11

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

(2024-25)

(EIGHTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

Action Taken by the Government on the Observations/Recommendations contained in the Fifth Report of the Standing Committee on Chemicals and Fertilizers (Eighteenth Lok Sabha) on 'Demands for Grants 2024-25' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

ELEVENTH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

AUGUST, 2025/ SHRAVAN, 1947 (SAKA)

CC&F NO. 191

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(2024-25)

(EIGHTEENTH LOK SABHA)

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(DEPARTMENT OF PHARMACEUTICALS)

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Presented to Lok Sabha on 20 August, 2025

Laid in Rajya Sabha on 20 August, 2025

LOK SABHA SECRETARIAT

NEW DELHI

AUGUST, 2025/ SHRAVAN, 1947 (SAKA)

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

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28. Dr. Kalpana Saini
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SECRETARIAT

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

INTRODUCTION

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

2. The Fifth Report was presented to Lok Sabha and also laid in Rajya Sabha on 16th December, 2024. The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers furnished their replies on 16th March, 2025 indicating Action Taken on the Observations/Recommendations contained in the Fifth Report. The Committee considered and adopted this Report at their Sitting held on 18th August, 2025.

3. An analysis of the Action Taken by the Government on the Observations/Recommendations contained in the Fifth 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;
18 August, 2025
27 Shravan, 1947 (Saka)

AZAD KIRTI JHA
CHAIRPERSON,
STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS.

CHAPTER-I

REPORT

This Report of the Standing Committee on Chemicals and Fertilizers deals with action-taken by the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) on observations/recommendations contained in their Fifth Report (18th Lok Sabha) on 'Demands for Grants (2024-25)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

1.2 The Fifth Report was presented to Lok Sabha and laid in Rajya Sabha on 16th December, 2024. It contained 33 Observations/Recommendations. The Action Taken Replies of Government in respect of all the Recommendations have been received and categorized as follows:

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

Rec.Para Sl. No. 2,3,4,5,6,7,8,9,12,13,14,15,16,17,18,19,22,23,24,25,26 27,28,29,30,31,32,33

(Total=28)

These are included in **Chapter II** of the Report.

(ii) Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:

Rec. Para No. -NIL- (Total=0)

These are included in **Chapter III** of the Report.

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

Rec. Para No. 1,10,11,20,21 (Total =5)

These are included in **Chapter IV** of the Report.

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

Rec. Para No. -NIL- (Total = 0)

These are included in **Chapter V** of the Report.

1.3 The Committee desire that the Action Taken Statement on the Observations/Recommendations contained in Chapter-I of this Report may be furnished to them at the earliest.

1.4 The Committee will now deal with action-taken by the Government on some of their Recommendations that require reiteration or merit comments.

PROPOSED AND APPROVED ALLOCATION FOR THE YEAR 2024-25

(RECOMMENDATION PARA NO. 1)

1.5 "The Committee note that the Department sought an amount of Rs.4089.95 crore for the financial year 2024-25. The Committee find consistent decline in funds allocated for various schemes/programmes run by the Department viz. For promotion of Bulk Drug Parks, Rs. 1,000.00 crore out of Rs. 1,352.00 crore sought; For Promotion of Medical Devices Parks, Rs. 150.00 crore out of Rs. 156.89 crore sought; For Human Resource Development in Medical Devices Sector (HRD) Rs.50.00 crore out of Rs.98.00 crore sought; For Assistance to Medical Device Cluster for Common Facilities (AMD-CF),Rs.40.00crore out of Rs.191.00 crore sought; and Consumer Awareness Publicity and Price Monitoring Rs. 4.00 crore out of Rs.6.00 crore sought. The Committee are perturbed to note that for Promotion of Research and Innovation in Pharma Med-Tech (PRIP), the allocation sought by the Department has been reduced by 50 percent. In this case, the allocation has been reduced to Rs.75.00 crore from Rs.150.00 crore sought by the Department. The Committee desire to be apprised of the reasons for reduced allocation of funds in each of the schemes/programmes being run by the Department and impact on their implementation. The Committee recommend that the Department should analyse the reasons for reduced allocation of funds in these Schemes and initiate corrective measures therein."

1.6 The Department in their Action Taken Replies has submitted as follows:

"The expected release under some schemes could not be made primarily due to lesser demand in infrastructure schemes on account of difficulties faced in successful completion of procurement processes, obtaining environmental and other

clearances/approvals, non-fulfilment of targeted achievements by beneficiary companies to be eligible to claim incentives.

The financial targets under the Scheme for Promotion of Medical Device Parks were not achieved due to non-submission of utilisation certificates by the selected States, despite follow- up. As a result, funds could not be released in past years. However, all approved State implementing agencies have now awarded tenders for civil construction of Common Infrastructure Facility buildings and work has started. Tenders for equipment to be installed in these buildings are at various stages of procurement. The second instalment is expected to be released within March 2025, upon due verification of requisite documents and submission of utilisation certificate for the first instalment.

Under the Capacity building and Skill development in Medical Device Sector scheme (formerly known as the Human Resource Development in Medical Devices Sector schemes), in- principle approval has been granted to 13 applicants for two-year degree or one-year postgraduate diploma courses and to five applicants for short-term certificate courses. These courses are expected to commence from the academic year 2025-2026, and release of funds will be on reimbursement basis, *i.e.*, the fund will be released once claim is submitted by the approved applicant. An amount of ₹ 0.90 crore has so far been utilised for payment towards professional fee of the project management agency.

Under the Scheme for Common Facilities for Medical Device Clusters, Budget Estimate (BE) for the financial year (FY) 2024-25 was ₹40 crore, which was reduced to ₹ 25 crore. This scheme was earlier known as the Assistance to Medical Device Cluster for Common Facilities scheme, and had provision for establishment of facilities for testing of medical devices and common facilities for manufacturing of medical devices. So far, six applicants have been selected to establish six testing facilities and four applicants have been selected to establish four common facilities for manufacturing of medical devices in the country. In-principle approval have been conveyed to all selected applicants between December 2024 to January 2025, and steps have been taken for opening of requisite Central Nodal Agency account to enable release of funds.

Further, under the new umbrella scheme of Strengthening of Medical Device Industry, launched on 8.11.2024, in-principle approval has been granted for proposals received under two sub-schemes, namely, the Capacity Building and Skill Development in the Medical Device Sector sub-scheme and the Common Facilities for Medical Device Clusters sub-scheme. For the selected applicants for the Common Facilities for Medical Device Clusters sub-scheme, the first instalment is expected to be released within March 2025, after due verification of requisite documents as per criteria specified in the scheme guidelines."

1.7. The Committee had noted that the Department had sought an amount of Rs. 4089.95 crore for the financial year 2024-25. The Committee also noted that there has been a significant reduction in the funds allocated for various schemes and programs run by the Department, including the Promotion of Bulk Drug Parks, Promotion of Medical Devices Parks, Human Resource Development in the Medical Devices Sector, Assistance to Medical Device Clusters for Common Facilities, and Consumer Awareness Publicity and Price Monitoring. The Department in their Action Taken Notes has submitted that the expected release under some schemes could not be made primarily due to lesser demand in infrastructure schemes on account of difficulties faced in successful completion of procurement processes, obtaining environmental and other clearances/approvals, non-fulfilment of targeted achievements by beneficiary companies to be eligible to claim incentives. Further the financial targets under the Scheme for Promotion of Medical Device Parks were not achieved due to non-submission of utilisation certificates by the selected States, despite follow up. The Committee are of the view that these issues were well under the administrative control of the Department and should be resolved expeditiously by the Department in consultation with the concerned organizations/agencies/State Governments. The Committee, therefore, recommend that necessary steps be initiated by the Department in this regard and the Committee be apprised accordingly to address the issues of reduced allocations to several challenges, including lower demand for infrastructure due to procurement difficulties, delays in obtaining necessary environmental clearances and non-fulfillment of targeted achievements by beneficiary

companies that are pre-requisites for claiming incentives. The Committee recommend that the Department ought to conduct a thorough analysis of the factors leading to decreased fund allocation and implement corrective measures, viz. streamlining the procurement process, improving communication with State implementing agencies to ensure timely submission of utilization certificates and timely completion of projects. The Committee may be apprised of the reasons for reduction in allocation of funds and the steps taken by the Department to ensure optimum utilization of resources.

1.7 A The Committee are also concerned to observe that BE for Financial Year 2024-25 which stood at Rs.40 crore was reduced to Rs.25 crore in respect of the 'Scheme for Common Facilities for Medical Devices Clusters' which was hitherto known as 'Assistance to Medical Devices cluster for common facilities Scheme.' Keeping in view the important target of the scheme viz. establishment of facilities for testing of medical devices and common facilities for manufacturing of medical devices, the Committee are of the considered view that reduction in the R.E. stage was apparently due to the inherent inefficiencies of the Department which would have definitely impacted the implementation of the Scheme. The Department's reply that steps have since been taken for opening of requisite Central Nodal Agency Account to enable release of funds also indicate the unpreparedness of the Department where action appears to have been initiated only at the fag end of the financial year and at the last quarter. The Committee may be apprised of the action taken in this regard.

SHOW CAUSE NOTICES ISSUED TO JAKS

(RECOMMENDATION PARA No. 10)

1.8 "The Committee are happy to note that about 42 Marketing Officers of PMBI are stated to have been deputed in different States / UTs to handle complaints of malpractice. Admittedly, Show Cause Notices are also issued for violating Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) norms resulting in a warning or cancellation in case of any confirmed malpractices. The Committee, however, desire

that the number of complaints received and resolved by the 42 Marketing Officers of PMBI during the last three years and also the number of Show Cause Notices issued under the Scheme including the number of warnings issued or cancellation for confirmed cases of malpractices found in JAKs may be furnished alongwith the analysis of the effectiveness of the extant monitoring system of JAKs.

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1.9 The Department in their Action Taken Replies has submitted as follows:

"During the financial year2022-23 and 2024-25, over 1,200, 1,500 and 1,800 show cause notices were respectively issued, with directions to remove violations and comply with conditions of the agreement. In case of repeated violations, PMBI takes steps to cancel the allotment of the Jan Aushadhi Kendra (JAK) concerned or to withhold its incentives for a specific period until the violation is resolved. There is effective monitoring of JAKs, and complaints are given priority for resolution.

