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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 Twenty First Report (Seventeenth Lok Sabha) on 'Demands for Grants (2021-22)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

TWENTY EIGHTH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

DECEMBER, 2021 / AGRAHAYANA, 1943 (SAKA)

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Presented to Lok Sabha on 02.12.2021

Laid in Rajya Sabha on 02.12.2021

LOK SABHA SECRETARIAT
NEW DELHI

DECEMBER, 2021 / AGRAHAYANA, 1943 (SAKA)

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2020-21)

Smt. Kanimozhi Karunanidhi - Chairperson

MEMBERS

LOK SABHA

2	Shri Maulana Badruddin Ajmal
3	Shri Deepak Baij
4	Shri Ramakant Bhargava
5	Shri Prataprao Govindrao Patil Chikhalikar
6	Shri Rajeshbhai Naranbhai Chudasama,
7	Shri Ramesh Chandappa Jigajinagi
8	Shri Pakauri Lal
9	Shri Kripanath Mallah
10	Shri Satyadev Pachauri
11	Smt Aparupa Poddar
12	Dr. M.K.Vishnu Prasad
13	Shri Atul Kumar Singh alias Atul Rai
14	Shri Arun Kumar Sagar
15	Shri M. Selvaraj
16	Shri Pradeep Kumar Singh
17	Shri Uday Pratap Singh
18	Shri Indra Hang Subba
19	Shri Prabhubhai Nagarbhai Vasava
20	Dr. Sanjeev Kumar Singari#
21	Vacant*

RAJYA SABHA

22	Shri G.C.Chandrashekhar
23	Dr. Anil Jain
24	Shri Ahmad Ashfaque Karim
25	Shri M.V. Shreyams Kumar
26	Shri Jaiprakash Nishad
27	Shri Anthiyur P. Selvarasu
28	Shri Arun Singh$
29	Shri A.D. Singh
30.	Shri Vijay Pal Singh Tomar
31.	Shri K. Vanlalvena

SECRETARIAT

1.	Shri Manoj Kumar Arora	-	Officer on Special Duty(LSS)
2.	Shri Nabin Kumar Jha	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Shri Kulvinder Singh	-	Deputy Secretary
5.	Ms Sonia Sankhla	-	Assistant Executive Officer
		-	

$Re-nominated to the Committee w.e.f. 23.12.2020.

#Nominated to the Committee w.e.f 28.12.2020 vice Shri Nandigam Suresh.

**Vacant vice* Shri Er. Bishweswar Tudu nominated MoS on 07.07.2021.

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 Prabhubhai 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 M.V. Shreyams Kumar
26. Shri Jaiprakash Nishad
27. Shri Anthiyur P. Selvarasu
28. Shri Arun Singh
29. Shri Vijay Pal Singh Tomar
30. Shri K. Vanlalvena
31. Vacant

SECRETARIAT

1. Shri Nabin Kumar Jha - Director
2. Shri C.Kalyanasundaram - Additional Director
3. Shri Kulvinder Singh - Deputy Secretary
4. Ms Sonia Sankhla - Assistant Executive Officer

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2021-22) having been authorized by the Committee, do present on their behalf this Twenty Eighth Report on Action taken by the Government on the Observations/ Recommendations of the Committee contained in their Twenty First Report (Seventeenth Lok Sabha) on "Demands for Grants (2021-22)", pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Twenty First Report was presented to Lok Sabha and also laid in Rajya Sabha on 17th March, 2021. The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) furnished their replies on 8th July, 2021 indicating action taken on the recommendations contained in that Report. The Committee at their sitting held on 16 November 2021 considered and adopted the Draft Report.

3. An analysis of the action taken by Government on the Observations/ Recommendations contained in the Twenty First Report (Seventeenth Lok Sabha) of the Committee is given in Appendix-II.

4. For the facility of reference and convenience Recommendations/ Observations/further comments of the Committee have been printed in bold letters in the body of the Report.

New Delhi;	**KANIMOZHI KARUNANIDHI**
16 November, 2021	**Chairperson,**
25 Kartika, 1943 (Saka)	**Standing Committee on Chemicals and Fertilizers**

CHAPTER I

1.1 This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Twenty First Report (Seventeenth Lok Sabha) of the Committee on "**Demands For Grants (2021-22)**" of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha and Rajya Sabha on 17.3.2021.In all, the Committee made 16 Observations / Recommendations in the Report.

1.2 Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the 21st Report within three months from the date of presentation of the Report. The Action Taken Replies of the Government in respect of all the 16 Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their OM No.23003/4/2021-IFD dated 08-07-2021 These Replies have been categorized as follows:-

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

Sl. Nos. 1,3,4,5,6,7,8,9,11,13,15 (Total = 11)

Included in **Chapter II** of the Draft Report.

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

Sl.No. Nil (Total = 0)

Included in **Chapter III** of the Draft Report.

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

Sl.No. 2, 10 (Total = 2)

Included in **Chapter IV** of the Draft Report.

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

Sl.No. 4, 14, 16 (Total=3)

Included in **Chapter V** of the Draft Report.

1.3 The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in **Chapter-I and V** of this Report should be furnished within three months from the date of presentation of this Report.

1.4 The Committee will now deal with action taken by the Government on some of the Observations/Recommendations which still require reiteration or further merit comments.

Recommendation No-1

Need for Enhanced Budgetary Allocation

1.5 While stressing on the need for enhancing the budgetary allocation, the Committee had recommended as below:-

> "The Committee note that the Department of Pharmaceuticals has vision to promote Indian pharmaceutical sector as the global leader for quality medicines and to ensure availability, accessibility and affordability of drugs and medical devices in the country. However, the Committee are dismayed to note that the Gross Budgetary allocation for the year 2021-22 is Rs. 470.41 Crore against the proposed outlay of Rs.2600.52 Crore which is only one sixth of the outlay proposed by the Department. Out of Rs 470.41 Crore allocated to the Department, Rs. 31.53 Crore is towards the administrative expenditures for both the Department of Pharmaceuticals and National Pharmaceuticals Pricing Authority (NPPA) against proposed Budget Estimate of Rs. 35.98 Crore. Budgetary allocation for Central Sector Schemes is Rs. 429.76 Crore against proposed Budget Estimates of Rs.2564.48 Crore. According to the Department of Pharmaceuticals, total funds allocated will fall short of the urgent fund requirements projected by the Department for carrying out its laid down mandate and will adversely affect the central sector schemes being implemented by the Department viz. Development of Pharmaceuticals Industry and National Institutes of Pharmaceuticals Education and Research (NIPER). In this regard, the Committee note that the Department has been allocated Rs. 234.34 crore against its requirement of Rs. 1220 crore for NIPERs and only Rs. 124.42 crore against the proposal of the Department of Pharmaceuticals for a budgetary allocation of Rs. 1256.16 core for the implementation of important umbrella

scheme of the Department for the development of Pharmaceuticals industry during 2021-22. Going by the pace at which this umbrella scheme with important sub schemes for the holistic development of the Pharmaceutical Industry is being implemented by the Department, it is not surprising to the committee that the Ministry of Finance has curtailed the allocation drastically. Since it is very much essential to develop state of the art common facilities, to provide funds for technology upgradation, to offer production linked incentives etc to the pharma industry including bulk drug and medical devices industries, the committee strongly recommend that the Department should take serious and concrete efforts for the implementation of all the sub schemes of the umbrella scheme in a time bound manner particularly to examine the proposals under various sub schemes expeditiously and to accord approval in a time bound manner so as to enable the Ministry of Finance allocate the requisite amount of funds for the implementation of various sub schemes under the umbrella scheme. It is also necessary to make realistic budgetary proposals on actual need basis. As far as fund allocation to NIPERs is concerned, the Committee take a serious view of non-allocation of requisite amount of funds by the Ministry of Finance for the infrastructural development of NIPERS even after a decade of their existence due to which these institutes are unable to attain their full potential. Since the subject matter pertaining to the Department of Pharmaceuticals is concerned with the drug security of the country, the Committee urge upon the Ministry of Finance to examine the budget proposals of the Department of Pharmaceuticals very carefully and the make adequate allocation of funds for the implementation of various Schemes and programmes of the Department. Since the allocation made at BE is very less to cope the fund requirements of various schemes which are at the advanced stages of proposal approval and fund release, the Department of Pharmaceuticals should prepare fresh proposals for fund release at RE stage of 2021-22 and the same should be submitted to Ministry of Finance for the allocation of necessary funds at RE stage. A copy of this recommendation may also be sent to Ministry of Finance for its compliance."

