20

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

(2025-26)

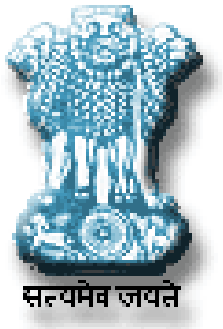
(EIGHTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

Action Taken by the Government on the Observations/Recommendations contained in the Eighth Report of the Standing Committee on Chemicals and Fertilizers (Eighteenth Lok Sabha) on 'Demand for Grants (2025-26)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

TWENTIETH REPORT



LOK SABHA SECRETARIAT

NEW DELHI

March, 2026/ Phalguna, 1947 (Saka)

TWENTIETH REPORT

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(EIGHTEENTH LOK SABHA)

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(DEPARTMENT OF PHARMACEUTICALS)

Action Taken by the Government on the Observations/Recommendations of the Committee contained in the Eighth Report (Eighteenth Lok Sabha) on 'Demand for Grants (2025-26)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

Presented to Lok Sabha on 13th March, 2026

Laid in Rajya Sabha on 13th March, 2026

LOK SABHA SECRETARIAT

NEW DELHI

MARCH, 2026/ PHALGUNA, 1947 (SAKA)

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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 Bharatsinhji Shankarji Dabhi
6. Smt. Kriti Devi Debbarman
7. Dr. Kalyan Vaijinathrao Kale
8. Shri Malvinder Singh Kang
9. Shri Babu Singh Kushwaha
10. Shri Utkarsh Verma Madhur
11. Shri Praveen Patel
12. Dr. Sambit Patra
13. Shri Balram Naik Porika
14. Shri Sachithanantham R.
15. Shri Eatala Rajender
16. Shri Rajesh Ranjan
17. Shri Daggumalla Prasada Rao
18. Shri Tharaniventhan M.S.
19. Shri Nalin Soren
20. 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 and Fertilizers (2025-26) having been authorized by the Committee, do present on their behalf this Twentieth Report on Action taken by the Government on the Observations/Recommendations of the Committee contained in their Eighth Report (Eighteenth Lok Sabha) on 'Demand for Grants (2025-26)' pertaining to the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals.

2. The Eighth Report was presented to Lok Sabha and also laid in Rajya Sabha on 19th March, 2025. The Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, furnished their replies on 22 December, 2025 indicating Action Taken on the Observations/Recommendations contained in the Eighth Report. The Committee considered and adopted this Report at their Sitting held on 12 March, 2026.

3. An analysis of the Action Taken by the Government on the Observations/Recommendations contained in the Seventh Report (Eighteenth Lok Sabha) of the Committee is given in **Appendix-II.**

4. For ease of reference, Observations/Recommendations of the Committee have been printed in bold letters in the Report**.**

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

Azad Kirti Jha
Chairperson,
Standing Committee on
Chemicals and Fertilizers

REPORT

CHAPTER – I

This Report of the Standing Committee on Chemicals and Fertilizers deals with Action Taken by the Government on the Observations/Recommendations contained in the Eighth Report (18th Lok Sabha) of the committee on Demands for Grants of the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals for the year 2025-26. This Report was presented to Lok Sabha and laid in Rajya Sabha on 19 March, 2025.

1.2 The Eighth Report (18th Lok Sabha) of the Committee contained 23 Observations/ Recommendations. The Action Taken Replies have been received from the Government in respect of all Observations/Recommendations contained in the Report in December, 2025. The replies to these Observations/Recommendations have been examined and categorized as follows :-

(i) Observations/Recommendations which have been accepted by the Government (Chapter II):

Para Nos. 3,4,6,7,8,9,10, 11,12, 15,16,17, 18, 19, 20, 22 and 23

(Total - 17)

(ii) Observations/Recommendations which the Committee do not desire to pursue in view of the replies received from the Government (Chapter III):

Para No. Nil

(Total - 0)

(iii) Observations/Recommendations in respect of which replies of Government have not been accepted by the Committee and which require reiteration (Chapter IV):

Para Nos. 1, 2, 5, 13, 14 and 21

(Total - 6)

(iv) Observations/Recommendations in respect of which final replies of the Government are still awaited (Chapter V):

Para No. Nil

(Total - 0)

1.3 The Committee desire that the Action Taken Notes in respect of comments of the Committee contained in Chapter I of the Report should be furnished to them at the earliest and in any case, not later than six months of the presentation of this Report.

1.4 The Committee, in the succeeding paragraphs, will now deal with the action taken by the Government on some of the Observations/Recommendations made in the Eighth Report (18th Lok Sabha) which either require reiteration or merit further comments.

Observation/Recommendation Nos. 1 and 2

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

1.5. The Committee had recommended as under:

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

The Committee note that the BE of the Department for the year 2023-24 was ₹ 3160.06 crore which was reduced to ₹ 2697.96 crore. 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 ₹ 6920.20 crore which has again been reduced to ₹5268.7 crore. As regard this reduction in the BE of the Department the Committee have been apprised that expected release under some schemes could not be made due to lesser demand in infrastructure schemes because of issues in tendering process, environmental clearances etc. non-fulfilment of targeted achievements to claim incentives etc. These were the primary reasons for which the budget had to be reduced at RE stage during FY 2023-24 and FY 2024-25. The Committee are of the view that the reasons cited by the Department are well within the administrative control of the Department itself. The Committee, therefore, recommend that the Department should initiate immediate steps to overcome issues related to tendering process, environmental clearances etc. and ensure that such issues does not hinder the Department from higher allocation of funds."

1.6 The Ministry in its Action Taken Reply has stated as under:

"As recommended by the Hon'ble Committee, the Department has taken steps to overcome issues related to tendering process, environmental clearances, etc. and to run schemes better. The following measures and improvements made as a result are submitted in this regard:

(a) To ensure proper budget utilisation, advance planning and disbursement is being done with a view to ensure timely release of funds, quarterly expenditure targets are fixed to prevent last minute expenditure rush, monthly/quarterly financial monitoring meetings are being held to assess fund utilisation and address bottlenecks if any, fund allocation is linked with the actual progress and expenditure trends to avoid over-estimation. Further, progress on this is monitored on a weekly basis with all programme divisions and the Integrated Finance Division. As a result, the Department could release and spend 93.6% of the RE Budget in 2024-25, which was higher than in the preceding financial years.

(b) To strengthen outreach for getting more applications under schemes to enable utilisation, in addition to publishing notices inviting applications in the newspaper and the website of the Department, social media handles of relevant organisations under the Department, other relevant Government Ministries, Departments and organisations as well as relevant industry associations are now being leveraged.

(c) Meetings are held regularly with Project Management Agencies (PMA), State Implementing Agencies, scheme implementing agencies and scheme beneficiaries and, where necessary, site visits are undertaken by officers of the Department / PMA to monitor the progress of schemes, expedite implementation and resolve issues.

(d) To institutionally and sustainably enhance programme management capabilities in the Department by avoiding fragmentation of project management across various schemes, a dedicated new scheme named "Scheme of Programme Management" for the five-year period beginning with the financial year 2026-27 has been approved. Under this, a pool of domain-specific experts, technical consultants and Young Professionals would be formed to create suitable capacities to support various Divisions of the Department, including a Management Team for professional management and technical guidance and oversight of the pooled resources. This will help ensure efficient resource utilisation, timely implementation and effective monitoring under various initiatives and facilitate sectoral expertise, optimise resource utilisation by identifying gaps and overlaps or duplication and facilitate review and appraisal of schemes.

(e) Under the Production Linked Incentive (PLI) schemes and the Strengthening of Medical Device Industry umbrella scheme, the Department, through the Project Development Cell (PDC) mechanism, is handholding applicants to facilitate resolution of issues related to commissioning of projects, as a result of which various issues such as land allotment, Petroleum and Explosive Safety Organisation (PESO) license, approval of the Central Drugs Standard Control Organisation (CDSCO), environmental clearances, etc. have been resolved.

(f) Under the Promotion of Research and Innovation in Pharma MedTech sector (PRIP) scheme, a consulting firm with demonstrated global and domestic experience

in both pharma-medtech and research domains was onboarded in January 2025 as PMA to develop the strategy. The Department undertook extensive stakeholder consultation to gather feedback, suggestions and potential project pipeline information, analyse the same in-depth. Based on these consultations and feedback, the scheme was amend and its guidelines revised, with a view to enhance the impact of the scheme. As a result of such initiatives, high number of proposals (710) has been received in response to the call for proposals and work is under way with a view to ensure that selection of projects, completion of requisite formalities and release of funds to industry and startups is done within the current financial year. Further, under the component for support to the National Institutes of Pharmaceutical Education and Research for setting up Centres of Excellence, the institutes have been asked to ensure industry participation before taking up projects, with a view to ensure relevance of projects to industry.

(g) Under the Scheme for Promotion of Bulk Drug Parks, all three State Implementing Agencies have drawn up Program Evaluation and Review Technique (PERT) charts, with a view to ensure timely implementation. Further, the long-pending environment clearance for the proposed bulk drug park in Himachal Pradesh has been obtained, enabling progress on this project.

(h) Under the scheme for Strengthening of Pharmaceutical Industry, extensive outreach has been done in partnership with industry and drugs regulators across States through webinars to elicit proposals, resulting in approval of 192 projects under the Revamped Pharmaceutical Technology Upgradation Assistance Scheme. Moreover, system of joint inspections by the Central and State drugs regulators has been put in place, with a view to ensure timely certification of compliance with WHO-GMP norms.

(i) Under the Promotion of Medical Device Parks scheme, all required clearances have been obtained by State Implementing Agencies (SIAs) and major tenders for construction of common infrastructure facility (CIF) buildings have been awarded. This has resulted in actual allotment of land to 194 manufacturing units in the approved medical device parks and 34 units have commenced construction of their plants. Further, tenders for equipment to be installed in CIF buildings are at different stages of procurement. Thus, available funds are now being utilised in an unhindered manner to ensure their optimal utilisation."

Comments of the Committee

1.7 The Committee note that as recommended by them, the Department has initiated measures to overcome issues related to tendering process, environmental clearances etc. so as to run the Schemes in a better way. Measures include inter-alia strengthening outreach programmes and progress under major schemes such as Production Linked Incentive (PLI) Schemes and the strengthening of Medical Device Industry Umbrella Scheme, Promotion of Research and Innovation in Pharma MedTech sector (PRIP), Promotion of Bulk Drug Parks, Strengthening of Pharmaceutical Industry and Promotion of Medical Device Parks. The Committee observe that though the measures initiated by

the Department appear to be elaborate, these measures should be implemented in letter and spirit by the Department. The Committee would like to be apprised of the outcomes of these measures.

Observation/Recommendation No. 5

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP)

Expansion of Janaushadhi Kendras (JAKs)

1.8 The Committee had recommended as under:

"The Committee note that while the Department has reported the establishment of 15,000 Jan Aushadhi Kendras (KAKs) as of 31.01.2025, their distribution across the country remains uneven, particularly in the Northeastern States and Union Territories. A closer examination of the state-wise data reveals that certain regions have a significantly lower number of JAKs, with only 9 in Andaman & Nicobar, 2 in Ladakh, 1 in Lakshadweep, 56 in Manipur, 25 in Meghalaya, 15 in Mizoram, 22 in Nagaland, 12 in Sikkim and 29 in Tripura. Given the objective of providing affordable medicines to all, the Committee believes that this distribution pattern needs urgent attention.

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

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

1.9 The Ministry in its action taken reply has stated as under:

"The Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme has an entrepreneur-driven model for opening of JAKs and expansion of the JAK network. Under this, applications are invited online through the scheme's website from individual entrepreneurs, non-governmental organisations, societies, trusts, firms, private companies, etc. With a view to

proactively expand the network, including in remoter and less developed areas of the country, a proactive, timebound expansion strategy is being pursued as under:

(a) Pursuant to the announcement made by the Hon'ble Prime Minister in his Independence Day 2023 speech, a target to increase the number of JAKs opened in the country to 25,000 is being pursued in a phased manner, with phase-wise targets being 10,000 JAKs by March 2024, 15,000 by March 2025, 20,000 by March 2026 and 25,000 by March 2027. Against these targets, the achievements so far have been 11,261 by March 2024, 15,403 by March 2025 and 17,610 by November 2025. Further, online applications are invited on a standing basis from all districts of the country through the scheme website (www.janaushadhi.gov.in) and in the processing of applications received, districts having less coverage are given special focus.

(b) Keeping in view population density, healthcare access and regional challenges, the following measures have been taken to ensure opening of JAKs in different parts of the country:

(i) One-time incentive of ₹2 lakh is provided to outlets opened in 112 aspirational districts, the North-Eastern States, Himalayan areas and Island territories, as support towards furniture, computers, refrigerators and other fixtures. This is in addition to the incentive of 20% of the monthly purchases made by JAK owners, subject to a monthly ceiling of ₹20,000 and meeting certain conditions such as maintaining stock of specified medicines, for which all JAK owners are eligible.

