23	STANDING COMMITTEE ON CHEMICALS ANDFERTILIZERS (2025-26) EIGHTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMAND FOR GRANTS

(2026-27)

TWENTY-THIRD REPORT

LOK SABHA SECRETARIAT

NEW DELHI

March, 2026/ Phalguna, 1947 (Saka)

CC&F.No. 203

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CHEMICALS AND FERTILIZERS

(2025-26)

(EIGHTEENTH LOK SABHA)

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DEMAND FOR GRANTS

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Presented to Lok Sabha on 13 March, 2026

Laid in Rajya Sabha on 13 March, 2026

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NEW DELHI

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

(2025-2026)

Shri Azad Kirti Jha - Chairperson

MEMBERS
LOK SABHA

2. Shri Brijmohan Agrawal
3. Shri Ajay Bhatt
4. Shri Robert Bruce C.
5. Shri BharatsinhjiShankarji 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. Shri Shivmangal Singh Tomar
21. Vacant*

RAJYA SABHA

22. Shri Naresh Bansal
23. Shri Subhash Barala
24. Dr. Bhagwat Karad
25. Shri Rwngwra Narzary
26. Shri Subhash Chandra Bose Pilli
27. Shri Arun Singh
28. Shri Akhilesh Prasad Singh
29. Shri Tejveer Singh
30. Shri G.K. Vasan
31. Vacant

** Vacant vice Dr. Ricky Andrew J. Syngkon, MP(LS), passed away on 19.02.2026 vide LS Table Office Notification No.21/4(8)/2026/TO(B) dated 20.02.2026.*

SECRETARIAT

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

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals & Fertilizers (2025-26) having been authorized by the Committee do present on their behalf this Twenty-third Report (Eighteenth Lok Sabha) on 'Demand for Grants (2026-27)' pertaining to the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals,.

2. The Committee considered the Demand for Grants (2026-27) pertaining to the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals for the Financial Year 2026-27 which were laid on the Table of the House on 13th February, 2026. After obtaining the Budget documents and Explanatory Notes, the Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals on 26th February, 2026. The Committee considered and adopted the Report at their sitting held on 12th March, 2026.

3. The Committee wish to express their thanks to the Officers of the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals 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;
12 March, 2026
21 Phalguna, 1947 (Saka)

Azad Kirti Jha
Chairperson,
Standing Committee on
Chemicals and Fertilizers

REPORT

PART- I

I. INTRODUCTORY

Indian pharmaceutical industry is the world's 3rd largest by volume and 11th largest by value. The total annual turnover of pharmaceuticals was ₹ 4,71,898 crore for financial year (FY) 2024-25 and has grown at a Compounded Annual Growth Rate (CAGR) of 9.5% since FY 21. In FY 2024-25, the total value of pharmaceuticals exports was ₹ 2,45,962 crore while that of pharmaceuticals imports was ₹ 63,573 crore. India is the largest supplier of generic drugs, accounting for about 20 percent of the global supply. India has the global highest number of United States Food and Drug Administration (USFDA) compliant pharmaceutical plants outside of the United States of America (USA). India contributes significantly to ensuring affordable medicines globally by supplying over 50% of Africa's requirement for generics, nearly 40% of generic demand in the US and approximately 25% of all medicine in the UK . India is the world's largest supplier of antiretroviral drugs, providing over 70% of the global supply and ensuring affordable access to the global south.

2. The Department of Pharmaceuticals was created on 1st July, 2008 under the Ministry of Chemicals and Fertilizers, with the objective of providing greater focus and thrust on the development of the pharmaceuticals sector in the country and to regulate various complex issues related to the availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to the pharmaceuticals sector, which requires coordination with other ministries. Business on the following subjects is allocated to the Department as per Government of India (Allocation of Business) Rules, 1961: -

(a) Drugs and Pharmaceuticals, excluding those specifically allotted to other Departments;
(b) Medical devices industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments;
(c) Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceuticals sector;
(d) Development of infrastructure, manpower and skills for the pharmaceuticals sector and management of related information;
(e) Education and training including high-end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector;
(f) Promotion of public- private partnership in pharmaceutical related areas;
(g) International co-operation in pharmaceuticals research, including work related to international conferences in related areas in India and abroad;

(h) 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;
(i) Technical support for dealing with national hazards in pharmaceutical sector;
(j) All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring;
(k) All matters relating to National Institutes of Pharmaceuticals Education and Research;
(l) Planning, development and control of, and assistance to all industries dealt with by the Department;
(m) Bengal Chemicals and Pharmaceuticals Limited;
(n) Hindustan Antibiotic Limited;
(o) Karnataka Antibiotics and Pharmaceuticals Limited;
(p) Indian Drugs and Pharmaceuticals Limited; and
(q) Rajasthan Drugs and Pharmaceuticals Limited.

3. The Department of Pharmaceuticals is the nodal department for policy-making, sectoral planning, promotion and development of the pharmaceutical and medical device industries. The administrative control of the Public Sector Undertakings (PSUs) of the Department, National Pharmaceutical Pricing Authority (NPPA) and Pharmaceuticals & Medical Devices Bureau of India (PMBI) is also vested in the Department.

4. The Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals presented their detailed Demand for Grants (Demand No. 7) for the financial year 2026-27 to Parliament on 13th February, 2026. The Budget Estimate of the Department showing Revenue and Capital expenditure for the year 2026-27 is as under:-

(₹ in crore)

Section	**2026-27 (BE)**
Revenue	5,329.42
Capital	1.80
Total	5,331.22

5. The breakup of the BE allocation to the Department of Pharmaceuticals for FY 2026-27 was given as under:

Sl. No.	**Schemes**	**BE**
1	Production Linked Incentive Schemes	2,499.84
2	Development of Pharmaceuticals Industry (including new scheme BioPharma SHAKTI 500 crore)	1,467.84

3	Promotion of Research and Innovation in Pharma Med-Tech	750.00
4	National Institute of Pharmaceutical Education and Research	215.00
5	Jan Aushadhi Scheme	200.50
6	Strengthening of Medical Device Industry	124.17
7	Secretariat Economic Services	26.47
8	Scheme of Programme Management	25.00
9	National Pharmaceuticals Pricing Authority	19.40
10	Consumer Awareness Publicity and Price Monitoring	3.00
	Total	**5,331.22**

II. PROPOSED AND APPROVED FINANCIAL OUTLAYS OF THE DEPARTMENT OF PHARMACEUTICALS (DoP) FOR THE FINANCIAL YEAR 2026-27

6. The details with regard to the proposed amount for each scheme of the Department of Pharmaceuticals for the year 2026-27 and the amount actually approved by the Ministry of Finance (MoF), as furnished by the Department was as under:-

(₹ in crore)

Schemes	**BE 2026-27 (Proposed)**	**BE 2026-27 (Approved)**
National Institute of Pharmaceutical Education and Research (NIPERs)	215.00	215.00
Promotion of Research and Innovation in Pharma Med-Tech (PRIP)	1480.00	750.00
Jan Aushadhi (PMBJP)	200.50	200.50
Production Linked Incentive Scheme		
Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/ Drug Intermediates and APIs	66.40	66.40
Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	183.44	183.44
Production Linked Incentive Scheme for Pharmaceuticals	2250.00	2250.00
Total PLI	2499.84	2499.84

Development of Pharmaceuticals Industry (DPI)		
Pharmaceutical Promotion and Development Scheme (PPDS)	2.00	2.00
Cluster Development	26.70	15.84
Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)	287.39	250.00
Promotion of Bulk Drug Parks	1563.00	700.00
Total DPI	1879.09	967.84
Strengthening of Medical Device Industry (SMDI)		
Promotion of Medical Device Parks	95.00	50.00
Capacity Building and Skill Development for Medical Devices	19.50	10.00
Common Facilities for Medical Devices Clusters	50.00	20.00
Marginal Investment Scheme for Reducing Import Dependence	60.00	20.00
Medical Device Clinical Studies Support Scheme	50.00	20.00
Medical Device Promotion Scheme	4.85	4.17
Total SMDI	279.35	124.17
Consumer Awareness Publicity and Price Monitoring (CAPPM) MH2852	5.00	3.00
Scheme of Programme Management)	28.80	25.00
Bio Pharma Shakti	*	500.00

* This scheme was announced under the Budget Announcement for FY 2026-27

III. BUDGETARY ALLOCATION *VIS-A-VIS* UTILISATION DURING 2022-23, 2023-24, 2025-26 and 2026-27

7. As regards the Budget Estimates (BE), Revised Estimates (RE) and actual expenditure for the years 2022-23, 2023-24, 2024-25, 2025-26 and 2026-27 of the Department of Pharmaceuticals, the following information was furnished to the Committee:-

					(₹ in crore)
FY	**BE**	**RE**	**Actuals**		**% against RE**
2022-23	2244.15	2268.54	2050.08		90.37
2023-24	3160.06	2697.95	2432.45		90.15
2024-25	4089.95	3387.96	3170.23		93.58
2025-26	5268.12	4369.70	2889.97 (as on 23.01.2026)	2893.92 (as on 12.02.2026)	
2026-27	4831.22*				

*final allocation for BE 2026-27 is **₹ 5,331.22 crore** (₹ 4,831.22 crore + ₹ 500.00 crore for Bio Pharma Shakti scheme) subsequent to Union Budget Announcement for 2026–27.

8. The Committee find from the aforementioned data that FY 2022-23 onwards, allocation at RE is almost 15–17% lower than BE. When asked to furnish reasons for the same and the remedial steps being taken by the Department to improve this trend, the Department submitted as under:

> " The budgetary allocation for the Department in the aforementioned FYs is primarily earmarked for two major schemes—namely, the PLI Schemes and the Promotion of Bulk Drug Parks—which together account for approximately 60% of the Department's total allocated budget. The actual expenditure under these two schemes did not align with the projections made for the respective financial years, primarily due to implementation delays—particularly in components involving infrastructure—on account of pending statutory clearances. Other contributing factors included the non-receipt of claims from beneficiaries under the Schemes in line with the projected timelines. Consequently, the overall utilization remained below the Budgetary Allocations. The Department is undertaking regular monitoring of Scheme expenditure in consultation with all stakeholders to ensure optimal fund utilization and effective implementation of the Schemes as envisaged."

9. It is evident from the information above that the BE (2023-24) was ₹ 3,160.06 crore which was reduced to ₹ 2,697.96 crore and the actual expenditure was ₹ 2,432.45 crore. The BE (2024-25) was ₹ 4,089.95 crore which was again reduced drastically to ₹ 3,387.96 crore and the actual expenditure was ₹ 3,170.23 crore. When asked to furnish reasons for actual expenditure being less than the allocated RE for three consecutive years, the Department submitted that the budgetary allocation for the Department is primarily for two schemes namely PLI and Promotion of Bulk Drug Parks, which is approximately 60% of the total budget allocated to the Department. The actual expenditure under these two schemes had not been in accordance with the projections made for those years and accordingly, the utilization was less than allocated RE.

10. On being asked about the reasons for major variations in RE for the year 2023-24, 2024-25 and 2025-26, the Department submitted that **t**he RE are determined by the Ministry of Finance on the basis of the utilisation achieved during the financial year up to the relevant point of time. Actual utilisation of the allocated budget is influenced by several factors, which in turn affect the pace and extent of expenditure. Accordingly, the RE is fixed with a view to meeting expenditure requirements for the remaining period of the financial year. These variables collectively account for year-to-year variations in the RE figures.

11. The Committee pointed out that the BE for the year 2025-26 was ₹ 5268.12 crore which was reduced to ₹ 4,369.70 crore. On being asked to state the reasons for this reduction, the Department submitted that in FY 2025–26, the BE was ₹ 5,268.12 crore. At the Revised Estimates (RE) stage, the Department proposed a reduction to ₹ 4,793.16 crore, as the actual expenditure at that point was lower than the projected figures. During discussions on the finalisation of the RE, the Ministry of Finance further reduced the allocation based on the expenditure trend. It was also indicated that, should additional funds be required for any scheme, the same could be considered and provided through Supplementary Grants.

12. The Committee further pointed out that as on 23.01.2026, the actual expenditure for FY 2025-26 is ₹ 2,889.97 crore, which is just 66.14% of the RE, and a whopping amount of ₹ 1,479.73 crore is yet to be utilized before closing of FY 2025-26. To a pointed query of the Committee that whether Department would be able to utilize the entire amount and reasons for slow pace of expenditure during the year 2025-26, the Department submitted that funds under the various schemes of the Department are released on the basis of audited expenditure statements submitted by beneficiaries for reimbursement of the actual expenditure incurred. As a result, a substantial portion of the funds is typically released during the last quarter/last month, of the financial year. Accordingly, it is expected that the major portion of the unspent funds will be utilised during the remaining period of the current financial year.

13. A perusal of the document furnished to the Committee revealed that the BE for the year 2023-24 was ₹ 3,160.06 crore which was enhanced to ₹ 4,089.95 crore and yet further enhanced to ₹ 5,268.12 crore, however, for the year 2026-27 the Department had reduced the BE and had been allocated ₹ 4,831.22 crore, which is ₹ 436.9 crore less than the BE of the previous year. When asked to furnish reasons for the same, the Department submitted as under:

> **"**The Department had proposed a budget allocation of ₹ 6,642.54 crore under the Budget Estimates (BE) for FY 2026–27. However, during the Pre-Budget Meeting, the Ministry of Finance allocated ₹4,831.22 crore to the Department. The Ministry of Finance, based on the discussions held, finalised the BE allocation taking into account the utilisation levels of the Department's schemes during the ongoing financial year. It was also conveyed that, should additional

funds be required during FY 2026–27, the same could be considered at the Revised Estimates (RE) stage, based on the actual utilisation up to that time.
Subsequently, at the time of the Union Budget Announcement for 2026–27, Ministry of Finance further increased the Department allocation by ₹1100.00 crore under two new schemes:

(i) ₹ 600 crore for Chemical Park
(ii) ₹ 500 crore for Bio Pharma Shakti

The "**Chemical Parks Scheme"** pertains to the Department of Chemicals and Petrochemicals. It has been inadvertently included under the Department of Pharmaceuticals by Ministry of Finance and Department of Petrochemicals have taken up the issue with MoF for resolution of the same.
Accordingly, **₹ 5,331.22 crore** (₹ 4,831.22 crore + ₹ 500.00 crore) has been allocated to the Department of Pharmaceuticals for FY 2026–27."

14. It was observed that the actual expenditure of the Department during the year 2023-24 was ₹2432.45 crore which rose to ₹ 3170.23 crore, however, in the year 2025-26, the actual expenditure (as on 23.01.2026) is much below the actual expenditure of the year 2024-25. When asked to furnish the reasons for the same, the Department submitted as under:

"In FY 2023–24, the Department incurred an expenditure of ₹2,432.45 crore against the Revised Estimate (RE) of ₹2,697.96 crore, reflecting a utilization of 90.15% of the allocated funds.

In FY 2024–25, against the Revised Estimate (RE) of ₹ 3387.96 crore, the Department incurred ₹ 3170.23 crore, reflecting a utilization of 93.58%. of the allocated funds.
In FY 2025–26, the Budget Estimate (BE) was ₹5,268.12 crore, which was reduced by the Ministry of Finance at the Revised Estimates (RE) stage to ₹4,369.71 crore. As on 12.02.2026, the Department has incurred an expenditure of ₹2,893.92 crore, reflecting a utilisation of 66.24% of the Revised Estimate. The Department will make all possible efforts to ensure that expenditure levels by the close of the financial year are comparable to, or higher than, those achieved in previous years."

15. The Department has been able to utilize just ₹ 2,889.97 crore as on 23.01.2026 out of the allocated RE of ₹4,369.70 crore for FY 2025-26. When asked to state how the schemes/plans of the Department have suffered or the Department has sacrificed and to what extent, the Department submitted that the expenditure incurred so far amounts to more than 66% of the allocated RE and is in line with the past trend and the nature of the schemes under the Department, wherein expenditure typically accelerates during the last quarter and, in particular, the final month of the financial year. Accordingly, it is expected that the allocated funds will be utilised. Further, expenditure under the schemes is being closely and regularly monitored. As regards

sacrificing any of the schemes under the Department, no such requirement is envisaged, as all schemes are being implemented as planned.

16. The percentage of actual expenditure against RE for the year 2023-24 it was 90.15 %, for the year 2024-25 it was 93.58 % whereas for the year 2025-26 (as on 23.01.2026) it is just 66.14 %. When asked to state reasons for the same, the Department submitted that a significant portion of expenditure under the schemes implemented by the Department is incurred during the last quarter/last month of the financial year—a trend consistently observed in the past—it is expected that the major portion of the allocated funds will be utilised by the end of the financial year, in line with historical trends.

17. When specifically asked whether the Department has initiated any steps to accelerate the pace of expenditure during the current financial year, the Department submitted that it regularly monitors expenditure under its schemes. To ensure optimal utilisation of funds, all concerned implementing agencies are sensitised on a regular basis through periodic interactions. Further, any bottlenecks identified during engagements with the monitoring agencies are addressed on an urgent basis to facilitate timely utilisation of the allocated funds and ensure smooth implementation of the schemes.

18. The Committee were informed that, excluding the allocation for Bio-Pharma SHAKTI scheme, there is a gap of approximately ₹ 1,800 crore between projection i.e. ₹ 6,642.54 crore and allocation i.e. ₹ 4,831.22 crore of DoP for BE 2026-27. The Committee desired to know about the schemes/projects of DoP which will be affected due to this mismatch between projection and allocation for BE 2026-27 and proactive steps being taken by the Ministry to ensure achievements of targets and objectives of such schemes. In this regard, the Department submitted as under:

> " The Budget Estimates are projected by the Department on the basis of the anticipated outgo, taking into account inputs received from the respective Scheme implementing agencies. Thereafter, these projections are discussed with the DEA/MoF, during the finalization of the RE for the current financial year and the BE for the ensuing financial year. After examining the Department's projected budgetary requirements, the Department of Economic Affairs (DEA) makes allocations based on the utilization trends of previous years. Further, in accordance with the prescribed procedure, any additional requirement of funds assessed for a particular Scheme is duly considered and provided for, with the approval of the Ministry of Finance, to ensure its smooth and effective implementation. Thus, there is no shortage of funds to ensure the smooth implementation of the Schemes. As regards the steps being taken by the Department to ensure achievement of the targets, the implementation of the Schemes is monitored regularly throughout the year. Regular interactions with all Scheme implementing agencies are ensured to address issues arising on the ground during implementation and to facilitate execution of the Schemes in the manner envisaged at the time of their formulation."

19. To a pointed query of the Committee regarding schemes/plans which would be sacrificed due to reduced allocation of funds for the year 2026-27, the Department submitted that the reduced allocation of funds for FY 2026–27 has been determined primarily on the basis of the anticipated expenditure on the ongoing schemes of the Department during the ensuing financial year. It does not envisage any sacrifices with respect to the Department's schemes or plans. Further, in accordance with the prescribed procedure, expenditure under ongoing schemes is reviewed at the Revised Estimates (RE) stage. If any additional requirement of funds is assessed for a particular scheme, the same is duly considered and provided for, with the approval of the Ministry of Finance, to ensure its smooth and effective implementation.

20. The Committee during oral evidence of the representatives of the DoP in connection with examination of DFG 2026-27, observed that on the one hand the BE proposed by the Department is being drastically reduced for various schemes year after year and on the other hand the Department is unable to optimally utilize allocated funds. In this regard, a representative of the DoP submitted as under:

> "Sir, there are many schemes where we have got the Budget as requested by us and the same budget has been agreed and allocated also. But there are few schemes, such as the promotion of research and innovation in pharma medicine, there is a PRIP. It is a R&D scheme, which is a very prestigious and flagship scheme of the Department
> Sir, in this scheme, there are two components. One is already in function, which is through the existing NIPER Mode. Another mode is the industry projects, which has been exhaustively modified in the entire scheme and its procedure. The applications have been received and the process has already started. Some of the R&D projects will be sanctioned in this financial year also. So, during discussion, the Finance Ministry asked us that you should start sanctioning the projects and in due course, we will give you more funds in the next financial year."

21. When asked whether verbal or written assurance from the Ministry of finance has been received in this regard, the representative submitted as under:

> "*Sir, in general, any scheme which has been approved by EFC or Cabinet, if we are spending, suppose the Finance has allocated us ₹ 500 crore and if we finish ₹ 500 crore and ask for another ₹ 200 crore within the overall ceiling, expenditure always gives. Whether we are not in this Department or any other Department, expenditure has not been denied to anyone except for very large schemes of different departments. For these types of schemes, Expenditure always provides funds.*
> *…Since the release of funds for the R&D projects, depends upon the sanctioning of those R&D projects. So, that was the understanding that once you sanction it, the allocation will be increased accordingly.*

Sir, I would like to mention one more thing. The scheme which was having an allocation of ₹ 5000 crore, that is, the PRIP scheme. It was till 2028. The Finance Ministry has extended the timelines, keeping in view that R&D projects require more time to get fructified. So, the scheme has been extended till 2029-30. So, the PRIP is having a full application period up to 2029-30."

22. On being asked about the specific procedural and financial reforms the Department had incorporated/proposed for enhancing effective budget utilization under various Major Budget Heads (MH) of their various Schemes/Programmes during the last three years and the current financial year 2026-27, the Department submitted as under:

"**Production Linked Incentive (PLI) Scheme for Bulk Drugs:** Regular meetings are held with PMA-IFCI under the chairpersonship of Bureau Head to monitor progress and performance made under the scheme. The regulatory issues such as land allotment, Environmental Clearance etc. have been resolved. The Empowered Committee (EC) chaired by CEO, NITI Aayog under the scheme, conducts periodic review of the schemes with respect to their investment, employment generation and production and release of eligible incentives to the PLI applicants under the Scheme. EC considers and approves the claims for disbursement of incentive based on the recommendation of the PMA. Further, the Empowered Group of Secretaries (EGoS) under the chairpersonship of Cabinet Secretary also regularly review the progress of the scheme.

For smooth release of incentive to the applicant, a Standard Operating procedure (SoP) has been formulated. The applicants can also file quarterly / half-yearly / yearly claim under the scheme.

Based on claim submission by the applicants and verification by PMA, cumulative incentive amount of ₹ 54.82 crore has been disbursed under the scheme till December, 2025.

PLI schemes for Pharmaceuticals: Regular meetings are held with PMA-SIDBI under the chairpersonship of Bureau Head to monitor progress and performance made under the scheme. The Scheme Selection and Steering Committee (SSSC) chaired by Secretary (Pharma) under the scheme, conducts periodic review of the schemes with respect to their investment, employment generation and production and release of eligible incentives to the applicants. Further, the Empowered Group of Secretaries (EGoS) under the chairpersonship of Cabinet Secretary also regularly review the progress of the scheme.

For smooth release of incentive to the applicant, a Standard Operating procedure (SoP) has been formulated. The applicants can also file quarterly / half-yearly / yearly claim under the scheme.

Based on claim submission by the applicants and verification by PMA, cumulative incentive amount of ₹6,022 crore has been disbursed under the scheme till December, 2025.

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

During 2023-24, ₹ 115 Crore was projected at BE stage for PMBJP and same was allocated. The amount was decreased to ₹ 110 crore at RE stage. The Department released the allotted amount, i.e., ₹ 110 crore to PMBI for implementation of PMBJP and achieving the target to open 10,000 Kendras and for enhancing the product basket upto 2000 medicines and 300 surgicals. As such, 100 % of the RE has been utilized during the F.Y. 2023-24.

During 2024-25, ₹ 284.50 Crore was projected at BE stage for PMBJP and same was allocated during BE-2024-25 and RE-2024-25. The budget provision of ₹ 284.50 crore was allocated under PMBJP Scheme with a view to have 20,000 Jan Aushadhi Kendras at the end of FY 2024-25. However, after review, target of JAKs has been reduced to 15,000 for the F.Y. 2024-25. As on 31.03.2025, Department has released ₹ 182.73 crore to PMBI and target to open 15,000 have already been achieved. Till 31.03.2025, 15,403 JAKs was opened across the country.
During 2025-26, ₹ 353.50 Crore was allotted at the BE stage for achieving the target to open 25000 Kendras by March, 2027. However, due to revision in the target to open JAKs from 25,000 to 20,000 by March, 2026, ₹ 190 crore was proposed at RE stage. Out of ₹ 190 Crore allocated at RE-2025-26, ₹ 146.06 crore has been released to PMBI till 31.01.2026.
For achieving the set target to open 25000 Jan Aushadhi Kendras by March, 2027 and implementation of PMBJP Scheme, an amount of ₹ 200.50 crore was sought for PMBJP scheme under BE-2026-27. Same has been allocated for the scheme in BE-2026-27.

Initiatives taken for effective utilization of finds under SMDI: The Department has permitted the submission of applications under its sub-schemes on a rolling basis. It has also conducted awareness initiatives and stakeholder outreach programs to encourage greater participation.