Financial year wise details of show cause notices issued and JAKs closed are as under:

S.No.	FY	No. of Show Cause notice issued to JAKs	JAKs Closed
1	2021-22	1349	191
2	2022-23	1284	252
3	2023-24	1539	611
4	2024-25	1839	267
Total		**6011**	**1321**

1.10. The Committee had noted in their recommendation that 42 Marketing Officers of PMBI are stated to have been deputed in different States / UTs to handle complaints of malpractice form. The Committee observe that the issuance of Show Cause Notices to Jan Aushadhi Kendras (JAKs) has shown an alarming upward trend over the past few years, with a total of 6,011 notices

issued from the year 2021-22 to the year 2024-25. This escalation in notices correlates with the significant number of JAK closures, which too has risen to 267 from 191 in the year 2021-2022. The Committee are concerned about the increasing number of both Show Cause Notices and JAKs closures which indicates persistent malpractices and a need for stringent check of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) norms. The Committee therefore, recommend that a more robust and effective monitoring system for JAKs network be put in place so as to obviate scope for such malpractices.

INCLUSION OF ESSENTIAL MEDICINES FOR TB AND MENTAL ILLNESSES

(RECOMMENDATION PARA NO. 11)

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

1.12. The Department in their Action Taken Replies has submitted as follows:

"The recommendations of the Hon'ble Committee have been taken note of. PMBI, as part of its continuous process of augmenting the product basket under Jan

Aushadhi, would review whether any more additions may be done. Insofar as Benzyl Penicillin is concerned, it is informed that it was earlier available in the PMBI basket, but due to low demand and no sales, its procurement was discontinued. For anti-tuberculosis (TB) medicines, TB Mukt Bharat Abhiyan was launched in the year 2021 and registration of all TB patients was done under a separate campaign by the Ministry of Health and Family Welfare with the aim of providing free medicines. PMBI surveyed more than 100 JAKs and decided not to include anti-TB medicines due to low demand and the free availability under the aforementioned campaign. It is further informed that more than 278 medicines for mental ailments/illness are available in the PMBI product basket and more medicines may be added based on suggestions or demand from stakeholders. The medicine Atropine is already available in the PMBI basket according to the demand pattern."

1.13 The Committee had desired that the Department Should make efforts towards requisite augmentation of JAKs so that they become a one stop place for all kinds of medicines for the common people by bringing the life saving drugs for TB or Mental illness. The Department has submitted in their Action Taken Notes that the recommendation of the Committee have been taken note of. The Committee hope that these live saving TB or Mental illness drugs would be included in the PMBJP Product Basket. However, as regards Benzylpenicillin, it has been informed that the injection was available in the PMBI Basket but due to low demand and no sales its procurement has since been discontinued. Keeping in view the importance of the medicines the Committee desire that the decision to discontinue procurement due to low demand may be reviewed from time to time.

COURSE/CASTE-WISE STUDENTS IN TAKE AT NIPER FOR THE YEARS 2022-24

(RECOMMENDATION PARA NO. 20)

1.14. "The Committee note that NIPER has provisions for reservation for SC/ST/OBC students for admission in its different courses as per Government of India rules and are also giving concession in fees to SC/ST/OBC students. The Committee desire that the

number of SC/ST/OBC students admitted vis-à-vis total in-take of students course-wise in all the seven Centres of NIPERs during the last three years may be furnished to them."

1.15. The Department in their Action Taken Replies has submitted as follows:

Details of number of students belonging to the Scheduled Castes (SC), Scheduled Tribes (ST) and Other Backward Class (OBC) admitted and the total intake of students, course-wise, in the seven NIPERs during the last three years are as under:

NIPER	Course	**2022**			
		Total Student Intake	SC	ST	OBC
Mohali	Masters	285	38	20	100
	PhD	61	14	1	16
Ahmedabad	Masters	166	24	12	44
	PhD	35	4	2	12
Hyderabad	Masters	180	26	9	47
	PhD	49	6	3	14
Guwahati	Masters	144	22	11	50
	PhD	35	4	3	14
Raebareli	Masters	109	20	5	49
	PhD	30	3	2	11
Kolkata	Masters	88	18	6	41
	PhD	28	0	0	1
Hajipur	Masters	91	13	6	29
	PhD	19	3	0	5

NIPER	Course	**2023**

		Total Student Intake	SC	ST	OBC
Mohali	Masters	305	38	20	99
	PhD	79	12	0	23
Ahmedabad	Masters	178	27	12	51
	PhD	35	4	1	16
Hyderabad	Masters	193	25	14	44
	PhD	59	9	1	18
Guwahati	Masters	189	26	11	80
	PhD	49	10	3	22
Raebareli	Masters	110	15	7	42
	PhD	27	4	0	14
Kolkata	Masters	112	16	8	40
	PhD	28	1	0	0
Hajipur	Masters	109	12	5	27
	PhD	24	3	1	7

NIPER	Course	**2024**			
		Total Student Intake	SC	ST	OBC
Mohali	Masters	257	34	10	102
	PhD	12	0	0	3
Ahmedabad	Masters	150	20	10	37
	PhD	4	0	0	1

Hyderabad	Masters	214	27	15	50
	PhD	5	-	-	-
Guwahati	Masters	164	30	15	82
	PhD	21	4	2	8
Raebareli	Masters	99	13	4	36
	PhD	14	3	2	6
Kolkata	Masters	96	10	5	31
	PhD	5	0	0	5
Hajipur	Masters	55	7	4	13
	PhD	10	1	0	3

1.16. The Committee observe that despite the provisions for reservation and fee concession for SC, ST and OBC students at NIPERs, there remains a consistently low rate of intake for these students in the Ph.D. Courses across all seven NIPERs during the years 2022-2024. The data reveals that the number of SC, ST and OBC students admitted to Ph.D. courses is significantly lower compared to their intake in Masters' Courses with some Centres showing particularly dismal figures, such as NIPER Mohali in 2024, which admitted only 3 OBC students to the Ph.D. programme. The Committee recommend that NIPERs should initiate corrective measures to address this disparity including targeted outreach and support programs to encourage more SC, ST and OBC students to apply for Ph.D. courses, as well as provide a more additional academic support, conducive environment for these students to pursue and succeed in research based courses.

EXPANSION PLANS FOR POSTGRADUATE PROGRAMMES AT NIPER HAJIPUR (RECOMMENDATION PARA NO. 21)

1.17. "The Committee are dismayed to find that for NIPER, Hajipur, only 572 students

have passed out since the inception of the Institute (2007) till the academic year 2023-24 which *inter-alia* include every low data of students of Masters (Two years course) from the year2019 till date where student in take capacities is 435, out of 426 admitted are, 261 students graduated so far upto the 2022-24 Session. The Committee, therefore, recommend that special focus be given to NIPER, Hajipur Centre by the Department to increase the student intake and also improve the number of successful students."

1.18. The Department in their Action Taken Replies has submitted as follows:

"As per the record of the institute, data regarding the total number of students admitted and passed out since inception till now are as under:

(a) Masters programme (two years)
(b) Ph D programme

In the academic/admission year 2024, the total student in take in the postgraduate programme was 65. In the forthcoming academic/admission year 2025, the institute has proposed an intake of 78 in the postgraduate programme, keeping in view the existing faculty-student ratio and facilities available. Expansion of facilities and construction of new building for NIPER Hajipur is in progress. As the construction of new academic/administration building gets finished, student intake and new specialisations will be introduced in phased manner.

1.19. The Committee had recommended that special focus be given the NIPER, Hajipur Centre by the Department for increasing the student intake and also to improve the number of successful students. The Department has apprised the Committee that expansion of facilities and construction of new building for NIPER Hajipur was in progress and once the new academic/administrative building gets functional, student intake and new specialization would be introduced in planned manner. The Committee hope and trust that as assured the intake capacity of Hajipur NIPER would be enhanced and new specialization coursed would be introduced without any loss of time. The Committee may be apprised of the action taken in the matter.

CHAPTER II

OBSERVATIONS/RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

RECOMMENDATION NO. 2 and 3

2.1. The Committee note that the increasing Budget Estimates (BE) of the Department viz. BE (2021-22) stood at Rs.470.41 crore, BE (2022-23) enhanced to Rs.2,244.15 crore, BE (2023-24) enhanced to Rs.3,160.06 crore; and BE (2024-25) enhanced to Rs.4,089.95 crore. The Department has submitted that the reasons for consistently enhanced allocation was introduction of the three new Production Linked Incentives (PLI) Schemes in the year 2021-22 for a period of 5/6 years with a combined outlay of Rs. 25,360 crore. The Budgetary provisions were started from 2022-23 onwards, which increased the BE figures of the Department. Similarly, some new schemes of Development of Pharmaceuticals & Medical Device Industries were also approved during this period causing enhancement of BE (2022-23) onwards in comparison to BE (2021-22). The Committee are of the view that while the BE of the Department has been increased considerably for running new PLI Schemes introduced in the previous years, the consistently reducing RE figures as cited in Recommendation No.1 apparently reveals gaps in the implementation process. The Committee, therefore, desire that the Department should utilize the allocated funds in a time bound manner for successful and timely implementation of the schemes.

The Committee also note that the BE for the year 2023-24 which was Rs. 3,160.06 crore was drastically reduced to Rs.2,697.96 crore. The Department has submitted that the RE was reduced due to the reason that expected release under some Schemes could not be made due to lesser demand in infrastructure schemes because of inherent issues in tendering process, environmental clearances etc, non-fulfillment of targeted achievements to claim incentives etc. The Committee recommended that the issues and constraints cited may be worked out in a time bound manner so that the intended benefits of the Schemes reach the beneficiaries in time.