(ii) State Governments have been requested from time to time to provide rent-free space for opening JAKs in government hospitals, community health centres and primary health centres, and to create awareness about the scheme. So far, a total of 2,397 JAKs have been opened in public health facilities and other government centres.

(iii) To increase the number of JAKs in rural areas, the cooperative sector has been partnered with for opening JAKs through Primary Agricultural Credit Societies (PACS) and other cooperative societies. Till 30.11.2025, a total of 804 JAKs have been opened through PACS and other cooperative societies across the country.

As a result, the number and proportion of rural JAKs has grown to 9,475 and 54% respectively.

(c) Sustainable expansion of JAK network needs to be driven by higher volume of sales to increase their viability and attractiveness to entrepreneurs. To this end, the following steps have been taken to make citizens aware of the features and benefits of the scheme and its products:

(i) *Awareness campaigns*: PMBI 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/calls*: Outreach and citizen engagement are also pursued through WhatsApp chatbot and outbound calls to inform citizens regarding the quality of Janaushadhi products and the large savings that accrue from purchase of the same from nearest JAK.

(iii) *Jan Aushadhi Week*: Pursuant to the Hon'ble Prime Minister's directions in 2019, 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, children engagement programmes, etc. are conducted across the nation to educate citizens, healthcare professionals and other stakeholders about the benefits of Janaushadhi generic medicines. The 7th Janaushadhi Diwas 2025 was observed on a substantially enhanced scale this year with participation of nine Union Ministers, two Chief Ministers, 156 Members of Parliament and 70 other State dignitaries. Events were held across 26 States and Union territories, at 231 locations, with a total of 32,431 participants. During the week, #JanAushadhi witnessed 996 mentions generating around 64,600 views and an estimated reach of 2.3 crore and #JanAushadhiDiwas was trending at number 3 in India on X. These campaigns aim to counter any incorrect perception about poor quality of generic medicines while emphasising the cost benefits of these medicines. The efforts taken to maintain the quality of Janaushadhi products are also highlighted in these campaigns.

(iv) *Directions for prescribing generic medicines:* The Department of Health and Family Welfare has issued directions to all Central Government hospitals and Central Government Health Scheme (CGHS) wellness centres to prescribe drugs with generic name.

(v) *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.

(vi) *Public engagement programme in rural areas*: To educate citizens in local languages/dialects, publicity is also done through health camps, *nukkad-natak*, audiovisual display at Common Service Centres and public engagement workshops in association with local JAKs in rural areas.

(vii) In order to promote Janaushadhi products, an app namely Janaushadhi Sugam has been developed, which is a convenient tool for the general public to obtain information on Janaushadhi generic products and locate nearby JAKs to purchase these products."

Comments of the Committee

1.10 The Committee, in their Eighth Report, had urged the Department to formulate a time-bound action plan to ensure that every District of the country has adequate number of Jan Aushadhi Kendras, taking into account population density, healthcare access and regional challenges. In its Action Taken Reply, the Department has submitted that as against phase-wise targets of opening of 15,000 Jan Aushadhi Kendras (JAKs) by March 2025, 17,610 JAKs have been opened by November 2025. As a result, the number and proportion of rural JAKs has grown to 9,475 and 54% respectively. However, the reply

does not clearly indicate whether the Department has undertaken feasibility studies, demand assessments and consultations with stakeholders to determine the optimal number and location of additional Kendras, as recommended by the Committee. The Committee are of the view that meaningful success of the Scheme will depend not only on numerical expansion but also on ensuring even distribution of JAKs in the entire Country, especially in rural and underserved areas. The Committee, therefore, reiterate their recommendation that the Department should undertake feasibility studies, demand assessments and consultations with stakeholders to determine the optimal number and location of additional Kendras. The Committee further take note of the steps taken by the Department to enhance the viability and attractiveness of JAKs to entrepreneurs and citizens through public awareness campaigns, digital outreach, celebration of Jan Aushadhi Week, directions for prescribing generic medicines to CGHS wellness centres, public engagement programmes in rural areas and development of 'Janaushadhi Sugam' app. In this regard, the Committee recommend that with a view to achieve expansion of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme in a sustainable manner, the Department institute additional measures to strengthen coordination with State Governments and healthcare providers to further integrate Janaushadhi medicines into public healthcare delivery system.

Observation/Recommendation No. 13

PROMOTION OF BULK DRUG PARKS

1.11 The Committee had recommended as under:

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

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

1.12 The Ministry in its action taken reply has stated as under:

"As recommended by the Hon'ble Committee, the Department is working in close cooperation with the State Governments concerned, with a view to expeditiously resolve issues that hinder progress. Steps taken in this regard are as under:

(a) Under the Scheme for Promotion of Bulk Drug Parks, all three State Implementing Agencies have drawn up PERT charts, with a view to ensure completion by March 2027. The Department of Expenditure has been requested to extend the scheme period by one year beyond March 2026.

(b) The long-pending environment clearance for the proposed bulk drug park in Himachal Pradesh has been obtained, enabling progress on this project.

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

(d) The Department has been conducting monthly review meetings with SIAs under the chairpersonship of the Joint Secretary concerned for monitoring physical and financial progress. During these interactions, the Department has been extending support to SIAs in expediting regulatory approvals, in coordination with the Ministries concerned.

(e) The Department / project management agency undertakes periodic site visits to the park sites to review progress with the representatives of the State Government, with a view to ensure the following:
    (i) Necessary regulatory approvals and clearances required for the Park;
    (ii) Release and award of tenders of approved CIF projects;
    (iii) Project execution within the Scheme tenure; and
    (iv) Fund utilisation.

(f) DO letters have been addressed to the Additional Chief Secretaries / Principal Secretaries concerned in the State Governments, apprising them of the progress and requesting expediting of progress."

Comments of the Committee

1.13 The Committee, in their Report, had recommended that the Bulk Drug Parks may be given a concrete shape and should be made ready by March, 2026 invariably. In its Action Taken Reply, the Department has submitted that it is working in close cooperation with the State Governments concerned, with a view to expeditiously resolve issues that

hinder progress. The Committee have been informed that under the Scheme for Promotion of Bulk Drug Parks, all three State Implementing Agencies have drawn up Program Evaluation and Review Technique (PERT) charts, with a view to ensure completion by March 2027. However, the Committee are concerned to note that the Department of Pharmaceuticals has requested the Department of Expenditure to extend the Scheme period by one year beyond March 2026. The Committee are of the considered view that timely completion of Bulk Drug Parks is critical for achieving the intended objectives of strengthening domestic manufacturing capacity and reducing import dependence of bulk drugs. The Committee, therefore, desire rigorous action on the part of the Department for expeditious resolution of issues hindering progress of the Scheme.

Observation/Recommendation No. 14

1.14 The Committee had recommended as under:

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

1.15 The Ministry in its action taken reply has stated as under:

"The pace of expenditure has been slow on account of various factors. The same are summarised below:

(a) Bulk drug manufacturing is categorised as a red category industry under environmental regulations, on account of their polluting nature and risk to the environment. Accordingly, environmental clearance (EC) is a prerequisite for commencing construction work. Following receipt of approvals to set up bulk drug parks, the respective State Governments applied for EC in FY2022-23.

(b) In Gujarat, EC was delayed by 16 months owing to the recommendations of the Ministry of Environment, Forest and Climate Change (MoEFCC) to relocate the proposed 60 million litre per day marine discharge pipeline and EC was finally granted to the park only in February 2024.

(c) In Andhra Pradesh, relocation of Bulk Drug Park from Kakinada to Nakkapalli due to requirement of partial denotification of Special Economic Zone land delayed the project

by 12 months. Following this, change to the new location was approved by the Scheme Steering Committee (SSC) in December 2023. Thereafter, EC for the project was received in March 2024. However, the State Government decided to accommodate an Integrated Steel Plant in the neighbourhood of the approved bulk drug park site and proposed modification of boundary at Nakkapalli, releasing 706.26 acres of existing land while adding 783.74 acres of new land. In-principle approval to the same was accorded by SSC on 23.6.2025.

(d) In Himachal Pradesh, EC was granted on 25.9.2025. The delay is primarily attributable to the complex terrain, seismic vulnerability and erosion-prone nature of the site. The draft Environment Impact Assessment (EIA) report was submitted to MoEFCC by the State Government in November 2023. Thereafter, the terms of reference for the EIA report were issued by MoEFCC in August 2024. Based on these, public hearing took place in November 2024 and final EIA report was submitted to MoEFCC by the State Government in January 2025. Following subsequent presentation by the State Government to MoEFCC, a site visit was conducted by MoEFCC's Expert Appraisal Committee (EAC) in April 2025. EAC recommended phased development, slope restrictions and soil and water conservation plans at the site. Based on these recommendations, the State Government, after complying with the suggestions, submitted a revised master plan, considering which MoEFCC finally accorded EC in September 2025.

As recommended by the Hon'ble Committee, the Department has analysed the reasons for the pace of fund utilisation and has taken the following steps to accelerate the pace of fund utilisation by the selected States:

(a) Under the Scheme for Promotion of Bulk Drug Parks, all three State Implementing Agencies have drawn up PERT charts, with a view to ensure completion by March 2027. The Department of Expenditure has been requested to extend the scheme period by one year beyond March 2026.

(b) The long-pending environment clearance for the proposed bulk drug park in Himachal Pradesh has been obtained, enabling progress on this project.

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

(d) The Department has been conducting monthly review meetings with SIAs under the chairpersonship of the Joint Secretary concerned for monitoring physical and financial progress. During these interactions, the Department has been extending support to SIAs in expediting regulatory approvals, in coordination with the Ministries concerned.

(e) The Department / project management agency undertakes periodic site visits to the park sites to review progress with the representatives of the State Government, with a view to ensure the following:

(v) Necessary regulatory approvals and clearances required for the Park;
(vi) Release and award of tenders of approved CIF projects;
(vii) Project execution within the Scheme tenure; and
(viii) Fund utilisation.

(f) DO letters have been addressed to the Additional Chief Secretaries / Principal Secretaries concerned in the State Governments, apprising them of the progress and requesting expediting of progress."

Comments of the Committee

1.16 The Committee are happy to note the steps taken by the Department to accelerate the pace of fund utilisation by the selected States under the Scheme for Promotion of Bulk Drug Parks include preparation of Program Evaluation and Review Technique (PERT) charts, sharing of physical and financial progress of the bulk drug park and conducting monthly review meetings with State Implementing Agencies and periodic site visits to review progress with the representatives of the State Government. The Committee expect that these measures should ensure effective utilization of funds allocated for the Scheme and desire that they be apprised of the tangible improvements in the pace of fund utilisation by the Department.

Observation/Recommendation No. 21

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

1.17 The Committee had recommended as under:

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

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

opinion that a considerable time has been elapsed after COVID-19 and the PLIMD scheme should not be got effected by the aftermath of COVID-19. The Department should initiate steps to overcome the problems posed by the COVID-19. The Committee would like to be apprised of the steps taken by the Department."

1.18 The Ministry in its action taken reply has stated as under:

"Against the backdrop of delays in commercial operations of projects selected under the Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices, on account of the covid pandemic and delays in securing requisite regulatory approvals, the Department of Pharmaceuticals had proposed to the Department for Promotion of Industry and Internal Trade (DPIIT) extension of the existing tenure of the scheme till the financial year 2026-27 (the last year for eligible production) by one year, *i.e.,* till the financial year 2027-28. However, DPIIT conveyed that the proposal for extension of the tenure for the scheme does not appear be consistent with the performance-linked construct of PLI schemes and may not be pursued further."

Comments of the Committee

1.19. The Committee note that with a view to address challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies, a Scheme called 'Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of Medical Devices {PLIMD}' was approved by the Government of India on 20.3.2020. The period of the Scheme was from FY 2020-21 to FY 2027-28 with total financial outlay of Rs. 3,420 crore. Under this Scheme, financial incentive was given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the target segments of the scheme, for a period of five years. The Committee had observed that in view of the delay in the commissioning of Category –A applicant projects and on account of approvals granted in FY 2023-24 and FY 2024-25 for Category-B applicants, the incentive allocated for 2022-23 could not be fully utilized despite the investments being made by the applicants. The Committee further note that the proposal of the Department for extension of the Scheme tenure by one year i.e. till FY 2026-27 (last year for eligible production) has not been agreed to by the Department for Promotion of Industry and Internal Trade (DPIIT), on the ground that such extension would not be consistent with the performance-linked construct of PLI Schemes. The Committee are constrained to note that the Department has not implemented the Scheme seriously and the term of the Scheme has come to an end. The Committee desire to be apprised of the financial implications of rejection of proposal of extension of tenure of PLIMD Scheme and future of investment made by the applicants under this Scheme. The Committee also

recommend that the Department of Pharmaceuticals should urgently undertake a comprehensive project-wise review of all delayed Category-A and Category-B applicants and take proactive and concrete steps so that the objectives of the PLIMD Scheme are achieved within the existing framework of the Scheme. The Committee would like to be apprised of the specific steps taken by the Department in this regard along with measurable outcomes in the Action Taken Statements.

