



**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2021-22)**

(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 Thirty-Fourth Report (Seventeenth Lok Sabha) on 'Demands
for Grants (2022-2023)' of the Ministry of Chemicals and
Fertilizers (Department of Pharmaceuticals)**

THIRTY-EIGHTH REPORT



सत्यमेव जयते

LOK SABHA SECRETARIAT

NEW DELHI

August, 2022/ Sravana, 1944 (Saka)

THIRTY-EIGHTH REPORT

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(2021-22)

(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
Thirty-Fourth Report (Seventeenth Lok Sabha) on 'Demands for Grants
(2022-2023)' of the Ministry of Chemicals and Fertilizers (Department
of Pharmaceuticals)**

Presented to Lok Sabha on 08 August, 2022

Laid in Rajya Sabha on 08 August, 2022



LOK SABHA SECRETARIAT

NEW DELHI

August, 2022/ Sravana, 1944 (Saka)

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**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2021-22)**

Smt. Kanimozhi Karunanidhi - Chairperson

**MEMBERS
LOK SABHA**

2. Shri Dibyendu Adhikari
3. Maulana Badruddin Ajmal
4. Shri Deepak Baij
5. Shri Ramakant Bhargava
6. Shri Prataprao Patil Chikhlikar
7. Shri Rajeshbhai Naranbhai Chudasama
8. Shri Sanjay Shamrao Dhotre
9. Shri Ramesh Chandappa Jigajinagi
10. Shri Kripanath Mallah
11. Shri Vasava Parbhubhai Nagarbhai
12. Shri Satyadev Pachauri
13. Smt Aparupa Poddar (Afrin Ali)
14. Dr. M.K.Vishnu Prasad
15. Shri Arun Kumar Sagar
16. Shri M. Selvaraj
17. Dr. Sanjeev Kumar Singari
18. Shri Atul Kumar Singh
19. Shri Pradeep Kumar Singh
20. Shri Uday Pratap Singh
21. Shri Indra Hang Subba

RAJYA SABHA

22. Shri Ayodhya Rami Reddy Alla
23. Shri G.C.Chandrashekhar
24. Dr. Anil Jain
25. Shri Anthiyur P. Selvarasu
26. Shri Arun Singh
27. Shri Vijay Pal Singh Tomar
28. Shri K. Vanlalvena
29. Vacant*
30. Vacant*
31. Vacant

SECRETARIAT

- | | | | |
|----|------------------------|---|-------------------|
| 1. | Shri Vinay Kumar Mohan | : | Joint Secretary |
| 2. | Shri Nabin Kumar Jha | : | Director |
| 3. | Shri Kulvinder Singh | : | Deputy Secretary |
| 4. | Ms. Sonia Sankhla | : | Executive Officer |

* Vacant *vice* Shri M.V. Shreyams Kumar (LJD), MP (RS) retired on 02.04.2022 from the Membership of Rajya Sabha. (RSS I.D. No. 1(2)/2019- Coord dated 18.01.2022).

* Vacant *vice* Shri Jaiprakash Nishad (BJP), MP (RS) retired on 04.07.2022 from the Membership of Rajya Sabha. (RSS I.D. No. 1(2)/2019- Coord dated 18.01.2022).

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2021-2022) having been authorized by the Committee, do present on their behalf this Thirty-Eighth Report on Action taken by the Government on the Observations/Recommendations of the Committee contained in their Thirty-Fourth Report (Seventeenth Lok Sabha) on 'Demands for Grants (2022-23)' pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Thirty-Fourth Report was presented to Lok Sabha and laid in Rajya Sabha on 21st March, 2022. The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) furnished their replies on 28th June, 2022 indicating Action Taken on the Observations/Recommendations contained in the Thirty-Fourth Report. The Committee considered and adopted the Draft Report at their sitting held on 4th August, 2022.

3. An analysis of the Action Taken by the Government on the Observations/Recommendations contained in the Thirty-Fourth 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;
08 August, 2022
13 Sravana, 1944 (Saka)

KANIMOZHI KARUNANIDHI
CHAIRPERSON,
STANDING COMMITTEE ON
CHEMICALS & FERTILIZERS.

CHAPTER-I

REPORT

1.1 This Report deals with the action taken by the Government on the Observations/ Recommendations of the Committee contains in their Thirty-Fourth (17th Lok Sabha) on 'Demands for Grants (2022-23)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

1.2 The Thirty-Fourth Report was presented to Lok Sabha and laid in Rajya Sabha on 21st March 2022. It contained 19 Observations/Recommendations. 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:-

Sl.Nos. 3,4,5,8,9,11,12,15,16,17,18 and 19 (Total=12)

These are included in Chapter II of the Report. Percentage: 64%

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

Sl.No. Nil (Total = 0)

These are included in Chapter III of the Report. Percentage:00.00%

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

Sl.No. 1,2,6,7,10,13 and14 (Total = 7)

These are included in Chapter IV of the Report. Percentage 36%

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

Sl.No. NIL (Total=0)

These are included in Chapter V of the Report. Percentage: 00.00%

1.3 The Committee desire that the Action Taken Notes on the Observations/Recommendations contained in Chapter-I of this Report may be

furnished expeditiously and not later than three months from the date of presentation of this Report.

1.4 The Committee will now deal with some of their earlier Observations/Recommendations which either require reiteration or merit further comments.

(Recommendation No. 1)

Budgetary allocation for the Department of Pharmaceuticals

1.5 With regard to the Budgetary allocation for the Department, the Committee had recommended as follows:-

“The Committee note that a gross budgetary allocation of Rs.2244.15 Crore has been made for the Department of Pharmaceuticals at Budget Estimate (BE) stage of 2022-23 against the outlay of Rs.10383.25 Crore proposed by the Department for the year. In comparison, the Gross Budgetary allocation for the year 2021-22 was Rs. 470.41 Crore against the proposed outlay of Rs.2600.52 Crore which was only 18% of the outlay proposed by the Department and this time it has increased to 21.6%. Even though the actual allocation for the year 2022-23 is very less when compared to the demand of the Department, the major chunk of this allocation has been made for Central Sector Schemes of the Department. Against the proposal of Rs.2313.02 Crore, an allocation of Rs. 2202.50 Crore has been made for the Central Sector Schemes of the Department. For the Heads relating to the “Development of Pharmaceutical Industry”, Rs.1729.00 Crore has been allocated against the demand of Rs.1767.02 Crore of the Department. Under the Capital Section of “Assistance to PSUs” , the Department demanded Rs.8026.78 Crore but only an allocation of Rs.5.30 Crore has been made at the BE stage of 2022-23. Since the demand for grants of the Department for implementing its developmental schemes has almost been fully met by the budgetary allocation, the Committee feel that the ball is now in the court of the Department. Unlike previous years, this year the hands of the Department have been strengthened with the requisite amount of budgetary allocation by the Ministry of Finance. Now the Department has to prove its mettle through effective implementation of all its development schemes. In this regard, the Committee recommend that an annual action plan with monthly achievable targets should be chalked out by the Department in respect of all the developmental schemes for which requisite amount of budgetary allocation has been made under Major Heads 2852 and 2552 and concrete steps should be taken for achieving targets under each of the developmental Schemes for timely and resourceful utilization of budgetary allocations made for the year. An effective monitoring of implementation of each of the development Schemes should be made at highest level in the Department and it should be ensured that the targets fixed for each of the Schemes are achieved in a time bound manner during the year 2022-23 through the full utilization of budgetary allocation. Progress made in this regard should be intimated to the Committee”.

REPLY OF THE GOVERNMENT

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

“For the FY 2022-23, the Department had proposed Rs. 10383.25 crore as Budget Estimates for the financial year. However, only Rs. 2244.15 crore was allocated by the Ministry of Finance. Department will seek additional funds from the Ministry of Finance at RE Stage, if need be. The Details in respect of various schemes are as under:

NIPER: Department has set targets, which have been conveyed to the individual NIPERs. Monthly review meetings with Directors of all NIPERs are held at the level of Secretary of the Department and on quarterly basis at the level of Hon'ble Minister for Chemicals & Fertilizers. It will be ensured that the funds allocated by Department of Expenditure will be utilized for construction of campuses of NIPERs at Raebareli, Ahmedabad, Kolkata, Hyderabad and Hajipur and also for purchase of equipment as well to meet recurring expenditure of the Institute.

Development of Pharmaceuticals and PLI Schemes: The Department has a concrete plan to achieve the targets envisaged schemes such as PLI, strengthening the Pharmaceutical Industry, etc. The prescribed monitoring mechanism envisaged under the Schemes such as Empowered Committee for the PLI schemes of Bulk Drugs and Medical Devices and the Scheme Steering Committee (SSC) of the SPI scheme, etc will be fully involved in the monitoring of the implementation of the schemes. Further, the Project Management Agencies (PMAs) appointed under the PLI and SPI schemes will be fully involved in monitoring the progress of the schemes, as per the milestones envisaged. Department has proposed an amount of Rs. 1767.02 crore as BE 2022-2023 for the ***Scheme “Development of Pharmaceutical Industry***. However, Rs. 1729.00 crore has been allocated. The additional funds will be sought from the Ministry of Finance at RE Stage if need be.

Jan Aushadhi Schemes: Department has proposed an amount of Rs. 100.00 crore as BE- 2022-23 for PMBJP to meet the target to open 1,000 new Kendras and enhance the product basket up to 1,800 medicines and 280 surgicals. However, an amount of Rs. 72.50 Crores only have been allotted under BE 2022-23. In order to effectively implement the scheme and achieve the vision targets under PMBJP, the Department will seek additional funds from the Ministry of Finance at RE stage.

NPPA: The total budget provision for the scheme Consumer Awareness, Publicity and Price Monitoring (CAPP) for the F.Y. 2022-23 is Rs. 6.00/- crore, viz. (i) Grant inAid for Assistance to PMRUs Rs. 5.00 Crore and (ii) Advertising and Publicity Rs.1.00 Crore. The budget allocation for Grant in Aid to PMRU for the F.Y. 2022-23 is Rs. 5.00 Crore which is at par with the budget allocation that was made in the F.Y. 2021-22. Price Monitoring and Resource Units (PMRUs) have been set up in Twenty Three (23)

States/UTs till 31st March 2022. There is a target to set up PMRUs in six (6) States in the F.Y. 2022-23 and in all the States/ UTs by the F.Y. 2023-24.

PSU: Department proposed an amount of Rs. 8026.78 crore for meeting various outstanding liabilities of various banks and other unsecured liabilities in respect of Department PSUs, i.e., HAL and IDPL. However, against the proposed amount, only, Rs. 5.30 crore have been allocated which shall be utilized for meeting contingent expenditure, court cases etc. for the FY 2022-23. Additional funds will be sought from the Ministry of Finance at RE Stage based on the requirements”.

1.7 The Committee note that for the 2022-23, the BE of the Department was Rs. 10383.25 crore but it was revised downward to just Rs. 2244.15 crore. Thus a drastic cut of about Rs 8139.10 crore has been made. Similarly for the year 2021-22 the BE was Rs. 2600.52 crore but it was revised downwards to Rs. 470.41 crore and a major cut of Rs. 2130.11 crore was made. Further for the year 2022-23 an allocation of Rs. 2202.50 crore has been made for the Central Sector Schemes of the Department. Noting the meagre amount allocated to the Department the Committee had recommended that (i) an annual action plan with monthly achievable targets should be chalked out by the Department in respect of all the developmental schemes for which requisite amount of budgetary allocation has been made under Major Heads 2852 and 2552 and (ii) concrete steps should be taken for achieving targets under each of the developmental Schemes for timely and resourceful utilization of budgetary allocations made for the year. However the Ministry has submitted that for ‘NIPER’ the Department has set targets which have also been conveyed to the individual NIPERs and monthly review meetings are also stated to be convened but their details have not been furnished to the Committee. Similarly, the Ministry has submitted that they have a ‘Concrete Plan’ for Development of Pharmaceuticals and PLI schemes but details thereof have not been furnished. Further for ‘Jan Aushadhi Schemes’ and ‘NPPA’ just their BE and RE have been furnished to the Committee. It appears to the Committee that the Department has not paid serious consideration to the recommendation of the Committee. The Committee, therefore, reiterate their earlier recommendation and desire that the Ministry should come out with the action plan with monthly achievable targets along with effective monitoring of implementation of all the Central Sector Schemes and the Committee be apprised accordingly.

(Recommendation No. 2)

Construction of campuses for National Institute of Pharmaceutical Education and Research (NIPER)

1.8 With regard to the Construction of campuses for National Institute of Pharmaceutical Education and Research (NIPER), the Committee had recommended as follows:-

The Committee note that an allocation of Rs.395.00 Crore has been made for NIPERS (in MH 2552 + 2852) against the proposal of the Department for Rs.440.00 Crore for 2022-23. The fund allocated by the Ministry of Finance will be utilized for construction of NIPER Campuses at Raebareli, Ahmedabad, Kolkata, Hyderabad and Hajipur and also for purchase of equipments/meeting recurring expenditures of the institutes. As far as construction of NIPER campuses is concerned, the Department proposes to complete 100% of construction in respect of Ahmedabad NIPER and 30% of construction in respect of Hajipur, Hyderabad, Raebarelli and Kolkata NIPERS. Recently, the Committee visited NIPERS at Guwahati and Kolkata. While construction of permanent campus for Guwahati was almost complete, the Kolkata NIPER was functioning in small rented premise which is not commensurate with the status of 'Institution of National Importance'. The Committee, therefore, feel that it is a matter of utmost importance that the state of the art permanent campuses for Hajipur, Hyderabad, Raebarelli and Kolkata NIPERS is created in a time bound manner so as to enable them to function in the true spirit of 'Institutions of National Importance'. The Committee, therefore, strongly recommend that the construction of permanent campuses for these four NIPERs should be completed within two years. Department, now proposed to complete 30% of construction during 2022-23 with the budgetary funds allocated for the purpose. Instead the Department may plan to complete 50% of construction of all the four NIPERs during 2022-23 and rest of the construction may be completed during 2023-24. In case of requirement of more funds for construction of these four NIPERs namely Hajipur, Hyderabad, Raebarelli and Kolkata additional demand may be made at RE /supplementary demands during 2022-23. This recommendation of the Committee may also be sent to the Ministry of Finance for its consideration. The Action taken in this regard should be intimated to the Committee.