Reply of the Government

1.6 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"Department has taken a matter with Department of Expenditure through EFC memos seeking the adequate funds for implementation of the ongoing schemes of Department. It is expected that the meeting of Expenditure Finance Committee (EFC) will be held shortly under the chairmanship of Secretary (Expenditure). Department will send the recommendation of committee to the Department of Expenditure as suggested."

Further Comments of the Committee

1.7 The Committee note that the reply given by the Department of Pharmaceuticals is silent to the specific recommendation of the Committee that the Department should take serious and concrete efforts for the implementation of all the sub schemes of the umbrella scheme in a time bound manner particularly to examine the proposals under various sub schemes expeditiously and to accord approval in a time bound manner so as to enable the Ministry of Finance allocate the requisite amount of funds for the implementation of various sub schemes under the umbrella scheme. One of the yardsticks being used by the Ministry of Finance for the allocation of funds to the Schemes/programmes of Ministries/Departments is the past performance**. The Committee, therefore, reiterate the earlier recommendation that earnest steps should be taken by the Department of Pharmaceuticals for the speedy and holistic implementation of the umbrella scheme of the Department so as to convince the Ministry of Finance about the credentials of the Department.**

1.8 The Committee note that the Department has taken up the matter with the Department of Expenditure through Expenditure Finance Committee (EFC) memos seeking the adequate funds for implementation of the ongoing schemes of Department. Meeting of EFC is expected to be held shortly. **In this regard, the Committee recommend that the matter may be pursued vigorously by Department at Secretary level with the Department of Expenditure and if necessary may be taken up at the Minister's level with the Minister of Finance. The progress made in this regard may be intimated to the Committee.**

1.9 The Committee are constrained to see the reply of the Department that it will send the recommendation of the Committee to the Department of Expenditure. Twenty First

Report was presented to Parliament on 17 March, 2021 and the copy of the report was sent to the Department immediately. But the Department had not sent the recommendation to the Department of Expenditure till 8th July 2021 when it furnished this Action Taken Reply to the Committee. Such delays will defeat the very purpose of the recommendation. **The Committee hope that such suggestions of the Committee to convey its recommendations to other Ministries/Departments would be sent immediately to the concerned Ministries/Departments for prompt action on their part.**

Recommendation No. 2

Major issue of drug security associated with overdependence on imported API/Bulk Drugs

1.8 While addressing the major issue of drug security associated with overdependence on imported API/Bulk Drugs, the Committee had made the following recommendation:-

> "The Committee note that pharmaceuticals has been identified as one of the champion sectors, which forms around 1.72 percent of the country's GDP but there is an urgent need to pay attention to major issue of drug security associated with overdependence on imported API/Bulk Drugs which if not handled can adversely affect the competitiveness of the domestic pharmaceutical sector in the years to come. In this regard, the Department of Pharmaceuticals has informed that the Active Pharmaceutical Ingredients (API)/Bulk drugs and intermediates form 63% of India's total pharma imports. Even production of some of the National List of Essential Medicines (NLEM) formulations is dependent on imported APIs and intermediates. India imports bulk drugs and intermediates largely on economic considerations. China with a share of 67.6 % is the major source for API. India, being one of the largest manufacturers of medicines and exporting these to over 200 countries, dependence on a single source for import of API is a matter of serious concern as any disruption in the supplies could jeopardize the pharma sector and affect the supplies of medicines both for domestic use and exports. In this regard, the Committee observed that during the early 90s, India was self-reliant in manufacturing APIs. However, with the rise of China as a producer of API, it captured the Indian market with its low-cost API manufacturing industry. The worst hit was the Indian fermentation based bulk drug Industry facing severe competition from overseas players mainly from

China. Local production slowly stopped when China started exporting these bulk drugs at very low prices in India. The cost of production of these bulk drugs was low in China due to multiplicity of factors including low cost of capital followed by aggressive government funding models, tax incentives, availability of subsidized utilities such as electricity, steam, brine, effluent treatment etc. In order to negate imports, the Department has issued guidelines dated 30.12.2020 for implementation of Public Procurement (Preference to Make in India) Order dated 16.09.2020 issued by Department for Promotion of Industry and Internal Trade, to Pharmaceuticals Sector which classify the suppliers for providing preference in public procurement based on their minimum local content for pharmaceuticals formulations. In 2020, the Committee under chairmanship of Dr Eswara Reddy identified APIs with high degree of import dependence. Further, a Production linked incentive scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country has been launched by the Government. The committee is also given to understand that Department has no policy to favourably distinguish between Pharma companies which manufacture drugs from domestically produced critical Key Starting Materials(KSMs)/Drug Intermediates (DI) and Active Pharmaceutical Ingredients (APIs) in comparison to those companies which manufacture drugs by importing API/KSM/DI from other countries. Since it is very much necessary to stop the dumping of cheap raw material in the country by China, there is a need to curtail this trend and therefore, the Committee recommend that the following measures should be taken:-

(i) NITI Ayog and the Department of Pharmaceuticals to make an indepth study of various concessions being provided by China to its bulk drug industry and to initiate immediate appropriate measures in a war footing manner for the creation of a very strong API/bulk drug/KSM industry in the country as a viable competitor and alternative source country for API/bulk drug/KSMs.

(ii) Need to provide manufacturing support infrastructure viz. subsidized utilities such as electricity, water, steam, brine, effluent treatment plant etc and help create economies of scale for fermentation based bulk drug Industry clusters.

(iii) Reclassify suppliers into three categories Class-I with 100 percent local content, Class-II 80 percent local content and Class-III with 60 percent local content and provide progressive incentives like zero duty on 100 percent local content suppliers and rationally increase duty on other two category of suppliers for both public and private procurements done in Pharmaceutical sectors.

(iv) Enhance the budget allocation for the scheme Promotion of Bulk Drugs during RE stage for the year 2021-22 to make effective stride in

establishing 3 Bulk Drug Parks in the country and expand the scheme to establish more Bulk Drug parks in future.

(v) Department of Pharmaceuticals to frame a comprehensive incentive policy for domestic bulk drugs producers.

This recommendation may also be sent to NITI Ayog for Action Taken Reply by both the Department of Pharmaceuticals and NITI Ayog."

Reply of the Government

1.9 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"As directed by Committee, the recommendation was also shared with NITI Aayog.

Regarding points (i),(ii) & (v) above: Department of Pharmaceuticals in consultation of NITI Aayog has launched following three schemes for promoting domestic manufacturing of bulk drugs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries:-

i. Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India;

ii. Scheme for Promotion of Bulk Drug Parks; and

iii. Production Linked Incentive Scheme for Pharmaceuticals.

Regarding point (iii) above: Department of Pharmaceuticals vide order dated 30.12.2020 has issued guidelines for implementation of Public Procurement (Preference to Make in India) (PPO) Order, 2017 to Pharmaceuticals Sector. The guidelines provide the percentage of local content which is to be used for providing preference in public procurement of goods & services related to Pharmaceuticals Sector as per PPO Order. The percentage of local content has been fixed at equal to or more than 80% for 'Class-I Local Supplier', more than 50% but less than 80% for 'Class-II Local Supplier' and less than or equal to 50% for 'Non-Local Supplier'.

Regarding point (iv) above: The Cabinet has granted approval of 3 Bulk Drug Parks. Department will seek additional funds in R.E. Stage for establishment of the parks. As and when the 3 three Bulk Drug Parks will be established, the

department will approach to Cabinet for establishing new bulk drug parks in the country."

