know as to how Many Price Monitoring and Resource units (PMRUs) have been set up now state-wise information and the date of their setting up, the following information was submitted:

As on 31.10.2024, PMRUs have been set-up in 31 States/UTs and the details of their setting-up are given below:

S. No.	State/UT	Date of Registration of PMRU Society
1	Kerala	03-01-2019

2	Gujarat	16-02-2019
3	Odisha	19-02-2019
4	Rajasthan	07-03-2019
5	Haryana	20-03-2019
6	Punjab	06-05-2019
7	Nagaland	29-05-2019
8	Tripura	25-06-2019
9	Uttar Pradesh	19-07-2019
10	Mizoram	22-01-2020
11	Jammu & Kashmir	31-03-2020
12	Andhra Pradesh	12-08-2020
13	Karnataka	12-08-2020
14	Telangana	25-08-2020
15	Maharashtra	17-09-2020
16	Goa	22-10-2020
17	Madhya Pradesh	12-11-2020
18	Chhattisgarh	24-03-2021
19	Jharkhand	18-06-2021
20	West Bengal	25-10-2021
21	Puducherry	29-10-2021
22	Ladakh	02-02-2022
23	Himachal Pradesh	22-03-2022
24	Bihar	18-06-2022
25	Uttarakhand	29-07-2022
26	Meghalaya	01-02-2023
27	Arunachal Pradesh	02-03-2023
28	Chandigarh	27-03-2023
29	Assam	08-06-2023
30	Dadra and Nagar Haveli and Daman and Diu	06-12-2023
31	Lakshadweep	25-01-2024

106. Asked to state the functions 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 function as the key collaborating partners of National Pharmaceutical Pricing Authority (NPPA) with information-gathering mechanisms at the grassroots levels. PMRUs create public awareness so that the benefits of the DPCO (revised from time to time) trickle down to the grassroots levels. Also PMRUs are expected to provide necessary

technical assistance to the State Drug Controllers and NPPA. Their activities, *inter-alia*, include:

a. Market-based data collection, compilation, and analysis in respect of scheduled/ non-scheduled formulations.
b. Monitoring of price movement of scheduled/ non-scheduled formulations
c. Collection/ purchase of test samples of medicines
d. Conducting Training, seminars and workshops at the State and District level for consumer awareness and publicity.

As on 31.10.2024, PMRUs has been set up in 31 States/UTs. All the PMRUs are functioning in their respective States/UTs as per the mandated activities.

107. 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) and are fully funded by NPPA under CAPPM scheme for establishment and recurring expenses as per the PMRU guidelines, the Department submitted that PMRUs are registered as a Society and a representative of NPPA is member of the executive committee of the PMRU Society. Further, all PMRU are required to submit a comprehensive monthly report which is analyzed in the NPPA and observations/directions is shared to PMRUs. Review meetings with the PMRUs are also conducted where their performance on various parameters is reviewed. Further, officials from NPPA also visit to PMRUs to monitor the activities on grass-root level. Necessary guidance/ handholding is also provided to the PMRUs through monthly webinars conducted on various topics.

108. Asked about the extent the PMRUs have been able to achieve their objectives, the Department submitted that since 2019, PMRUs have been set-up in 31 States/UTs till date and most of them are performing satisfactorily. In FY 2023-24, a total of 320 Information, Education and Communication activities (IEC activities) were conducted by PMRUs. Also, during this period, a total 1356 'likely Violation Cases' were reported by these PMRUs. For ensuring availability of essential drugs in the country, availability surveys are conducted by PMRUs. A total of 1107 surveys were conducted by PMRUs in the FY 2023-24.

109. Asked to state whether the Department and NPPA has ever reviewed the functioning of PMRUs, the Department submitted that NPPA reviews the activities and functioning of the PMRUs on a monthly basis through the Monthly Reports submitted by the PMRUs. Further, Annual review of PMRUs is also carried out at NPPA. The Performance Review for the FY 2023-24 was carried out in the month of February 2024 with officials of the PMRU in a meeting held under the Chairpersonship of Chairman, NPPA.

110. Asked to offer suggestions by the Department as well as NPPA making the functioning of PMRUs more effective, the Department stated that based on regular monitoring of the activities of PMRU through monthly reports and through performance review of all PMRUs, NPPA identifies the issues in under-performing PMRUs and observations/ guidance are communicated at the appropriate level for improvement.

111. 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 as per PMRU Guidelines (Guidelines for Setting up Price Monitoring and Resource Units (PMRUs) at the State / Union Territories under the Central Sector Scheme of Consumer Awareness, Publicity and Price Monitoring), States/UTs are divided in to three categories based on the population. The annual budget outlay for each category is as indicated below:

a. **Category I-**States/UTs having population of more than 3% of all India population and annual budget outlay is Rs. 55 Lakh.
b. **Category II-**States/UTs having population of less than 3% but more than 1% of all India population and annual budget outlay is Rs. 49 Lakh.
c. **Category III-** States/UTs having population of less than 1% of all India population and annual budget outlay is Rs. 42 Lakh.

The allocated amount is disbursed to the respective PMRUs as per the Department of Expenditure, Ministry of Finance Instructions/Orders regarding flow of fund under central sector scheme.

112. When asked that in how many states there is not even a single PMRUs set up so far and by what time PMRUs are likely to be set in those states, the adverse effects noted/observed in those states where not even a single PMRU could be established, the Department submitted that PMRU can be set-up in a State/UT with the consent and approval of the respective State government. As on date, out of 36 States/UTs, PMRUs are yet to be set up in 5 States/UTs i.e. Andaman & Nicobar Island, Tamil Nadu, Delhi, Sikkim, Manipur. NPPA is making efforts at all levels for setting-up of PMRUs in these remaining States/UTs. Letters have been written to the State/UT authorities followed by regular follow-ups. Officers from NPPA have also been deputed to some of the States to expedite the process.

In these States/ UTs, NPPA ensures availability of drugs based on the information regarding shortage, if any, received from the respective Drug controllers. Also, in respect of overcharging of the drug price, prompt action is taken based on the complaints received through PMOPG portal, CPGRAMS, emails, Pharma Sahi Daam App of NPPA, etc.

However, various IEC activities; availability surveys etc. are not conducted in these States/UTs.

113. Asked about the training seminars and workshops 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 in FY 2023-24, total 320 IEC activities were carried out. In FY 2024-25 (till Aug'24), total 114 IEC activities have been carried out by 31 PMRUs.

114. Asked to state as to how many participants have undergone in the trainings seminars/workshops conducted by PMRUs so far. It was replied that PMRUs conduct most of their IEC activities and outreach programmes in public places like Schools, Colleges, Hospitals etc., and hence, the impact of IEC activities is spread through the participants to the society at large.

115. The BE 2021-22 for Consumer Awareness Publicity and Price Monitoring was Rs.6.00 crore. The RE was also Rs.4.50 crore but the actual expenditure was Rs.2.82 crore only. For the year 2022-23, the BE was Rs.6.00 crore which was reduced to Rs.3.75 crore but the actual expenditure was Rs.2.20 crore. The BE 2023-24 was Rs.5.00 crore which was reduced to Rs.3.00 crore but actual expenditure was Rs.2.95 crore. On being asked the reasons, the Department submitted that Consumer Awareness Publicity and Price Monitoring (CAPPM) scheme has two components, one related to setting up of Price Monitoring Resource Units (PMRUs) in States/UTs across the country and the other component relating to advertising and publicity. Major component under CAPPM is for setting-up and operations of PMRUs. PMRUs are set-up with the consent of respective State/UT government including their registration as a Society by the State/UT government and they function under the direct supervision of the State Drug Control administration. During FY 2021-22, FY 2022-23 and FY 2023-24, NPPA has been striving towards setting up of PMRU in all States/UTs of the country and has been successful in setting up of PMRU in 31 States/UTs.