Scheme of Programme Management: The Department has launched a new scheme, namely, the Scheme of Programme Management for pooling of programme management capacities/resources with a view to address fragmentation of capacities/resources and ensure optimal utilisation and

allocation of both budgetary allocations and the resources engaged hitherto under different scheme. “

IV. SCHEME WISE ANALYSIS OF BUDGET UTILIZATION AND TARGETS

23. Various Schemes/Projects/Programmes under implementation by the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were stated to be as follows:

A. National Institutes of Pharmaceutical Education and Research (NIPERs):

B. Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP):

C. Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

D. 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)
   ii. PLI for Pharmaceuticals
   iii. Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device

E. Strengthening of Pharmaceutical Industry (SPI)/ Development of Pharmaceuticals Industry
   i. Assistance to Pharmaceutical Industry for Common Facilities (API-CF)
   ii. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
   iii. Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)
   iv. Scheme for Promotion of Buk Drug Parks

F. Strengthening of Medical Device Industry (SMDI)
   i. Scheme for Promotion of Medical Device Parks:
   ii. Scheme for Strengthening of Medical Device Industry
      (a) Common Facilities for Medical Device Clusters
      (b) Marginal Investment Scheme for Reducing Import Dependence:
      (c) Capacity Building and Skill Development in the Medical Device Sector:

(d) Medical Device Clinical Studies Support Scheme:

(e) Medical Device Promotion Scheme:

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

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

ii. Advertisement and Publicity for CAPPM

H. Scheme of Programme Management

The details of Scheme-wise Budget Estimate (BE), Revised Estimate (RE) and actual utilization of gross allocations during the years 2023-24, 2024-25 and 2025-26 are as under:

(₹ in crore)

		2023-24			**2024-25**			**2025-26**		
Sl. No	**Scheme Name/**	**BE**	**RE**	**Actual exp.**	**BE**	**RE**	**Actual exp.**	**BE**	**RE**	**Actual Exp as on 20.02.2026**
1	National Institutes of Pharmaceutical Education and Research (NIPERs)	550	228.80	228.80	242.00	248.00	248.00	200.07	281.07	268.07
2	Jan Aushadhi Scheme	115	110	110	284.50	284.50	182.73	353.50	190.00	146.06
3	Development of Pharmaceuticals Industry									
	Pharmaceuticals Promotion Development Scheme (PPDS)	4	7	2.77	5.00	4.00	2.02	5.00	3.83	1.72
	Cluster Development	51	44.50	23.84	50.00	50.00	33.06	50.00	31.00	17.48
	Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	95	0.02	0.00	5.00	5.00	0.00	100.00	92.09	0.00
	Promotion of Bulk Drug Parks	900	85.15	2.24	1000.00	300.00	2.24	1460.00	810.00	621.12
	Promotion of Medical Device Parks	200	64	0.90	150.00	-	-	-	-	-
	Human Resource Development in Medical Devices Sector	0	31.0025	0.00	50.00	-	-	-	-	-

										(₹ in crore)
		2023-24			2024-25			2025-26		
Sl. No	Scheme Name/	BE	RE	Actual exp.	BE	RE	Actual exp.	BE	RE	Actual Exp as on 20.02.2026
	Assistance to Medical Device Cluster for Common Facilities (AMD-CF)		33.0025	0.00	40.00	-	-	-	-	-
4	Production Linked Incentive (PLI)									
	Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs	100	16.13	11.66	58.00	22.00	21.30	40.00	52.86	23.41
	Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	100	48.16	40.30	85.00	82.00	81.99	104.93	139.85	27.14
	Production Linked Incentive Scheme for Pharmaceuticals	1000	1632.00	1552.46	2000.00	2330.00	2330.00	2300.00	2300.00	1548.44
5	Consumer Awareness Publicity and Price Monitoring	5	3.00	2.95	4.00	4.50	4.21	6.00	4.00	3.68
6	Promotion of Research and Innovation in Pharma Med-Tech (PRIP)	0	1.00	0.00	75.00	95.00	48.44	245.00	245.00	107.23
7	**Strengthening of Medical Device Industry (SMDI) (MH 2852)**									
	Promotion of Medical Device Parks					100.00	0.90	125.00	120.80	120.14
	Capacity Building and Skill Development for Medical Devices					5.00	0.50	60.00	20.00	0.29
	Common Facilities for Medical Devices Clusters					30.00	0.00	60.00	30.00	10.56

										(₹ in crore)
		2023-24			2024-25			2025-26		
Sl. No	Scheme Name/	BE	RE	Actual exp.	BE	RE	Actual exp.	BE	RE	Actual Exp as on 20.02.2026
	Marginal Investment Scheme for Reducing Import Dependence					20.00	1.27	60.00	1.17	0.52
	Medical Device Clinical Studies Support Scheme					10.00	0.50	50.00	0.60	0.29
	Medical Device Promotion Scheme					1.00	0.15	5.00	4.52	0.05

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

24. The Committee were informed that the National Institute of Pharmaceuticals Education and Research (NIPER), Mohali was set up as a registered society under the Societies Registration Act, 1860 and given statutory recognition by an Act of Parliament, namely, the National Institutes of Pharmaceutical Education and Research Act, 1998 and declared an institution of national importance. Subsequently, six more NIPERs, one each at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli were established under the Act in 2007. NIPERs have been established as institutions of national importance to nurture and promote quality and excellence in education and research in pharmaceutical sciences and medical technologies. NIPERs impart postgraduate and doctoral education, conduct high-end research in various pharmaceutical and medical technology specialisations and promote industry-academia linkage.

25. As per the National Institutional Ranking Framework (NIRF) of the Ministry of Education, under the 'Pharmacy' category, all seven NIPERs are ranked among the top 30 pharmacy institutes in the country, with Hyderabad ranked 5th, Mohali 9th, Guwahati 12th, Raebareli 17th, Ahmedabad 21st, Kolkata 29th and Hajipur 30th in NIRF, 2025. They also rank high in terms of the calibre of their faculty, which includes 42 faculty members who figure in the prestigious Stanford Top 2% Scientists list.

26. The Committee were informed that so far, 12,172 students have graduated from NIPERs, consisting of 806 doctoral students, and 11,366 postgraduate/MBA degree-holders contributing to the availability of professional manpower to both industry and academia, which prefer NIPER graduates in recruitment. This is reflected in the high placement rates of NIPERs, which had an average placement rate of 89.28% in 2025

for NIPER Ahmedabad, NIPER Hajipur and NIPER Raebareli. Placement at NIPER Mohali, Kolkata, Guwahati and Hyderabad is ongoing.

27. The details of NIPER wise course offered, Students enrolled, Students passed out and placement status, as furnished by the Department, were as follows:

1. NIPER Hyderabad

Courses offered:

(a) Medicinal Chemistry
(b) Pharmaceutical Technology (Process Chemistry)
(c) Natural Products
(d) Pharmaceutical Analysis
(e) Pharmacology and Toxicology
(f) Regulatory Toxicology
(g) Pharmacoinformatics
(h) Biopharmaceuticals/ Biotechnology
(i) Pharmaceutics
(j) Medical Devices
(k) Regulatory Affairs
(l) Pharmaceutical Management

Description	**2023-24**	**2024-25**	**2025-26**
No. of Students Enrolled	252	214	218
No. of Students passed out	192	191	218
Placement Rate	100%	90%	90%*

*(*Placement is ongoing)*

2. NIPER Mohali

(a) Medicinal Chemistry
(b) Pharmacoinformatics
(c) Natural Products
(d) Traditional Medicine
(e) Pharmaceutical Analysis
(f) Pharmacology & Toxicology
(g) Regulatory Toxicology
(h) Pharmaceutical Technology (Formulations)
(i) Pharmaceutical Technology (Process Chemistry)
(j) Pharmaceutical Technology (Biotechnology)
(k) Pharmaceutics
(l) Biotechnology
(m) Pharmacy Practice
(n) Clinical Research
(o) Medical Devices
(p) Pharmaceutical Management

Description	**2023-24**	**2024-25**	**2025-26**
No. of Students Enrolled	384	269	226
No. of Students Passed out	288	310	307
Placement Rate (%)	89.69	93.01	54.85*

*(*Placement is going on)*

3. NIPER Ahmedabad

(a) Biotechnology
(b) Medicinal Chemistry
(c) Medical Devices
(d) Natural Products
(e) Pharmaceutical Analysis
(f) Pharmacology & Toxicology
(g) Pharmaceutics

Description	2023-24	2024-25	2025-26
No. of Students Enrolled	235	154	155
No. of Students Passed out	157	175	211
Placement Rate (%)	90.4	98.6	48.36*

**placement is going on*

4. NIPER Guwahati

(a) Pharmacy Practice
(b) Pharmacology & Toxicology
(c) Biotechnology
(d) Pharmaceutical Analysis
(e) Pharmaceutics
(f) Medicinal Chemistry
(g) Pharmaceutical Technology (Formulations)
(h) Medical Devices
(i) Pharmacy Practice
(j) Pharmacology & Toxicology
(k) Biotechnology
(l) Pharmaceutical Analysis
(m) Pharmaceutics
(n) Medicinal Chemistry
(o) Pharmaceutical Technology (Formulations)
(p) Medical Devices

Description	2023-24	2024-25	2025-26
No. of Students Enrolled	241	190	138
No. of Students Passed out	127	148	227
Placement Rate (%)	64.15	81.92	ongoing

5. NIPER Raebareli

(a) Medicinal Chemistry
(b) Pharmaceutical Analysis
(c) Pharmaceutics
(d) Pharmacology and Toxicology
(e) Regulatory Affairs
(f) Regulatory Toxicology
(g) Biotechnology

(h) Medical Devices

Description	2023-24	2024-25	2025-26
No. of Students Enrolled	138	113	127
No. of Students Passed out	90	114	115
Placement Rate (%)	95.00	90.00	82.00

6. NIPER Hajipur

(a) Pharmacy Practice
(b) Pharmaceutical Analysis
(c) Pharmaceutics
(d) Pharmacology & Toxicology
(e) Biotechnology

Description	2023-24	2024-25	2025-26
No. of Students Enrolled	131	62	69
No. of Students Passed out	74	93	114
Placement Rate (%)	89.2	95.7	92.1

7. NIPER Kolkata

(a) Medical Devices
(b) Medical Technology
(c) Medicinal Chemistry
(d) Natural Products
(e) Pharmaceutical Analysis
(f) Pharmaceutics
(g) Pharmacoinformatics
(h) Pharmacology and Toxicology

Description	2023-24	2024-25	2025-26
No. of Students Enrolled	120	121	98
No. of Students Passed out	84	97	95
Placement Rate (%)	90	90	ongoing

28. When asked about the steps NIPER had taken to increase the placement rate of its students and details of the companies where the students of NIPER have got placements, the Department submitted as under:

> "NIPERs have undertaken comprehensive and structured initiatives to enhance placement opportunities and strengthen industry engagement. Faculty members have actively participated in national and international conferences, workshops, and technical forums, significantly improving institutional visibility and fostering strong academic–industry linkages. Regular Industry–Academia interaction programs, conferences, webinars, and training sessions with active industry participation have been organized to facilitate networking, recruitment engagement, and exposure to current industrial practices.

A dedicated Training and Placement mechanism functions as a bridge between students and the pharmaceutical, biotechnology, and healthcare sectors. Students are encouraged to undertake industry internships and participate in innovation challenges to enhance practical exposure and employability.
Details of the company where students get placement are as below:

1. NIPER Hyderabad
   The companies where students get placement from NIPER Hyderabad includes Novartis, Amgen, HCL Technologies, etc.

2. NIPER Mohali
   The major companies which have recruited students from NIPER Mohali are as follows : Stryker, Sai Life Sciences, Dr. Reddy's Laboratories (DRL), Syngene, Accenture, Godrej (GCPL), L.E.K. Consulting, SIDVIM, PharmaAce, Startoon Labs, Aspect Ratio, Aragen, IQVIA, AdametNext, Granules India, Alembic Pharma, Baxter, Clarivate, Novartis, Enveda, ConnectHEOR, Unimrkt, Xogene, Glenmark, Syneos Health, Sun Pharma, HCL Technologies, Alkem Laboratories, Lupin, MSN Laboratories, Evalueserve, LSC, Axtria, Empower Swiss, Zydus, Merck, Beta Drugs, Strides Pharma, CI Scientist, Cipla, Intas Pharma, Sentiss Pharma, Leumas, Hycon Labs, Pharmanza, Sandoz, Wissen Research, EBM Health, Rubicon Research, Torrent Pharma, Tirupati Group, Veeda Lifesciences, RegDesk, Advent, DelveInsight, WNS, SPM Medical Devices, Satyarx Pharma, Spirant Communications, ZS Associates, Acme Generics, Mankind Pharma, Continuum, Krystellis, Fresenius Kabi, Skyward Analytics, Pharsights Business Solutions, Norstella, and CARI etc.

3. NIPER Ahmedabad
   The major companies which have recruited students from NIPER Ahmedabad are as follows : Acme Formulations, Acme Generics, ACS International Ltd., Aculife, Aculife Healthcare Pvt. Ltd., Aegis Lifesciences, Aimil Pharmaceuticals, Aishwarya Health Care, Alceon Medtech Consulting, Alembic Pharmaceuticals, American Chemical Society, Amgen, Amneal Pharmaceutical Pvt. Ltd., Apan Imex Pvt. Ltd., Aragen Lifesciences, Arcolab, Aristo Pharmaceuticals, Aten Porus, Auexin, Axtria, Baxter, BDR Pharma, Biocon, Biological E Limited, Biophore, Biorx Venture Advisors Pvt. Ltd., Biotekortho, Cadila Pharmaceuticals etc.

4. NIPER Guwahati
   The major companies which have recruited students from NIPER Guwahati are as follows : Access Infinity, Advance Med Tech Solutions, Aizant, Aragen Life Sciences, Arcolab, Aurigene Pharmaceutical Services Limited, Aurobindo Pharma, Bharat Biotech, Biocon Biologics Ltd., BioPlus Life Sciences, BVG Life Sciences Ltd., Cadila Pharmaceuticals, Certara,

Cognizant, Dexter Pharma, Dr. Reddy's Laboratories, Emami, Encube Ethicals Pvt. Ltd., EnergOn Labs, Evolvus, Exeltis, Ferring Pharmaceuticals, Finoso Pharma, GenPro Research, Gland Pharma, Glenmark Pharmaceuticals, GSK, HiMedia Laboratories Pvt. Ltd., Hycon, Indegene, Innomagine, Intas Pharmaceuticals, Jodas Expoim Pvt. Ltd., Labcorp Drug Development, Leumas, Lorven Biologics Pvt. Ltd., Lupin Ltd., Macleods Pharmaceuticals, Mankind Pharma,etc.

5. NIPER Raebareli
   The major companies which have recruited students from NIPER Raebareli are as follows: AstraZeneca, Pfizer, Johnson & Johnson, Merck & Co., Sun Pharma, Patanjali, Piramal Healthcare, Lupin, BresMed, Springer, Tata Consultancy Services (TCS), Medivisual, Oxygen Healthcare, Almelo Pharma, Jubilant Chemsys, APCER Life Sciences, NEC Life, Novo Nordisk, Curadev Pharma Pvt. Ltd., Intas Pharmaceuticals, and Hetero Labs etc.

6. NIPER Hajipur
   The major companies which have recruited students from NIPER Hajipur are as follows :Zydus, Serum Institute of India, Bharat Biotech, Intas Pharma, Dr. Reddy's, Aurobindo Pharma, Fryer Solutions, Vimta, Jubilant Pharma, Cipla, Reckitt Benckiser, Vipragen, Taj Pharma, Johnsons & Johnsons, Panacea Biotech, Shilpa Biologics, Mankind Pharma, GeneSys, Delveinsight, Parexel, Ltd, etc.

7. NIPER Kolkata
   The major companies which have recruited students from NIPER Kolkata are as follows: Sai Life Sciences, Hyderabad; Aragen, Hyderabad; Biocon, Bangalore; Ferring, Hyderabad; Dr. Reddy's Lab Ltd, Hyderabad; Intas, Ahmedabad; Macleods, Mumbai; Suven Life Sciences, Hyderabad; Daicel, Hyderabad; Mu Sigma, Hyderabad; Endo Pharma, Indore etc."

29. As part of academia-industry linkage, NIPERs signed 352 Memoranda of Understanding with industries and other academic institutions, filed 478 patents (of which 202 patents were granted and 11 patents are commercialised) and published 8,825 research papers in reputed journals. During FY 2025-2026, as on 30.11.2025, 437 research papers were published, 35 patent filed and 28 Memoranda of Understanding signed by NIPERs.

30. The number of MoUs signed by NIPERs were as follow:

NIPER	Number of MoUs signed
Hyderabad	63

Mohali	67
Ahmedabad	43
Guwahati	64
Raebareli	34
Hajipur	22
Kolkata	36
Total	**329***

*as on 31.1.2026

Note- The data regarding the MoU signed by NIPERs is dynamic. The earlier figures were based on the monthly inputs received from NIPERs. The recent data reflects updated and revised information.

31. Out of 478 patents filed and 202 granted, only 11 patents have been commercialized. On being asked about the constraints being faced in commercialisation of patents and steps being taken by the Department in this regard, a representative of the DoP submitted as under:

"बेसिकली जो इंडस्ट्री है, to improve the industry-academy interaction, we have set up a committee where industry is also on board or all the NIPERs are on board. Interaction is not sufficient. That is why the industry is not aware of what NIPERs are doing.

We have recognised this and we have set up a committee, that is, the Industry-Academia committee. In this committee, the department is also engaged. We have held the first meeting of this committee, where we are bringing all the stakeholders, the industry and the NIPERs and the department, to let them know what work NIPERs are doing, what requirement of industry is there for research, so that research is focused to meet the industry need and the industry is also aware that these are the patents or the developments which have happened in NIPERs. "

32. On this matter, the representative supplemented as under:

"नंबर ऑफ पेटेंट्स एप्लाइड, ग्रांटेड एंड नंबर ऑफ रिसर्च पेपर्स पब्लिश्ड, मतलब जो हमारी एनआईआरएफ रैंकिंग है, हमारा प्रमोशन सिस्टम है, प्राइवेट और सरकारी सभी शैक्षणिक संस्थानों में हमने इंसेंटिव मैकेनिज्म उसकी तरफ कर दिया है, बजाय इसके कि हम अपने रिसर्च वर्क को कितना कमर्शियलाइज कर पा रहे हैं और कितना हम इंडस्ट्री के साथ कोलैबोरेट करके रिसर्च कर रहे हैं। कितने इंडस्ट्री प्रायोजित प्रोजेक्ट्स पर हम रिसर्च कर रहे हैं। Probably, we need to re-align our incentive mechanism so that our academic institutions, both in Government and in private, work in that direction."

33. On the same issue, the Department further submitted as under:

"The difference between patents filed, granted, and commercialized across all NIPERs primarily arises from the early-stage nature of research outputs, which require further technological validation, regulatory approvals, clinical studies, and industry alignment before becoming market-ready. The patent granting process itself involves statutory examination procedures that typically take 1–2 years, followed by additional time for commercialization depending on commercial viability and industry demand. Commercialization in pharmaceutical and biotechnology sectors further requires scale-up infrastructure, funding support, and regulatory compliance, leading to extended timelines beyond patent grant. Moreover, a significant number of patents across NIPERs have been filed in recent years and are currently under examination, and are expected to be granted and progress toward commercialization in the coming years. In addition, a closer academia-industry interaction may further promote mutually beneficial research and innovation ecosystem. Accordingly, NIPER Academia-Industry Coordination Committee has been set up as an institutional mechanism to promote strategic coordination between NIPERs and pharmaceuticals and medical devices industry."

34. To a specific query of the Committee as to how signing of the Memoranda have helped the students of NIPERs, the Department submitted as under:

"The signing of Memoranda of Understanding (MoUs) by NIPERs with reputed national and international industries, research organizations, hospitals, and academic institutions has significantly strengthened academic–industry collaboration and enhanced student opportunities. These MoUs facilitate internships, industry projects, collaborative research, clinical research exposure, and hands-on training, enabling students to gain practical experience beyond classroom learning. They also promote regular industry interaction through expert lectures, workshops, training programs, and exposure to advanced research facilities and instrumentation.

Through these partnerships, students benefit from joint research initiatives, dissertation work, co-guided research programs, technology transfer exposure, and patent guidance. International MoUs further support student exchange programs and opportunities to work with eminent scientists and global research teams. Additionally, strong industry linkages established through these agreements contribute to improved placement prospects and career readiness."

35. The details regarding **n**umber of Patents filed and research papers published by NIPERs, as furnished by the Department, since inception are as follow:

NIPER	Number of patents filled	Number of Research Paper Published
Hyderabad	49	2021
Mohali	280	3835
Ahmedabad	37	1406
Guwahati	38	845
Raebareli	43	998
Hajipur	15	700
Kolkata	18	663
Total	480*	10468*

**as on 31.1.2026*

Note- The data regarding the Research papers published, Patents filed is dynamic and subject to periodic updates. The earlier figures were based on the monthly inputs received from NIPERs including Research papers with impact factor more than equal to 3. The recent data reflects updated including impact factor less than 3 also.

36. To a pointed query of the Committee that whether the target for filing research papers during the year 2023-24 was 1350 but 1095 could be filed and reasons for the same, the Department submitted that there was decline in publications due to superannuation of the faculty members.

37. When further queried that whether the targets for research papers, filing of patents and signing of Memoranda of Understanding by NIPERs have been achieved, the Department submitted that the targets for Research Papers, filing of patents and Memoranda of Understanding were setup under Output Outcome Monitoring Framework (OOMF) 2025-26. The details and achievement are as under:

OOMF 2025-26		
Parameters	Target	Achievement
Research Papers	250	490
Patents	25	37
MoU	NA	30

38. Construction of campuses of NIPERs: In EFC meeting held in September, 2021, the Ministry of Finance has approved ₹1500 crore for strengthening of existing 7 NIPERs and construction of campuses of six NIPERs at Guwahati, Ahmedabad, Hyderabad, Kolkata, Raebareli and Hajipur. NIPER Mohali already had a well-functioning campus. The campus of NIPER, Mohali was completed in May 1995. The construction of campus at Guwahati and Ahmedabad has been completed and campus was dedicated to the nation in September 2023 and January 2024 respectively. The construction of campuses of the other four NIPERs at Hyderabad, Kolkata, Raebareli and Hajipur are in progress. As on 2 31.12.2025, 73% of the

construction work at NIPER Hajipur, 68% at NIPER Hyderabad, 73% at NIPER Kolkata, and 95% at NIPER Raebareli has been completed.

39. On being asked to state the timeframe by which the pending work at NIPERs Hyderabad, Kolkata, Raebareli and Hajipur are likely to be completed, the Department submitted as under:

NIPER	Status of Construction of NIPER Campus as on 19.2.2026 (in percentage)	Target dated of completion	Initial Target date of completion
Hyderabad	75%	30.7.2026	01.09.2025
Kolkata	75%	30.7.2026	30.09.2024
Raebareli	98%	30.4.2026	-
Hajipur	75%	31.5.2026	01.08.2024

40. When asked to furnish details of current status of NIPER, Madurai, a representative of the Ministry during oral evidence submitted as under:

> *"Basically, the NIPER, Madurai project was announced in budget, and we had gone to Ministry of Finance for clearance from the Department of Expenditure for EFC approval. At that stage, Department of Expenditure has said that the existing six NIPERs needs to be constructed first, and we should come with the proposal subsequently. So, that project has not been taken up, and recently, Government of Tamil Nadu has asked for and taken the land also back. So now the land is also not there, and expenditure has not been approved. There were five NIPERs to be set up. We had taken the proposal to Expenditure, asking for a fund. They had said that this will not be, this can be taken up subsequently, but was not supported at that stage. So, we could not take up the project. Meanwhile, Government of Tamil Nadu has sent a communication…..saying that this land is in environmentally sensitive area, so on that ground, they have stated that the land that the land maybe treated as not given."*

41. When asked whether courses run in NIPER can be taught in other private colleges/educational institutions, a representative submitted as under:

> *"सर, आप यह कह रहे हैं कि फार्मेसी के कोर्सेज शुरू करने में जो फार्मेसी काउंसिल का प्रेस्क्राइब्ड सेलेबस है, उसके बजाय नाइपर का सेलेबस शुरू करने में, अगर हमारा सेलेबस फार्मेसी काउंसिल के सेलेबस से बेटर है, तो हम फार्मेसी काउंसिल के साथ बात करके इन कॉलेजेज के सेलेबस और कोर्स कंटेंड में इम्प्रुवमेंट के लिए काम करेंगे।"*

42. The Committee further desired details and process of regulatory approvals in this regard. The Department informed the Committee as under:

"As per the List I (Union List) in the Seventh Schedule of the Constitution of India, institutions are declared by Parliament by law to be as institutions of national importance. NIPER are set up as institutions of national importance under NIPER Act, 1998. The Act provides for establishment, governance, and functioning of NIPERs. The Act also provides that the Central Government may, by notification in the Official Gazette, establish similar Institutes in different parts of the country. Accordingly, private sector participation in establishing institutions with the status of NIPER is not permissible under the existing statutory framework. Any course at NIPERs is started as per the procedure and guidelines laid down in NIPER Act, Statutes and Ordinances. "

43. To a further query of the Committee that weather permitting private sector participation in establishing NIPER like institutions under a regulated framework may be considered, the Department submitted as under:

"The establishment of pharmacy colleges may be undertaken by State governments, private entities including societies or companies and such colleges have to be mandatorily approved by the Pharmacy Council of India (PCI). Further, introduction of new courses for such institutions are regulated by PCI which designs and updates the core curriculum for all pharmacy programs."

44. When asked about the legal and regulatory authorities and processes involved in allowing private institutions to offer equivalent high-level pharmaceutical education and research programs similar to the ones offered in NIPER, the Department reiterated the reply given to above point.

45. A NIPER Academia-Industry Coordination Committee has been set up to provide an institutional mechanism for promoting strategic coordination between NIPERs and pharmaceuticals and medical devices industry. The Committee would inter alia facilitate greater synergies between NIPERs and industry and support research-driven growth, innovation, skilling, and translation of academic research into industrial applications.

46. The Committee desired details of the NIPER Academia-Industry Coordination Committee and the sittings held by this Committee so far, its major recommendations and how the formation of Committee has helped the NIPER to achieve its goals and objectives in a better way. In this regard, the Department submitted following information:

"The NIPER Academia–Industry Coordination Committee has been constituted to promote structured coordination between NIPERs and the pharmaceutical and medical devices industry, fostering research-driven growth, innovation,

skilling, and translation of academic outcomes into industrial applications. Its first meeting was held on 21 November 2025 under the chairpersonship of the Secretary, Department of Pharmaceuticals. The Committee emphasised aligning academic programmes and research with industry requirements and to constitute four Standing Sub-Committees on Regular Study; Continuing Education and Training; Chief Industry Coordinator and Industry–Institute Cell; and Research and Consultancy."

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

47. The Committee were informed that the scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) has been launched by the Department with an approved outlay of ₹ 5,000 crore and scheme duration of up to the Financial Year 2029-30. The scheme aims to strengthen India's pharmaceutical and MedTech ecosystem by shifting focus from generic manufacturing to innovation-led growth through support for research, product development, and industry–academia collaboration.

48. The details of the funds utilized, as on 31.1.2026, were as follow:

(in ₹ crore)

Sl. No	Name of the Scheme	Year	BE	RE	Actual
(i)	Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP)	2023-24	-	-	-
		2024-25	75.00	95.00	48.44
		2025-26	245.00	245.00	108.92 (as on 31.1.2026)

The above stated funds were released to NIPERs for establishment of CoEs and payment to the onboarded Project Management Agency under the scheme.

49. When categorically asked that whether by the year 2029-30 the scheme would achieve its goals and objectives, the Department submitted as under:

"The scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) has been launched by the department with an approved outlay of ₹5,000 crore approved for a five-year period from FY 2023–24 to FY 2027–28. It is designed to provide catalytic support during the most critical phases of the innovation lifecycle, including ideation, proof-of-concept, validation, and early-stage commercialization. In view of the inherent nature and timelines for the R&D and innovation projects, extension of the duration of the scheme by two years, i.e., up to 31st March 2030 was obtained, without any increase in

the existing financial outlay of ₹5,000 crore. This extension ensures that selected projects receive adequate support across their typical 4 to 5-year development cycles, particularly enabling early-stage initiatives to achieve clinical trial readiness and regulatory engagement and assisting later-stage projects through Phase I or II clinical trials. This will enhance their investment readiness and commercialization prospects. The proposed extension will help in achieving measurable outcomes and ensure optimal utilization of already committed resources."