Comments of the Committee

1.10 The Committee note that the Department in consultation with NITI Aayog has launched three schemes viz. Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/DIs and APIs In India, Scheme for Promotion of Bulk Drug Parks and Production Linked Incentive Scheme for Pharmaceuticals. **While appreciating the above mentioned steps taken by the Department, the Committee feel that it is necessary to make an indepth study of various concessions being provided by China to its bulk drug industry and to initiate further measures in a war footing manner so as to make the country a viable competitor to China in the field of production of API/bulk drug/KSMs. The Committee hope that immediate steps will be taken in this regard. An action taken reply may be furnished to the Committee in the matter.**

1.11 The Committee are also of the strong view that it is very much necessary to facilitate API/KSM/DI manufacturing sector with robust infrastructural support and subsidized utilities such as electricity, water, steam, brine, effluent treatment plant etc to help create economies of scale for fermentation based bulk drug Industry clusters. **The Committee hope that the above mentioned schemes launched by the Government would have addressed these necessities for the creation of a strong fermentation based bulk drug industry in the country. The Committee may be intimated about the extent of infrastructural and utilities support being provided under the new schemes launched by the Government for the promotion of API/bulk drug/KSMs industries in the country.**

1.12 In regard to the reclassification of suppliers into three categories, the Committee note that the action taken reply given by the Department has stuck to the guidelines issued by it for implementation of Public Procurement (Preference to Make in India) (PPO) Order, 2017 to Pharmaceuticals Sector and the reply is silent on the recommendation of the Committee to provide progressive incentives like zero duty on 100 percent local content suppliers and rationally increasing duty on other two categories of suppliers for both public and private procurements done in Pharmaceutical sector. **In this regard, the Committee strongly feel that the reclassification of local suppliers and giving attractive incentives to manufacturers for the use of local content is the need of the hour to promote the domestic API/KSM/bulkdrug/DI industry and to discourage imports. The Committee, therefore, reiterate its earlier recommendation on reclassification of suppliers as stated above at para No. 1.8 (iii).**

1.13 The Committee also note that the Department will seek additional funds at RE for Bulk Drugs Park Scheme for its implementation during 2021-22. **The Committee hope that this Scheme will get adequate and timely financial support from the Ministry of Finance and the progress made in this regard may be intimated to the Committee. Moreover, alongwith the establishment of three bulk drug parks, the Committee recommend that the work to establish more such parks should also start at the right earnest so as to create a strong base for the manufacturing of bulk drugs in the country.**

1.14 The Committee note that the Department has shared above cited recommendations of the Committee with the NITI Aayog but the action taken replies of NITI Ayog have not been furnished. **Specific action taken replies of NITI Ayog**

should be furnished to the Committee alongwith the action taken replies of the Department on this report.

Recommendation No.5

Promotion of Medical Devices Parks

1.15 While stressing on the need for promotion of Medical Devices Parks, the Committee had recommended as under:-

> "The Committee are constrained to note that another sub-scheme named "Assistance to Medical Device Industry for Common Facility Centre" was also not properly implemented by the Department and the same has been revised by the Union Cabinet During 2020-21. The sub-scheme has been renamed as "Promotion of Medical Devices Parks" with a total financial outlay of Rs. 400 crore. The objective of the sub-scheme is creation of world class infrastructure facilities in order to make Indian medical device industry a global leader. The tenure of the scheme is from 2020-2021 to 2024-2025. Maximum assistance under the scheme for one Medical Device Park would be limited to ₹ 100 crore. Under this Scheme an allocation of Rs.7.50 crore was made at BE stage of 2020-21 and the same was increased to Rs. 21.05 crore but the Department is able to spend only Rs 7.49 crore so far. In this background, the Department had demanded Rs.120 crore for the implementation of the Scheme during 2021-22 but the Ministry of Finance has allocated only Rs.60 crore at BE stage. The Committee note that in-principle approvals were given to the proposals received from Andhra Pradesh, Kerala, Tamil Nadu and Telangana. Subsequently the proposal of Andhra Pradesh was first taken up. After revision of the scheme by the Union Cabinet, the guidelines of the revised scheme were issued on 27.07.2020. After the revision of the scheme, 16 proposals have been received in accordance with the revised guidelines of the scheme. All the proposals are being evaluated for giving in-principle approval. Taking into consideration the importance of common laboratory and testing facilities in reducing the production cost of medical devices, the Committee recommend that the Department should take earnest steps for granting expeditious approvals to the eligible proposals under the Scheme during 2021-22 and financial assistance should also be provided to them according to the Scheme guidelines in a time bound manner. In case of necessity of further funds for the implementation of the Scheme during 2021-22, concrete proposals for allocation of the same at RE stage should be made to the Ministry of Finance. The Committee hope that the Department would act fast in coordination with State Implementing Agency (SIA), would expedite the approval procedures and disburse the funds allocated at BE 2021-22, so as to enable the Ministry of Finance consider favourably the

allocation of further funds at RE stage. The progress made in this regard may be intimated to the Committee.

Reply of the Government

1.16 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated that as under:-

> **"**Under the sub-scheme as "Assistance to Medical Device Industry for Common Facility Center", the Department has given approval for financial assistance of Rs. 25 crore to the project of Andhra Pradesh Medtech Zone Ltd (AMTZ), Andhra Pradesh for development of Common Facility Center for superconducting magnetic coils testing and research facility. A Budgetary allocation of Rs. 7.50 crore was allocated under the scheme in Budget Estimates 2020-21. The Department has released 1st instalment of Rs. 7.49 crore for the project to AMTZ on 11.9.2020. The budget allocation was increased to Rs. 21.05 crore in Revised Estimates but no re-appropriation order was issued to enable this Section to release the fund. Hence, the actual allocation was of Rs. 7.50 crore.
>
> The sub scheme has been revised and renamed as "Promotion of Medical Device Parks". The guidelines of the scheme have been issued on 27.7.2020. The scheme is under implementation. A budgetary allocation of Rs. 60 crore has been allocated for the FY 2021-22. The application window of the scheme was closed on 15.10.2020. A total number of 16 States/UTs have submitted their proposal under the scheme which are under evaluation."

Further Comments of the Committee

1.17 The Committee are concerned to note that little progress has been made since the revision of the Sub-Scheme "Promotion of Medical Device Parks" on 27.07.2020. As per the above action taken reply, application window of the Scheme was closed on 15.10.2020 and 16 proposals submitted by States/UTs are still under evaluation till 08.07.2021 when this reply was furnished to the Committee. That means evaluation process has not completed even after the lapse of nine months. **The Committee feel that the Department should chalk out a time frame for completing the exercise of evaluation instead of lingering on indefinitely. This scheme is very crucial to**

make our country self reliant and major manufacturing hub of medical devices. The Committee, therefore, strongly reiterate the earlier recommendation that the Department should take earnest steps for granting expeditious approvals to the eligible proposals under the Scheme during 2021-22 and financial assistance should also be provided to them according to the Scheme guidelines in a time bound manner The progress made in this regard should be furnished to the Committee in the Final Action Taken Replies by the Department.

Recommendation No-9

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

1.18 While stressing on the need to ensure sustainability of PMBJP outlets the Committee had recommended as under:-

> "The Committee note that Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals in the year 2008 with an objective of making quality generic medicines available at affordable prices to all especially for the poor and the deprived ones. Under this scheme, dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJK) are opened all over the country to provide generic medicines to the masses. The Scheme has been approved for continuation with the financial outlay of Rs. 490 crore for the period 2020-2021 to 2024-2025. The Committee note that PMBJP is designed to function on a self-financing model like a business. Budgetary support is provided to the Scheme mainly for promotion and for providing incentives to the entrepreneurs. An amount of Rs.65 Crore has been allocated at BE stage for 2021-22 against the proposal of the Department for Rs.80 Crore. In regard to the better implementation of the Scheme, the Committee recommend the following:-
>
> i. Although a total of 7259 PMBJP kendras have been opened as on 31 January, 2021 and all the districts in the country have been covered, the Department should take necessary steps for opening PMBJP kendras in every block at each district in the country.
>
> ii. Presently three warehouses are functioning at Gurgoan, Chennai and Guwahati. Fourth warehouse is under construction in Surat. The Department should consider opening a few more warehouses particularly in those regions of the country where there is no PMBJP warehouse.
>
> iii. Requisite number of distributors should be appointed in each State according to the size and number of PMBJP Kendras of the State.

iv. Entrepreneurs who set up kendras under the Scheme should be provided more incentives and the budgetary allocation in this regard may be increased for successful running of the Scheme

v. Awareness Programmes about the features of the Scheme should be increased and should aimed at reaching poor people including those living in slums and other economically deprived areas. Budgetary allocation in this regard may be increased commensurately.

vi. Marketing Officers who is responsible for smooth implementation of the Scheme at State and district levels should be appointed in each State/Union Territory and effective steps should be taken for monitoring the functioning of each and every BMBJP Kendra at district level.

vii. The Government/Department should forgo the self financing model for opening Janaushadhi Kendras in North East, hilly and island areas of the country. Instead the Department should open government funded JanaushadhiKendras in North East states, hilly areas and island territory and allot them to Women, Divyang, SC, ST."