REPLY OF THE GOVERNMENT

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

MoUs have been signed between CPWD and NIPERs for construction of campus at Raebareli, Kolkata and Haripur. Construction of campus at NIPER Ahmedabad is at full swing and expected to be completed by August, 2022 while construction of campus NIPER Hyderabad will start shortly by M/s NPCC Limited, the PMC appointed for construction of campus. Progress of construction activities is regularly reviewed at Department level. Additional funds at RE stage will also be sought to complete the

targeted quantum of construction activities. Further, the recommendation of the Committee has been sent to the Ministry of Finance for its consideration.

1.10 The Committee have been informed that for construction of NIPERs MoUs have been signed with CPWD at Raebareli, Kolkata and Hajipur. Construction of campus at NIPER Ahmedabad is at full swing and expected to be completed by August, 2022 while construction of campus NIPER Hyderabad will start shortly by M/s NPCC Limited. Progress of construction activities is regularly reviewed at Department level. In this regard the Committee had strongly recommended that the construction of four NIPERs should be completed within two years. However the Department proposed to complete 30% of construction during 2022-23 but the Committee were of the view that the Department may plan to complete 50 percent of construction during 2022-23 and rest of the construction be completed by 2023-24. However, in the reply furnished by the Department such seriousness is not reflecting as no target date for construction of NIPERs have been furnished. In this regard, the Committee note that though the construction of campus at NIPER Ahmedabad is expected to be completed by August, 2022 but construction of campus NIPER Hyderabad is yet to commence and MoUs have been signed between CPWD and NIPERs for construction of campus at Raebareli, Kolkata and Hajipur. It appears that completion of even 30% construction work of these NIPERs as committed by the Department during 2022-23 seems to be difficult. Reiterating their earlier recommendation, the Committee, therefore, strongly recommend that a target date for construction of NIPERs may be fixed and the construction may be vigorously reviewed to complete the construction work in time.

(Recommendation No. 6)

Setting up of five new NIPERS

1.11 With regard to the Setting up of five new NIPERS, the committee had recommended as follows:-

“The Committee are constrained to note that the proposal to set up five new NIPERs in Tamil Nadu (Madurai), Karnataka (Bangalore), Chhattisgarh, Rajasthan and Maharashtra are still on paper without any concrete action to set up them. In this regard, the Committee note that the Department had asked the Expenditure Finance Committee (EFC) to allocate Rs.4300.00 Crore for present seven NIPERs and additional five NIPERs for the next five years. However, EFC has earmarked only Rs.1500.00 Crore for NIPERs with the rider that this allocation should be utilized only for the existing seven NIPERs. In this regard, the Department of Pharmaceuticals now proposed to explore the alternate ways of funding of these NIPERs. Since the present number of seven NIPERs are hardly sufficient to meet the requirements of the country in the field of Pharmaceutical Education and Research, the Committee strongly recommend that all necessary steps should be taken by the Department of Pharmaceuticals for the early setting up of five new NIPERs. In this regard, a fresh proposal may be submitted to EFC for reconsideration of their decision and the concern expressed by this Committee may be conveyed to them. The Department may also explore alternate ways of funding of these NIPERs including financial contribution by both the Union and the concerned state Governments so that these five NIPERs are also developed and completed in a time bound manner. Progress made in this regard may be conveyed to the Committee”.

REPLY OF THE GOVERNMENT

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 recommendations of the Committee have been noted and a Committee has since been set up with the approval of Hon’ble Minister of Chemicals & Fertilizers for exploring other options for setting up of new NIPERs”.

1.13 The Department has submitted that the recommendation of the Committee have been noted and a Committee has since been set up with the approval of Hon’ble Minister of Chemicals & Fertilizers for exploring other options for setting up of new NIPERs. However, the details of the Committee and steps taken by it so far for exploring alternate ways of funding of NIPERs have not been furnished . The Committee desire that the details regarding composition of the Committee, date of constitution of the Committee, sittings held so far by the Committee, a gist of major recommendations made and major decision taken etc. may please be furnished for the consideration of the Committee at the earliest.

(Recommendation No. 7)

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

1.14 With regard to the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), the Committee had recommended as follows:-

“The Committee note that a Budgetary allocation of Rs. 72.50 Crore has been made for PMBJP against the Department of Pharmaceutical’s proposal for Rs. 100.00 Crore for 2022-23. Under this Scheme, a target has been fixed to open new 1000 Kendras and enhance the product basket upto 1,800 medicines and 280 surgicals during the year 2022-23. Further, a sale target of Rs. 775.00 Crore has also been prescribed for the year. As per the Department, the funds allocated at BE stage are not sufficient and less allocation of funds will hamper effective implementation of the scheme. The Scheme aims to make available quality generic medicines at affordable prices to all especially for the poor and the deprived ones. As on 15.02.2022, 8683 PMBJP outlets have been opened in the country with product basket of 1451 medicines and 240 surgicals. In this regard, the Committee feel that the number of PMBJP outlets in the country are inadequate when compared to nine lakh plus medical shops in the country. Further with regard to the present population of the country i.e. near about 140.52 crore it is noted that one Kendra is catering to approximately 16 lakh population. Hence, there is a need to increase the number of PMBJP outlets in the country and also to increase the product basket of the outlets. The Committee, therefore, recommend that the Department of Pharmaceuticals should impress upon the Ministry of Finance for the allocation of remaining funds (Rs. 27.50 Crore) required for effective implementation at RE stage of 2022-23. This recommendation of the Committee should also be sent to the Ministry of Finance for its implementation”.

REPLY OF THE GOVERNMENT

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

The government has set up a target to open 10,000 stores by March, 2024. This will imply about one store for a population of 1.50 lakhs. The Kendras have been opened in all district of the country. Now the government intends to reach all the Blocks, with more stress towards aspirational districts, NE areas, hilly and island territories. However, financial viability of individual Kendra is also required to be taken into consideration, while expanding the scheme.

During the financial year 2022-23, a target has been fixed to open about new 1,000 Kendras with cumulative total to about 9300 Kendras and to enhance the product basket up to 1,800 medicines and 280 surgicals.

The Recommendation of the Committee for allocation of additional funds has been sent to the Ministry of Finance on 26.05.2022 for necessary action. Department will approach M/o Finance at RE stage 2022-23 for allocation of additional funds.

1.16 The Committee note an amount of Rs. 72.50 crore has been made for PMBJP against the proposal for Rs. 100.00 crore during the year 2022-23. Thus there is a shortfall of Rs. 27.50 crore and the Department has submitted that at RE stage the matter would be taken up with the Ministry of Finance for allocation of the remaining amount. The Committee further note that the target to set up 10,000 stores by March, 2024 has been set by the Government. The Committee, therefore, desire to know about the utilization of funds out of the allocated amount of Rs. 72.50 crore so far and steps taken for achievement of the target for opening 10,000 stores.

(Recommendation No. 10)

Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

1.17 With regard to the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), the Committee had recommended as follows:-

“The Committee note that the Department had sought Rs 100.00 Crore for the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) but the approved BE allocation is Rs 62.00 Crore for the year 2022-23. According to the Department, the reason for this difference in proposed and approved BE allocation is the present revision of scheme guidelines of PTUAS as per EFC approval. Once approved, eligible applications will be considered in FY 2022-23. Only token allocation was made to this important Scheme during the financial years 2019-20, 2020-21 and 2021-22. For the first time, the scheme has got the needed financial support of Rs 62.00 Crore at BE stage of 2022-23. The aim of PTUAS is to provide interest subvention to the Pharmaceutical Medium Small and Micro Enterprises (Pharma MSMEs) to upgrade their standards both in terms of quality and technique to WHO-Good Manufacturing Practices so that the Pharma MSMEs would be able to produce quality drugs and become globally competitive. This Scheme enables upgradation of these enterprises from Schedule M to WHO-GMP standards so that they are eligible to export in global markets and earn foreign exchange. Out of 6790 SMEs in manufacturing bulk and API drugs, only 2006 are WHO-GMP certified and more than 4500 remain outside the purview of WHO-GMP certification. The Committee are constrained to note that this Scheme remained on paper with token allocations during the last three financial years. With the allocation of funds made for 2022-23, it is time for the Department to initiate concrete and time bound efforts to start implementing this Scheme from 2022-23 onwards. The Committee, therefore, strongly recommend:

i) Guidelines of the scheme should be finalized quickly and the fund allocated for 2022-23 should be fully utilized”.

REPLY OF THE GOVERNMENT

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

i) The guidelines of the Scheme “Strengthening of Pharmaceuticals Industry” (SPI) has been finalized and published in the Department's Website on 11.03.2022, which includes the sub-scheme PTUAS. The sub-scheme, PTUAS has been incorporated under the Scheme SPI with the budget allocation of Rs. 300.10 crore for Financial Year 2021-2022 to 2025-2026. Further, M/s SIDBI have been appointed as the Project Management Consultant (PMC) for implementation of the Scheme.

ii) Department will seek additional funds from the Ministry of Finance at RE Stage, if need be.

iii) Under the PTUAS scheme, a target has been set by the Department to provide support to about 420 Pharma MSMEs for upgrading their technology to meet WHO-GMP or Schedule M standards till March 2026. Efforts will be made to achieve the above targets in a time bound manner.

1.19 **The Committee note that for the year 2022-23, an amount of Rs. 62.00 crore have been allocated for Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) whereas during the year 2019-20, 2020-21 and 2021-22 only token allocation was made. This is for the first time that needed financial support of Rs. 62.00 crore has been made. The Committee further note that the aim of PTUAs is to provide interest subvention to the Pharmaceuticals, Medium, Small and Micro enterprises (Pharma MSMEs) to upgrade their standards both in terms of quality and technique to WHO-GMP Manufacturing practices to enable them to produce quality drugs and become globally competitive. Considering there important facts, the Committee had recommended that the guidelines of the schemes be finalized and they have been finalized too. However, with regard to upgrading of MSMEs (Pharma MSMEs) the Committee had noted that out of 6790 Pharma MSME only 2006 are WHO-GMP certified and more than 4500 remained outside the purview of WHO-GMP certification. In this regard, the Department has submitted that a target to provide support to just 420 pharma MSMEs for upgrading their technology to meet WHO-GMP or schedule M standards till March 2026 has been set up. The Committee are surprised to note the small figure of MSMEs taken up for up-gradation that too upto 2026. When about 4500 MSMEs remained outside the purview of WHO-GMP certification. The Committee strongly**

recommend that the Department should review the target of upgrading just 420 MSMEs by the year 2026 and increase this figure as well try to decrease the time period involved in the process. The Committee desire that the remaining 4500 MSMEs also be upgraded to WHO-GMP certification at the earliest.

(Recommendation No. 13)

Promotion of Bulk Drug Parks (Assistance to Bulk Drug Industry for Common Facilitation Center)

1.20 With regard to the Promotion of Bulk Drug Parks (Assistance to Bulk Drug Industry for Common Facilitation Center), the Committee had recommended as follows:-

- (i) “The Committee note that the objective of this sub scheme is to promote three Bulk Drug Parks by providing Grants-in-Aid for creation of World class Common Infrastructure facilities (CIF). A Financial assistance of Rs. 1000 crore per Park or 70% of the cost of the CIF, whichever is less is provided. 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 note that this Scheme has not been able to take off since 2019-20. During 2019-20 only a token allocation was made. Later during 2020-21, Rs.1.68 Crore was utilized out of RE allocation of Rs.1.69 Crore for Project Management Agency. Further during 2021-22, Rs.36.24 Crore at RE stage remained unutilized as the process to select beneficiary states could not be completed. However, it is noted that an amount of Rs.900.00 Crore has been allocated in BE 2022-23. This amount will be used to give first instalment of Rs. 300.00 Crore each to the three selected states for creation of Common Infrastructure Facilities (CIFs) as grant-in-aid. Thirteen states have applied for assistance under the Scheme. Since the Project Management Agency (PMA) has identified certain issues in the proposals received under this scheme during 2021-22, an advisory Committee has been constituted with CEO NITI Aayog, Secretary, DoP and representatives of DPIIT & Department of Expenditure which has advised the Department to apply a set of qualitative filters to the proposals received looking at the higher technology, market and environmental risks emerging in the last year in respect of the Bulk Drug segment. The process in this regard is presently underway in the Department. The country is in urgent need of meeting the requirements of bulk drugs indigenously rather than dependence on other countries. The Committee, therefore, recommend that the process of selection of three beneficiary states should be expedited and the first instalment of Rs.300.00 Crore should be released to the States which are to be selected for implementation of the Scheme so that the undesirable situation of surrender of unutilized budgetary allocation does not recur again”.