REPLY OF THE GOVERNMENT

2.2 The Hon'ble Committee's observations/recommendations have been taken note of.

The BE and Revised Estimate (RE) figures under the three PLI schemes for the last three years and the current status of their implementation and fund utilisation are as under:

(i) *Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs:* Under this scheme, FY 2022-23 and FY 2023-24 were the first years of performance for chemical-synthesis-based products and fermentation-based products respectively, under Greenfield projects. Establishment of the projects was initially impacted due to the COVID pandemic. Many projects under the scheme also faced challenges in acquisition of land, obtaining environmental clearance, drug-licensing approvals, etc., impacting their progress. As of December2024,a total of 34projects have been established for 25bulk drugs. It is expected that BE will be utilised fully in FY 2024-25.

(ii) *PLI Scheme for Pharmaceuticals:* Under the scheme, FY 2022-23 was the first year of performance. During the initial years, several selected applicants were unable to achieve their threshold investment criteria under the scheme guidelines, due to which they were found to be ineligible for claim of incentive amount. Implementation has since gathered pace. As of December 2024, the 55 selected applicants had made total actual investment to the tune of ₹ 34,771 crore against investment commitment of ₹ 17,275 crore. It is expected that RE allocated will be utilized fully in FY2024-25.

(iii) *PLI Scheme for Promoting Domestic Manufacturing for Medical Device:* Under the scheme, FY 2022-23 was the first year of performance, through Greenfield projects. Progress of the projects was impacted initially due to the COVID pandemic. Many projects under the scheme also faced challenges related to environmental clearance, manufacturing-licensing approvals, etc., impacting their progress. As of December 2024, a total of 19 projects have been established for 46 medical devices. It is expected that RE will be utilized fully in FY2024-25.

(iv) *Other schemes*: The fund utilisation position in respect of other key schemes has been submitted in the reply to point no. 1.

2.3 The Committee acknowledges the significant increases in the Budget Estimates (BE) for the Department, primarily driven by the introduction of three Production Linked Incentive (PLI) schemes aimed at bolstering domestic manufacturing, but expresses concern over the corresponding reductions in Revised Estimates (RE), indicating implementation challenges. The Committee urge the Department to address issues such as tendering processes, environmental clearances, and investment criteria compliance in a timely manner to ensure effective fund utilization and achievement of targeted outcomes. The Committee emphasizes the necessity for the Department to enhance its implementation strategies to guarantee that the benefits of these schemes reach the intended beneficiaries without delay, thereby supporting the overarching goal of promoting domestic production in the pharmaceuticals and medical device sectors.

RECOMMENDATION No. 4

2.4 The Committee are dismayed to note that the actual expenditure of the Department for the years 2021-22, 2022-23, 2023-24 also remained far less than the allocated funds. The Department has submitted that in the infrastructure's Schemes (Bulk Drug Parks, Medical Device Parks, Cluster Development Schemes) the release of funds depends upon the actual expenditure on the capital projects by the State agencies. This further depends upon the tendering processes and mandatory clearances from regulatory bodies and adding their shares of funds. Similarly, in the PLI Schemes, the actual release of incentives depends upon the fulfilment of Scheme guidelines and sanction provisions. The Committee were apprised that the Department has reviewed the functioning of the Schemes of Medical Devices and has formulated a new Umbrella Scheme in 2024-25 for Strengthening of Medical Device Industry for more focused approach and efficient utilization of funds. The Committee finds consolation to note that the Department has reviewed the functioning of the Schemes of

Medical Devices and has formulated the new Umbrella Scheme in the current financial year 2024-25. The Committee, however, desire that the Department should take up the matter at the highest level with State agencies etc. for more robust coordination to ensure timely and optimal utilization of funds in future.

REPLY OF THE GOVERNMENT

2.5 The slow progress in the medical device sector can be attributed to several factors, including initial delays in obtaining regulatory approvals, such as environmental clearance, and the emerging nature of the sector, which required additional time for the necessary technical support to prepare tenders.

The financial targets under the Scheme for Promotion of Medical Device Parks were not achieved due to the non-submission of utilisation certificates by the selected states, despite repeated follow-ups. As a result, funds were not released in the past years. However, all the approved states have now awarded major tenders for the civil construction of CIF buildings, and work has already started. Tenders for equipment to be installed in the CIF buildings are at different stages of procurement. The second installment is likely to be released by March 2025, after the verification of all documents and the submission of the utilisation certificate for the first installment. So far, land has been allotted to 140 medical device manufacturers in the selected medical device parks.

For effective implementation and optimal utilization of funds under the PLI schemes: Regular meetings are held with Project Management Agencies (PMAs) under the chairpersonship of Secretary, Department of Pharmaceuticals to monitor the progress and performance under PLI schemes. Through the Project Development Cell (PDC) mechanism, the Department also handholds applicants to facilitate resolution of issues related to commissioning of projects. Issues such as land allotment, Petroleum and Explosives Safety Organisation(PESO) licence, approval of the Central Drugs Standard Control Organisation (CDSCO), environmental clearance, etc. have been resolved.

2.6 The Committee finds that the actual expenditure of the Department for the years 2021-22, 2022-23, and 2023-24 was significantly lower than allocated funds due to delays in regulatory approvals, tendering processes, and state agencies'

contribution. While the Department has formulated a new Umbrella Scheme for the medical device industry in 2024-25 to improve fund utilization, the Committee recommends that the Department engage with state agencies and other relevant stakeholders at the highest level to ensure more robust coordination and timely, optimal utilization of funds in the future. This would help avoid underutilization and delays in project implementation.

RECOMMENDATION No. 5

2.7 . The Committee have noted that the fund utilized by the Department was94.14 percent, 90.37 percent, 90.15 percent for the year 2021-22, 2022-23, and 2023-24 respectively. Further, the Department have stated that the expenditure upto October, 2024 was Rs. 1,363.55 crores (33.34%) of BE and it will pick up in the subsequent months when the PLI beneficiary companies will be raising claims for incentives. Moreover, the releases under the Pharmaceuticals companies and Medical Devices Schemes will be made on the basis of demand from the concerned agencies and sanctioning of new proposals etc. The Committee hope and trust that the Department would be able to utilize the funds allocated in an efficient manner for the year 2024-25 too.

REPLY OF THE GOVERNMENT

2.8 The Department expects to utilize the funds allocated in RE 2024-25.

2.9 The Committee note that the Department utilized 94.14%, 90.37%, and 90.15% of the allocated funds for the years 2021-22, 2022-23, and 2023-24, respectively, and that as of October 2024, only 33.34% of the allocated funds for 2024-25 have been utilized. The Department has stated that expenditure will increase as PLI beneficiary companies raise claims for incentives and as releases under the Pharmaceuticals and Medical Devices Schemes are made based on demand and new proposals. The Committee hopes and trusts that the Department will efficiently utilize the allocated funds for 2024-25, ensuring timely and effective expenditure.

RECOMMENDATION No. 6

JAN AUSHADHI KENDRAS

2.10. The Committee note that in order to open Jan Aushadhi Kendras (JAKs) in rural and remote areas of the Country, the Department have apprised that the Pradhan Mantri Bhartiya Pariyojana (PMBJP) has partnered with the Cooperative Sector to maximize benefits of PMBJP Kendras in interior parts of the Country. Further, Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency of PMBJP has also entered in to an agreement for setting up of Jan Aushadhi Kendras in Primary Agricultural Cooperative Credit Society (PACs). In this regard, till 31st October 2024, 4,400+ PACS from 647 districts have applied & 2,695 Primary Agricultural Cooperative Credit Society (PACS) have also been given initial approval letter, of which 676 Jan Aushadhi Kendras have been opened in PACS. Besides, more than 1,000 applicants of PACS have been given online training. The Committee are happy that concerted efforts have been taken at the right time by the PMBJP and desire that the Department ensure that these JAKs opened in rural and remote areas are made functional at the earliest.

REPLY OF THE GOVERNMENT

2.11 The Department of Pharmaceuticals, in coordination with the Ministry of Cooperation, is facilitating the opening of Jan Aushadhi Kendras (JAKs) in Primary Agricultural Credit Societies (PACS) and other cooperative societies to enable the benefits of quality Jan Aushadhi medicines reach rural and remote are as of the country.Asof31.1.2025, the number of JAKs opened by PACs and other cooperative societies stood at 719. Review meetings are held from time to time with officials from the Ministry of Cooperation and State Governments, including Registrars of Cooperative Societies, to facilitate the opening of JAKS in PACS and other cooperative societies.

2.12 The Committee are not satisfied with the Action Taken Notes furnished by the Ministry which are not only evasive but also lack clarity on critical issues such as issues relating to reduction in the double regulatory burden to comply

with labelling and packaging requirements; exemption of accessories /components pertaining to medical devices from compulsory registration. The Committee are not satisfied with the casual and routine reply of the Ministry on these issues. The Committee while reiterating their earlier recommendations urge the Ministry to intensify the measures to address the issues which are still under the deliberation of NMDPC with utmost sincerity as they are associated with medical products which may have implications on quality and safety of medical device products.

RECOMMENDATION No.7

2.13 The Committee have been apprised with regard to the quality of generic medicines and their review by the Department that PMBI procures medicines only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers for ensuring the quality of the products. Apart from this, each batch of drug is tested at laboratories accredited by 'National Accreditation Board for Testing and Calibration Laboratories' (NABL) and only after passing the quality tests, the medicines are dispatched to PMBJP Kendras. PMBI also does routine quality audit of the facilities of vendors and carries out public outreach & campaigns throughout India to do away the false perception about poor quality of generic medicines and emphasize that the quality of Jan Aushadhi generic medicines areas good as branded ones. The Committee are happy to observe that PMBI has initiated sufficient measures to ensure the quality of the medicines made available at JAKs. The Committee, however, recommend that PMBI as well as the Department should make surprise visits at JAKs and undertake requisite tests on samples of medicines etc., from JAKs to keep them on their toes with the overall aim to ensure the quality of medicines sold by JAKs.

REPLY OF THE GOVERNMENT

2.14 The Hon'ble Committee's recommendation to collect samples of medicines from Jan Aushadhi Kendras (JAKs) is taken note of for necessary action.

