**45**

# STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
# (2023-24)

## (SEVENTEENTH LOK SABHA)

## MINISTRY OF CHEMICALS AND FERTILIZERS
## (DEPARTMENT OF PHARMACEUTICALS)

**Action Taken by the Government on the Observations/Recommendations of the Committee contained in their Forty-Second Report (Seventeenth Lok Sabha) on ‘Demands for Grants (2023-2024)’ of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)**

## FORTY- FIFTH REPORT

सत्यमेव जयते

**LOK SABHA SECRETARIAT**

**NEW DELHI**

***December, 2023/ Agrahayana, 1945 (Saka)***

**CC&F NO. 173**

# FORTY-FIFTH REPORT

## STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

## (2023-24)

## (SEVENTEENTH LOK SABHA)

## MINISTRY OF CHEMICALS AND FERTILIZERS
## (DEPARTMENT OF PHARMACEUTICALS)

**Action Taken by the Government on the Observations/Recommendations of the Committee contained in their Forty-Second Report (Seventeenth Lok Sabha) on 'Demands for Grants (2023-2024)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)**

***Presented to Lok Sabha on 19 December, 2023***

***Laid in Rajya Sabha on 19 December, 2023***

सत्यमेव जयते

**LOK SABHA SECRETARIAT**

**NEW DELHI**

***December, 2023/ Agrahayana, 1945 (Saka)***

## CONTENTS



***To be appended**

**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2023-24)**

**Dr. Shashi Tharoor - Chairperson**

**MEMBERS**
**LOK SABHA**

2. Shri Dibyendu Adhikari
3. Maulana Badruddin Ajmal
4. Shri C.N. Annadurai
5. Shri Deepak Baij
6. Shri Ramakant Bhargava
7. Shri Prataprao Patil Chikhalikar
8. Shri Rajeshbhai Naranbhai Chudasama
9. Dr. Sanjay Jaiswal
10. Shri Ramesh Chandappa Jigajinagi
11. Shri Kripanath Mallah
12. Shri Satyadev Pachauri
13. Smt. Aparupa Poddar
14. Shri Arun Kumar Sagar
15. Shri Muniyan Selvaraj
16. Dr. Sanjeev Kumar Singari
17. Shri Atul Kumar Singh
18. Shri Pradeep Kumar Singh
19. Shri Indra Hang Subba
20. Shri Parbhubhai Nagarbhai Vasava
21. Vacant*

**RAJYA SABHA**

22. Shri G. C. Chandrashekhar
23. Dr. Anil Jain
24. Shri Arun Singh
25. Shri Ram Nath Thakur
26. Shri Vijay Pal Singh Tomar
27. Vacant
28. Vacant
29. Vacant
30. Vacant
31. Vacant

**SECRETARIAT**

| | | | |
|---|---|---|---|
| 1. | Shri Chander Mohan | - | Joint Secretary |
| 2. | Smt. Geeta Parmar | - | Director |
| 3. | Ms. Sonia Sankhla | - | Executive Officer |

* Vacant *vice* Shri Uday Pratap Singh, MP (LS) who resigned his seat in LS w.e.f. 06.12.2023. [Lok Sabha Secretariat Notification No.21/1(1)/2023/T(B) dated 6th December, 2023]

# INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2023-24) having been authorized by the Committee, do present on their behalf this Forty-Fifth Report on Action Taken by the Government on the Observations/Recommendations of the Committee contained in their Forty-Second Report (Seventeenth Lok Sabha) on 'Demands for Grants (2023-24)' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

2. The Forty-Second Report was presented to Lok Sabha and laid in Rajya Sabha on 21st March, 2023. The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers furnished their replies on 20th June, 2023 indicating Action Taken on the Observations/Recommendations contained in the Forty-Second Report. The Committee considered and adopted the Draft Report at their sitting held on 4th December, 2023.

3. An analysis of the Action Taken by the Government on the Observations/Recommendations contained in the Forty-Fifth Report (Seventeenth 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;**
**14 December, 2023**
**23 Agrahayana, 1945 (Saka)**

**DR. SHASHI THAROOR**
**CHAIRPERSON,**
**STANDING COMMITTEE ON**
**CHEMICALS AND FERTILIZERS.**

# CHAPTER-I

## REPORT

This Report deals with action taken by the Government on observations/recommendations of the Standing Committee on Chemicals and Fertilizers contained in their Forty-Second Report (17th Lok Sabha) on 'Demands for Grants (2023-24)' of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

1.2 The Forty-Second Report was presented to Lok Sabha and laid in Rajya Sabha on 21st March, 2023. It contained 17 Observations/Recommendations. Replies of Government in respect of all of the Recommendations have been received and are categorized as under :

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

Rec. Para No. 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17

**Chapter- II**
**Total-16**

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

Rec. Para No. Nil **Chapter - III**

**Total - NIL**

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

Rec. Para .No. 3 **Chapter- IV**

**Total - 1**

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

Rec. Para No. **Chapter - V**

**Total - NIL**

**1.3 The Committee desire that the Action Taken Notes in respect of the Observations/Recommendations contained in Chapter-I of this Report may be furnished to the Committee within three months of the presentation of this Report.**

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

**(Recommendation Para No. 2)**

**Budgetary allocation and utilization during 2020-21, 2021-22 and 2022-23**

1.5 With regard to the Budgetary allocation and utilization during 2020-21, 2021-22 and 2022-23, the Committee in their original report had noted that recurring under-utilization of allocated funds during the years 2020-21, 2021-22 and 2022-23, had adversely affected the implementation of various central sector schemes of public importance. The Department could utilise Rs. 456.16 crore (96.97%) out of Rs. 470.41 crore during 2020-21, Rs. 774.94 crore (94.14%) out of Rs. 823.11 crore during 2021-22 and Rs. 843.78 crore (as on 20.02.2023, 37.19%) out of Rs. 2268.54 crore during 2022-23. Further, while expressing concern over the under-utilization of funds for PLI schemes during 2022-23 where, as on 20.02.2023 only Rs. 470.93 crore was spent out of Rs.1663.20 crore, the Committee had recommended that the Department should take timely corrective measures to ensure optimum utilization of funds. Hence, the Committee desired to know about the overall utilization of funds along with funds utilized in respect of PLI schemes during the year 2022-23.

1.6 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

"Rs.2050.06 crore has been incurred by the Department as on 31.3.2023. The expenditure details in respect of PLI schemes of the Department during the FY 22-23 as under:

| Sl. No. | Name of Scheme | Budget Estimate | Revised Estimate | Actual Expenditure | % based on RE |
|---|---|---|---|---|---|
| 1. | PLI Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in | 390.00 | 06.66 | 05.95 | 89.33 |

| | | | | | |
|---|---|---|---|---|---|
| | the Country. | | | | |
| 2. | PLI Scheme for Promoting Domestic Manufacturing of Medical Devices. | 216.00 | 21.56 | 11.50 | 53.33 |
| 3. | PLI Scheme for Pharmaceuticals | 03.00 | 694.20 | 655.15 | 94.37 |