- (ii) The Committee also feel that three bulk drug parks are not adequate to meet the production needs of bulk drugs in the country particularly keeping in view its status of “World Pharmacy”. Since there is vast potential for export in the pharma sector, the Committee recommend that more Bulk Drug Parks may be set up in all the aspiring states and the Ministry of Finance may be approached for requisite budgetary allocation for the purpose.

REPLY OF THE GOVERNMENT

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

- (i) “The recommendation of the committee is well taken. It is further stated that as provided by the guidelines of the scheme, the selection of States shall take place once in-principle approval is granted and DPRs are finalized. In pursuance to the same and guidance provided by the Advisory Committee constituted under the chair of CEO, NITI Aayog, continuous effort is being undertaken by the Department to ensure early selection of States and subsequent release of financial assistance under the aforesaid Scheme”.
- (ii) After implementation of the scheme for 3 bulk drug parks and evaluation of performance thereof, a considered view may be taken to assess need for expansion in view of prevailing situation in terms of level of drug security achieved, proliferation of parks/clusters, adequacy of market incentives and incentives given by respective State Governments, etc.

1.22 The Committee note that the objective of the Assistance to Bulk Drug Subsidy for common facilitation Centre is to promote three Bulk Drug Parks by providing Grant-in-aid for creation of world class common infrastructure facilities. In this regard, thirteen states have applied for assistance under the scheme, and an advisory committee has been constituted with CEO NITI Aayog, Secretary DoP, representative of DPIIT and Department of Expenditure. The Committee have been informed that the selection of states shall take place once ‘in-principle’ approval is granted and DPRs are finalized and continuous efforts are being undertaken to ensure early selection of States and subsequent release of financial assistance under the scheme. In this regard, the Committee in the first instance desire to know the precise reason for delay in according ‘in-principle’ approval and finalization of DPRs. The Department should had ‘in-principle’ approval and DPRs finalized before requesting states to provide their inputs. The Committee strongly recommend that the Department should pursue

the matter at the highest level and the needed 'in-principle' approval etc be accorded. The Committee would like to be apprised of the action taken by the Department in this regard.

Recommendation No. 14

Promotion of Medical Devices Parks (Assistance to Medical Device Industry for Common Facilitation Center)

1.23 With regard to the Promotion of Medical Devices Parks (Assistance to Medical Device Industry for Common Facilitation Center), the Committee had recommended as follows:-

- i. The Committee note that the objective of the scheme is 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. Financial assistance is 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 are concerned to note funds allocated for this Scheme during 2020-21 and 2021-22 were not fully utilized. During 2020-21, out of Revised Estimate allocation of Rs.21.05 Crore, only Rs.7.49 Crore was spent. During 2021-22, the Department had spent Rs.50.62 Crore out of allocated amount of Rs. 137.02 Crore at RE stage till the time information was furnished to the Committee. In this regard, the Department has assured the Committee that the remaining amount would be released to the States before the end of the financial year. The details of Actual Expenditure incurred as on 31 March, 2022 may be furnished to the Committee. In this backdrop, Rs.120.00 Crore has been provisioned in BE 2022-23 which the Department will release as the 2nd grant to 4 Medical Device Parks States with proportionate contribution by the State Implementing Agencies (SIAs). Medical Devices Sector being a sunrise sector of the Indian Economy, creation of state of the art Common Infrastructure Facilities (CIF) in Medical Devices Parks is need of the hour and their creation will attract private investment in Medical devices Industry. The Committee, therefore, strongly recommend that the Department should take necessary steps for the early release of budgetary funds to four Medical Devices Parks being set up in Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh and it should also be monitored by the Department whether the released funds are resourcefully utilized by the concerned states. The progress made in achieving the physical and financial targets set under the scheme should be intimated to the Committee.

- ii. The Committee also recommend to examine the necessity of setting up of more Medical Devices Parks in the country and appropriate steps should be initiated there for the setting up of Medical Devices Parks in other States as well”.

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

- 1."i. The Department, in full agreement with the recommendations of the committee, has taken steps to release the funds to the four Medical Device Parks, sanctioned to the States of Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh and progress in this regard, is being reviewed regularly The details of Expenditure under the scheme are as follows: In FY 2020-21, Rs.7.49 Crore was allocated at BE stage and later at RE stage, additional funds of Rs.21.05 Crore were requested but the funds could not be allocated. Hence, only Rs.7.49 Crores was spent during FY 2020-21. In FY 2021-22, Rs.60 Crore was allocated at BE stage which was later increased to Rs. 137.02 crore at RE stage under the Scheme “Promotion of Medical Device Parks” (erstwhile known as “Assistance to Medical Device Industry for Common Facility Centre”). The entire Budget of Rs.137.02 Cr were fully utilized as on 31st March, 2022. This includes release of an amount of Rs.30 Crores each as 1st installment of Grant-in-aid to the States of Madhya Pradesh, Himachal Pradesh, Tamil Nadu and Uttar Pradesh in FY 2021-22. Accordingly, in BE 22-23, Rs. 120 Cr has been requisitioned to process for release of 2nd instalment to the States, subject to commensurate release from the States to the Parks and commensurate progress as per the committed timelines. There is proper mechanism to monitor the utilization of funds as well as monitor the progress in achieving the physical and financial targets under the scheme through the Project Management Agency (PMA) for the scheme. The progress made in achieving the physical and financial targets set under the scheme is being monitored through the Quarterly Review Reports (QRR) and the Special Purpose Vehicle formed by the State Governments to develop the medical device parks shall furnish a quarterly progress report to the Department as per the scheme guidelines. Same will be furnished to the Committee as requested.
- ii. Based on the budget provisioned and based on the examination of the proposals received under the Scheme, four States of Madhya Pradesh, Himachal Pradesh, Tamil Nadu and Uttar Pradesh have been selected and being supported to create common infrastructure facilities. Presently, no budget is available under the scheme to support creation of common infrastructure facilities in the Medical Device Parks being developed or planned to be developed by other States. The States, interested to develop such Medical Device Parks in their States, will, however, be provided necessary technical guidance."

1.25 The Committee have been informed that the objective of the scheme 'Promotion of Medical Devices Parks' is to promote Medical Device Parks' by providing Grants-in aid for creation of common infrastructure facilities. The Committee have also been informed that first installment of Grant-in-aid of Rs. 30 crore to each of the four states namely Madhya Pradesh, Himachal Pradesh, Tamil Nadu and Uttar Pradesh during the year 2021-22 and for the release of 2nd installment to the States Rs. 120 crore has been requisitioned and is under process. However, the Committee note with concern that at present budget is not available under the scheme to support creation of common infrastructure facilities in the medical Device Parks being developed or planned to be developed by States other than Madhya Pradesh, Himachal Pradesh, Tamil Nadu and Uttar Pradesh. Though the Department would provide necessary technical guidance to states interested to develop Medical Device Parks. The Committee desire that in order to create Common infrastructure facilities in other states too, the Department should consider allocation of budgetary funds/support to them. The Committee would also like to know as to how many 'other states' have shown interest to set up medical Device Park in their states so far.

CHAPTER II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

(Recommendation No. 3)

Monitoring the Performance of NIPERs

2.1 With regard to the Monitoring the Performance of NIPERs, the Committee had recommended as follows:-

“The Committee are concerned to note that NIPERs have only published 602 Research publications as on 15 February, 2022 against the target of 900 Research publications for 2021-22. Similarly, only 13 patents have been filed /granted against the target of 45 for the year. Presently NIPERS at Mohali and Guwahati are functioning in permanent campuses with very good infrastructure facilities but their performance in terms of student intake, research paper publication and patents filing is not better than other NIPERs which are presently lacking sound infrastructure facilities. For the year 2022-23, for instance Guwahati NIPER has set physical target regarding intake of 185 students, 140 Research Publications and only 8 patents which are less than Hyderabad, Mohali and Ahmedabad NIPERs. In this regard, the Committee expect that the NIPERs with own infrastructure and requisite number of faculties should perform better than others. The Committee, therefore, recommend that the Department of Pharmaceuticals should regularly monitor the performance of NIPERs and ensure that the targets fixed in respect of student intake, research publications and patents are achieved by them without fail. A quarterly review of performance of each NIPER may be made at the Department level and the difficulties being faced by NIPERs in achieving their targets may be addressed to by the Department”.

REPLY OF THE GOVERNMENT

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

“Department of Expenditure has created 156 faculty post for 6 NIPERs in February, 2019. Framing of their RRs and actual filling took some time and as of now about nearly 80% posts have been filled while, remaining are under process. Due to absence of regular faculty, there has been a shortfall in achieving the targets. Further, as the educational institutes could not function to their full capacity due to COVID lock downs/ restrictions, there has been a slight decline.

The matter has been also deliberated regularly at the Institute/ Board and department level, and all NIPERs have been directed to achieve the vision targets. As of 31st March, 2022(FY 2021-22), about 795 research papers have been filed and 30 patents have been filed by NIPERs. Further, monthly Review Meetings under the

chairmanship of Secretary (Pharma) are held regularly to monitor the performance of NIPERs and ensure achievement of the targets fixed”.

(Recommendation No. 4)

Assistance in Research and Development by NIPERs

2.3 With regard to the Assistance in Research and Development by NIPERs, the Committee had recommended as follows:-

“The Committee also note that NIPERs are presently functioning in an insulated atmosphere without much public visibility and engagements. As per the Department of Pharmaceuticals, a Common Research Programme has been worked out under which most common health problems faced by the people of the country have been identified for common research by NIPERS. Major pharmaceutical companies in private sector have their own R & D facilities but Pharma Medium Small and Micro Enterprises (MSMEs) lack them. Since it is very much necessary for NIPERs to play a catalytic role in pharmaceutical research, the Committee would like to make the following recommendations:-

- i. A time bound programme should be chalked out for Common Research Programme of NIPERS and a few areas of health concerns of the country may be identified for common research by NIPERs
- ii. NIPERs may render research and development assistance to MSMEs and a workable model in this regard may be worked out by Department of Pharmaceuticals in coordination with the NIPERs”.

REPLY OF THE GOVERNMENT

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

“The recommendations of the committee, which are very valuable have been noted for compliance. In this regard, it is mentioned that the Department is taking monthly reports from NIPERs on implementation of the Common Research Programme. It has taken steps for enhance academia – industry linkage and in this regard has recently launched NIPER Research Portal to disseminate information about research activities, patents filed etc. by NIPERs. Further, Innovation and Entrepreneurship Guidelines have been finalized recently and circulated to NIPERs for compliance. Department has also finalized draft Policy for catalyzing Research & Innovation in Pharma- MedTech sector, which has been submitted to the Cabinet for approval. Further, in all schemes, including PLIs, Parks and scheme especially designed for MSME sector, viz., Pharmaceutical Technological Up-gradation Scheme, the NIPERs have been involved for providing technical assistance”.

(Recommendation No. 5)

Filling up of faculty positions in NIPERs

2.5 With regard to the Filling up of faculty positions in NIPERs, the Committee had recommended as follows:-

“The Committee note that the Department of Expenditure has created 156 faculty posts for NIPERs in February, 2019. Presently 70% of the faculty positions have been filled up and the remaining are under process. Since the availability of requisite number of faculty is very much essential for the effective performance of NIPERs, the Committee recommend that the process of recruitment of requisite number of faculty for all NIPERs should be a continuous process till the recruitment of all the sanctioned posts of faculties in all NIPERs. Progress made in this regard may be intimated to the Committee”.

REPLY OF THE GOVERNMENT

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

“NIPERs have been advised to fill up the posts of faculty based on the requirement while taking in consideration AICTE's guidelines. Presently, about 80% sanctioned posts have been filled while remaining are under process”.

(Recommendation No. 8)

Coverage and product basket of PMBJP

2.7 With regard to the Coverage and product basket of PMBJP, the Committee had recommended as follows:-

“The Committee note that all 739 districts of the country have already been covered under Pradhan MantriBharatiyaJanaushadhiPariyojana (PMBJP). In order to popularize the Scheme and expand opening of Kendras in the aspirational districts, Himalayan, Island territories and the North-Eastern States, a new incentive plan has been launched. Such Kendras now get a one-time grant of ₹ 2 lakh in addition to normal incentives viz. Rs.1.50 lakh for reimbursement of furniture and fixtures and Rs.0.50 lakh for reimbursement for computer, internet, printer, scanner etc. Pharmaceuticals and Medical Devices Bureau of India (PMBI) has released various newspaper advertisements for inviting applications for opening of PMBJP outlets in July, 2021 for opening of PMBJP outlets in 265 districts of the different States where coverage is less. Since continuous efforts are to be made for expanding coverage of the Scheme so as to achieve its objectives of providing quality generic medicines and medical devices at affordable prices to the people of the country, the Committee would like to make the following recommendations:-

- i. An action plan should be chalked out to open more Jan Aushadi outlets in urban fringes particularly near slum pockets and other urban areas where concentration of poor and below poverty line people is more, semi urban areas, rural areas, remote areas and hilly areas so as to enable the people of these areas get benefited from the Scheme.
- ii. Additional Incentives which are offered to the entrepreneurs of aspirational districts, Himalayan, Island territories and the North-Eastern States may be offered to all the entrepreneurs who come forward to set PMBJP outlets in any part of the country so as to make it attractive to them.
- iii. A study/evaluation may be conducted by the Department of Pharmaceuticals and PMBI on the continuous viability of these outlets even after the incentive period including the need for permission to sell other products alongwith Janaushadi medicines and medical devices and necessary follow up action may be taken up according to the outcome of the Study/evaluation.
- iv. Measures should be taken by the Department along with PMBI and National Pharmaceuticals Pricing Authority (NPPA) to educate the people about the quality, efficacy and affordability of generic medicines being sold through PMBJP outlets so as to attract more people towards these outlets.
- v. Department of Pharmaceuticals, NPPA and the Ministry of Health and Family Welfare may make coordinated efforts to make the medical practitioners prescribe quality generic medicines rather than exorbitant branded medicines. This recommendation may also be sent to the Ministry of Health and Family Welfare.