Reply of the Government

1. 19 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"(i) The Department has taken various steps, which is as under:-

1. Bureau of Pharma PSUs of India (BPPI) has already placed notice on its website and print media for inviting attention of applicants for applying for PMBJK in uncovered blocks of the country on priority basis.

2. Preference is being given to applicants applying for PMBJK in uncovered block.

3. Special incentive of Rs. 2.00 lakhs in addition to the normal incentives shall be granted for PMBJK opened by the Women entrepreneurs, divyaang, SC, ST & any entrepreneurs open PMBJK at aspirational districts (backward district) as notified by the NITI Aayog& in Himalayan, Island territories and North- Eastern state as per the new incentive plan for furthering the interest of applicants.

(ii) As of now, PMBJP have three warehouses at Gurugram, Chennai and Guwahati which are strategically located at northern, southern and eastern part of the country, respectively. The fourth warehouse at Surat is under construction which shall be catering to the western part of the country. Thus, with the functioning of all the four warehouses at northern, eastern, southern and western parts of the country along with the support network of suitable Distributors established across the country in most of the States/UTs, warehousing and logistics is expected to cater to the requisite need. However,

warehousing and logistics facilities can be scaled up on the basis of demand and requirement.

(iii) As of now, 37 Distributors has been appointed in most of the States/UTs across the country. Notice inviting expression of interest for appointment of Distributor for anticipated location(s) is under process. However, appointment of more Distributor can be scaled up on the basis of demand and requirement.

(iv) As per the revised incentive plan, PMBJK run by entrepreneurs/Pharmacist/NGOs/NGOs & Charitable organization that are linked with BPPI headquarters through software will get incentive up to Rs. 5.00 lakhs. The incentive will be given @ 15% of monthly purchase made from BPPI by these PMBJKs subject to ceiling of Rs 15,000/- per month up to total limit of 5.00 lakhs. It will also cover PMBJK opened by Women entrepreneurs, Divyang, SC, ST & any entrepreneurs open 'PradhanMantriBhartiyaJanaushadhi Kendra (PMBJK)' at aspirational districts as notified by the NITI Aayog, In Himalayan, Island territories and North- Eastern state.

This will be applicable to existing PMBJK also whose existing limit of incentives of Rs 2.50 lakh is fully disbursed, moreover it will also cover the PMBJK opened in government premises to whom one-time grant of Rs 2.50 lakh was disbursed. They will get incentive of Rs 2.50 lakh based on purchase made by them from BPPI as per other terms and conditions applicable to all PMBJKs.

In addition to this, special incentive amount of Rs. 2.00 lakhs shall be granted for PMBJK opened by the Women entrepreneurs, divyaang, SC, ST & any entrepreneurs opening PMBJK at aspirational districts (backward district) as notified by the NITI Aayog& in Himalayan, Island territories and North- Eastern state.

(v) Government is spreading awareness about the salient features of PMBJP including Janaushadhi Suvidha Oxo-Biodegradable Sanitary Napkin through various types of advertisements such Print Media, Radio advertisement, TV advertisement, Cinema Advertisements and Outdoor publicity like Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping, etc. In addition to this, BPPI 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.

(vi) As of now, BPPI is having a total of 36 on roll field staffs consisting of Jr. Marketing Officer, Marketing Officer, Sr. Marketing Officer, Assistant Manager, Deputy Manager, Area Manager and Zonal Manager in a well-defined hierarchy of command and control for the smooth implementation of the Scheme in the States/UTs. At least one field staff is present in most of the States/UTs, baring a few north eastern states and UTs. However, the north eastern states and UTs where field staffs are not deployed, implementation and monitoring of the scheme is done by field staff of the adjacent States/UTs. Even, 2 to 3 field staffs are deployed in some States/UTs depending on need and Marketing & Sales prospects of the State/UT.

Moreover, Information Technology (IT) enabled End-to-End supply chain system with Point-of-Sale (POS) application for value added services has been implemented in PMBJP. To ensure the efficient management and operation of the PMBJK, and the reporting of data and information to BPPI, a computerized point of sale system (the "POS System") consisting of all sales transactions those are fed & updated in the system including placement of online orders/ indents, outstanding amount, etc. are in place. Technical training for running the POS system and trouble-shooting are also managed and assisted by BPPI by means of installation of software and technical guidance. The basic know-how and training videos are made available to the user remotely for ease of access and ready reference.

(vii) As per the revised incentive plan, PMBJK run by entrepreneurs/Pharmacist/NGOs/NGOs & Charitable organization that are linked with BPPI headquarters through software will get incentive up to Rs. 5.00 lakhs. The incentive will be given @ 15% of monthly purchase made from BPPI by these PMBJKs subject to ceiling of Rs 15,000/- per month up to total limit of 5.00 lakhs. It will also cover PMBJK opened by Women entrepreneurs,Divyang, SC, ST & any entrepreneurs open PMBJK at aspirational districts as notified by the NITI Aayog, In Himalayan, Island territories and North- Eastern state.

This will be applicable to existing PMBJK also whose existing limit of incentives of Rs 2.50 lakh is fully disbursed, moreover it will also cover the PMBJK opened in government premises to Whom one-time grant of Rs 2.50 lakh was disbursed. They will get incentive of Rs 2.50 lakh based on purchase made by them from BPPI as per other terms and conditions applicable to all PMBJKs.

In addition to this, special incentive amount of Rs. 2.00 lakhs shall be granted for PMBJK opened by the Women entrepreneurs, divyaang, SC, ST & any entrepreneurs opening PMBJK at aspirational districts (backward district) as notified by the NITI Aayog& in Himalayan, Island territories and North- Eastern state."

Further Comments of the Committee

1.20 The Committee note that Pharmaceuticals and Medeical Devices Bureau of India (PMBI) has invited applications in its website and print media for PMBJP outlets in uncovered blocks of the country on priority basis. The Committee also note the assurance of the Department to scale up the opening of more warehouses and appointment of more distributors can be scaled up on the basis of demand and requirement. **The Committee hope that the Department will review and**

take all the necessary steps on continuous basis on these matters particularly on opening more outlets at block level. The progress made in this regard may be furnished to the Committee.

1.21 The Committee note the various measures taken by PMBI for creating awareness among people about the Scheme but the Committee are of the view that these awareness programmes are either inadequate or not planned properly for the reach of the targeted population. **Since most of the people belong to lower middle class, poor and down trodden sections of the society are still unaware of the availability of quality medicines and medical devices at affordable prices under the Scheme, the Committee would like to reiterate the earlier recommendatation that awareness Programmes about the features of the Scheme should be increased and should aimed at reaching poor people including those living in slums and other economically deprived areas. Budgetary allocation in this regard may also be increased commensurately.**

1.22 The Committee further note that PMBI is implementing a revised incentive plan for all PMBJKs including those run by women entrepreneurs, divyang, SC, ST and also for PMBJKs opened at aspirational districts, Himalayan, Island territories and North- Eastern states. In this regard, **the Committee recommend that the Department and PMBI may analyse the improvements made in implementation of the Scheme particularly in attracting more entrepreneurs after the upward revision of incentives under the Scheme and based on the outcome of the analysis further steps may be taken for increasing incentives under the Scheme so as to attract more entrepreneurs.**

In case of continued failure to attract the entrepreneurs, the Department and PMBI may consider opening of government funded Janaushadhi Kendras in North East states, hilly areas and island territories in place of self financing model.