**1.7 The Committee had observed in their original Report that during 2022-23 (upto 20.02.2023), the Department could utilize Rs. 843.78 crore (37.19%) out of BE allocation of Rs. 2268.54 crore and there was major under-utilization of funds for PLI schemes where as on 20.02.2023 only Rs. 470.93 crore was spent, out of Rs.1663.20 crore. The Committee had desired to be informed of the overall utilization of funds along with funds utilized in respect of PLI schemes during the year 2022-23 (as on 31.03.2023).The Committee has observed from the action taken reply that though the Department has utilized Rs. 2050.06 crore (90.36 %), out of RE allocation of Rs. 2268.54 crore, there has been underutilization of funds under two of the PLI scheme during 2022-23. For PLI scheme for 'promotion of domestic manufacturing of API', BE of Rs. 390 crore was reduced to only Rs. 6.66 crore at RE stage and the actual utilization was Rs. 5.95 crore. Likewise, the BE allocation of Rs. 216 crore under PLI scheme for 'promoting domestic manufacturing of Medical Devices' was also reduced to only Rs. 21.56 crore at RE stage and the actual expenditure was again just Rs. 11.50 crore. Whatever might be the reasons for under utilisation of funds, the probabilities should be taken into consideration at the sanction stage of the scheme. The Committee further observe that for 'PLI scheme for pharmaceuticals' BE allocation of Rs. 3 crore was enhanced to Rs. 694.20 crore at RE stage against which Rs. 655.15 crore has been utilized. While noting a huge variation in BE and RE allocations for PLI schemes, the Committee would desire the Department to carry out its budgetary exercise with due diligence and henceforth try to make a realistic assessment of the funds required for various schemes.**

**(Recommendation Para No. 3)**

**New Schemes under National Institute of Pharmaceutical Education and Research (NIPER) MH-2852**

1.8 With regard to the New Schemes under National Institute of Pharmaceutical Education and Research (NIPER) MH-2852, the Committee in their original report had noted that for the year 2023-24, the Department proposed an allocation of Rs. 1286 crore [Rs. 560 crore for NIPERs, Rs. 200 crore for National Institute of Medical Devices Education and Research (NIMERs), Rs. 233 crore for Centres of Excellence (CoEs), Rs. 50 crore for Indian Council of Research & Development and Innovation in Pharma-MedTech Sector (ICPMR) and Rs 243 crore for Promotion of Research & Innovation in Pharmaceutical Sector (PRIP)]. However, only Rs. 550 crore was allocated for NIPERs and no fund has been allocated for new initiatives. In view of the significance of these new initiatives for Pharma innovations and multidisciplinary courses in field of Medical Devices education, the Department took the stand of seeking additional funds from Ministry of Finance at later stage. The Committee had strongly recommended to increase the funds for NIPER scheme and also to establish of a NIPER in a Southern State where interest in pharmaceutical education is high.

1.9 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "The committee's concerns/ recommendations have been duly noted. It is further informed that the department has since obtained approval for the "Promotion of Research and Innovation in Pharma- MedTech Sector (PRIP)" scheme during the EFC meeting held on 15.03.2023 with an overall budget of Rs. 5,000 crore for a duration of 5 years, from 2023-24 to 2027-28. The Scheme would be placed for approval of the Cabinet after recommendations of the Empowered Technology Group (ETG)."

**1.10 For the Financial year 2023-24, the Department had sought an allocation of Rs.1286 crore which included Rs. 560 crore for NIPERs and the rest for other new initiatives under NIPER scheme viz. Rs. 200 crore for National Institute of Medical Devices Education and Research (NIMERs), Rs. 233 crore for Centres of Excellence (CoEs), Rs. 50 crore for Indian Council of Research & Development and Innovation in Pharma-MedTech Sector (ICPMR) and Rs.243.00 crore for Promotion of Research & Innovation in Pharmaceutical Sector (PRIP). However, no fund was allocated for these new initiatives and only Rs. 550 crore has been allocated for NIPERs. In the light of the above, the Committee in their original**

**report, while observing that no allocation for new schemes will adversely affect the progress and growth of NIPER scheme, had recommended that financial allocation may be enhanced for the NIPER scheme. The Department in their action taken reply have stated that for Promotion of Research & Innovation in Pharmaceutical Sector (PRIP) scheme, the Economic Finance Committee (EFC) has approved Rs. 5000 crore for 5 years from 2023-24 to 2027-28. However, the reply is silent on the fund allocation for new schemes of NIPER viz. NIMERs, CoEs and ICPMR and for establishment of a NIPER in Southern State where interest in pharmaceutical education is high, as recommended by the Committee. The Committee reiterate their earlier recommendation in this regard.**

**(Recommendation No. 11)**

**Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)**

1.11 With regard to Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), the Committee in their original report noted nil utilisation of funds during the last three years viz. 2020-21, 2021-22 and 2022-23 under Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) scheme was attributed to lukewarm response to the scheme despite extensive outreach conducted on its benefits. The Committee, therefore, desired the Department to look into these factors and take remedial measures accordingly. The matter may be discussed with the stakeholders, and if needed, possibility of revising the scheme guidelines may also be looked into.

1.12 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "The Committee's suggestion regarding identification of the factors responsible for the lukewarm response to the scheme is noted. In this regard, it is submitted that the Department organized outreach programmes in 10 States having majority of pharma clusters / MSMEs in coordination with Pharmaceuticals Associations to provide the wide dissemination about the sub-scheme "Pharmaceutical Technology Upgradation Assistance Scheme" (PTUAS), to enable the eligible Pharma MSME units to avail the benefits under the scheme. Further, the Department took several pro-active steps with a view to increase the response to the Scheme by way of amending the guidelines - for increasing the project completion period by 30 months from 18 months; achievement of technological upgradation by 30 months from 18 months from receiving of the first disbursement of loan. The Department also expanded the eligibility criteria by adding Public Financial Institutions registered with Reserve Bank of India along-with Scheduled Commercial Bank/All India Financial Institution.

As explained before the Hon'ble Committee, presently, there is no market or regulatory compulsion for these Pharma MSME units to upgrade their standards to national and international regulatory standards such as WHO-GMP or Schedule-M, as the case may be, despite there is a felt need.
Hence, the Department is continuously pursuing with the State Regulators and the various Industry Associations to increase the uptake of the scheme. Further, the Scheme Steering Committee in its meeting on 13th March, 2023 accorded its final approval for capital subsidy to 2 projects."

**1.13 The Committee are satisfied to note that by introducing amendments in the scheme guidelines and eligibility criteria the scheme has received response and Scheme Steering Committee has given final approval to 2 projects. The Committee had raised concern over nil utilization under the scheme during last three years from 2020-21 to 2022-23 and had recommended to the Department to look into factors responsible for the lukewarm response to the scheme. In this regard, one of the factors that the Department has stated is that there is no market or regulatory compulsion for MSMEs units to upgrade their standards to national and international regulatory standards such as WHO-GMP or Schedule-M, as the case may be, despite the felt need to do so. The Committee would like the Department to find a feasible solution to this issue and if desirable provide suitable financial incentives to MSME units on upgradation to national and international standards. Expressing their apprehension that Pharma MSMEs units are facing issues in enjoying the benefits of the scheme, the Committee desire that the issues should be adequately and widely discussed with the Pharma MSME industry associates and State Regulators and suitable measures should be taken to make the scheme attractive for the beneficiaries.**

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# CHAPTER – II

# OBSERVATIONS/ RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

## Recommendation No.1

**Proposed and Approved budgetary allocation for the year 2023-24**

2.1 The Committee note that the Department of Pharmaceuticals (DoP) projected a budget allocation of Rs. 5728.57 crore for its various schemes/programmes and other activities during the year 2023-24.However, the Ministry of Finance reduced the same and has allocated Rs. 3160.06 crore only. Similarly, during 2022-23, the proposed allocation of Rs. 10383.25 crore was reduced to Rs. 2244.15 crore. The DoP, however is largely satisfied with an overall increase of 40.84 % in gross budget allocations in 2023-24 as compared to 2022-23 except that in two of its schemes viz. National Institute of Pharmaceutical Education & Research (NIPER) and Production Linked Incentive Scheme for Pharmaceuticals (PLI-Pharmaceuticals) in which the proposed allocation has been drastically reduced. Under the NIPER scheme (Major Head 2852 and 2552), against the projected allocation of Rs. 1286.00 crore, Rs. 500.00 crore and Rs. 50.00 crore have been sanctioned for NIPERs (Major Head 2852 and Major Head 2552, respectively). Again, in case of PLI-Pharmaceuticals scheme, against the proposed budget outlay of Rs. 2203.00 crore which was required to provide the incentives to the applicants under the scheme, only Rs. 1000.00 crore has been sanctioned.