50. The Committee were informed that BE, RE and actual expenditure under the Promotion of Research and Innovation in Pharma Med-Tech (PRIP) in the years 2022-23, 2023-24 and 2024-25 are as follows:-

(₹ In crore)

		2022-23				2023-24				2024-25			
Sl. No	**Scheme Name/ Non Scheme**	**BE**	**RE**	**Actual Exp.**	**% increase w.r.t previous year (RE to RE basis)**	**BE**	**RE**	**Actual Exp.**	**% increase w.r.t previous year (RE to RE basis)**	**BE**	**RE**	**Actual Exp.**	**% increase w.r.t previous year (RE to RE basis)**
1.	Promotion of Research and Innovation in Pharma Med-Tech (PRIP)					0	1	0		75	95	48.44	9400%

51. The Committee then desired to know the reasons for having NIL BE, RE and Actual expenditure during the year 2022-23. In this regard, the Department submitted that the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) Scheme was notified on 17.08.2023 after obtaining necessary approvals of the competent authority. Since the Scheme was not approved or operational during FY 2022–23, no Budget Estimate (BE), Revised Estimate (RE), or Actual Expenditure was provided for that year. Accordingly, the allocation and expenditure remained NIL in FY 2022–23.

52. The Committee also desired to know reasons for a meagre ₹1.00 crore RE during the year 2023-24 and NIL utilization of the RE. In this regard, the Department submitted that although the PRIP Scheme was notified in August 2023 (during FY 2023–24), the Scheme guidelines, operational framework, and implementation mechanisms were finalized subsequently. The token RE provision of ₹1.00 crore was made primarily to operationalize the Scheme and meet initial administrative or preparatory expenses, if required. However, as implementation activities such as

identification of Centres, project approvals, tendering, and institutional readiness were still underway, no expenditure could be incurred during FY 2023–24.

53. Regarding the reasons for enhancement of BE for the year 2024-25 from ₹75 crore to ₹95 crore at RE stage, the Department stated as under:

- Progress in operationalization of Scheme components,
- Anticipated approvals of projects under Component-A (Centres of Excellence) and Component-B (Industry),
- Expected expenditure commitments during the second half of the financial year.

54. When asked to give reason for actual expenditure of ₹48.44 crore during the year 2024-25, the Department submitted that the actual expenditure during FY 2024–25 amounted to ₹48.44 crore towards component-A (establishment of COEs). The shortfall vis-à-vis RE occurred due to the following implementation-related factors:

- Delay in tendering processes for construction and procurement activities by implementing institutions (NIPERs).
- Delay in hiring of contractual/project staff necessary for operationalization of approved projects.

55. When categorically asked that whether with such low utilization of funds the PRIP scheme can be run by the Department, the Department submitted as under:

"The Department recognizes the initial low utilization levels, which are typical in the early phase of large research and infrastructure-oriented schemes.

To strengthen implementation:

- The PRIP Scheme has been restructured and revised.
- Revised Scheme Guidelines were issued on 01.10.2025.
- The Scheme period has been extended from the earlier duration (FY 2022–23 to FY 2027–28) up to FY 2029–30.
- Monitoring mechanisms have been strengthened, including periodic review meetings and milestone-based fund release.

With the revised framework and extended timeline, the Scheme will achieve its intended objectives effectively. "

56. The Scheme has two components viz., Component A and Component B. Under Component A, seven Centres of Excellence (CoEs) has been established, one at each NIPER, in identified areas of specialisation with an overall outlay of ₹700 crore. As on December 2025, the CoEs have approved 111 research projects to be taken up under the scheme. Further, fifty-two research papers have been published and six patents were filed. Details of the CoEs are as follows:

S. no.	NIPER	Specialisation 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

57. When asked about the mandate, functions and objectives of CoEs, the Departement submitted as under:

> **"**These CoEs will function as hubs for research and development, providing state-of-the-art testing and certification facilities while offering targeted capacity-building programs designed to empower both industry professionals and students. Additionally, the CoEs will contribute to reducing import dependence, establish incubation facilities for startups, and facilitate skill development training programs. They will also serve as skilling hubs to address existing gaps in industry capacity development.
> The CoEs would strengthen research infrastructure at the seven NIPER, build world-class research atmosphere at NIPERs; promote industry academia collaboration; and, make a talent pool of qualified and trained students available to the industry.
> These CoEs are set up in the following pre-identified areas, with an outlay of ₹700 crore:

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

58. When specifically asked whether seven CoEs are sufficient enough to cater the need of NIPERs in general and also the needs of the country, the Departemnt submitted as under:

> **"**The seven Centres of Excellence (CoEs) established at NIPERs are sufficient to meet their collective needs and contribute to national priorities, as they strengthen translational research, enhance scientific infrastructure, and bridge

the gap between laboratory research and commercialization. By promoting innovation and industry collaboration, these CoEs would facilitate development of research outcomes into viable commercial products and thereby help employment generation, revenue creation, and the overall growth of India's pharmaceutical and healthcare sectors.

The establishment of three new NIPERs, as per the budget announcement, will provide further boost to the development of the biopharma ecosystem by expanding research infrastructure and facilitating better availability of skilled human resource to the sector."

59. When enquired about the type of services the CoEs have been rendering to the country, the Department submitted that the Centres of Excellence (CoEs) provide advanced research and development services across the pharmaceutical and medical technology sectors. They conduct both collaborative and in-house R&D in therapeutics, medical devices, diagnostics, drug-device combinations, and novel formulations, advancing technologies from the laboratory stage toward commercialization.

Under Component A of the PRIP Scheme, seven Centres of Excellence (CoEs) has been established, one at each NIPER, in identified areas of specialisation with an overall outlay of ₹700 crore. Details of the CoEs are as follows:

S. No.	**NIPER**	**Specialisation 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

The CoEs also offer state-of-the-art testing and validation facilities, including accredited laboratories, to support product development, regulatory compliance, and quality assurance for industries, SMEs, and start-ups.

In addition, the CoEs focus on training and skill development by organizing certificate courses, workshops, and industry-oriented programs tailored to emerging technologies, regulatory standards, and quality systems. These initiatives help upskill students, professionals, and the workforce to meet national manpower requirements and strengthen the country's healthcare and MedTech sectors.

The CoEs also foster industry–academia collaboration and provide consultancy services to address technological and regulatory challenges. They promote innovation and the development of globally competitive technologies, including safe and affordable biotherapeutics and new biological drugs. Collectively, these services

enhance research infrastructure, innovation, human capital development, employment generation, and the overall growth of the country's pharmaceutical and healthcare ecosystem.

60. To a pointed query of the Committee that whether these CoEs are functioning as per their mandate assigned to them, the Department submitted that CoE established at NIPERs are working as per the mandate assigned to them. In addition, as on January 2026 the CoEs have approved 113 research projects to be taken up under the scheme. Further, sixty-three research papers have been published and eight patents filed.

The details of number of research project approved, research papers published and patents filed by the NIPERs under the CoEs, as furnished by the Department, are as follow:

NIPER	Number of Research projects approved	Number of research papers published	Number of patents filed
Hyderabad	7	0	0
Mohali	33	17	1
Ahmedabad	19	7	0
Guwahati	11	2	0
Raebareli	23	21	3
Hajipur	7	2	0
Kolkata	11	3	2
Total	**111**	**52**	**6**

61. Component B of the PRIP scheme provides for disbursement of financial assistance to industries, MSMEs, start-ups for eligible R&D projects for the development or expeditious validation of new medicines; complex generics and biosimilars; and novel medical devices in identified priority areas taken up either in-house or in collaboration with the academia. Both Early-Stage Projects and Later Stage Projects will be eligible for disbursement of financial assistance

i. Early-Stage Projects: eligible R&D projects undertaken by startups and MSMEs, aiming to take products or technologies at Technology Readiness Levels (TRL) 1, 2 or 3 in any priority area to higher stages, but not beyond TRL 5 will be provided financial assistance up to ₹5 crore per project. Such projects will receive 100% funding support up to ₹1 crore, and in case the approved project cost exceeds ₹1 crore, half of the project cost exceeding ₹1 crore will be co-funded by the applicant.

ii. Later-Stage Projects: R&D projects undertaken by industry and startups, focusing to take products or technologies from TRL 4, 5, or 6 to higher TRLs will be eligible for milestone based financial assistance. Such assistance for eligible projects will be provided up to 35% of the project cost or ₹100 crore, whichever is lower. In case of projects under Strategic Priority Innovation areas such as rare diseases, neglected tropical diseases, drugs for

antimicrobial resistance, vaccines and pandemic related areas etc., a higher support of up to 50% of the project cost would be provided.

62. When queried as to how many industries, MSMEs, startups have been disbursed financial assistance so far and whether under the scheme the financial assistance is disbursed annually or one time to the applicants, the Department submitted as under:

> **"**A total of 710 applications were received during the call for applications under the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) Scheme, between October–November 2025. These applications are undergoing a structured and multi-stage appraisal process. Final sanction and release of financial assistance, if any, are undertaken only after completion of all prescribed appraisal stages and fulfilment of scheme guidelines."

63. When further queried whether the Department monitors that after disbursing the financial assistance to the MSMEs, industries and startups, the amount is utilized for the purpose for which it was granted, the Department submitted as under:

> **"**(a)Financial assistance will be released only into a dedicated project-specific bank account and disbursed in instalments linked to verified technical milestones. The funds are released through PFMS via CNA model to eligible applicants.
> (b) Each instalment requires submission of milestone completion reports, documentary evidence, and proportionate co-funding. The final instalment is reimbursement-based, ensuring end-stage verification before full release of funds.
> (c) Beneficiaries are required to submit quarterly technical and financial reports through the Scheme portal. The Department (through PMA and committees) will track progress and retains the right to inspect project sites, verify documents with third parties, and conduct special/forensic audits of the project account.
> (d) The Scheme explicitly restricts eligible expenditures. In case of deviation from approved milestone plan & budget costs (which cannot be supported by necessary justifications), or non-achievement of milestones, the Government may terminate the project and recover funds as per the clawback mechanism specified under PRIP scheme guidelines."

64. The Committee were informed that under Component B, applications were invited through online portal. A total of 710 applications from start-ups, MSMEs, and industry were received by the final submission date of 19.11.2025. The Technical Committee (TC), held meetings to review the screening progress, guide the evaluation framework, and facilitate timely advancement of the assessment process. As per the recommendations of the Technical Committee, interaction with applicants were organaised for such proposals where 50% or more of the expert technical reviewers

had assessed the project as having demonstrated strong technical merit ("Green review"), wherein 25 proposals were assessed regarding overview, credentials, credibility and impact of their R&D project. TC shortlisted 12 eligible projects 3 that may be considered for recommendation to Project Appraisal and Approval Committee (PAAC) subject to receipt of requisite clarifications sought by the TC.

65. When asked to state reasons for considering a few numbers of proposals out of the list of 710 applicants and recommending just 12 eligible projects that may be considered for recommendation to PAAC, the Department submitted as under:

> **"** (a) The Technical Committee (TC) under the PRIP Scheme adopted a structured, multi-stage evaluation process for the 710 applications received under the first call. Considering the substantial volume of applications and the limited availability of subject matter experts, the evaluation has been undertaken in a phased manner.
> (b) Following screening and technical assessment, 44 proposals completed the requisite expert review stage (later-stage projects underwent three domain expert reviews and early-stage projects two domain expert reviews). Of these, 25 proposals meeting the prescribed merit threshold were shortlisted for interaction, and 17 projects were placed before the TC based on panel evaluation.
>
> (c) In its 5th meeting, the TC accorded in-principle technical approval to 12 projects, subject to stipulated conditions and detailed scrutiny.
> (d) Accordingly, the progression of 12 projects out of 710 applications reflects a rigorous and phased evaluation process. The remaining eligible applications are at various stages of review and have not been rejected."

66. When specifically asked that whether guidelines of the scheme are very strict and render the applicants ineligible from the benefits of the scheme, the Department submitted as under:

> " (a) The eligibility criteria prescribed under the Scheme are structured to ensure transparency, accountability, and alignment with the objectives of the Scheme.
> (b) Eligibility is extended to any entity registered in India in the form of a company (other than certain excluded categories), a Limited Liability Partnership (LLP), or a registered partnership firm. These provisions cover a broad spectrum of legally recognised business entities and do not impose arbitrary structural restrictions.
> (c) For Early Stage Projects, eligibility is specifically reserved for startups certified by DPIIT or MSMEs holding a valid Udyam Registration. This targeted eligibility is intended to ensure fairness and to channel support towards emerging and growth-oriented enterprises that may otherwise face constraints in accessing capital for research and innovation.

(d) The ineligibility provisions are limited to objective and reasonable safeguards, such as conviction of key managerial personnel for serious offences or the applicant being subject to insolvency or liquidation proceedings, in order to protect public funds. Additionally, sole proprietorships and one-person companies (without limited liability) are not eligible to apply under the Scheme.

(e) Thus, the guidelines are calibrated to ensure responsible utilisation of Government support, alignment with national priorities, and equitable access for eligible entities, and do not operate in a manner that renders applicants ineligible in a strict manner."

67. When categorically asked that whether in view of the Department, the scheme is functioning well and also serving its purpose against the backdrop that only a few applicants are being selected, the Department submitted as under:

" (a) The Department is of the considered view that the Scheme is functioning effectively and in alignment with its stated objectives.

(b) A total of 710 applications were received under the first call across the three priority areas such as New Medicines, Complex Generics & Biosimilars, and Novel Medical Devices, reflecting strong participation from industry, startups, and MSMEs, and demonstrating robust stakeholder engagement within the Pharma and MedTech innovation ecosystem.

(c) Given the substantial volume of applications and the limited availability of subject matter experts, the Technical Committee (TC) has undertaken a structured, multi-stage evaluation process in a phased manner.

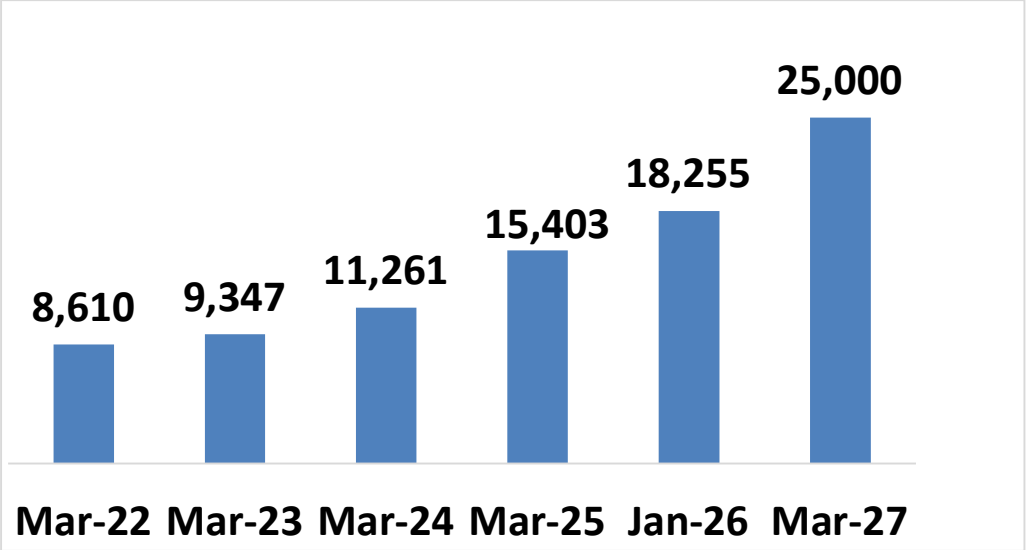
(d) The limited number of projects selected at each stage is attributable to the rigorous, merit-based framework designed to ensure technical soundness, feasibility, financial prudence, and alignment with national priorities, thereby safeguarding public resources and promoting commercially viable outcomes.

(e) It is clarified that the remaining eligible applications are at various stages of review and have not been rejected; they may be considered further upon successful progression through subsequent evaluation stages in accordance with the Scheme guidelines."

C. PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP)

68. The Committee have learnt that 'Jan Aushadhi' Scheme was launched in 2008 with the objective to make quality generic medicines available at affordable prices to all. The Scheme was revamped and renamed the Pradhan Mantri Jan Aushadhi Yojana (PMJAY) in September 2015 and was subsequently renamed the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) in December 2016. Under the Scheme, dedicated outlets known as Jan Aushadhi Kendras (JAKs) are established to provide quality generic medicines at affordable prices to the public.

As on 31.12.2025, a total of 17,990 Jan Aushadhi Kendras have been opened across the country. The PMBJP continues to expand its product basket. As on 31.12.25, 2,110 types of medicines and 315 surgicals, medical consumables, and devices have been included. These products cover all major therapeutic groups, including cardiovascular, anti-cancer, anti-diabetic, anti-infective, anti-allergic, gastro-intestinal medicines, nutraceuticals, and others.



NUMBER OF KENDRAS

69. When asked whether the 17990 JAKs are sufficient for the 140 crore people of the Country, the Department has submitted as under:

> **"**As on 31.01.2026, a total of 18,255 Jan Aushadhi Kendras (JAKs) have been opened across the country.
> Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency of PMBJP has carried out an analysis in respect of the implementation of PMBJP based on the density of the population and availability of one PMBJK for every 60,000 population.
> With a view to further expand the coverage of the scheme and to meet the needs of citizens, the Government has set a target to open 25,000 JAKs by March 2027. JAKs are opened by inviting applications from individual entrepreneurs, non-governmental organisations, societies, trusts, firms, private companies, etc. Online applications have been invited from all districts of the country through the website www.janaushadhi.gov.in."

70. When further asked about number of JAKs in rural areas, remote areas and urban areas, the Department informed as under:
As on 31.01.2026, 18,255 JAKs have been opened across the country, of which 9407 JAKs have been opened in rural and 8848 JAKs have been opened in urban areas under PMBJP. The details of JAKs opened in four metro cities are as under:-

S. No.	Name of the City	No. of JAKs opened till 31.01.2026
1.	Delhi	604
2.	Mumbai	93
3.	Kolkata	120
4.	Chennai	216
Total		**1033**

71. The Committee, during oral evidence of the representatives of DoP in connection with examination of DFG 2026-27, desired to know details regarding average annual turnover per Kendra, and number of Kendras which are proving to be financially self-sustaining and viable. In this regard, a representative of DoP submitted as under:

"खासतौर से बड़े शहरों के बाहर जो जन औषधि केन्द्र खुले हैं, उनकी वायबिलिटी एक मुद्दा है। अभी हम लोगों ने काफी विस्तार से इसका एग्जामिनेशन किया है कि कैसे उनकी वायबिलिटी बढ़ाई जाए या कैसे उनके मार्जिन्स बढ़ाए जाएं। जन औषधि केन्द्र के लिए दी-तीन चीजें की गई हैं।

पहला, आर्डर्स प्लेस करने में विघटन हुआ है। अब हमने उसमें थोड़ा बहुत सुधार किया है। हम आने वाले कुछ महीनों उसमें पूरी तरह से सुधार करेंगे। जो आर्डर्स प्लेस हो रहे हैं, वे स्मूथ हो सकें, ताकि सप्लाई में विघटन न आए।

दूसरा, ये सस्ती दवाइयां हैं। हम दवाइयों पर करीब 20 प्रतिशत मार्जिन देते हैं। यदि कोई स्ट्रिप एक रुपये की होती है, अगर हम उस पर 20 प्रतिशत मार्जिन देते हैं, तो वह 20 पैसा होता है। यदि कोई दवाई 20 रुपये की है, अगर उसमें 20 प्रतिशत मार्जिन होता है, तो चार रुपये होते हैं। दोनों में वर्किंग कैपिटल कॉस्ट अलग-अलग होती है। जो कॉस्ट ऑफ सेलिंग है, दुकान की कीमत है, फार्मासिस्ट की लागत है, उन दोनों में वह लगभग बराबर ही होता है। जो कम कीमत वाली दवाइयां हैं, हम उनमें 20 प्रतिशत मार्जिन देते हैं, संभवतया वह पर्याप्त नहीं है। हम लोग सरकारी योजनाओं के द्वारा इन्सेंटिव्स भी दे रहे हैं। यदि कोई 200 आवश्यक दवाइयां रखता है, तो उसको अतिरिक्त इन्सेंटिव दिया जाता है। जो कम सेल वाली दुकानें हैं, शायद हमें उनकी वायबिलिटी बढ़ाने की जरूरत है, ताकि वे ज्यादा से ज्यादा माल रख सकें और उनको प्रॉफिट हो सके। आपने लाभप्रदता के बारे में भी पूछा है।"

72. In this regard, representative further elaborated on the issue as under:

"पिछले साल हमने औसतन 2,000 करोड़ रुपये का टर्नओवर अचीव किया था। अगर हम 15,000 केन्द्रों का औसत निकालें, तो प्रति वर्ष 13,00,000 रुपये का टर्नओवर हुआ था। सभी केन्द्र महीनेवार अलग-अलग स्तर पर बिक्री करते हैं। हम लोग कोशिश कर रहे हैं कि ज्यादा से ज्यादा केन्द्रों का मुनाफा बढ़ा सकें।"

73. In its written reply, the Department provided following information regarding the average annual turnover per Kendra, and Kendras which are proving to be financially self-sustaining:

"As on 31.03.2025, 15,403 Jan Aushadhi Kendras (JAKs) were opened under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) across the country. The total annual sales turnover registered by PMBI at MRP during FY 2024-25 was Rs.2022 Cr leading to an average annual turnover of ₹13.12 lakhs per JAK.

Like any retail enterprise, a Jan Aushadhi Kendra requires time to stabilize operations and achieve financial self-sustainability. The initial transition phase generally involves building customer awareness, establishing regular prescription flow, managing working capital and maintaining an optimal mix of fast-moving and slow-moving medicines.

Recognizing these early-stage challenges, the Government provides structured financial support and handholding mechanisms, including retail trade margins on medicines, performance-based incentives linked to monthly purchases and additional support for Kendras in aspirational districts, North-East, hilly, and remote regions. These measures enable Kendras to manage operational expenses, improve inventory turnover, and gradually build a stable and recurring customer base.

Recent trends indicate a clear movement towards financial self-reliance among JAKs, driven by increased public awareness and trust in generic medicines, higher acceptance of Jan Aushadhi products, expansion of the product basket (including surgical items, nutraceuticals, and consumables), improved supply chain management and digital monitoring systems and enhanced margin realization through the introduction of high-MRP, high-demand Jan Aushadhi products.

It is estimated that a turnover of ₹2,00,000/- is indicative of JAK operating in a continuous self sustaining mode. 1339 JAKs, opened before 31st March 2023 have shown notable financial stabilization by achieving this turnover on a sustained basis. PMBI is taking steps to enhance this number by way of enhancing retailer margin, improving stock flow to retailers and ensuring stringent quality check measures to improve the customer confidence on Janaushadhi products. These steps are being adopted to facilitate transition of significant proportion of mature Kendras from incentive-dependent units to financially viable retail enterprises."

74. Regarding the benefit accruing to the common man from the Scheme, the Committee have been apprised that for every one rupee spent, there is a saving of ₹4 on drugs purchased through PMBI. Last year, the total sales of drugs at MRP value amounted to ₹2,022 crore, which translates into an estimated saving of nearly ₹8,000 crore. This represents a notional benefit to every patient purchasing medicines through PMBI. Since the launch of the Jan Aushadhi scheme, it is estimated that cumulative savings of approximately ₹40,000 crore have been passed on to patients.

75. The Committee desired information regarding JAKs functioning in North Eastern States of the Country and the steps taken by the Department to increase number of JAKs in the North Eastern States to provide quality generic medicines at affordable prices to the people. In this regard, the Department apprised the Committee as under:

> **"**As on 31.01.2026, 18,255 JAKs have been opened across the country, under PMBJP Scheme of which 394 JAKs have been opened in North Eastern States of the country.
> Further, in order to encourage setting up of JAKs in remote areas, special incentive is provided towards reimbursement of expenditure of up to ₹ 2 lakh incurred on setting up of JAKs in North-Eastern States, Himalayan areas, Island territories and aspirational districts."

76. The Committee were apprised that as on 31.01.2026, 394 JAKs have been opened in North Eastern States of the country under the PMBJP. The State wise details are as under: -

S. No.	Name of the State/UTs	No. of JAKs opened
1.	Arunachal Pradesh	35
2.	Assam	179
3.	Manipur	68
4.	Meghalaya	25
5.	Mizoram	17
6.	Nagaland	22
7.	Sikkim	15
8.	Tripura	33
Total		**394**

77. When asked whether the Department has any proposal or has any scheme to open more JAKs in the North Eastern States, the Department submitted that with a view to further expand the coverage of the scheme, the Government has set a target to open 25,000 JAKs by March 2027. JAKs are opened by inviting applications from individual entrepreneurs, non-governmental organisations, societies, trusts, firms, private companies, etc. Online applications have been invited across the country, including North Eastern States through the website www.janaushadhi.gov.in.

Further, in order to encourage setting up of JAKs in remote areas, special incentive is provided towards reimbursement of expenditure of up to ₹ 2 lakh incurred on setting up of JAKs in North-Eastern States, Himalayan areas, Island territories and aspirational districts.

78. When asked to furnish current stats of JAK in Cherrapunji, Meghalaya, the Committee were apprised as under:

"मेघालय में रामकृष्ण मिशन जन औषधि केन्द्र नहीं खोल पा रहा है, क्योंकि उनके पास लोकल फार्मासिस्ट का लाइसेंस नहीं था। पीएमबीआई ने उनसे बात की है। संबंधित संस्थान को फार्मासिस्ट मिल जाएगा। पीएमबीआई इसको देख रहा है। हम उनको लगातार सुविधाएं देंगे, ताकि वहां पर जन औषधि केन्द्र खुल सके।"

79. Utilization of funds under Jan Aushadhi Scheme is stated to be as under:-

(₹ In crore)

		2022-23				2023-24				2024-25			
Sl. No	**Scheme Name/ Non Scheme**	**BE**	**RE**	**Actual Exp.**	**% increase w.r.t previous year (RE to RE basis)**	**BE**	**RE**	**Actual Exp.**	**% increase w.r.t previous year (RE to RE basis)**	**BE**	**RE**	**Actual Exp.**	**% increase w.r.t previous year (RE to RE basis)**
1.	Jan Aushadhi Scheme	72.50	100.00	100.00	5.84%	115.00	110.00	110.00	10%	285.50	284.50	182.73	158.63%

80. The Committee were further been informed that against the BE allocation of ₹ 353.50 crore for PMBJP scheme, RE allocated is ₹ 190 crore and actual expenditures on 20.2.2026) is ₹ 146.06 crore.

81. It may be seen that during the year 2022-23 and 2023-24 the RE was fully utilized, however during the year 2024-25 out of the allocated RE of ₹284.50 crore just ₹182.73 core has been utilized so far. On being asked to furnish specific reasons for slow pace of utilization of funds, the Department submitted as under:

"For the Financial Year 2024-25, the budget provision of ₹ 284.50 crores was made for Pharmaceuticals & Medical Devices Bureau of India (PMBI) and out of this allocation, ₹ 142.21 crores was released for the first two quarters.

The provision of this amount was based on the target decided for opening of 20000 Jan Aushadhi Kendras (JAKs) by 31.03.2025. Later on, the number of JAKs to be opened in FY 2024-25 was revised to 15,000 only. Accordingly, the demand of incentive proportionately reduced both for purchase-based incentive and for special incentive.

Overall, the budgetary provision was revised to ₹ 182.73 crores against ₹ 284.50 crore."