2.15 The Committee feels that the Action Taken Note submitted by the Ministry is not only ambiguous but is also devoid of facts. The soft peddling

being done by the Ministry to ask the existing medical device testing laboratories to submit without any follow up action clearly indicates the casual approach of the Ministry in dealing with the critical issue of such magnitude. The Committee are of the view that the Ministry should make genuine efforts to take cognizance of the recommendation given by the Standing Forum on Medical Device Association in order to streamline logistics and also to optimize the transition towards licensing of all types of medical devices and requirement of testing equipments and testing infrastructure for Class A,B,C and D type of medical devices. The Committee further desires that the Ministry of H&FW/CDSCO ought to monitor implementation of the recommendations of the standing forum and device a framework to establish right kind of environment and infrastructure to ensure smooth transition. The Committee may be apprised of the progress /status from time to time.

RECOMMENDATION No. 8

2.16 The Committee note that, as on date, about 3188 number of applications for opening of Jan Aushadhi Kendras was pending with PMBI at different stages out of which 2,692 applications are stated to have been given in principle approval and 496 applications are stated to be under review. As regards the complaints filed by customers/general people regarding availability and quality of medicines, the Committee have been apprised that Pharmaceuticals & Medical Devices Bureau of India (PMBI) has a Store Complaint & Facilitation cell (e-mail ID-complaints@janaushadhi.gov.in) to analyze and resolve the queries of the customers as well as entrepreneurs. Further, a toll – free helpline number 18001808080is also being operated with 06 (Six) telecallers to address the queries of the customers, Jan Aushadhi Kendra owners and applicants etc. Besides, the complaints/ grievances received through other portals like RTI, CPGRA Mare also addressed by PMBI regularly in a timely manner and strict quality control mechanisms are in place to ensure compliance of standards and no major quality issue has arisen so far. The Committee observe that though the complaint redressal system of PMBI appears to be satisfactory, the Committee, however desire that all the complaints received as well as the 496 number of applications lying pending with the PMBI may be disposed off at the earliest.

REPLY OF THE GOVERNMENT

2.17 Most queries regarding the opening of new Jan Aushadhi Kendras (JAKs) pertain to procedure and are not in the nature of complaints from citizens. All complaints received via email are attended to by the divisions concerned in PMBI and reviewed at senior management level. With regard to the number of pending applications, it is informed that all such applications are reviewed and disposed of in due course. PMBI receives applications for opening new JAKs online every month, making it a continuous process. Therefore, there will always be some applications under review due to deficiencies in documentation or failure to meet eligibility criteria. Such applicants are informed and advised to complete the necessary documentation to facilitate the opening of a new JAK. Further, the details of the 496 applications are under:

Initial approval given—	297
Documents awaited	176
Applications rejected	23
Total	**496**

RECOMMENDATION No. 9

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

REPLY OF THE GOVERNMENT

2.19 The monitoring mechanism to ensure best quality is already in place, and there have been no specific concerns regarding the quality of medicines in the last two years. As regards the quantity of medicines sold, the entire process of supplies to Jan Aushadhi Kendras (JAKs) are captured in the Point of Sale (PoS) system run under Systems, Applications and Products (SAP).Through SAP, complete supply of a

particular JAK is recorded and based on these records, JAK is eligible for both purchase-based and stock-based incentives with maximum limit of ₹ 10,000 each.

2.20 The Committee note with satisfaction that the applications for grant of manufacturing license for all class of medical devices will be reviewed and processed subject to fulfillment of eligibility criteria. While the Ministry has spelt out the course of action for the grant of license in respect of Class C&D medical device with effect from 01.10.2023, the Action Taken Notes do not mention insofar as grant of license in respect of Class A&B medical devices are concerned. The Committee reiterate their earlier recommendation and impress upon the Ministry to ensure that all the necessary arrangements will be made to complete the process of issuance of license to the manufacturers of all kind of device in a time bound manner.

The Committee also recommends that since Class A&B categories are regulated by the State License Authorities (SLA), the Ministry should sensitize the States that on their part that arrangements are required to be made so that best practices are implemented without unnecessary skewed delays as is commonly believed.

RECOMMENDATION No. 12

2.21 The Committee note that in order to ensure that the medicines being sold under PMBJP scheme are not duplicate or 'expired' and to obviate scope for such irregularities in Jan Aushadhi Kendras, the Department has come out with a "Janaushadhi Sugam" mobile application which serves as a vital resource for the general public, offering a user- friendly digital platform that provides a range of convenient services at their fingertips. Through this App, users can easily locate nearby Janaushadhi Kendras (JAKs) with directions powered by Google Maps, search for Janaushadhi medicines, and compare the prices of generic versus branded medicines, highlighting potential savings in MRP. The Committee were apprised that there has been no instance of any duplicate medicines ever reported; JAKs have to ensure that 'expired medicines' are not sold to customers; and PMBI does not supply those medicines which have short life of 03 months or less. The Committee appreciate the launch of "Janaushadhi Sugam" mobile application. The Committee, however, feel that

it is the duty of the PMBI and the Department to ensure stoppage of expired or duplicate/substandard medicines at JAKs and it should not be left in the hands of only the JAKs. The Committee, therefore, recommend that more stringent steps may be taken to obviate scope for this malpractice. The Committee would like to be apprised of the steps taken by the Department/PMBI in this regard.

REPLY OF THE GOVERNMENT

2.22 As per PMBI's policy, PMBI does not sell medicines that have a remaining shelf life of three months or less. Further, legal provisions require that expired medicines not be sold by any retailer at any JAK as they are bound by the drug license conditions issued to them by the respective State Governments / Union Territory Administrations. The entire supply chain of Jan Aushadhi medicines is in a closed loop and medicines are supplied to distributors and retailers only after centralised procurement and quality testing. No complaint has been received regarding duplication of Jan Aushadhi medicines. Campaigns by way of newspapers and social media advertisements are also run to sensitise customers/beneficiaries, with a view to enable them to identify the Jan Aushadhi logo while making purchases and encouraging them to take advantage of Jan Aushadhi products. In view of the recommendations of the Hon'ble committee, PMBI field officers have been instructed to monitor compliance of instructions.

(RECOMMENDATION PARA NO. 13)

2.23 The Committee note that under the PMBJP, sanitary pads at Rs. 1/- per pad are sold through its network of more than 14,000 JAKs functioning across the Country. The Committee further note that in an appreciable noteworthy initiative, the Government of Telangana have made available sanitary napkins in Schools for girls students by installing booths/vending machines. The Committee are of the opinion that the Telengana model need to be replicated across the Country. The Department submitted that the matter does not pertain to Jan Aushadhi and they have referred it to the Ministry of Health and Family Welfare. The Committee are not happy with the contention of the Department as sanitary napkins are already being sold at the rate of Rs. 1/- per pad in JAKs and it was just the step of making it easily accessible for the convenience of the girl students across the Country by installation of dispensing machines/booths. The

Committee, therefore, recommend that the Department may consider the feasibility in consultation with the Ministry of Women and Child Development or Ministry of Health and Family Welfare, if required. The Committee would like to be apprised of the steps taken by the Department/PMBI in this regard.

REPLY OF THE GOVERNMENT

2.24 As on 31.1.2025, a total of 15,000 Jan Aushadhi Kendras (JAKs) had been opened across the country. Sanitary napkins are available in all JAKs, and their consumption has increased significantly. Till 31.3.2025, approximately 72.63 crore pads have been sold across the country at ₹ 1.00 per sanitary pad through these 15,000 JAKs.

Recommendation of the Hon'ble committee for considering feasibility of dispensing machine/booths in consultation with the Ministry of Women and Child Development or the Ministry of Health and Family Welfare have been taken note of for necessary action.

RECOMMENDATION No. 14

National Institute of Pharmaceuticals Education and Research (NIPERs)

2.25 The Committee note that since the inception of NIPER, a total number of 10,810 students (10,159 – M Pharma/MBA; 651- PhD) have passed out who are working in the industry as well as R&D and Academic Institutions. Further, NIPERs have signed about 303 MOUs with industries and other academic institutions till September 30, 2024 more than 425 patents have been filed till September 30, 2024 and about 8,048 research papers have been published in various reputed journals by the seven working NIPERs till September 30, 2024. The committee find that during the last three years, 3,608 students were enrolled in different courses offered by NIPERs out of which 2,937 students successfully. The Committee, however, find that since inception of NIPER, out of 14,890 students enrolled in seven centres of NIEPRs at Mohali, Guwahati, Ahmedabad, Hyderabad, Hajipur, Kolkata and Raebareli, only 10,960 students passed out successfully indicating a large number of students who were declared unsuccessful i.e 3,930. The Committee recommend that the Department in consultation with NIPER undertake a serious study to analyse the gap between the number of students enrolled

and number of students declared successful each year with a view of take concrete steps to improve the scenario.

REPLY OF THE GOVERNMENT

2.26 The difference between the number of students enrolled and number of students declared successful from NIPER may be attributed to the ongoing postgraduate and PhD programmes. At the postgraduate level, which is a two-year course, there would be two batches of students who are enrolled but currently pursuing their studies and hence have not passed out. Similarly, there are students at PhD level who are enrolled and pursuing their studies. Additionally, factors such as health issues, selection for government jobs, offers for a better course at other institutions in India and abroad may also contribute to difference in the number of students enrolled and passed out from NIPERs.

RECOMMENDATION No. 15

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

REPLY OF THE GOVERNMENT

2.28 Graduating PhD students have either been absorbed by pharmaceutical companies or found post-doctoral positions in academia in India or abroad. NIPER Mohali is taking proactive steps to enhance placement every year. In the last year batch (2022-2024), out of 262 interested students, 235students were placed(placement 89.69%)and80companies visited NIPER Mohali for recruitment.

Actions taken by NIPER Ahmedabad for improving placement footprint include the following:

(a) The visibility of NIPER Ahmedabad to local industries has been increased through various events, including industry-academia interactions, alumni meet, etc.

(b) Individual departmental faculty coordinators for each department have been identified for making connections with alumni working in industry.

(c) Training in soft skills has been imparted to students.

(d) NIPER Ahmedabad has been working on feed back received from industry and has implemented a policy for securing better employability of students.

(e) NIPER Ahmedabad has enhanced infrastructure relevant to industry needs, which has helped in making students industry-ready.