CHAPTER II

OBSERVATIONS/RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Observation/Recommendation No. 3

2.1 The Committee had recommended as under:

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

2.2 The Ministry in its action taken reply has stated as under:

"The allocation for schemes in the Department is sought based on projections and expected progress during a financial year. At the time of Budget discussions for the coming financial year, allocations on the demands made by the Department are made by the Ministry of Finance based on their assessment for the sector and keeping in view available fiscal space. However, during the financial year, if more funds are needed based on progress, the same are sought at the RE/Supplementary Demands for Grant stage with due justifications with a view to ensure that schemes/programmes do not suffer due to paucity of funds."

Observation/Recommendation No.4

2.3 The Committee had recommended as under:

"As regards the actual expenditure of the Department the Committee note that the actual expenditure of the Department for the year 2022-23 was Rs. 2050.08 crore against allocated amount of Rs. 2268.54 crore. During the year 2023-24 expenditure was Rs. 2432.45 crore against allocated amount of Rs. 2697.96 crore. During the year 2024-25 expenditure was Rs. 2432.44 crore against allocated amount of Rs. 3387.96 crore. Thus, the Department has not been able to utilize the allocated funds to it for the three consecutive years. In this regard the Department has submitted their justification for under utilisation of funds that the Pharma Industry is a growing industry and the targets are based on projections, which at times do not fructify on ground due to various reasons

primarily related to infrastructure development for the projects due to various clearances required to be obtained in the time bound manner. Despite, these impediments due to constant monitoring of the scheme by the Department at micro level, 90.37% of RE in FY 2022-23 and 90.15% of RE in FY 2023-24, was utilized. As regards, FY 2024-25, the actual figures for expenditure would only be known on completion of the FY 2024-25 on 31st March, 2025. The Committee do appreciate the contention of the Department that targets set by it are based on projections, which at times do not fructify on ground due to various reasons. However, the Committee recommend that the Department should fix the realistic targets after careful analysis of all the aspects. The Committee would like to be apprised of the steps taken by the Department in this regard."

2.4 The Ministry in its action taken reply has stated as under:

"In pursuance of the Committee's recommendations, the Department has undertaken in-depth assessment of eight ongoing schemes whose approved period is due to expire at the end of the current financial year and in respect of whom continuation of the scheme has been sought. This has been done as part of the preparation of the memoranda for appraisal by the Expenditure/Standing Finance Committee, taking into account the key findings of external evaluations carried out for each of these eight schemes.

Further, to ensure better match between budgetary allocation and its utilisation, advance planning and disbursement is being done with a view to ensure timely release of funds, quarterly expenditure targets are fixed to prevent last minute expenditure rush, monthly/quarterly financial monitoring meetings are being held to assess fund utilisation and address bottlenecks if any, fund allocation is linked with the actual progress and expenditure trends to avoid over-estimation. Further, progress on this is monitored on a weekly basis with all programme divisions and the Integrated Finance Division. As a result, the Department could release and spend 93.6% of the RE Budget in 2024-25, which was higher than in the preceding financial years."

Observation/Recommendation No.6

Disclosure of Complaints Regarding Quality of Medicines

2.7 The Committee had recommended as under:

"The Committee notes the importance of ensuring transparency and accountability in maintaining the quality of medicines supplied through Janaushadhi Kendras (JAKs). While the department has stated that all batches of medicines undergo 100% quality testing before distribution, it has not provided the exact number of complaints received regarding medicines quality through the CPGRAMS portal of the Government of India and emails to the Pharmaceuticals & Medical Devices Bureau of India (PMBI). The Committee believes that sharing such data is essential for public confidence in the Janaushadhi Scheme and for reinforcing the Department's commitment to quality

assurance. Instead of a general assurance, the Committee urges the Department to provide concrete information on the number of complaints received, the nature of concerns raised, and the corrective measures undertaken. This will help in addressing public apprehensions and ensuring that necessary actions are taken to uphold medicines quality. The Committee is particularly interested in understanding whether medicines failing quality checks are promptly recalled and whether appropriate measures, including penalties, are imposed on defaulting suppliers."

2.8 The Ministry in its action taken reply has stated as under:

"Any person may lodge grievances regarding 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. As against about 15 lakh consumers served daily through JAKs, 81 grievances lodged in the financial year (FY) 2024-25 related to quality issues, which is about 0.000015% of the total sale transactions in the year, *i.e.*, about 1.5 grievances per crore sale transaction.

The nature of such grievances pertains to issues like breaking of tablet, capsules becoming soft, consumer's doubt regarding effectiveness of medicine, etc. Immediately on receipt of such a grievance in respect of any medicine, *prima facie* verification of the grievance is carried out to verify details and sale of such batch of that medicine is put on hold till the anonymised medicine sample is tested and cleared. Such testing is done at labs accredited and periodically inspected by the National Accreditation Board for Testing and Calibration Laboratories (NABL) and, in addition, assessed by the scheme implementing agency (Pharmaceuticals and Medical Devices Bureau of India) for compliance with Good Laboratory Practices. To ensure that the medicine is not sold by any JAK till the sample has been tested and adherence to standards established, such sale is technologically barred on the point-of-sale (PoS) application using which Janaushadhi products are sold. In case the sample fails, sale of the batches concerned of that medicine is stopped forthwith across the supply chain and any batches available in the supply channel are recalled. Further, appropriate contractual action, such as forfeiture of security deposit, recovery of cost of entire batch and blacklisting or debarment of the manufacturer/drug supplied, is taken against the manufacturer."

Observation/Recommendation No.7

<u>Establishment of Price Monitoring and Resource Units (PMRUs) in All States/UTs</u>

2.9 The Committee had recommended as under:

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

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

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

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

2.10 The Ministry in its action taken reply has stated as under:

"PMRUs are operational in 31 States / Union territories (UTs). PMRU are yet to be established in five States/UTs, namely, Andaman and Nicobar Islands, Tamil Nadu, Delhi, Sikkim and Manipur. PMRU is set up as a registered society that functions under the direct supervision of the State drug control administration of the State/UT concerned. Therefore, PMRU can be set up in a State/UT only with the consent of the Government of the State/UT concerned.

NPPA is making efforts at all levels to set up PMRUs in the remaining States/UTs. In addition to letters to State/UT authorities, the matter has also been followed up with them on a sustained basis by deputing officers to expedite the process. As a result, the Government of the National Capital Territory (NCT) of Delhi has conveyed its consent for the proposed setting up of PMRU in the NCT of Delhi."

Observation/Recommendation No. 8

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

2.11 The Committee had recommended as under:

"The Committee notes that while the Department had submitted a proposal in 2021 for the establishment of new National Institute of Pharmaceutical Education and Research (NIPER) centres, the Expenditure Finance Committee (EFC) recommended prioritizing the strengthening and infrastructure development of the existing seven NIPERs instead. Consequently, the Department did not receive any budgetary support for setting up a new NIPER centre in Tamil Nadu.

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

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

2.12 The Ministry in its action taken reply has stated as under:

"With regard to enhancement of infrastructure in the seven existing NIPERs, including the specific steps taken for the same and the timelines and financial allocations earmarked therefor, institute-wise status is as under:

(a) The campus of NIPER, Mohali was completed in May 1995.

(b) *NIPER, Ahmedabad:* An amount of ₹ 103.88 crore was approved for construction of an area of 12,480 sq. metre in April 2018. The approved campus elements included institutional area, administrative area, residential area, hostels, guest house, Director's bungalow, and various campus amenities. The work was assigned to the Hindustan Steelworks Construction Limited (HSCL). After tender, work was awarded in December 2019 and construction started in June 2021. The work was completed in August 2023 and the campus was dedicated to the nation in September 2023.

(c) *NIPER, Guwahati:* Outlay for construction of campus was approved in FY2021-22 as part of the approval of NIPER scheme that year. An amount of ₹ 174.84 crore was approved for construction of an area of 27,688 sq. metre during January 2015 to September 2022. The approved campus elements included administrative block, academic blocks, hostels, residential quarters for staff and faculty, Director Bungalow, recreation facilities, animal house, central animal facility and various other developmental work. The work was assigned to the Engineering Projects (India) Ltd (EPIL). After tender, work was awarded in November 2012 and construction started in July 2015. The work was completed in October 2023 and the campus was dedicated to the nation in January 2024.

(d) *NIPER, Hajipur:* Outlay for construction of campus was approved in FY2021-22 as part of the approval of NIPER scheme that year. An amount of ₹ 72.65 crore was approved for construction of an area of 10,016 sq. metre in September 2022. The approved campus elements included administrative/academic building, hostel building and electrical substation. The work was assigned to the Central Public Works Department (CPWD). After tender, work was awarded in February 2023 and

construction started in February 2023. So far, 72% of work has been completed. Completion is expected by March 2026.

(e) *NIPER, Hyderabad:* Outlay for construction of campus was approved in FY2021-22 as part of the approval of NIPER scheme that year. Completion of land registration and transfer was done in May 2022. An amount of ₹ 103 crore was approved for construction of an area of 19,470 sq. metre in September 2022. The approved campus elements included R&D block, hostels and electric sub-station. The work was assigned to the National Projects Construction Corporation. After tender, work was awarded in September 2023 and construction started in January 2024. So far, 62% of work has been completed. Completion is expected by January 2026.

(f) *NIPER, Kolkata:* Outlay for construction of campus was approved in FY2021-22 as part of the approval of NIPER scheme that year. Completion of land registration and transfer was done in March 2022. An amount of ₹ 78.56 crore was approved for construction of an area of 10,974 sq. metre in September 2022. The approved campus elements included administrative and academic building, hostels, central animal facility / animal house building, boundary wall, and site development. The work was assigned to CPWD. After tender, work was awarded in April 2023 and construction started the same month. So far, 73% of work has been completed. Completion is expected by April 2026.

(g) *NIPER, Raebareli:* Outlay for construction of campus was approved in FY2021-22 as part of the approval of NIPER scheme that year. An amount of ₹ 77.92 crore was approved for construction of an area of 12,659 sq. metre in September 2022. The approved campus elements included administrative building, academic and research centre, animal house, Hostels, residential quarters, canteen, powerhouse and other utility services. The work was assigned to CPWD. After tender, work was awarded in March 2023 and construction started in March 2023. So far, 93% of work has been completed. Completion is expected by December 2025.

With regard to research facilities, faculty recruitment and industry collaborations, the status is as under:

(a) *Research facilities:* Under the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) scheme of the Department of Pharmaceuticals, each of the seven NIPERs has established a Centre of Excellence with aggregate budget outlay of ₹700 crore, with the aim of fostering advanced research and innovation and contributing to self-reliance in pharmaceuticals and medical technology. These are focussed on medical devices (at NIPER, Ahmedabad), bulk drugs (at NIPER, Hyderabad), phytopharmaceuticals (at NIPER, Guwahati), anti-viral and anti-bacterial drug discovery and development (at NIPER, Mohali), biological therapeutics (at NIPER, Hajipur), novel drug delivery system (at NIPER, Raebareli) and flow chemistry and continuous manufacturing (at NIPER, Kolkata).

Altogether, NIPERs have created capacities for excellence in research and development in diverse areas. Collectively, they have established 19 Centres of Excellence (CoEs). These include CoEs for National Centre for Pharmacoengineering, Centre of Excellence for Tribal Health Care, GMP Extraction Facility, Value Addition Center for Herbal Industry in the Northeastern States of India, GLP-Facilitated Animal Breeding and Husbandry Facility, Advanced Centre for

Computer Aided Drug Design, Adverse Drug reactions Monitoring Centre, National Toxicology Center, Natural Products Field Laboratory and Safe Technology Development Centre — Pilot Plant, Central Instrumentation Laboratory-CIL, Dr. Chigurupati Centre for Excellence in Innovative and Sustainable Pharmaceutical Development (CCE-ISPD), TDC-Dosage form (Formulation), Small and Medium Pharmaceutical Industry Centre, Central Animal Facility, Centre For Safety Pharmacology, Centre For Pharmaceutical Nanotechnology, National Bioavailability Centre.

(b) *Faculty recruitment:* As against 140 regular faculty members in position in November 2024 and total of 217 sanctioned faculty posts, 167 faculty members now are currently in position and offer letters have been issued against another 8 faculty posts, while recruitment against the remaining posts is in process.

(c) *Industry collaborations:* As part of academia-industry collaboration and exchange, NIPERs have signed more than 344 MoU with industries and other academic institutions, reflecting a strong commitment to fostering innovation through industry-academia collaboration.

(d) In line with the recommendations of the Hon'ble Committee, pursuant to a decision of the NIPER Council, a NIPER Academia-Industry Coordination Committee has been set up under the chairpersonship of the Secretary, Department of Pharmaceuticals as an institutional mechanism to promote strategic coordination between NIPERs and pharmaceuticals and medical devices industry by, among other things, facilitating greater synergies between NIPERs and industry and supporting research-driven growth, innovation, skilling and translation of academic research into industrial applications.