82. When queried whether the Department has analysed the reasons for slow pace of utilization under the Jan Aushadhi Scheme and any ameliorative steps have been taken in this regard, the Department submitted as under:

> **"** Under PMBJP actual expenditure and RE are same for the F.Y. 2022-23, 2023- 24. However, due to revision in the target of opening Janaushadhi Kendras, actual expenditure was less than that of RE for the year 2024-25.
> With a view to further expand the coverage of the scheme, the Government has set a target to open 25,000 JAKs by March 2027. JAKs are opened by inviting applications from individual entrepreneurs, non-governmental organisations, societies, trusts, firms, private companies, etc. Online applications have been invited across the country, including North Eastern States through the website www.janaushadhi.gov.in.
>
> Further, in order to encourage setting up of JAKs in remote areas, special incentive is provided towards reimbursement of expenditure of up to ₹ 2 lakh incurred on setting up of JAKs in North-Eastern States, Himalayan areas, Island territories and aspirational districts."

83. The BE for the scheme for the year 2025-26 was ₹ 353.50 crore which was reduced drastically to ₹190.00crore and the actual expenditure as on 23.01.2026 is stated to be just ₹146.06crore. when asked to state reasons for reduction in the BE for the year 2025-26 and reasons for low utilization of funds during the year 2025-26, the Department submitted as under:

> **"**The target for opening Jan Aushadhi Kendras (JAKs) during FY 2025–26 was 25,000. However, after review of the implementation capacity, ground-level preparedness, and expenditure trends, the target for new JAKs was revised downward from 25,000 to 20,000.
> Consequent to the rationalization of targets, the budget allocation was correspondingly reduced to align with the realistic requirement of funds and to avoid excess provisioning."

84. For the year 2026-27 a BE of ₹200.50 crore has been proposed which is lower than the BE for the year 2024-25 and for the year 2025-26. When asked about reasons for the same, the Department submitted as under:

> **"**The provision of amount sought for the scheme during BE is based on the target set at that time for the proposed year. Earlier target for the year 2024-25 was to open 20,000 Jan Aushadhi Kendras (JAKs) by 31.03.2025 accordingly, 284.50 Crore was sought in BE 2024-25. Later on, the number of JAKs to be opened in FY 2024-25 was revised to 15,000 only. Accordingly, the demand of incentive proportionately reduced both for purchase-based incentive and for special incentive. Overall, the budgetary provision was revised to ₹ 182.73

crores against ₹ 284.50 crores. Similarly, BE for Financial Year 2025-26, was ₹ 353.50 crores which was reduced to ₹ 190.00 Crore due to revision in the target for opening of JAKs from 25000 to 20000 by March, 2026.

For the year 2026-27 the Department proposed a BE of ₹200.50 crore and the same has been allocated which will be utilized for implementation of PMBJP Scheme and achieving the set target to open 25000 JAKs by March, 2027.

Further, it is proposed to increase the sales margin of JAKs from 20% at present to 27.5%, while reducing the margin generated at the level of PMBI. Further, one-time incentive of ₹ 2 lakh, by way of reimbursement towards meeting expenditure incurred on furniture, computers, refrigerators and other fixtures would be provided to JAKs opened— (i) in the North-Eastern States, Himalayan areas, island territories and aspirational districts; or (ii) by a woman pharmacist entrepreneur or an ex-serviceman, divyang or a person belonging to the Scheduled Castes or Scheduled Tribes. Earlier, all women entrepreneurs were eligible for the special incentive under the Scheme. However, after review and discussions, the eligibility criteria have been rationalized and now the special incentive is proposed to be restricted only to eligible women beneficiaries as per the revised guidelines.

In view of the above revision in incentive eligibility and rationalization of targets, the overall budget requirement has decreased as compared to the Budget Estimates (BE) of FY 2024–25 and FY 2025–26. Consequently, the budget demand for the current financial year is lower."

85. For the year 2026-27, the Department proposed a BE of ₹200.50 crore and the same has been allocated. When asked to state the steps taken by the Department for optimal utilization of the BE, the Department submitted as under:

" For the year 2026-27 the Department proposed a BE of ₹200.50 crore and the same has been allocated for implementation of PMBJP Scheme and achieving the set target to open 25000 JAKs by March, 2027. Online applications have been invited across the country, through the website www.janaushadhi.gov.in.

Accordingly, the budget allocated for the financial year 2026–27 will be utilized in alignment with the approved components of the Scheme, inter alia:

- Incentives to Jan Aushadhi Kendras (JAKs)
- Procurement and supply of Suvidha Sanitary Napkins at affordable prices
- Media & Publicity activities for awareness generation
- Administrative and establishment expenses

The allocation will be utilized in a phased and need-based manner to ensure timely achievement of the target and optimal fund utilization."

86. The Committee were apprised that against the target to open 20,000 JAKs by March, 2026, a total of 18,255 JAKs have been opened till 31.1.2026 across the country. With a view to further expand the coverage of the scheme, the Government has set a target to open 25,000 JAKs by March 2027. JAKs are opened by inviting applications from individual entrepreneurs, non-governmental organisations, societies, trusts, firms, private companies, etc. Online applications have been invited across the country, through the website www.janaushadhi.gov.in.

87. The Committee were also informed that the Jan Aushadhi scheme targets 25000 Jan Aushadhi Kendras in 2026-27. When categorically asked that How will the scheme achieve target of 25,000 JAKs by March 2027 with proposed BE 2026-27 of ₹ 200.50 crore, given past precedent of reduction of target to 15000 JAKs in place of 20000 JAKs in 2024-25 with allocation of ₹ 284.50 crore at RE 2024-25 stage, a representative of the DoP submitted as under:

"जैसा कि मैं अभी कह रहा था कि प्रॉफिटेबिलिटी बढ़ाने के लिए हम केन्द्रों को जो 20 प्रतिशत का मार्जिन दे रहे थे, हम उसे बढ़ा रहे हैं। हम जो इंसेंटिव दे रहे थे, हम उस पर टार्गेटिड इंटरवेंशन के द्वारा रेशनालाइजिंग कर रहे हैं। हम अपने बेनिफिशियरीज़ को विमेन फार्मासिस्ट्स पर लिमिट कर रहे हैं। हम अभी तक 20 प्रतिशत दे रहे थे, उसे अब 12 प्रतिशत पर कर रहे हैं, क्योंकि हम मार्जिन बढ़ा रहे हैं। मार्जिन बढ़ाने से उनकी सेल में वृद्धि होगी और उनको डायरेक्ट प्रॉफिट रियलाइज़ होगा। इस हिसाब से हम अपने ग्रांट के फंड को रेशनलाइज़ कर रहे हैं। उसी के साथ हम यह भी इन्श्योर कर रहे हैं कि हम उन्हें ज्यादा प्रॉफिटेबिलिटी दे पाएंगे।"

In its written reply, the Department submitted as under:

"A provision of amount of ₹ 284.50 crore in the budget was based on an initial target of opening of 20,000 Jan Aushadhi Kendras (JAKs) by 31.03.2025. Later, the total number of JAKs to be opened up to end of FY 2024-25 was revised to 15,000. Accordingly, the AE incurred during the year was ₹ 182.73 crore. Further, the RE for the FY 25-26 is ₹ 190 crore. With respect to BE for FY 26-27 amounting to ₹ 200.50 crore, it is submitted that the incentive provided to JAKs under the scheme is proposed to be rationalized from 20% to 12% and the implementing agency, i.e, PMBI, proposes to compensate this by way of increased margin for the JAKs, tentatively at 27.5%. Moreover, the budget under the component Media and Publicity has also been rationalized as the implementing agency intends to use social and other digital media tools in greater proportion."

88. The Committee have observed that the general public is not very much assured about the quality and effectiveness of the medicines provided at JAKs, though according to the Department the medicines available for sale at JAKs go through stringent quality checking. However, steps needed to be initiated to restore the faith of general public in JAKs in this regard. In this regard, the Department submitted as under:

"To promote acceptability of medicines supplied through JAKs, targeted awareness campaigns about the benefits of Janaushadhi medicines are conducted on a regular basis:

i. *Awareness campaigns*: Pharmaceuticals and Medical Devices Bureau of India (PMBI), which is the implementing agency for PMBJP conducts awareness campaigns in coordination with bodies and platforms such as the Central Bureau of Communication, PIB, MyGov and MY Bharat, in various modes such as print, television, radio, social media platforms, outdoor hoardings, community engagement, etc.
ii. *Interactive messages*: Outreach and citizen engagement are also pursued through WhatsApp chatbot to inform citizens regarding the quality and affordability of Janaushadhi products.
iii. *Jan Aushadhi Week*: Jan Aushadhi Week is celebrated every year in the first week of March during which special campaigns such as public rallies, health camps, seminars in pharmacy colleges, etc. are conducted across the nation to educate citizens about the benefits of Janaushadhi generic medicines.
iv. *Messages from eminent persons*: Audio/video messages from well-known persons such as public representatives and eminent doctors are disseminated on social media platforms to highlight the benefits of Janaushadhi medicines and dispel myths associated with respect to their quality.
v. *Public engagement programme in rural areas*: To educate citizens in local languages/dialects, publicity is also done through health camps, *nukkad-natak*, audiovisual display etc. in association with local JAKs in rural areas.

Further, following concrete mechanisms are in place to ensure quality of medicines available at JAKs:

(i) *Supply only from WHO Good Manufacturing Practices (GMP) certified plants:* Only plants that are certified as WHO-GMP compliant by the Central Drugs Standard Control Organisation (CDSCO) are eligible for supply of Janaushadhi medicines.
(ii) *Distribution only after 100% pre-testing of all medicine batches:* Samples are drawn from 100% of batches supplied at PMBI's warehouses for anonymised testing, and medicines are dispatched for supply to JAKs only after the quality test is passed.
(iii) *Testing only at labs compliant with Good Laboratory Practices (GLP):* Samples are tested only at labs accredited and periodically inspected by the National Accreditation Board for Testing and Calibration Laboratories (NABL) and, in addition, assessed by PMBI for GLP compliance."

89. In this regard, representative submitted as under:

> *"I agree with you. Reputational issues are there. जो दवाइयां इन केंद्रों पर मिल रही है, हम लोग उनकी काफी फ्रिक्वेंट टेस्टिंग करवा रहे हैं। उन दवाइयों की एनएबीएल एक्रेडेटिड लैब्स में टेस्टिंग कराने के साथ ही हम लोग टेस्टिंग का एक नया प्रोसीजर शुरू कर रहे हैं।*

The primary issue is related to timely supply of drugs and viability of the shops. It has got our attention and we are taking to address these two items. There have been delays in placement of orders. We would be providing more funding from our side to the shops, more working capital and a better margin so that the shop viability improves. ”

90. It had come to the notice of the Committee that certain operational, supply chain, regulatory and policy-level challenges are affecting both public service delivery and the sustainability of Jan Aushadhi Kendras. During deliberation on DFG 2026-27, following points for policy intervention emerged. The Department has submitted its response to those points as under**:**

“a. Shortage of Essential Medicines: Many important and life-saving medicines are frequently unavailable. Before expanding the number of stores across the country, a robust mechanism ensuring 100% uninterrupted supply must be implemented.

Number of steps have been taken to ensure effective and regular supply of medicines at Jan Aushadhi Kendras (JAKs), including the following:

(i) Since September 2024, stocking by JAKs of 200 commonly used medicines, consisting of the 100 top-selling medicines in the scheme product basket and 100 fast-selling medicines in the market, has been incentivised, under which JAK owners are eligible for monthly incentive based on the stocks that they maintain of these medicines.

(ii) An end-to-end information-technology-enabled supply chain system is in place to connect a robust supply chain system consisting of one central warehouse, four regional warehouses and a growing network of distributors across the country, currently numbering 41.

(iii) In addition, with a view to ensure availability of commonly used products, 400 fast-moving products are monitored regularly by the scheme implementing agency {Pharmaceuticals and Medical Devices Bureau of India (PMBI)} and demand for the same is forecasted on an ongoing basis. Further, steps have been taken to digitise the forecasting method to augment the procurement process through automation.

b. Mandatory 1 KM Distance Policy: A uniform 1-kilometer distance policy must be enforced across villages, towns, and metropolitan cities. Removal of the distance policy adversely affects existing Kendras that have built their business over years and invested significantly.

To safeguard the financial viability of Kendras, a minimum distance policy was introduced in 2019 under the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana, mandating a minimum distance of 1.5 km between two Jan Aushadhi Kendras, which was subsequently revised to 1 km in 2023 to facilitate further expansion while maintaining viability.

Thereafter, in view of the scheme’s growth and evolving urban demand patterns, it was decided to revise the distance criteria to 500 mtrs instead of the 1 KM

requirement in seven metropolitan cities and 46 million-plus cities across the country, and retain the existing 1 km minimum distance norm in all other towns and cities beyond the aforementioned 53 cities.

The revised policy is designed to balance accessibility of JAKs in densely populated urban areas with that of viability of these JAKs. The revised framework aims to strengthen last-mile availability of affordable medicines while fostering entrepreneurship and employment generation.

c. Demand–Supply Gap: Orders are often partially fulfilled (e.g., 1000 strips ordered but only 500 supplied). Fast-moving products frequently face shortages. A scientific demand forecasting and supply planning system must be introduced.

In order to ensure availability of 400 fast-moving products, it is submitted that stock availability of these products is monitored daily by the scheme implementing agency {Pharmaceuticals and Medical Devices Bureau of India (PMBI)} and demand for the same is forecasted on an ongoing basis. Further, steps have been taken to digitise the forecasting method to augment the procurement process through automation which will result in scientific forecasting of the products intended to be procured by PMBI. The supply chain is backed by an end-to-end IT enabled supply chain management system which ensures real time monitoring of supply of Janaushadhi products and assists in timely forecasting of Janaushadhi products to be procured.

d. Incentive Policy Reform: The incentive margin should be increased from 20% to 30%. Incentives must be credited monthly without delay. The purchase-linked incentive cap should be increased substantially, and a proposal to allow up to 35% effective benefit may be examined to ensure sustainability.

PMBI is actively working on proposal which intends to enhance effective benefit derived by JAK owners in line with the suggestion of the hon'ble committee. The proposal aims to improve the financial viability of Kendra owners and enable better stocking of medicines at JAKs.

PMBI credits the sales incentive on the basis of monthly purchases made by Kendras and stock of 200 identified products as maintained by them. The finance team at PMBI is sensitized to ensure timely release of incentives due to the JAK owners.

e. Expiry Return Policy: Expired PMBI-supplied medicines should be mandatorily returnable with credit adjustment to prevent financial loss to Kendras.

An upfront discount of 2% is provided to the JAKs/ distributors in order to compensate against any financial loss which may arise on account of expiry of medicines.

f. Continuity of Product Supply: Once a product is introduced, supply must not be abruptly discontinued. Sudden stoppage of products such as whey protein damages customer trust and causes permanent loss of clientele.

Number of steps have been taken to ensure effective and regular supply of medicines at Jan Aushadhi Kendras (JAKs), including the following:

(i) Since September 2024, stocking by JAKs of 200 commonly used medicines, consisting of the 100 top-selling medicines in the scheme product basket and 100 fast-selling medicines in the market, has been incentivised, under which JAK owners are eligible for monthly incentive based on the stocks that they maintain of these medicines.

(ii) An end-to-end information-technology-enabled supply chain system is in place to connect a robust supply chain system consisting of one central warehouse, four regional warehouses and a growing network of distributors across the country, currently numbering 41.

(iii) In addition, with a view to ensure availability of commonly used products, 400 fast-moving products are monitored regularly by the scheme implementing agency {Pharmaceuticals and Medical Devices Bureau of India (PMBI)} and demand for the same is forecasted on an ongoing basis. Further, steps have been taken to digitise the forecasting method to augment the procurement process through automation.

(iv) As a result of above steps, PMBI envisages to avoid situations such as sudden stoppage of products.

g. Batch Failures and Quality Concerns: Increasing batch failures and inconsistent quality are affecting credibility. Stronger quality audits and transparent reporting are required. Surgical products such as cotton bandages require quality standardization.

With a view to ensure quality of medicines available at JAKs so that health of patients is not compromised, concrete mechanisms have been put in place to ensure continuous inspection, testing and standardisation, including the following:

i. Supply only from WHO Good Manufacturing Practices (GMP) certified plants: Only plants that are certified as WHO-GMP compliant by the Central Drugs Standard Control Organisation (CDSCO) after direct inspection are eligible for supply.

ii. Distribution only after 100% pre-testing of all medicine batches: Samples are drawn from 100% of batches supplied at PMBI's warehouses for testing anonymously, and medicines are dispatched for supply to JAKs only after the quality test is passed.

iii. Testing only at labs compliant with Good Laboratory Practices (GLP): Samples are tested only at labs accredited and periodically inspected by the National Accreditation Board for Testing and Calibration Laboratories (NABL) and, in addition, assessed by PMBI for GLP compliance.

iv. PMBI also conducts periodic random sampling and testing of its medicines sourced from JAKs in order to check the quality of the medicines in the downstream of the supply chain. The random sampling is done based on scientific sampling design prepared by PMBI in coordination with ICMR.

Quality standardization of surgical products, such as cotton bandages, is essential to ensure patient safety. All products are tested with strict adherence to pharmacopeial and regulatory standards in accredited laboratories, and periodic audits are reinforced.

Specifications for absorbency, sterility, and fibre quality are being standardized to eliminate variability.

h. Uniform Packaging and Branding: Frequent batch-to-batch changes in packaging, strip size, color, and branding create confusion among customers. Standardized nationwide packaging guidelines must be implemented.

Uniformity in packing size, packing colour and tablet dimension, colour of the medicines etc. are the part of product permission and is governed through the Drugs and Cosmetics Act 1940 and rules thereunder 1945. This is implemented through the concerned regulatory authority as per applicable standards.

PMBI follows Indian Pharmacopoeia (IP) and The Legal Metrology Rules, 2011 for standardization of pharmaceutical packaging. The Pack Size is maintained adhering to the Schedule P1 of Drugs and Cosmetics Rules, 1945.

i. Near-Expiry Stock Supply: Medicines close to expiry are being supplied, leading to losses. A mandatory 75–80% minimum shelf-life policy at dispatch stage must be enforced. Short-expiry supply should be automatically eligible for return and credit.

A policy is already in place to prevent short-expiry supplies. Under this policy medicines that are supplied must have a remaining shelf life of more than six (6) months at the time of dispatch. Further, medicines having a remaining shelf life of less than four (4) months shall not be supplied under any circumstances.

j. Distributor Stock Transparency: A centralized digital dashboard must display product availability at each distributor along with batch number, expiry date, and available quantity. Kendras must have full visibility before placing orders.

Current ordering mechanisms are designed to ensure supply continuity, while distributors manage stock rotation according to standard operating procedures. The suggestion of the committee to create a centralized digital dashboard is noted for active consideration by PMBI.

k. Expiry Visibility at Central Ordering Level: When placing orders through the central portal, expiry dates are not visible. This must be made mandatory. No order should be processed without transparent expiry disclosure.

The warehousing ordering system is designed to ensure strict adherence to FEFO (First-Expiry-First-Out) principles at the warehouse level. Dispatches are governed by established inventory management norms to minimize the risk of short-expiry stock being supplied.

Making batch-wise expiry visibility mandatory at the time of order placement could slow down order processing, increase system complexity, and affect overall operational efficiency, particularly in high-volume operations.

However, safeguards are already in place at the warehouse level to prevent short expiry dispatches.

l. Railway Station Kendras: Restricting sales only to PMBI-listed products makes stores nonviable in railway premises. Selected OTC products should be permitted for sustainable operations.

It is submitted that all Jan Aushadhi Kendras (JAKs) are primarily permitted to sell products supplied under the Jan Aushadhi portfolio uniformly across the country.

However, with a view to enhancing the financial viability and sustainability of Kendras, the sale of selected OTC and allied products at all JAKs including those located at railway stations is already permitted.

m. Distributor Policy Reform: Distributors should function purely as supply facilitators. Kendras should have fair opportunity to procure and execute institutional business. Monopoly-style supply positioning should be avoided.

Under the present supply chain management structure, the JAKs are free to order their product requirements from any of the 41 distributors across India as well as directly from the 5 existing PMBI warehouses as per their necessity.

n. Expansion of Product Range: The insulin range must be expanded. Life-saving injectables, pediatric formulations, vaccines, dental products, and broader OTC ranges including diapers, sanitizers, and essential wellness products should be included.

The introduction of new products in the PMBI product basket is done periodically, based on patent expiry status, public demand, modified dosage formulations etc. by a committee constituted for this purpose.

Currently, the PMBI product basket includes 9 insulin related products, 60 pediatric items, 06 dental products and 13 variants of diapers.

o. Customer Confidence Measures: Batch consistency and continuous supply are essential to prevent customer anxiety regarding product availability and quality.

Number of steps have been taken to ensure effective and regular supply of medicines at Jan Aushadhi Kendras (JAKs), including the following:

(i) Since September 2024, stocking by JAKs of 200 commonly used medicines, consisting of the 100 top-selling medicines in the scheme product basket and 100 fast-selling medicines in the market, has been incentivised, under which JAK owners are eligible for monthly incentive based on the stocks that they maintain of these medicines.

(ii) An end-to-end information-technology-enabled supply chain system is in place to connect a robust supply chain system consisting of one central warehouse, four regional warehouses and a growing network of distributors across the country, currently numbering 41.

(iii) In addition, with a view to ensure availability of commonly used products, 400 fast-moving products are monitored regularly by the scheme implementing agency {Pharmaceuticals and Medical Devices Bureau of India (PMBI)} and demand for the same is forecasted on an ongoing basis. Further, steps have

been taken to digitise the forecasting method to augment the procurement process through automation.

p. Government Hospital Kendras – Exclusive Regulatory Control: Permission to open Kendras inside Government hospitals must be granted strictly through PMBI. If complaints arise (such as sale of private generics instead of PMBI products), immediate show-cause notices must be issued. PMBI should have authority to recommend cancellation through the State Drug Control Authority. A strict enforcement mechanism under the CEO's authority is necessary to protect brand integrity.

The opening of Jan Aushadhi Kendras (JAKs) in Government hospital premises is subject to the allotment of space/room by the concerned hospital authority. Once the hospital issues the allotment letter in favour of the applicant, the applicant is required to apply for initial approval with the Pharmaceuticals and Medical Devices Bureau of India (PMBI).

It is pertinent to note that Government hospitals do not fall under the administrative purview of PMBI. Accordingly, allotment of space within hospital premises is entirely subject to the policies, procedures, and discretion of the respective hospital authorities.

After obtaining the required Drug Licence from the concerned State Drug Regulatory Authority, the applicant must execute an agreement with PMBI, undertaking to comply with all rules, guidelines, and conditions prescribed under the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP).

Furthermore, if any complaint regarding irregularities is received, PMBI takes prompt and appropriate action. This includes issuance of show-cause notices and initiation of necessary proceedings as deemed fit. This mechanism ensures accountability, regulatory compliance, and adherence to the PMBJP scheme's objectives.

q. Compliance and Enforcement Authority: PMBI must be legally empowered to suspend or cancel non-compliant Kendras in coordination with State Drug Controllers to ensure discipline and uniformity nationwide.

All Jan Aushadhi Kendras (JAKs) are required to operate strictly in accordance with the terms and conditions of the working agreement executed between the Kendra owner and the Pharmaceuticals and Medical Devices Bureau of India (PMBI). Compliance with scheme guidelines, regulatory provisions, and ethical business practices is mandatory.

In cases where any JAK is found to be regularly committing malpractice or violating scheme conditions, PMBI follows a structured enforcement procedure, which includes:

1. Issuance of up to three show-cause notices, providing Kendra with an adequate opportunity to respond and rectify the irregularities.
2. If the response is unsatisfactory or violations persist, termination of the Agreement executed between PMBI and the concerned JAK.

3. Recommendation to the respective State Government / Drug Regulatory Authority for cancellation of the Drug Licence by formally writing to the competent authority.

This process ensures due opportunity, procedural fairness, and strict enforcement to maintain the integrity and credibility of the Jan Aushadhi scheme.

r. Transfer and Succession Policy: In cases where the Kendra owner dies, becomes medically incapacitated, or is unable to continue operations due to genuine hardship, transfer to legal heirs or an approved third party should be permitted. Entrepreneurial investment must be protected.

In the event of the death of a Jan Aushadhi Kendra (JAK) owner, or where the owner becomes physically incapacitated and is unable to operate the Kendra, the PMBI permit transfer of ownership to the legal heir of the JAK owner, in accordance with the prevailing policy guidelines.

s. Simplified Store Transfer Mechanism: A transparent and time-bound transfer process (e.g., approval within 60 days) must be implemented with clearly defined documentation requirements.

PMBI has already established a well-defined Standard Operating Procedure (SOP) to ensure that applications for opening new Jan Aushadhi Kendras (JAKs) are processed and approved within a stipulated timeframe.

PMBI examines every application to open a new JAK proactively and facilitates the applicant at every stage, from day one. This hand-holding support includes guidance on documentation, compliance with scheme requirements, and coordination with the relevant authorities.

Further, wherever required, PMBI extends support by formally communicating with the respective State Drug Regulatory Authorities to expedite the issuance of the Drug Licence, so that the Kendra can become operational at the earliest.

t. Administrative Strengthening: A permanent CEO appointment in PMBI is essential. A structured grievance redressal system with tracking mechanism should be established. Quarterly consultations with Kendra representatives and periodic national supply chain audits must be institutionalized.

The suggestion of Hon'ble committee for appointment of permanent CEO is noted.

A structured grievance redressal system Is already in place in PMBI. Any person may lodge complaint regarding quality and availability of generic medicines supplied through JAKs in the country using the Centralised Public Grievance Redress and Monitoring System (CPGRAMS) portal of the Government of India, or by emailing to complaints@janaushadhi.gov.in, or calling the PMBJP helpline number 1800 180 8080.

Consultations with kendra representatives are conducted on quarterly basis and feedback is obtained from them to strengthen the PMBJP scheme. The supply chain network is backed by end to end IT enabled supply chain management system

and thus facilitates real time monitoring of movement of Janaushadhi products across the supply chain."

D. Production Linked Incentive (PLI) Scheme

(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)

91. With a view to avoid disruption in supply of critical APIs (used to make critical drugs for which there are no alternatives) by reducing excessive dependence on a single source, scheme, "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India" (commonly known as PLI scheme for Bulk Drugs) was approved by the Government of India on 20.3.2020. The scheme intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. The total quantum of the incentive for the scheme is ₹6,940 crore. Out of the total outlay of ₹ 6,940 crore, an amount of ₹ 54.83 crore has been utilized to release incentive claims to the eligible applicants till December, 2025.