The placement record of NIPER Raebareli for the academic session 2023-2024 has been exceptional, with 97% of students securing positions in leading pharmaceutical industries and the remaining 3% pursuing higher studies at reputed institutions, achieving a 100% absorption in either jobs or higher studies.

NIPER Kolkata is imparting soft skill development training to students. Five companies have participated in placements. The institute has invited more companies for placement, with a view to enhance placement. Number of steps have been taken by the institute for this, which include the following:

(a) The institute is providing its students exposure to industry through industrial training and hands-on work experience, thereby ensuring that students are well-prepared for the industry with practical knowledge and real-world problem-solving experience.

(b) It is imparting training to develop soft skills of its students.

(c) It is doing extensive outreach to bring companies to participate in on-campus placement activities, resulting in more than 50 companies participating in the current round of placements.

NIPER Hajipur has established a Placement and Training cell in the year 2021.Thereafter, placement in industry and percentage of Masters students enrolled for higher studies has improved significantly. The placement rate was 86.44% immediately

after three months of graduation for the batch that graduated in the year2024. Placement percentage for the graduating batch has touched about 95%.

RECOMMENDATION No. 16

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

REPLY OF THE GOVERNMENT

2.30 Seven Centres of Excellence (CoEs) have been established, one at each NIPER. As of 3.2.2025, these CoEs have approved a total of 67 projects, filed two patent applications, and published three research papers. Procurement of capital equipment, consumables, engagement of requisite manpower and construction activities are in progress.

RECOMMENDATION No. 17 and 18

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

The Committee further note with concern that the BE(2024-25) of NIPERs has been proposed at Rs.242.00crore which is almost 50% less than BE (2023-24) which

was Rs.550.00 crore. The Committee were apprised by the Department that based on the reduced expenditure pattern of previous year and in accordance with the EFC ceiling, the BE 2024-25 has been kept at Rs. 242 crore. The Committee desire that the Department should take ameliorative steps for timely utilization of the allotted funds.

REPLY OF THE GOVERNMENT

2.32. EFC approved ₹ 1,500 crore for the seven existing NIPERs, including for construction in six NIPERs. Out of this,₹823.13crore was released till FY2022-2023(₹372crorein FY2021- 22 and ₹ 451.13 crore in FY 2022-23). BE 2023-24 of ₹ 550 crore was in accordance with the EFC ceiling, including the capital grant for the construction in six NIPERs. However, due to slow pace of expenditure, the estimates were revised to ₹ 228.80 crore at RE stage, which was utilised fully. In accordance with the overall EFC ceiling, BE 2024-25 has been kept at ₹ 242 crore and it has been revised to ₹ 248 at the RE stage as per the requirement of NIPER.

Due to technical formalities in on boarding the Treasury Single Account (TSA) model, expenditure till September 2024 was slow. However, out of ₹ 248 crore, ₹ 246.20 crore now stands released. The balance is also expected to be released during the remaining period of FY 2024-25.

2.33 The Committee observed that though much has been done to boost domestic manufacturing of medical devices, however, the Committee desires that the Ministry may device a mechanism to see to it that attractive duty concessions and reasonable reduction in the GST rates are effectuated in consultation with other stake holders so that the momentum is not lost and the benefits of PMP are able to reach beyond the realms of a few medical devices. The Committee may be apprised of the status in this regard.

RECOMMENDATION No. 19

2.34 The Committee note that construction of regular campuses in four NIPERs centres at Hajipur, Hyderabad, Kolkata and Raebareli is in progress. At Hajipur Centre, 38 percent of work is stated to have been completed; Centres at Hyderabad and Kolkata record 25 percent and 43 percent work completion respectively; Raebareli Centre, 70 percent of work has been completed. The estimated dates of completion of these construction work is stated to be01.04.2025, 01.07.2025, 30.06.2025 and 31.03.2025respectively. The Committee recommend that the estimated dates of

completion of these campuses must be adhered to strictly through a robust monitoring mechanism.

REPLY OF THE GOVERNMENT

2.35 The construction progress of NIPER campuses is being closely monitored to ensure timely completion. NIPER Hajipur has achieved 57% progress as of December 2024. The progress of construction is reviewed with the Central Public Works Department (CPWD), Patna every fortnight. At NIPER Hyderabad,35% of the construction has been completed. To facilitate smooth execution, NIPER Hyderabad has been conducting weekly reviews with the project management consultant and the third-party quality assurance consultant. At NIPER Kolkata,61% of the construction is completed, and CPWD, Kolkata has committed to handing over the fully equipped campus by July 2025. NIPER Raebareli has completed 75% of its permanent campus, with the construction agency working efficiently to meet the deadline.

RECOMMENDATION No. 22

2.36 The Committee note that 07 applications were short listed under the Development of Pharmaceutical Industry Scheme out of which 06 projects were given final approval and 01 project has been given 'in principle' approval by the Scheme Steering Committee. The Committee recommend that the 06 projects may be given concrete shape at the earliest for the development of pharmaceutical industry

REPLY OF THE GOVERNMENT

2.37 The six projects approved under the scheme are at various stages of implementation and are expected to be completed, as envisaged, by the end of FY 2025-26.

RECOMMENDATION No.23

Bulk Drug Parks Scheme

2.38 The Committee note that the Department proposes to establish Bulk Drug Parks

with the total financial outlay of Rs. 3,000 crore during a 05-year tenure from the year 2020-21 to 2024-25. Though the current financial year i.e.2024-25 is the last year of the Scheme, on the request of the State Governments of Gujarat, Himachal Pradesh and Andhra Pradesh, the Scheme tenure has since been extended till 2025-26.The Committee further note that out of the total of Rs. 1,054.90 crore, Rs. 750.00 crore from Central Grant and Rs. 304.94 crore from State Fund, a meagre sum of Rs. 198.81 crore is stated to have been utilized by the States. The Committee have been informed that the 03 Bulk Drug Parks have submitted revised timelines upto March, 2026 keeping in view the laudable objectives of the Bulk Drug Parks to provide easy access to Common Infrastructure Facilities (CIF) to bulk drug units located in the park, so as to significantly reduce the manufacturing cost of bulk drugs. The Committee observe the delay in setting up of these parks may defeat the very purpose for which they have been setup. Moreover, keeping in view that these parks with the CIF and with subsidized power, water, land etc. are expected to optimize the cost of manufacturing bulk drugs in India. The Committee recommend that the targets set for the 03 Bulk Drug Parks due to come up by March, 2026 in the States Gujarat, Himachal Pradesh and Andhra Pradesh may be achieved in a time bound manner. The Committee would like to be apprised of the steps taken by the Department in this regard**.**

REPLY OF THE GOVERNMENT

2.39 The recommendation of Hon'ble committee has been taken note of. To expedite project implementation, the Department of Pharmaceuticals has been engaging continuously with the state implementing agencies (SIAs) of the three bulk drug parks to support the development of these parks. The Department has also been periodically taking stock of the progress through monthly review reports obtained from the implementing states. It is conducted reviews on an ongoing basis, wherein the representatives of SIAs have been advised to expedite fund utilisation. The Department had also addressed DO letters on 1.5.2024 and 12.6.2024 to the Additional Chief Secretary / Principal Secretary concerned in the State Governments, apprising them of the slow progress in completion of the bulk drug parks and requesting them to speed up the physical progress and fund utilisation.

RECOMMENDATION No. 24

Schemes for Promotion of Medial Device Park

2.40 The Committee note that the Scheme for Promotion of Medical Device Park being implemented by the Department received proposals from 16 States Governments for creation of CIF. However, after evaluation, proposals of 4 (four) States *viz*. Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh were finally approved. The BE for the year 2021-22 was Rs.60 crore which was enhanced to Rs.137 crore but reduced to Rs.32.93 crore in the year 2022-23 and again goes to Rs.200.00 crore in the year 2023-24 and reduced toRs.150.00 crore in the year 2024-25. The Committee are perturbed to note that a meagre amount of Rs.0.90 crore was the actual expenditure during the year 2022-23 and2023-24. What is more perturbing to the Committee is the fact that Himachal Pradesh has withdrawn from the Scheme of Promotion of Medical Device Parks. The Department will have to obtain proposal from another State, evaluate the same and release grant, which is a very time consuming process and would cause considerable delay in the implementation of the Scheme. The Committee desire that the Department may initiate concrete steps in this regard to expeditiously set up the Medical Devices Parks in the remaining two States.

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REPLY OF THE GOVERNMENT

2.41 Recently, the Government of Himachal Pradesh has withdrawn from the scheme and informed that it will fund the project using its own resources. Currently, the Department of Pharmaceuticals is focused on the establishment of the remaining three approved medical device parks and is not in the process of inviting proposals from other States.

Regular review meetings are being held with the stakeholders concerned of the medical device schemes at the levels of the Secretary, Joint Secretary, Empowered Committee and Empowered Group of Secretaries (EGoS), to monitor progress, ensure optimal utilisation of funds and expedite the setting up of the medical device parks.

RECOMMENDATION No. 25

Consumer Awareness Publicity and Price Monitoring (CAPPM).

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

REPLY OF THE GOVERNMENT

2.43 PMRUs are set-up in a State or Union Territory (UT) with the consent and approval of the State/UT Government/Administration concerned. As on date, out of 36 States/UTs, PMRUs have been set up in all, except Andaman and Nicobar Islands, Tamil Nadu, Delhi, Sikkim and Manipur. NPPA is making efforts for the setting up of PMRUs in the said remaining States/UTs as well. DO letters have been written from the level of Chairman, NPPA to the State/UT Departments concerned in all the said five States/UTs and the matter is being followed up regularly.

RECOMMENDATION No. 26

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

2.44 The Committee note that the Department is implementing Production Linked Incentive (PLI) Scheme for Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs for a ten (10) year tenure from the year 2020-21 to 2029-30 with a total financial outlay of Rs. 6,940 crore. The Committee were apprised that while a

total number of 249 applications were received, 48 green field projects for 33 bulk drugs have been approved with a total committed investment of Rs. 3,938 crore. Selected applicants have already made an actual investment worth Rs 4,155 crore and generated employment for 4,241 individuals, as per the September 2024 Quarterly Review Report. As of October 2024, the selected applicants have commissioned a total of 34 projects for 25 bulk drugs, resulting in cumulative capacity creation of 56,800 MT per annum. The Committee are happy to note the development under the scheme and desires that the scheme may be brought to its logical conclusion at the earliest.