As a result of infrastructure development, recruitment of quality faculty and research and collaborations, the existing NIPERs have emerged as strong, high-quality pharmaceutical education and research, as evidenced by the following:

(a) NIPERs have so far published 8,722 research papers in various reputed journals and filed over 470 patents.

(b) 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 2025. They also rank high in terms of the calibre of their faculty, which includes 40 faculty members who figure in the prestigious Stanford Top 2% Scientists list.

(c) NIPERs are rich in terms of the specialisations that they offer. Collectively they have a total of 20 Departments. These include Biological Sciences, Biopharmaceuticals, Biotechnology, Clinical Research, Chemical Sciences, Medical Devices, Medicinal Chemistry, Natural Products, Pharmaceutical Analysis, Pharmaceutical Management, Pharmaceutical Technology (Biotechnology), Pharmaceutical Technology (Formulations), Pharmaceutical Technology (Process Chemistry), Pharmaceutics, Pharmacoinformatics, Pharmacology and Toxicology, Pharmacy Practice, Regulatory Affairs, Regulatory Toxicology and Traditional Medicine.

(d) NIPERs have established number of incubators to support innovation through startups. Collectively, NIPERs have established 16 incubators.

(e) So far, 10,974 students have graduated from NIPERs, consisting of 721 doctoral students, 8,894 postgraduates and 1,359 MBA degree-holders. These have contributed 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 of about 90%.

With regard to secure additional funding to expedite infrastructure strengthening while also facilitating the future establishment of new NIPERs, the status is as under:

(a) As part of the Expenditure Finance Committee (EFC) proposal for continuation of the scheme beyond March 2026, additional funding has been sought for further strengthening of infrastructure. In addition, under the PRIP scheme, beneficiary industry has been incentivised to collaborate with reputed Government academic and research institutions, including NIPERs, to augment research capacities at such institutions by way of utilisation of funds for collaborative projects approved under the scheme for creation of capital assets at the institution.

(b) The Department of Pharmaceuticals is in the process of formulating a proposal for a budget announcement regarding opening of new NIPERs."

(c)

Observation/Recommendation No.9

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

2.13 The Committee had recommended as under:

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

2.14 The Ministry in its action taken reply has stated as under:

"With a view to make optimal utilisation of the amount allocated under PRIP scheme, as recommended by the Hon'ble Committee, the Department of Pharmaceuticals has taken the following steps:

(a) Extension of the scheme beyond the financial year (FY) 2027-28 by two years, till FY2029-30 has been sought and secured from the Department of Expenditure.

(b) Under component A of the scheme, a Centre of Excellence have been established in each of the seven NIPERs and they have approved 111 research projects, published

46 research papers and filed six patents. Thus, utilisation of funds under this component is well under way.

(c) For component B of the scheme, extensive stakeholder consultation was undertaken, and the feedback, suggestions and information on potential project pipeline gathered during the consultations were used to analyse the scheme in-depth, with a view to enhance its impact. Based on the analysis, certain amendments to the scheme and revised guidelines were notified on 1.10.2025, and applications were invited through an online portal. By the final submission date of 19.11.2025, a high number of proposals (710) have been received from startups and industry and are being evaluated by the Technical Committee for submitting its recommendations to the Project Appraisal and Approval Committee for consideration and approval, with a view to ensure that funds are released to industry and startups for eligible projects within the current financial year."

Observation/Recommendation No. 10 & 11

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

2.15 The Committee had recommended as under:

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

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

2.16 The Committee further note that out of the 20 applications received under the strengthening of pharmaceutical scheme, 07 applicants have been shortlisted and just 06 applicants have been given final approval whereas in principal approval granted to one applicant has been cancelled and at present the Department has NIL number of applications. The

Committee desire to know whether in principle approval granted to a few applicants is sufficient enough to meet the objectives of the scheme."

2.17 The Ministry in its action taken reply has stated as under:

"As recommended by the Hon'ble Committee, the Department is undertaking regular, detailed review of the scheme, including for identification and addressing of any bottlenecks, utilisation of funds as well as their impact on the pharmaceutical sector, on an ongoing basis, through—

(a) meetings of the Scheme Steering Committee;
(b) meetings held by the Joint Secretary concerned in the Department with the applicants for the Assistance to Pharmaceutical Industry for Common Facilities (API-CF) sub-scheme and the Revamped Pharmaceuticals Technology Upgradation Scheme (RPTUAS) of the SPI scheme;
(c) the project management agency (SIDBI);
(d) webinars for industry, organised across States in association with industry associations and drugs regulators, for extensive outreach to elicit proposals for RPTUAS; and
(e) system of joint inspections by the Central and State drugs regulators, with a view to ensure timely certification of compliance with WHO-GMP norms in approved projects under RPTUAS.

Under API-CF sub-scheme, 8 projects with total approved grant-in-aid to the tune of ₹139.33 crore to pharmaceutical clusters for creation of common facilities and are at various stages of execution. Once these common facilities are created, they are expected to provide access to common facilities to around 1,300 existing pharmaceutical units, besides catalysing the augmentation of capacities at these clusters through the setting up of new pharmaceutical units and expansion of existing units. It is submitted that the same may be considered as substantially meeting the objectives of the scheme.

RPTUAS sub-scheme, launched in 2024, aims to support upgrade of production facilities of small and medium pharmaceutical companies having average turnover of less than ₹500 crore, to attain the standards specified in the revised Schedule M to the Drugs Rules, 1945 and the World Health Organization — Good Manufacturing Practices (WHO-GMP), thereby improving their competitiveness, both domestically and globally. Under RPTUAS, till 30.11.2025, 192 applications have been approved. Out of this, 86 applicants have reported completing upgrade of their pharmaceutical manufacturing units to the revised Schedule M and WHO-GMP standards. The remaining are at various stages of implementing technological upgrade.

Enabled by the SPI scheme launched in March 2022 and other initiatives, the annual turnover of the pharmaceutical sector has grown from ₹3.44 lakh crore in FY2021-22 to ₹4.72 lakh crore in FY2024-25.

Detailed status report, outlining specific projects funded, industry beneficiaries and measurable improvements that have resulted or are targeted, is at Annex."

Observation/Recommendation No. 12

PROMOTION OF MEDICAL DEVICE PARK

2.18 The Committee had recommended as under:

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

2.19 The Ministry in its action taken reply has stated as under:

"The second instalment of ₹30 crore each has been released to the three States, raising the total release to the States to ₹180 crore. Total fund utilisation till 30.11.2025 is ₹184.71 crore, which also includes Project Management Agency charges. Civil construction for the three parks is at the final stages and as of September 2025, 194 medical devices manufacturers stood allotted land in the three parks with a total area of 298.58-acre and 34 units had also commenced construction of their plants. Progress is being actively monitored with a view to ensure due completion of the parks at the earliest."

Observation/Recommendation No. 15

PRODUCTION LINKED INCENTIVE SCHEME (PLI Scheme)

2.24 The Committee had recommended as under:

"The Committee note that the tenure of PLI Scheme is from the year 2020-21 to 2029-30 with the total financial outlay of Rs. 69.40 crore and the selected applicants have already made an actual investment of Rs. 4253.92 crore and have also generated employment for 4473 individuals. Further, they have commissioned a total of 34 projects for 25 Bulk Drugs. The scheme has resulted in capacity creation for Bulk Drugs which were hithereto imported in the Country besides strengthening of fermentation technology manufacturing capability by commissioning of projects. The Committee are of the view that the objectives of the scheme are laudable and the Department has been able to implement the scheme successfully. The Committee recommend that the scheme may be strengthened further and the allocated outlay of Rs. 6940 crore may be optimally utilized till the end of the tenure of the scheme in the year 2029-30. The Committee have also been informed that a national level workshop was organized by the National Health Authority for all the States/UTs to check the misuse and irregularities under the PLI Scheme and necessary guidelines have also been issued. The Committee recommend that adequate action may be initiated so that the guidelines may be implemented in letter and spirit."

2.25 The Ministry in its action taken reply has stated as under:

"As recommended by the Hon'ble Committee, steps have been taken to further strengthen the scheme and optimally utilise the allocated outlay. These include the following:

(a) Projects for 5 more products have been approved recently.
(b) Proposals have also been invited for 2 more products.
(c) Legitimate representations of applicants have been considered with a view to resolve issues and to enable them to take optimal benefit of the scheme.
(d) Proactive coordination is being effected with the approved applicants through the Project Management Agency with a view to encourage and facilitate raising of claims on a quarterly basis, as against annual raising of claims earlier.
(e) Visa applications of foreign technical experts facilitated.

As regards the reference to a national level workshop organised by the National Health Authority for all States/UTs, it is submitted that to the best of knowledge, no such workshop has been organised in connection with the PLI scheme."

Observation/Recommendation No. 16 & 17

2.26 The Committee had recommended as under:

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

The Committee recommend that stringent action continue to be taken in similar cases in the future to ensure accountability. More importantly, the Department, in consultation with the Ministry of Health and Family Welfare, must urgently formulate clear guidelines and protocols to prevent such incidents from recurring. These guidelines should establish strict procedural safeguards for informed consent, adherence to medical ethics, and monitoring mechanisms to ensure compliance in all healthcare institutions."

2.27.

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

2.28 The Ministry in its action taken reply has stated as under:

"Under the Government of India (Allocation of Business) Rules, 1961, all matters relating to the medical profession and drugs standards are allocated to the Department of Health and Family Welfare. In respect of the matter of death of two patients after alleged performance

of angioplasty by Dr. Khyati Hospital, Ahmedabad, as intimated in the replies to points no. 23 and 56 of the list of points for written replies sent *vide* Department of Pharmaceuticals' OM F. no. 23003/2/2025-IFD, dated 10.3.2025, the said Department had earlier informed as under:

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

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

The Department of Health and Family Welfare has now further informed as follows:

(a) The National Health Authority under the Department has instituted robust safeguards and accountability mechanisms under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) scheme and has adopted a zero-tolerance approach towards any form of misuse or unethical medical practice under it. Dedicated National and State Anti-Fraud Units are operational to detect and act on fraudulent activities by empanelled hospitals. These units employ both rule-based triggers and advanced artificial intelligence / machine language techniques, including image de-duplication, fuzzy logic and social network analysis, to flag suspicious transactions. Based on these, desk and field audits are conducted, leading to stringent punitive actions wherever necessary.

(b) To further institutionalise clinical and ethical oversight, the following State-level committees have been mandated:

  (i) Medical audit committee;
  (ii) Mortality and morbidity review committee;
  (iii) Claim review committee; and
  (iv) Whistleblower committee.

(c) Significant efforts have been made to enhance technological safeguards and system transparency through the adoption of upgraded platforms — TMS 2.0, BIS 2.0 and HEM 2.0 — for real-time fraud detection, improved access control, and transparent claims processing. Over 23,000 hospitals have been linked to the Health Facility Registry and compliance with the Health Professional Registry has been made mandatory.

(d) A national workshop was organised on 17.1.2025 with participation from all States and Union territories, focussing on strengthening fraud control mechanisms and digital systems. The adoption of the aforesaid upgraded platforms was emphasised for improved transparency, real-time fraud detection and access control.

(e) A user management portal has been deployed to enforce secure access protocols, resulting in the removal of over 11 lakh inactive logins and geo-fencing of approvers to prevent misuse. States have been directed to immediately disable information technology access for hospitals found involved in serious misuse, and to act promptly

on system-generated alerts. An alert mechanism on the TMS platform now prompts State Health Agencies to initiate action on suspicious hospitals.

(f) Guidelines have been revised to mandate that action be taken in such cases within seven days, followed by Secretary-level review to ensure follow-through. As of March 2025, 9,361 hospitals have been flagged, of which 887 have been de-empanelled.

(g) Fund release is now limited to compliance with the National Anti-Fraud Guidelines, including mortality audits, medical audits and monthly fraud reporting. Face authentication has been integrated into card creation, empanelment, claims and grievance modules. Auto-approved packages are being reviewed.

(h) States have been asked to form Anti-Fraud Committees and adopt the Whistleblower Policy. Capacity-building of State Health Agencies, Third Party Administrators and public hospitals is done on an ongoing basis.

The National Health Authority has stated that the above measures demonstrate that the Authority, in coordination with States, is actively enforcing anti-fraud guidelines to uphold the integrity of AB PM-JAY and that it remains committed to maintaining the highest standards of ethical medical care under the scheme and to further formulate clear and enforceable guidelines on informed consent, ethical medical practices, and institutional accountability, in line with the committee's recommendation."

Observation/Recommendation No. 18

2.29 The Committee had recommended as under:

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

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

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

and ensure that patients have access to these life-saving interventions at genuinely affordable rates."