Keeping in view an enhanced budgetary allocations during 2023-24, the Committee impress upon the Department to strategically plan, evaluate, monitor and implement its five central sector schemes, namely (a)National Institute of Pharmaceutical Education & Research (NIPER), (b) Production Linked Incentive (PLI) Schemes, (c) Development of Pharmaceutical Industry, an Umbrella Scheme (d) Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and (e) Consumer Awareness, Publicity and Price Monitoring (CAPPM) thus ensuring optimal utilisation of allocated funds and making sufficient ground for approval of the proposed requirement of funds at RE stage.

2.2 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "The Department of Pharmaceuticals has a concrete plan to achieve the targets envisaged under the Production Linked Incentive (PLI) Schemes, Development of Pharmaceutical Industry (DPI) renamed as Strengthening of Pharmaceuticals Industry (SPI).

The prescribed monitoring mechanism envisaged under the Schemes such as Empowered Committee under the PLI schemes of Bulk Drugs and Medical Devices and Scheme Selection and Steering Committee (SSSC) under the PLI Scheme for Pharmaceuticals, the Scheme Steering Committee (SSC) of the SPI scheme, etc. will be fully involved in the regular monitoring of the implementation of the schemes, including the timely release of incentives and Redressal of the issues faced by the applicants.

Further, the Project Management Agencies (PMAs) appointed under the PLI and SPI schemes will be fully involved in handholding the applicants and monitoring the progress of the schemes, as per the milestones envisaged. The additional funds will be sought from the Ministry of Finance at RE Stage if need be.

**Promotion of Bulk Drug Parks:** Suggestions of the Committee are noted. Rs. 1000 crore has been allocated for the scheme for FY 23-24. The allotted funds for the Scheme during 2023-24 would be utilized effectively. The additional funds will be sought from the Ministry of Finance at RE Stage if need be.

**Promotion of Medical Devices Parks:** Suggestions of the Committee are noted. Under the "Promotion of Medical Devices Parks" scheme, the proposals of Uttar Pradesh, Madhya Pradesh, Tamil Nadu and Himachal Pradesh have been approved for providing maximum GIA of Rs. 100 crore to each State, for creation of Common Infrastructure Facilities in the Parks, being developed by the said four States. The first instalment of Rs. 30 crore each has been released in FY 2021-22. A provision of Rs.120.00 crore was kept as BE 22-23 for release of 2nd instalment to the 4 States in FY 2022-23. However, as per the scheme guidelines, the States have to utilize 75% of the 1st instalment and also do the proportionate expenditure of its own fund committed for the CIF project before the 2nd instalment is released. The physical development work is underway in the 4 parks. The grant-in-aid provided by this Department is dedicated only towards development of Common Infrastructure Facility (CIF) to be developed in these parks and State Funding is dedicated to both CIF development as well as physical infrastructure development. The State Governments have floated tenders for the land levelling works, internal road construction, drainage, power station, etc. Since the States could not utilize the prescribed amount as per guidelines, the 2nd instalment could not be released. Rs.89 lakhs were released to the Project Management Agency towards the annual fee.The additional funds will be sought from the Ministry of Finance at RE Stage if need be

**National Institute of Pharmaceuticals Education and Research (NIPER):** Rs. 1286.00 crore was sought, which included Rs. 560 crore for NIPERs and Rs. 233.00cr forCentre of Excellence (CoE), Rs. 50.00 crore, for Indian Council of Research & Innovation and Development and Innovation in Pharma Med Tech Center (ICPMR) Rs. 200.00 cr. For National Institute of Medical Device

Education and Research (NIMERs) and Rs. 243.00 crore for "Promotion of Research and Innovation in Pharma- MedTech Sector (PRIP)"

While Rs. 500.00 crore and Rs. 50.00 crore sought for NIPERs (Major Head 2852 and Major Head 2552, respectively) have been sanctioned by the Ministry of Finance, in case of other schemes final approval of the appraising agencies concerned (Cabinet/ EFC/SFC) is awaited. The demand for these schemes would be raised again on approval of the competent authorities. The allotted funds for NIPER Scheme during 2023-24 would be utilized effectively. The additional funds will be sought from the Ministry of Finance at RE Stage if need be

**Jan Aushadhi Scheme(PMBJP):** Rs. 115.00 crore has been allocatedunder this scheme for Budget Estimate 2023-24. The amount allotted in BE-2023-24 would be utilized to achieve the target for the year, i.e., to open 10,000 Kendras and enhance the product basket up to 2000 medicines and 300 surgicals. The effective utilization of funds is ensured by regular monitoring of the scheme by Pharmaceutical and Medical Devices Bureau of India (PMBI), the Implementing Agency of the scheme. Further, the performance of the scheme is regularly reviewed by the Executive Council and Governing Council of PMBI. Moreover, periodic meetings are held at the level of the Secretary of the Department, as well as at the level of Minister of Chemicals & Fertilizers to review the performance and to ensure fulfilment of its mandate. The additional funds will be sought from the Ministry of Finance at RE Stage if need be.

**Consumer Awareness, Publicity and Price Monitoring Scheme (CAPPM):**In so far as Consumer Awareness, Publicity and Price Monitoring Scheme is concerned, NPPA will ensure optimal utilization of allocated fund in a planned manner.The additional funds will be sought from the Ministry of Finance at RE Stage if need be".

**Recommendation No.2**

**Budgetary allocation and utilization during 2020-21, 2021-22 and 2022-23**

2.3 The Committee are constrained to observe the recurring under-utilization of allocated funds by DoP during the last three years. During FYs 2020-21, 2021-22 and 2022-23, out of the allocated funds at RE stage of Rs. 470.41 crore, Rs. 823.11 croreandRs. 2268.54 crore, respectively, the Department could utilise Rs. 456.16 crore (96.97%), Rs. 774.94 crore (94.14%) and Rs. 843.78 crore (37.19%) (as on 20.02.2023), respectively. Obviously, under-utilization of funds in past and especially during the current year 2022-23 where only 37.19 percent of allocated funds have been utilised up to 20.02.2023 would have adversely affected the implementation of the various central sector schemes of the Department which are of paramount importance in the interest of general public and speaks poorly on the functioning of the Department.

The Committee are unhappy to note the tardy progress in implementation of three PLI schemes of the Department during 2022-23 as the Department has been able to utilise Rs. 470.93 crore (28.31%) of the allocation of Rs.1663.20(up to 20.02.2023). While expressing their concern over the gross under-utilisation of allocated funds during 2022-23 so far for PLI schemes, the Committee exhort the Department to implement the schemes with all seriousness and take timely corrective measures so as to ensure optimum utilization of the remaining allocated funds by 31st March, 2022. The Committee would like to be apprised of the overall utilization of funds by the Department during 2022-23 up to 31.03.2023 and in particular in respect of its PLI schemes.