REPLY OF THE GOVERNMENT

2.45 The recommendation of Hon'ble committee has been taken note of. Under the said PLI scheme, selected applicants have so far made actual investment worth ₹ 4,254 crore and generated employment for 4,473 individuals (as per the December 2024 Quarterly Review Report). As of December 2024, a total of 34 projects for 25 bulk drugs stood completed. Further, six more projects are expected to be completed and commence production in FY 2025-26.

RECOMMENDATION No. 27

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

REPLY OF THE GOVERNMENT

2.47 The observations/recommendations of the Hon'ble Committee have been taken note of. The Department is taking earnest steps to implement the PLI schemes as envisaged.

RECOMMENDATION No. 28

2.48 As regard Promotion of Research and Innovation in Pharma Med-Tech Sector (PRIP), the committee note that for the year 2023-24, the Department sought 'NIL' funds at BE stage but at RE stage (2023-24) and amount of Rs. 1.00 crore was allocated but the actual expenditure is Rs. 0.00 crore. In this regard the Department have submitted that the scheme was approved by Cabinet in July, 2023 as such funds under the Promotion of Research and Innovation in Pharma Med Tech (PRIP) Scheme in the fiscal year prior to that were not sought and in the year 2023-24, engaging a PMA as per scheme guidelines was planned and finally a tender in this regard was floated but due to non-receipt of any valid response, the tender could not be utilized. Under these circumstances the Committee recommended that all the issues involved in the Scheme may be fixed at the earliest.

REPLY OF THE GOVERNMENT

2.49 Under Component A of the under the Promotion of Research and Innovation in Pharma- MedTech sector (PRIP) Scheme, the Department has set up a Centre of Excellence (CoE) at each of the seven NIPERs, with total budget outlay of ₹700 crore over the period from FY 2023-24 to FY2027-28. ₹ 88 crore have been released to NIPERs in FY 2024-25 for establishment of CoEs. Under Component B of the scheme, the Department has appointed a Project Management Agency (PMA) for strategy development and implementation of the scheme after following due procedure. Expressions of Interest (EoI) from interested companies for projects to be funded under the scheme have been interested.

RECOMMENDATION No. 29

Spurious/Adulterated Drugs

2.50 The Committee find that during the years 2015-16 to 2018-19, 2.3 lakh samples of drugs/spurious were test out of which 593 were declared as 'spurious' and 9,266 were declared as 'Not of Standard Quality (NSQ)'Drugs/medicines. Apparently, only 35 convictions were made in all these cases amounting to a meager 5.9%. The Committee,

however, observes that as on date only 5.9% of the total 593 cases relating to spurious/adulterated drugs have been resolved, with the remaining cases at various stages in respective Courts. The Committee are surprised to find that the conviction rate data is not maintained centrally for penal action for spurious/adulterated drugs. Admittedly, the figureof5.9% does not represent the conviction rate but percentage of cases decided as per the data obtained for States/UTs. The Committee are concerned about the delays in disposal of cases as also the maintenance of centralized data pertaining to enforcement of penalties for spurious/adulterated drugs. The Committee, therefore recommend stringent action to be taken in a time bound manner for exemplary punishments for spurious/adulterated drugs.

REPLY OF THE GOVERNMENT

2.51 The Ministry of Health and Family Welfare has informed that the recommendation of the Hon'ble committee has been taken note of, and that various measures are being taken for monitoring such cases and ensuring stringent action. Drugs inspectors are being trained from time to time for updating knowledge on legal provisions on spurious, adulterated, misbranded and Not of Standard Quality drugs and the procedure to be adopted for launch of prosecution and court proceedings. Further, SUGAM lab portal has been developed, which has provision for updating of status of prosecution cases of CDSCO, etc. Also, a digital regulatory system is proposed to be developed to build trust and confidence on quality of drugs in the domestic and global market, transparency and accountability in the regulation of quality of drugs, effective enforcement of quality, safety and efficacy at the field level and ensuring compliance with Indian pharmacopeia and standards. The proposed digital regulatory system will also take care of, amongst other aspects, maintenance of database of Not of Standard Quality, spurious, adulterated and misbranded products in the public domain.

RECOMMENDATION No. 30

2.52 The Committee note with serious concern that National Survey of Drugs (2014-16) revealed that 10% of samples from Government sources were substandard, compared to only 3% from Private sources indicating 3.17 times more prevalence in Government channels than in the retail market, undoubtedly pointing to loopholes in the

procurement processes. Admittedly, various measures are taken by the Ministry of Health and Family Welfare to ensure that better quality and more effective, and safe drugs are made available to consumers. The Committee, however find the Department's reply on the higher prevalence of Not of Standard Quality (NSQ) drugs from Government sources did not address the core reasons for the flaws, and enabling factors contributing to the higher prevalence of NSQ drugs from Government sources. Furthermore, the Committee find the Department's response does not outline the measures in place of ensure the quality and integrity of pharmaceutical products throughout all stages of the distribution process, including procurement, purchasing, storage, distribution, transportation, documentation, and record-keeping. The Committee desire that the Government come out with more clarity on the previous legal authority and enforceability of rules governing these distribution guidelines so that accountability be fixed accordingly.

REPLY OF THE GOVERNMENT

2.53 The Ministry of Health and Family Welfare has informed that a series of measures have been taken to ensure that the quality, safety and efficacy of medicines are not compromised from source to end-consumer including strengthening of legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections. These aspects include procurement, storage, distribution, transportation, documentation and record-keeping practices. Sales, stock and distribution of drugs in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 by State Licensing Authorities (SLAs) appointed by the States/UT Governments concerned. SLAs are legally empowered to take stringent action in case of any non-compliance. Further, the Central Drugs Standard Control Organisation (CDSCO) and the Ministry of Health and Family Welfare have taken various measures to ensure quality, efficacy and safety of medicines manufactured in the country.

CDSCO and the Ministry of Health and Family Welfare have taken several measures to ensure the quality, safety and efficacy of medicines, as described below:

a) In order to assess the 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. 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. Risk-based inspections have provided valuable insights into manufacturing practices being followed, led to corrective actions and resulted in discernable improvements in the regulatory framework.

b) The Central Government, *vide* its notification dated 28.12.2023, amended the Drugs Rules,1945to revise Schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. From 29.6.2024, the revised schedule has become effective for drug manufacturers with turnover of over ₹ 250 crore. For manufacturers having a turnover of up to ₹ 250 crore, *vide* notification dated 11.2.2025, time for implementation has been granted till 31.12.2025.

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 from 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.

d) On 18.1.2022, the Drugs Rules, 1945 were amended to provide that every active pharmaceutical ingredient (bulk drug) 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.

e) On11.2.2020, the Drugs Rules,1945wereamendedto provide with effect from1.3.2021 that, 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 these rules.

f) The Drugs and Cosmetics Act, 1940 was amended through an amending Act of 2008 to provide for stringent penalties for manufacture of spurious and adulterated drugs. Certain offences were also made cognizable and non-bailable.

g) 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.

h) 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 some drugs.

i) 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 manufacturing license is granted by such authority.

j) The number of sanctioned posts in CDSCO has been increased significantly over the last 10 years.

k) 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.

l) The Central Government is providing regular residential and regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. Since April 2023, CDSCO has trained over 35,000 persons.

RECOMMENDATION No. 31

India’s Active Pharmaceutical Ingredient (API)

2.54 the Committee note that India's Active Pharmaceutical Ingredient (API) manufacturing industry has demonstrated growth, particularly in exports, but remains heavily reliant on imports, predominantly from China, for many APIs and Key Starting Materials (KSMs).The Committee further note that China’s dominance in this sector was attributed to its State-supported robust industrial infrastructure and large-scale

manufacturing capabilities for production APIs and KSMs at significantly lower costs, driven by economies of scale and subsidized utilities such as water, steam, and power. Consequently, Indian manufacturers face challenges in competing, which have led to the closure of several local fermentation-based production plants for antibiotics and vitamins. In response to the query of the Committee regarding measures to create a level playing field for domestic manufacturers, the Department outlined the Ministry's initiatives to reduce dependency on imported APIs. While appreciating these efforts, the Committee find that particularly the Production Linked Incentive (PLI) Scheme, provides 20% incentives for fermentation-based products and 10% 9+for chemically synthesized products. The Committee, however, note with concern that, to date, only nine fermentation-based production plants have been approved under the Scheme, with just three operational at present. Keeping in view the importance of achieving self-sufficiency in API production the Committee recommends efforts for enhancing the existing incentives for fermentation- based plants and leveraging Government infrastructure to establish additional plants. To this end, the Committee desire that these facilities should be also provided with highly subsidized utilities such as power, water, and steam to support domestic manufacturers and ensure competitiveness in the global market.

REPLY OF THE GOVERNMENT

2.55 Out of nine approved fermentation-based projects, three are already operational and four more are expected to commence production in FY 2025-26. The technologically challenging fermentation-based projects are eligible for higher incentive of 20% on sales, compared to 10% of incentive on sales of chemical synthesis-based projects. Further, under the Bulk Drug Parks scheme, three bulk drug parks are under construction in Bharuch (Gujarat), in Nakkapalli (Andhra Pradesh) and in Una (Himachal Pradesh) districts. These parks will support projects that use fermentation, as well as those that use chemical synthesis.

In the three bulk drug parks, state governments, with support from the central government, are developing common facilities for effluent treatment, steam generation, solvent storage, recovery and distillation, testing, warehousing, etc. Further, the state governments are providing utilities such as power, water, steam, effluent treatment, solid waste management, etc. on highly subsidised rates and industrial land on long

lease rentals, to investors for setting up green field projects in the bulk drug parks. Also, State subsidies, such as capital subsidy, GST subvention, interest rate subvention, exemption of stamp duty and registration charges etc., are being extended to prospective investors for setting up projects in the approved bulk drug parks.