1.23 The Committee also note that 36 field officers have been deployed in the states for smooth implementation of the scheme. The Committee also note that at least one field staff is present in most of the States/UTs, baring a few north eastern states and UTs. However, the north eastern states and UTs where field staffs are not deployed, implementation and monitoring of the scheme is done by field staff of the adjacent States/UTs. **Since the requisite number of field officers are necessary for smooth implementation of the Scheme in every state, the Committee recommend that a review may be made by PMBI on the requirement of number of field officers in every State/UT and appropriate steps may be taken to increase the number of field officers in each State/UT. Atleast one field officer may be posted in each of North East States/UTs for smooth implementation of the Scheme in those States/UTs.**

Recommendation No-10

National Pharmaceutical Pricing Authority (NPPA)

1.24 While analyzing the role of National Pharmaceutical Pricing Authority (NPPA), the Committee had recommended as under:

> " The Committee note that the National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals is entrusted with the responsibilities of fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. However, the Committee are concerned to note that NPPA fixes ceiling prices of only scheduled formulations which constitutes only about 17.2 per cent of the total formulations. The rest of 82.8 per cent of medicines are in the non-scheduled

segment and the NPPA does not fixes ceiling price of those medicines/drugs. However, their price increase is permitted only up to 10 per cent of MRP per annum. So, there is a limitation of regulatory powers of NPPA in fixing and monitoring of prices of non-scheduled drug formulations. Since the expenditure on medicines constitutes more than 50 per cent of expenditure on health, it is very much affecting poor families who struggle to cope with the high cost of medicines for treatment of any disease. The Committee feel that there is immediate need to increase the percentage of regulation of medicines from 17.2 percent to at least 50 percent within a year by incorporating suitable policy changes in this regard. Moreover, the Committee also feel that there is a need to regulate the prices of medicines charged by private hospitals from the patients as a part of the overall treatment charges. In view of the above, the Committee recommend the following:-

i. There is a need for introducing policy changes in the National Pharmaceutical Pricing Policy, 2012 and Drug Price Control Order (DPCO) wherein NPPA should be given autonomy to regulate the base prices of at least 50 percent of all drugs sold in the domestic market, to expand NPPA price regulation function in an effective way beyond the scheduled drugs mentioned in the National List of Essential Medicine (NLEM);

ii. Apart from fixing the prices of scheduled drugs, NPPA should also fix the ceiling prices of all non-scheduled drug formulations which are prescribed more often by medical practitioners for treating many of the common ailments;

iii. Department of Pharmaceuticals and NPPA should examine critically whether it is necessary to permit 10% increase of MRP of non-scheduled drugs per annum particularly when the prices of raw materials, etc does not increase and appropriate steps should be initiated on the basis of outcome of the such critical examination;

iv. Also examine the rationalization of fixation of Maximum Retail Price (MRP), as MRP itself is fixed on the higher side and subsequent 10 percent increase in price per annum makes the cost of drugs unaffordable for the common people; and

v. Department of Pharmaceuticals and NPPA should also examine the issues pertaining to high prices of medicines charged by private hospitals."

Reply of the Government

1.25 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"(i) & (ii) - The objective of the National Pharmaceuticals Pricing Policy (NPPP), 2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – 'essential medicines' – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well-being for all. The key principles for regulation of prices in

the National Pharmaceuticals Pricing Policy 2012 are (i) Essentiality of Drugs, (ii) Control of Formulations prices only, and (iii) Market Based Pricing.

The current Drugs (Prices Control) Order (DPCO), 2013 is based on NPPP, 2012. National Pharmaceutical Pricing Authority (NPPA) gets its mandate from the DPCO. NPPA fixes the ceiling price of scheduled medicines specified in the Schedule-I (Schedule I of DPCO is the National List of Essential Medicines which is notified by Ministry of Health and Family Welfare from time to time) of the DPCO, 2013 in accordance with the provisions of the DPCO. All manufactures of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. A manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation branded or generic launched by it. However, as per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum as per Para 20 of the DPCO, 2013. So far as regulation of drugs used for common ailments prescribed by the medical practitioners are concerned, it is stated that all the essential drugs are included in the NLEM by the Committee of experts under MHFW from time to time. In addition to above, Para 19 of DPCO, 2013 empowers the Government "*to fix ceiling price of any drug in extraordinary circumstances, if it considers necessary so to do in public interest for such period as it may deem fit"*.

The recommendation of the Committee for introducing policy changes in the National Pharmaceutical Pricing Policy, 2012 and Drug Price Control Order (DPCO) have been noted.

(iii) & (iv) - DPCO, 2013 is framed as per the principles laid down in the NPPP, 2012. The policy marked a shift to market-based pricing based on one of the principles enunciated in NPPP, 2012. Thus, DPCO, 2013 does not consider the aspect of cost while fixing the ceiling price of scheduled formulations.

(v) As per the provisions of the DPCO, no manufacturer can sell a scheduled or non-scheduled formulation at a price more than the MRP. If any complaint regarding overcharging by hospital(s) is received, NPPA initiates action in case of violations against the manufacturers as per the provisions of DPCO, 2013."

Further Comments of the Committee

1.26 The Committee note that the Department has shown positive intent to make policy changes in the National Pharmaceutical Policy 2012 and Drugs Price Control Order 2013 with respect to the recommendation of the Committee that NPPA should be given autonomy to regulate the base prices of at least 50 percent of all drugs sold in the

domestic market and to expand NPPA price regulation function in an effective way beyond the scheduled drugs mentioned in the National List of Essential Medicine (NLEM). Merely noting the recommendation is not adequate. **The Committee hope that prompt action would be taken by the Department in this regard. The Committee would like to know the progress made in this regard in the final action taken replies.**

1.27 The Committee are not satisfied with the reply given by the Department to the recommendation of the Committee that it alongwith NPPA should examine critically the necessity of permitting 10% increase of MRP of non-scheduled drugs per annum particularly when the price of raw materials, etc does not increase. The reply given by the Department that DPCO, 2013 does not consider the aspect of cost while fixing the ceiling price of scheduled formulations as the policy marked a shift to market-based pricing based on one of the principles enunciated in National Pharmaceutical Pricing Policy, 2012 is not acceptable to the Committee**. Any pricing policy cannot be against the interest of common man. Leaving everything to the market forces would defeat the goals of a welfare state. Since the blanket permission to increase the price of non scheduled drugs upto 10 % even when the price of raw materials does not increase is an unjustified provision which may result in increased spending on medicines by the people of the country and may pinch their pockets, the Committee reiterate the earlier recommendation and hope that the recommendation be examined in proper prospective for the benefit of the common man. Action taken reply in this regard may be furnished to the Committee**

Recommendation No-14

Disinvestment of Public Sector Undertakings (PSUs)

1.28 While stressing on the need to reconsider the Disinvestment of profit making PSUs of the Committee had recommended had stated as under:-