92. The financial incentive under the scheme is to be provided on sales of 41 identified products categorized into four Target Segments. In total, 258 applications were received in five rounds of application window, of which 48 projects have been selected and approved with investment commitment of ₹4,329.95 crore. 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 2025

Sl. No.	Target Segment	Total Applicants approved	Total investment commitment (in crore ₹)	Actual investment up to September 2025 (in crore ₹)	Actual Employment up to September 2025 (No. of persons)
1	Key Fermentation based KSMs/Drug Intermediates	5	2,658.8	2,928.09	2,726
2	Fermentation based niche KSMs/Drug Intermediates /APIs	5	300.27	455.50	351
3	Key Chemical Synthesis based KSMs/Drug Intermediates	6	517.9	341.79	283
4	Other Chemical Synthesis based KSMs/ DIs	32	852.98	1,037.96	1,569
Total		**48**	**4,329.95**	**4,763.34**	**4,929**

The list of selected applicants is available on website of Department of Pharmaceuticals (https://pharma-dept.gov.in/sites/default/files/List%20of%20approved%20applicants%20Dated%2006th%20November%2C%202023.pdf)

93. A total investment of ₹4,814.10 crore has been made by approved applicants, exceeding the committed investment of ₹4,330 crore till December 2025. As of December 2025, applicants under the scheme have achieved sales worth ₹2,720 crore, including exports worth ₹527.96 crore, thereby avoiding imports worth ₹2,192.04 crore since inception of the scheme in FY2022-23.

94. The key achievements of the scheme are stated to be as under:

i. 48 projects have been approved under the scheme. A total investment of ₹4,814.10 crore has been made by approved applicants, exceeding the committed investment of ₹4,330 crore till December 2025.
ii. The scheme has led to the commissioning of 38 projects for manufacturing 28 APIs/ KSMs, including fermentation-based products such as Penicillin-G, Clavulanic acid and Rifampicin, which were earlier primarily imported.
iii. As of December 2025, applicants under the scheme have achieved sales worth ₹2,720 crore, including exports worth ₹527.96 crore, thereby avoiding imports worth ₹2,192.04 crore since inception of the scheme in FY2022-23.

iv. The scheme has facilitated employment opportunities for around 4,896 persons, as of December 2025, contributing to job creation in the high-value pharmaceutical manufacturing sector.

(Reply to DFG LOP Pt 60)

95. When asked as to what extent the scheme has been able to reduce dependence on a single source for production of Critical Drugs and boost domestic manufacturing of identified KSMs etc., the Department submitted as under:

> **"**The primary objective of the Scheme is to boost domestic manufacturing of 41 identified critical products and thereby attain self-reliance in key APIs/ KSMs which were largely imported prior to implementation of the Scheme. Out of the 41 identified products, 33 have been subscribed. Among these, production has commenced for 17 products and manufacturing capacity has been established for 11 additional products. Thus, capacity creation has been completed for 28 notified products. Domestic manufacturing capacity of approximately 56,800 MT per annum has been developed for these 28 critical products. These products cater to important therapeutic areas such as antibiotics, cardiovascular diseases, pain management, seizure disorders, steroid-based treatments and infections.
>
> The scheme has a budgetary outlay of ₹ 6,940 crore. Till December 2025, investment of ₹ 4,814 crore has already been made against an investment commitment of ₹ 4,330 crore over the period of six years in greenfield projects. Further, production capacities have been created for 28 KSMs/ DIs/ APIs, which were earlier primarily imported. The scheme has resulted in cumulative sales of ₹ 2,720 crore reported till December 2025, including exports of ₹ 527.96 crore, thereby avoiding imports worth ₹ 2,192.04 crore. The tenure of the scheme is till the financial year 2029-30.
>
> Key products now being manufactured under the Scheme include Penicillin G, Clavulanic Acid, Atorvastatin, Telmisartan, Para Amino Phenol, Oxcarbazepine, Olmesartan, Sulfadiazine, Diclofenac Sodium and Artesunate and Aspirin."

96. The BE for the year 2022-23 for the scheme was ₹ 390 crore which was drastically reduced to just ₹ 14.61 crore at RE stage and a miniscule amount of only ₹ 5.95 crore was the actual expenditure. Similarly, for the year 2023-24 BE was ₹ 100 crore which was again drastically reduced to ₹ 16.13 crore at RE stage, and the expenditure was ₹ 11.66 crore. For the year 2024-25 the BE allocation was ₹ 58 crore, reduced to ₹ 22 crore at RE stage. The Committee desired to know about reasons for drastic reduction in the BE of the scheme and also for actual expenditure being less than the allocated RE for three consecutive years. In this regard, the Department submitted as under:

> **"**Under the PLI Scheme for promotion of domestic manufacturing of critical KSMs/DIs/APIs, incentives are sales-linked and disbursed only after

completion of committed investment, establishment of annual production capacity and achievement of eligible sales as per the provisions of the Scheme Guidelines. Some of the key challenges observed in implementing this scheme are as follows:

i. Greenfield projects have been developed from scratch, requiring land and various statutory approvals, including environmental clearance and drug licenses. Their gestation periods have also been observed to be longer, typically 2 years or more for chemical synthesis-based products and 3 years or more for fermentation-based products.
ii. Production technologies for some of the products have not been readily available and developed after trial and testing.
iii. The microorganism used for fermentation-based processes have not been readily available and have to be adapted to the local environment.
iv. The fermentation process requires process optimization techniques involve refining and improving the conditions, steps, and parameters of the fermentation process to obtain desired yields and outputs.
v. Products manufactured through fermentation routes have been found to be challenging, owing to tropical climate with hot and dry summer Also, it imposes high cost of utilities for cooling & humidification, besides affecting yield.
vi. The bulk drug industry falls into red category industry as per environmental laws, regulatory approvals such as environmental clearance (EC), consent to establish (CTE), consent to operate (CTO), etc. have taken longer period.

Since incentives are payable strictly on verified eligible sales and within the approved ceiling, lower-than-anticipated production and sales in the stabilization phase resulted in lower disbursement during FY2022–23 to FY2024–25. Accordingly, Revised Estimates were aligned with actual claim trends and production performance. The scheme architecture inherently links expenditure to realized sales rather than budgetary allocation alone."

97. When asked to provide details of steps taken by the Department for optimal utilization of the allocated funds for BE 2026-27 i.e. ₹ 66.40 crore, it was submitted as under:

"To ensure optimal utilization of allocated funds under the Scheme, following supportive measures / interventions have been undertaken by the Department towards effective implementation of the scheme:

i. Matters have been taken up with the State Government concerned or Ministry of Environment Forest and Climate Change to expedite environmental clearance processes.
ii. Coordination with State drug regulators have been done to expedite approvals for bulk drugs.
iii. Facilitation and coordination have been done with the State Governments for land and other statutory approvals for the projects.

iv. The scheme features *pari passu* payment of incentives through quarterly incentive cycles.
v. Preference in public procurement for PLI participants is available.
vi. The visit of foreign technical experts for PLI projects has been facilitated through support in visa application processing.
vii. Higher incentive rate of 20% is available on sales of fermentation-based products for first four years during the scheme.

These measures are expected to strengthen production stabilization, improve eligible sales and thereby enhance fund utilization under the Scheme."

ii. <u>Production Linked Incentive for Pharmaceuticals (PLI Pharma)</u>

98. With the objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector, the Union Cabinet approved the PLI Scheme for Pharmaceuticals on 24.2.2021. Further, with a view to improve drug security of the country, the scheme also supports production of APIs/ KSMs/ DIs other than those notified under the PLI scheme for Bulk Drugs to ensure resilience of the Indian pharmaceutical industry to external shocks.

The scheme will provide financial incentives on the incremental sales of pharmaceutical goods and *in-vitro* diagnostic medical devices to selected applicants based on pre-defined selection criteria. The incentives will be paid for a maximum period of 6 years for each participant depending upon the threshold investments and sales criteria to be achieved by the applicants. The total quantum of the incentive for the scheme is ₹15,000 crore. *Out of the total outlay of ₹15,000 crore, an amount of ₹ 6,022 crore has been utilized to release incentive claims to the eligible applicants till December, 2025.*

The applications were invited in three applicant groups, i.e. A, B and C to ensure fair competition and broad coverage amongst the industry players. The categories were based on the size of the applicant as determined by the global manufacturing revenues from pharmaceutical manufacturing. Total 278 applications were received, against which a maximum of 55 applicants have been selected, including five applicants of *In-vitro* Diagnostics (IVD) devices. The product category and incentive rates are as follows:

Product category	Incentive rate	Incentive period
1 and 2: Bio-pharmaceuticals, Complex Generics, Patented or off patent drugs, complex excipients, Orphan drugs, APIs/KSMs/DIs other than those notified under PLI scheme for Bulk Drugs, etc.	10% (first 4 years), 8% (5th year) and 6% (6th year)	2022-23 to 2027-28
3 : Repurposed drugs, auto-immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs anti-retroviral drugs, IVD devices, etc.	5% (first 4 years), 4% (5th year) and 3% (6th year)	2022-23 to 2027-28

The applicant group wise incentive ceilings for the tenure of the scheme is detailed as under:

Group	Incentive ceiling per applicant	Ceiling of additional incentive per applicant, if any	Total Incentive ceiling for the group
A	₹1,000 crore	₹200 crore	₹11,000 crore
B	₹250 crore	₹50 crore	₹2,250 crore
C	₹50 crore	₹10 crore	₹1,750 crore

The list of selected applicants is available on website of Department of Pharmaceuticals (https://pharma-dept.gov.in/sites/default/files/Revised%20list%20of%20applicant%20-%20PLI%20for%20Pharma%20as%20on%2003.05.2023_0.pdf)

99. Status of Projects/ Plants: The details of investment and employment generated under the scheme as per quarterly review report of September, 2025 is as follows:

Sl. No.	Category of Applicants	Total Applicants approved	Total Investment commitment (in crore ₹)	Actual Investment up to September 2025 (in crore ₹)	No. of mfg. locations	No. of R&D locations	Actual Employment up to September 2025 (No. of persons)
1	Group A	11	11,000	24,085	162	14	23,160
2	Group B	9	2,250	11,450	71	9	35,557

3	Group C (Non-MSME)	14	700	2,836	55	5	25,672
4	Group C (MSME)	16	3,161.10	2,201	67	1	19,144
5	Group C - IVD	5	163.86	318	19	2	2,524
Total		**55**	**17,275**	**40,890**	**374**	**31**	**1,06,057**

100. The objectives achieved under the scheme are stated to be as follows:

- Fifty-five (55) applicants have been selected under the scheme including 20 MSMEs.
- The scheme has attracted an actual investment of ₹41,920 crore as of December 2025, significantly exceeding the targeted investment of ₹17,275 crore.
- The scheme has created 1,12,094 jobs, comprising both skilled and unskilled workforce as of December 2025.
- Beneficiary companies have achieved cumulative sales of ₹3,33,836 crore, including exports worth ₹2,14,780 crore from inception of the scheme in FY2022-23 till December 2025.

101. On being asked as to what extent the PLI scheme for Pharmaceuticals has been able 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, the Department submitted as under:

"The progress achieved under the Scheme up to December 31, 2025, is mentioned below (based on Quarterly Review Reports furnished by the applicants):

Parameters	**Target (for scheme tenure)**	**Actual (up to December 2025)**
Investment (in crore ₹)	15,000	41,920
Total Sales including exports (in crore ₹)	2,92,000	3,33,836
Employment (in nos.)	1,00,000	1,12,094

As can be seen from the table above, the selected applicants have achieved the total sales of approx. ₹3.34 lakh crore till 31.12.2025 against initial projection/ scheme target of ₹2.92 lakh crore. The applicants have reported investment of ₹41,920 crore during the above-mentioned period against initial projection/ scheme target of ₹ 15,000 crore.

Under the scheme, Biopharmaceuticals are also eligible products, falling under Category One, allowing applicants to claim incentives at higher incentive rate

of 10% on incremental sales. By including Biopharmaceuticals in the scheme, the government aims to:

i. Promote domestic manufacturing: Encouraging local production of high value & essential pharmaceutical goods.
ii. Reduce import dependence: Decreasing reliance on imported high value pharmaceutical goods, enhancing self-sufficiency & Atmanirbharta in the pharmaceutical sector.

iii. 81 Biopharmaceutical molecules are approved under the PLI scheme for Pharmaceuticals. Out of these 81 molecules, 46 Biopharmaceutical molecules are currently being manufactured under the scheme. Based on quarterly information submitted by the applicants, total sales of ₹26,832 crore, with exports contributing ₹16,290 crore of these eligible Biopharmaceuticals products under the scheme has been achieved."

102. When further asked as to what extent the scheme has been fruitful for the pharmaceutical sector, the Department submitted as under:

"The scheme has been fruitful for the pharmaceutical sector as it has been able to achieve the desired objectives and targets which were made during the inception of the scheme. The progress made under the scheme are as follows:

- Fifty-five (55) applicants have been selected under the scheme including 20 MSMEs.
- The scheme has attracted an actual investment of ₹41,920 crore as of December 2025, significantly exceeding the targeted investment of ₹17,275 crore.
- The scheme has created 1,12,094 jobs, comprising both skilled and unskilled workforce as of December 2025.
- Beneficiary companies have achieved cumulative sales of ₹3,33,836 crore, including exports worth ₹2,14,780 crore from inception of the scheme in FY2022-23 till December 2025.
- 726 APIs/ KSMs/ DIs are being manufactured under the scheme, including 191 which have been manufactured for the first time under the scheme. Cumulative domestic sales of APIs/ KSMs/ DIs produced under the scheme till December 2025 is worth ₹28,067 crore and thereby contributing to import avoidance."

103. When enquired about reasons for selection of very few applicants i.e. 55 Out of the 278 applications received under the scheme, the Department submitted as under:

"As per Scheme Guidelines, there was provision of 55 number of applicants only to be selected in 3 groups as categorised below:

Applicant Groups		Group mfg. revenue (in crore ₹)	No. of applicants
Group A		≥ 5,000	11 with maximum of 4 Foreign MNCs
Group B		500 to 5,000	9 with maximum of 3 Foreign MNCs
Group C	Non-MSME	< 500	15 with Minimum of 5 in vitro diagnostic medical devices manufacturers
	MSME		20
TOTAL			**55**

104. The BE for the scheme in FY 2025-26 was ₹ 2300 crore which was retained at the same amount at the RE stage, however, the actual expenditure as on 23.01.2026 was stated to be just ₹ 1542.42 crore. The Committee desired to be apprised regarding reasons for the slow pace of expenditure and steps taken to accelerate the same. In this regard, the Department submitted as under:

> **"**As per the PLI scheme guidelines, reconciliation applications for disbursement of the balance 25% incentive amount are to be submitted by December 31 of the respective year. For the FY2024-25 performance year, the last date for submission was December 31, 2025, which was subsequently extended to January 25, 2026, based on requests from applicants. These reconciliation applications are currently being processed during the last quarter (January to March 2026). It is expected that all applications will be processed by the 1st to 2nd week of March 2026, ensuring that the requisite Budget Estimates (BE) expenditure is utilized well within the stipulated timelines.
> Additionally, it is to be informed that RE for FY2025-26 proposed by Pharma-I division was ₹ 2,100.00 crore based on the incentive claim projection submitted by the Project Management Agency-SIDBI. However, the RE has been retained at ₹2,300.00 crore for FY2025-26. The expected amount to be utilized till March, 2026 will be ₹2,100.00 crore under the said scheme".

105. The Committee were informed that under the scheme ₹47,000 crore investment has been grounded by Dec 2025, against scheme target of ₹21,000 crore. When asked that whether the target of the scheme is going to be revised in this case, the Department submitted as under:

> " Under the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India (commonly known as "PLI Scheme for Bulk Drugs'), the investment commitment target for the entire scheme tenure i.e. from FY2022-2023 to 2028-29 is ₹4,329.95 crore. Further, investment of ₹4,814 crore has already been made in greenfield projects.

2. Further, Under the PLI Scheme for Pharmaceuticals, the investment commitment target for the entire scheme tenure i.e. from FY2022-2023 to 2027-28 is ₹17,275 crore which stands substantially exceeded with cumulative investment of ₹41,920 crore made in both brownfield and greenfield projects.

3. The scheme target of both the above-mentioned schemes combined up to ₹21,000 crore approx., which is fixed for the entire scheme tenure. The cumulative investment achieved under both the schemes amounts to ₹47,000 crore approx."

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

106. Indian medical devices industry has grown at a phenomenal pace in the last 6–7 years. With a view to address certain disadvantages in manufacturing of medical devices in India, a scheme called "Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of Medical Devices" was approved by the Government of India on 20.03.2020. The guidelines for implementation of the scheme were issued on 29.10.2020.

This scheme is applicable only to greenfield projects and intends to boost domestic manufacturing and attract large investments in the medical devices sector. The Scheme is operational for the period from FY 2020–21 to FY 2027–28, with a total financial outlay of ₹3,420 crore. Under the Scheme, financial incentives are provided to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and falling under the target segments of the Scheme, for a period of five years.

107. In total 77 applications were received in five rounds of application window. Out of 77 applications, 28 applicants have been approved with committed investment of ₹1,161.53 cr. and expected employment generation for around 7399 persons.

108. **Reduction of import dependence for Medical Devices -**

- 22 projects have already been commissioned with manufacturing of 55 Medical Devices.
- Against the targeted investment of ₹1,161.53 crores, investments worth ₹ 1093.69 crore have been made under the scheme.
- Under the scheme, domestic manufacturing of high-end medical devices has started which include Linear Accelerator (LINAC), CT-Scan, MRI Scan, Mammogram, C-Arm, MRI Coils, etc.
- As of September 2025, sales worth ₹ 12,344.37 crore including exports worth ₹ 5,869.36 crore have been made under the scheme.
- Status of Projects/ Plants: Investment as per Quarterly review report of September 2025:

Sl. No.	Target Segment	Total approved Applicants		Total Committed Investment (₹ in crore)		Actual Investment (₹ in crore)	Actual Employment (No. of Persons)
		Cat A	Cat B	Cat A	Cat B		
1	Cancer care / Radiotherapy medical devices	1	2	24.50	9.50	32.74	454
2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	6	4	332.14	183.57	472.06	1288
3	Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardiorespiratory Category & Renal Care Medical Devices	6	4	300.64	145.61	365.44	1,697
4	All Implants including implantable electronic devices	4	1	135.57	30.00	223.45	1962
Total		**17**	**11**	**792.85**	**368.68**	**1,093.69**	**5401**

The list of selected applicants is available on Department of Pharmaceuticals website (https://pharmaceuticals.gov.in/sites/default/files/List%20of%20approved%20applicants%20under%20PLI%20Medical%20Devices%20Dated%2006th%20November%2C%202023.pdf)

109. When asked to furnish the achievement of the scheme so far and to what extent it has been able to help in achieving self-sufficiency in the manufacturing of Medical Devices, the Department submitted that under the PLI scheme out of 28 approved applicants, 24 applicants have commissioned their projects and 57 unique products have been commissioned out of 96 approved products. Further High-end medical devices like LINAC, Rotational Cobalt Machine, CT scan, MRI and Cath-Lab are being manufactured domestically. The details of investment, sales, exports and employment under the Scheme is as follows-

	Committed by Applicant (till March 2027)	Committed by Applicant (till March 2026)	Actual as on 31.12.2025
Investment (INR crore)	1,161.53	1,074.71	1,138.95
Sales (INR crore)	30,383.13	21,409.95	13,624.52
Exports (INR crore)	10,324.79	7,151.43	6,425.48
Employment	7,399	6,339	5,458

110. For the year 2023-24 the BE was ₹100.00 crore which was reduced to ₹48.16 crore. When asked to furnish reasons for the same, the Department submitted as under:

“ Under the PLI Scheme for promoting domestic manufacturing of medical devices in India, incentives are strictly sales-linked and disbursed only after approved applicants complete their committed investments for the respective incentive year while achieving the required eligible sales thresholds as per the Scheme Guidelines.

In the initial implementation years, many of the 28 approved projects faced extended gestation periods due to significant challenges in obtaining regulatory licenses and transferring technology. Compounding these difficulties, the sales threshold for Category A applicants doubled from ₹60 crore in FY 2022-23 to ₹120 crore in FY 2023-24, making compliance increasingly challenging. Consequently, only 6 out of the 28 approved applicants filed for incentives during this period.”

E. Strengthening of Pharmaceutical Industry (SPI)/ Development of Pharmaceuticals Industry

111. With an objective to strengthen the existing infrastructure facilities and in order to make India a global leader in the Pharma Sector, the Department of Pharmaceuticals released the guidelines for the scheme “Strengthening of Pharmaceutical Industry” (SPI), with a total financial outlay of ₹ 500 crore for the period from FY 21-22 to FY 25-26 on 11.3.2022. The scheme addresses the rising demand in terms of support required to existing Pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability. The objectives of the scheme “Strengthening of Pharmaceutical Industry” (SPI) are to strengthen the existing infrastructure facilities in order to make India a global leader in the Pharma Sector. This Scheme is a Central Sector Scheme and comprises the following sub-schemes:

i. **Assistance to Pharmaceutical Industry for Common Facilities (API-CF)**
ii. **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)**
iii. **Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)**
iv. **Scheme for Promotion of Bulk Drug Parks**

The above three sub-schemes are already approved in the Department of Pharmaceuticals as part of scheme for ‘Development of Pharmaceutical Industries’ (DPI). In March 2022, 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 and outcomes.

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.

112. **(i) Assistance to Pharmaceutical Industry for Common Facilities (API-CF),** 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. The Financial Outlay is ₹178.40 crores for the period FY 2021-22 to FY 2025-26. Out of the allocated budget of ₹ 178.40 crore:

i. ₹ 20.15 crore was released to old projects, which are now commissioned.
ii. ₹ 139.33 crore is sanctioned to eight new projects approved during FY2021-22 to FY2025-26, of which ₹ 93.24 crore has been released to the applicants. Out of these eight projects, three projects have been completed and commissioned. Further, three projects are likely to be commissioned by March, 2026.

113. 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 ₹ 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 ₹ 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 ₹ 31.44 crores.

114. Under the new sub scheme Assistance to Pharmaceutical Industry for Common Facilities (API-CF) of Strengthening of Pharmaceutical Industry (SPI) Scheme, application window was opened from 1st August- 7th October, 2022 for inviting applications for project proposals. Out of 20 applications received under the Scheme, Eight (08) projects have been given 'Final Approval' (04 projects in 2022-23, 02 projects in 2023-24, 01 project in 2024-25 and 01 project in 2025-26) by Scheme Steering Committee (SSC). Out of these eight (08) projects, three (02) projects have been completed.

115. **(ii) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)** 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

116. The sub-scheme 'Pharmaceutical Technology Upgradation Assistance Scheme'(PTUAS) has been revised and renamed as 'Revamped Pharmaceuticals Technology Upgradation Scheme' (RPTUAS) on 11.03.2024 with a view to increase the uptake and to help our pharmaceutical industry to align its production process with

best global standards. The Financial Outlay is ₹300.10 crores for the period FY 2021-22 to FY 2025-26.

117. The RPTUAS scheme has been further revised in September 2024 for better uptake. As a result, the Scheme has registered a very good response. About 447 registrations have been made under the Scheme, with 388 successful applicants. 255 applicants have been approved with a sanctioned amount of ₹248.3 by the Scheme Steering Committee (SSC) (as on 12.01.2026)

118. The Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS), aim to facilitate technology and processes upgradation of existing pharmaceutical units to Revised Schedule-M and World Health Organization - Good Manufacturing Practices (WHO-GMP) certification. The scheme guidelines were revised in March 2024 to enhance its uptake and support the technological advancement of the Indian pharmaceutical industry, ensuring alignment with global standards. Thereafter, ₹248.20 crore were sanctioned during FY 2024–25 and FY 2025–26 till date and it is expected that the complete outlay of ₹300.10 crore will be sanctioned in the current financial year (FY 2025–26).

119. However, the release and utilization of financial assistance under the scheme are contingent upon the completion of procurement of plant and machinery, installation, technology upgradation, and the receipt of certification & verification from the concerned drug regulatory authority/authorities confirming compliance with the revised Schedule M of the Drugs Rules, 1945, and the World Health Organization – Good Manufacturing Practices. The approved projects are at different stages of implementation. However, approval of ₹18.24 crore in favour of 18 applicants, who had applied during the initial phase of the scheme, is under process and the amount will be released shortly. Therefore, funds have not been disbursed under the scheme so far, and to that extent the corresponding financial outlay is committed expenditure. Consequently, the scheme is expected to have an estimated committed liability which has been taken care of during EFC proposal for scheme continuation in next financial cycle.

120. The Committee were apprised that out of the 287 pharmaceutical units approved for incentive under the scheme, 68 units have obtained WHO-GMP/Schedule M certification. Out of these 68 pharma units, authenticity of the certificates of 50 pharmaceutical units have been verified from concerned State Drug Controllers and the Scheme Steering Committee (SSC) has approved disbursement of incentive to these 50 pharmaceutical units and the funds will be released shortly. The certificates submitted by remaining 18 pharmaceutical units are under verification at the level of the respective State Drug Controllers for authentication of certificates. The other sanctioned units are at various stages of upgradation and are expected to reach the certification stage.

121. Against the BE allocation of ₹ 95 crore in 2023-24, ₹ 5 crore in 2024-25 and ₹ 100 crore in 2025-26, the actual expenditure under the PTUAS has been 'nil'. In this regard, a representative of the DoP submitted as under:

> *"Sir, basically, this scheme is aimed at upgrading the capabilities of the individual industries and also upgrading them to World Health Organisation, GMP standards. So, that is why we are giving certain amount of subsidies to them.*
>
> *……हमारे पास एक मैन्युफैक्चरिंग प्रणाली है, उसको अपग्रेड करने में समय लगता है। समय कैसे लगता है कि पहले हमारा, अभी क्या चल रहा है कि एक बार डॉक्यूमेंट होगा एंड वर्ल्ड हेल्थ ऑर्गनाइजेशन जीएमपी फैसेलिटीज में क्या होगा, उसका गैप एनॉलिसिस होता है और उसके बाद उसके रेस्पांस में हमें अलग मशीन्स लेनी पड़ेंगी और दैन, उदाहरण के लिए हेपा फिल्टर होता है, अलग हेपा फिल्टर, पहले चार नैनो मीटर का होगा बाद में छह नैनो मीटर का होगा। यह सारा प्रोक्योरमेंट होता है तो उसमें समय लगता है। उसके बाद उसका सर्टिफिकेशन होता है, वेरीफिकेशंस होते हैं, इसके लिए 2-2.5 साल लगते हैं। अचानक से यह हो गया है कि 31 दिसंबर 2025 की डेडलाइन मिल गई, तो सारों ने, करीब 1400 इंडस्ट्रीज हैं। A lot of them were MSMEs, they started working on it. उसमें कंसल्टेंट्स की भी कमी हुई और उसके लिए मशीन्स के प्रोक्योरमेंट में भी थोड़ा सा स्नैग आया।"*

122. The representative, with regard to the scheme further deposed as under:

> *"हमारी स्कीम तो यह है कि जिसको भी स्कीम में असिस्टेंस चाहिए, वह कंसल्टेंट से रिपोर्ट बनाकर हमारे पास एप्लाई कर दे। हम सैंशन कर देते हैं। उसके बाद कंसल्टेंट और वह, जो प्राइवेट पार्टी है, वह आपस में काम करके अपनी यूनिट अपग्रेड करते हैं। उसके बाद स्टेट ड्रग कंट्रोलर के पास जाकर उसको रिवाइज्ड शेड्यूल एम और डब्ल्यूएचओ जीएमपी का सर्टिफिकेशन उनसे, सेन्ट्रल रेगुलेटर से लेकर उसकी कॉपी जब हमारे पास भेजते हैं तो हम उनको पैसे दे देते हैं।*
>
> *.....हम लोगों का फील्ड में, इस स्कीम में जो परिकल्पित है कि फील्ड पर यूनिट्स के साथ इंटरैक्शन परिकल्पित नहीं था। यह था कि आप हमारे पास एप्लीकेशन डाल दीजिए, जब आप सर्टिफिकेट ले आएंगे तो पैसे लेकर चले जाइए। यह इस स्कीम का नेचर रहा है।"*

123. On the same issue, the Department through its written reply submitted as under:

> "….the initial design of the Scheme, which provided financial assistance through interest subvention on loans, did not gain the anticipated traction from the industry. Feedback from Micro, Small, and Medium Enterprises (MSMEs) indicated that the substantial capital investment required for technology upgradation made additional borrowing financially unviable, potentially straining their operational stability.
>
> Recognizing these challenges, the Department undertook a comprehensive restructuring of the Scheme in March 2024, with further

refinements in September 2024. The core financial mechanism was transitioned from interest subvention to a capital-linked financial incentive. Under the revised framework, assistance is provided as a percentage of the total project cost (capped at ₹2 crore) for upgradation. This shift ensures that units can achieve regulatory compliance—specifically the revised Schedule M of the Drugs Rules, 1945, and WHO-GMP standards—while maintaining financial sustainability.