2.4 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

"Rs. 2050.06 crore has been incurred by the Department as on 31.3.2023. The expenditure details in respect of PLI schemes of the Department during the FY 22-23 as under:

| Sl. No. | Name of Scheme | Budget Estimate | Revised Estimate | Actual Expenditure | % based on RE |
|---|---|---|---|---|---|
| 4. | PLI Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the Country. | 390.00 | 06.66 | 05.95 | 89.33 |
| 5. | PLI Scheme for Promoting Domestic Manufacturing of Medical Devices. | 216.00 | 21.56 | 11.50 | 53.33 |
| 6. | PLI Scheme for Pharmaceuticals | 03.00 | 694.20 | 655.15 | 94.37 |

**COMMENTS OF THE COMMITTEE**

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

## Recommendation No. 4

**National Institutes of Pharmaceutical Education and Research (NIPERs) (MH2852)**

2.5 The National Institutes of Pharmaceutical Education and Research (NIPERs) are autonomous institutes of national importance, which have been established by an Act passed in Parliament in 1998, for imparting postgraduate and doctorate education and conducting research in various specializations of pharmaceutical science. At present, there are seven functional NIPERs at Mohali, Ahmedabad, Hyderabad, Hajipur, Guwahati, Raebareli and Kolkata.

The Committee note with satisfaction that regular faculty and administrative posts sanctioned in all NIPERs have been filled up as per current needs. The Committee, however, are constrained to note that except NIPER- Mohali and NIPER-Guwahati, all the other five NIPERs do not have their own campuses and are functioning with the assistance of their mentor institutes.

Campus construction of NIPER Guwahati is just completed, about 60% construction has been completed at NIPER Ahmedabad, and Administrative Approval & Expenditure Sanction for construction of campuses of NIPERs at Kolkata, Hajipur and Raebareli through CPWD and at Hyderabad through NPCC has been made and the tenders are under finalization. The Committee are not happy with figures of utilization of funds so far during 2022-23 as out of the RE of Rs. 422.00 crore, the actual expenditure as on 31.12.2022 remained Rs.231.00 crore. The Department has, however been assured that before the end of this financial year, the maximum amount will be utilized as about Rs.190.00 crore will be disbursed for construction of campuses of three NIPERS viz. Kolkata, Hajipur and Raebareli by CPWD subject to award of tender. The Committee further note that Rs. 550 crore has been allocated for the year 2023-24 under NIPER scheme for various activities viz. the construction of campuses, up-gradation of laboratories, payment of salaries to faculty/staff and fellowship to students etc. The Committee hope that as assured Rs. 422.00 crore allocated at RE, 2022-23 would be fully utilized and would like to be apprised of the figures for utilization of funds by NIPERs during 2022-23. The Committee would further like to be assured that construction of Campuses of NIPER Ahmedabad, Kolkata, Hajipur, Raebareli and Hyderabad would be accorded top priority and whatever might be the constraints, serious efforts will be made to complete the construction without further delay.

2.6 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> “As informed earlier, the department has been able to effectively utilized Rs. 451.13 crore out of the allocated Rs. 463.53crore, i.e. 97.32% for the F.Y. 2022-23.

As regard construction of the campuses, it is informed that tenders for three of NIPERs have already been finalized, whereas in the case of NIPER Hyderabad, it has to be re-tendered as the L1 bid was more than 20% higher than the estimate. Revised tender therein has already been issued. The progress of the construction of NIPERs' campuses is being periodically monitored by their respective Directors/Board of Governors (BoGs) and the department."

**Recommendation No. 5**

**Production Linked Incentive (PLI) Schemes (MH2852)**

2.7. The Committee note that among the three Production Linked Incentive (PLI) schemes, the PLI schemes for promotion of domestic manufacturing of API and Medical Devices were approved by the Government on 20 March, 2020 and scheme guidelines were issued on 29.10.2020. The third PLI scheme for Pharmaceuticals was approved on 24.02.2021. The Committee note that an amount of Rs.1629.00 crore was allocated for PLI schemes during 2022-23, which was increased to Rs.1663.20 crore at RE stage. However, the actual utilization as on 20.02.2023 was Rs.470.93 crore only. The Committee do appreciate the Department's view that there is a gestation period for one to two years and then there is a period of production and a period of incentive being released. However, the Committee fail to understand why an allocation of Rs.1629.00 crore was made and then enhanced to Rs.1663.20 crore at RE, 2022-23 and at the end of the year the maximum amount remained unspent. The Committee consider it to be a bad budgeting. The Secretary, DoP during evidence also admitted that they had made provisions for incentives to be released in 2022-23 whereas 2022-23 was the year of production and they could have actually made this provision next year. The Committee desire that henceforth, the Department should be more realistic in projecting its estimates for better utilisation of funds.

2.8 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

"It is submitted that as informed by the Secretary before the Hon'ble Committee, the Department utilized Rs. 672.60 crore (about 93% utilization of Revised RE) in F.Y. 2022-23 of the PLI scheme allocation. The suggestion of the Committee regarding projection of estimates is noted."

**Recommendation No. 6**

**PLI for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) (MH2852)**

2.9. The PLI scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs)was launched on 20 March, 2020 to boost domestic manufacturing of 41 identified KSMs/ DIs and APIs, by attracting large investments in the sector and thereby reducing India's import dependence in critical APIs. The scheme has been formulated based on the recommendations of the Technical Committee, wherein the dependency of these products are more than 85% from a single country. Accordingly, DoP has notified 41 products under the Scheme. The Committee trust that the PLI scheme, subject to its effective implementation, will enable the country to attain self-sufficiency in critical APIs. The Committee desire that the Department should strive hard and periodically review the scheme to further reduce the dependency of KSMs/ DIs and APIs on a single country.

2.10 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "The suggestion of the Committee in this regard is noted. The Department of Pharmaceuticals takes all the necessary measures to effectively implement the PLI scheme to achieve the objectives envisaged under the Scheme, to reduce the import dependency of critical Bulk Drugs and strengthen the domestic production capabilities to ensure supply chain resilience. The monitoring mechanism envisaged under the PLI Schemes such as Empowered Committee under the PLI schemes of Bulk Drugs and Medical Devices and Scheme Selection and Steering Committee (SSSC) under the PLI Scheme for Pharmaceuticals, will be in effective implementation".

**Recommendation No. 7**

**Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device (MH2852)**

2.11 The Committee note that the DoP proposed an allocation of Rs. 102 crore for FY 2023-24 under PLI Scheme for Promoting Domestic Manufacturing for Medical Device, however, Rs.100.00 crore has been allocated. The proposed amount was based on consultation with the selected applicants and sales projections submitted by them to Small Industries Development Bank of India (SIDBI)which is Project Management Agency (PMA) for this scheme. The Committee desire that the momentum be continued unabated with added thrust and impetus for attracting investment for promoting domestic manufacturing of medical devices. The Committee expect optimal utilization of Rs. 100 crore allocated for the purpose during FY 2023-24.

2.12 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "The proposed Budget Estimate was based on the consultation with the selected applicants and projections submitted by them to Project Management Agency - IFCI - for the *PLI Scheme for Medical Devices*. The suggestion of the Committee on providing necessary impetus for successful implementation is noted. The Department will take necessary steps for utilization of budget allocated for Financial Year 2023-2024.The additional funds will be sought from the Ministry of Finance at RE Stage if need be."