Specific Action Taken Reply may be given with respect to each of the above recommendations”.

REPLY OF THE GOVERNMENT

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

“The requisite details are as under:

(i) Department of Pharmaceuticals & PMBI are continuously making efforts for expanding the scheme so as to achieve its objectives of providing generic medicines at affordable prices to the people of the country. In order to have better coverage of the PMBJKs in the under-covered areas of the country, Department of Pharmaceuticals and PMBI sends letters to various authorities of all the State Governments regularly for expediting opening of PMBJKs.

The Committee’s recommendation has been noted. PMBI has recently invited applications for opening Kendras in urban fringes at Block levels for about 3,500 locations, particularly where concentration of poor and below poverty line people is more.

(ii) The present budgetary allocation will not suffice for expanding the scope of beneficiaries eligible for additional incentives. Department of Pharmaceuticals will approach Ministry of Finance with recommendations of the Committee for additional funds for the purpose.

(iii) As per policy, the Kendras are not permitted to sell other products along with Janaushadi medicines and medical devices. As per field reports of PMBI, most of the Kendras are viable after end of incentive period. The recommendation of the Committee for conducting a study/ evaluation has, however, been noted for compliance. Accordingly, necessary action is being taken for inclusion of the study under Pharmaceutical Promotion and Development Scheme (PPDS) of the Department.

(iv) Department/ PMBI is spreading awareness about the salient features of PMBJP through various types of advertisements such as Print Media, Radio advertisement, TV advertisement, Cinema Advertisements and Outdoor publicity like Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping, etc. In addition, PMBI is also educating the public about the usages of Janaushadhi generic medicines through social media platforms like Facebook, Twitter, Instagram, YouTube, etc. regularly on daily basis. In addition, PMBI spreads 7th March every year as Jan Aushadhi Diwas. During the week-long celebrations held from 1st to 7th March, 2022 this year, various activities like organizing seminars, health camps, heritage, health walks and award distribution etc. were organized. On 7th March, 2022, awards under various categories were given and Hon'ble PM interacted with the beneficiaries and other stakeholders.

(v) Department of Pharmaceuticals, on its part, regularly takes up the issue with the Ministry of Health & Family Welfare as well as State/ UT governments to issue directions to Government doctors to prescribe generic drugs only. The Recommendation of the Committee has been sent to the Ministry of Health & Family Welfare on 26.05.2022 (**ANNEXURE-III**) for necessary action”.

(Recommendation No. 9)

Scheme for strengthening the Pharmaceutical Industry

2.9 With regard to the Scheme for strengthening the Pharmaceutical Industry, the Committee had recommended as follows:-

“The Committee note that Expenditure Finance Committee (EFC) has recommended to de-link three sub schemes viz (i) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS); (ii) Assistance to Pharmaceutical Industry for Common Facilities (APICF) and (iii) Pharmaceutical Promotion and Development Scheme (PPDS) from the Umbrella scheme of Development of Pharmaceutical Industry and implement them as a separate scheme. Accordingly, the Department is implementing a particular scheme called Scheme for strengthening the Pharmaceutical Industry. Above mentioned three Schemes have been included under this new Scheme. According to the Department, EFC has earmarked Rs.500 crore for five years to implement these three schemes. In

this regard, the Department has done extensive stakeholders' consultation before arriving at the scheme guidelines, which are being accordingly revised and put up for the approval for the Minister. As recommended by the Committee last year, the Department is in the process of appointing professional PMC – Project Management Consultant for the implementation of these Schemes in a systemic, professional and transparent manner without any delay. Keeping in view the assured financial allocation for next five years, the Committee is now hopeful that the Department will raise the level of implementation of these sub-schemes so that the Department will be able to achieve the goal of ensuring drug security for the country. In this regard, the Committee recommend that the Department should act swiftly to finalize the revised guidelines for the Scheme with the approval of the Minister and each sub scheme should be implemented from 2022-23 onwards in letter and spirit. Progress made in this regard should be intimated to the Committee”.

REPLY OF THE GOVERNMENT

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 Department has incorporated three sub-scheme i.e. “Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), “Assistance to Pharmaceutical Industry for Common Facilities” and “Pharmaceutical Promotion and Development Scheme (PPDS)” in a single scheme namely “Strengthening of Pharmaceuticals Industry” (SPI) with the approval of Hon’ble Minister (C&F) and released the guidelines of the Scheme on 11.03.2022 on the website of the Department. The selection of Project Management Consultant (PMC) for implementation of the Scheme through open tender basis is also finalized and M/s SIDBI has been appointed as PMC and work order has been issued on 25.5.2022.

Further, Secretary, DoP has written to Chief Secretaries of all the States/UTs and Industry departments of all the States/UTs on 25.5.2022, seeking support for the dissemination of the schemes to the eligible Pharma Industries in the States/UTs and to encourage eligible Pharma Industries to avail benefits under the Scheme. Further, it is planned to issue notification to invite applications under the sub schemes ‘API-CF’ and ‘PTUAS’ as early as possible”.

(Recommendation No.11)

Assistance to Pharmaceuticals Industry for Common Facilitation Center (previously known as Cluster Development)

2.11 With regard to the Assistance to Pharmaceuticals Industry for Common Facilitation Center (previously known as Cluster Development, the Committee had recommended as follows:-

(i) “The Committee note that the scheme Assistance to Pharmaceuticals Industry for Common Facilitation Center Scheme (previously known as Cluster Development) is

implemented in a Public Private Partnership (PPP) mode. Financial assistance under this sub-scheme is provided for creation of Common Facilities, such as Common Testing Centre, Training Centre, R&D Centre, Central Effluent Treatment Plan (CETP), Common Logistic Centre, etc. For the ensuing year 2022-23, the Department has been allocated an amount of Rs. 36.00 Crore which is 50 percent hike in comparison to RE stage allocation of Rs. 15.61 Crore during 2021-22. However, during 2021-22 the Committee noticed sheer underutilization of funds. The actual utilization as on 11.02.2022 is only 9.6 percent that is Rs. 1.51 Crore out of Rs 15.61 Crore available at Revised Estimates stage with the Department. In this regard, the Committee note the assurance given by the Department that they will release funds to some projects before 31 March, 2022. The details of actual fund utilized under the Scheme on or before 31 March 2022 should be intimated to the Committee. Having noted that some Common Effluent Treatment Plants, Testing laboratory etc. are under approval/implementation stages under the Scheme, the Committee recommend that concrete and time bound steps should be initiated by the Department for the successful completion and commissioning of these projects during 2022-23 and for fully utilizing the funds allocated for the year.

(ii) The Committee also recommend that the Department should take steps for the expansion of PPP projects under the scheme so as to involve all the States/UTs that have strong presence of private Pharma industries and also the States/UTs which strive to develop pharma industries”.

REPLY OF THE GOVERNMENT

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

(i) “It is submitted that the utilization of fund under the Scheme “Assistance to Pharmaceutical Industry for Common Facilities” (API-CF) for FY 21-22 till 31.03.2022 is Rs. 9.88 Crore. Further, under the scheme, an amount of Rs.55.44 lakhs has been released in first quarter of FY 2022-23 for the approval given in FY 21-22.

(ii) Secretary, DoP has written to Chief Secretaries of all the States/UTs and Industry departments of all the States/UTs on 25.5.2022, seeking their support for dissemination of the schemes to the eligible Pharma Industries in the States/UTs and to encourage eligible Pharma Industries to avail benefits under the Scheme”.

(Recommendation No. 12)

Pharmaceutical and Medical Devices Promotion Development Scheme (PMPDS)

2.13 With regard to the Pharmaceutical and Medical Devices Promotion Development Scheme (PMPDS), the Committee had recommended as follows:-

(i) “The Committee note that the Pharmaceutical and Medical Devices Promotion Development Scheme (PMPDS) aims at promotion, development and export promotion in Pharmaceutical sector by extending financial support for conducting seminars, conferences, exhibitions, conducting studies/ consultancies etc. Presently, the new scheme guidelines are being finalized by the Department. Out of RE allocation of Rs. 2.00 Crore for 2021-22, the Department has utilized only Rs.1.01 Crore as on 11.02.2022. In this regard, the Committee note that 5 studies have been approved in FY 2021-22 and part instalments are to be released for the purpose. Further, few events, seminars, conferences are to be organized and It is expected that entire RE will be utilized till 31st March, 2022. Progress made in regard to utilization of RE allocation during 2021-22 should be furnished to the Committee. For the year 2022-23, the Department has again received an allocation of Rs. 2.00 Crore. According to the Department, earlier studies conducted under the scheme were ad-hoc and now the Department has collected the requirements of study from all the Departments/Organizations/Industry and is now conducting studies in a systematic way. The Committee feel that the effective implementation of this Scheme will provide a helping hand in promotion and development of the pharma sector in the country and hence the Committee recommend that an annual calendar of events to be organized/studies to be conducted under the Scheme should be chalked out well in advance before the starting of a financial year and concrete steps should be taken for resourceful spending of budgetary allocation made rather than rushing for last quarter spending”.

REPLY OF THE GOVERNMENT

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

(i) “The recommendation of the Committee is noted. The Department has sought inputs from various Divisions and Organizations/ Agencies under its aegis and is in the process of finalization of Calendar of events / studies for Financial Year 2022-2023 under PPDS scheme.

(ii) The recommendation of the Committee is noted. In this regard, it is submitted that the Department, in coordination with FICCI, organized an annual mega-conference titled ‘India Pharma and India Medical Devices 2022’, from April 25-27, 2022 at Dr BR Ambedhkar International Centre, New Delhi. This three days conference is seventh in series and included CEOs RoundTable of Pharma and MedTech industries and thematic full day conference sessions on various topics concerning the pharma and MedTech industries. In this event, detailed deliberations were held for the holistic promotion and development of Pharma and MedTech Sector. The discussions were focused on envisaging the growth of the Industry for India@2047”.

(Recommendation No. 15)

Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs)

2.15 With regard to the Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs), the Committee had recommended as follows:-

“The Committee note that the scheme provides for financial incentives to manufacturers selected under the scheme for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). The scheme provides for incentives on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940.00 Crore and its tenure is from FY 2020-2021 to 2029-30. The Committee note that the Department has been allocated an amount of Rs. 390.00 Crore at BE stage for the year 2022-23 in comparison to only Rs 2.79 Crore at RE stage in 2021-22. According to the Department, good response has been received from the pharmaceutical sector. Total 239 applications were received in Round I and Round II. 49 applicants have been approved with committed investment of Rs. 3,685.38 Crore. Out of these 49 applicants, 8 have already commissioned their plants and 13 more are expected to commission their plants by the end of March, 2022. The main objective of this scheme is to reduce dependency on imports for 41 critical APIs. However, the Committee note that out of 41 critical APIs only 33 APIs found their bidders among domestic manufacturers and the response is poor in respect of other 8 APIs as these APIs do not have demand in the market and are fermentation based whose technology is difficult as well as costly which requires greater investment. Further, the private players hesitate to invest in these 8 APIs as their end products are not competitive in global market. In this regard the Committee note that other countries are providing very high level of support in terms of power cost, water cost and the environmental cost. Since it is very much necessary to create a strong manufacturing base for critical Key Starting Materials / Drug Intermediates and Active Pharmaceutical Ingredients so that the country entirely meet the requirements of these materials indigenously both for the domestic medicine needs as well as for exports, the Committee, therefore strongly recommend the following:-

(i) Department should chalk out an action plan for the time bound and resourceful utilization of budgetary allocation of Rs.390.00 Crore under the Scheme. For that purpose, concrete steps should be taken by the Department for the expeditious commissioning of plants by all the 49 applicants approved under the Scheme and timely start of sales by these plants so that the incentive is disbursed to them in the form of production linked incentives. Progress made in this regard should be intimated to the Committee”.

(ii) Since fermentation technology is difficult and large scale investment is required, the Department should consider providing high level support to the entrepreneurs who come forward to set up these industries in terms of subsidized power cost, adequate water supply at low cost, single window environmental clearance, lower environmental cost, etc. in coordination with the State/UT Governments so as to attract more investment in this sector.

(ii) The Department in consultation with various stake holders should prepare a list of alternate products in place of 8 APIs/KSMs which are no longer necessary because of less demand and seek Cabinet approval for those alternate APIs for inclusion under the Scheme.

(iv) As the Fermentation based APIs are based on complex and costly technology, research and development may be encouraged for the invention of cost effective alternate technology for fermentation process. NIPERs may also be engaged in Research and Development in this regard.

REPLY OF THE GOVERNMENT

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

(i) “ Under the PLI scheme for Bulk Drugs, as on date, 10 projects have been commissioned and 12 more projects are expected to be ready for commissioning by June 2022. It is expected that Rs. 390 crores will be utilized by the end of F.Y. 2022-23.

Further, applications were re-invited under Round III to fill the remaining slots under the scheme. A total of 9 applications have been received, which are under examination for final approval.