Following these reforms, the Scheme has witnessed a robust response. The current status of applications and sanctions is summarized below:

Parameter	Status / Value
Applications Sanctioned (FY 2024–25)	103
Total Amount Sanctioned (FY 2024–25)	₹105.01 Crore
Total Approved Applications (to date)	287
Cumulative Sanctioned Amount	₹281.30 Crore

Since technology upgradation typically involves a gestation period of 12–18 months (encompassing installation, validation, and regulatory certification), the Department anticipated the release of funds against these sanctioned projects starting from the latter half of FY 2024–25 and continuing into FY 2025–26. Consequently, a Budget Estimate of ₹100 crore was proposed for FY 2025–26 to meet these committed liabilities.

Out of 287 sanctioned applications, 68 units have been received required certification and is expected to disbursed in the current FY. For ensuring timely utilization of funds, timelines-based Milestone have been set for each of the applicants during sanction the project itself. Also, Department regularly take follow-up on the progress made under the scheme."

124. **(iii) Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)** 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 Financial Outlay is ₹ 21.50 crores for the period FY 2021-22 to FY 2025-26. Till 31.01.2026 an amount of ₹ 8.01crore has been release under this sub-scheme. Under PMPDS, as on date 25 studies have been awarded out of which 20 studies have been completed successfully. Further, 01 study each awarded in 2022-23 and 2023-24 and 02 studies awarded in 2024-25 to the selected agencies are under finalization. Financial support has been given to a total of 45 events so far under the scheme.

(iv). Promotion of Bulk Drug Parks

125. 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 ₹ 3000 crore for the Scheme tenure from FY 2020-2021 to FY 2026-2027.

126. The grant-in-aid given under the scheme has a maximum limit of ₹ 1000 crore per park or 70% of the project cost of Common Infrastructure Facilities (**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.

127. 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).

128. 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 - ₹300 crore released to Gujarat on 14.10.2022, ₹225 crore released to H.P. on 20.02.2023 and ₹ 225 crore released to Andhra Pradesh on 13.03.2023. Second Instalment of ₹ 300 crore has been released to Gujarat on 12.11.2025. Expected Employment Generation is around 1,00,000 persons in the three selected Bulk Drug Parks.

129. The State-wise financial progress was stated to be as under:

State	Approved CIF Cost	Central Grant Released	State Fund Released	Total Fund Utilized
Gujarat	1457.01	600*	274.20*	473.15
Andhra Pradesh	1438.89	225	132.30	324.56
Himachal Pradesh	1118.46	225	35.54	52.45

*Two Instalments released

130. Physical progress overview of the Bulk Drugs Parks, as furnished by the Department was stated to be as under:

A. Gujarat Bulk Drug Park (Jambusar, Bharuch)

i. EC Approval: Environment clearance was granted in February, 2024
ii. Physical Progress: Tenders worth ₹878.21 crore have been awarded, covering roads, drainage, effluent treatment plants, solvent recovery and solid waste management. Basic infrastructure is expected to be completed by March 2026.
iii. Action Plan: Land allotment to manufacturers is scheduled to commence in June 2026, with full operationalization targeted for March 2027.

B. Andhra Pradesh Bulk Drug Park (Nakkapalli, Anakkapalli)

i. EC Approval: Environmental clearance for the project (2001 acre land) has been received in March 2024. Later, Govt. of Andhra Pradesh proposed modification in land boundaries of 816.6 acre, to accommodate big captive steel plant in neighborhood. Environmental clearance of the additional land was granted on 13.01.2026. Land Acquisition of the complete 816.6 acre is expected to be completed by March, 2026.
ii. Physical Progress: Tenders worth ₹511.83 crore have been awarded basic utilities covering roads, drains, buildings, power, water and utility corridors.
iii. Action Plan: Basic infrastructure is slated for completion by September 2026, with land allotment beginning in December 2026.

C. Himachal Pradesh Bulk Drug Park (Haroli, Una)

i. EC Approval: Environment Clearance approval received on 25th September 2025.
ii. Physical Progress: Following the EC grant in September 2025, water infrastructure and internal road works (₹178.72 crore)have been awarded. Major tenders for Steam Generation and CETP (₹573.6 crore) are currently under evaluation.
iii. Action Plan: Site demarcation and land leveling for Phase 1 (900 acres) are currently in progress.

131. On being further asked about time by which the Bulk Drug Parks would be set up completely and any target date fixed in this regard, the Department submitted as under:

> **"** All the three approved BD Parks have submitted revised timeline up to March 2027, towards commissioning of Bulk Drug Park. Subsequently, the Scheme Steering Committee and Department of Expenditure have approved the extension of Bulk Drug Park Scheme up to 2026-27."

132. During oral evidence the representative also apprised the Committee regarding the progress of Bulk Drug as under:

> *"बल्क ड्रग पार्क तीन है सर। एक आंध्र प्रदेश में नाकापल्ली में है,एक गुजरात में भरूच में है और तीसरा हिमाचल में ऊना डिस्ट्रिक्ट में है। यह तीनों मिलाकर प्रोजेक्ट कोस्ट 6306 करोड़ का है। यह अनुमान है कि करीब 6000 यूनिट्स यहां पर आएंगे और सारे मिलाकर 5421 एकड़ में डेवलप कर रहे हैं। इन तीनों में 1000 करोड़ रुपए का सेंट्रल ग्रांट है और 70 परसेंट सेंट्रल ग्रांट है, 30 परसेंट स्टेट कॉन्ट्रिब्यूशन है। But in Himachal Pradesh, since it is a hilly State, there is 90 per cent Government of India grant and 10 per cent is the State contribution. It is expected that by 2027, all these three will be operational. यह जरूर है कि कुछ ऐसे मुद्दे आए हैं, जैसे आंध्र प्रदेश में एसीजेड को डी-नोटिफाई करना था, उसकी वजह से एक साल का डिले हुआ। In order to establish captive steel plant, 731 acres were denotified. They recently got the environmental clearance. That is*

why another one year of delay happened. Even in Himachal Pradesh, environmental clearance was delayed."

133. The BE for the scheme in year 2023-24 was ₹ 900 crore which was reduced to just ₹ 85.15 crore and the actual expenditure was meagre ₹ 2.24 crore. For the year 2024-25, the BE allocated was ₹ 1000 crore which was reduced to ₹ 300 crore and the actual expenditure was ₹ 2.24 crore. The BE proposed for the year 2025-26 was ₹ 1460 crore which was again reduced to ₹ 810 crore out of which as on 23.01.2026, only ₹ 621.12 crore could be utilized. When asked to furnish reasons in this regard, the Department submitted as under:

"The Scheme for Scheme for Promotion of Bulk Drug Parks has a total financial outlay of ₹ 3,000 crore, with a maximum grant-in-aid of ₹1,000 crore per park (or 70% of CIF cost; 90% for North Eastern/Hilly States). The variation between BE, RE and actual expenditure during FY 2023–24 and FY 2024–25 is primarily attributable to implementation-related challenges faced by the approved States, particularly delays in obtaining Environmental Clearances (EC), land-related issues, tendering delays and utility package restructuring, as detailed below:

a) **Environmental Clearances (EC):** Bulk drug manufacturing falls under the 'Red Category' industry and EC is a pre-requisite before commencement of civil construction.
   - In Gujarat, EC was delayed by 16 months due to relocation of the 60 MLD marine discharge pipeline as recommended by MoEF&CC; EC was granted in February 2024.
   - In Andhra Pradesh, relocation of the park from Kakinada to Nakkapalli due to SEZ land denotification delayed the project by 12 months; EC was granted in March 2024. Further, for Govt. of Andhra Pradesh proposed modification in land boundaries of 783 acre, to accommodating a big captive steel plant in neighbourhood, for the new land EC was granted on 13.01.2026.
   - In Himachal Pradesh, EC was granted on 25.09.2025 after detailed scrutiny by the Expert Appraisal Committee owing to terrain and environmental sensitivities.

b) **Tendering and Utility Delays:**
   - In Gujarat, key utility tenders such as Steam Generation and Centre of Excellence faced repeated delays due to poor response and ineligible bids.
   - In Andhra Pradesh, initial tender for all CIF components received no bids, necessitating repackaging. CETP and marine outfall tenders also faced delays due to limited industry response.
   - In Himachal Pradesh, delay in EC consequently delayed issuance of major CIF tenders.

c) **Site-specific and Technical Challenges:**

- Heavy rainfall in Gujarat temporarily halted civil works.
- Boundary modification proposal in Andhra Pradesh to accommodate an integrated steel plant required in-principle approval of the Scheme Steering Committee.
- Hilly terrain, seismic vulnerability and erosion-prone site conditions in Himachal Pradesh required additional technical scrutiny and phased planning.

Due to the above factors, expenditure during FY 2023–24 and FY 2024–25 remained lower than Budget Estimates and allocations were accordingly rationalized at RE stage based on actual fund requirement and absorptive capacity.

With resolution of major clearances and award of key civil and infrastructure tenders, implementation has now accelerated. As per reported financial progress:

- Gujarat has utilized ₹ 473.15 crore of the approved CIF cost.
- Andhra Pradesh has utilized ₹ 324.56 crore of the approved CIF cost.
- Himachal Pradesh has utilized ₹ 52.45 crore of the approved CIF cost .

In FY 2025–26, with substantial progress in award and execution of works, fund utilization has improved significantly, and as on 23.01.2026, ₹621.12 crore has been utilized.

The scheme tenure has also been extended up to FY 2026–27 with approval of the Scheme Steering Committee, considering the implementation status and anticipated completion timelines.

Accordingly, the reduction at RE stage in earlier years was aligned with actual implementation progress and milestone-based releases, and does not reflect any curtailment of the approved outlay or objectives of the scheme. Implementation is presently in advanced stages in all three approved parks, and operationalization of parks at Bharuch (Gujarat) and Nakkapalli (Andhra Pradesh) is expected by FY 2026–27."

134. A representative, during oral evidence, threw light on the fund utilization under the scheme as under:

"The first reason was when the scheme was set for approval and the financial projection for each year was made, probably it was over ambitious in the first year. When the first year and second year came, when the first year went on getting the land and getting the necessary approvals, and environmental clearance, there was no expenditure at all. This was not anticipated…….later on the reassessment said that the funds were not required.**"**

135. When categorically asked whether the reduction in BE for three consecutive years has not diluted the very objectives of Bulk Drug Parks, the Department submitted as under:

“ The Budget Estimates (BE) allocation under the Scheme for Scheme for Promotion of Bulk Drug Parks has shown variations over the past three financial years; however, this does not imply dilution of the objectives of the scheme. The scheme is a demand-driven, milestone-based central sector scheme, and funds are released to selected States strictly based on achievement of prescribed milestones and submission of utilization certificates. The lower BE in certain years reflects the actual fund requirement and implementation pace of the approved Bulk Drug Parks, rather than any policy shift or reduction in commitment.

The core objectives of the scheme ”emai’ fully intact. Further, the overall financial outlay approved for the scheme remains unchanged, and adequate funds are being made available as per implementation requirements. The Department continues to closely monitor progress with the selected States to ensure timely execution and achievement of intended outcomes.

Accordingly, the reduction in BE in certain years should be viewed as a phasing of expenditure aligned with project timelines, and not as a dilution of the objectives of the Bulk Drug Parks initiative.”

F. Scheme for Strengthening of Medical Device Industry

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

- 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 instalment of ₹30 crore was released to each of the four selected states in the financial year 2021-2022. The State of Himachal Pradesh submitted a withdrawal letter Dev. F (16) MDP/2024/Vol-V10130 dated 07th September 2024 to withdraw the application from the scheme.

- The Second instalment of the ₹30 crore was released to all three medical device parks in May 2025. The Civil construction of all three medical device parks is either completed or at the final stage of construction. As of now, 193 Medical Devices Manufacturers have been allotted land in the approved Medical Devices Parks. (UP - 101, MP - 66, Tamil Nadu - 26) in 297.93-acre area with the Projected Investment of ₹4735.41 crore and Projected Employment - 27148. Out of these 193 manufacturers allotted land in Medical Device Parks, 4 parks have commenced production

Medical Devices Parks			
S. No.	**State Name**	**Allotted Land**	**Commenced Production**
1	Uttar Pradesh	101	-
2	Madhya Pradesh	66	-
3	Tamil Nadu	26	4
		193	4

(ii) **Scheme for Strengthening of Medical Device Industry**: In order to provide support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion, a new scheme "Strengthening of Medical Device Industry" with five sub-schemes has been launched by Union Minister of Chemicals & Fertilizers and Health & Family Welfare on 8.11.2024 with financial outlay of ₹ 500 crore. As on 28.02.2026, an amount of ₹22,86,08,606/- has been utilized under the Scheme for Strengthening of Medical Device Industry out of the total financial outlay of ₹500 crore. Objective of the sub-schemes under the scheme are as follows:

(a) Common Facilities for Medical Device Clusters: Under the sub-scheme Common Facilities for Medical Device Clusters, Final approvals has been granted for three proposals to set up common facilities and six proposals to set up testing facilities. Out of the three common manufacturing facilities two are proposed to be established in AMTZ, Vizag and one at Stated owned Medical Device Park at Sultanpur, Hyderabad. Six Testing facilities will be established across various clusters of medical devices in the country namely, Bangalore, Trivandrum, Vishakhapatnam, Ambala, Noida and Chennai.

(b) Marginal Investment Scheme for Reducing Import Dependence: Under the scheme, 48 proposals were received and the approved projects involve the establishment of large-scale manufacturing facilities, which are critical to enhance domestic production capacity and reducing reliance on imports in the medical device sector for X-ray tube, polymer tubing and antigen/antibodies for IVDs. A total of 15 applicants have already been granted in-principle approvals.

(c) Capacity Building and Skill Development in the Medical Device Sector: A total of thirteen proposals under Component A for Master's programmes and five proposals under Component B for PG Diploma programmes have been approved for a two-year period. Implementation has commenced, with student enrolment completed for the forthcoming academic session. Procurement of laboratory equipment under both Non-Recurring and Recurring heads has been initiated, and the Department has begun receiving reimbursement claims in this regard. A grant-in-aid of ₹9.64 crore have been approved for disbursement under the Scheme in Jan 2026.

(d) Medical Device Clinical Studies Support Scheme: A total of 63 applications were received. The programme is currently supporting studies with large sample sizes conducted across multiple states and study sites. These studies cover pre-clinical testing, clinical investigations, post-market surveillance, and performance evaluation of new IVDs. A total of 19 proposals have been approved by the SSC for final approval.

(e) Medical Device Promotion Scheme: The scheme aims to promote the medical device industry by bringing together industry leaders, academia, and policymakers to share knowledge and experience for the overall development of the sector. It also seeks to facilitate sectoral growth through seminars and workshops, awareness programmes, studies, database creation, and related activities. The total outlay of the scheme is ₹10 crore.

India MedTech Expo 2025 was organized by the Department of Pharmaceuticals (DoP) in collaboration with the Export Promotion Council for Medical Devices (EPCMD). The second edition of India MedTech Expo 2025 was successfully held from 4–6 September 2025 at Bharat Mandapam, New Delhi. In addition, outreach and awareness workshops under the scheme are being conducted to ensure wider participation and to inform prospective applicants.

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

137. The Scheme has 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 the 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.

138. 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.

139. Setting up of PMRUs in the State/UT: PMRUs are the key collaborating partners of NPPA with an information gathering mechanism at the grassroots level. They are expected to create public awareness so that the 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.

140. The Activities undertaken by PMRUs are as under:

- Market availability survey on selected essential drugs and medical devices every week.
- 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, precautions to be taken while purchasing medicines etc.

141. As on 20.02.2026, out of 36 States/UTs, PMRUs have been set up in 32 States/UTs, except 4 States/UTs i.e Tamil Nadu, Sikkim, Andaman and Nicobar Islands and Manipur. The establishment of PMRUs in the above mentioned States/UTs is in process. The National Pharmaceuticals Pricing Authority is constantly pursuing the matter with concerned State/UT authorities for early establishment of PMRUs.

H. Scheme of Programme Management:

142. The Scheme of Programme Management is designed as an enabling and cross- cutting scheme to Strengthen the implementation, monitoring and evaluation of the Schemes of the Department of Pharmaceuticals, as also facilities sectoral expertise through hiring of consultants. The scheme will subsume the component of engagement of individual consultants and PMAs currently funded through schemes.

I. Biopharma Shakti Initiative

143. Underlining the importance of Biologic medicines at affordable costs to longevity and quality of life, 'Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology & Innovation)' scheme has been announced in Union Budget 2026 with a total outlay of ₹ 10,000 crore over the next five years. The programme is designed to develop India into a global biopharmaceutical manufacturing hub by building a strong and self-reliant ecosystem for the domestic production of biologics and biosimilars. The Department of Pharmaceuticals (DoP) will act as the Nodal Ministry for implementation of the Biopharma SHAKTI initiative.

144. The representative, during oral evidence, explained the features of the new scheme as under:

> *"Sir, in the process of devising the scheme, as part of that, एक्सपेंडिचर किस साल में कितना होगा, is being worked out with that. There are three major components of the scheme. One is about the biosimilars. जैसे स्मॉल कैमिकल्स में जेनेरिक्स होते हैं। बायोफार्मा में बायोसिमिलर्स उनको कहते हैं। एक फोकस है कि बायोसिमिलर्स का प्रोडक्शन, क्योंकि काफी ज्यादा ड्रग्स ऑफ पेटेंट जा रही हैं, जो दुनिया में बायोलॉजिकल ड्रग्स हैं। अगले तीन-चार साल में और उसके बाद भी बायोसिमिलर्स का प्रोडक्शन बढ़ाने के लिए ग्रांट देने का इंडस्ट्री को, एक तो वह कम्पोनेन्ट है। दूसरा कम्पोनेन्ट है कि जो ड्रग डिस्कवरी साइड में और उसके कैमिकल ट्रायल साइड में हम लोग इंडस्ट्री को सपोर्ट करें। थोड़ा-थोड़ा पीआरआईपी जैसा कम्पोनेन्ट है। तीसरा कम्पोनेन्ट है कि हम वेंचर फंडिंग में इंडस्ट्री में इन्वेस्टमेंट करें थ्रू फंडिंग ताकि उनकी इक्विटी लेकर उनको हम ड्रग डिस्कवरी साइड और क्लीनिकल ट्रायल साइड में उनको सपोर्ट प्रोवाइड कर सकें।*
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> *चौथा कंपोनेंट है कि बायोलॉजिकल्स के लिए जो नए मेडिकल डिवाइसेज़ डेवलप हो रहे हैं। इनमें पंप्स हैं, पेन हैं और भी अन्य पांच-सात तरह की नई मेडिकल डिवाइसेज़ हैं, उनका भी प्रोडक्शन इंडिया में हो और उसके लिए प्रोडक्ट डेवलपमेंट और मैन्युफैक्चरिंग को सपोर्ट देना है। ये चार कंपोनेंट्स डायरेक्टली हमारे डिपार्टमेंट की डीलिंग वाले हैं। इंडिया में करीब 300 के लगभग क्लिनिकल ट्राइल्स साइट्स हैं, जिन पर बहुत से फेज 3 क्लीनिकल ट्रायल्स होते हैं। आईसीएमआर के साथ मिलकर सरकारी और प्राइवेट हॉस्पिटल्स की क्लिनिकल ट्रायल्स की जो पॉसिबल साइट्स हैं, उनमें इंफ्रास्ट्रक्चर इम्प्रूवमेंट, एसओपी इम्प्रूवमेंट और इसके साथ ही आईसीएमआर उनको एक्रीडिटेशन देगी, ताकि इंडस्ट्री आसानी से काम कर सके। क्लिनिकल ट्रायल साइट्स में एक शिकायत आती है कि पेशेंट्स से जो डेटा कलेक्ट किया जाता है, उसे बाद में अपलोड किया जाता है, तो उस डेटा की क्रेडिबिलिटी को फॉरेन रेगुलेटर्स कम मानते हैं, इसलिए डेटा इलेक्ट्रॉनिकली कैप्चर होकर तुरंत अपलोड हो जाए, ऐसा सिस्टम भी आने वाले कुछ सालों में आईसीएमआर इन एक हजार क्रियेटेड क्लिनिकल साइट्स में लेकर आएगा।*
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> *सर, अगला कंपोनेंट CDSCO में साइंटिफिक कैडर करीब डेढ़ हजार लोगों के रिक्रूटमेंट का प्रपोजल है और उसकी फंडिंग का है। अभी जो बायोलॉजिकल ड्रग्स हैं, हमारा CDSCO का जितना भी रेगुलेटरी स्टाफ है, उसकी सारी ट्रेनिंग केमिकल साइट में हुई है, उन्होंने कभी बायोलॉजिकल साइट में काम नहीं किया है। इसके लिए CDSCO का सारा सिस्टम सब्जेक्ट एक्सपर्ट कमेटीज़ पर निर्भर है। उसमें काफी डिले होती है। इंडस्ट्री की एक डिमांड रही है कि हमारे यहां जो रिसर्च हो रही है और जो क्लिनिकल ट्रायल्स के लिए अप्रूवल हो रहे हैं, वे फास्टर हों। जितना यूएस और चाइना में फास्ट हो रहे हैं, उतना ही फास्ट या उससे ज्यादा फास्ट हम लोग अप्रूवल दे सकें।"*

145. When asked to provide details of year-wise phasing of the ₹10,000 crore allocation under the Biopharma Shakti initiative and the amount earmarked for FY 2026–27, the Department submitted as under:

"Emphasising strengthening of pharmaceutical education and research in the country, establishment of three new National Institutes of Pharmaceutical Education and Research (NIPERs) along with the upgradation of the existing seven NIPERs has been announced.

As regards the year-wise phasing of funds and the component-wise bifurcation, the scheme is presently at an initial stage of formulation. The detailed year-wise allocation, including the amount earmarked for FY 2026–27, and the component-wise distribution are under further examination and finalisation by the Department of Pharmaceuticals in consultation with the concerned Ministries/Departments and other stakeholders.

The final allocations will be notified upon approval of the competent authority.

The Department is actively pursuing the establishment of three new National Institutes of Pharmaceutical Education and Research (NIPERs) with a dedicated focus on biopharmaceutical sciences. A comprehensive scheme in this regard is presently under formulation which will be followed by structured stakeholder consultations, before appraisal and approval. The proposed scheme will also encompass upgradation and strengthening of biopharma specialization in seven existing NIPERs with introduction of relevant courses and taking up of research in biologics, biopharmaceuticals and biosimilars by the NIPERs."

V. Prices of medicines

146. The Committee were informed that prices of drugs are regulated as per the provisions of the Drugs (Prices Control) Order 2013 (DPCO, 2013) that is based on the National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012). The objective of the extant price regulation framework is to ensure the availability of essential medicines at reasonable prices while providing sufficient opportunity for innovation and competition to support the growth of industry. It follows the principles of essentiality, pricing of formulations only and market-based pricing. The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) controls prices of medicines as per the provisions of DPCO, 2013. Accordingly, it fixes and revises the ceiling prices of formulations specified in Schedule-I to DPCO, 2013 which is based on the National List of Essential Medicines (NLEM) released by Ministry of Health & Family Welfare; fixes the retail price of new drugs as defined under DPCO, 2013 and monitors the increase in prices of non-scheduled formulations. The manufacturers of non-scheduled drugs are required to not increase the maximum retail price (MRP) of such formulations by more than 10% of MRP during preceding 12 months.

147. The Committee were apprised that as per impact on prices of NLEM drugs, Ceiling price has been refixed periodically which has led to 16.82% average reduction in ceiling price on refixation as per NLEM, 2022. This is currently effective for 935

formulations. Regarding impact on prices of non-NLEM drugs, retail price fixation of new drugs has been for 3682 formulations.

148. When asked whether the Department had received any formal complaints regarding the alleged renaming or rebranding of imported medicines and their subsequent sale under different names in the domestic market, the Department submitted as under:

> " The Department has not received any such formal complaints regarding the alleged renaming or rebranding of imported medicines and their subsequent sale under different names in the domestic market as renaming or rebranding of medicines does not come under the purview of NPPA/DoP. The import, labelling and sale of drugs in the country are regulated under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, which is administered by Ministry of Health and Family Welfare."

149. The Committee pointed out that there have been allegations that certain medicines are being sold at prices 6 to 8 times higher than their cost. When asked whether any specific complaints in this regard have been received, the Department submitted that under the existing price regulatory framework, prices of drugs are governed as per the provisions of DPCO, 2013 which follows the principle of market-based pricing. Cost based pricing is not taken into consideration. The ceiling price of scheduled formulations and retail price of new drugs are fixed by adding 16% margin to the average PTR of all brands having market share of more than or equal to 1%. In respect of non-scheduled formulations, the manufacturers are required to not increase the maximum retail price (MRP) of a drug by more than 10% of the MRP of that drug in preceding 12 months.

150. It was submitted that prices of 3,682 non-NLEM medicines/formulations are under Government regulation. When asked whether any violations of price caps have been detected in respect of these medicines/formulations, the Department submitted that no instance of any manufacturer selling the formulation above the notified retail prices (plus applicable taxes) has come to the notice of NPPA.