It is expected that the operationalisation of bulk drug parks will lead to competitively-priced bulk drugs produced from these facilities.

RECOMMENDATION No. 32

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

2.56 The Committee find that as on December, 2023, 60 percent of the sanctioned strength of drug inspectors, 303 out of 504 were vacant despite the fact that the Parliamentary Standing Committee on Health and Family Welfare may back in the year 2012 had recommended hiring people on short-term contractual bases till the vacancies are filled. The Committee were apprised that recruitment delays were caused by the court on matters related to Recruitment Rules and following its orders from the Hon'ble Supreme Court of India, in this regard steps have now been initiated to expedite the recruitment process. While urging the Department to prioritize filling these vacancies without further delay, the Committee expresses concern that the existing sanctioned strength of 504 posts are insufficient to meet the Country's regulatory requirements for the medicines/drugs regime more specifically considering the fact that the country has more that 750 districts. The Committee, therefore, recommend that the responsible authorities conduct a comprehensive assessment of the actual staffing needs with a holistic vision of increasing the number of sanctioned posts to ensure effective regulation and oversight owe the multifaceted issues grappling the spurious/NSQ Drugs.

REPLY OF THE GOVERNMENT

2.57 The Ministry of Health and Family Welfare has informed that the recommendation of the Hon'ble committee has been note of, and that as per records available with CDSCO (HQ), in the year 2008, CDSCO had 62 posts of Drugs Inspectors. Further, to combat counterfeit medicines and as per requirement of CDSCO

for other regulatory work, various inspector posts were sanctioned by the Department of Expenditure (DoE) from time to time, depending on the increasing work load of the CDSCO. Accordingly, budgetary resources are enhanced time to time as per requirement of CDSCO. Over time, the number of posts of Drugs Inspectors have been increased and currently the number of posts of Drugs Inspectors in CDSCO is 504 (Regulatory and Medical Devices Vertical). Apart from CDSCO, each State regulatory authority has drugs inspectors for licensing, enforcement activities, etc. in their respective jurisdiction.

Filling up of vacancies is an ongoing process and the matter is being pursued. The Ministry has further informed that it is working at full pace in accordance with Mission Recruitment and that recruitment rules for the Medical Devices Vertical of CDSCO have been notified in November 2024, and advertisement for the said posts has been published in the Employment News for filling up the posts on deputation basis. In addition, indents for the recruitment of Drugs Inspector (Medical Devices) and Assistant Drugs Controller (Medical Devices) are being sent to the Union Public Service Commission (UPSC) through Single Window System as per UPSC calendar. In respect of the regulatory cadre of CDSCO, as per directions of the Hon'ble Central Administrative Tribunal, High Court and Supreme Court, criteria for recruitment are to be revised and draft recruitment rules have been sent to the Department of Personnel and Training. Once the recruitment rules are finalised and notified, the recruitment process may be initiated.

RECOMMENDATION No. 33

National Pharmaceutical Pricing Authority (NPPA)

2.58 The Committee find that the NPPA notified ceiling price for area 920 essential medicines including oxygen, general anaesthetics and opoids. The Committee further find that while sending prices of essential medicines are raise on the basis of changes in the Wholesale Price Index (WPI), the NPPA also monitor the pricing of non-essential devices to ensure that manufactures do not hike the MRP of the medicines by more than10 percent of the MRP in the last one year. The Committee find that NPPA issued on order dated 15th October, 2024 increasing the prices of 11 drug formulation by 50

percent. Admittedly, this was done in response to several applications requesting on price rise to accommodate rising production cost over the years. The Committee observe with serious concern that in the face of apparent increasing prices of medicines affecting the whole nation, particularly hard hiring the poorest of the poor, the NPPA which has the ambit of monitoring and enforcement of pricing of medicine, have allowed this situation to prevail. The Committee, therefore, desires a detailed note be furnished on the price hike.

REPLY OF THE GOVERNMENT

2.59 The National Pharmaceutical Pricing Authority (NPPA) received applications in respect of 77 formulations for increase in their price. The price increase has been sought by various manufacturing/ marketing companies for reasons like increase in cost of production, increase in cost of active pharmaceuticals ingredients, changes in exchange rate, etc.

As per its mandate, NPPA, while regulating prices of essential medicines under DPCO, 2013, has to also keep in view the objectives of availability of essential medicines in the market. NPPA receives withdrawal notices and requests for upward revision of prices of critical drugs from manufacturers for reasons mentioned above that made the production and marketing of these drugs unviable. To deliberate on such representations, a consultative mechanism in the form of an Inter-Ministerial Committee (IMC) of technical experts consisting of representatives from CDSCO, Director General of Health Services and NPPA exists in NPPA. IMC examines the requests keeping in view parameters like essentiality of these medicines, period since when they have been under price control, trend of API prices over the last three years, concerns regarding possible shortages, if any, and requests received for discontinuation of essential medicines from the manufacturing companies.

The mechanism for one-time price increase of 50% under paragraph 19of DPCO,2013 is as per the guidance given by the Committee on Affordable Medicines and Health Products (CAMPH) of NITI Aayog. This mechanism has been invoked from time to time since 2019 with a view to ensure continued availability of essential drugs to the general public. Earlier, such measures were taken in the years 2019 and 2021, when prices of 21scheduled formulations of 12 medicines and 9 scheduled formulations

of 3 drugs respectively were increased by 50% under paragraph 19 of DPCO, 2013, in public interest, on similar grounds.

Based on detailed deliberations and the recommendations of IMC, NPPA invoked paragraph 19 under DPCO, 2013 for 11 formulations of 8 drugs in October 2024, allowing one-time increase in the ceiling prices of the aforesaid drugs to ensure their continued availability in the market. The drugs whose prices have been revised upwards are low-cost and generally used as the first line of treatment, and are crucial to public health programmes. These drugs are used for the treatment of asthma, glaucoma, thalassemia, tuberculosis, mental health disorders, etc. Details of these drugs are as under:

S. No.	Name of formulation	Therapeutic category	Ceiling Price as on 1.4.2024 (in ₹)	Price after 50% increase (in ₹)
1	Benzyl Penicillin 10 lakh IU injection	Anti infective	9.71/Vial	14.57/Pack
2	Atropine Injection 0.6mg/ml	Anaesthesia preoperative medication and sedation	4.57/ML	6.86/ML
3	Streptomycin 750 mg injection	Anti tuberculosis	10.10/Vial	15.15/Vial
4	Streptomycin 1000 mg injection	Anti tuberculosis	10.86/Vial	16.29/Vial
5	Salbutamol 2mg tablets	Anti asthmatic	0.18/Tablet	0.27/Tablet
6	Salbutamol 4mg tablets	Anti asthmatic	0.21/Tablet	0.32/Tablet
7	Salbutamol 5mg respiratory solution	Anti asthmatic	0.68/ML	1.02/ML
8	Pilocarpine 2% eye drops	Miotics and Antiglaucoma medicines	10.83/ML	16.25/ML
9	Cefadroxil Tablet 500mg	Anti-infective and anti-bacterial	4.47/Tablet	6.71/tablet
10	Desferrioxamine 500mg Powder for injection	Antidotes and other substances used in management of poisoning/envenomation	188.65/Vial	282.98/Vial
11	Lithium Tablet 300mg	Bipolar disorder	1.63 /tablet	2.45/tablet

CHAPTER III

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

- NIL -

CHAPTER - IV

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

(RECOMMENDATION No. 1)

4.1 The Committee note that the Department sought an amount of Rs.4089.95 crore for the financial year 2024-25. The Committee find consistent decline in funds allocated for various schemes/programmes run by the Department viz. For promotion of Bulk Drug Parks, Rs. 1,000.00 crore out of Rs. 1,352.00 crore sought; For Promotion of Medical Devices Parks, Rs. 150.00 crore out of Rs. 156.89 crore sought; For Human Resource Development in Medical Devices Sector (HRD) Rs.50.00 crore out of Rs.98.00 crores ought; For Assistance to Medical Device Cluster for Common Facilities (AMD-CF),Rs.40.00crore out of Rs.191.00 crore sought; and Consumer Awareness Publicity and Price Monitoring Rs. 4.00 crore out of Rs.6.00 crore sought. The Committee are perturbed to note that for Promotion of Research and Innovation in Pharma Med-Tech (PRIP), the allocation sought by the Department has been reduced by 50 percent. In this case, the allocation has been reduced to Rs.75.00 crore from Rs.150.00 crore sought by the Department. The Committee desire to be apprised of the reasons for reduced allocation of funds in each of the schemes/programmes being run by the Department and impact on their implementation. The Committee recommend that the Department should analyse the reasons for reduced allocation of funds in these Schemes and initiate corrective measures therein.

REPLY OF THE GOVERNMENT

4.2 The expected release under some schemes could not be made primarily due to lesser demand in infrastructure schemes on account of difficulties faced in successful completion of procurement processes, obtaining environmental and other

clearances/approvals, non-fulfilment of targeted achievements by beneficiary companies to be eligible to claim incentives.

The financial targets under the Scheme for Promotion of Medical Device Parks were not achieved due to non-submission of utilisation certificates by the selected States, despite follow- up. As a result, funds could not be released in past years. However, all approved State implementing agencies have now awarded tenders for civil construction of Common Infrastructure Facility buildings and work has started. Tenders for equipment to be installed in the these buildings are at various stages of procurement. The second instalment is expected to be released within March 2025, upon due verification of requisite documents and submission of utilisation certificate for the first instalment.

Under the Capacity building and Skill development in Medical Device Sector scheme (formerly known as the Human Resource Development in Medical Devices Sector schemes), in- principle approval has been granted to 13 applicants for two-year degree or one-year postgraduate diploma courses and to five applicants for short-term certificate courses. These courses are expected to commence from the academic year 2025-2026, and release of funds will be on reimbursement basis, *i.e.*, the fund will be released once claim is submitted by the approved applicant. An amount of ₹ 0.90 crore has so far been utilised for payment towards professional fee of the project management agency.