(ii) The recommendation of the Committee is noted. The Department is having a Project Development Cell, maintained by Invest India, to facilitate and provide high level support to the entrepreneurs and PLI applicants and participants to resolve any issues regarding setting up the Industries. Further, under National Single Window System of DPIIT, all the Participants of the PLI schemes have been oriented on 26.5.2022 to available the benefits of single window clearance of various regulator / stakeholder departments for the units, being set by them. The Department will take appropriate action to coordinate with State/UT Governments as and when such representations are received from the PLI participants.

(iii)The recommendation of the Committee is noted. It is submitted that applications were re-invited under Round III to fill the 22 vacant slots including fermentation based products under the scheme. A total of 9 applications have been received which are under examination. The suggestion of the Committee has been duly noted and will be taken in consideration at appropriate stage.

(iv) NIPERs are institutes of national importance, which besides imparting postgraduate and doctorate education conduct high end research. The Department has involved NIPERs and their faculty for technical evaluation/ assistance of various proposals under the PLI scheme. Further, all the NIPERs have come together and formulated a Common Research Programme, based on national needs and their expertise and are engaged in R&D on various topics, including development of APIs”.

Recommendation No. 16:

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

2.17 With regard to the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device, the Committee had recommended as follows:-

(i) “The Committee note that Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices was approved by the Government of India on 20.03.2020 to address the challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies. The guidelines for implementation of the scheme were issued on 29.10.2020. The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of Rs. 3,420.00 Crore. Under this Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the target segments of the scheme, for a period of five years. The Committee note that for the year 2022-23, the Department has been allocated Rs.216.00 Crore at BE stage which is a marked enhancement in comparison to Rs.3.31 Crore allocated at RE stage during 2021-22. Further, the Department has approved 21 applicants under the scheme. Since it is very much important that all the 21 applicants commission their plants in a time bound manner and start production and sale of medical devices so that they become eligible to get incentive under the Scheme, the Committee, therefore, recommend that concrete steps should be taken by the Department of Pharmaceuticals for timely commissioning of plants by these applicants and ensure full utilization of budgetary allocation of Rs.216.00 Crore for the disbursement of incentives to them based on their production and sale of medical devices. A definite responsibility may be fixed on Project Management Agency in this regard. The details of progress made in implementation of the Scheme during 2022-23 should be intimated to the Committee.

(ii) The Committee note that the incentives provided under the scheme are for incremental sales only and in no way address the major challenges faced by Greenfield projects viz. poor infrastructure, weak domestic supply chain and logistics, high cost of project finance, inadequate power backup, limited design capabilities, low investment in R&D and skill development, etc. Unless these challenges are overcome it is difficult to visualize that the domestic Medical Device

Industry can reap the real benefits out of the PLI scheme. Hence, the Committee recommend that the Department may ponder over the ways and means to address these grass root challenges faced by the medical device industry and initiate appropriate steps thereon”.

REPLY OF THE GOVERNMENT

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

(i) “Under the PLI scheme for Medical Devices, 9 projects have been commissioned till date and 5 more will be commissioned by June 2022. The Department has fixed the roles & responsibilities of PMA, which is responsible for examination of claims for disbursement of incentives and making appropriate recommendations to the Empowered Committee.

(ii) The recommendation of the Committee is noted. Knowing the need for a holistic policy to accelerate growth and exploit the potential of the Sunrise medical devices sector and to put in place a comprehensive set of measures for ensuring sustained growth and development of the sector and to bring together the range of interventions into a coherent policy framework that would facilitate focused and efficient support and facilitation for the sector by the respective agencies, due to diversity and multi-disciplinary nature of the sector and for ensuring smooth transition to the regulation and licensing of Medical devices, after extensive consultation, the Department has circulated a draft Cabinet Note on **National Medical Devices Policy, 2022** to stakeholder departments for inter-ministerial consultations. Various initiatives taken by Department to address issues faced by the Industry are given at **Annexure-1”**.

(Recommendation No. 17)

Production Linked Incentive (PLI) Scheme for Pharmaceuticals

2.19 With regard to Production Linked Incentive (PLI) Scheme for Pharmaceuticals, the Committee had recommended as follows:-

“The Committee note that the Production Linked Incentive scheme for Pharmaceuticals was approved by the Cabinet on 11.11.2020 with the objective to enhance India’s manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. The outlay of the scheme is Rs. 15,000.00 Crore and pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme is proposed to be from FY 2021 to 2028-29. (Ref: Para 3.50) However for the year 2022-23 the Department has received only Rs. 3.00 Crore at BE stage. During 2021-22, out of total RE allocation of Rs. 3.00 Crore, Rs.1.24 Crore have been released as service fee to Small Industries Development Bank of India (SIDBI), the Project

Management Agency and the remaining amount of Rs.1.76 Crore has been surrendered. As on date 11 applicants under Group A, 9 applicant's Under Group 'B' and 35 applicants under Group 'C' category have been shortlisted by the Selection Committee of the Department for assistance under the Scheme. Since the implementation of the Scheme in letter and spirit will give a boost to the pharmaceutical sector in the country, the Committee, therefore recommend the following:-

- iii. Immediate steps should be taken for the effective implementation of the Scheme from 2022-23 onwards. Particularly, the commissioning of plants by all the 55 approved applicants belonging to all the three categories should be ensured during 2022-23 so as to start disbursing incentives to them.
- iv. Allocation of only Rs.3.00 Crore for 2022-23 out of Rs.15,000.00 Crore earmarked for the Scheme is miniscule. In this regard, the Department should make demand for requisite allocation of fund at RE stage for the disbursement of incentives to applicants who start production and sale during 2022-23.
- v. Under Category 2 of this Scheme, Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates have been included. Since there is a separate PLI Scheme for APIs/KSMs/DIs, the Department may examine the necessity of Category 2 under this Scheme and take appropriate action thereon.
- vi. The number of applicants approved under all the three categories is less considering the scope of production of pharmaceuticals under these categories. In this regard, the Department may create an enabling ecosystem for the pharmaceutical start-ups and young entrepreneurs through this PLI scheme and upscale the financial and physical targets under the scheme to make India world leader in production of medicines”.

REPLY OF THE GOVERNMENT

2.20 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 all necessary steps for effective implementation of the scheme.

(i) As per the scheme guidelines, the scheme cover brownfield investments as well. All the 55 PLI participants have their plants already running and hence implementation does not seem to be a challenge.

(ii) The allocation of ₹3 crore for FY 2022-23 at BE stage is sufficient to meet payment of professional charges to the Project Management Agency (PMA), which is the only stipulated expenditure to be incurred in the said FY. As regard incentive, FY 2022-23 will be the first production year and incentives are to be given on annual incremental sales in the following year, viz., FY 2023-24 as per the scheme guidelines. The Department will consult with Department of Expenditure on the possibility of earlier payment.

(iii) The Indian Pharmaceutical industry is 3rd largest in the world by volume. India exported pharmaceuticals worth Rs.1,80,551 crore in the financial year 2020-21. India exported Bulk Drugs/ Drug Intermediates worth Rs.32,857 crore in financial year 2020-21. However, the country also imports various Bulk Drugs/ Active Pharmaceutical Ingredients (APIs) for producing medicines from various countries. The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing.

PLI scheme for Bulk Drugs covers 41 APIs/KSMs/DIs (Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates), based on the recommendation of the Technical Committee constituted in this regard, with the objective of reducing import dependency. Under the PLI Scheme for Pharmaceuticals, APIs excluding those 41 already covered under the PLI Scheme for Bulk Drugs are being considered. Based on the necessity to support the domestic manufacturing of APIs, the category-2 was incorporated under the scheme for Pharmaceuticals, to cover the APIs, other than those covered under the PLI scheme for Bulk Drugs.

(iv) Through PLI Schemes, the aim is to support creation of global champions in a self-sustaining manner. Incentive is envisaged to be disbursed only after investment and production (and subsequently sales) takes place, as per criteria laid down in the scheme guidelines. Hence, only few entities which have attributes of a champion, using cutting edge technology, are willing to make required investment and fulfill criteria pertaining to incremental growth and the ability to grow in scale and size have been selected.

Further, at present, there is no scope to upscale the physical and financial targets under the scheme as the Cabinet-approved physical and financial targets have been attained with the selection of 55 PLI Participants. Department, in close coordination with other Department such as DPIIT, strives to create an enabling environment for the pharmaceutical start-ups”.

(Recommendation No. 18)

Research and Development of Pharma Sector and future strategy

2.21 With regard to the Research and Development of Pharma Sector and future strategy, the Committee had recommended as follows:-

(i) “The Committee are concerned to note that only a token allocation of Rs.1 lakh has been made for Research and Development in Pharma Sector for the year 2022-23. In this regard, the Committee note that the Department of Pharmaceuticals has come out with a Policy for Catalyzing Research and Development and innovation in pharmaceutical and medical sector. A draft Cabinet note has already been circulated. We have received extensive comments, both from industry as well as from the Departments. Now the Policy is under finalization stage. Since it is necessary to take pharma sector to the next level of development and to increase the value of this sector

in the global market, the Committee strongly recommend that this Policy should be finalized at the earliest and necessary steps should be taken up by the Department of Pharmaceuticals to implement the Policy in letter and spirit. Separate budgetary allocation is also ought to be made for Research and Development so as to put in the necessary finances into research and development in pharma sector specifically in the medical devices industry. Department of Pharmaceuticals should impress upon the Ministry of Finance about the necessity of budgetary allocation for research and development in pharma sector. This recommendation of the Committee may also be shared with that Ministry for the purpose.

ii) The Committee feel that it is important that the Government should come out with clear strategies in terms of manner in which the support should be given to pharma sector for holistically developing the sector in all fronts and to make it a world leader. In this regard, the Committee recommend that the Government should chalk out a long term plan/strategy with the help of best of the policy makers and experts in the field so as to create a world class infrastructure in the country for the all-round development of the pharma sector in the country”.

REPLY OF THE GOVERNMENT

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

“A DCN on ‘Policy to Catalyse R&D and Innovation in the Pharma- MedTech Sector in India’ has been circulated for inter-departmental consultations on 22.10.2021. Based on the comments/ suggestions from various departments and inputs received from industry stakeholders, the policy document has been refined, incorporating the suggestions, as appropriate. The Final Cabinet Note on R& D policy has also been sent to Cabinet Secretariat on 13.05.2022 for consideration and approval of the Cabinet.

The policy is built upon three focus areas, viz., streamlining the regulatory framework, incentivizing investments and creating a Facilitatory ecosystem for Innovation. Policy focuses on incentivizing private sector investment in research and evaluate various funding mechanisms – Budgetary support, Venture capital, CSR funding, etc. and fiscal incentives to support innovation. The policy focuses on the provision of appropriate fiscal and non-fiscal incentives for Pharmaceuticals/ MedTech innovations by introduction of direct/ indirect funding support to promote India as an innovation hub; and also mentions few measures to be explored, such as; Creation of Pharma-Med-Tech Innovation fund, Introduction of long-term, secure “innovation bonds”, Reimbursement of R&D spending and appropriate fiscal incentives, and others. The recommendations of the Committee will be shared with Ministry of Finance for seeking requisite funds after approval of the Cabinet.

(ii) The recommendations of the committee, which are very valuable have been noted for compliance. In this regard, it is mentioned that the Department as part of its mandate and as per earlier recommendations of the Departmental Parliamentary Standing Committee has set up an Inter-Departmental Committee (IDC) in January, 2019 to periodically review & coordinate research in a collaborative, synchronized &

synergized way, utilize funds allocated in an optimum manner and ensure no overlapping and duplication of efforts and resources. The Committee includes representatives from various other scientific departments such as Dept of Health & Family Welfare/ Department of Health Research / Council of Scientific and Industrial Research/ Dept of Biotechnology/ Dept of Science & Technology/ Department of Higher Education/ Indian Council of Medical Research/ AYUSH. The Committee meets periodically and consider proposals from time to time. Six meetings of IDC have been convened till date.

One of the pillars of the draft "Policy to Catalyse R&D and Innovation in the Pharma- MedTech Sector in India' is creation of world-class Facilitatory Ecosystem for Research and innovation in the Pharma sector. As soon as the policy is accorded approval by the competent authority a scheme would be devised and implemented by the department as proposed in the policy".

(Recommendation No. 19)

Assistance to PSUs

2.23 With regard to the Assistance to PSUs, the Committee had recommended as follows:-

"The Committee are concerned to note that only Rs.5.30 Crore has been allocated under the Head "Assistance to PSUs" against the demand of Rs.8021.48 Crore by the Department of Pharmaceuticals for the year 2022-23. The Department has proposed an amount of Rs. 6988.50 Crore for Indian Drugs and Pharmaceuticals Ltd (IDPL) and Rs. 1038.24 Crore for Hindustan Antibiotics Ltd (HAL). However the allocated amount at BE stage for 2022-23 is only Rs. 4.00 Crore and Rs. 1.26 Crore for these two PSUs respectively. According to the Department of Pharmaceuticals, PSU Division of the Department has proposed funds as sought by IDPL (Rs. 6988.50 Crore) and HAL (Rs. 1038.24 Crore) for meeting various liabilities like outstanding liabilities of various banks, financial institutions and unsecured liabilities. The pending employees dues (serving/retired/VRS) of IDPL, HAL and Rajasthan Drugs & Pharmaceuticals Limited (RDPL) have been settled by providing budgetary support as loans in FY 2019-20, 2020-21 & 2021-22 and EPFO interest payment of HAL employees (Rs. 76.00 Crore) released in 2021-22. Now, only the minimum amount of Rs.5.30 Crore needed for meeting contingent expenditure, court cases etc. has been provided for HAL and IDPL in BE 2022-23. Further, the Committee note that IDPL plants at various locations have been closed and the IDPL plant at Rishikesh is being returned back to the Government of Uttarakhand. RDPL has also been closed and the proposal to transfer it to the Government of Rajasthan is under active consideration of the Department. Regarding other three PSUs, the Government proposed strategic sale of HAL which is loss making and strategic disinvestment of profit making KAPL and BCPL. Having concerned to note the way in which the affairs relating to the PSUs are being dealt by the Government, the Committee strongly recommend the following:-

- i. Appropriate steps should be taken for immediately clearing various liabilities of IDPL and HAL like outstanding liabilities of various banks, financial institutions and unsecured liabilities.
- ii. The process of transferring the factories of IDPL, Rishikesh and RDPL to the respective State Governments should be completed in a time bound manner.
- iii. Efforts should be made to transfer the closed IDPL plants at Gurgaon, Hyderabad, Chennai and other places to the respective State Governments for their continuous operation”.