151. On being asked about the proactive measures being taken by the Department to prevent misuse of re-branding, renaming practices or excessive price mark-ups in the pharmaceutical sector, the Department submitted as under:

> "The matter related to re-branding, renaming practices is not in purview of NPPA/DoP. Under the existing framework, PTR is taken as the basis for price fixation. The ceiling price of scheduled formulations and retail price of new drugs are fixed by adding 16% margin to the average PTR of all brands having market

share of more than or equal to 1%. In case of non-scheduled formulations, manufacturers are required to not increase their MRP of a drug by more than ten percent of the MRP of that drug during the preceding twelve months. However, NPPA, has taken steps, from time-to-time, to rationalise high trade margin which are as follows:

(i) The MRP of 106 non-scheduled drug formulations were capped in 2014, which includes 22 diabetic and 84 cardiovascular drugs.

(ii) A cap on Trade Margin @ 30% on 42 selected non-scheduled anti-cancer medicines was put under 'Trade Margin Rationalisation' approach in February, 2019. Under this, price of 526 brands of medicines were reduced by an average of around 50% leading to annual savings of ₹984 crore to the patients.

(iii) During COVID-19, the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer were regulated under "Trade Margin Rationalisation" approach by fixing trade margins on these devices in June/July 2021 under paragraph 19 of DPCO, 2013."

VI. India-EU Free Trade Agreement (FTA)

152. The Committee were informed that in line with India's strategy to expand trade partnerships and deepen global economic integration, India has recently concluded Free Trade Agreements with the European Union (January 2026). As per Directorate General of Commercial Intelligence and Statistics data, currently, India's exports to the European Union cover about 481 tariff lines, which includes 172 bulk drug/drug intermediate lines, 169 formulation lines, and 140 medical device lines. Under the Agreement, both sides have provided for immediate tariff elimination on certain tariff lines and phased tariff elimination or reduction over 5 or 10 years.

India's offer covers a total of 536 tariff lines (TLs) with a phased liberalization approach. Immediate tariff elimination at entry into force (EIF) applies to 63 TLs, while the majority are scheduled for gradual reduction 182 TLs over 5 years (E5), 136 TLs over 7 years (E7), and 127 TLs over 10 years (E10). A smaller subset involves partial reductions from a base rate of 10% to lower final rates ranging between 3.75% and 11% across different timelines. Additionally, 2 TLs are excluded (EL) from commitments. Overall, the structure reflects a calibrated strategy balancing market access with protection for sensitive sectors.

The EU's offer covers 263 tariff lines (TLs), A dominant share 237 TLs will see immediate tariff elimination at entry into force (EIF). A small number of lines are phased out over time, including 2 TLs in 3 years (S3), 18 TLs in 5 years (S5), and 1 TL in 7 years (S7). Only 5 TLs are excluded (EL) from concessions. Overall, the offer indicates a strong and early market-access commitment, with very limited exclusions or long transition periods.

153. On being asked about the envisaged benefits of this FTA agreement for Indian pharmaceutical sector and medical devices sector, the Department submitted as under:

"(i) FTA would enable deeper market integration between the world's 4th and 2nd largest economies. The FTA unlocks access to the $572.3 billion EU pharmaceuticals & medical devices market giving impetus to the Indian Pharmaceuticals sector.
(ii) Successful tariff treatment combined with regulatory harmonisation could generate 15 - 25% CAGR growth in Indian medical device exports to the EU over the FTA's first 5 years.
(iii) This would enable Pharma industries to scale, generate employment, and reinforce India's positioning as a reliable partner in the pharmaceuticals sector underlining its growing stature as the pharmacy of the world.
(iv) It is expected to expand skilled jobs, industrial employment, stronger MSME participation and strengthen global supply chain integration.
(v) India's medical Instruments, appliances, and vital Supplies built on cutting-edge manufacturing, innovation, and skilled talent is set for a quantum leap in the EU. Tariffs of up to 6.7% eliminated across 99.1% of trade lines, enabling cost-competitive entry in European markets for lenses, spectacles, medical devices, measuring and testing instruments."

154. When asked as to what extent will tariff reductions actually translate into lower prices of pharmaceuticals/medical devices for patients, the Department submitted that tariff reduction may lower import costs of pharmaceutical products and medical devices. However, the extent of reduction in end-user prices will depend on factors such as supply chain costs, distribution margins, and market dynamics. High-value imported products may witness relatively greater price moderation.

155. On being further asked about effect of FTA on the affordability of essential medicines in India, the Department submitted that the agreement may improve access to affordable raw materials and medical products by diversifying import sources and reducing input costs. This may support domestic manufacturing, enhance supply chain resilience, and contribute to maintaining affordability of essential medicines.

156. When categorically asked in context of pharmaceutical sector, whether 'voluntary licensing' and 'compulsory licensing' is better/more suited to India's current pharmaceutical needs and ambitions, the Department submitted that Voluntary licensing refers to licensing granted by the patent holder on mutually agreed terms, while compulsory licensing is granted by the Government under specific conditions. Both mechanisms support access to affordable medicines while maintaining innovation incentives.

157. The compulsory licensing position allowed India under WTO framework to manufacture drugs at affordable rates, which were protected by patent privileges. When asked about the Department's comments in this regard, it has been informed that Voluntary licensing facilitates access to patented medicines through mutually agreed arrangements, while compulsory licensing remains a safeguard available under the World Trade Organization framework and India's domestic law to address public health requirements. India continues to uphold its commitment to ensuring

access to affordable medicines in accordance with its legal and international obligations. However, a detailed explanation can be given once the agreement is formally signed and published.

VII. Medical Devices

158. The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for prevention, diagnosis, treatment and management of all medical conditions and disabilities. The medical devices sector is a multi-disciplinary sector, with following broad classifications (a) electro-medical equipment, (b) implants, (c) consumables and disposables. (d) surgical instruments and (e) in vitro diagnostic reagents. Several segments in the medical device industry are highly capital-intensive, with long gestation period requiring continuous induction of new technologies and continuous training of healthcare professionals to adapt to new technologies in the sector. India is one of the fastest growing markets in the global medical devices industry, expected to grow at a CAGR of 15 percent. India is the fourth largest medical device market after Japan, China and South Korea, and among the top 20 global medical device markets in the world. India is currently exporting ventilators, personal protective equipment (PPES), diagnostic kits, surgical gloves, coronary stents, radio-imaging equipment, body implants, etc.

159. When asked whether the Department is aware of certain allegations that certain medical devices (including stents) imported from China are being relabelled as "Make in India" products, a representative of the Department submitted as under:

> *"सर, कल भी हमारी एक और मीटिंग में यह चर्चा हो रही थी कि कई मेडिकल डिवाइसेज़ चीन से इंपोर्ट होती है और यह आरोप लगाया जाता है कि उसमें इंडिया की लेबलिंग करके मेक इन इंडिया में उनका बेनिफिट वो लोग लेते हैं। कल डीपीआईआईटी वालों से और कैबिनेट सेक्रेटरी से भी चर्चा हो रही थी तो उन लोगों का यह कहना था कि आप लोग स्पेसिफिक स्टांसेज़ पॉइंट आउट कीजिए और Let us take action against those people who have not verified because in each hospital, they are doing a purchase of a particular equipment and if it is alleged that this equipment was claiming 'Make in India' they are supposed to verify. एक तो सर्टिफिकेट इशू होता है जिसमें मेक इन इंडिया कंपोनेंट क्या है तो जिसने सर्टिफिकेट इशू किया है और जिसने एक्सेप्ट किया है, प्रोक्योरिंग एजेंसी Let us action in few cases. Probably that would be the best course of action that was what advised by Cabinet Secretary and I took his point कि जनरल स्टेटमेंट के बजाय If he can look it at specific instances, we will also interact with hospitals. But if any specific instances are there, let us take action against them. "*

160. On the same issue, in its written reply, the Department submitted as under:

> "The quality, safety and efficacy of drugs and medical devices is regulated under the provisions of Drugs & Cosmetics Act, 1940. Further, there are provisions related to *Spurious drugs* ("if it is manufactured under a name which

belongs to another drug") also covered under the said Act and Rules made thereunder. The said Act is administered by the Department of Health & Family Welfare. Also, import license as well as manufacturing license for coronary stents is granted by CDSCO. Further, the Department is not in receipt of any such reference or complaint pertaining to sale of imported and wrongly labelled coronary stents as Make in India".

161. Despite the increase in domestic production, imports of medical devices during the year 2024–25, as highlighted in the PPT given to the Committee, stands at USD 8.8 billion, whereas exports are slightly above USD 4 billion. In this context, the Committee desired to know about the specific steps being taken by the Department to reduce this gap, particularly in the manufacturing of high-end medical devices such as imaging devices and implants, where a significant disparity between imports and exports is evident. In this regard, during oral evidence, a representative of the DoP submitted as under:

"मेडिकल उपकरणों में हम लोग बहुत ज्यादा आयात करते हैं। हम लगभग 9 बिलियन डॉलर के उपकरणों का आयात करते हैं। इस 9 बिलियन डॉलर में जो 65 प्रतिशत आयात है, वह इलेक्ट्रॉनिक मेडिकल उपकरणों का है। यह ज्यादातर अमेरिका, जर्मनी, जापान, नीदरलैंड, आयरलैंड तथा चाइना इत्यादि देशों से किया जाता है। मैं आपको बताना चाहता हूं कि किन-किन उपकरणों का आयात हो रहा है। सीटी स्कैन, एमआरआई, ईसीजी, डायलिसिस मशीन तथा एंडोस्कोपी मशीन इत्यादि का आयात होता है। ज्यादातर जो इलेक्ट्रॉनिक मशीन्स हैं, हम लोग उनका आयात करते हैं। वर्ष 2020 में पीएलआई स्कीम आई थी, उसका प्राथमिक उद्देश्य यही था कि आयात कि निर्भरता को कम किया जाए।

महोदय, मुझे आपको यह बताते हुए खुशी हो रही है कि हम लोगों के जितने भी इम्पोर्ट आइटम्स हैं, चाहे वह सीटी स्कैन मशीन्स हों, एमआरआई मशीन्स हों, एंडोस्कोप्स हों, मैमोग्राफी मशीन्स हों या कैंसर केयर से रिलेटेड लाइनैक मशीन्स हों, वे सभी अब इंडिया में बनने लग गई हैं। पीएलआई स्कीम के अंदर ही जो एप्लीकेंट्स सेलेक्ट किए गए, उन्होंने टेक्नोलॉजी लाकर और अपनी टेक्नोलॉजी खुद डेवलप करके यह करना शुरू कर दिया है। हम लोग आज की तारीख में इंडिया में जो मशीन्स बना रहे हैं, उनकी क्वॉलिटी भी अच्छी है, क्योंकि हम उन्हें एक्सपोर्ट भी कर रहे हैं। उनके दाम भी काफी कम हैं। एग्जाम्पल के तौर पर हम लोगों ने लाइनैक मशीन का एक कंपैरिजन किया था। लाइनैक मशीन बेसिकली कैंसर पेशेंट्स के इलाज में रेडियोथैरिपी करने के काम आती है।

हम लोगों के दो डोमेस्टिक प्लेयर्स हैं, जो इन्हें बना रहे हैं। डोमेस्टिकली मैनुफैक्चर्ड मशीन लगभग 10 से 11 करोड़ रुपए में आ जाती है। जबकि, इम्पोर्टेड मशीन 18 से 20 करोड़ रुपए की हुआ करती थी। इससे हेल्थ केयर सेक्टर को एक बड़ा बेनिफिट मिल रहा है। इसके साथ ही साथ एक इम्पोर्टेड हार्ट वॉल्व 15 से 20 लाख रुपए की आती थी, आज वह इंडिया में ही सात से नौ लाख रुपए में मिल रही है। वह अच्छी क्वालिटी की है, क्योंकि उनके पास सीई सर्टिफिकेशन भी है और वे लोग यूएसएफडीए भी अप्लाई कर रहे हैं। इसलिए ऐसा नहीं है कि हम लोग इंडिया में इन्फीरियर क्वॉलिटी का माल बनाकर बेच रहे हैं। वह एट-पार है और हमारी इंडस्ट्रीज़ इसमें अच्छा काम कर रही हैं। हमें आने वाले दिनों में हाई एंड मेडिकल डिवाइसेज़

का इंपोर्ट कम होने की पूरी उम्मीद है। इसके साथ ही साथ हम लोग इनके बड़े एक्सपोर्टर बनकर भी उभरेंगे। फिलिप्स और जीई जैसी मल्टीनेशनल कंपनीज़ जो मशीन्स इंपोर्ट करके हमें बेचती थीं, अब वे उन्हें खुद बनाने लगी हैं। वे पूरे कॉम्पोनेंट्स तो नहीं बना रही हैं, लेकिन वे काफी क्रिटिकल कॉम्पोनेंट्स इंडिया में बनाने लगे हैं।"

162. Regarding the same issue, the Department in its written reply submitted as under:

"The Department of Pharmaceuticals has undertaken several key measures to promote domestic manufacturing of high-end medical devices, addressing the significant import-export gap, which stood at USD 8.8 billion in imports versus slightly over USD 4 billion in exports for the year 2024–25. Major initiatives include the Production Linked Incentive (PLI) Scheme for Medical Devices, the Scheme for Promotion of Medical Device Parks, and the Strengthening of Medical Device Industry Scheme, all aimed at enhancing manufacturing capacity and reducing import dependence.

The Medical Device Parks Scheme focuses on establishing world-class common infrastructure facilities such as 3D design labs, biomaterial testing centre, electronic assembly lines, electromagnetic interference and compatibility (EMI & EMC) centers, and other critical infrastructure to support high-quality manufacturing and innovation. The Strengthening of Medical Device Industry Scheme provides support in key areas including the manufacturing of components and accessories, skill development, clinical study support, development of common infrastructure, and industry promotion.

The PLI Scheme for Medical Devices targets key segments to reduce imports by promoting domestic manufacturing in areas such as:

- Cancer care/Radiotherapy medical devices
- Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices
- Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices
- All Implants including implantable electronic devices like Cochlear Implants and Pacemakers

By focusing on these high-value segments, the scheme aims to boost local production, decrease import reliance, and improve the affordability of high end medical devices.

Additionally, policy interventions such as the National Medical Device Policy 2023, the National Medical Devices Promotion Council, and the Export Promotion Council for Medical Devices have been established to foster innovation, streamline regulations, and enhance export potential.

The priority devices for domestic production include those used in cancer treatment (linear accelerators and cobalt machines); imaging devices (MRI scanners, CT scanners, mammography, ultrasound machines); cardiac devices (heart valves, drug-eluting stents, defibrillators); respiratory support devices (ventilators); dialysis machines for kidney care; and orthopaedic implants (knee and hip implants) are now being produced in India. These combined efforts are expected to narrow the import-export gap by strengthening domestic capabilities and making advanced medical technologies more affordable."

163. To a pointed query of the Committee that whether the medical devices are only being assembled in the country, it was submitted that currently 30 percent of domestic content exists which will increase gradually.

164. The representative further deposed on this aspect as under:-

"मेरा कहना यह है कि जैसे पीएलआई स्कीम में करीब कुल 1,100 करोड़ रुपए का कुल इंवेस्टमेंट हुआ है। पीएलआई स्कीम के तहत 12,344 करोड़ रुपए की सेल हुई है। उसमें से करीब 6,000 करोड़ रुपए का एक्सपोर्ट हुआ है। 24 ग्रीनफील्ड प्रोजेक्टस हैं, जो 55 डिवाइसेज़ बना रहे हैं। जीई और फिलिप्स जैसी कंपनीज़ ने अपने प्लांट्स भी डाले हैं। ये कुछ कंपोनेंट्स इंडिया में बना रही हैं और कुछ कंपोनेंट्स इंपोर्ट कर रही हैं। इसके साथ ही इलेक्ट्रॉनिक इंडस्ट्री की जो पीएलआई स्कीम है, जिसे डिपार्टमेंट ऑफ इन्फॉर्मेशन एंड टेक्नोलॉजी चलाता है, वह भी इलेक्ट्रॉनिक कंपोनेंट्स को बनाने में काफी सपोर्ट दे रही है। उसका और इसका कंबाइंड इफेक्ट यह है कि हाई एंड एक्विपमेंट का परसेंटेज़ ग्रेजुअली बढ़ रहा है।
महोदय, यह एक दिन में होने वाला काम नहीं है, क्योंकि इनकी आर एंड डी आसान नहीं है। ये जो मल्टीनेशनल कंपनीज़ हैं, इनमें चेंजेज़ बहुत तेजी से आते रहते हैं और इंप्रूवमेंट्स आते रहते हैं। उनका इकोसिस्टम और सपोर्ट सिस्टम डेवलप होने में समय लगता है। लेकिन, इन हाई एंड डिवाइसेज़ में अच्छी प्रगति हुई है। हां, अभी काफी इंपोर्ट होता है। हमारी ओर से कंज्यूमेबल साइड में भी काफी प्रगति हो रही है।"

165. When asked further to delineate a clear roadmap being adopted for technology transfer, strengthening of research and development (R&D) and integration into the global value chain to address imbalance between exports and imports, the Department submitted as under:

"The Promotion of Research & Innovation in Pharma-MedTech (PRIP) Scheme has been designed to promote research with a clear translational focus in the pharmaceutical and medical technology sectors. Under Component B of the Scheme, financial assistance is extended to industry-linked and industry-led R&D projects across different Technology Readiness Levels (TRLs), with defined progression towards product development, validation, and eventual market deployment.

In the medical devices sector, the scheme seeks to strengthen the research and innovation ecosystem by supporting industry-relevant and translational research aimed at reducing import dependence, encouraging indigenous technology development, and enhancing India's participation in the global medical device value chain.

Projects supported under the scheme are required to outline a clear technology development pathway, including proof-of-concept, prototype development, validation, regulatory considerations, and potential commercialization. During the evaluation process, proposals are assessed for their technological feasibility, clinical relevance, scalability, and alignment with national healthcare priorities. This ensures that supported research progresses beyond basic research towards product development and technology transfer.

The scheme also promotes collaborative partnerships between academic institutions, research organizations, medical institutions, and industry, which are critical for successful development and deployment of medical devices. Such collaborations facilitate access to clinical validation, manufacturing expertise, and market linkages, thereby strengthening the ecosystem for device innovation and enabling smoother technology transfer to industry.

Further, milestone-based monitoring and periodic review mechanisms are incorporated to ensure that projects achieve defined developmental stages such as prototype development, testing, regulatory preparedness, and demonstration of commercial viability. These mechanisms help maintain alignment with the broader objective of translating research outcomes into deployable medical device technologies.

Accordingly, through its structured evaluation framework, emphasis on translational research, and promotion of academia–industry collaboration, the PRIP Scheme aims at strengthening R&D capabilities, facilitating technology transfer, and supporting integration of indigenous medical device innovations into national and global value chains."

VIII. Drug Procurement Manual

166. On being categorically asked whether there is an absence of a dedicated drug procurement manual in the country and will a specific Drug Procurement Act enacted by Parliament help to improve quality of drugs or whether the Ministry concerned will issue binding guidelines to ensure it, the Department submitted as under:

" At the outset, it is submitted that the Department of Pharmaceuticals (DoP) does not undertake any direct procurement of medicines or medical supplies. Procurement of drugs is carried out by various Central/State Government procuring entities and agencies in accordance with the extant financial and procurement rules. At present, procurement of medicines by Government agencies is governed by the General Financial Rules (GFR), 2017, the Manual for Procurement of Goods, 2017 and other instructions issued by the Ministry of Finance from time to time. In addition, procurement is subject to the

provisions of the Public Procurement (Preference to Make in India) Order, 2017 and related clarifications. Drug procurement involves specific technical parameters such as statutory compliance under the Drugs and Cosmetics Act and Rules, adherence to Good Manufacturing Practices (GMP), quality testing, shelf-life requirements, and traceability. These requirements are incorporated through detailed technical specifications and qualification criteria within the existing procurement framework. In view of the above, it is considered that the present procurement architecture under GFR and related orders is comprehensive and sufficiently flexible to address the sector-specific requirements of drug procurement. Issuance of a separate procurement manual exclusively for drugs may not be necessary at this stage, as it may result in duplication of existing provisions. However, the Department will once again examine the necessity of having a procurement manual as there are both types of cases, the one with procurement manual and the other by way of GFR, where procurement is going on smoothly."

PART - II

OBSERVATIONS/RECOMMENDATIONS

BUDGETARY ALLOCATION *VIS-A-VIS* UTILISATION

Projection *vs* allocation of funds to the Department of Pharmaceuticals for BE 2026-27

The Committee note that against the projected requirement of ₹ 6,642.54 crore at the Budget Estimates (BE) stage for FY 2026–27, the Department has been allocated ₹ 4,831.22 crore, on the basis of utilisation levels of the Department of Pharmaceuticals's schemes during the ongoing financial year. Taking into account this significant gap of ₹ 1800 crore between the projection and the final allocation to the Department of Pharmaceuticals based on utilisation trends, the Committee would like to be apprised on the course of action of the Department to run its schemes with reduced allocation.

Reduction of funds allocated at RE stage

2. The Committee note that the budgetary allocations of the Department of Pharmaceuticals have shown a consistently increasing trend from ₹ 3,160.06 crore (BE 2023-24) to ₹ 4,089.95 crore (BE 2024-25) and further to ₹ 5,268.12 crore (BE 2025-26). However, Budget Estimates (BE) allocation of the Department for the year 2023-24 was ₹ 3160.06 crore which was reduced to ₹ 2697.9 crore at Revised Estimates (RE) stage. Similarly, the BE for the year 2024-25 was ₹ 4089.95 crore which was again reduced to ₹ 3387.96 crore and BE for the year 2025-26 was ₹ 5268.72 crore which was reduced to ₹ 4369.70 crore. Thus, FY 2023-24 onwards, allocation at RE stage is almost 15–17% lower than BE. In this regard, the Department submitted that the budgetary allocation for the Department in the aforementioned FYs was primarily earmarked for two major schemes—namely, the PLI Schemes and the Promotion of Bulk Drug Parks—which together account for approximately 60% of the Department's total allocated budget. The actual expenditure under these two schemes did not align with the projections made for the respective financial years, primarily due to implementation delays—particularly in components involving infrastructure—on account of pending statutory clearances. Other contributing factors included

the non-receipt of claims from beneficiaries under the Schemes in line with the projected timelines. The Committee are of the considered view that recurring reduction at the RE stage indicate systemic issues in budgetary planning and project readiness of the Department. Therefore, the Committee recommend that concrete steps may be taken by the Department to align budgetary projections with actual implementation capacity so that allocated funds are not revised at RE stage.

<u>Utilization of funds allocated at RE stage</u>

3. As regards the actual expenditure of allocated funds by the Department of Pharmaceuticals, the Committee note that in the FY 2023–24, the Department could incur an expenditure of ₹ 2,432.45 crore against the Revised Estimate (RE) of ₹ 2,697.96 crore, reflecting a utilization of 90.15% of the allocated funds. In FY 2024–25, against the Revised Estimate (RE) of ₹ 3387.96 crore, the Department could incur ₹ 3,170.23 crore, reflecting a utilization of 93.58%. of the allocated funds. The Committee regret to note that although the funds allocated at BE stage were reduced at RE stage to the tune of 15-17 percent for three consecutive years, the Department was still unable to optimally utilize even the curtailed amount for 2023-24 and 2024-25.

In respect of incurring an expenditure of ₹ 2,893.92 crore by the Department as on 12.02.2026, reflecting a utilisation of 66.24% of the Revised Estimate allocated for FY 2025-26, it has been submitted that funds under the various schemes of the Department are released on the basis of audited expenditure statements submitted by beneficiaries for reimbursement of the actual expenditure incurred. As a result, a substantial portion of the funds is typically released during the last quarter/last month, of the financial year. Accordingly, it is expected by the Department that the major portion of the unspent funds will be utilised during the remaining period of the current financial year. However, the Committee are of the considered view that underutilization of even revised funds allotted at RE stage affect credibility of budgetary projections and effective implementation of the schemes by the Department. Hence, the Committee recommend that rigorous mechanism to enhance financial discipline and utilisation efficiency may be instituted by the Department and the Committee be accordingly apprised.

Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology & Innovation) scheme

4. The Committee note that underlining the importance of Biologic medicines at affordable costs to longevity and quality of life, 'Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology & Innovation)' scheme has been announced in Union Budget 2026 with a total outlay of ₹ 10,000 crore over the next five years. The programme is designed to develop India into a global biopharmaceutical manufacturing hub by building a strong and self-reliant ecosystem for the domestic production of biologics and biosimilars. The Department of Pharmaceuticals (DoP) will act as the nodal Ministry for implementation of the Biopharma SHAKTI initiative. As regards the year-wise phasing of funds and the component-wise bifurcation, the scheme is presently at an initial stage of formulation. The detailed year-wise allocation, including the amount earmarked for FY 2026–27 and the component-wise distribution are under further examination and finalisation by the Department of Pharmaceuticals in consultation with the concerned Ministries/Departments and other stakeholders. The final allocations will be notified upon approval of the competent authority. The Committee desire that they be apprised of the details regarding final scheme structure and financial phasing once the same is approved by the competent authority.

Funds allocated for BE 2026-27

5. The Committee note that for FY 2026-27, an amount of ₹ 500 crore has been allocated to the Biopharma SHAKTI scheme at BE stage. In this regard, the Committee would like to be apprised of the comprehensive action plan of the Department of Pharmaceuticals to utilize the fund allocated for the coming financial year.

NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPERs)

Construction of NIPER Campuses

6. The Committee note that the Expenditure Finance Committee (EFC) at its meeting held in September 2021, had approved ₹ 1,500 crore for strengthening

of existing 7 NIPERs and construction of campuses of six NIPERs at Guwahati, Ahmedabad, Hyderabad, Kolkata, Raebareli and Hajipur. The construction of campus at Guwahati and Ahmedabad has been completed and campus was dedicated to the nation in September 2023 and January 2024, respectively. The construction of campuses of the other four NIPERs at Hyderabad, Kolkata, Raebareli and Hajipur are in progress. The Committee also note that target date of completion of NIPER Raebareli is 30.04.2026, NIPER Hajipur is 31.05.2026 and NIPER Hyderabad and Kolkata is 30.07.2026. However, the initial target date of completion for NIPER Hajipur, Hyderabad and Kolkata was 01.08.2024, 01.09.2025 and 30.09.2024, respectively. The status of construction of NIPER Campus, as on 19.2.2026, is 98% for NIPER Raebareli and 75% for NIPERs Hyderabad, Kolkata and Hajipur.

Taking into account the status of construction of the four NIPER campuses, the Committee recommend that strict adherence to the timelines without any further revisions for completion of campuses at Hyderabad, Kolkata and Hajipur and Raebareli may be ensured by the Department. Further, as Raebareli campus has already reached 98% completion, efforts may be intensified for dedicating the campus of NIPER Raebareli to the nation at the earliest.