However, the reasons for downward revision in the BE are twofold, one there was less demand of funds from existing PMRUs in States/ UTs as there was delay in recruitment of manpower by few PMRUs. This impacts the activities to be carried out by PMRUs that would have led to fund utilization. Secondly, the setting up of new PMRUs during FY 2023-24 in remaining States/UTs took time. Hence, the Budget Estimates for PMRUs were revised based on an estimate of actual scale of activities reported by PMRUs. Also, the under-utilization of funds during the F.Y. 2021-22 was due to COVID Pandemic. With regular follow up, PMRUs are raising their scale of activities which has resulted into proposed increase in spending and therefore the NPPA has proposed an increase in RE from Rs 3.00 crores to Rs 3.50 crores in the current Financial Year 2024-25.

116. When asked whether the State Level Price Monitoring Unit, its modus operandi and function is to create awareness among the public about the drug price control i.e. the price of the drug should be reduced, the Department submitted as under:

Price Monitoring Resource Units (PMRUs) are set-up at the State/UT level as a registered society and they function under the direct supervision of the State Drug Control administration. Their activities, *inter-alia*, include:

a. Market-based data collection, compilation, and analysis in respect of scheduled/ non-scheduled formulations.
b. Monitoring of price movement of scheduled/ non-scheduled formulations
c. Collection/ purchase of test samples of medicines
d. Advertisement and publication of newsletter, etc.
e. Conducting Training, seminars and workshops at the State and District level for consumer awareness and publicity.
f.

As on 31.03.2024, PMRUs have been set-up in 31 States/UTs. Apart from periodical market surveys to collect market-based data, PMRUs also conduct various information, education and communication activities to inform public-at-large about various provisions of Drugs Price Control Order (DPCO,2013); fixation of drug prices by NPPA; about 'Pharma SahiDaam (PSD)' App of NPPA available on Android as well as iOS platforms. PSD provides the facility for not only checking the prices of various drugs but also allows to register complaints regarding pricing and availability issues. During FY 2023-24, a total of 320 IEC activities were conducted by PMRUs largely a public places like hospitals, colleges, schools, etc.

Production Linked Incentive (PLI) Scheme for Domestic Manufacturing of Critical KSMs/Drug Intermediates andAPIs

117. Production Linked Incentive Schemes:-

(i). Production Linked Incentive Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India (PLI BD).

- With the objective to attain self-reliance and reduce import dependence in critical KSMs/DIs/APIs, the Union Cabinet approved the PLI Scheme for promotion of Domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India (PLI Scheme for Bulk Drug) on 20.03.2020. The tenure of the scheme is from financial year 2020-21 to 2029-30, with the total financial outlay of Rs. 6,940 crore. The Financial incentive under the scheme is to be provided on sales of 41 identified products categorized into four Target Segments.

- In total, 249 applications were received in four round of application window. Out of 249 applications, 48 projects have been approved with committed investment

of Rs. 3,938.57cr, and expected employment generation for around 9,618 persons.

- Incentive rates under the scheme are 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%

- Status of Projects / Plants: Investment as per Quarterly review report of September 2024

Sl. No.	Target Segment	Total Applicants approved	Total Committed Investment (₹ in crore)	Actual Investment up to June 2024 (₹ in crore)	Actual Employment up to June 2024 (No. of persons)
1	**A. Key Fermentation based KSMs/Drug Intermediates**	4	2,299.17	2428.23	2105
2	**B. Fermentation based niche KSMs/Drug Intermediates /APIs**	5	300.27	341.73	277
3	**C. Key Chemical Synthesis based KSMs/Drug Intermediates**	5	436.90	341.32	289
4	**D. Other Chemical Synthesis based KSMs/ DIs**	34	902.23	1044.49	1620
Total		**48**	**3,938.57**	**4155.77**	**4,241**

- The list of selected applicants is available on Department of Pharmaceuticals website

(https://pharmaceuticals.gov.in/sites/default/files/REVISED%20GUIDELINES%20FOR%20BULK%20DRUGS-29-10-2020_1.pdf)

118. To a specific query on the tenure of PLI Scheme from the year 2020-21 to 2029-30 with the total financial outlay of Rs. 6,940 crore and the gist of achievements of the PLI scheme since the inception of the scheme till date, 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 4,155 crores and generated employment for 4,241 individuals, as per the September 2024 Quarterly Review Report. As of November 2024, the selected applicants have commissioned a total of 34 projects for 25 bulk drugs, resulting in cumulative capacity creation of 56,800 MT per annum. Remaining 14 projects are under development. Under the scheme cumulative sales worth Rs 1331 crores, including export sales worth Rs 390 crores has taken place till September 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.

119. Asked about percentage utilization of allocated amount of Rs. 6940 crore and how the rest of the allocation is proposed to be utilized, it was 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 October 2024, an incentive amount of Rs 20.32 crores has been disbursed to applicants, out of total financial allocation of Rs 6,940 crores. Further, seven more projects are likely to commission in FY 2024-25. Hence, based on increase in sales more incentive is expected to be disbursed in the future

120. When asked to give details of 41 identified products categorized into four Target segments, the Department furnished the following information regarding 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

121. When asked as to how the PLI scheme is functioning and also asked to offer comments on the overall functioning of PLI scheme and its details, it was submitted that under the PLI scheme for Bulk Drugs, applicants have made an actual investment of Rs 4,155 crores against the committed investment of Rs 3,938 crores and sales worth Rs.1331 crores have been made including export sales worth Rs.390 crores. 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

122. When pointed out that out of 249 applications received under the scheme 48 projects have been approved and its details and how many more projects are proposed to be approved in the near future, the Department submitted that in four rounds of application window, 48 projects were approved for 33 products. As of October 2024, there is no proposal for opening the application window in near future

123. Asked about applications lying pending in the Department and at what level and also by what time the pending applications were likely to be disposed off, the Department replied that as of October 2024, no applications are pending with the Department for approval or for disposal

124. Asked to state whether the PLI scheme is generating employment as per expectations of the Department, it was 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 September 2024, 4,241 jobs have been generated by the selected applicants.

125. The BE 2021-22 for Production Linked Incentive (PLI) Scheme for Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs was Rs.2.79 crore. The RE was alsoRs.2.79 crore but the actual expenditure was Rs.2.18 croreonly. For the year 2022-23, the BE was Rs.390.00 crore which was reduced to Rs.14.61 crore but the actual expenditure was Rs. 5.95 crore. The BE 2023-24 was Rs.100.00 crore which was reduced to Rs.16.13 crore but actual expenditure was Rs.11.66 crore only. On being asked the reasons for the under utilization of funds for three consecutive years, the Department stated that under the Production Linked Incentive (PLI) Scheme for Bulk Drugs, FY 2021-22 was the gestation period for Chemical Synthesis products and FY 2021-22 and FY 2022-23 was the gestation period for Fermentation based products. The first year of performance/sales is FY 2022-23 for Chemical Synthesis products and FY 2023-24 for Fermentation based products. These projects have faced challenges in land acquisition, obtaining environmental clearance, drug-licensing approvals etc. In some cases, projects have also been delayed due to technology availability issues. The projects under the scheme were also impacted due to COVID during FY 2020-21 and FY 2021-22. The production of Bulk Drugs can only be gradually scaled up. It can take one to two years to reach the maximum/full-capacity of production. Due to above reasons, the funds requirement has been revised at RE stage and

consequentially are reflected in the actual expenditure under the scheme.

Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (PLIMD)

126. 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, the Committee therefore desired its details, the Department submitted as under:

An incentive amount of Rs. 48.85 crore has been approved and disbursed to 6 applicants under the Scheme. The details are provided below:

S. No.	Performance Year	Applicant Name	Incentive Amount Approved (In Rs. Crore)	Amount Disbursed (In Rs. Crore)
1	2022-23	Panacea Medical Technologies Pvt. Ltd.	3.10	3.10
2	2022-23	Wipro GE Healthcare Private Limited	8.00	8.00
3	2022-23	Nipro India Corporation Private Limited	3.61	3.61
4	2022-23	Meril Life Sciences Private Limited	6.14	6.14
5	2022-23	Siemens Healthcare Private Limited	8.00	6.40*
6	2022-23	Philips Global Business Services LLP	8.00	8.00
	2023-24	Philips Global Business Services LLP	17.00	13.60*
Total			**53.85**	**48.85**

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

127. When asked as to how the outlay of Rs. 3420 crore for PLIMD is proposed to be optimally utilized. The Department stated under the PLI scheme for Medical Devices, FY 2022-23 was the first year of performance. As on October 2024, the incentive amount of

Rs 48.85 cr (1.42%) has been disbursed to applicants. Further, Rs 85 crore is expected to be disbursed in FY 2024-25. Based on Industry consultations, it has been observed that Threshold Minimum Incremental Sales of Manufactured Goods year on year was found to be very high for Category –A applicants and Gestation Period for setting up of Green-field plants in one year is insufficient.

Accordingly, the Department has amended the scheme guidelines with the approval of Empowered Group of Secretaries and "Category B" of applicants has been introduced with reduced cumulative incentives and 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 has been received out of which 13 applications have been approved.

Further, in view of the delay in commissioning of projects and on account of approvals granted to category –B applicants in FY 2023-24 and FY 2024-25, 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 delay in the scheduled commercial operation owing to Covid-19, a proposal has been submitted to DPIIT for extension of tenure of the scheme (last year of eligible production) by one year from FY 2026-27 to FY 2027- 28. The proposal has been included in the consolidated Cabinet note. DPIIT has sent the Consolidated Cabinet note for approval on 12.10.2024. If approved, the allocated financial outlay is expected to utilized.

128. Asked to state the percentage utilization of the allocated outlay of Rs.3420 crore and how, the Department submitted that **u**nder the PLI scheme for Medical Devices, FY 2022-23 was the first year of performance. As on October 2024, incentive amount of Rs 48.85 cr (1.42%) has been disbursed to applicants, out of total financial allocation of Rs 3,420 cr (100%).

129. When asked whether the Department is hopeful of utilizing the entire outlay of Rs.3420 crore by the year 2027-28 i.e, when the tenure of the scheme would end, the Department submitted as 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 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 cr. and expected employment generation of around 8,437 persons. Incentive amount of Rs. 2,819 cr is to be utilized provided the applicants meet the performance thresholds. As of September 2024, total 19

(18 – Category-A and 1 - category-B) projects have been commissioned for 44 products, out of 154 approved products (44 – Category-A and 110 – Category-B).

The commencement of projects by Category-A 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 commissioning of their Greenfield Projects due to COVID-19 and pending regulatory approvals. Further, thirteen Category-B applicants with 110 products got their approval in the month of February and August 2023 and September 2024. The projects of these applicants are under implementation stage, with production expected to commence from FY 2023-24 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 delay in the scheduled commercial operation owing to Covid-19, a proposal has been submitted to DPIIT for extension of tenure of the scheme (last year of eligible production) by one year from FY 2026-27 to FY 2027- 28. The proposal has been included in the consolidated Cabinet note. DPIIT has sent the Consolidated Cabinet note for approval on 12.10.2024. If approved, the allocated financial outlay is expected to utilised.

130. Asked to state as to 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 1356.94 crore, against which an investment of Rs 1057.47 crore has been made by September, 2024. The sales made under the scheme as per September 2024 Quarterly Review Report are Rs.8036.63 crore, including export sales worth of Rs.3844.11 crore. 19 Projects have been commissioned for 44 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.

131. When the Committee desired to know 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 by Category-A 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 their 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 2023-24 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 owing to COVID-19, the tenure of the scheme (last year of eligible production) may be extended by one year from FY 2026-27 to FY 2027-28. Hence, the Department has sent one-year extension proposal for cabinet approval to DPIIT for inclusion in the consolidated Cabinet note. DPIIT has sent the Consolidated Cabinet note for approval on 12.10.2024. If approved, the allocated financial outlay is expected to be utilized.

132. Asked about the response of the medical devices manufactures towards PLIMD, 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 for 154 products.

133. When asked whether any complaint/suggestions has been received from the medical devices manufacturers and details of the action taken by the Department on such complaints/suggestions, the Department submitted that based on Industry consultations, it has been observed that Threshold Minimum Incremental Sales of Manufactured Goods year on year was found to be very high for Category –A applicants and Gestation Period for setting up of Green-field plants in one year is insufficient.

As per above learnings, the Department has amended the scheme guidelines with the approval of EGoS and “Category B” of applicants has been introduced with reduced cumulative incentives and 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 have been received out of which 13 applications have been approved.

As Gestation Period for setting up of Green-field plants in one year turned out to be insufficient, the competent authority i.e. Empowered Committee after examination has approved the extension of Scheduled Commercial Operation Date (SCOD) for the delayed projects. Due to the delay in the scheduled commercial operation owing to COVID-19, the tenure of the scheme (last year of eligible production) may be extended by one year from FY 2026-27 to FY 2027-28. Hence, the Department has sent one-year extension proposal for Cabinet approval to DPIIT for inclusion in the consolidated Cabinet note. DPIIT has sent the Consolidated Cabinet note for approval on 12.10.2024.

134. When asked whether PLIMD is generating the 'employment' as expected, the Department submitted that as per September 2024 Quarterly Review Report, employment of 5453 persons has been generated against the expected employment of 8437 persons upto March 2027.

135. The BE 2021-22 for Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device was Rs.2.36 crore. The RE was also Rs.3.31 crore but the actual expenditure was Rs.3.31 crore. For the year2022-23, the BE was Rs.216.00 crore which was reduced toRs.21.56 crore but the actual expenditure was Rs. 11.50 crore. The BE 2023-24 was Rs.100.00 crore which was reduced to Rs.48.16 crore but actual expenditure was Rs.40.30 crore only. On being asked to explain the reasons for the under utilization of funds for 2022-23 and 2023-24, the Department submitted that under the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, the first year of performance/sales was FY 2022-23. The incentive is disbursed to applicants based on achieving the eligibility criteria as per scheme guidelines which include sales target to be achieved and committed investment. Due to Covid outbreak in 2020-21, the overall scheme implementation got impacted. Further, due to Greenfield projects to be setup, the projects also faced other challenges in form of delays in Manufacturing-licensing approvals from state and central licensing authority. In some cases, the projects also suffered delays because of non-availability of technology. Though expenditure has been low, Rs. 958.72 crore worth of investment was grounded up to March 2024 and sales worth Rs. 5986.56 crore have been made, out of which exports are to the tune of Rs. 2806.37 crore.

PLI for Pharmaceuticals

136. When asked about the extent the PLI for Pharmaceuticals has been able to achieve its objectives, the Department submitted that the objective of the Scheme was 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 September 2024 Quarterly Review Report is worth Rs 2,26,992 crores which includes exports worth Rs 1,44,428 crores.

137. On being asked as to how PLI for Pharmaceuticals has enhanced country's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification etc, the Department submitted that as per Quarterly Review Report of September 2024, the actual investment made by the applicants are Rs 33,344.66 Crore against the committed investment of Rs.17,275 crore. The cumulative sales made under the scheme is worth Rs 2,26,992 crores, including export sales worth of Rs 1,44,428 crores. 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.

138. Asked as to how many applicants for financial incentives have been provided since inception of the scheme and what were their response to the Scheme, the Department stated as under:

"Total incentive worth Rs 3220.52 crores has been disbursed to applicants for performance year FY 2022-23 and FY 2023-24. Applicant wise financial incentive disbursed is as under:

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	127.50
3	Dr. Reddy's Laboratories Limited	330.00	
4	Glenmark Pharmaceuticals Limited	151.88	
5	Intas Pharmaceuticals Limited	149.96	
6	Lupin Limited	62.89	150.01
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	
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	Aarti Pharmalabs Limited	14.80	0.00
19	Aragen Life Sciences Limited	4.09	
20	BDR Pharmaceuticals International Private Limited	13.51	7.50
21	Concord Biotech Limited	14.81	
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	0.00
28	Symbiotec Pharmalab 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	
32	Poly Medicure Limited (IVD)	0.81	1.06
33	Abhilash Life Sciences LLP	4.51	0.00
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	
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	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		**2228.07**	**992.45**

*Incentive claims have been received which are under examination with PMA-SIDBI and further incentive of Rs.1066 crores is expected to be disbursed by the end of FY 2024-25.