**Recommendation No. 8**

**<u>Production Linked Incentive Scheme for Pharmaceuticals (MH2852)</u>**

2.13 The Committee note that PLI Scheme for Pharmaceuticals has been approved with an objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high-value goods in the pharmaceutical sector. During 2022-23, against the RE allocation of Rs.694.20 crore, the Department could utilize Rs.165.74 crore up to 31.12.2022. However, it has been assured that a substantial amount of Rs. 538.00 crore, out of the allocated amount would be utilized by the end of this financial year. During 2023-24, against the proposed allocation of Rs. 3584.50 crore, the Department has been allocated Rs. 1000.00 crore only. The Department has stated that as PLI applicants have projected a claim of about Rs. 2203.20 crore for FY 2022-23, the allocated amount is 55 percent less than the projected applicant claims. Appreciating the initiative taken by the Department towards enhancing domestic manufacturing capabilities that will contribute to product diversification to high-value goods in the pharmaceutical sector, the Committee would like to emphasize on the need of developing an effective monitoring mechanism to constantly review the progress of the ongoing projects in the pharmaceutical sector to ensure that there is no let-up in fulfillment of the core objectives of the scheme. The Committee are of the opinion that in no case the financial constraints under the PLI scheme for pharmaceuticals be allowed to bring down the physical achievements. Hence, funds for this scheme should be adequately enhanced at RE stage.

2.14 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "It is submitted that as informed by the Secretary before the Hon'ble Committee, the Department utilized Rs. 672.60 crore (about 93% utilization of Revised RE) in F.Y. 2022-23 of the PLI scheme allocation and under the PLI scheme for Pharmaceuticals, the Utilization of Revised RE of FY 22-23 was Rs. 672.60 crore (93%) against the allocated fund of Rs. 722.20 cr. The Department has constituted a Scheme Selection and Steering Committee (SSSC) under the Chairmanship of Secretary, Department of Pharmaceuticals to monitor regularly the progress of the implementation. As suggested, the additional funds will be sought from the Ministry of Finance at RE Stage if need be."

## Recommendation No. 9

**Strengthening of Pharmaceutical Industry (SPI) (MH-2852)**

2.15 The Committee note that three sub-schemes of the DoP viz. (i) Assistance to Pharmaceutical Industry for Common Facilities (API-CF), (ii) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) and (iii) Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS) which earlier came under the umbrella scheme 'Development of Pharmaceutical Industries' (DPI) has been rearranged into a new Central Sector Scheme i.e. 'Strengthening of Pharmaceutical Industry (SPI)'. Thereupon the sub-scheme guidelines were modified under SPI and released on 11.3.2022 after stakeholder consultations. The SPI scheme aims to strengthen the existing infrastructure facilities and make India a global leader in the Pharma Sector. SIDBI has been appointed as the Project Management Consultant (PMC) for the SPI.

The Committee note that for SPI, a total financial outlay of Rs.500.00 crore has been fixed for the period from FY 2021-22 to FY 2025-26 and for FY 2023-24, the Department has been allocated an amount of Rs.149.00 crore against the proposed allocation of Rs.171.20 crore. The Committee are hopeful that with required modifications in sub-scheme guidelines under SPI scheme after consultations with the stakeholders, the performance under the sub-schemes of SPI will improve and Rs.149.00 crore allocated for SPI scheme will be optimally utilised.

2.16 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "After launching of the Scheme "Strengthening of Pharmaceuticals Industry" (SPI), the Department has accorded final approval to 4 projects and "in-principle" approval to 1 project under the sub-scheme "Assistance to Pharmaceutical Industry for Common Facilities (API-CF). The financial assistance (30% of the approved project cost as 1st instalment) in the form of grant-in-aid was released to 4 new approved projects in FY 2022-2023 itself.
>
> Further, the Department has awarded 5 new Studies under the "*Pharmaceutical and Medical Devices Promotion and Development Scheme" (PMPDS)* for conducting studies and 1st instalment (30%) has been released to the selected agencies towards conducting the Studies. The Department has organized various outreach programme for awareness of the sub-scheme "Pharmaceutical Technology Upgradation Assistance Scheme" (PTUAS) among Pharmaceutical Industries. Necessary steps shall be taken to utilize the allocated budget under the Scheme SPI."

**Recommendation No. 10**

**<u>Assistance to Pharmaceutical Industry for Common Facilities (API-CF)</u>**

2.17. The Committee note that sub-scheme 'Assistance to Pharmaceutical Industry for Common Facilities (API-CF)' of the Central Sector Scheme i.e. 'Strengthening of Pharmaceutical Industry (SPI)' aims to strengthen the existing pharmaceutical clusters' capacity by creating common facilities. The Committee, however, note that under the sub-scheme API-CF, during 2021-22 and 2022-23, against the allocation of Rs.15.61 crore and Rs. 32.00 crore, the actual utilization was Rs.9.89 crore and Rs.7.67 crore (as on 31.12.2022), respectively. Obviously there was shortfall in achievement of physical targets during these years. The target related to approval of 3 Common Facility Centres (CFC)during 2021-22 remained unachieved. Till date, only 1 project has been made functional i.e. Common Effluent Treatment Plant (CETP) at Alathur, TamilNadu. Other two projects that were approved on 31.12.2021 *viz*. (i) a Common Testing Facility, R&D with pilot plant and common logistic center at Pune, Maharashtra and (ii) Common Effluent Treatment Plant (CETP) at Sirmaur, Himachal Pradesh are still in process of commissioning. During the FY2022-23, 5 projects targeted to be approved are still awaiting final approval. The Committee are concerned about the tardy implementation of the projects under sub-scheme API-CF of SPI scheme and urge the Department that API-CF scheme should be implemented with all seriousness and every effort should be made to remove the bottlenecks in expeditious implementation of the projects so that the allocation of Rs.51.00 crore during the year 2023-24 is optimally utilised.

2.18 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "Till date 3 projects i.e. "Common Effluent Treatment Plant (CETP) at Alathur, Tamil Nadu", "Common Testing Facility, R&D with pilot plant and common logistic centre at Pune, Maharashtra" and "Common Effluent Treatment Plant (CETP) at Sirmaur, Himachal Pradesh" has been commissioned and all are functional.
>
> Department invited applications under API-CF from 1st Aug. – 7th Oct., 2022. Various awareness programmes were organized in **10 States / UT** having majority of pharma clusters. In response, 20 applications were received from 9 States / UTs. Department accorded final approval to 4 projects and "in-principle" approval to 1 project under the sub-scheme API-CF; The financial assistance (30% of the approved project cost as 1st instalment) in the form of grant-in-aid was released to the 4 new approved projects in FY 2022-2023 itself.
>
> It is submitted that there is no tardiness in the implementation of the Scheme. Technical Committee under CDSCO evaluates the proposals received and then, the Scheme Steering Committee approves the proposals based on the recommendations of the Technical Committee. The Department is taking all necessary actions to utilize the budget allocated in FY 23-24."