"The Committee note there are five Public Sector Undertakings (PSUs) under the aegis of the Department of Pharmaceuticals. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL) and Hindustan Antibiotics Limited (HAL) are presently functional. While the first two are profit making, the third one is sick. Indian Drugs & Pharmaceuticals Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL) are under closure. In 2016, The Government of India decided for strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru, strategic sale of BCPL and closure of HAL. At that point of time, both BCPL and HAL were loss making but BCPL has turned into profit making PSU as it was able to reduce procurement cost substantially, financial leakages, etc. due to concrete steps taken such as centralization of Procurement System, Accounting System and HRM Record Maintenance System. On Similar lines, HAL has been able to improve sales turnovers over the last few years, though still making losses with a number of initiatives taken, such as downsizing manpower through VRS scheme, product diversification and cost cutting measures. In the aftermath of COVID 19 pandemic, Minister of Chemicals and Fertilizers had requested NITI Aayog to reconsider the decision of disinvestment of KAPL including Hindustan Antibiotics Limited (HAL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL). The Department is following up this matter with NITI Aayog for reconsideration of disinvestment/ feasibility of merger through in-depth examination by the Aayog itself or by awarding a comprehensive study to an independent agency on priority. Even though there is a strong private pharmaceutical industry, the Committee are of the firm view that it is very much necessary to retain functional public sector pharmaceutical units as the coexistence of both the public and private sector pharmaceutical industry is beneficial to the country particularly to make available quality medicines at affordable prices to all sections of the society including poor and needy. Moreover, the Government is committed to provide drug security at affordable cost for the people of the country. This can be ensured only with the strengthening of Pharmaceutical PSUs because private sector is driven by profit motive and market demand sentiment which does not cater to the needs of the lower middle class, poor and down trodden people for the availability of quality drugs at affordable prices. Keeping in view the wellbeing of the common people the, Committee, therefore, strongly recommend the following:-

i. The proposal of strategic disinvestment of KAPL, which is a profit making mini ratna PSU, should be dropped.

ii. The proposal of strategic sale of BCPL which has emerged as a profit making PSU should also be dropped.

iii. The proposal for closure of HAL should also be dropped and corrective measures should be taken to make it profit making on the lines of BCPL.

iv. Rather than disinvestment/sale, the Government should consider various measures for successful/profitable running of PSUs including reforms at administrative/ management level like professionalization of Board of Pharma PSUs, promotion of Corporate Governance practices etc. to safeguard the interest of the common people who are dependent on affordable and quality medicines produced by Pharmaceutical PSUs."

Reply of the Government

1.29 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated that as under:-

" The Union Cabinet had decided on 28.12.2016 to strategically disinvest HAL & BCPL. Separately the CCEA on 01.11.2017 had decided to strategically disinvest 100% of Central Govt. equity in KAPL based on the Cabinet note moved by DIPAM.

Being a Policy decision, earlier Hon'ble Minister (C&F) vide D.O. dated 03.07.2020 and 23.12.2020 has requested to Vice Chairman, NITI Aayog for reconsideration of the decision of disinvestment of three pharma PSUs namely KAPL, BCPL & HAL. Further, Secretary (P) vide D.O. dated 29.07.2020, 26.10.2020, and 27.11.2020 has requested to CEO, NITI Aayog to get the feasibility to merger of the pharma PSUs under disinvestment and examined in depth either by the Aayog itself or by awarding a comprehensive study to an independent agency on priority. However, reply is still awaited."

Further Comments of the Committee

1.30 The Committee note that the reply of NITI Aayog with respect to reconsideration of the decision of strategic disinvestment/ strategic sale/ closure of three Pharma PSUs namely KAPL, BCPL & HAL respectively is still awaited. **In this regard, the Committee are of the strong view that manufacturing of medicines/medical**

devices should be considered as a strategic sector as it involves drug security of the country. Leaving entire drug manufacturing at the hands of private sector may not be a prudent step as the prime motive of private sector is profit making. Hence, it is necessary that profit making and functioning pharma PSUs be encouraged to function in a healthy atmosphere. **The Committee, therefore, reiterate the earlier recommendation that the decision on the strategic sale/ disinvestment of profit making PSUs viz. KAPL and BCPL should be dropped and the proposal for closure of HAL should also be dropped and corrective measures should be taken to make it profit making on the lines of BCPL.** The Committee also feel that rather than disinvestment of profit making PSUs, Government should provide enabling environment and bring about required administrative and management reforms at higher decision making levels so that sound business practices and professional management techniques, processes and behavioural changes are inculcated to profitably manage these assets of the Government, which have been playing very important role of providing affordable and quality medicines for the people of the country who cannot afford the costly branded medicines sold in the market. **The Department of Pharmaceuticals should send this recommendation to NITI Ayog and it should furnish its specific reply to the Department of Pharmaceuticals for the submission of the same to the Committee within three months.**

CHAPTER II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendation No.1

Need for Enhanced Budgetary Allocation

2.1 The Committee note that the Department of Pharmaceuticals has vision to promote Indian pharmaceutical sector as the global leader for quality medicines and to ensure availability, accessibility and affordability of drugs and medical devices in the country. However, the Committee are dismayed to note that the Gross Budgetary allocation for the year 2021-22 is Rs. 470.41 Crore against the proposed outlay of Rs.2600.52 Crore which is only one sixth of the outlay proposed by the Department. Out of Rs 470.41 Crore allocated to the Department, Rs. 31.53 Crore is towards the administrative expenditures for both the Department of Pharmaceuticals and National Pharmaceuticals Pricing Authority (NPPA) against proposed Budget Estimate of Rs. 35.98 Crore. Budgetary allocation for Central Sector Schemes is Rs. 429.76 Crore against proposed Budget Estimates of Rs.2564.48 Crore. According to the Department of Pharmaceuticals, total funds allocated will fall short of the urgent fund requirements projected by the Department for carrying out its laid down mandate and will adversely affect the central sector schemes being implemented by the Department viz. Development of Pharmaceuticals Industry and National Institutes of Pharmaceuticals Education and Research (NIPER). In this regard, the Committee note that the Department has been allocated Rs. 234.34 crore against its requirement of Rs. 1220 crore for NIPERs and only Rs. 124.42 crore against the proposal of the Department of Pharmaceuticals for a budgetary allocation of Rs. 1256.16 core for the implementation of important umbrella scheme of the Department for the development of Pharmaceuticals industry during 2021-22. Going by the pace at which this umbrella scheme with important sub schemes for the holistic development of the Pharmaceutical Industry is being implemented by the Department, it is not surprising to the committee that the Ministry of Finance has curtailed the allocation drastically. Since it is very much essential to develop state of the art common facilities, to provide funds for technology upgradation, to offer production linked incentives etc to the pharma industry including bulk drug and medical devices industries, the committee strongly recommend that the Department should take serious and concrete efforts for the implementation of all the sub schemes of the umbrella scheme in a time bound manner particularly to examine the proposals under various sub schemes expeditiously and to accord approval in a time bound manner so as to enable the Ministry of Finance allocate the requisite amount of funds for the implementation of various sub schemes under the umbrella scheme. It is also necessary to make realistic budgetary proposals on actual need basis. As far as fund allocation to NIPERs is concerned, the Committee take a serious view of non-allocation of requisite amount of funds by the Ministry of Finance for the infrastructural development of NIPERS even after a decade of their existence due to which these institutes are unable to attain their full potential. Since the subject matter pertaining to the Department of Pharmaceuticals is concerned with the drug security of

the country, the Committee urge upon the Ministry of Finance to examine the budget proposals of the Department of Pharmaceuticals very carefully and the make adequate allocation of funds for the implementation of various Schemes and programmes of the Department. Since the allocation made at BE is very less to cope the fund requirements of various schemes which are at the advanced stages of proposal approval and fund release, the Department of Pharmaceuticals should prepare fresh proposals for fund release at RE stage of 2021-22 and the same should be submitted to Ministry of Finance for the allocation of necessary funds at RE stage. A copy of this recommendation may also be sent to Ministry of Finance for its compliance.

Reply of the Government

2.2 Department has taken a matter with Department of Expenditure through EFC memos seeking the adequate funds for implementation of the ongoing schemes of Department. It is expected that the meeting of Expenditure Finance Committee (EFC) will be held shortly under the chairmanship of Secretary (Expenditure). Department will send the recommendation of committee to the Department of Expenditure as suggested.