<u>Commercialisation of patents</u>

7. The Committee learn that as part of academia-industry linkage, NIPERs have signed 352 Memoranda of Understanding with industries and other academic institutions, filed 478 patents (of which 202 patents were granted and 11 patents are commercialised) and published 8,825 research papers in reputed journals. During FY 2025-2026, as on 30.11.2025, 437 research papers were published, 35 patent filed and 28 Memoranda of Understanding were signed by NIPERs. While the Department has constituted an Industry–Academy Committee to strengthen interaction between NIPERs and industry, the Committee are of the view that commercialisation of only 11 patents out of 202 granted patents highlights need for better alignment of academic research with industry needs. During oral evidence in connection with examination of DFG 2026-27, representative of the Department also admitted that interaction of NIPERs with industry was not sufficient and hence need for greater visibility of

the work of NIPERs. The Committee, therefore, recommend that a suitable mechanism may be put in place by the Department for enhancement of patent commercialisation, translation of academic and research output to commercial outcome and bridging gap between academic research and real-world industry requirements.

NIPER courses in private institutions

8. The Committee note that the National Institutes of Pharmaceutical Education and Research (NIPERs) are stated to be institutions of national importance established under the NIPER Act, 1998 and under the existing statutory framework, private sector participation in establishing institutions with the status of NIPER is not permissible. The establishment of pharmacy colleges may be undertaken by State governments, private entities including societies or companies and such colleges have to be mandatorily approved by the Pharmacy Council of India (PCI). Further, introduction of new courses for such institutions are regulated by PCI which designs and updates the core curriculum for all pharmacy programs. The Committee also note the submission of the Department that, if the curriculum and course content of the NIPER are considered superior to the syllabus prescribed by the Pharmacy Council of India (PCI), the Department would engage with PCI to explore improvements in pharmacy course content across other institutions. In this regard, the Committee desire that details of engagement of the Department with PCI to explore improvements in pharmacy course content across other institutions may be furnished to them at the earliest.

PROMOTION OF RESEARCH AND INNOVATION IN PHARMA MEDTECH SECTOR (PRIP)

Fund utilisation for FY 2024-25

9. The Committee note that the scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) has been launched by the Department with an approved outlay of ₹ 5,000 crore and scheme duration of up

to the Financial Year 2029-30. The scheme was notified in August 2023 and aims to strengthen India's pharmaceutical and MedTech ecosystem by shifting focus from generic manufacturing to innovation-led growth through support for research, product development, and industry–academia collaboration. The Committee further note that although the Budget Estimate (BE) for Financial Year 2024–25 was enhanced from ₹75 crore to ₹ 95 crore at RE stage on account of anticipated approvals and operational progress, the actual expenditure was only ₹ 48.44 crore i.e. 51 percent, primarily under Component-A, due to delay in tendering processes for construction and procurement activities by implementing institutions (NIPERs) and hiring of contractual/project staff necessary for operationalization of approved projects. In the Committee's opinion, such administrative and procedural matters were well within the control of the Department and should not have affected fund utilisation under such as significant scheme for FY 2024-25. Therefore, the Committee recommend that the Department may initiate corrective steps in this regard so that administrative and procedural matters delays/bottlenecks do not recur in future. The Committee may be apprised of the steps taken in this regard.

<u>Fund utilization in FY 2025-26</u>

10. The Committee note that for the Financial 2025-26, while there has been no revision of funds allotted at BE stage to RE stage, the utilized amount stands at ₹ 107.23 crore (as on 20.02.2026) out of ₹ 245 crore i.e. 44 percent fund utilization upto 31st January, 2026. The Committee take note of the Department's submission that initial low utilization is typical in research and infrastructure-oriented schemes and that the PRIP Scheme has since been restructured with revised guidelines (issued on 01.10.2025), extended timeline up to FY 2029–30 and strengthened monitoring mechanisms. In this regard, the Committee hope that with the revised framework and strengthened oversight in respect of PRIP, substantial improvement in fund utilization in FY 2025-26 and the coming financial years may be achieved by the Department to ensure that the Scheme is successful in materializing its intended objectives.

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP)

Financial sustainability and viability of Jan Aushadhi Kendras (JAKs)

11. As regard JAKs, the Committee note that as on 31 January, 2026, 18255 JAKs are stated to have been opened across the country, out of which 9407 JAKs have been opened in rural and 8848 JAKs have been opened in urban areas under Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP). Further, with a view to further expand the coverage of the scheme and to meet the needs of citizens, the Government has set a target to open 25,000 JAKs by March 2027. As regards the number of JAKs proving to be financially self-sustaining and viable, the Department has submitted that viability of JAKs, especially those located outside big cities, is a concern. Further, plans to improve the order and supply system, reviewing 20% margin on low-priced medicines and provision additional incentives, such as rewards for stocking essential medicines, are being contemplated/initiated by the Department to help JAKs become more profitable. In this regard, the Committee recommend that the Department may consider generation of revenue/income through diversified sources such as offering of life insurance products and sale of medical devices, for Jan Aushadhi Kendras and an action plan for enhancing revenue sustainability of JAKs may also be devised by the Department.

Increasing credibility and acceptability of Jan Aushadhi Kendras (JAKs)

12. The Committee note that there are some public apprehensions regarding quality of medicines available at JAKs. As regards steps to promote acceptability of medicines supplied through JAKs, the Committee note that targeted awareness campaigns about the benefits of Janaushadhi medicines are conducted by the Department on a regular basis. In this context, the Committee opine that a prescription/certificate from a Government doctor or a local reputed Doctor to the effect that generic medicines available at Jan Aushadhi Kendras are therapeutically equivalent to branded medicines and

displaying such certification prominently at Jan Aushadhi Kendras in the local or regional language will definitely contribute to enhancing trust among local populace. The Committee recommend that the Department may consider this proposal and apprise the Committee accordingly. The Committee also recommend that effective practices such as operationalization of Jan Aushadhi Kendras in Government hospitals and even some private hospitals, doctors being encouraged to prescribe medicines available under the Jan Aushadhi scheme regardless of purchasing capacity of the patients, as prevalent in certain States may be studied and replicated across the Country to further advance the objective of affordable healthcare.

BE for FY 2026-27 for PMBJP and target of 25000 JAKs

13. The Committee note that the target under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is to establish 25,000 Jan Aushadhi Kendras (JAKs) by March 2027, with a Budget Estimate (BE) of ₹ 200.50 crore for FY 2026–27. The Committee further note that in FY 2024–25, the initial target of 20,000 JAKs was revised downward to 15,000, and the allocation at the Revised Estimates (RE) stage stood at ₹284.50 crore, with actual expenditure of ₹ 182.73 crore. The Committee take note of the Department's submission in this regard that the incentive provided to JAKs under the scheme is proposed to be rationalized from 20% to 12% and the implementing agency, i.e, PMBI, proposes to compensate this by way of increased margin for the JAKs, tentatively at 27.5%. Moreover, the budget under the component Media and Publicity has also been rationalized as the implementing agency intends to use social and other digital media tools in greater proportion. The Committee are not convinced with the Department's rationale and doubt that proposed expansion of JAKs may be achieved by compensating a comparatively lower BE with improved margins and rationalisation of budget under the Media and Publicity component, considering nominal prices of certain medicine strips available at JAKs. In this regard, the Committee desire that a comprehensive financial plan clearly demonstrating how the revised incentive structure and enhanced margins will sustainably support expansion to 25,000 JAKs within the BE allocation for FY 2026-27 may be furnished to the Committee.

Creation of Digital dashboard for JAKs

14. The Committee, during examination of DFG 2026-27, had forwarded certain suggestions for enhancing the overall effectiveness of the PMBJP. The suggestion of the Committee that a centralized digital dashboard must display product availability at each distributor along with batch number, expiry date, and available quantity and JAKs must have full visibility before placing orders is noted for active consideration by PMBI. The Committee urge the Department/PMBI to expedite the development and implementation of this digital platform and keep the Committee apprised of the progress made in this regard.

Appointment of permanent CEO in Pharmaceuticals & Medical Devices Bureau of India (PMBI)

15. The Committee note that PMBJP is implemented by PMBI. In this regard, the Committee recommend that a permanent Chief Executive Officer (CEO) be appointed in PMBI at the earliest to ensure continuity in policy execution and operational management.

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)

Reduction in excessive dependence on a single source of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India

16. With a view to avoid disruption in supply of critical APIs (used to make critical drugs for which there are no alternatives) by reducing excessive dependence on a single source, 'Production Linked Incentive (PLI) Scheme for

promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India' (commonly known as PLI scheme for Bulk Drugs) was approved by the Government of India on 20th March, 2020. The scheme intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. The primary objective of the Scheme is to boost domestic manufacturing of 41 identified critical products and thereby attain self-reliance in key APIs/ KSMs which were largely imported prior to implementation of the Scheme. The tenure of the scheme is till the financial year 2029-30.

Regarding the extent to which the scheme has been able to reduce dependence on a single source for production of Critical Drugs and boost domestic manufacturing of identified KSMs etc., the Committee have been apprised that out of the 41 identified products, 33 have been subscribed. Among these, production has commenced for 17 products and manufacturing capacity has been established for 11 additional products. Thus, capacity creation has been completed for 28 notified products. Domestic manufacturing capacity of approximately 56,800 MT per annum has been developed for these 28 critical products. The scheme has resulted in cumulative sales of ₹ 2,720 crore reported till December 2025, including exports of ₹ 527.96 crore, thereby avoiding imports worth ₹ 2,192.04 crore. The Committee note that 8 out of the 41 identified products are yet to be subscribed and production has commenced only for 17 out of the 41 targeted products, indicating that the intended level of domestic manufacturing is yet to be fully realized. Given that the scheme will remain operational until FY 2029-30, the Committee recommend that the Department may intensify efforts to ensure boosting of domestic manufacturing of the remaining products under the Scheme.

<u>Utilization of funds</u>

17. The total quantum of the incentive for the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) is ₹ 6,940 crore. Out of the total outlay of ₹ 6,940 crore, an

amount of ₹ 54.83 crore has been utilized to release incentive claims to the eligible applicants till December, 2025.

The Committee note that the BE for the year 2023-24 for the Scheme was ₹ 100.00 crore which was reduced to only ₹ 16.13 crore at RE stage, and the expenditure was ₹ 11.66 crore. For the year 2024-25, the BE allocation was ₹ 58.00 crore, reduced to ₹ 22.00 crore at RE stage and actual expenditure was ₹ 21.30 crore. The Committee note the submission of the Department in this regard that under this Scheme, incentives are sales-linked and disbursed only after completion of committed investment, establishment of annual production capacity and achievement of eligible sales as per the provisions of the Scheme Guidelines. The Committee also find that in FY 2025-26, a little improvement is shown in fund utilisation where RE has increased from ₹ 40 crore to ₹ 52.86 crore and ₹ 23.41 crore has been utilized, as on 20.02.2026. The Committee also note supportive measures/interventions such as expedited environmental clearances, coordination with State drug regulators, enhanced incentive rates for fermentation-based products and quarterly incentive cycles etc. as outlined by the Department to ensure optimal utilization of allocated funds under the Scheme. In view of the allocation of an amount of ₹ 66.40 crore for BE 2026–27 for the Scheme, the Committee recommend that the Department may ensure that the supportive measures/interventions translate into quantifiable improvement in fund utilization.

REVAMPED PHARMACEUTICALS TECHNOLOGY UPGRADATION ASSISTANCE SCHEME (RPTUAS)

Expenditure incurred under the Scheme

18. The Committee learn that Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS), a sub-scheme under Scheme for Strengthening of Pharmaceutical Industry (SPI)/ Development of Pharmaceuticals Industry, aims to facilitate technology and processes upgradation of existing pharmaceutical units to Revised Schedule-M and World Health Organization - Good Manufacturing Practices (WHO-GMP) certification. The scheme guidelines were revised in March 2024 to enhance its uptake and

support the technological advancement of the Indian pharmaceutical industry, ensuring alignment with global standards. The Financial outlay is ₹ 300.10 crore for the period FY 2021-22 to FY 2025-26. However, the Committee regret to note that despite Budget Estimates allocation of ₹ 95 crore in 2023–24, ₹ 5 crore in 2024–25 and ₹ 100 crore in 2025–26, no actual expenditure has been incurred under the Scheme so far.

The Committee have been given to understand that release and utilization of financial assistance under the scheme are contingent upon the completion of procurement of plant and machinery, installation, technology upgradation and the receipt of certification and verification from the concerned drug regulatory authority/authorities confirming compliance with the revised Schedule M of the Drugs Rules, 1945, and the World Health Organization – Good Manufacturing Practices. The approved projects are at different stages of implementation. However, approval of ₹ 18.24 crore in favour of 18 applicants, who had applied during the initial phase of the scheme, is under process and the amount will be released shortly. Therefore, funds have not been disbursed under the scheme so far, and to that extent the corresponding financial outlay is committed expenditure. During oral evidence, it was also submitted by the representative of the Department that interaction with units on the ground was not envisioned as part of this Scheme. In this regard, the Committee observe that sole reliance on post-certification reimbursement model and lack of field-level engagement with beneficiary MSME units have rendered the funds allotted under the Scheme completely unspent. Therefore, the Committee recommend that urgent measures to ensure that funds under the RPTUAS earmarked for technological upgradation of eligible MSMEs are disbursed in a time-bound manner in the final Financial Year i.e. 2025-26 may be taken by the Department and the Committee be apprised accordingly.

<u>Strengthening of Pharmaceutical Industry (SPI)/ Development of Pharmaceuticals Industry: Scheme for Promotion of Bulk Drug Parks</u>

<u>Completion of Bulk Drug Parks</u>

19. The Committee learn that 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. Three Bulk Drug Parks, at Nakkapalli (Andhra Pradesh), Bharuch (Gujarat) and Una District (Himachal Pradesh), have been approved with a combined project cost of ₹ 6,306 crore, spread over 5,421 acres and expected to host approximately 6,000 industrial units.

The Committee take note that the scheme timeline has been extended up to FY 2026-27 with the approval of the Scheme Steering Committee and the Department of Expenditure. All three approved Parks have submitted revised timelines accordingly. Implementation is presently in advanced stages in all three approved Parks and operationalization of Parks at Bharuch (Gujarat) and Nakkapalli (Andhra Pradesh) is expected by FY 2026–27. The Committee strongly urge the Department to adhere to the new deadline with no further slippages.

Release of instalments

20. The Scheme for Promotion of Bulk Drug Parks has a total financial outlay of ₹ 3,000 crore, providing a maximum grant-in-aid of ₹ 1,000 crore per park or 70% of the project cost of Common Infrastructure Facilities (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 ₹ 1000 crore or 90% of the project cost, whichever is less. The Scheme is being implemented through the State Implementing Agencies (SIAs) of all the three States. The Committee note that first instalment has been released to the three States in F.Y. 2022-23; ₹300 crore released to Gujarat on 14.10.2022, ₹225 crore released to H.P. on 20.02.2023 and ₹ 225 crore released to Andhra Pradesh on 13.03.2023. Second Instalment of ₹ 300 crore has been released to Gujarat on 12.11.2025. In this regard, the Committee desire that details regarding release of second instalment to Himachal Pradesh and Andhra Pradesh may be furnished to them at the earliest. Further, reasons for delay, if any, in releasing second instalments for Himachal Pradesh and Andhra Pradesh may also be given to the Committee.

Utilization of funds

21. The Committee regret to note the gross underutilisation of budgetary allocations under this scheme over three consecutive financial years. In 2023-24, the BE of ₹ 900 crore was reduced to ₹ 85.15 crore and the actual expenditure was a mere ₹ 2.24 crore. In 2024-25, the BE of ₹ 1,000 crore was reduced to ₹ 300 crore, with actual expenditure again standing at only ₹ 2.24 crore. In 2025-26, against BE of ₹1,460 crore which was revised to ₹ 810 crore at RE stage, an expenditure of ₹ 621.12 crore was incurred as on 20th February, 2026. As submitted by the Department, the variation between BE, RE and actual expenditure is primarily attributable to implementation-related challenges faced by the approved States, particularly delays in obtaining Environmental Clearances (EC), land-related issues, tendering delays and utility package restructuring. The Committee also note the Department's candid admission that the initial financial projections were over-ambitious and did not factor in the time required for land acquisition and regulatory clearances in the early years of the Scheme. The Committee are of the considered view that under-utilization of funds, due to any reason, tantamounts to blocking of scarce resources which could have been utilized for other fruitful purposes. The Committee, therefore, recommend that the Department may ensure that BE allocations are commensurate with on-ground implementation capacity under the Scheme to avoid surrendering the funds at the end of a Financial Year.

SCHEME FOR STRENGTHENING OF MEDICAL DEVICE INDUSTRY (SMDI)

Scheme for Promotion of Medical Device Parks: **Progress of Medical Device Parks**

22. The Committee note that under the Scheme for Promotion of Medical Device Parks, proposals from 16 States were received, out of which 4 States i.e. 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. However, Himachal Pradesh withdrew from the Scheme in 2024. The Committee also observe that while 193 Medical Devices manufacturers have been allotted land in the approved Medical Devices Parks with a projected investment of ₹ 4,735.41 crore and estimated employment

generation of about 27,148, only four units in Tamil Nadu park have commenced production so far, while the parks in Uttar Pradesh and Madhya Pradesh are yet to begin production despite land allotments. In this regard, the Committee recommend that the Department consistently monitor the progress of the Parks in coordination with the State Implementing Agencies concerned and take necessary steps to expedite commencement of production by the remaining allotted units. The Committee would also like to know about tenure of the Scheme and targeted timelines for operationalisation of the approved units in the three States.

Export-import gap in Medical Devices

23. The Committee note that the Department has undertaken several key measures to promote domestic manufacturing of high-end medical devices, addressing the significant import-export gap, which stood at USD 8.8 billion in imports versus slightly over USD 4 billion in exports for the year 2024–25. Major initiatives by the Department include the Production Linked Incentive (PLI) Scheme for Medical Devices, the Scheme for Promotion of Medical Device Parks, and the Strengthening of Medical Device Industry Scheme, all aimed at enhancing manufacturing capacity and reducing import dependence.

The Committee acknowledge the progress made in domestic production of several high-end devices such as those used in cancer treatment (linear accelerators and cobalt machines); imaging devices (MRI scanners, CT scanners, mammography, ultrasound machines); cardiac devices (heart valves, drug-eluting stents, defibrillators); respiratory support devices (ventilators); dialysis machines for kidney care; and orthopaedic implants (knee and hip implants) and the entry of both domestic manufacturers and multinational companies into local production. The Committee further observe that currently 30 percent of domestic content exists in medical device manufacturing indicating that a substantial proportion of components continue to be imported. In this context, the Committee are of the view that concrete and sustained efforts are required to decrease imported content in indigenous manufacturing of medical devices. Therefore, the Committee recommend the Department to

promote stronger collaboration among pharmaceutical industry, academic institutions and research organizations to accelerate indigenous development and manufacturing of advanced medical devices and thereby reducing significant import-export gap in the medical devices sector.

Drug procurement manual

24. The Committee note that the Department of Pharmaceuticals (DoP) does not undertake any direct procurement of medicines or medical supplies. Procurement of drugs is carried out by various Central/State Government procuring entities and agencies in accordance with the extant financial and procurement rules. At present, procurement of medicines by Government agencies is governed by the General Financial Rules (GFR), 2017, the Manual for Procurement of Goods, 2017 and other instructions issued by the Ministry of Finance from time to time. In addition, procurement is subject to the provisions of the Public Procurement (Preference to Make in India) Order, 2017 and related clarifications. Drug procurement involves specific technical parameters such as statutory compliance under the Drugs and Cosmetics Act and Rules, adherence to Good Manufacturing Practices (GMP), quality testing, shelf-life requirements and traceability. These requirements are incorporated through detailed technical specifications and qualification criteria within the existing procurement framework. In view of the Department, it is considered that the present procurement architecture under GFR and related orders is comprehensive and sufficiently flexible to address the sector-specific requirements of drug procurement. However, the Department has also submitted that it will once again examine the necessity of having a procurement manual as there are both types of cases, the one with procurement manual and the other by way of GFR, where procurement is going on smoothly.

The Committee desire to be apprised of the outcome of the Department's examination in this regard at the earliest.

New Delhi;
12 March, 2026
21 Phalguna, 1947 (Saka)

Azad Kirti Jha
Chairperson,
Standing Committee on
Chemicals and Fertilizers

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
(2025-26)

Minutes of the Thirteenth Sitting of the Committee

The Committee sat on Tuesday, the 26th February, 2026 from 1100 hrs to1300hrs in Committee Room B, PHA, New Delhi.

PRESENT

Shri Azad Kirti Jha – Chairperson

MEMBERS

LOK SABHA

2. Shri Brijmohan Agrawal
3. Shri Ajay Bhatt
4. Shri Rober Bruce C.
5. ShriBharatsinhji Shankarji Dabhi
6. Shri Babu Singh Kushwaha
7. Shri Praveen Patel
8. Shri Sachithanantham R.
9. Shri Eatala Rajender
10. Shri Daggumalla Prasada Rao
11. Shri Shivmangal Singh Tomar

Rajya Sabha

12. Shri Subhash Barala
13. Dr. Bhagwat Karad
14. Shri Arun Singh
15. Shri Tejveer Singh

SECRETARIAT

1. Smt. Maya Lingi - Joint Secretary
2. Ms. Miranda Ingudam - Director
3. Shri Kulvinder Singh - Deputy Secretary

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

(i) Shri Manoj Joshi, Secretary, Department of Pharmaceuticals
(ii) Shri Awadhesh Kumar Choudhary, Senior Economic Adviser, DoP
(iii) Shri Manoj Sethi, JS& FA, DoP
(iv) Shri P. Krishnanmurthy, Chairman, National Pharmaceutical Pricing Authority (NPPA)
(v) Shri Satyaprakash TL, JS, DoP
(vi) Shri Aman Sharma, Joint Secretary
(vii) Shri Vishal Vishwanath Nair, Economic Adviser, DoP
(viii) Smt S. Ahlladini Panda, Member Secretary, NPPA
(ix) Shri Santosh Kumar, Chief Controller of Accounts, DoP
(x) Shri Rahul Sharma, Deputy Director General
(xi) Shri Vijay Kumar Srivastava, Director, DoP
(xii) Shri Hitendra Sahu, Director, DoP
(xiii) Ms. Gunjan Verma, Director, DoP
(xiv) Ms. Anugraha P, Director, DoP
(xv) Shri Suvasis Das, Deputy Secretary, DoP& CEO, Pharmaceuticals & Medical Devices Bureau of India (PMBI)
(xvi) Ms. KhayiLeishingam, Joint Director
(xvii) Shri Amlan Das, Deputy Secretary
(xviii) Ms Nirja Saraf, Managing Director (HAL)

2. At the outset, the Hon'ble Chairperson welcomed the Members of the Committee and the representatives of the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals (DoP) to the sitting convened to examine the Demands for Grants (2026–27) of the Department. Drawing the attention of the witnesses to Direction 55(1) of the Directions by the Speaker, Lok Sabha regarding confidentiality of the proceedings of the Committee, the Chairperson asked them to apprise the Committee regarding Demands for Grants (2026–27). The Secretary, DoP, briefy provided the Committee through a Power Point Presentation an overview of the

work allocation of the Department, organisations under the Department, Pharmaceutical Industry in India, Schemes being implemented, price regulation of medicines, research, education and innovation in Pharmaceutical sector, National Institutes of Pharmaceutical Education and Research (NIPERs), Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology & Innovation)' scheme, Public Sector Undertakings, and Budget Estimates (BE) for Financial Year 2026-27. The Committee referred to the budgetary trends of the Department and observed that although the Budget Estimates (BE) of the Department had increased over the years but the actual expenditure had not increased proportionately. The Committee further desired to know the reasons for the gap between the allocations and actual expenditure and the steps taken by the Department to ensure optimal utilization of the allocated funds. The Committee also drew attention to the substantial reductions in Budget Estimates at the Revised Estimates (RE) stage for certain schemes, particularly the Promotion of Bulk Drug Parks Scheme and the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs).

3. Thereafter, the Committee sought certain clarifications on the issues related to examination of Demands for Grants of the Department for the year 2026-27 and posed several queries which *inter-alia* included the following:-

(i) certain allegation regarding re-labeling of medical devices (including stents) imported from China as 'Make in India' products;
(ii) loan licences;
(iii) establishment of National Institute of Pharmaceutical Education and Research (NIPER) , Madurai;
(iv) Jan Aushadhi Kendra in Cherrapunji;
(v) Export-import gap in medical devices sector;
(vi) roadmap being adopted for technology transfer, strengthening of research and development (R&D) and integration n into the global value chain;
(vii) guidelines/procedures for public procurement of drugs;

(viii) financial sustainability and viability of operational Jan Aushadhi Kendras (JAK);

(ix) Budget Estimates (BE) allocation for FY 2026-27 for Pradhan Mantri Bharatiya Janaushadhi Pariyojana and achievement of target of 25000 JAKs by March 2027;

(x) suggestions regarding enhancing overall effectiveness of Pradhan Mantri Bharatiya Janaushadhi Pariyojana;

(xi) impact of gap between projection and allocation of BE for FY 2026-27 to the Department of Pharmaceuticals;

(xii) Drug Procurement Manual;

(xiii) progress of Bulk Drug Parks;

(xiv) construction of NIPER campuses;

(xv) recent India-EU Free Trade Agreement (FTA) and its impact on Indian pharmaceutical sector;

(xvi) compulsory and voluntary licensing in pharmaceutical sector;

(xvii) NIPER courses in private institutions;

(xviii) commercialisation of patents in NIPER;

(xix) nil expenditure under Revised Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS); and

(xx) Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology & Innovation)' scheme.

4. As some points required detailed information, the Chairperson asked the representatives to furnish detailed written replies and to the queries raised by the Members which remained unanswered during the Sitting, 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 BRANCH

(2025-26)

Minutes of the Fifteenth Sitting of the Committee

The Committee sat on Thursday, The 12th March, 2026 from 1000 hrs. to 1030 hrs. in Committee Room 'D', Parliament House Annexe (PHA), New Delhi.

PRESENT

Shri Azad Kirti Jha– Chairperson

LOK SABHA

2.	Shri Ajay Bhatt
3.	Shri Bharatsinhji Shankarji Dabhi
4.	Dr. Kalyan Vaijinathrao Kale
5.	Shri Malvinder Singh Kang
6.	Shri Babu Singh Kushwaha
7.	Shri Utkarsh Verma Madhur
8.	Shri Praveen Patel
9.	Shri Balram Naik Porika
10.	Shri Eatala Rajender
11.	Shri Daggumalla Prasada Rao
12.	Shri Tharaniventhan M.S.
13.	Shri Nalin Soren
	RAJYA SABHA
14.	Shri Naresh Bansal
15.	Shri Subhash Barala
16.	Dr. Bhagwat Karad
17.	Shri Arun Singh
18.	Shri Tejveer Singh

SECRETARIAT

1. Smt. Maya Lingi - Joint Secretary
2. Ms. Miranda Ingudam - Director
3. Shri Kulvinder Singh - Deputy Secretary
4. Shri Abhishek Kumar - Deputy Director

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;

(ii) xxxx;

(iii) xxxx; and

(iv) Twenty-third Report on 'Demand for Grants (2026-27)' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

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

4. The Committee then authorized the Chairperson to finalize the Reports and present/lay the Reports in both the Houses of Parliament in the ongoing Session of Parliament.

***The Committee then adjourned*.**

xxxx Matter does not pertain to the Report