Under the Scheme for Common Facilities for Medical Device Clusters, Budget Estimate (BE) for the financial year (FY) 2024-25 was ₹40 crore, which was reduced to ₹ 25 crore. This scheme was earlier known as the Assistance to Medical Device Cluster for Common Facilities scheme, and had provision for establishment of facilities for testing of medical devices and common facilities for manufacturing of medical devices. So far, six applicants have been selected to establish six testing facilities and four applicants have been selected to establish four common facilities for manufacturing of medical devices in the country. In-principle approval have been conveyed to all selected applicants between December 2024 to January 2025, and steps have been taken for opening of requisite Central Nodal Agency account to enable release of funds.

Further, under the new umbrella scheme of Strengthening of Medical Device Industry, launched on 8.11.2024, in-principle approval has been granted for proposals received under two sub-schemes, namely, the Capacity Building and Skill Development in the Medical Device Sector sub-scheme and the Common Facilities for Medical Device Clusters sub-scheme. For the selected applicants for the Common Facilities for Medical Device Clusters sub-scheme, the first instalment is expected to be released within March 2025, after due verification of requisite documents as per criteria specified in the scheme guidelines.

Comments of the Committee

(Please see Para No. 1.7 of Chapter-1 of the Report)

RECOMMENDATION No. 10

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

REPLY OF THE GOVERNMENT

4.4 During the financial year2022-23 and 2024-25, over 1,200, 1,500 and 1,800 show cause notices were respectively issued, with directions to remove violations and comply with conditions of the agreement. In case of repeated violations, PMBI takes steps to cancel the allotment of the Jan Aushadhi Kendra (JAK) concerned or to withhold its incentives for a specific period until the violation is resolved. There is effective monitoring of JAKs, and complaints are given priority for resolution.

Financial year wise details of show cause notices issued and JAKs closed are as under:

S.No.	FY	No. of Show Cause notice issued to JAKs	JAKs Closed
1	2021-22	1349	191
2	2022-23	1284	252
3	2023-24	1539	611
4	2024-25	1839	267
Total		**6011**	**1321**

Comments of the Committee

(Please see Para No. 1.10 of Chapter -1 of the Report)

(RECOMMENDATION PARA NO. 11)

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

REPLY OF THE GOVERNMENT

4.6 The recommendations of the Hon'ble Committee have been taken note of. PMBI, as part of its continuous process of augmenting the product basket under Jan Aushadhi, would review whether any more additions may be done. Insofar as Benzyl Penicillin is concerned, it is informed that it was earlier available in the PMBI basket, but due to low demand and no sales, its procurement was discontinued. For anti-tuberculosis (TB) medicines, TB Mukt Bharat Abhiyan was launched in the year 2021 and registration of all TB patients was done under a separate campaign by the Ministry of Health and Family Welfare with the aim of providing free medicines. PMBI surveyed more than 100 JAKs and decided not to include anti-TB medicines due to low demand and the free availability under the aforementioned campaign. It is further informed that more than 278 medicines for mental ailments/illness are available in the PMBI product basket, and more medicines may be added based on suggestions or demand from stakeholders. The medicine Atropine is already available in the PMBI basket according to the demand pattern.

Comments of the Committee

(Please see Para No. 1.13 of Chapter – 1 of the Report)

(RECOMMENDATION PARA NO. 20)

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

REPLY OF THE GOVERNMENT

4.8 Details of number of students belonging to the Scheduled Castes (SC), Scheduled Tribes (ST) and Other Backward Class(OBC) admitted and the total intake of students, course-wise, in the seven NIPERs during the last three years are as under:

NIPER	Course	**2022**			
		Total Student Intake	SC	ST	OBC
Mohali	Masters	285	38	20	100
	PhD	61	14	1	16
Ahmedabad	Masters	166	24	12	44
	PhD	35	4	2	12
Hyderabad	Masters	180	26	9	47
	PhD	49	6	3	14
Guwahati	Masters	144	22	11	50
	PhD	35	4	3	14
Raebareli	Masters	109	20	5	49
	PhD	30	3	2	11
Kolkata	Masters	88	18	6	41
	PhD	28	0	0	1
Hajipur	Masters	91	13	6	29
	PhD	19	3	0	5

NIPER	Course	**2023**			
		Total Student Intake	SC	ST	OBC

Mohali	Masters	305	38	20	99
	PhD	79	12	0	23
Ahmedabad	Masters	178	27	12	51
	PhD	35	4	1	16
Hyderabad	Masters	193	25	14	44
	PhD	59	9	1	18
Guwahati	Masters	189	26	11	80
	PhD	49	10	3	22
Raebareli	Masters	110	15	7	42
	PhD	27	4	0	14
Kolkata	Masters	112	16	8	40
	PhD	28	1	0	0
Hajipur	Masters	109	12	5	27
	PhD	24	3	1	7

NIPER	Course	**2024**			
		Total Student Intake	SC	ST	OBC
Mohali	Masters	257	34	10	102
	PhD	12	0	0	3
Ahmedabad	Masters	150	20	10	37
	PhD	4	0	0	1
Hyderabad	Masters	214	27	15	50
	PhD	5	-	-	-

Guwahati	Masters	164	30	15	82
	PhD	21	4	2	8
Raebareli	Masters	99	13	4	36
	PhD	14	3	2	6
Kolkata	Masters	96	10	5	31
	PhD	5	0	0	5
Hajipur	Masters	55	7	4	13
	PhD	10	1	0	3

Comments of the Committee

(Please see Para No. 1.16 of Chapter – 1 of the Report)

(RECOMMENDATION PARA NO. 21)

4.9. The Committee are dismayed to find that for NIPER, Hajipur, only 572 students have passed out since the inception of the Institute (2007) till the academic year 2023-24 which *inter-alia* include every low data of students of Masters (Two years course) from the year2019 till date where student in take capacities is 435, out of 426 admitted are, 261 students graduated so far upto the 2022-24 Session. The Committee, therefore, recommend that special focus be given to NIPER, Hajipur Centre by the Department to increase the student intake and also improve the number of successful students

REPLY OF THE GOVERNMENT

4.10 As per the record of the institute, data regarding the total number of students admitted and passed out since inception till now are as under:

(a) Masters programme (two years)
(b) Ph D programme

In the academic/admission year 2024, the total student in take in the postgraduate programme was 65. In the forthcoming academic/admission year 2025, the institute has

proposed an intake of 78 in the postgraduate programme, keeping in view the existing faculty-student ratio and facilities available. Expansion of facilities and construction of new building for NIPER Hajipur is in progress. As the construction of new academic/administration building gets finished, student intake and new specialisations will be introduced in phased manner.

Comments of the Committee

(Please see Para No. 1.19 of Chapter – 1 of the Report)

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CHAPTER V

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

- NIL –

New Delhi;
18 AUGUST, 2025
27 SHRAVAN, 1947 (Saka)

AZAD KIRTI JHA
CHAIRPERSON,
STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS.

APPENDIX I

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

The Committee sat on Monday, the 18th August, 2025 from 1500 hrs. to 1700 hrs. in the Committee **Room '2', EPHA, New Delhi.**

PRESENT

SHRI AZAD KIRTI JHA - CHAIRPERSON

MEMBERS

LOK SABHA

2. Shri Brijmohan Agrawal
3. Shri Ajay Bhatt
4. Shri Robert Bruce C.
5. Shri Malvinder Singh Kang
6. Shri Babu Singh Kushwaha
7. Shri Utkarsh Verma Madhur
8. Shri Praveen Patel
9. Dr. Sambit Patra
10. Shri Balram Naik Porika
11. Shri Sachithanantham R.
12. Shri Eatala Rajender
13. Shri Nalin Soren
14. Dr. Ricky Andrew J. Syngkon

RAJYA SABHA

15. Shri Subhash Barala
16. Dr. Bhagwat Karad
17. Shri Subhash Chandra Bose Pilli
18. Shri Naresh Bansal
19. Shri Sanjay Raut
20. Shri Meda Raghunadha Reddy
21. Shri Arun Singh
22. Shri Tejveer Singh

SECRETARIAT

5. Smt. Maya Lingi - Joint Secretary
6. Ms. Miranda Ingudam - Director
7. Shri Kulvinder Singh - Deputy Secretary
8. Shri Nagendra Suman - Deputy Secretary

9. Shri Panna Lal - Deputy Secretary
10. Shri Abhishek Kumar - Deputy Director
11. Ms. Neelam Bhave - Under Secretary

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

(i) XXXX XXXX XXXX XXXX
(ii) XXXX XXXX XXXX XXXX
(iii) Eleventh Report (18th Lok Sabha) on Action Taken by the Government on the Observations/Recommendations of the Committee contained in their Fifth Report (18th Lok Sabha) on 'Demands for Grants (2024-25)' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.
(iv) XXXX XXXX XXXX XXXX
(v) XXXX XXXX XXXX XXXX
(vi) XXXX XXXX XXXX XXXX
(vii) XXXX XXXX XXXX XXXX
(viii) XXXX XXXX XXXX XXXX

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

4. After some deliberations the Committee decided to Adopt five (05) Draft Reports *viz*, 03 ATRs and 02 subject Reports i.e, the Ninth, Tenth, Eleventh, Twelfth and Thirteenth draft Reports. The Committee then authorized the Chairperson to finalize the Reports and present/lay the Reports in the ongoing Session in both the Houses of Parliament.

5. The Committee decided to consider Draft Report No. Fifteenth and Sixteenth for adoption in the next Sitting of the Committee to be held on 19.08.2025 at 1600 hrs. onwards.

***The Committee then adjourned*.**

APPENDIX II

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FIFTH REPORT (EIGHTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2024-25) ON 'DEMANDS FOR GRANTS (2024-25)' PERTAINING TO THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS).

	Total No. of Recommendations	**33**
I.	**Observations/Recommendations which have been accepted by the Government:** **(Sl. Nos. 2,3,4,5,6,7,8,9,12,13,14,15,16,17,18,19,22,23,24,25,26 27,28,29,30,31,32,33)**	**28**
Percentage of Total:		**85 %**
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. 1,10,11, 20, 21)**	**05**
Percentage of Total:		**15%**
IV.	**Observations/Recommendations in respect of which the final replies of the Government are still awaited:** **NIL**	**00**
Percentage of Total:		**0%**