2.30 The Ministry in its action taken reply has stated as under:

"NPPA fixed and notified ceiling prices for Bare Metal Stent (BMS) and Drug Eluting Stent (DES), including metallic DES and Bioresorbable Vascular Scaffold (BVS) /Biodegradable Stents. Effective from 1.4.2025, the ceiling prices are ₹10,692.69 for Bare Metal Stents (BMS) and ₹38,933.14 for Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/Biodegradable Stents. All manufactures/marketers are required to sell coronary stents within the ceiling price fixed by NPPA.

Vide National Pharmaceuticals Pricing Authority notification S.O. 412(E), dated 13.2.2017, institutions such as hospitals, nursing homes and clinics utilising coronary stents are required to mention specifically and separately the cost of the coronary stent, along with its brand name, name of the manufacturer, importer, batch number and any other details, in their billing to the patients or their representatives.

NPPA has not received any complaint during last five years regarding overcharging for coronary stents."

Observation/Recommendation No. 19

2.31 The Committee had recommended as under:

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

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

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

2.32 The Ministry in its action taken reply has stated as under:

"NLEM is released by the Ministry of Health and Family Welfare (MoHFW). The inclusion/exclusion of the drugs in NLEM is done based on the recommendation of the Standing National Committee on Medicines (SNCM) constituted by MoHFW under the chairpersonship of the Director General, Indian Council of Medical Research (ICMR) and having on it all stakeholders and experts. The process of inclusion or deletion in NLEM is done by SNCM so constituted, from time to time, after comprehensive review to address the evolving healthcare needs of the country as arrived at through wide stakeholder consultation and expert opinion. Based on review by and the recommendations of SNCM as constituted by MoHFW, MoHFW issued the revised NLEM in September 2022. As per the NLEM 2022 report, the criteria adopted for inclusion of medicines are as under:

(a) The medicine should be approved/licensed in India.
(b) The efficacy and safety profile of the medicine should be based on robust scientific evidence.
(c) The medicine should be useful in disease which is a public health problem in India.
(d) All medicines enlisted in National Health Programmes/National Disease Control Programmes are as such essential and hence included in the NLEM, 2022.
(e) The medicine should be affordable to the community in the Indian context.
(f) The medicine should be readily accessible at Primary, Secondary and Tertiary healthcare levels.
(g) When more than one medicine are available from the same therapeutic class, preferably one prototype/ best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, availability and affordability.
(h) Overall cost of therapy was considered and not just the unit cost of the medicine.
(i) A Fixed Dose Combination (FDC) was generally not included unless the combination had unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance."

Observation/Recommendation No. 20

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

2.33. The Committee had recommended as under:

"As regard the availability of small scanning machine and other Medical Devices in rural areas for examination of pregnant women etc. the Department has submitted that the National Health Policy, 2017 recommends free drugs and diagnostics in public hospitals and aims to improve the quality of diagnosis and treatment. Under the National Health Mission (NHM), the Ministry provides financial and technical support to the States/UTs to strengthen their healthcare system for the provision of accessible, affordable and quality healthcare to all the people. The Ministry focuses on the availability of drugs and

diagnostics at all levels of healthcare as recommended in the National Essential Diagnostic List (NEDL) and Free Diagnostic Service Initiative (FDSI). Availability of diagnostics leads to a reduction in out-of-pocket expenditure of the patients. The Ministry of Health and Family Welfare had launched the FDSI programme under the National Health Mission in 2015 to provide accessible and affordable pathological and radiological diagnostics services closer to the community, which in turn reduces the out-of-pocket expenditure. In this regard the Committee desire to know whether the provisions of National Health Policy, 2017 are good in paper only and whether practically the benefits of the Policy are being delivered to the common man practically also."

2.34 The Ministry in its action taken reply has stated as under:

"The Department of Health and Family Welfare has informed that under the National Health Mission, financial support is provided to States and Union territories for provision of free essential medicines, based on needs identified in their respective Programme Implementation Plans. To standardise access, the Essential Medicines List (EML) was introduced in the year 2012 and revised in the year 2022, outlining the number of essential drugs to be made available at each level of public health facility. States are expected to notify their facility-wise Essential Drug Lists in alignment with the EML issued under the Indian Public Health Standards.

In parallel, the Free Diagnostics Services Initiative (FDSI), launched in the year 2015 and revised in the year 2019, has significantly expanded access to free diagnostic services across public health facilities. This initiative mandates availability of 14 tests at Ayushman Arogya Mandir (AAM) Sub Centres, 63 at AAM Primary Health Centres, 97 at Community Health Centres, 111 at Sub Divisional Hospitals and 134 at District Hospitals, thereby reducing high out-of-pocket expenditure incurred by patients on diagnostics. Currently, about 60% of the recommended diagnostics under FDSI are available at public health facilities. Further, the challenges associated with availability and accessibility of diagnostics are being addressed in various forums for improving the diagnostics infrastructure in the country. In this connection, a diagnostic module has been developed by the Department of Health and Family Welfare in the existing information technology platform for the Drugs and Vaccine Distribution Management System, with a view to mitigate supply chain bottlenecks in the availability of diagnostic reagents and consumables.

The National Survey Sample Office data from the 71st round in 2014 and the 75th round in 2017 show increase in utilisation of care at public health facilities from 28.3% to 32.5% in rural areas and from 21.2% to 26.2% in urban areas. Further, out-of-pocket expenditure as a share of total health expenditure has declined consistently over time, from 62.6% in the financial year (FY) 2014-15 to 39.4% in FY2021-22."

Observation/Recommendation No. 22

Strict Implementation of Drug Regulations to Curb Spurious and Adulterated Medicines

2.37 The Committee had recommended as under:

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

Despite these regulatory provisions, the Committee remains deeply concerned about the persistent issue of spurious and adulterated drugs circulating in the market, posing a serious threat to public health and safety. The Committee strongly emphasizes that mere amendments to regulations are not enough unless their implementation is strict, uniform, and effectively monitored across all States and Union Territories. There is an urgent need to ensure full compliance with these regulatory provisions, particularly in high-risk regions where counterfeit drugs are prevalent.

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

2.38 The Ministry in its action taken reply has stated as under:

Under the Government of India (Allocation of Business) Rules, 1961, all matters relating to drugs standards are allocated to the Department of Health and Family Welfare. The

said Department has informed that on 28.12.2023, the Government of India notified revised Schedule M requirements, whereby the requirements relating to “Good Manufacturing Practices” were upgraded to “Good Manufacturing Practices and Requirements of Plan and Equipment for Pharmaceutical Products”. For purposes of the revised requirements, manufacturers were divided into two categories, namely, large manufacturers with annual turnover of over ₹ 250 crore, and small and medium manufacturers with annual turnover of up to ₹ 250 crore, who were given timeframe timeframe of six months and 12 months respectively to comply. For the large drug manufacturers, the revised Schedule M has come into effect from 29.6.2024.

Considering representation made by small and medium manufacturers for extending the timeframe to enable improvement in infrastructure, training of personnel and arranging of financial resources, the Central Government amended the Drugs Rules, 1945 *vide* its notification dated 28.12.2023. Under the amended provisions, *vide* notification dated 11.2.2025, small and medium manufacturers have been given a timeframe of three months from 11.2.2025 to submit to the Central License Approving Authority, in specified form, their plan for upgrade and for such manufacturers who submit the said details, for the implementation timeframe to be extended till 31.12.2025.

For uniformity in the administration of the Drugs and Cosmetics Act, 1940, the Central Drugs Standard Control Organisation (CDSCO) as the Central drugs regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee meetings held with the State Drugs Controllers.

Further, drugs inspectors from CDSCO and State Drugs Controllers are trained from time to time to update their knowledge on legal provisions on spurious, adulterated, misbranded and Not of Standard Quality (NSQ) drugs and the procedure adopted for launch of prosecution and court proceedings.

The proposal regarding guidelines on Good Distribution Practices for pharmaceutical products was deliberated upon in a meeting of the Drug Consultative Committee held on 19.6.2024. As recommended by the said committee, the draft guidelines on Good Distribution Practices for pharmaceutical products have been posted on the website of CDSCO for comments from stakeholders. The comments received are under examination for further review by the committee.

In order to assess regulatory compliance of drug manufacturing premises in the country, CDSCO, in collaboration with State regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. So far, 905 units have been inspected, resulting in 694 actions being taken. Depending on the severity of non-compliance, the actions taken include orders to stop production, orders to stop testing, suspension or cancellation of licence and issuance of warning or notice to show cause.

This initiative has provided valuable insights into the ground reality of manufacturing practices and has led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

Further, as part of surveillance and monitoring activities, drugs inspectors draw drug samples from the supply chain at regular frequency for quality checks. In case the sample

is found to be Not of Standard Quality (NSQ), spurious, adulterated or misbranded, actions are initiated as per the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder.

The list of drugs of various companies that are declared NSQ, spurious, misbranded or adulterated by the Central Drugs Testing Laboratories are regularly uploaded on the website of CDSCO (www.cdsco.gov.in) under the heading “Drug Alert”.

DoHFW has further informed that as per information received from the Drugs Controllers of various States and Union territories, the number of drug samples reported NSQ, spurious or adulterated and the enforcement actions taken by the Drugs Controllers during the last three financial years are as under:

Financial year	Number of drugs samples tested	Number of drugs samples declared NSQ	Number of drugs samples declared spurious or adulterated	Number of prosecutions launched for manufacturing, sale and distribution of spurious or adulterated drugs
2021-22	88,844	2,545	379	592
2022-23	96,713	3,053	424	663
2023-24	1,06,150	2,988	282	604

Observation/Recommendation No. 23

2.39 The Committee had recommended as under:

“The Committee has been apprised that out of 4,57,910 drug samples tested, as many as 13,735 samples were found not of standard quality, and 1,547 samples were declared spurious or adulterated. Further, 2,516 prosecutions were initiated for the manufacture, sale, and distribution of spurious/adulterated drugs, leading to the arrest of 1,228 persons during the period 2019-20 to 2023-24.The Committee is deeply perturbed by these figures, which expose the alarming prevalence of spurious and substandard drugs in the market. While the detection of non-standard and spurious drugs is a serious concern in itself, the Committee finds it equally disturbing that the number of prosecutions and arrests is disproportionately low compared to the number of substandard and spurious drug samples identified. This indicates weak enforcement, inadequate punitive action, and possible lapses in regulatory oversight, which ultimately compromise public health and safety.

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

In this regard, the Committee recommends that the Department and the Ministry take urgent and concrete steps to: 1. Enhance surveillance and inspections across all manufacturing units, particularly in high-risk regions. 2. Expedite legal proceedings and ensure maximum penalties for those involved in the production and distribution of spurious drugs. 3. Increase inter-agency coordination, including collaboration with law enforcement agencies, to dismantle networks engaged in counterfeit drug production. 4. Strengthen penalties under the Drugs and Cosmetics Act to serve as a deterrent against the manufacture and sale of substandard drugs. 5. Launch a national awareness campaign to educate consumers and healthcare professionals about identifying counterfeit medicines and reporting violations.

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

2.40 The Ministry in its action taken reply has stated as under:

"Under the Government of India (Allocation of Business) Rules, 1961, all matters relating to drugs standards are allocated to the Department of Health and Family Welfare. The said Department has informed that as quality is the first and foremost priority, the Department and the Central Drugs Standard Control Organisation (CDSCO) are engaged continuously to address challenges and strengthen the drug enforcement system in the country. It has further informed that CDSCO and the Department have taken several measures to address the quality, safety and efficacy of medicines, as described below:

(a) In order to assess regulatory compliance of drug manufacturing premises in the country, CDSCO, in collaboration with State drugs regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. Depending on the severity of non-compliance, the actions taken include orders to stop production, orders to stop testing, suspension or cancellation of licence, and issuance of warning or notice to show cause.

(b) The Central Government, *vide* its notification dated 28.12.2023, amended the Drugs Rules, 1945 to revise Schedule M to the said rules, which relates to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. The revised Schedule came into effect from 29.6.2024 for drug manufacturers with annual turnover of over ₹ 250 crore. *Vide* notification dated 11.2.2025, manufacturers with annual turnover of up to ₹ 250 crore have been given time till 31.12.2025 to comply.

(c) To require manufacturers to print or affix on packaging labels of top-300 brands of drug formulation products bar code or Quick Response (QR) code that stores data or information legible with software application, to facilitate authentication, the Drugs Rules, 1945 were amended through notification dated 17.11.2022, which came into force on 1.8.2023, to provide for such printing or affixation in respect of the drug formulation products specified in Schedule H2 to the said rules. On 18.1.2022, the Drugs Rules, 1945 were amended to provide that every active pharmaceutical ingredient manufactured or imported in India shall bear QR code on its label at each level of packaging that stores data or information, readable with software application to facilitate tracking and tracing. Such stored data or

information shall include the minimum particulars, including unique product identification code, batch number, manufacturing date, expiry date, etc.

(d) On 11.2.2020, the Drugs Rules, 1945 were amended to provide that with effect from 1.3.2021, along with the manufacturer, any marketer who sells or distributes any drug shall be responsible for the quality of that drug as well as other regulatory compliances under said rules.