**Recommendation No. 11**

**Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)**

2.19 The sub-scheme Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) under the Central Sector Scheme, 'Strengthening of Pharmaceutical Industry (SPI), aims at facilitating Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards (WHO-GMP or Schedule-M) by making provision for them of interest subvention or capital subsidy on their capital loans, which will further facilitate the growth in volumes as well as in quality. However, the Committee note that during 2020-21 and 2021-22, against the token allocation of Rs. 2 Lakhs and Rs. 1 lakh, respectively, there was nil utilization of funds. Though a higher allocation of Rs. 62.00 crore was made at BE, 2022-23, it was reduced to Rs. 1.00 crore at RE, 2022-23 and again there is nil utilization of funds. As a result, the physical target of upgrading 500 and 150 MSME units during 2020-21 and 2022-23, respectively was also not achieved. The Committee find that there is no use of fixing the targets when there is no progress with regard to the implementation of the scheme and nothing is spent on the scheme during the year. Nil utilisation of funds during the last three years under PTUAS scheme is attributed to lukewarm response to the scheme despite extensive outreach conducted on the benefits of the scheme. The Committee desire that the factors responsible for the lukewarm response to the PTUAS scheme are required to be looked into and remedial measures should be taken accordingly. Matter may be discussed with the stakeholders, and if needed, possibility of revising the scheme guidelines may be looked into.

2.20 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "The Committee's suggestion regarding identification of the factors responsible for the lukewarm response to the scheme is noted. In this regard, it is submitted that the Department organized outreach programmes in **10 States** having majority of pharma clusters / MSMEs in coordination with Pharmaceuticals Associations to provide the wide dissemination about the sub-scheme "Pharmaceutical Technology Upgradation Assistance Scheme" (PTUAS), to enable the eligible Pharma MSME units to avail the benefits under the scheme. Further, the Department took several pro-active steps with a view to increase the response to the Scheme by way of amending the guidelines - for increasing the project completion period by 30 months from 18 months; achievement of technological upgradation by 30 months from 18 months from receiving of the first disbursement of loan. The Department also expanded the eligibility criteria by adding Public Financial Institutions registered with Reserve Bank of India along-with Scheduled Commercial Bank/All India Financial Institution.
>
> As explained before the Hon'ble Committee, presently, there is no market or regulatory compulsion for these Pharma MSME units to upgrade their standards to national and international regulatory standards such as WHO-GMP or Schedule-M, as the case may be, despite there is a felt need.
>
> Hence, the Department is continuously pursuing with the State Regulators and the various Industry Associations to increase the uptake of the scheme. Further, the Scheme Steering Committee in its meeting on 13$^{th}$ March, 2023 accorded its final approval for capital subsidy to 2 projects."

## COMMENTS OF THE COMMITTEE

### (Please see Para No. 1.13 of Chapter - I of the Report)

### Recommendation No. 12

2.21. The Committee note with satisfaction that four applications have been received in the year 2023 which are under scrutiny of Project Management Agency (SIDBI) and the Department is expecting better MSME industry response in 2023-24. The Committee further desire that the Department should continue to pay focussed attention for adequate publicity of the PTUAS scheme among MSMEs. The Committee would like to be assured that the Department would take immediate corrective measures and allocation of Rs.95.00 crore for the PTUAS scheme during FY 2023-24 will be fully utilised.

2.22 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "Department is taking earnest steps for positive response for the Scheme and to fully utilize the funds allocated for the Scheme in 2023-24. In continuation of the reply to Question No.11, it is submitted that under the scheme, there is provision for the selected Pharma MSME units to opt either interest subvention or capital subsidy on their capital loans to avail the benefits under the scheme. Capital subsidy will be released to the selected applicants after the successful completion of the projects and interest subvention will be released to the banks on quarterly basis. The utilization of the budget allocation in FY 23-24 depends on the options exercised by the selected applicants. Hence, depending on the applications received and options exercised by the selected applicants, necessary re-appropriation will be exercised by the Department."

**Recommendation No. 13**

**<u>Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)</u>**

2.23 The sub-scheme 'Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)' under the Central Sector Scheme, 'Strengthening of Pharmaceutical Industry (SPI)' is designed to facilitate growth and development of Pharmaceutical and Medical Device Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry. The Committee are distressed to note the under-utilization of allocated funds under the scheme. During 2020-21 and 2021-22, against the allocation Rs. 1.00 crore and Rs. 2.00 crore, the Department could utilise Rs. 0.49 crore and Rs. 1.20 crore, respectively. During 2022-23, against the allocated funds of Rs. 3.00 crore, the actual utilization is Rs. 0.24 crore (as on 31.12.2021). The Department has failed to achieve the physical targets in respect of studies and seminars during 2021-22 and 2022-23. The Committee feel that the Pharmaceutical & Medical Devices Promotion and Development scheme should be given the attention it deserves for the growth and development of Pharmaceutical and Medical Device Sectors. Hence, the Committee urge the Department to take necessary steps to achieve the physical targets fixed for the FY 2023-24 under the scheme so that allocated funds of Rs. 4 crore are fully utilised.

2.24 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "The Department has fixed a target to conduct 25 events/seminars/workshops on various topics for growth of Pharmaceutical and Medical Devices Industries in the Financial Year 2023-2024. Calendar for the event to be organized in this Financial Year is under finalization. The Department has also decided to conduct 6 studies in the Financial Year 2023-2024. Department is taking earnest steps to utilize the funds allocated for the Sub-scheme in 2023-24."

**Recommendation No. 14**

**Scheme for Promotion of Medical Devices Parks (MH 2852)**

2.25 The Committee observe that the umbrella scheme 'Development of Pharmaceuticals Industry' includes the sub-scheme 'Promotion of Medical Devices Parks' with an objective to promote 4 Medical Device Parks by providing Grants-in-Aid for creation of Common Infrastructure facilities (CIF). Total financial outlay for the Scheme is Rs. 400.00 crore for the period 2020-21 to 2024-25 and Rs.100.00 crore per Park or 70% of the cost of the CIF, whichever is less. The assistance would be 90% for North Eastern Region and Hill States. The Committee, however, are greatly concerned to note the severe shortfall in utilization of allocated funds during FY 2022-23, where out of the allocated amount of Rs.120.00 crore at RE stage, the Department could utilize Rs.89 lakhs only up to February, 2023. The reason for the shortfall is stated to be that funds were not utilized as the States could not spend the 60 percent of 1st instalment of Rs.30.00 crore and equivalent amount of the state funds, in order to become eligible for receiving 2nd instalment as per the scheme guidelines as Utilization Certificates (UCs) could not be submitted to receive second instalment of Rs.30.00 crore. The Committee are of the strong view that scheme for promotion of Medical Parks for creation of Common Infrastructural Facilities should not be allowed to suffer for procedural delays. Hence, the Department should take up the matter with the respective State Governments at the highest level without further loss of time for early issue of Utilisation Certificates from respective States. Though this project entail substantial investment initially, the benefits accruing out of it over a period of time would also be far greater. The Committee hope that the Department would take immediate steps in this direction and would be able to optimally utilize BE, 2023-24 of Rs.200.00 crore under the scheme.

2.26 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> “Suggestions of the Committee are noted. Under the "Promotion of Medical Devices Parks" scheme, the proposals of Uttar Pradesh, Madhya Pradesh, Tamil Nadu and Himachal Pradesh have been approved for providing maximum GIA of Rs. 100 crores to each State, for creation of Common Infrastructure Facilities in the Parks, being developed by the said four States. The first instalment of Rs. 30 crore each has been released in FY 2021-22. A provision of Rs.120.00 crore was kept as BE 22-23 for release of 2nd instalment to the 4 States in FY 2022-23. However, as per the scheme guidelines, the States have to utilize 75% of the 1st instalment and also do the proportionate expenditure of its own fund committed for the CIF project before the 2nd instalment is released. The physical development work is underway in the 4 parks. The grant-in-aid provided by this Department is dedicated only towards development of Common Infrastructure Facility (CIF) to be developed in these parks and State Funding is dedicated to both CIF development as well as physical infrastructure development. The State Governments have floated tenders for the land levelling works, internal road construction, drainage, power station, etc. Since the States could not utilize the prescribed amount as per guidelines, the 2nd instalment could not be released. Rs.89 lakhs were released to the Project Management Agency towards the annual fee. Regular follow-up and review meetings are being done for utilization of BE 2023-24 of Rs.200.00 crore under the scheme.”