139. Asked to state that about 278 applications are stated to have been received by the closing date of 31.08.2021 and 55 applications have been selected and details and the incentives extended to these 55 selected applicants so far and their contribution in enhancing manufacturing capabilities of the country in Pharmaceuticals Sector, the Department submitted as under:

'As per Quarterly Review Report of September 2024, the actual investment made by the applicants are Rs 33,344.66 Crore against the committed investment of Rs.17,275 crores. The cumulative sales made under the scheme is worth Rs 2,26,992 crores, including export sales worth Rs 1,44,428 crores.Applicant wise financial incentive disbursed are as under:

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	127.50
3	Dr. Reddy's Laboratories Limited	330.00	
4	Glenmark Pharmaceuticals Limited	151.88	

5	Intas Pharmaceuticals Limited	149.96	
6	Lupin Limited	62.89	150.01
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	
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	Aarti Pharmalabs Limited	14.80	0.00
19	Aragen Life Sciences Limited	4.09	
20	BDR Pharmaceuticals International Private Limited	13.51	7.50
21	Concord Biotech Limited	14.81	
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	0.00
28	Symbiotec Pharmalab 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	
32	Poly Medicure Limited (IVD)	0.81	1.06
33	Abhilash Life Sciences LLP	4.51	0.00
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	
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	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		**2228.07**	**992.45**

*Incentive claims have been received which are under examination with PMA-SIDBI and further incentive of Rs.1066 crores is expected to be disbursed by the end of FY 2024-25.'

140. The BE 2021-22 for Production Linked Incentive (PLI) Scheme for Pharmaceutical was Rs.3.00 crore. The RE wasalso Rs.3.00 crore but the actual expenditure was Rs1.24 crore only. For the year 2022-23, the BE was Rs.3.00 crorewhich was enhanced to Rs.694.20 crore but the actual expenditure was Rs. 655.15 crore. The BE 2023-24 was Rs.1000.00 crore which was enhanced to Rs.1632.00 crore but actual expenditure was Rs.1552.46 crore. On being asked about the trend, the Department stated that under the Production Linked Incentive (PLI) Scheme for Pharmaceuticals, the first year of performance/sales is FY 2022-23. Hence, only the expenditure of Project Management Agency fees is made in FY 2021-22. The BE and RE is the estimate for expenditure based on the expected sales to be made by the selected applicants. For the BE and RE estimate, the maximum allocation has been utilised based on actual performance by the selected applicants.

Promotion of Research and Innovation in Pharma Med Tech Sector (PRIP)

141. Asked to comment on the contribution of PRIP in the Indian Pharma Med Tech Sector so far, the Department stated as under:

The Cabinet, in its meeting held on 25.07.2023, approved the Scheme for Promotion of Research and Innovation in Pharma-Med Tech (PRIP) with an outlay of Rs. 5000 crore for five years (2023-24 to 2027-28). The scheme has been notified on 17.08.2023.

The scheme consists of two components:

Component A: Establishment of 7 CoEs at NIPERs in pre-identified areas with a financial outlay of Rs. 700 crores over period of 5 years.

Component B: Promotion of research in the pharmaceutical sector by encouraging R&D in six priority areas (e.g., New Chemical/Biological Entities, complex generics, precision medicine, orphan drugs, etc.), with financial assistance provided to industries, MSMEs, SMEs, and startups for both in-house R&D and collaborative R&D with government institutes. The financial outlay for this component is Rs. 4250 crores.

The scheme aims to transform the Indian pharmaceutical sector from cost-based to innovation-driven growth by strengthening the country's research infrastructure. It promotes industry-academia collaboration for R&D in priority areas and fosters a culture of quality research to nurture the scientific talent pool, thereby contributing to global competitiveness and quality employment generation.

Present Status: In accordance with gazette notification, guideline of the scheme has been released. The monitoring structure (Empowered Committee-PAAC-Technical Committee etc) as devised in the scheme guideline has been constituted. Dept has set up PMU (Programme Management Unit) within the Dept of overall management of the scheme. Hiring of professionals for the PMU is under process. Dept is in the process of developing the Portal for component B in consultation with NIC; and, engaging consultancy service for strategy development and implementation of the scheme.

Under component, A-Proposals of CoE as received from NIPERs were examined by Steering Committee under the chairmanship of Secretary, DoP. The Steering Committee in its meeting held in March 24 has approved Rs 700 Cr over a period of 5 yrs for establishment of seven CoEs. As recommended by the Steering Committee, Dept has prepared the financial outlay and under process to release grants for year 24-25.

142. On being asked as to why the Department sought 'Nil" funds for years 2021-22 and2022-23. For the year 2023-24, the Department sought 'Nil" funds at BE stage but RE 2023-24 was Rs.1.00 crore and actual expenditure was Rs.0.00 crore, the Department submitted that the scheme was approved by the Cabinet in July, 2023. Hence, funds under the Promotion of Research and Innovation in Pharma Med-Tech (PRIP) Scheme in the fiscal years prior to that were not solicited. In the year 2023-24, engaging a PMA as per scheme guidelines was planned. A tender in this regard was floated but due to non-receipt of any valid response. The tender could not be utilized.

Spurious/Adulterated Drugs

143. On being inquired about the reasons for the low conviction rate of 5.9% for cases related to the manufacturing, selling, and distribution of spurious or adulterated drugs, the Department of Pharmaceuticals conveyed that, as per information provided by the Ministry of Health and Family Welfare, conviction rate data is not maintained centrally. It further clarified that the figure of 5.9% does not represent the conviction rate but rather the percentage of cases decided according to data obtained from States and Union Territories. (Question 3, Supplementary List of Points for Examination of Demands for Grants (2024-25)

On the sale of spurious drugs in the open market, noting that between 2015-16 and 2018-19, out of 2.3 lakh drug samples examined by State Drugs Controllers, 593 were declared spurious and 9,266 were found to be of substandard quality.Apparently, only 35 convictions were done.

In response, the Department of Pharmaceuticals stated:

> "1. The State Drug Controllers conduct random sampling of drugs every month. Based on the finding upon analysis of the samples, various actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses/product licenses etc. are taken by the State Licensing Authority as per provisions of the Drugs Rules, 1945.
>
> 2. Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken various measures to ensure quality, efficacy and safety of medicines manufactured in the country. The key measures are as stated below;
>
> i. In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) have conducted risk-based inspections of more than 400 premises. The firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality, complaints, criticality of the products etc. Based on findings of inspections, more than 300 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.
>
> ii. Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. As per the amendment, the revised Good Manufacturing Practices and Requirements shall come into force for manufacturers for implementation as under:

Category of manufacturers [Based on turnover (INR)]	Time line for implementation
Large manufacturers (Turnover > 250 crores)	Six months from the date of publication of these rules.
Small and Medium manufacturers (Turnover ≤ 250 crores)	Twelve months from the date of publication of these rules.

iii. On 17-11-2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

iv. On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

v. On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

vi. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

vii. States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

PART - II

OBSERVATIONS/RECOMMENDATIONS

PROPOSED AND APPROVED ALLOCATION FOR THE YEAR 2024-25

1. The Committee note that the Department sought an amount of Rs.4089.95 crore for the financial year 2024-25. The Committee find consistent decline in funds allocated for various schemes/programmes run by the Department *viz.* For promotion of Bulk Drug Parks, Rs.1000.00 crore out of Rs.1352.00 crore sought; For Promotion of Medical Devices Parks, Rs.150.00 crore out of Rs.156.89 crore sought; For Human Resource Development in Medical Devices Sector (HRD) Rs.50.00crore out of Rs.98.00 crore sought; For Assistance to Medical Device Cluster for Common Facilities (AMD-CF), Rs.40.00 crore out of Rs.191.00 crore sought; and Consumer Awareness Publicity and Price Monitoring Rs. 4.00 crore out of Rs.6.00 crore sought. The Committee are perturbed to note that for Promotion of Research and Innovation in Pharma Med-Tech (PRIP), the allocation sought by the Department has been reduced by 50 percent. In this case, the allocation has been reduced to Rs.75.00 crore from Rs.150.00 crore sought by the Department. The Committee desire to be apprised of the reasons for reduced allocation of funds in each of the schemes/programmes being run by the Department and impact on their implementation. The Committee recommend that the Department should analyse the reasons for reduced allocation of funds in these Schemes and initiate corrective measures therein.