REPLY OF THE GOVERNMENT

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

(i) “As per Cabinet’s decision of December 2016, Hindustan Antibiotics Ltd. (HAL) is to be strategically disinvested after meeting its liabilities from sale of its surplus land. HAL has identified 87.7 acres land as surplus land, out which 3.5 acres land has been sold to EPFO at negotiated price of Rs.42 crore. It is proposed to refer HAL to DIPAM for strategic disinvestment. Whereas in respect of IDPL, which is under closure, the Department is proposing to transfer the free hold lands to the Special Purpose Vehicle (SPV) to be constituted for the purpose of assets monetization by the Department of Public Enterprises (DPE) and seek budgetary support for meeting its pending liabilities.

(ii) The transfer of lease hold land of Rishikesh to Govt. of Uttarakhand is in advance stage. Valuations of Plants and Machinery have been done and Board’s approval obtained. Lease of the land has already expired. The matter has now been taken by the Hon’ble Minister of Chemicals & Fertilizers with the Chief Minister, Uttarakhand to expedite the process. The approval of the Committee of Ministers is being sought for transfer of RDPL to the Government of Rajasthan instead of closure. Thereafter, the Department may move a Cabinet Note.

(iii) The Department has already conveyed approval to IDPL to continue the process of disposal of movable assets in respect of its plants at Gurugram& Hyderabad and Bihar Drugs & Organic Chemicals Limited (BDOCL) Muzaffarpur through approved Auctioning Agency viz. M/s. Metal Scrap Trade Corporation Ltd. (MSTC) following DPE guidelines. Accordingly, IDPL is taking action as per guidelines. With regard to IDPL (TN), State Government has proposed to dispose of plant & machineries of its Chennai plant”.

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. 1)

Budgetary allocation for the Department of Pharmaceuticals

4.1 With regard to the Budgetary allocation for the Department, the Committee had recommended as follows:-

“The Committee note that a gross budgetary allocation of Rs.2244.15 Crore has been made for the Department of Pharmaceuticals at Budget Estimate (BE) stage of 2022-23 against the outlay of Rs.10383.25 Crore proposed by the Department for the year. In comparison, the Gross Budgetary allocation for the year 2021-22 was Rs. 470.41 Crore against the proposed outlay of Rs.2600.52 Crore which was only 18% of the outlay proposed by the Department and this time it has increased to 21.6%. Even though the actual allocation for the year 2022-23 is very less when compared to the demand of the Department, the major chunk of this allocation has been made for Central Sector Schemes of the Department. Against the proposal of Rs.2313.02 Crore, an allocation of Rs. 2202.50 Crore has been made for the Central Sector Schemes of the Department. For the Heads relating to the “Development of Pharmaceutical Industry”, Rs.1729.00 Crore has been allocated against the demand of Rs.1767.02 Crore of the Department. Under the Capital Section of “Assistance to PSUs” , the Department demanded Rs.8026.78 Crore but only an allocation of Rs.5.30 Crore has been made at the BE stage of 2022-23. Since the demand for grants of the Department for implementing its developmental schemes has almost been fully met by the budgetary allocation, the Committee feel that the ball is now in the court of the Department. Unlike previous years, this year the hands of the Department have been strengthened with the requisite amount of budgetary allocation by the Ministry of Finance. Now the Department has to prove its mettle through effective implementation of all its development schemes. In this regard, the Committee recommend that an annual action plan with monthly achievable targets should be chalked out by the Department in respect of all the developmental schemes for which requisite amount of budgetary allocation has been made under Major Heads 2852 and 2552 and concrete steps should be taken for achieving targets under each of the developmental Schemes for timely and resourceful utilization of budgetary allocations made for the year. An effective monitoring of implementation of each of the development Schemes should be made at highest level in the Department and it should be ensured that the targets fixed for each of the Schemes are achieved in a time bound manner during the year 2022-23 through the full utilization of budgetary allocation. Progress made in this regard should be intimated to the Committee”.

REPLY OF THE GOVERNMENT

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

For the FY 2022-23, the Department had proposed Rs. 10383.25 crore as Budget Estimates for the financial year. However, only Rs. 2244.15 crore was allocated by the Ministry of Finance. Department will seek additional funds from the Ministry of Finance at RE Stage, if need be. The Details in respect of various schemes are as under:

NIPER: Department has set targets, which have been conveyed to the individual NIPERs. Monthly review meetings with Directors of all NIPERs are held at the level of Secretary of the Department and on quarterly basis at the level of Hon'ble Minister for Chemicals & Fertilizers. It will be ensured that the funds allocated by Department of Expenditure will be utilized for construction of campuses of NIPERs at Raebareli, Ahmedabad, Kolkata, Hyderabad and Hajipur and also for purchase of equipment as well to meet recurring expenditure of the Institute.

Development of Pharmaceuticals and PLI Schemes: The Department has a concrete plan to achieve the targets envisaged schemes such as PLI, strengthening the Pharmaceutical Industry, etc. The prescribed monitoring mechanism envisaged under the Schemes such as Empowered Committee for the PLI schemes of Bulk Drugs and Medical Devices and the Scheme Steering Committee (SSC) of the SPI scheme, etc will be fully involved in the monitoring of the implementation of the schemes. Further, the Project Management Agencies (PMAs) appointed under the PLI and SPI schemes will be fully involved in monitoring the progress of the schemes, as per the milestones envisaged. Department has proposed an amount of Rs. 1767.02 crore as BE 2022-2023 for the **Scheme "Development of Pharmaceutical Industry**. However, Rs. 1729.00 crore has been allocated. The additional funds will be sought from the Ministry of Finance at RE Stage if need be.

Jan Aushadhi Schemes: Department has proposed an amount of Rs. 100.00 crore as BE- 2022-23 for PMBJP to meet the target to open 1,000 new Kendras and enhance the product basket up to 1,800 medicines and 280 surgicals. However, an amount of Rs. 72.50 Crores only have been allotted under BE 2022-23. In order to effectively implement the scheme and achieve the vision targets under PMBJP, the Department will seek additional funds from the Ministry of Finance at RE stage.

NPPA: The total budget provision for the scheme Consumer Awareness, Publicity and Price Monitoring (CAPP) for the F.Y. 2022-23 is Rs. 6.00/- crore, viz. (i) Grant in Aid for Assistance to PMRUs Rs. 5.00 Crore and (ii) Advertising and Publicity Rs.1.00 Crore. The budget allocation for Grant in Aid to PMRU for the F.Y. 2022-23 is Rs. 5.00 Crore which is at par with the budget allocation that was made in the F.Y. 2021-22. Price Monitoring and Resource Units (PMRUs) have been set up in Twenty Three (23) States/UTs till 31st March 2022. There is a target to set up PMRUs in six (6) States in the F.Y. 2022-23 and in all the States/ UTs by the F.Y. 2023-24.

PSU: Department proposed an amount of Rs. 8026.78 crore for meeting various outstanding liabilities of various banks and other unsecured liabilities in respect of Department PSUs, i.e., HAL and IDPL. However, against the proposed amount, only, Rs. 5.30 crore have been allocated which shall be utilized for meeting contingent expenditure, court cases etc. for the FY 2022-23. Additional funds will be sought from the Ministry of Finance at RE Stage based on the requirements.

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

(Recommendation No. 2)

Construction of campuses for National Institute of Pharmaceutical Education and Research (NIPER)

4.3 With regard to the Construction of campuses for National Institute of Pharmaceutical Education and Research (NIPER), the Committee had recommended as follows:-

“The Committee note that an allocation of Rs.395.00 Crore has been made for NIPERS (in MH 2552 + 2852) against the proposal of the Department for Rs.440.00 Crore for 2022-23. The fund allocated by the Ministry of Finance will be utilized for construction of NIPER Campuses at Raebareli, Ahmedabad, Kolkata, Hyderabad and Hajipur and also for purchase of equipments/meeting recurring expenditures of the institutes. As far as construction of NIPER campuses is concerned, the Department proposes to complete 100% of construction in respect of Ahmedabad NIPER and 30% of construction in respect of Hajipur, Hyderabad, Raebarelli and Kolkata NIPERS. Recently, the Committee visited NIPERS at Guwahati and Kolkata. While construction of permanent campus for Guwahati was almost complete, the Kolkata NIPER was functioning in small rented premise which is not commensurate with the status of ‘Institution of National Importance’. The Committee, therefore, feel that it is a matter of utmost importance that the state of the art permanent campuses for Hajipur, Hyderabad, Raebarelli and Kolkata NIPERS is created in a time bound manner so as to enable them to function in the true spirit of ‘Institutions of National Importance’. The Committee, therefore, strongly recommend that the construction of permanent campuses for these four NIPERs should be completed within two years. Department, now proposed to complete 30% percent of construction during 2022-23 with the budgetary funds allocated for the purpose. Instead the Department may plan to complete 50% of construction of all the four NIPERs during 2022-23 and rest of the construction may be completed during 2023-24. In case of requirement of more funds for construction of these four NIPERs namely Hajipur, Hyderabad, Raebarelli and Kolkata additional demand may be made at RE /supplementary demands during 2022-23. This recommendation of the Committee may also be sent to the Ministry of Finance for its consideration. The Action taken in this regard should be intimated to the Committee.

REPLY OF THE GOVERNMENT

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

MoUs have been signed between CPWD and NIPERs for construction of campus at Raebareli, Kolkata and Haripur. Construction of campus at NIPER Ahmedabad is at full swing and expected to be completed by August, 2022 while construction of campus NIPER Hyderabad will start shortly by M/s NPCC Limited, the PMC appointed for construction of campus. Progress of construction activities is regularly reviewed at Department level. Additional funds at RE stage will also be sought to complete the targeted quantum of construction activities. Further, the recommendation of the Committee has been sent to the Ministry of Finance for its consideration.

Comments of the Committee

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

(Recommendation No. 6)

Setting up of five new NIPERS

4.5 With regard to the Setting up of five new NIPERS, the committee had recommended as follows:-

“The Committee are constrained to note that the proposal to set up five new NIPERs in Tamil Nadu (Madurai), Karnataka (Bangalore), Chhattisgarh, Rajasthan and Maharashtra are still on paper without any concrete action to set up them. In this regard, the Committee note that the Department had asked the Expenditure Finance Committee (EFC) to allocate Rs.4300.00 Crore for present seven NIPERs and additional five NIPERs for the next five years. However, EFC has earmarked only Rs.1500.00 Crore for NIPERs with the rider that this allocation should be utilized only for the existing seven NIPERs. In this regard, the Department of Pharmaceuticals now proposed to explore the alternate ways of funding of these NIPERs. Since the present number of seven NIPERs are hardly sufficient to meet the requirements of the country in the field of Pharmaceutical Education and Research, the Committee strongly recommend that all necessary steps should be taken by the Department of Pharmaceuticals for the early setting up of five new NIPERs. In this regard, a fresh proposal may be submitted to EFC for reconsideration of their decision and the concern expressed by this Committee may be conveyed to them. The Department may also explore alternate ways of funding of these NIPERs including financial contribution by both the Union and the concerned state Governments so that these five NIPERs are also developed and completed in a time bound manner. Progress made in this regard may be conveyed to the Committee”.

REPLY OF THE GOVERNMENT

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

“The recommendations of the Committee have been noted and a Committee has since been set up with the approval of Hon’ble Minister of Chemicals & Fertilizers for exploring other options for setting up of new NIPERs”.

Comments of the Committee

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

(Recommendation No. 7)

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

4.7 With regard to the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), the Committee had recommended as follows:-

“The Committee note that a Budgetary allocation of Rs. 72.50 Crore has been made for PMBJP against the Department of Pharmaceutical’s proposal for Rs. 100.00 Crore for 2022-23. Under this Scheme, a target has been fixed to open new 1000 Kendras and enhance the product basket upto 1,800 medicines and 280 surgicals during the year 2022-23. Further, a sale target of Rs. 775.00 Crore has also been prescribed for the year. As per the Department, the funds allocated at BE stage are not sufficient and less allocation of funds will hamper effective implementation of the scheme. The Scheme aims to make available quality generic medicines at affordable prices to all especially for the poor and the deprived ones. As on 15.02.2022, 8683 PMBJP outlets have been opened in the country with product basket of 1451 medicines and 240 surgicals. In this regard, the Committee feel that the number of PMBJP outlets in the country are inadequate when compared to nine lakh plus medical shops in the country. Further with regard to the present population of the country i.e. near about 140.52 crore it is noted that one Kendra is catering to approximately 16 lakh population. Hence, there is a need to increase the number of PMBJP outlets in the country and also to increase the product basket of the outlets. The Committee, therefore, recommend that the Department of Pharmaceuticals should impress upon the Ministry of Finance for the allocation of remaining funds (Rs. 27.50 Crore) required for effective implementation at RE stage of 2022-23. This recommendation of the Committee should also be sent to the Ministry of Finance for its implementation.