**Recommendation No. 15**

**Scheme For Promotion of Bulk Drug Parks (MH 2852)**

2.27 Another sub-scheme under the umbrella scheme ‘Development of Pharmaceuticals Industry’ (MH-2852) is ‘Promotion of Bulk Drug Parks’ which aims at promoting 3 Bulk Drug Parks by providing Grants-in-Aid for creation of World class Common Infrastructure Facilities (CIF). A Financial assistance of Rs. 1000.00 crore per Park or 70% of the cost of the CIF, whichever is less, is provided and the assistance would be 90% for North East Region and Hill States. Total financial outlay for the Scheme is Rs.3000.00 crore and the duration of its implementation is 2020-21 to 2024-25. The Committee are, however, dismayed to note that the three beneficiary States have been selected under this scheme after a long period of 2 years and 9 months. The scheme was launched in February, 2020 and the States were selected in October/ November, 2022. Resultantly, during 2022-23, out of an allocation of Rs. 900 crore under the scheme, Rs.301.50 crore only could be utilized up to February, 2023. The Committee draw some satisfaction from the fact that the State Implementing agencies (SIA) have indicated completion of these projects within next 24-28 months which will be around the year 2024-2025 being the last year of the scheme period. It is pertinent to note that the country is in urgent need of meeting the requirement of bulk drugs indigenously rather than through imports. The Committee have been apprised that a High Level Committee has been constituted under the Hon'ble Union Minister to oversee the implementation of the scheme. Regular review meetings are being held at the level of Secretary. PMA is also pursuing with the States for implementation of the scheme as per the scheme guidelines. The Committee are appreciative of the measures taken by the Government for effective implementation of the 'Promotion of Bulk Drug Parks' scheme and hope that an amount of Rs.900.00 crore allocated under the scheme for FY 2023-24 would be fully utilized.

2.28 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> "The recommendation of the committee is noted. It is further stated that for the year 2022-23, a sum of Rs. 900 crore is allocated in BE for scheme for "Promotion of Bulk Drug Parks". Out of Rs. 900 crore, total amount of Rs. 751.50 crore has been released to three selected states i.e. Andhra Pradesh, Himachal Pradesh and Gujarat under the Grant-in-Aid head (1st instalment to each state) as well as Profession Charges to IFCI, Project Management Agency (PMA) for the scheme. For the Financial Year 2023-24, Rs. 900 crore has been allocated. Department will make best efforts to utilize the whole allocated amount under the scheme."

**Recommendation No. 16**

**<u>Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) (MH 2852 and MH2552)</u>**

2.29 A financial outlay of Rs. 490.00 crore has been approved by the Government for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) for the period 2020-2021 to 2024-2025. The Committee are happy to note that the DoP has been able to optimally utilise the funds allocated for the PMBJP during the last three years. Besides, physical targets fixed during these years to open new aushadhi kendras and enhance the product basket of medicines & surgicals and establishing wares have been largely achieved except in respect of warehouses where during 2020-21, 2021-22 and 2022-23 as against the target to open 04, 05 an 06 warehouses, 03, 04 & 05 warehouses(expected), respectively could be opened. The Department has, however, stated that it is targeted to establish 6 warehouses in the country by 2025 and accordingly, two more warehouses are planned to be opened in the country in couple of years, based on the requirement. The Committee appreciate the efforts of the Government in making quality generic medicines available to all at affordable prices. Further, a budget outlay of Rs. 115.00 crore has been made for FY 2023-24 for PMBJP, which is on a higher side as compared to BE, 2022-23 of Rs. 72.50 crore. Keeping in view the previous record in utilisation of funds, the Committee sincerely hope that the DoP would be able to optimally achieve the physical and financial targets kept for FY 2023-24.

2.30 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

"Department has been able to achieve the physical targets fixed under the PMBJP scheme (except opening of warehouses), as per details as under:

| **Financial Year** | **Target (Number of Kendras)** | **Achievement (Number of Kendras )** | **Target (Product basket) (Medicine, Surgicals)** | **Achievement (Product Basket) (Medicine, Surgicals)** | **Target (No. of Warehouses)** | **Achievement (No. of Warehouses)** |
|---|---|---|---|---|---|---|
| **2020-21** | 7300 | 7557 | 1400<br>220 | 1449<br>204 | 4 | 3 |
| **2021-22** | 8300 | 8610 | 1600<br>240 | 1616<br>250 | 5 | 4 |
| **2022-23** | 9300 | 9304 | 1800<br>280 | 1800<br>285 | 6 | 4 |
| **2023-24** | **10,000** | **9480 (As on 31.05.2023)** | **2000**<br>**300** | **1800**<br>**285 (As on 31.05.2023)** | **6** | **4 (As on 31.05.2023)** |

Under-achievement for establishing the warehouses was partly due to Covid Pandemic.

At present, four modern warehouses at Gurugram, Guwahati, Chennai and Surat for storage and distribution of drugs are functional with storage area of approx. 2,15,000sqft. It is targeted to establish 6 warehouses in the country by 2025 and accordingly, two more warehouses are planned to be opened in the country in a couple of years, based on the requirement. In addition to 36 existing distributors, PMBI is also doing direct supply to stores from warehouses to ensure sufficient availability of medicines.

For the F.Y. 2023-24, Rs. 115.00 Crore was projected at BE stage for PMBJP. Same has been allotted for the scheme. Department will utilize the amount allotted i.e. Rs. 115 crores for further expansion of scheme and achieving the set targets for the F.Y.2023-24 i.e. to open 10,000 PMBJKs by March 2024 and enhance the product basket upto 2000 medicines and 300 surgicals.

## Recommendation No. 17

**National Pharmaceutical Pricing Authority (NPPA) (Non Scheme-MH 2852)**

2.31 The NPPA is an autonomous body under the administrative control of the DoP and categorized under the non-scheme of the Department. This body administers fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), monitoring and enforcement of prices and providing inputs to the Government on pharmaceutical policy & issues related to the affordability, availability and accessibility of medicines.The Committee find that since its establishment in 1997, NPPA has been able to regulate prices of only 20 percent drug formulations under scheduled drugs category whereas 80 percent of non-scheduled drugs are still under 10 percent annual ceiling price. NPPA has capped the trade margin of non-scheduled formulations of 42 select anti-cancer medicines under “Trade Margin Rationalization” approach as a successful pilot for proof of concept in February 2019 and later in June/July 2021 for Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under the same approach during Covid.

The Committee desire that NPPA being the national drug price regulator should put in extra efforts for access by common man to affordable medicines and medical devices and therefore DoP/NPPA shall jointly resolve the challenges in the way of effective implementation of the provisions of Drugs Price Control Order 2013 to ensure that maximum formulations are covered under the scheduled drug price regulation in the minimum time possible. The Committee would like to be apprised of the progress in this regard from time to time.

The Committee would also desire to be apprised of the progress with regard to the proposal to regulate the prices of non-scheduled drugs which is under consideration of the DoP.