2. The Committee note that the increasing Budget Estimates (BE) of the Department *viz.* BE (2021-22) stood at Rs.470.41 crore; BE (2022-23) enhanced to Rs.2244.15 crore; BE (2023-24) enhanced to Rs.3160.06 crore; and BE (2024-25) enhanced to Rs.4089.95 crore. The Department has submitted that the reasons for consistently enhanced allocation was introduction of the three new Production Linked Incentives (PLI) Schemes in the year 2021-22 for a period of 5/6 years with a combined outlay of Rs. 25,360 crore. The Budgetary provisions were started from 2022-23 onwards, which increased the BE figures of the Department. Similarly, some new schemes of Development of Pharmaceuticals & Medical Device Industries were also approved during this period causing enhancement of BE (2022-23) onwards in comparison to BE (2021-22). The Committee are of the view that while the BE of the Department has been increased considerably for running new PLI Schemes introduced in the previous years, the consistently reducing RE figures as cited in Recommendation No.1 apparently reveals gaps in the implementation process. The Committee, therefore, desire that the Department should utilize the allocated funds in a time bound manner for successful and timely implementation of the schemes.

3. The Committee also note that the BE for the year 2023-24 which was Rs.3160.06 crore was drastically reduced to Rs.2697.96 crore. The Department has submitted that the RE was reduced due to the reason that expected release under some Schemes could not be made due to lesser demand in infrastructure schemes because of inherent issues in tendering process, environmental clearances etc, non-fulfillment of targeted achievements to claim incentives etc. The Committee recommend that the issues and constraints cited may be worked out in a time bound manner so that the intended benefits of the Schemes reach the beneficiaries in time.

4. The Committee are dismayed to note that the actual expenditure of the Department for the years 2021-22, 2022-23, 2023-24 also remained far less than the allocated funds. The Department has submitted that in the infrastructure's Schemes (Bulk Drug Parks, Medical Device Parks, Cluster Development Schemes) the release of funds depends upon the actual expenditure on the capital projects by the State agencies. This further depends upon the tendering processes and mandatory clearances from regulatory bodies and adding their shares of funds. Similarly, in the PLI Schemes, the actual release of incentives depends upon the fulfillment of Scheme guidelines and sanction provisions. The Committee were apprised that the Department has reviewed the functioning of the Schemes of Medical Devices and has formulated a new Umbrella Scheme in 2024-25 for Strengthening of Medical Device Industry for more focused approach and efficient utilization of funds. The Committee finds consolation to note that the Department has reviewed the functioning of the Schemes of Medical Devices and has formulated the new Umbrella Scheme in the current financial year 2024-25. The Committee, however, desire that the Department should take up the matter at the highest level with State agencies etc. for more robust coordination to ensure timely and optimal utilization of funds in future.

5. The Committee have noted that the fund utilized by the Department was 94.14 percent, 90.37 percent, 90.15 percent for the years 2021-22, 2022-23 and 2023-24, respectively. Further, the Department have stated that the expenditure up to October, 2024 was Rs. 1,363.55 crores (33.34% of BE) and it will pick up in the subsequent months when the PLI beneficiary companies will be raising claims for incentives. Moreover, the releases under the Pharmaceuticals and Medical Device Schemes will be made on the basis of demand from the concerned agencies and sanctioning of new proposals etc. The Committee hope and trust that the Department would be able to utilize the funds allocated in an efficient mannerfor the year 2024-25 too.

<u>JAN AUSHADHI KENDRAS</u>

6. The Committee note that in order to open Jan AushadhiKendras (JAKs) in rural and remote areas of the Country, the Department have apprised that the PradhanMantriBhartiyaPariyojana (PMBJP) has partnered with the Cooperative

Sector to maximize benefits of PMBJP Kendras in interior parts of the Country. Further, Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency of PMBJP has also entered into an agreement for setting up of Jan AushadhiKendras in Primary Agricultural Cooperative Credit Society (PACs). In this regard, till 31st October 2024, 4400+ PACS from 647 districts have applied & 2695 Primary Agricultural Cooperative Credit Society (PACS) have also been given initial approval letter, of which 676 Jan AushadhiKendras have been opened in PACS. Besides, more than 1000 applicants of PACS have been given online training. The Committee are happy that concerted efforts have been taken at the right time by the PMBJP and desire that the Department ensure that these JAKs opened in rural and remote areas are made functional at the earliest.

7. The Committee have been apprised with regard to the quality of generic medicines and their review by the Department thatPMBI 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 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. The Committee are happy to observe that PMBI has initiated sufficient measures to ensure the quality of the medicines made available at JAKs. The Committee, however, recommend that PMBI as well as the Department should make surprise visits at JAKs and undertake requisite tests on samples of medicines etc., from JAKs to keep them on their toes with the overall aim to ensure the quality of medicines sold by JAKs.

8. The Committee note that, as on date, about 3188 number of applications for opening of Jan AushadhiKendras was pending with PMBI at different stages out of which 2692 applications are stated to have been given in principle approval and 496 applications are stated to be under review. As regards the complaints filed by customers/general people regarding availability and quality fo medicines, the Committee have been apprised that Pharmaceuticals & Medical Devices Bureau of India (PMBI) has a Store Complaint &Facilitation cell (e-mail ID-complaints@janaushadhi.gov.in) to analyse and resolve the queries of the customers as well as entrepreneurs. Further, a toll-free helpline number 18001808080 is also being operated with 06 (Six) telecallers to address the queries of the customers, Jan Aushadhi Kendra owners and applicants etc. Besides, the complaints/ grievances received through other portals like RTI, CPGRAM are also addressed by PMBI regularly in a timely manner and strict quality control mechanisms are in place to ensure compliance of standards and no major quality issue has arisen so far. The Committee observe that though the complaint redressal system of PMBI appears to be satisfactory, the Committee, however,

desire that all the complaints received as well as the 496 number of applications lying pending with the PMBI may be disposed off at the earliest.

9. The Committee are dismayed to note that as regards the mechanism to inspect the JAK retail outlets and malpractices in JAKs, the Department has not furnished any specific reply. However, the Department has submitted that there are more than 14,000 Jan Aushadhi Kendras (JAKs) located in 773 Districts which are operated and run by private entrepreneurs with their own funds and establishment. The Committee are of the view that since the JAKs are owned and run by private entrepreneurs, it becomes imperative on the part of PMBI to check the quality and quantity of medicines being sold at JAKs and also to curb malpractices of the JAKs owners that the benefits of the Scheme reaches the common man in a seamless manner.

10. The Committee are happy to note that about 42 Marketing Officers of PMBI are stated to have been deputed in different States / UTs to handle complaints of malpractice. Admittedly, Show Cause Notices are also issued for violating Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) norms resulting in a warning or cancellation in case of any confirmed malpractices. The Committee, however, desire that the number of complaints received and resolved by the 42 Marketing Officers of PMBI during the last three years and also the number of Show Cause Notices issued under the Scheme including the number of warnings issued or cancellation for confirmed cases of malpractices found in JAKs may be furnished along with the analysis of the effectiveness of the extant monitoring system of JAKs.