(e) The Drugs and Cosmetics Act, 1940 was amended to provide for stringent penalties for manufacture of spurious and adulterated drugs. Certain offences were also made cognizable and non-bailable.

(f) For speedy disposal of cases relating to offences under the Drugs and Cosmetics Act, 1940, State and Union Territory Governments have set up special courts.

(g) To ensure efficacy of drugs, the Drugs Rules, 1945 have been amended to provide that applicants for grant of manufacturing license shall submit along with their application the result of bioequivalence study of oral dosage form of certain drugs.

(h) The Drugs Rules, 1945 have been amended to make it mandatory that applicants submit to the State Licensing Authority evidence of stability, safety of excipients, etc. before such authority grants manufacturing license.

(i) The number of sanctioned posts in CDSCO has increased significantly over the last ten years.

(j) For uniformity in the administration of the Drugs and Cosmetics Act, 1940, the Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee meetings held with the State Drugs Controllers.

(k) The Central Government organises regular residential, regional training and workshops on Good Manufacturing Practices for officials of CDSCO and State Drug Regulatory Authorities. Over the last two financial years, CDSCO has trained 43,405 persons."

CHAPTER III

OBSERVATIONS/RECOMMENDATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLY

NIL

CHAPTER IV

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE WHICH REQUIRE REITERATION

Observation/Recommendation Nos. 1 and 2

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

5. The Committee had recommended as under:

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

The Committee note that the BE of the Department for the year 2023-24 was ₹3160.06 crore which was reduced to 2697.96 crore. 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 ₹6920.20 crore which has again been reduced to ₹5268.7 crore. As regard this reduction in the BE of the Department the Committee have been apprised that expected release under some schemes could not be made due to lesser demand in infrastructure schemes because of issues in tendering process, environmental clearances etc. non-fulfilment of targeted achievements to claim incentives etc. These were the primary reasons for which the budget had to be reduced at RE stage during FY 2023-24 and FY 2024-25. The Committee are of the view that the reasons cited by the Department are well within the administrative control of the Department itself. The Committee, therefore, recommend that the Department should initiate immediate steps to overcome issues related to tendering process, environmental clearances etc. and ensure that such issues does not hinder the Department from higher allocation of funds."

6. The Ministry in its Action Taken Reply has stated as under:

"As recommended by the Hon'ble Committee, the Department has taken steps to overcome issues related to tendering process, environmental clearances, etc. and to run schemes better. The following measures and improvements made as a result are submitted in this regard:

(a) To ensure proper budget utilisation, advance planning and disbursement is being done with a view to ensure timely release of funds, quarterly expenditure targets are fixed to prevent last minute expenditure rush, monthly/quarterly financial monitoring meetings are being held to assess fund utilisation and address bottlenecks if any, fund allocation is linked with the actual progress and expenditure trends to avoid over-estimation. Further, progress on this is monitored on a weekly basis with all programme divisions and the Integrated Finance Division. As a result, the Department could release and spend 93.6% of the RE Budget in 2024-25, which was higher than in the preceding financial years.

(b) To strengthen outreach for getting more applications under schemes to enable utilisation, in addition to publishing notices inviting applications in the newspaper and the website of the Department, social media handles of relevant organisations under the Department, other relevant Government Ministries, Departments and organisations as well as relevant industry associations are now being leveraged.

(c) Meetings are held regularly with Project Management Agencies (PMA), State Implementing Agencies, scheme implementing agencies and scheme beneficiaries and, where necessary, site visits are undertaken by officers of the Department / PMA to monitor the progress of schemes, expedite implementation and resolve issues.

(d) To institutionally and sustainably enhance programme management capabilities in the Department by avoiding fragmentation of project management across various schemes, a dedicated new scheme named "Scheme of Programme Management" for the five-year period beginning with the financial year 2026-27 has been approved. Under this, a pool of domain-specific experts, technical consultants and Young Professionals would be formed to create suitable capacities to support various Divisions of the Department, including a Management Team for professional management and technical guidance and oversight of the pooled resources. This will help ensure efficient resource utilisation, timely implementation and effective monitoring under various initiatives and facilitate sectoral expertise, optimise resource utilisation by identifying gaps and overlaps or duplication and facilitate review and appraisal of schemes.

(e) Under the Production Linked Incentive (PLI) schemes and the Strengthening of Medical Device Industry umbrella scheme, the Department, through the Project Development Cell (PDC) mechanism, is handholding applicants to facilitate resolution of issues related to commissioning of projects, as a result of which various issues such as land allotment, Petroleum and Explosive Safety Organisation (PESO) license, approval of the Central Drugs Standard Control Organisation (CDSCO), environmental clearances, etc. have been resolved.

(f) Under the Promotion of Research and Innovation in Pharma MedTech sector (PRIP) scheme, a consulting firm with demonstrated global and domestic experience in both pharma-medtech and research domains was onboarded in January 2025 as PMA to develop the strategy. The Department undertook extensive stakeholder consultation to gather feedback, suggestions and potential project pipeline information, analyse the same in-depth. Based on these consultations and feedback, the scheme was amend and its guidelines revised, with a view to enhance the impact of the scheme. As a result of such initiatives, high number of proposals (710) has been received in response to the call for proposals and work is under way with a view to ensure that selection of projects, completion of requisite formalities and release of funds to industry and startups is done within the current financial year. Further, under the component for support to the National Institutes of Pharmaceutical Education and Research for setting up Centres of Excellence, the institutes have been asked to ensure industry participation before taking up projects, with a view to ensure relevance of projects to industry.

(g) Under the Scheme for Promotion of Bulk Drug Parks, all three State Implementing Agencies have drawn up Program Evaluation and Review Technique (PERT) charts, with a view to ensure timely implementation. Further, the long-pending environment clearance for the proposed bulk drug park in Himachal Pradesh has been obtained, enabling progress on this project.

(h) Under the scheme for Strengthening of Pharmaceutical Industry, extensive outreach has been done in partnership with industry and drugs regulators across States through webinars to elicit proposals, resulting in approval of 192 projects under the Revamped Pharmaceutical Technology Upgradation Assistance Scheme. Moreover, system of joint inspections by the Central and State drugs regulators has been put in place, with a view to ensure timely certification of compliance with WHO-GMP norms.

(i) Under the Promotion of Medical Device Parks scheme, all required clearances have been obtained by State Implementing Agencies (SIAs) and major tenders for construction of common infrastructure facility (CIF) buildings have been awarded. This has resulted in actual allotment of land to 194 manufacturing units in the approved medical device parks and 34 units have commenced construction of their plants. Further, tenders for equipment to be installed in CIF buildings are at different stages of procurement. Thus, available funds are now being utilised in an unhindered manner to ensure their optimal utilisation."

COMMENTS OF THE COMMITTEE

(Please see Para No. 1.7 of Chapter – I of the Report)

Observation/Recommendation No. 5

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP)

Expansion of Janaushadhi Kendras (JAKs)

11. The Committee had recommended as under:

"The Committee note that while the Department has reported the establishment of 15,000 Jan Aushadhi Kendras (KAKs) as of 31.01.2025, their distribution across the country remains uneven, particularly in the Northeastern States and Union Territories. A closer examination of the state-wise data reveals that certain regions have a significantly lower number of JAKs, with only 9 in Andaman & Nicobar, 2 in Ladakh, 1 in Lakshadweep, 56 in Manipur, 25 in Meghalaya, 15 in Mizoram, 22 in Nagaland, 12 in Sikkim and 29 in Tripura. Given the objective of providing affordable medicines to all, the Committee believes that this distribution pattern needs urgent attention.

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

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

12. The Ministry in its action taken reply has stated as under:

"The Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme has an entrepreneur-driven model for opening of JAKs and expansion of the JAK network. Under this, applications are invited online through the scheme's website from individual entrepreneurs, non-governmental organisations, societies, trusts, firms, private companies, etc. With a view to proactively expand the network, including in remoter and less developed areas of the country, a proactive, timebound expansion strategy is being pursued as under:

(d) Pursuant to the announcement made by the Hon'ble Prime Minister in his Independence Day 2023 speech, a target to increase the number of JAKs opened in the country to 25,000 is being pursued in a phased manner, with phase-wise targets

being 10,000 JAKs by March 2024, 15,000 by March 2025, 20,000 by March 2026 and 25,000 by March 2027. Against these targets, the achievements so far have been 11,261 by March 2024, 15,403 by March 2025 and 17,610 by November 2025. Further, online applications are invited on a standing basis from all districts of the country through the scheme website (www.janaushadhi.gov.in) and in the processing of applications received, districts having less coverage are given special focus.

(e) Keeping in view population density, healthcare access and regional challenges, the following measures have been taken to ensure opening of JAKs in different parts of the country:

(iv) One-time incentive of ₹2 lakh is provided to outlets opened in 112 aspirational districts, the North-Eastern States, Himalayan areas and Island territories, as support towards furniture, computers, refrigerators and other fixtures. This is in addition to the incentive of 20% of the monthly purchases made by JAK owners, subject to a monthly ceiling of ₹20,000 and meeting certain conditions such as maintaining stock of specified medicines, for which all JAK owners are eligible.

(v) State Governments have been requested from time to time to provide rent-free space for opening JAKs in government hospitals, community health centres and primary health centres, and to create awareness about the scheme. So far, a total of 2,397 JAKs have been opened in public health facilities and other government centres.

(vi) To increase the number of JAKs in rural areas, the cooperative sector has been partnered with for opening JAKs through Primary Agricultural Credit Societies (PACS) and other cooperative societies. Till 30.11.2025, a total of 804 JAKs have been opened through PACS and other cooperative societies across the country.

As a result, the number and proportion of rural JAKs has grown to 9,475 and 54% respectively.

(f) Sustainable expansion of JAK network needs to be driven by higher volume of sales to increase their viability and attractiveness to entrepreneurs. To this end, the following steps have been taken to make citizens aware of the features and benefits of the scheme and its products:

(viii) *Awareness campaigns*: PMBI 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.

(ix) *Interactive messages/calls*: Outreach and citizen engagement are also pursued through WhatsApp chatbot and outbound calls to inform citizens regarding the quality of Janaushadhi products and the large savings that accrue from purchase of the same from nearest JAK.

(x) *Jan Aushadhi Week*: Pursuant to the Hon'ble Prime Minister's directions in 2019, 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, children engagement programmes, etc. are conducted across the nation to educate citizens, healthcare professionals and other stakeholders about the benefits of Janaushadhi generic medicines. The

7th Janaushadhi Diwas 2025 was observed on a substantially enhanced scale this year with participation of nine Union Ministers, two Chief Ministers, 156 Members of Parliament and 70 other State dignitaries. Events were held across 26 States and Union territories, at 231 locations, with a total of 32,431 participants. During the week, #JanAushadhi witnessed 996 mentions generating around 64,600 views and an estimated reach of 2.3 crore and #JanAushadhiDiwas was trending at number 3 in India on X. These campaigns aim to counter any incorrect perception about poor quality of generic medicines while emphasising the cost benefits of these medicines. The efforts taken to maintain the quality of Janaushadhi products are also highlighted in these campaigns.

(xi) *Directions for prescribing generic medicines:* The Department of Health and Family Welfare has issued directions to all Central Government hospitals and Central Government Health Scheme (CGHS) wellness centres to prescribe drugs with generic name.

(xii) *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.

(xiii) *Public engagement programme in rural areas*: To educate citizens in local languages/dialects, publicity is also done through health camps, *nukkad-natak*, audiovisual display at Common Service Centres and public engagement workshops in association with local JAKs in rural areas.

(xiv) In order to promote Janaushadhi products, an app namely Janaushadhi Sugam has been developed, which is a convenient tool for the general public to obtain information on Janaushadhi generic products and locate nearby JAKs to purchase these products."

COMMENTS OF THE COMMITTEE

(Please see Para No. 1.10 of Chapter – I of the Report)

Observation/Recommendation No. 13

PROMOTION OF BULK DRUG PARKS

14. The Committee had recommended as under:

" The Committee note that the scheme for Promotion of Bulk Drug Parks was approved way back in the year 2020 and the tenure of the Scheme is from the year 2020-21 to 2025-26. The objective of the scheme is stated to be to promote Bulk Drug Parks in the country for providing easy access to world class common infrastructure facility to Bulk Drug Unit located in the Parks to significantly bring down the manufacturing cost of Bulk Drugs and to make our Country selfreliant in Bulk Drugs by increasing the

competitiveness of the domestic Bulk Drug industry. For this purpose 03 States namely Gujarat, Himachal Pradesh and Andhra Pradesh have been selected and construction activities are stated to be in progress in these 03 States. However, the Committee regret to note that out of the 03 States selected for promotion of Bulk Drug Parks 02 states namely Gujarat and Himachal Pradesh are lagging behind and Development of the Bulk Drug Parks in these States is behind scheduled owing to delay in environmental clearances and change in location of Bulk Drug Parks etc. Under these circumstances the 03 States have submitted revised timeline upto March, 2026 for commissioning of Bulk Drug Parks. The Committee recommend that the Department should work in close cooperation with the State Government of Gujarat and Himachal Pradesh to resolve the issues which are hindering the development/construction work of Bulk Drug Parks in these States. The Committee also recommend that the issues be resolved expeditiously and vigorously pursued with the State Governments. The Committee also recommend that the Bulk Drug Parks may be given a concrete shape and should be made ready by March, 2026 invariably. The Committee would like to be apprised by the steps taken in this regard by the Department."