REPLY OF THE GOVERNMENT

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

The government has set up a target to open 10,000 stores by March, 2024. This will imply about one store for a population of 1.50 lakhs. The Kendras have been

opened in all district of the country. Now the government intends to reach all the Blocks, with more stress towards aspirational districts, NE areas, hilly and island territories. However, financial viability of individual Kendra is also required to be taken into consideration, while expanding the scheme.

During the financial year 2022-23, a target has been fixed to open about new 1,000 Kendras with cumulative total to about 9300 Kendras and to enhance the product basket up to 1,800 medicines and 280 surgicals.

The Recommendation of the Committee for allocation of additional funds has been sent to the Ministry of Finance on 26.05.2022 (**ANNEXURE-II**) for necessary action. Department will approach M/o Finance at RE stage 2022-23 for allocation of additional funds.

Comments of the Committee

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

(Recommendation No. 10)

Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

4.9 With regard to the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), the Committee had recommended as follows:-

“The Committee note that the Department had sought Rs 100.00 Crore for the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) but the approved BE allocation is Rs 62.00 Crore for the year 2022-23. According to the Department, the reason for this difference in proposed and approved BE allocation is the present revision of scheme guidelines of PTUAS as per EFC approval. Once approved, eligible applications will be considered in FY 2022-23. Only token allocation was made to this important Scheme during the financial years 2019-20, 2020-21 and 2021-22. For the first time, the scheme has got the needed financial support of Rs 62.00 Crore at BE stage of 2022-23. The aim of PTUAS is to provide interest subvention to the Pharmaceutical Medium Small and

Micro Enterprises (Pharma MSMEs) to upgrade their standards both in terms of quality and technique to WHO-Good Manufacturing Practices so that the Pharma MSMEs would be able to produce quality drugs and become globally competitive. This Scheme enables upgradation of these enterprises from Schedule M to WHO-GMP standards so that they are eligible to export in global markets and earn foreign exchange. Out of 6790 SMEs in manufacturing bulk and API drugs, only 2006 are WHO-GMP certified and more than 4500 remain outside the purview of WHO-GMP certification. The Committee are constrained to note that this Scheme remained on paper with token allocations during the last three financial years. With the allocation of funds made for 2022-23, it is time for the Department to initiate concrete and time bound efforts to start implementing this Scheme from 2022-23 onwards. The Committee, therefore, strongly recommend:

i) Guidelines of the scheme should be finalized quickly and the fund allocated for 2022-23 should be fully utilized”.

REPLY OF THE GOVERNMENT

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

i) The guidelines of the Scheme “Strengthening of Pharmaceuticals Industry” (SPI) has been finalized and published in the Department’s Website on 11.03.2022, which includes the sub-scheme PTUAS. The sub-scheme, PTUAS has been incorporated under the Scheme SPI with the budget allocation of Rs. 300.10 crore for Financial Year 2021-2022 to 2025-2026. Further, M/s SIDBI have been appointed as the Project Management Consultant (PMC) for implementation of the Scheme.

ii) Department will seek additional funds from the Ministry of Finance at RE Stage, if need be.

iii) Under the PTUAS scheme, a target has been set by the Department to provide support to about 420 Pharma MSMEs for upgrading their technology to meet WHO-GMP or Schedule M standards till March 2026. Efforts will be made to achieve the above targets in a time bound manner.

Comments of the Committee

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

(Recommendation No. 13)

Promotion of Bulk Drug Parks (Assistance to Bulk Drug Industry for Common Facilitation Center)

4.11 With regard to the Promotion of Bulk Drug Parks (Assistance to Bulk Drug Industry for Common Facilitation Center), the Committee had recommended as follows:-

“The Committee note that the objective of this sub scheme is to promote three Bulk Drug Parks by providing Grants-in-Aid for creation of World class Common Infrastructure facilities (CIF). A Financial assistance of Rs. 1000 crore per Park or 70% of the cost of the CIF, whichever is less is provided. 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 note that this Scheme has not been able to take off since 2019-20. During 2019-20 only a token allocation was made. Later during 2020-21, Rs.1.68 Crore was utilized out of RE allocation of Rs.1.69 Crore for Project Management Agency. Further during 2021-22, Rs.36.24 Crore at RE stage remained unutilized as the process to select beneficiary states could not be completed. However, it is noted that an amount of Rs.900.00 Crore has been allocated in BE 2022-23. This amount will be used to give first instalment of Rs. 300.00 Crore each to the three selected states for creation of

Common Infrastructure Facilities (CIFs) as grant-in-aid. Thirteen states have applied for assistance under the Scheme. Since the Project Management Agency (PMA) has identified certain issues in the proposals received under this scheme during 2021-22, an advisory Committee has been constituted with CEO NITI Aayog, Secretary, DoP and representatives of DPIIT & Department of Expenditure which has advised the Department to apply a set of qualitative filters to the proposals received looking at the higher technology, market and environmental risks emerging in the last year in respect of the Bulk Drug segment. The process in this regard is presently underway in the Department. The country is in urgent need of meeting the requirements of bulk drugs indigenously rather than dependence on other countries. The Committee, therefore, recommend that the process of selection of three beneficiary states should be expedited and the first instalment of Rs.300.00 Crore should be released to the States which are to be selected for implementation of the Scheme so that the undesirable situation of surrender of unutilized budgetary allocation does not recur again”.

REPLY OF THE GOVERNMENT

4.12 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 well taken. It is further stated that as provided by the guidelines of the scheme, the selection of States shall take place once in-principle approval is granted and DPRs are finalized. In pursuance to the same and guidance provided by the Advisory Committee constituted under the chair of CEO, NITI Aayog, continuous effort is being undertaken by the Department to ensure early selection of States and subsequent release of financial assistance under the aforesaid Scheme”.

ii The Committee also feel that three bulk drug parks are not adequate to meet the production needs of bulk drugs in the country particularly keeping in view its status of “World Pharmacy”. Since there is vast potential for export in the pharma sector, the Committee recommend that more Bulk Drug Parks may be set up in all the aspiring states and the Ministry of Finance may be approached for requisite budgetary allocation for the purpose.

After implementation of the scheme for 3 bulk drug parks and evaluation of performance thereof, a considered view may be taken to assess need for expansion in view of prevailing situation in terms of level of drug security achieved, proliferation of parks/clusters, adequacy of market incentives and incentives given by respective State Governments, etc.

Comments of the Committee

(Please see Para No. 1.22 of Chapter- I of the Report)

Recommendation No. 14

Promotion of Medical Devices Parks (Assistance to Medical Device Industry for Common Facilitation Center)

4.13 With regard to the Promotion of Medical Devices Parks (Assistance to Medical Device Industry for Common Facilitation Center), the Committee had recommended as follows:-

- vii. The Committee note that the objective of the scheme is 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. Financial assistance is 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 are concerned to note funds allocated for this Scheme during 2020-21 and 2021-22 were not fully utilized. During 2020-21, out of Revised Estimate allocation of Rs.21.05 Crore, only Rs.7.49 Crore was spent. During 2021-22, the Department had spent Rs.50.62 Crore out of allocated amount of Rs. 137.02 Crore at RE stage till the time information was furnished to the Committee. In this regard, the Department has assured the Committee that the remaining amount would be released to the States before the end of the financial year. The details of Actual Expenditure incurred as on 31 March, 2022 may be furnished to the Committee. In this backdrop, Rs.120.00 Crore has been provisioned in BE 2022-23 which the Department will release as the 2nd grant to 4 Medical Device Parks States with proportionate contribution by the State Implementing Agencies (SIAs). Medical Devices Sector being a sunrise sector of the Indian Economy, creation of state of the art Common Infrastructure Facilities (CIF) in Medical Devices Parks is need of the hour and their creation will attract private investment in Medical devices Industry. The Committee, therefore, strongly recommend that the Department should take necessary steps for the early release of budgetary funds to four Medical Devices Parks being set up in Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh and it should also be monitored by the Department whether the released funds are resourcefully utilized by the concerned states. The progress made in achieving the physical and financial targets set under the scheme should be intimated to the Committee.
- viii. The Committee also recommend to examine the necessity of setting up of more Medical Devices Parks in the country and appropriate steps should be initiated there for the setting up of Medical Devices Parks in other States as well.

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

1. The Department in their action taken reply has stated as under:

- "i. The Department, in full agreement with the recommendations of the committee, has taken steps to release the funds to the four Medical Device Parks, sanctioned to the States of Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh and progress in this regard, is being reviewed regularly. The details of Expenditure under the scheme are as follows: In FY 2020-21, Rs.7.49 Crore was allocated at BE stage and later at RE stage, additional funds of Rs.21.05 Crore were requested but the funds could not be allocated. Hence, only Rs.7.49 Crores was spent during FY 2020-21. In FY 2021-22, Rs.60 Crore was allocated at BE stage which was later increased to Rs. 137.02 crore at RE stage under the Scheme "Promotion of Medical Device Parks" (erstwhile known as "Assistance to Medical Device Industry for Common Facility Centre"). The entire Budget of Rs.137.02 Cr were fully utilized as on 31st March, 2022. This includes release of an amount of Rs.30 Crores each as 1st installment of Grant-in-aid to the States of Madhya Pradesh, Himachal Pradesh, Tamil Nadu and Uttar Pradesh in FY 2021-22. Accordingly, in BE 22-23, Rs. 120 Cr has been requisitioned to process for release of 2nd instalment to the States, subject to commensurate release from the States to the Parks and commensurate progress as per the committed timelines. There is proper mechanism to monitor the utilization of funds as well as monitor the progress in achieving the physical and financial targets under the scheme through the Project Management Agency (PMA) for the scheme. The progress made in achieving the physical and financial targets set under the scheme is being monitored through the Quarterly Review Reports (QRR) and the Special Purpose Vehicle formed by the State Governments to develop the medical device parks shall furnish a quarterly progress report to the Department as per the scheme guidelines. Same will be furnished to the Committee as requested.
- iii. Based on the budget provisioned and based on the examination of the proposals received under the Scheme, four States of Madhya Pradesh, Himachal Pradesh, Tamil Nadu and Uttar Pradesh have been selected and being supported to create common infrastructure facilities. Presently, no budget is available under the scheme to support creation of common infrastructure facilities in the Medical Device Parks being developed or planned to be developed by other States. The States, interested to develop such Medical Device Parks in their States, will, however, be provided necessary technical guidance."

Comments of the Committee

(Please see Para No. 1.25 of chapter –I of the Report)

CHAPTER – V

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

NIL

**New Delhi;
08 August, 2022
13 Sravana 1944 (Saka)**

**KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals & Fertilizers.**

Government Initiatives for the Medical Devices Sector

The Government of India has recognized medical devices as a sunrise sector under the 'Make in India' campaign in 2014. Subsequent Union Budgets have announced several measures to encourage manufacturing, streamline regulatory approvals and announced attractive fiscal incentives. To further promote the medical devices sector in the country with a focus on indigenization and reducing share of imports, the Government has implemented following key incentives and schemes:

1. Scheme for Promotion of Medical Device Parks:

1.1. The sub-scheme termed as "**Assistance to Medical Device Industry for Common Facility Centre**" was a Central Sector Scheme under the umbrella scheme for Development of Pharmaceutical Industry. The total size of the above sub-scheme was ₹ 100 crore for 2018-2020. The sub-scheme proposed to provide a one-time grant-in-aid of ₹ 25 crore or 70% of the project cost, whichever was less, to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose. The purpose of the grant was to render financial assistance for establishment of common facilities in any upcoming Medical Device Park promoted by a State Government/State Corporation. The Department has supported the proposal of Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh under the said sub-scheme.

1.2. Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre" has been revised and renamed as "**Promotion of Medical Device Parks**" which has been approved by the Government of India on 20th March 2020. The parks will provide common testing and laboratory facilities/centre at one place reducing the manufacturing cost significantly and will help in creating a robust ecosystem for medical device manufacturing in the country. The total financial outlay of the scheme is ₹ 400 crore and the maximum assistance under the scheme for one Medical Device Park would be limited to ₹ 100 crore. Under the Scheme, the selected Medical Device Park project will be implemented by a State Implementing Agency (SIA).

1.3. A total number of 16 States submitted their proposals under the scheme. The Government has in-principally approved financial assistance for common infrastructure facilities for 4 medical device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh. Subsequent to evaluation of their DPRs, Final Approvals have been given to all the four States. First installment of 30 Cr is also released to all the four States. States are taking necessary actions to establish the Parks as per the DPRs.

2. Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices:

2.1. The domestic medical devices industry faces challenges related to considerable cost of manufacturing disability, among other things, on account of lack of adequate infrastructure, domestic supply chain and logistics, high cost of

finance, inadequate availability of quality power, limited design capabilities and low investments on R&D and skill development. With a view to address these challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies, a scheme called “Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices” has been approved by the Government of India on 20th March, 2020.

2.2. The Scheme is applicable **only to the Greenfield projects** and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The tenure of the scheme is from FY 2020-21 to FY 2027-28. The total financial outlay of the Scheme is ₹ 3,420 crore.

2.3. The identified products under this Scheme have been categorized into four Target Segments which is (i) “Cancer care/Radiotherapy medical devices, (ii) Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices (iii) Anaesthetics& Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices and (iv) All Implants including implantable electronic devices”.