11. The Committee note that important medicines/injections like Benzylpenicillin, Atropine, Streptomycin, used for treatment of tuberculosis, mental ailments, are not available at JAKs and only Atropine Sulphate injection is procured as per demand and supplied to selected JAKs. The Committee were apprised that Benzylpenicillin and Streptomycin injection are not part of PMBJP product basket and are not at all procured. Further, tuberculosis medicines are also not part of PMBJP product basket as there is a separate TB Programme of Ministry of Health & Family Welfare to provide free medicines for TB patients under TB Eradication Plan. The Committee observe that the capacity of JAKs need further augmentation and feasibility studies for bringing these life saving drugs for TB or Mental illnesses into the PMBJP Product Basket may be carried out. The Committee, therefore, desire that the Department make efforts towards requisite augmentation of JAKs so that they become a one stop place for all kinds of medicines for the common people.

12. The Committee note that in order to ensure that the medicines being sold under PMBJP scheme are not duplicate or 'expired' and to obviate scope for such irregularities in Jan AushadhiKendras, the Department has come out with a "JanaushadhiSugam" mobile application which serves as a vital resource for the

general public, offering a user-friendly digital platform that provides a range of convenient services at their fingertips. Through this App, users can easily locate nearby JanaushadhiKendras (JAKs) with directions powered by Google Maps, search for Janaushadhi medicines, and compare the prices of generic versus branded medicines, highlighting potential savings in MRP. The Committee were apprised that there has been no instance of any duplicate medicines ever reported; JAKs have to ensure that 'expired medicines' are not sold to customers; and PMBI does not supply those medicines which have short life of 03 months or less. The Committee appreciate the launch of "JanaushadhiSugam" mobile application. The Committee, however, feel that it is the duty of the PMBI and the Department to ensure stoppage of expired or duplicate/substandard medicines at JAKs and it should not be left in the hands of only the JAKs. The Committee, therefore, recommend that more stringent steps may be taken to obviate scope for this malpractice. The Committee would like to be apprised of the steps taken by the Department/PMBI in this regard.

13. The Committee note that under the PMBJP, sanitary pads at Rs.1/- per pad are sold through its network of more than 14000 JAKs functioning across the Country. The Committee further note that in an appreciable noteworthy initiative, the Government of Telangana have made available sanitary napkins in Schools for girls students by installing booths/vending machines. The Committee are of the opinion that the Telenganamodel need to be replicated across the Country. The Department submitted that the matter does not pertain to Jan Aushadhi and they have referred it to the Ministry of Health and Family Welfare. The Committee are not happy with the contention of the Department as sanitary napkins are already being sold at the rate of Rs.1/- per pad in JAKs and it was just the step of making it easily accessible for the convenience of the girl students across the Country by installation of dispensing machines/booths. The Committee, therefore, recommend that the Department may consider the feasibility in consultation with the Ministry of Women and Child Development or Ministry of Health and Family Welfare, if required. The Committee would like to be apprised of the steps taken by the Department/PMBI in this regard.

<u>National Institute of Pharmacuetical Education and Research (NIPERs)</u>

14. The Committee note that since the inception of NIPER, a total number of 10,810 students (10,159- M Pharma/ MBA; 651- PhD) have passed out who are working in the industry as well as R&D and Academic Institutions. Further, NIPERs have signed about 303 MOUs with industries and other academic institutions till September 30, 2024. Besides, more than 425 patents have been filed till September

30, 2024 and about 8,048 research papers have been published in various reputed journals by the seven working NIPERs till September 30, 2024. The Committee find that during the last three years, 3608 students were enrolled in different courses offered by NIPERs out of which 2937 students passed out successfully. The Committee, however, find that since inception of NIPER, out of 14890 students enrolled in seven centres of NIPERs at Mohali, Guwahati, Ahmedabad, Hyderabad, Hajipur, Kolkata and Raebareli, only 10960 students passed out successfully indicating a large number of students who were declared unsuccessful i.e. 3930. The Committee recommend that the Department in consultation with NIPER undertake a serious study to analyse the gap between the number of students enrolled and number of students declared successful each year with a view to take concrete steps to improve the scenario.

15. The Committee further find that the placement percentage in NIPERs is stated to be 79.54% for Mohali Centre, 82.08% for Hajipur and 86.44% for Kolkata Centre and 100% for Guwahati and Hyderabad centres. The Committee hope that the placement percentage of NIPER Centres at Mohali, Hajipur, Kolkata and other Centres may also follow the laudable achievements of 100% placement of Gawahati and Hyderabad Centres.

16. The Committee note that seven Centers of Excellence (CoEs) are being established at the respective National Institutes of Pharmaceutical Education and Research (NIPERs) under Promotion of Research and Innovation in Pharma Med-Tech Sector (PRIP) Scheme with the overall budget outlay of Rs.700 crore over a period of 5 years. The Committee look forward to the establishment of the CoEs in a time bound manner as envisaged by the Department.

17. The Committee note with concern that the BE (2021-22) of ….. was enhanced to Rs.372.00 crore at RE stage and BE (2022-23) of Rs.395.00 crore was also enhanced to Rs.451.13 crore whereas the BE (2023-24) of Rs.550.00 crore was reduced drastically to Rs.228.80 crore. The Committee find that BE (2023-24) of Rs 550 crore which was in accordance with EFC ceiling including Capital grant for construction of the NIPERs were revised to Rs.228.80 crore at RE stage due to slow pace of expenditure. The Committee desire that the reasons for slow pace of expenditure by the Department/NIPERs along with steps taken to accelerate the pace may be furnished to them.

18. The Committee further note with concern that the BE (2024-25) of NIPERs has been proposed at Rs.242.00 crore which is almost 50% less than BE (2023-24) which was Rs.550.00 crore. The Committee were apprised by the Department that based on the reduced expenditure pattern of previous year and in accordance with the EFC ceiling, the BE 2024-25 has been kept at Rs 242 crore. The Committee desire that

the Department should take ameliorative steps for timely utilization of the allotted funds.

19. The Committee note that construction of regular campuses in four NIPERs centres at Hajipur, Hyderabad, Kolkata and Raebareli is in progress. At Hajipur Centre, 38 percent of work is stated to have been completed; Centres at Hyderabad and Kolkata record 25 percent and 43 percent work completion respectively; Raebareli Centre, 70 percent of work has been completed. The estimated dates of completion of these construction work is stated to be 01.04.2025, 01.07.2025, 30.06.2025 and 31.03.2025 respectively. The Committee recommend that the estimated dates of completion of these campuses must be adhered to strictly through a robust monitoring mechanism.

20. The Committee note that NIPER has provisions for reservation for SC/ST/OBC students for admission in its different courses as per Government of India rules and are also giving concession in fees to SC/ST/OBC students. The Committeedesire that the number of SC/ST/OBC students admitted vis-à-vis total in-take of students course-wise in all the seven Centres of NIPERs during the last three years may be furnished to them.

21. The Committee are dismayed to find that for NIPER, Hajipur, only 572 students have passed out since the inception of the Institute (2007) till the academic year 2023-24 which *inter-alia* include very low data of students of Masters (Two years course) from the year 2019 till date where student intake capacities is 435, out of 426 admitted are, 261 students graduated so far up to the 2022-24 Session. The Committee, therefore, recommend that special focus be given to NIPER, Hajipur Centre by the Department to increase the student intake and also improve the number of successful students.

<u>Development of Pharmaceutical Industry Scheme</u>

22. The Committee note that 07 applications were short listed under the Development of Pharmaceutical Industry Scheme out of which 06 projects were given final approval and o1 project has been given 'in principle' approval by the Scheme Steering Committee. The Committee recommend that the 06 projects may

be given concrete shape at the earliest for the development of pharmaceutical industry.