15. The Ministry in its action taken reply has stated as under:

"As recommended by the Hon'ble Committee, the Department is working in close cooperation with the State Governments concerned, with a view to expeditiously resolve issues that hinder progress. Steps taken in this regard are as under:

(g) Under the Scheme for Promotion of Bulk Drug Parks, all three State Implementing Agencies have drawn up PERT charts, with a view to ensure completion by March 2027. The Department of Expenditure has been requested to extend the scheme period by one year beyond March 2026.

(h) The long-pending environment clearance for the proposed bulk drug park in Himachal Pradesh has been obtained, enabling progress on this project.

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

(j) The Department has been conducting monthly review meetings with SIAs under the chairpersonship of the Joint Secretary concerned for monitoring physical and financial progress. During these interactions, the Department has been extending support to SIAs in expediting regulatory approvals, in coordination with the Ministries concerned.

(k) The Department / project management agency undertakes periodic site visits to the park sites to review progress with the representatives of the State Government, with a view to ensure the following:

(ix) Necessary regulatory approvals and clearances required for the Park;

(x) Release and award of tenders of approved CIF projects;

(xi) Project execution within the Scheme tenure; and

(xii) Fund utilisation.

(l) DO letters have been addressed to the Additional Chief Secretaries / Principal Secretaries concerned in the State Governments, apprising them of the progress and requesting expediting of progress."

COMMENTS OF THE COMMITTEE
(Please see Para No. 1.13 of Chapter – I of the Report)

Observation/Recommendation No. 14

17. The Committee had recommended as under:

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

18. The Ministry in its action taken reply has stated as under:

"The pace of expenditure has been slow on account of various factors. The same are summarised below:

(e) Bulk drug manufacturing is categorised as a red category industry under environmental regulations, on account of their polluting nature and risk to the environment. Accordingly, environmental clearance (EC) is a prerequisite for commencing construction work. Following receipt of approvals to set up bulk drug parks, the respective State Governments applied for EC in FY2022-23.

(f) In Gujarat, EC was delayed by 16 months owing to the recommendations of the Ministry of Environment, Forest and Climate Change (MoEFCC) to relocate the proposed 60 million litre per day marine discharge pipeline and EC was finally granted to the park only in February 2024.

(g) In Andhra Pradesh, relocation of Bulk Drug Park from Kakinada to Nakkapalli due to requirement of partial denotification of Special Economic Zone land delayed the project by 12 months. Following this, change to the new location was approved by the Scheme Steering Committee (SSC) in December 2023. Thereafter, EC for the project was received in March 2024. However, the State Government decided to accommodate an Integrated Steel Plant in the neighbourhood of the approved bulk drug park site and proposed modification of boundary at Nakkapalli, releasing 706.26 acres of existing land while adding 783.74 acres of new land. In-principle approval to the same was accorded by SSC on 23.6.2025.

(h) In Himachal Pradesh, EC was granted on 25.9.2025. The delay is primarily attributable to the complex terrain, seismic vulnerability and erosion-prone nature of the site. The draft Environment Impact Assessment (EIA) report was submitted to MoEFCC by the State Government in November 2023. Thereafter, the terms of reference for the EIA report were issued by MoEFCC in August 2024. Based on these, public hearing took place in November 2024 and final EIA report was submitted to MoEFCC by the State Government in January 2025. Following subsequent presentation by the State Government to MoEFCC, a site visit was conducted by MoEFCC's Expert Appraisal Committee (EAC) in April 2025. EAC recommended phased development, slope restrictions and soil and water conservation plans at the site. Based on these recommendations, the State Government, after complying with the suggestions, submitted a revised master plan, considering which MoEFCC finally accorded EC in September 2025.

As recommended by the Hon'ble Committee, the Department has analysed the reasons for the pace of fund utilisation and has taken the following steps to accelerate the pace of fund utilisation by the selected States:

(g) Under the Scheme for Promotion of Bulk Drug Parks, all three State Implementing Agencies have drawn up PERT charts, with a view to ensure completion by March 2027. The Department of Expenditure has been requested to extend the scheme period by one year beyond March 2026.

(h) The long-pending environment clearance for the proposed bulk drug park in Himachal Pradesh has been obtained, enabling progress on this project.

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

(j) The Department has been conducting monthly review meetings with SIAs under the chairpersonship of the Joint Secretary concerned for monitoring physical and financial progress. During these interactions, the Department has been extending support to SIAs in expediting regulatory approvals, in coordination with the Ministries concerned.

(k) The Department / project management agency undertakes periodic site visits to the park sites to review progress with the representatives of the State Government, with a view to ensure the following:

(xiii) Necessary regulatory approvals and clearances required for the Park;
(xiv) Release and award of tenders of approved CIF projects;
(xv) Project execution within the Scheme tenure; and
(xvi) Fund utilisation.

(l) DO letters have been addressed to the Additional Chief Secretaries / Principal Secretaries concerned in the State Governments, apprising them of the progress and requesting expediting of progress."

COMMENTS OF THE COMMITTEE

(Please see Para No. 1.16 of Chapter – I of the Report)

Observation/Recommendation No. 21

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

20. The Committee had recommended as under:

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

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

21. The Ministry in its action taken reply has stated as under:

"Against the backdrop of delays in commercial operations of projects selected under the Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices, on account of the covid pandemic and delays in securing requisite regulatory approvals, the Department of Pharmaceuticals had proposed to the Department for Promotion of Industry and Internal Trade (DPIIT) extension of the existing tenure of the scheme till the financial year 2026-27 (the last year for eligible production) by one year, *i.e.,* till the financial year 2027-28. However, DPIIT conveyed that the proposal for extension of the tenure for the scheme does not appear be consistent with the performance-linked construct of PLI schemes and may not be pursued further."

COMMENTS OF THE COMMITTEE

(Please see Para No. 1.19 of Chapter – I of the Report)

CHAPTER V

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT ARE STILL AWAITED

- Nil –

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

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

Annexure

Status report outlining specific projects funded, industry beneficiaries and measurable improvements that have resulted or targeted

I. ***Assistance to Pharmaceutical Industry for Common Facilities sub-scheme***

S. no.	Name of applicant	State / Union territory	District	Amount sanctioned (crore ₹)	Amount disbursed (crore ₹)
1.	Tirupati Research & Development Pvt. Ltd.	Andhra Pradesh	Chittoor	20.00	10.00
2.	Welzo Research & Development Pvt. Ltd.	Himachal Pradesh	Solan	19.53	17.58
3.	Himachal Pharma Testing Lab Ltd.		Solan	17.87	0.00
4.	Inducare Pharmaceuticals & Research Foundation	Maharashtra	Pune	7.18	6.46
5.	Tindivanam Pharma Park Association	Tamil Nadu	Tindivanam	15.88	6.00
6.	Jeedimetla Effluent Treatment Ltd.	Telangana	Medchal Malkajgiri	20.00	18.00
7.	Telangana Lifesciences Foundation (earlier Hyderabad Pharma city Limited)		Hyderabad	18.87	4.72
8.	Devbhumi Pharmaceutical Analytical Testing and Training Foundation	Uttarakhand	Haridwar	20.00	18.00

Status of ongoing projections under API-CF

1. Devbhumi Pharmaceuticals Analytical Testing and Training Foundation

1.1 Final approval was accorded on 22.3.2023 for setting up of chemistry lab testing and pharmaceutical microbiology testing at Haridwar, Uttarakhand, with total project cost of ₹23.68 crore and approved grant-in-aid of ₹20.00 crore.

1.2 A total of three instalments, amounting to 18 crores, have been released so far.

1.3 The project is already implemented during August 2025, SPV has applied for drug license and SPV informed that the inspection from Drugs Controller has been conducted during August 2025 and issuance of certificate is expected in 2 weeks. After receiving drug license, SPV will apply for NABL certificate. On completion, around 200 pharmaceutical units are expected to benefit from the project. Disbursement of final 10% instalment is expected in September 2025.

2. Welzo Research and Development Pvt. Ltd.

2.1 Final approval was accorded on 15.3.2023 for setting up of research and development and testing laboratory for pharmaceutical raw materials and formulation development at Baddi, Himachal Pradesh, with total project cost of ₹29.90 crore and approved grant-in-aid is ₹19.53 crore.

2.2 A total of three instalments, amounting to ₹17.57 crore, have been released so far.

2.3 The project is already implemented during August 2025, SPV has already obtained drug license and NABL Certification for NIPER, SPV informed that within two weeks SPV will apply for claim application. Around 200 pharmaceutical units are expected to benefit from the project. Disbursement of final 10% instalment is expected in September 2025.

3. Jeedimetla Effluent Treatment Ltd.

3.1 Final approval was accorded on 13.3.2023 for upgrade of common effluent treatment plant at Hyderabad, Telangana with total project cost of ₹29.17 crore and approved grant-in-aid of ₹20.00 crore.

3.2 A total of three instalments amounting to ₹18.00 crore has been released so far.

3.3 The project is already implemented during August 2025, SPV has applied Unit has been visited by SIDBI official on 12.9.2025, during visit it has been observed the overall operation of the unit were satisfactory. SPV has applied for final disbursement of final 10% instalment, same is proposed in present meeting. Around 400 pharmaceutical units are expected to benefit from the project.

4. Inducare Pharmaceuticals and Research Foundation (Phase-II)

4.1 Final approval was accorded on 12.9.2024 for upgrade of common testing facility quality control laboratory (GLP) process validating laboratory at Pune, Maharashtra, with total project cost of ₹14.38 crore and approved grant-in-aid of ₹7.l 8 crore.

4.2 A total of three instalments, amounting to ₹6.46 crore have been released so far.

4.3 The project is already implemented during August 2025, SPV has applied for NABL certification from NIPER, SPV informed that the inspection from NIPER has been conducted and issuance of certificate is expected in two weeks. On completion, around 150 pharmaceutical units are expected to benefit from the project. Disbursement of final instalment is expected in September 2025.

5. Tindivanam Pharma Park Association

5.1 Final approval was accorded on 17.3.2023 for setting up of common effluent treatment plant at Viluppuram, Tamil Nadu, with total project cost of ₹31.76 crore and approved grant-in-aid of ₹15.88 crore.

5.2 First instalment of Rs.6.00 crore has been released.

5.3 The project is under implementation, the construction of the ETP Project under process and approx. 60% of the work is completed. All machinery is expected to install at project site before 30.09.2025. SPV is hopeful of completion of Project by the end of December 2025. SPV would be seeking next instalment in September 2025 and last 10% in January 2025. The project is expected to be completed by 31.3.2026. On completion, around 40 pharmaceutical units are expected to benefit from the project.

6. Tirupati Research & Development Pvt. Ltd.

6.1 Final approval was accorded on 2.1.2024 for setting up of common facility centre for the research and development and testing and training facility at Tirupati, Andhra Pradesh, with total project cost of ₹29.90 crore and approved grant-in-aid is ₹20.00 crore.

6.2 First instalment of ₹5.00 crore has been released.

6.3 The project is under implementation stage, construction of the project site is completed, Machinery installation is under process and same will be completed before December 2025. On completion, around 150 pharmaceutical units are expected to benefit from the project.

7. Telangana Life Sciences Foundation (earlier Hyderabad Pharma City Ltd.)

7.1 Final approval was accorded on 21.9.2023 for setting up of antimicrobial resistance centre of excellence at Hyderabad, Telangana with total project cost of Rs.26.02 crore and approved grant-in-aid of ₹18.87 crore.

7.2 First instalment of ₹4.7l crore has been released. The project is expected to be completed by 31.3.2026.

7.3 The project is at implementation stage, construction of the project site is completed, order for Machinery and installation is under process. SPV has informed that the project is expected to be completed in March 2026. On completion, around 50 pharmaceutical units are expected to benefit from the project. SPV informed that they will apply for second instalment during September 2025.

8. Himachal Pharma Testing Lab Ltd

8.1 Final approval was accorded on 11.8.2025 for setting up of Contract Research Organisation (CRO) comprising of R&D-cum-production sections for the manufacturing of tablets, capsules, liquid dosage form, ointment and injection at Jharmajri, Tehsil Baddi District, Solan, Himachal Pradesh under API-CF Scheme, with total project cost of ₹19.87 crore and approved grant-in-aid is ₹17.87 crore.