Comments of the Committee

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

Recommendation No.3

Assistance to Pharmaceuticals Industry for common facilitation centre

2.3 The Committee are concerned to note the very slow progress is being made under the sub scheme of "Assistance to Pharmaceuticals Industry for common Facilitation center". This sub scheme earlier known as cluster Development has been rechristened after a dint of unsuccessful implementation. Grant-in-aid of Rs. 20 crore per cluster or 70% of the cost of the project whichever is less is granted under this sub scheme. During 2019-20, only Rs. 2.23 crore was spent on this scheme. During 2020-21, Rs, 12 crore allocated at BE stage was reduced to Rs. 7.23 crore at RE stage due to the inability of the Department to spend but the actual utilization was only Rs. 22 lakh. Under the sub scheme, one proposal from Chennai has already been approved. During 2020-21, there new proposals have been given in-principle approval in the months of September and October, 2020 but the same are under examination of PMC and as a result, no funds have so far been utilized under this sub-scheme. Such a slow approach on the part of the Department has resulted in on-paper existence of sub schemes under the umbrella scheme. While deprecating such lackadaisical approach of the Department towards this important scheme, the committee strongly recommend to expedite the process of final approval of the projects so as to demand the funds required from the Ministry of Finance at RE stage. Progress made in this regard should be intimated to the Committee.

Reply of the Government

2.4 The Scheme Steering Committee (SSC) of Assistance to Pharmaceutical Industry for Common Facilities (API-CF) in its meeting held on 26.3.2021 has accorded final approval to two projects viz: (i) Inducare Pharmaceuticals and Research Foundation (IPRF), Pune, Maharashtra for creation of Common Testing Facility, Research & Development with Pilot Plant and Common Logistic Centre. Total cost of the project is Rs 31,43,75,174/-. The eligible grant in aid is Rs. 20.00 crore. (ii) Kala Amb Infrastructure Development Company (KIDC), Kala Amb, Himachal Pradesh to set up a Common Effluent Treatment Plant (CETP). The total cost of the project is Rs 7,19,69,000/-. The eligible grant in aid is Rs 5,03,78,300/-.

The Department has also released first installment of Rs 5,48,97,816/- to IPRF and Rs.1,51,13,490/- to KIDC on 30.3.2021. Thus Department has completely utilized RE 2021-21. Details given below:

(Rs. in crore)

Head	BE 2020-21	RE 2020-21	Expenditure as on 31.3.2021
GIA-General	11.99	7.22	7.22
GIA-Capital	0.01	0.01	00

Recommendation No.4

Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)

2.5 The Committee are dismayed to note that the important sub scheme of Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) remains a non-starter since its approval in 2016. Only a token allocation of Rs. 1 lakh was provided for the sub scheme for the financial years 2019-20 and 2020-21. Even though the Department had demanded Rs. 185 crore for the sub scheme, again only a token allocation of Rs. 1 lakh has been made by the Ministry of Finance for 2020-21. This clearly shows the lack of faith in Department's credentials to implement this important scheme which aims to facilitate small and medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to WHO GMP standards so as to enable them to participate and compete in global markets. As per the sub scheme, assistance in the form of interest subvention against the sanctioned loan by any scheduled commercial bank/financial institution, both in public and private sector will be provided to 900 Pharma SMEs of proven track record. The scheme is to be implemented by a Public Sector Financial Institution (PSFI). But everything remains on paper without any concrete action to implement the scheme. Non receipt of applications for financial assistance was the reason given by the Department for the non-moving of the scheme ahead. In this regard, the recommendations made in third party evaluation viz. need for enough brain storming to set one liner objective for the Scheme, need for implementation with liberal terms and conditions and opening of the scheme to MSME sector instead of SME sector are worth for consideration. It is a matter of serious concern that the Department could not appoint Public sector Financial Institution (PSFI) during the last 4 years of implementation of the scheme. Since it is very much necessary to raise the standards of Pharma production units to that of WHO GMP

standards in order to medicines/drugs of highest standards to the people of the country and also for the export purpose, the Committee strongly recommend that the Department should take prompt steps for the early Expenditure Finance Committee approval of the scheme for implementation of the sub scheme from 2021-22 to 2025-26. PSFI should be appointed immediately after the EFC approval and prompt steps should be taken for the successful implementation the schemes from 2021-22 onwards. The Progress made in this regard should be intimated to this committee within 3 months.

Reply of the Government

2.6 The EFC Note has already been sent to Department of Expenditure. Further recommendations are noted for compliance.

Recommendation No.5

Promotion of Medical Devices Parks

2.7 The Committee are constrained to note that another sub-scheme named "Assistance to Medical Device Industry for Common Facility Centre" was also not properly implemented by the Department and the same has been revised by the Union Cabinet During 2020-21. The sub-scheme has been renamed as "Promotion of Medical Devices Parks" with a total financial outlay of Rs. 400 crore. The objective of the sub-scheme is creation of world class infrastructure facilities in order to make Indian medical device industry a global leader. The tenure of the scheme is from 2020-2021 to 2024-2025. Maximum assistance under the scheme for one Medical Device Park would be limited to ₹ 100 crore. Under this Scheme an allocation of Rs.7.50 crore was made at BE stage of 2020-21 and the same was increased to Rs. 21.05 crore but the Department is able to spend only Rs 7.49 crore so far. In this background, the Department had demanded Rs.120 crore for the implementation of the Scheme during 2021-22 but the Ministry of Finance has allocated only Rs.60 crore at BE stage. The Committee note that in-principle approvals were given to the proposals received from Andhra Pradesh, Kerala, Tamil Nadu and Telangana. Subsequently the proposal of Andhra Pradesh was first taken up. After revision of the scheme by the Union Cabinet, the guidelines of the revised scheme were issued on 27.07.2020. After the revision of the scheme, 16 proposals have been received in accordance with the revised guidelines of the scheme. All the proposals are being evaluated for giving in-principle approval. Taking into consideration the importance of common laboratory and testing facilities in reducing the production cost of medical devices, the Committee recommend that the Department should take earnest steps for granting expeditious approvals to the eligible proposals under the Scheme during 2021-22 and financial assistance should also be provided to them according to the Scheme guidelines in a time bound manner. In case of necessity of further funds for the implementation of the Scheme during 2021-22, concrete proposals for allocation of the same at RE stage should be made to the Ministry of Finance. The Committee hope that the Department would act fast in coordination with State Implementing Agency (SIA), would expedite the approval procedures and disburse the funds allocated at BE 2021-22, so as to enable the

Ministry of Finance consider favourably the allocation of further funds at RE stage. The progress made in this regard may be intimated to the Committee.

Reply of the Government

2.8 Under the sub-scheme as "Assistance to Medical Device Industry for Common Facility Center", the Department has given approval for financial assistance of Rs. 25 crore to the project of Andhra Pradesh Medtech Zone Ltd (AMTZ), Andhra Pradesh for development of Common Facility Center for superconducting magnetic coils testing and research facility. A Budgetary allocation of Rs. 7.50 crore was allocated under the scheme in Budget Estimates 2020-21. The Department has released 1st installment of Rs. 7.49 crore for the project to AMTZ on 11.9.2020. The budget allocation was increased to Rs. 21.05 crore in Revised Estimates but no re-appropriation order was issued to enable this Section to release the fund. Hence, the actual allocation was of Rs. 7.50 crore.

The sub scheme has been revised and renamed as "Promotion of Medical Device Parks". The guidelines of the scheme have been issued on 27.7.2020. The scheme is under implementation. A budgetary allocation of Rs. 60 crore has been allocated for the FY 2021-22. The application window of the scheme was closed on 15.10.2020. A total number of 16 States/UTs have submitted their proposal under the scheme which are under evaluation.

Comments of the Committee

(Please see Para No. 1.15 of Chapter - I of the Report)

Recommendation No.6

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

2.9 The Committee note that under the Umbrella Scheme of "Development of Pharmaceuticals Industry", a new sub-scheme "Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device" has been approved by the Union Cabinet in its meeting dated 20.3.2020 with a total outlay of Rs. 3420 Crore. However, only Rs.2.00 Crore was sought under the first batch of Supplementary Demands for Grants 2020-21 from Ministry of Finance for implementation of the sub-scheme during the year and only an allocation of Rs. 2.36 Crore has been made at BE stage for 2021-22. In regard to the reasons for less allocation of fund for the sub-scheme, the Committee note that as per scheme guidelines, the incentive to the applicants under four target segments will be applicable from 2022-23 onwards only and as such the funds for disbursal of incentives to selected applicants are not required. Accordingly, the fee of Project Management Agency (PMA) will only be paid during 2020-21 and 2021-22. The Committee further

note that 28 applications for four Target Segments of the Scheme were received and out of them nine applications have been approved till 15th February, 2021. As the country is largely dependent on imports for meeting its medical devices requirements, the Committee recommend that due attention should be paid by the Department for the timely implementation of this sub-scheme in letter and spirit. The progress made in this regard may be intimated to the Committee.