Bulk Drug Parks Scheme

23. The Committee note that the Department proposes to establish Bulk Drug Parks with the total financial outlay of Rs.3000 crore during a 05 year tenure from the year 2020-21 to 2024-25. Though the current financial year i.e. 2024-25 is the last year of the Scheme, on the request of the State Governments of Gujarat, Himachal Pradesh and Andhra Pradesh, the Scheme tenure has since been extended till 2025-26. The Committee further note that out of the total of Rs.1054.9 crore, Rs.750.00 crore from Central Grant and Rs.304.94 crore from State Fund, a meagre sum of Rs.198.81 crore is stated to have been utilized by the States. The Committee have been informed that the 03 Bulk Drug Parks have submitted revised timelines upto March, 2026 keeping in view the laudable objectives of the Bulk Drug Parks to provide easy access to Common Infrastructure Facilities (CIF) to bulk drug units located in the park, so as to significantly reduce the manufacturing cost of bulk drugs. The Committee observe the delay in setting up of these parks may defeat the very purpose for which they have been set up. Moreover, keeping in view that these parks with the CIF and with subsidized power, water, land etc. are expected to optimize the cost of manufacturing bulk drugs in India. The Committee recommend that the targets set for the 03 Bulk Drug Parks due to come up by March, 2026 in the States Gujarat, Himachal Pradesh and Andhra Pradesh may be achieved in a time bound manner. The Committee would like to be apprised of the steps taken by the Department in this regard.

Schemes for Promotion of Medical Device Park

24. The Committee note that the Scheme for Promotion of Medical Device Park being implemented by the Department received proposals from 16 States Governments for creation of CIF. However, after evaluation, proposals of 4 (four) States *viz*. Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh were finally approved. The BE for the year 2021-22 was Rs.60 crore which was enhanced to Rs.137 crore but reduced to Rs.32.93 crore in the year 2022-23 and again goes to Rs.200.00 crore in the year 2023-24 and reduced to Rs.150.00 crore in the year 2024-25. The Committee are perturbed to note that a meagre amount of Rs.0.90 crore was the actual expenditure during the year 2022-23 and 2023-24. What is more perturbing to the Committee is the fact that Himachal Pradesh has withdrawn from the Scheme of Promotion of Medical Device Parks. The Department will have to obtain proposal from another State, evaluate the same and release grant which is a very time consuming process and would cause considerable delay in the implementation of the Scheme. The Committee desire that the Department may initiate concrete steps

in this regard to expeditiously set up the Medical Devices Parks in the remaining two States.

Consumer Awareness Publicity and Price Monitoring (CAPPM)

25. The Committee find that the Consumer Awareness Publicity and Price Monitoring (CAPPM) has two components (i) Assistance to Price Monitoring and Resource Units (PMRUs) in States and UTs; and (ii)Advertisement and Publicity for CAPPM. The Committee were apprised that as on date, PMRUs are stated to have been set up in 31 States/UTs and are statedly performing their functions satisfactorily. However, in the States of Andaman and Nicobar Island, Tamil Nadu, Delhi, Sikkim and Manipur, the PMRUs are yet to be set up. Notably, letters have been issued by the Department to the States/UT Authorities for regular follow ups and Officers from NPPA have also been deputed to Some of the States to expedite the process. The Committee desire that the PMRUs be set up in these five remaining States at the earliest so that the benefits of the Scheme reaches these States too.

PLI Scheme for Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs

26. The Committee note that the Department is implementing Production Linked Incentive(PLI) Scheme for Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs for a ten (10) year tenure from the year 2020-21 to 2029-30 with a total financial outlay of Rs. 6,940 crore. The Committee were apprised that while a total number of 249 applications were received, 48 green field projects for 33 bulk drugs have been approved with a total committed investment of Rs. 3,938 crore. Selected applicants have already made an actual investment worth Rs 4,155 crore and generated employment for 4,241 individuals, as per the September 2024 Quarterly Review Report. As of October 2024, the selected applicants have commissioned a total of 34 projects for 25 bulk drugs, resulting in cumulative capacity creation of 56,800 MT per annum.The Committee are happy to note the development under the scheme and desires that the scheme may be brought to its logical conclusion at the earliest.

27. The Committee note that the Department is implementing Production Link Incentive (PLI) Scheme for Promoting Domestic Manufacturing and Production Link Incentive Scheme for Pharmaceuticals and considerable progress in terms of utilization of allocated funds etc., has been made. The Committee recommend that these PLI schemes may be implemented in letter and spirit and brought to their logical conclusion.

28. As regard Promotion of Research and Innovation in Pharma Med-Tech Sector (PRIP), the Committee note that for the year 2023-24, the Department sought'Nil"fundsatBEstagebut atRE stage (2023-24) an amount of

Rs.1.00crore was allocated but the actualexpenditureisRs.0.00crore in this regard the Department have submitted that the scheme was approved by the Cabinet in July, 2023 as such funds under the Promotion of Research and Innovation in Pharma Med-Tech (PRIP) Scheme in the fiscal years prior to that were not sought and in the year 2023-24, engaging a PMA as per scheme guidelines was planned and finally a tender in this regard was floated but due to non-receipt of any valid response, the tender could not be utilized. Under these circumstances the Committee recommend that all the issues involved in the Scheme may be fixed at the earliest.

Spurious/Adulterated Drugs

29. The Committee find that during the years 2015-16 to 2018-19, 2.3 lakh samples of drugs/spurious were test out of which 593 were declared as 'spurious' and 9266 were declared as 'Not of Standard Quality (NSA)' Drugs/medicines. Apparently, only 35 convictions were made in all these cases amounting to a meager 5.9%.The Committee, however, observes that as on date only 5.9% of the total 593 cases relating to spurious/adulterated drugs have been resolved, with the remaining cases at various stages in respective Courts. The Committee are surprised to find that the conviction rate data is not maintained centrally for penal action for spurious/adulterated drugs. Admittedly, the figure of 5.9% does not represent the conviction rate but percentage of cases decided as per the data obtained for States/UTs. The Committee are concerned about the delays in disposal of cases as also the maintenance of centralized data pertaining to enforcement of penalties for spurious/adulterated drugs. The Committee, therefore recommend stringent action to be taken in a time bound manner for exemplary punishments for spurious/adulterated drugs.

30. The Committee note with serious concern that National Survey of Drugs (2014–16) revealed that 10% of samples from Government sources were substandard, compared to only 3% from Private sources indicating 3.17 times more prevalence in Government channels than in the retail market, undoubtedly pointing to loopholes in the procurement processes. Admittedly, various measures are taken by the Ministry of Health and Family Welfare to ensure that better quality and more effective, and safe drugs are made available to consumers. The Committee, however find the Department's reply on the higher prevalence of Not of Standard Quality (NSQ) drugs from Government sources did not address the core reasons for the issue. The Committee, therefore, demand a detailed explanation of the challenges, flaws, and enabling factors contributing to the higher prevalence of NSQ drugs from Government sources. Furthermore, the Committee find the Department's response does not outline the measures in place to ensure the quality and integrity of pharmaceutical products throughout all stages of the distribution process, including procurement, purchasing, storage, distribution, transportation,

documentation, and record-keeping. The Committee desire that the Government come out with more clarity on the previous legal authority and enforceability of the rules governing these distribution guidelines so that accountability be fixed accordingly.