6.2 First instalment is yet to be released.

6.3 The project is at initial stage, agreement with State Govt. for leasing of land and order for machinery is under process. The project is expected to be completed by 31.8.2027. On completion, around 150 pharmaceutical units are expected to benefit from the project.

II. *Revamped Pharmaceuticals Technology Upgradation Scheme*

S. no.	Name of the applicant approved/rejected	State/ Union Territory	District	Amount sanctioned (in lakh ₹)
1	Alivira Animal Health Limited	Andhra Pradesh	Anakapalli	112.54
2	Sionc Pharmaceutical Private Limited			170.63
3	Dinakara Life Science Private Limited		NTR	200
4	Inchem Laboratories Private Limited			33.24
5	Alapati Pharma		Prakasam	50.27
6	Aparna Pharmaceuticals Private Limited		Srikakulam	200

7	Signova Healthcare Pvt Ltd Unit-Ii	Assam	Kamrup	46.87
8	Ornate Labs Pvt Ltd	Bihar	Muzaffarpur	3.94
9	V S International Pvt Ltd	Daman	Daman	120.94
10	Navil Laboratories Pvt Ltd	Gujarat	Ahmedabad	126.51
11	Kentreck Laboratories Private Limited			76.68
12	Vasa Pharmachem Private Limited			50.26
13	Neha Life Science Pvt. Ltd.			52.6
14	Swati Chemicals			145.24
15	Manish Pharma Lab			93.8
16	Rajdip Pharmaceuticals			53.72
17	Trio Lifescience Pvt. Ltd.			55.04
18	Trio Remedies Pvt Ltd			90.87
19	Sg Healthcare Private Limited			48.67
20	Suchem Laboratories			107.84
21	Krozex Remedies Private Limited			57.32
22	Shelat Brothers			16.07
23	Carewin Pharmaceuticals Gujarat Private Limited			50.04
24	B. Sharda Pharma Pellets Private Limited		Banaskantha	45.04
25	Bakul Pharma Private Limited		Bharuch	111.45
26	Luxica Pharma Inc			67.62
27	Maruti Industries			11.74
28	Techno Drugs And Intermediates Pvt Ltd			53.83
29	Denis Chem Lab Ltd		Gandhinagar	66.91
30	Adrhim Pharmaceuticals Llp			75.71
31	Sbf Pharma Private Limited			200
32	Sruzam Labs Private Limited			47.7
33	Yash Medicare Private Limited		Himmatnagar	20.18
34	Pulse Pharma Manu Co			54.7
35	C P M Enterprise			16.4
36	Rusan Pharma Limited		Kutch	200
37	Sangharsh Lifecare Private Limited		Mehsana	177.98
38	Arnav Research Laboratories			67.95
39	Nucare Laboratories India			82.37
40	Shiva Healthcare			30.25
41	Shree Pharma (India)			200

42	Lexmark Pharmaceuticals Private Limited			58.1
43	Hbc Healthcare Private Limited			54.39
44	Lex-Mark Healthcare Llp			40.3
45	Seejar Pharmaceuticals			27.9
46	Exotic Pharma		Panchmahal	58.27
47	Parth Laboratories Private Limited		Rajkot	53.75
48	Adani Pharmachem Private Limited			21.16
49	Snj Labs Private Limited			176.33
50	Altis Finchem Private Limited		Sabarkantha	162.15
51	Salus Pharmaceuticals			104.5
52	Sanket Healthcare			19.46
53	Virdev Intermediates Pvt Ltd		Surat	200
54	Shc Pharmaceuticals			9.46
55	Sahajanand Life Sciences Private Limited			6.72
56	Vm Chemicals		Surendranagar	16.39
57	Nira Life Sciences Private Limited			10.33
58	Bdr Lifesciences Pvt. Ltd.		Vadodara	168.62
59	Bdr Pharmaceuticals International Pvt Ltd			200
60	Exemed Pharmaceuticals			163.95
61	Nebula Healthcare Limited			145.23
62	Ethicare Pharmaceuticals Pvt Ltd			81.18
63	Padmavati Chemicals Private Limited		Valsad	24
64	Avik Pharmaceutical Limited			113.12
65	Mcneil And Argus Pharmaceuticals Limited	Haryana	Ambala	128.09
66	Mitra Industries Private Limited		Faridabad	200
67	Protech Biosystem Pvt Ltd		Gurugram	85.97
68	M Sea Pharmaceuticals Private Limited	Himachal Pradesh	Sirmaur	82
69	Three B Healthcare Limited			109.4
70	Pharma Force Lab			200
71	Sirmour Remedies Pvt Ltd			167.21
72	Mediforce Healthcare Pvt Ltd			22.76
73	Brit Lifescience			128.4
74	Next Wave India			42.39
75	Varav Biogenesis Private Limited			192.09

76	Gnosis Pharmaceuticals Private Limited			48.65
77	Algen Healthcare Limited			112.22
78	Nixi Laboratories Private Limited			200
79	Caspian Pharmaceuticals			114.54
80	Saphnix Life Sciences			61.8
81	Athens Life Sciences			117.08
82	Park Pharmaceuticals		Solan	188.33
83	Ethix Health Care			97.46
84	Bennet Pharmaceuticals Limited			112.8
85	Higgs Healthcare			200
86	Goish Remedies Limited			107.56
87	Maxwell Pharma			102.46
88	Auraya Healthcare Unit-Ii			102.83
89	Medoz Pharmaceuticals Pvt Ltd			90.39
90	Unispeed Pharmaceuticals Private Limited			55.7
91	Alexi Pharmicia Pvt Ltd			65.39
92	Biodeal Pharmaceuticals Limited			105.3
93	Unix Biotech			34.6
94	Medicef Pharma			142.74
95	Osper Formulation Private Limited			200
96	Brd Medilabs			35.88
97	Legen Healthcare			77.47
98	Purobien Lifesciences			60.6
99	Healkraft Pharma (India) Private Limited			32.6
100	Dm Pharma Private Limited			40.21
101	Smayan Healthcare Private Limited			87.64
102	Soft Touch Pharmaceuticals Private Limited			31.46
103	Magbro Health Care Private Limited			58.73
104	Brooks Laboratories Limited			50.96
105	Syskem Pharmocrats			200
106	Auraya Healthcare			200
107	Lifecare Neuro Products Ltd			200
108	Hanuchem Laboratories Unit Three			91.03
109	Vowcare Products	Jammu & Kashmir	Pulwama	11.39
110	Protech Biopharma Pvt Ltd			89.14

111	Ce Chem Pharmaceuticals Private Limited	Karnataka	Bangalore	120.75
112	Recipharm Pharmaservices Pvt Ltd			200
113	Kemwell Biopharma Private Limited			93.6
114	Anglo-French Drugs & Industries Limited			124.58
115	Nandu Chemical Industries		Dharwad	60.93
116	Nandu Chemicals Pvt. Ltd.		Dharwad	133.35
117	M N Chemicals Limited		Uttara- Kannada	79.97
118	Chethana Formulations Pvt. Ltd.	Kerala	Malappuram	157.67
119	Labinduss Ltd		Palakkad	49.47
120	Megasys Biotek Private Limited		Thrissur	70.4
121	Hind Pharma	Madhya Pradesh	Bhopal	103.36
122	Beryl Drugs Limited		Dhar	67.95
123	Zenith Drugs Limited		Indore	113.5
124	Schon Pharmaceuticals Limited			97.4
125	Modern Laboratories			200
126	Nandani Medical Laboratories Pvt Ltd			200
127	Leben Laboratories Pvt Ltd	Maharashtra	Akola	200
128	Nitika Pharmaceutical Specialities Private Limited		Nagpur	200
129	Arco Life Science (India) Private Ltd			6.31
130	Scitech Specialities Pvt Ltd		Nasik	39.33
131	Emil Pharmaceutical Industries Private Ltd		Palghar	200
132	Sunshine Organics Pvt Ltd			200
133	Aveo Pharmaceuticals Private Limited			92.94
134	Oceanic Laboratories Private Limited			157.24
135	Surajlok Chemicals Private Limited			87.06
136	Korten Pharmaceuticals Private Limited			200
137	Murli Krishna Pharma Pvt Ltd		Pune	57.77
138	Aqua Fine Injecta Pvt Ltd			33.79
139	Hindustan Antibiotics Limited			200
140	Eisen Pharmaceutical Co Pvt Ltd			111.09

141	Sydler Remedies Pvt Ltd			17.93
142	Srikem Laboratories Private Limited		Raigad	24.2
143	Embio Limited			200
144	Sequent Scientific Limited			170.47
145	Kores (India) Limited			166.84
146	Anek Prayog Pvt Ltd			10.01
147	Vav Lipids Pvt Ltd		Ratnagiri	13.18
148	Great Pacific Export Private Limited		Thane	176.13
149	Anant Pharmaceuticals Pvt Ltd			17.66
150	Unilab Chemicals And Pharmaceuticals Pvt Ltd			5.67
151	Zen Chemicals Pvt Ltd			15.61
152	Orex Pharma Pvt Ltd			72.22
153	U S Pharma (India) Private Limited			136.24
154	Flamingo Pharmaceuticals Limited			94.14
155	M/S Jagannath Chemical And Pharmaceutical Works Private Limited	Odisha	Cuttack	66.34
156	Systacare Remedies	Punjab	Amritsar	11.07
157	Velite Pharmaceuticals		Ludhiana	35.56
158	Anuja Healthcare Limited		Mohali / Sas Nagar	188.7
159	Saurav Chemicals Limited			31.86
160	Torque Pharmaceuticals Pvt Ltd			112.3
161	Lark Laboratories India Ltd	Rajasthan	Khairthal - Tijara	63.83
162	Life Care Formulations Pvt Ltd	Tamil Nadu	Puducherry	5.44
163	Linux Life Sciences Private Limited			63.74
164	Saimirra Innopharm Private Limited		Chennai	115.88
165	Tychos Therapeutics Private Limited		Kancheepuram	73.89
166	Medibest Pharma Pvt. Ltd		Krishnagiri	200
167	Pharm Products Private Limited		Thanjavur	10.96
168	Sreepathi Pharmaceuticals Limited	Telangana	Hyderabad	105.84
169	Dano Vaccines & Biologicals Pvt Ltd		Medchal-Malkajgiri	56.2
170	Magnum Chemi Gran Pvt Ltd			200
171	Sanzyme Pvt Limited			69.53
172	Radicon Laboratories Limited	Uttar Pradesh	Gautam Buddha Nagar	35.7

173	Daffodills Pharmaceuticals Limited		Meerutt	29.9
174	Daffohils Laboratories Pvt Ltd	Uttarakhand	Dehradun	74.6
175	Karnani Pharmaceuticals Pvt Ltd			85.8
176	Pro-Pharma Care Pvt		Haridwar	114.68
177	Sarv Pharmaceuticals			52.5
178	Talent Healthcare			126.35
179	Prochem Pharmaceuticals Pvt Ltd			79.65
180	Evolet Pharmaceuticals Private Limited			170.25
181	Indian Drug Vision			31.69
182	Cotec Health Care Private Limited			143.88
183	Aagya Biotech Private Limited			22.61
184	Tulbros Formulations		Udham Singh Nagar	107.37
185	Tosc International Pvt Ltd			31.55
186	Pharma Impex Laboratories Private Limited	West Bengal	24-Parganas	200
187	Diamond Drugs Private Limited		Howrah	27.32
188	Vulcan Laboratories Pvt Ltd		Kolkata	191
189	Mendine Pharmaceuticals Pvt Ltd			23.52
190	Gena Pharmaceuticals Limited			26.52
191	Hygeia Pharmaceuitcals Mfg Pvt Ltd			30.2
192	Tetradrip Pharma Private Limited		Purba Bardhaman	70.4

APPENDIX I

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) Twentieth Report (18th Lok Sabha) on Action Taken by the Government on the Observations/Recommendations contained in the Eighth Report of the Standing Committee on Chemicals and Fertilizers (18th Lok Sabha) on 'Demand for Grants (2025-26)' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers;

(ii) xxxx;

(iii) xxxx; and

(iv) xxxx.

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

APPENDIX II

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE EIGHTH REPORT (EIGHTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2025-26) ON DEMAND FOR GRANTS (2025-26)' PERTAINING TO THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

	Total No. of Recommendations	23
I.	Observations/Recommendations which have been accepted by the Government: (Sl. Nos. 3, 4, 6, 7, 8, 9, 10, 11, 12, 15, 16, 17, 18, 19, 20, 22 and 23)	17
	Percentage of Total:	74 %
II.	Observations/Recommendations which the Committee do not like to pursue in view of the Government's replies: NIL	00
	Percentage of Total:	0%
III.	Observations/Recommendations in respect of which the replies given by the Government have not been accepted by the Committee and which require reiteration: (Sl. Nos. 1, 2, 5,13,14 and 21)	06
	Percentage of Total:	26 %
IV.	Observations/Recommendations in respect of which the final replies of the Government are still awaited: NIL	00
	Percentage of Total:	100%