2.32 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> “The National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling prices of formulations listed in Schedule I of DPCO, 2013, which is notified by Department of Pharmaceuticals (DoP) based on the National List of Essential Medicines (NLEM) notified by MoH&FW from time to time. Accordingly, revised Schedule-I of DPCO, 2013 was notified by DoP on 11th November 2022. 32012/1/2022-Admn(NPPA) I/5892/2023 As on 24.05.2023, ceiling prices for 671 scheduled formulations have been fixed under NLEM, 2022. In case of few formulations that have been included under NLEM 2022 for the first time, high inter brand price

variations of the same formulation sold by a particular company were observed. Therefore, as per various provisions of DPCO,2013 for the newly added formulations of NLEM, 2022, where interbrand variation (including Meropenem) of the same company is more than 10% prices were re-fixed. Further, NPPA also fixes retail prices of new drugs and as on 24.05.2023, Retail price of 2376 new drugs under DPCO, 2013 has been fixed."

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# CHAPTER – III

## OBSERVATION / RECOMMENDATION WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLY

NIL

## CHAPTER – IV

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

### RECOMMENDATION NO. 3

**New Schemes under National Institute of Pharmaceutical Education and Research (NIPER) MH-2852**

4.1 The Committee acknowledge the budgetary challenges faced by the DoP with respect to NIPER scheme. The Department had sought Rs. 4300.00 crore for a period of 5 years from 2021-22 to 2025-26.However, the Economic Finance Committee (EFC) approved Rs. 1500 crore only. Again, for the FY 2023-24, the Department sought an amount of Rs.1286.00 crore with an objective to launch new initiatives viz. National Institute of Medical Devices Education and Research (NIMERs) (Rs.200.00 crore), Centres of Excellence (CoEs) (Rs.233.00 crore), Indian Council of Research & Development and Innovation in Pharma-MedTech Sector (ICPMR) (Rs.50.00 crore) and Promotion of Research & Innovation in Pharmaceutical Sector (PRIP) (Rs.243.00 crore).However, no funds have been allocated for the same and Rs. 550.00 crore only has been allocated for the existing NIPER scheme. The Committee are of the view that reduced budget allocation will adversely affect the progress and growth of NIPER scheme of the Department. This is regrettable since the establishment of more NIPERs across the country would fill a vital need. The Committee also recommend the establishment of a NIPER in a Southern State where interest in pharmaceutical education is high.

The Department has, however stated that keeping in view the budget 2023-24 announcements with respect to Pharma innovations and multidisciplinary courses for medical Devices, additional funds will be sought from Ministry of Finance at later stage. The Committee are of the view that the proposed initiatives of the Department viz. NIMERs will provide specialized courses in the field of medical devices and CoEs under PRIP are crucial to strengthen the foundation of research and development in pharmaceutical and medical device sector in the country which is still lagging far behind other countries. Further, setting up an R & D Council like ICPMR is also the need of the hour to enable the Department for uninterrupted promotion and coordination in Pharma-MedTech field. The Committee share the concern of the Department that our country needs support in high end therapeutics and medical devices and would strongly recommend that financial allocations be stepped up for the NIPER scheme of the Department and at least maintained at the previous level of Rs. 1286.00 crore.

4.2 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:

> “The Committee's concerns/ recommendations have been duly noted. It is further informed that the department has since obtained approval for the "Promotion of Research and Innovation in Pharma-Med Tech Sector (PRIP)" scheme during the EFC meeting held on15.03.2023 with an overall budget of Rs. 5,000 crore for a duration of 5 years, from 2023-24 to 2027-28. The Scheme would be placed for approval of the Cabinet after recommendations of the Empowered Technology Group (ETG).”

**COMMENTS OF THE COMMITTEE**

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

# CHAPTER – V

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

**NIL**

**New Delhi;**
**14 December, 2023**
**23 Agrahayana 1945 (Saka)**

**DR. SHASHI THAROOR**
**Chairperson,**
**Standing Committee on**
**Chemicals and Fertilizers.**

**STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2023-24)**

**Minutes of the Fourth Sitting of the Committee**

The Committee sat on Monday, the 04th December, 2023 from 1600 hrs. to 1715 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

**PRESENT**

**Dr. Shashi Tharoor – CHAIRPERSON**

**MEMBERS**

**LOK SABHA**

2. Shri Prataprao Patil Chikhlikar
3. Shri Rajeshbhai Naranbhai Chudasama
4. Shri Satyadev Pachauri
5. Smt. Aparupa Poddar
6. Shri Arun Kumar Sagar
7. Shri Pradeep Kumar Singh

**RAJYA SABHA**

8. Dr. Anil Jain
9. Shri Ram Nath Thakur
10. Shri Vijay Pal Singh Tomar

**SECRETARIAT**

| | | | |
|---|---|---|---|
| 1. | Shri Chander Mohan | - | Joint Secretary (CM) |
| 2. | Smt. Geeta Parmar | - | Director |
| 3. | Shri Kulvinder Singh | - | Deputy Secretary |

**LIST OF WITNESSES**

**I. REPRESENTATIVES OF MINISTRY OF CHEMICALS AND FERTILIZERS**

**(DEPARTMENT OF CHEMICALS AND PETROCHEMICALS)**

| | | | |
|---|---|---|---|
| 1. | Ms. Nivedita Shukla Verma | - | Secretary (C&PC) |
| 2. | Shri Deepak Mishra | - | Joint Secretary (Petrochemicals) |
| 3. | Shri Susanta Kumar Purohit | - | Joint Secretary (Chemicals) |
| 4. | Ms. Divya Parmar | - | Economic Adviser |

5. Shri Awijit Rakshit - Director (Petrochemicals)

6. Shri Ram Sajeevan - Director (Statistics and Monitoring)

**II. REPRESENTATIVE OF CENTRAL INSTITUTE OF PETROCHEMCIALS ENGINEERING AND TECHNOLOGY (CIPET)**

1. Shri Shishir Sinha - Director General

**III. REPRESENTATIVE OF MINISTRY OF ENVIRONMENT, FORESTS AND CLIMATE CHANGE**

1. Shri Satyendra Kumar - Director (HSMD), MoEFCC

2. At the outset, the Chairperson welcomed the Members to the sitting of the Committee convened to consider and adopt the Draft Report and for having a Briefing by the representatives of the Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers on the subject 'Setting up of Plastic Waste Management Centres'.

3. The Committee took up for consideration the draft Action Taken Report on the 40th Report on "Demand for Grants (2023-24)" pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers and adopted the same without any modifications/amendments. The Committee, then authorized the Chairperson to finalize and present the Report to the Parliament.

4. XXXX XXXX XXXX XXXX XXXX XXXX

5. XXXX XXXX XXXX XXXX XXXX XXXX

6. XXXX XXXX XXXX XXXX XXXX XXXX

7. XXXX XXXX XXXX XXXX XXXX XXXX

8. A copy of the verbatim record of the proceedings of the sitting has been kept.

*(The witness then withdrew).*

*The Committee then adjourned.*

**APPENDIX-II**

**ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FORTY SECOND REPORT (SEVENTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2023-24) ON DEMAND FOR GRANTS (2023-24) OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS).**

| | | |
|---|---|---|
| | Total No. of Recommendations | 17 |
| I | Observations/Recommendations which have been accepted by the Government:<br><br>(*Vide* Recommendation Nos.<br><br>(1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17) | 16 |
| | Percentage of Total | 94% |
| II | Observations/Recommendations that the Committee do not like to pursue in view of the Government's replies:<br><br>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:<br>(Vide Recommendation No. 3) | 01 |
| | Percentage of Total | 6% |
| IV | Observations/Recommendations in respect of which the final replies of the Government are still awaited:<br><br>(*Vide* Recommendation No. Nil ) | 0 |
| | Percentage of Total | 0% |