India's Active Pharmaceutical Ingredient (API)

31. . **The Committee note thatIndia's Active Pharmaceutical Ingredient (API) manufacturing industry has demonstrated growth, particularly in exports, but remains heavily reliant on imports, predominantly from China, for many APIs and Key Starting Materials (KSMs). The Committee further note that China's dominance in this sector was attributed to its State-supported robust industrial infrastructure and large-scale manufacturing capabilities for production APIs and KSMs at significantly lower costs, driven by economies of scale and subsidized utilities such as water, steam, and power. Consequently, Indian manufacturers face challenges in competing, which have led to the closure of several local fermentation-based production plants for antibiotics and vitamins. In response to the query of the Committee regarding measures to create a level playing field for domestic manufacturers, the Department outlined the Ministry's initiatives to reduce dependency on imported APIs. While appreciating these efforts, the Committee find that particularly the Production Linked Incentive (PLI) Scheme, provides 20% incentives for fermentation-based products and 10% for chemically synthesized products. The Committee, however, note with concern that, to date, only nine fermentation-based production plants have been approved under the Scheme, with just three operational at present. Keeping in view the importance of achieving self-sufficiency in API production the Committee recommends efforts for enhancing the existing incentives for fermentation-based plants and leveraging Government infrastructure to establish additional plants. To this end, the Committee desire that these facilities should be also provided with highly subsidized utilities such as power, water, and steam to support domestic manufacturers and ensure competitiveness in the global market.**

Vacancies in Drug Inspector Posts in Central Drugs Standard Control Organisation (CDSCO)

32. **The Committee find that as on December, 2023, 60 percent of the sanctioned strength of drug inspectors, 303 out of 504 were vacant despite the fact that the Parliamentary Standing Committee on Health and Family Welfare may back in the year 2012 had recommended hiring people on short-term contractual bases till the vacancies are filled. The Committee were apprised that recruitment delays were caused by the Court on matters related to Recruitment Rules and following its orders from the Hon'ble Supreme Court of India, in this regard steps have now been initiated to expedite the recruitment process. While urging the Department to**

prioritize filling these vacancies without further delay, the Committee expresses concern that the existing sanctioned strength of 504 posts are insufficient to meet the Country's regulatory requirements for the medicines/drugs regime more specifically considering the fact that the country has more than 750 districts. The Committee, therefore, recommend that the responsible authorities conduct a comprehensive assessment of the actual staffing needs with a holistic vision of increasing the number of sanctioned posts to ensure effective regulation and oversight owe the multifaceted issues grappling the spurious/NSQ Drugs.

National Pharmaceutical Pricing Authority (NPPA)

33. The Committee find that the NPPA notified celling price for area 920 essential medicines including oxygen, general anesthetics and opoids. The Committee further find that while selling prices of essential medicines are raised on the basis of changes in the Wholesale Price Index (WPI), the NPPA also monitor the pricing of non –essential devices to ensure that manufactures do not hike the MRP of the medicine by more than 10 percent of the MRP in the last one year. The Committee find that NPPA issued on order dated 15th October, 2024 increasing the prices of 11 drug formulation by 50 percent. Admittedly, this was done in response to several applications requesting on price rise to accommodate rising production cost over the years. The Committee observe with serious concern that in the face of apparent increasing prices of medicines affecting the whole nation, particularly hard hitting the poorest of the poor, the NPPA which has the ambit of monitoring and enforcement of pricing of medicine, have allowed this situation to prevail. The Committee, therefore, desires a detailed note be furnished on this price hike.

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New Delhi;
…. December, 2024
….. Agrahayana, 1946 (Saka)

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

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
(2024-25)

Minutes of the Fifth Sitting of the Committee

The Committee sat on Wednesday, the 13th November, 2024 from 1500 hrs. to 1700 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Shri Azad Kirti Jha – Chairperson

MEMBERS

LOK SABHA

2. Shri Robert Bruce C.
3. Shri Bharatsinhji Shankarji Dabhi
4. Smt. Kriti Devi Debbarman
5. Shri Babu Singh Kushwaha
6. Shri Utkarsh Verma Madhur
7. Shri Balram Naik Porika
8. Shri Sachithanantham R.
9. Shri Eatala Rajender
10. Shri Daggumalla Prasada Rao
11. Dr. Ricky Andrew J. Syngkon

RAJYA SABHA

12. Shri Subhash Barala
13. Shri Niranjan Bishi
14. Shri Subhash Chandra Bose Pilli
15. Shri Meda Raghunadha Reddy
16. Dr. Kalpana Saini
17. Shri Akhilesh Prasad Singh
18. Shri Tejveer Singh

SECRETARIAT

1.	**Smt. Suman Arora**	**-**	**Additional Secretary**
2.	**Ms. Miranda Ingudam**	**-**	**Director**
3.	**Shri Kulvinder Singh**	**-**	**Deputy Secretary**
4.	**Shri Nagendra Suman**	**-**	**Deputy Secretary**
5.	**Shri Abhishek Kumar**	**-**	**Deputy Director**
6.	**Ms. Neelam Bhave**	**-**	**Committee Officer**

LIST OF WITNESSES

I Representatives of Department of Pharmaceuticals

1. **Dr. Arunish Chawla, Secretary**
2. **Shri Awadhesh Kumar Choudhary, Sr. Economic Adviser**
3. **Shri Manoj Sethi, JS&FA**
4. **Ms. Palka Sahni, Joint Secretary**
5. **Ms. Gayatri Nair, Economic Adviser**
6. **Ms. Vinod Kotwal, Member Secretary (NPPA)**
7. **Dr. Ajay Shanker Singh, CCA**
8. **Shri Abhishek Kumar Singh, Director**
9. **Shri Hitendra Sahu, Director**
10. **Ms. Khayi Leishingam, Joint Director**

II Representative of Pharmaceutical and Medical Devices Bureau of India (PMBI)

1. **Shri Ravi Dadhich, CEO (PMBI)**

2. At the outset, the Chairperson welcomed 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 (2024-25)'. Their attention was then drawn to Direction 55 (1) of the 'Directions by the Speaker' regarding confidentiality of the proceedings of the Committee.

3. The Chairperson in his opening remarks sought to know the broad parameter on the basis of which budgetary provisions have been made by the Department under different heads and how the Department plan to utilize the allocated funds for effective and timely implementation of schemes.

4. The Secretary, DoP then 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 2024-25 vis-à-vis funds allocated to the Department, overview of the Pharma and Medical Device Industry, Central Sector Schemes of the Department, strategy for Pharmaceutical and medical devices sector, National Institutes of Pharmaceutical Education & Research (NIPERs) their achievements and Initiatives, Challenges & Initiatives of NIPERs, PLI Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India, PLI Scheme for Promoting Domestic Manufacturing of Medical Devices, PLI Scheme for Pharmaceuticals, Bulk Drugs Parks Scheme, Promotion of Medical Device Parks, Strengthening of Pharmaceutical Industry Scheme, Assistance to Pharmaceutical

Industry for Common Facilities (API-CF), Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS), Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS), Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS), Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP), Public Sector Undertakings, Budgetary performance in 2023-24, Details of Scheme-wise Allocation Financial Year 2023-24, Achievements in FY 2023-24 and Plans for FY 2024-25.

5. The Secretary, DoP also informed the Committee about the mandate and strategies, Central Sector Schemes, Achievements, challenges and initiatives of National Institute of Pharmaceuticals Education & Research (NIPER), PLI Schemes for promoting Medical Devices and Pharmaceuticals, Bulk Drugs Parks Scheme, Promotion of Medical Device Parks, Strengthening of Pharmaceutical Industry Scheme, Revamped Pharmaceutical Technology up-gradation Assistance Scheme (RPTUAS) etc.

6. The Committee, thereafter, sought certain clarifications on the issues related to examination of Demands for Grants of the Department of Pharmaceuticals for the Financial Year 2024-25 which were responded to by the representatives. 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, within 2-3 days.

(The witnesses then withdrew)

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

The Committee then adjourned.

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

The Committee sat on Thursday, the 12th December, 2024 from 1500 hrs. to 1600 hrs. in the Committee Room 'D', PHA, New Delhi**.**

PRESENT

SHRI AZAD KIRTI JHA - CHAIRPERSON

MEMBERS

LOK SABHA

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

RAJYA SABHA

16. Shri Subhash Barala
17. Shri Subhash Chandra Bose Pilli
18. Shri Meda Raghunadha Reddy
19. Dr. Kalpana Saini
20. Shri Akhilesh Prasad Singh
21. Shri Tejveer Singh

SECRETARIAT

1. Smt. Suman Arora - Additional Secretary
2. Ms. Miranda Ingudam - Director
3. Shri Kulvinder Singh - Deputy Secretary
4. Shri Nagendra Suman - Deputy Secretary
5. Shri Abhishek Kumar - Deputy Director
6. 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) XXXX XXXX XXXX XXXX
(iv) XXXX XXXX XXXX XXXX and
(v) Fifth Report on 'Demands for Grants (2024-25)' 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.

***The Committee then adjourned*.**