3. **Production Linked Incentive (PLI) scheme for Pharmaceuticals:**

3.1. To enhance India’s manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector, a scheme called “Production Linked Incentive Scheme for Pharmaceuticals” has been approved by the Government of India on 24th March, 2021. The guidelines of the scheme were issued on 1st June, 2021. The scheme covers In-vitro diagnostic devices amongst other pharmaceutical goods. Five (5) industry applicants have been selected under the scheme for In-vitro diagnostic medical devices and the scheme provides for incentives based on their incremental sales for 6 years. The tenure of the scheme is from FY 2020-2021 to 2028-29.

3.2. Further, the challenges for the Sector are in terms of regulatory streamlining of the medical devices which is at a nascent stage, skilling of human resources and lack of technology for high end equipment and lack of appropriate infrastructure. Medical devices sector has seen significant activity in recent years with increase in demand, roll out of the regulatory timeline, introduction of PLI Schemes etc., all of which have contributed to a need to take on board a range of views on important policy issues. Medical devices sector had segmented participation from well-established Global MNCs (importing, manufacturing, exporting & investing in innovation, research & development), Indian firms and start-ups manufacturing, exporting & innovating a limited range of Medical Devices. The sector requires special co-ordination and communication among Industry and Stakeholders because of its diversified nature, continuous innovation & variation.

4. **Attractive Foreign Direct Investment (FDI) Policy:** In order to attract investments in this sector, the Government has allowed 100% foreign direct

investments (FDI) in medical devices sector with estimated inflows of around USD 2.17 billion from April 2000 to December 2020.

5. The **National Pharmaceutical Pricing Authority (NPPA)** is monitoring the prices of Non-scheduled medical devices and fixed the ceiling prices of for scheduled Medical Devices.

5.1. **TRADE MARGIN RATIONALISATION ON MEDICAL DEVICES:** NPPA capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level. Similarly, trade margin on Pulse Oximeter, Glucometer, Blood Pressure Monitor, Nebulizer and Digital Thermometer was capped. These have further been extended for Oxygen Concentrators and the five medical devices till 31st May 2022 and 31st July 2022 respectively. Expected savings to the consumers will be around Rs. 1000 crore per annum.

5.2. **MEDICAL OXYGEN:** To ensure its continued availability for COVID and other emergencies, NPPA, in public interest, capped the price of Liquid Medical Oxygen (LMO) and the Oxygen Inhalation (Medicinal gas). NPPA has also extended ceiling price of Liquid Medical Oxygen (LMO) & Medical Oxygen Gas (in cylinders) up to 31.03.2022 respectively. It is to mention that Medical Oxygen including LMO and Medical Oxygen Gas are not medical devices.

6. To improve access, the Government has made available 250 types of surgical supplies in **over 8700 stores or Jan Aushadhi Kendras** at highly affordable prices under the Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana.

7. Besides, the regular interaction with the industry representatives to redress the specific challenges, the following are the **institutional mechanisms**, adopted by the Department.

7.1. **Standing Forum of Medical Devices Associations :** A Standing Forum of medical device Industry associations has been set up on 25th August 2021 by the Department of Pharmaceuticals to provide a platform for discussion on various challenges being faced by the sector and arrive at well-rounded views. The Department has constituted a Standing Forum of various Medical Device associations which deliberate on various issues with all the stakeholders including regulators and then the forum comes up with workable solutions after the consensus is built between various associations.

- Representatives from CII, AiMED, FICCI, USIBC, ADMI, AMTZ, MTAI, Advamed, PHDCCI, USISPF, AMCHAM, ASSOCHAM are part of this Standing Forum with DoP as facilitator
- The main objective of the Standing Forum is to deliberate upon issues pertaining to the sector and arrive at inputs from Industry for **Policy and Program formulation**, by DoP
- Tasks undertaken by the Standing Forum so far:
- Drafting of **Uniform Code for Medical Device Marketing Practices (UCMDMP)**, separate from the existing code for Drugs. The draft code is under

stakeholder consultation.

- Consolidation of the views of the Industry on the "**Streamlining of the Regulatory framework for Medical Devices**". The recommendations received pertain to different regulators and are being processed.
- More tasks as and when identified will be assigned to the forum.

7.2. Coordinating Regular interactions of the Industry with the Regulators: Medical Device sector has multiple regulators (CDSCO, NPPA, MoEF&CC, BIS, AERB etc) for different aspects of the medical devices. Hence, the Department is holding regular meetings of the industry with the regulators to ascertain issues on short term and long-term basis for redressal.

7.3. India Medical Device- Annual event : The Department convenes an annual event both for Pharmaceuticals as well as Medical Devices sector known as **India Pharma and India Medical Devices Annual Event**. In the India Pharma event, experts and regulators from the sector are invited for wide ranging discussions on innovations, regulatory issues, financing and investment, start-ups in medical technologies etc. In the recently held India Pharma and India Medical Devices 2022 event from 25-27 April 2022, CEOs of the MedTech Sector participated and deliberated on the various issues related to the MedTech Sector ranging from developing a visionary approach for MedTech Sector in India @2047, to addressing the supply chain issues and deliberating on the efforts to be made in the Research and Innovation front as well.

8. Public Procurement (Preference to Make in India) Order, 2017: The Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce & Industry issued the Order and designated the Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions related to medical devices. DoP issued its guidelines in May 2018 prescribing that domestically sourced components must contribute to 25-50 per cent of the cost of medical devices to qualify for public tenders, which would be subsequently increased in a phased manner to 25-75% over a period of time [27]. Also, Department vide Order dated 16.02.2021 & 25.03.2021 has notified 135 in-vitro diagnostic medical devices and 19 medical devices where there is sufficient local capacity and local competition available in the country, under Para 3(a) of PPO Order dated 16.09.2020 to enable procurement of the notified items only from the "Class-I local suppliers" The exercise is being resorted on regular basis, to update the details of Indian Manufacturers of Medical Devices with the Central Procurement Agencies.

F. No. 35030/57/2021-Scheme
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi
Dated the 26th May, 2022

OFFICE MEMORANDUM

Subject: Thirty-Fourth Report on Demand for Grants (2022-23) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals).

The undersigned is directed to refer to Lok Sabha Secretariat (Standing Committee on Chemicals & Fertilizers)'s O.M. No. LAFEAS-C&F027/9/2022-SCCF dated 22.03.2022 on the above mentioned subject (Copy enclosed).

2. A copy of Recommendation No.7 of the Departmental Parliamentary Standing Committee for information and appropriate action. As recommended by the Committee, the Department will approach M/o Finance for provision of balance Rs. 27.50 Crore at the stage of RE 2022-23.

3. This has the approval of the competent authority.

Encl:- As above

Uma Magesh

(Uma Magesh)
Under Secretary to the Govt. of India
Ph. 23383392

To,

Joint Secretary (Budget),
(Sh. Ashish Vachhani)
Department of Economic Affairs,
Budget Division,
Ministry of Finance,
North Block, New Delhi -110001
(Email : ashish.vachhani@nic.in)

Copy to:-

Under Secretary, IFD, Department of Pharmaceuticals, Janpath Bhawan, New Delhi

Thirty-Fourth Report on Demand for Grants (2022-23) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals).

Recommendation No. 7: Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

The Committee note that a budgetary allocation of Rs. 72.50 Crore has been made for PMBJP against the Department of Pharmaceutical's proposal for Rs. 100.00 Crore for 2022-23. Under this Scheme, a target has been fixed to open new 1000 Kendras and enhance the product basket upto 1,800 medicines and 280 surgicals during the year 2022-23.

Further, a sale target of Rs. 775.00 Crore has also been prescribed for the year. As per the Department, the funds allocated at BE stage are not sufficient and less allocation of funds will hamper effective implementation of the scheme. The Scheme aims to make available quality generic medicines at affordable prices to all especially for the poor and the deprived ones. As on 15.02.2022, 8683 PMBJP outlets have been opened in the country with product basket of 1451 medicines and 240 surgicals. In this regard, the Committee feel that the number of PMBJP outlets in the country are inadequate when compared to nine lakh plus medical shops in the country. Further with regard to the present population of the country i.e. near about 140.52 crore it is noted that one Kendra is catering to approximately 16 lakh population. Hence, there is a need to increase the number of PMBJP outlets in the country and also to increase the product basket of the outlets. The Committee, therefore, recommend that the Department of Pharmaceuticals should impress upon the Ministry of Finance for the allocation of remaining funds (Rs. 27.50 Crore) required for effective implementation at RE stage of 2022-23. This recommendation of the Committee should also be sent to the Ministry of Finance for its implementation.

F. No. 35030/57/2021-Scheme
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi
Dated the 26th May, 2022

OFFICE MEMORANDUM

Subject: Thirty-Fourth Report on Demand for Grants (2022-23) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals).

The undersigned is directed to refer to Lok Sabha Secretariat (Standing Committee on Chemicals & Fertilizers)'s O.M. No. LAFEAS-C&F027/9/2022-SCCF dated 22.03.2022 on the above mentioned subject (copy enclosed) and to forward herewith a copy of Recommendation No. 8 (v) of the Departmental Parliamentary Standing Committee for information and appropriate action.

2. This has the approval of the competent authority.

Encl:- As above

Uma Magesh

(Uma Magesh)
Under Secretary to the Govt. of India
Ph. 23383392

To,

Under Secretary (Drug Regulation Section),
Department of Health and Family Welfare,
Nirman Bhawan,
New Delhi – 110011
Email:-drugsdiv-mohfw@gov.in

Copy to:-

Under Secretary, IFD, Department of Pharmaceuticals, Janpath Bhawan, New Delhi

Thirty-Fourth Report on Demand for Grants (2022-23) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals).

Recommendation No. 8: Coverage and product basket of PMBJP

The Committee note that all 739 districts of the country have already been covered under Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP). In order to popularize the Scheme and expand opening of Kendras in the aspirational districts, Himalayan, Island territories and the North-Eastern States, a new incentive plan has been launched. Such Kendras now get a one-time grant of ₹ 2 lakh in addition to normal incentives viz. Rs.1.50 lakh for reimbursement of furniture and fixtures and Rs.0.50 lakh for reimbursement for computer, internet, printer, scanner etc. Pharmaceuticals and Medical Devices Bureau of India (PMBI) has released various newspaper advertisements for inviting applications for opening of PMBJP outlets in July, 2021 for opening of PMBJP outlets in 265 districts of the different States where coverage is less. Since continuous efforts are to be made for expanding coverage of the Scheme so as to achieve its objectives of providing quality generic medicines and medical devices at affordable prices to the people of the country, the Committee would like to make the following recommendations:-

v) Department of Pharmaceuticals, NPPA and the Ministry of Health and Family Welfare may make coordinated efforts to make the medical practitioners prescribe quality generic medicines rather than exorbitant branded medicines. This recommendation may also be sent to the Ministry of Health and Family Welfare.

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2021-22)

Minutes of the Ninth Sitting of the Committee

The Committee sat on Thursday, the 04th August, 2022 from 1500 hrs. to 1645 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Smt. Kanimozhi Karunanidhi, Chairperson

Lok Sabha

2. Shri Ramakant Bhargarva
3. Shri Rajeshbhai Naranbhai Chudasama
4. Shri Ramesh Chandappa Jigajinagi
5. Shri Kripanath Mallah
6. Shri Satyadev Pachauri
7. Dr. M. K. Vishnu Prasad
8. Shri Arun Kumar Sagar
9. Shri Indra Hang Subba

Rajya Sabha

10. Shri Ayodhya Rami Reddy Alla
11. Dr. Anil Jain
12. Shri Arun Singh
13. Shri Vijay Pal Singh Tomar
14. Shri K. Vanlalvena

SECRETARIAT

- | | | |
|---------------------------|---|------------------|
| 1. Shri Vinay Kumar Mohan | - | Joint Secretary |
| 2. Shri Nabin Kumar Jha | - | Director |
| 3. Shri Kulvinder Singh | - | Deputy Secretary |
| 4. Shri Panna Lal | - | Under Secretary |

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XXX

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2. At the outset, the Chairperson welcomed the Members to the sitting of the Committee, convened for consideration and adoption of the following Draft Action Taken Reports:

- | | | | |
|------|---|-----|-----|
| i. | XXX | XXX | XXX |
| ii. | XXX | XXX | XXX |
| iii. | XXX | XXX | XXX |
| iv. | Thirty-Eighth Report on Action Taken by the Government on the observations/recommendations contained in the Thirty-Fourth Report (17 th Lok Sabha) on 'Demands for Grants 2022-23' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals). | | |

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

4. The Committee, then, took up the Draft Action Taken Reports one by one for consideration and after some discussions adopted them.

5. The Committee then authorized the Chairperson to finalise the Action Taken Reports and present the same to the Parliament.

XXX – Matter Not related

APPENDIX-V

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE THIRTY FOURTH REPORT (SEVENTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2021-22) ON DEMAND FOR GRANTS (2022-23) OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS).

	Total No. of Recommendations	19
I	Observations/Recommendations which have been accepted by the Government: (Vide Recommendation Nos. (3, 4, 5, 8,9,11,12,15,16,17,18,19)	12
Percentage of Total		64%
II	Observations/Recommendations that 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: (Vide Recommendation No. 1,2,6,7,10,13,14)	07
Percentage of Total		36%
IV	Observations/Recommendations in respect of which the final replies of the Government are still awaited: (Vide Recommendation No. Nil)	0
Percentage of Total		0%