Reply of Government

2.10 All the 28 applications received have been processed and 14 applications with committed investment of Rs. 873.93 crore have been approved under the scheme. The commercial production is projected to commence from 1st April, 2022 onwards. The disbursal of production linked incentive by the Government over the five years period would be up to a maximum of about Rs. 1,694 crore.

Recommendation No.7

Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country

2.11 The Committee note that a new sub scheme "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country" has been approved by the Union Cabinet in its meeting held on 20.3.2020 with a total outlay of Rs. 6940 Crore under Umbrella Scheme of "Development of Pharmaceuticals Industry". However, only Rs. 1.55 crore was sought for this sub-scheme under 1st batch of Supplementary Demand for Grants 2020-21 from Ministry of Finance. Moreover, only a token allocation of Rs. 2.79 crore has been made at BE stage for 2021-22 for this Scheme. According to the Department of Pharmaceuticals, as per scheme guidelines of PLI scheme for Bulk Drugs, the gestation period for fermentation-based products is up to 2022-23 and up to 2021-22 for chemical synthesis-based products. As such, funds for disbursal of incentives to selected applicants are not required. Accordingly, the fee of Project Management Agency (PMA) will only be paid during 2020-21 and 2021-22. The Committee note that a total 215 applications have been received for the four Target Segments of the PLI scheme for Bulk Drugs. Out of it only five applications have been approved till 15th February, 2021 by the Empowered Committee under the chairmanship of CEO, NITI Aayog. In this regard, the Committee feel that outrightly rejecting vast majority of applications may not be conducive for the development of a strong bulk drug industry in the country. The Committee, therefore, recommend that the prospective entrepreneurs, who are eager to set up API/bulk drug/KSMs industry in the country, whose applications have been rejected may be given a chance to resubmit their applications after fulfilling the requirements of Scheme guidelines so as to encourage setting up of required number of bulk drug manufacturing units in the country. The Committee also recommend that the Department should act swiftly for the effective and total implementation of this vital scheme aimed at

safeguarding drug security of the country. The Committee should be apprised of the progress made in implementation of the Scheme.

Reply of Government

2.12 All the 215 applications received have been processed and a total of 47 applications (excluding 2 successful applications withdrawn subsequently) with committed investment of Rs. 5366.35 crore have been approved by the Government. The commercial production of these plants is projected to commence from 1st April, 2023 onwards. The disbursal of production linked incentive by the Government over the six years period would be up to a maximum of about Rs. 6,000 crore.

Recommendation No.8

Assistance to Bulk Drug Industry for Common Facilitation Center

2.13 The Committee are also constrained to note the on paper existence of another sub scheme "Assistance to Bulk Drug Industry for Common Facilitation Center" under the umbrella scheme of "Development of Pharmaceutical Industry". The sub scheme has now been renamed as "Promotion of Bulk Drug Parks". The guidelines of the sub-scheme were released on 27.07.2020. Only a token allocation of Rs.2.00 lakh was made for the Scheme during 2019-20. Rs. 21.52 crore was allocated at BE stage of 2020-21 which got reduced to only Rs. 1.69 crore at RE stage but no expenditure has so far been made under the Scheme during 2020-21. In this backdrop, the Department had sought Rs.900.00 crore for the implementation of the Scheme during 2021-22 but the Ministry of Finance has allocated only Rs.36.24 crore at BE stage. In this regard, Department of Pharmaceuticals clarified that a total number of 13 proposals have been received which are under evaluation. The Department will soon accord 'in-principle' approval to three States/UTs under the scheme. Those three States/UTs will submit a detailed project report within 180 days of date of issuance of in-principle approval letter. As per scheme guidelines, the Department has to release first installment of 30% of the total financial assistance of Rs. 1000 crore at the time of final approval of the project by the Scheme Steering Committee. Since the final approval may be accorded during 2021-22, there will be need of Rs. 900 crore (Rs. 300 crore each for 3 parks). As there is an urgent need to create a very strong bulk drug industry in the country to meet the bulk drugs requirements of the country, the Committee recommend that definite time limits may be set for issuing in-principle and final approvals by the Department of Pharmaceuticals. Moreover, the concerned States may be requested to submit the detailed project reports within three months (90 days) rather than six months (180 days) so as to facilitate early implementation of the Scheme. Department of Pharmaceuticals should initiate prompt steps as recommended above for according final approvals to three parks well before projecting the requirement of Rs.900 Crore for RE 2021-22 allocation so as to enable the Ministry of Finance allocate the same at RE stage.

Reply of the Government

2.14 As per the guidelines of the Scheme, the Project Management Agency will evaluate the proposals received from States and give its recommendations to the Department. The recommendations will then be placed before the Scheme Steering Committee for considering in-principal approval to three (03) States. Thereafter, the Department will issue a letter of in-principle approval to the three (03) selected States. Proposals from 13 States have been received by the Project Management Agency which are under evaluation. All efforts will be made for expeditious implementation of the timelines.

Recommendation No.9

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

2.15 The Committee note that Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals in the year 2008 with an objective of making quality generic medicines available at affordable prices to all especially for the poor and the deprived ones. Under this scheme, dedicated outlets known as PradhanMantriBhartiyaJanaushadhiKendras (PMBJK) are opened all over the country to provide generic medicines to the masses. The Scheme has been approved for continuation with the financial outlay of Rs. 490 crore for the period 2020-2021 to 2024-2025. The Committee note that PMBJP is designed to function on a self-financing model like a business. Budgetary support is provided to the Scheme mainly for promotion and for providing incentives to the entrepreneurs. An amount of Rs.65 Crore has been allocated at BE stage for 2021-22 against the propososal of the Department for Rs.80 Crore. In regard to the better implementation of the Scheme, the Committee recommend the following:-

i. Although a total of 7259 PMBJP kendras have been opened as on 31 January, 2021 and all the districts in the country have been covered, the Department should take necessary steps for opening PMBJP kendras in every block at each district in the country.

ii. Presently three warehouses are functioning at Gurgoan, Chennai and Guwahati. Fourth warehouse is under construction in Surat. The Department should consider opening a few more warehouses particularly in those regions of the country where there is no PMBJP warehouse.

iii. Requisite number of distributors should be appointed in each State according to the size and number of PMBJP Kendras of the State.

iv. Entrepreneurs who set up kendras under the Scheme should be provided more incentives and the budgetary allocation in this regard may be increased for successful running of the Scheme

v. Awareness Programmes about the features of the Scheme should be increased and should aimed at reaching poor people including those living in slums and

other economically deprived areas. Budgetary allocation in this regard may be increased commensurately.

vi. Marketing Officers who is responsible for smooth implementation of the Scheme at State and district levels should be appointed in each State/Union Territory and effective steps should be taken for monitoring the functioning of each and every BMBJP Kendra at district level.

vii. The Government/Department should forgo the self financing model for opening Janaushadhi Kendras in North East, hilly and island areas of the country. Instead the Department should open government funded JanaushadhiKendras in North East states, hilly areas and island territory and allot them to Women, Divyang, SC, ST.

Reply of Government

2.16 (i) The Department has taken various steps, which is as under:-

1. Bureau of Pharma PSUs of India (BPPI) has already placed notice on its website and print media for inviting attention of applicants for applying for PMBJK in uncovered blocks of the country on priority basis.

2. Preference is being given to applicants applying for PMBJK in uncovered block.

3. Special incentive of Rs. 2.00 lakhs in addition to the normal incentives shall be granted for PMBJK opened by the Women entrepreneurs, divyaang, SC, ST & any entrepreneurs open PMBJK at aspirational districts (backward district) as notified by the NITI Aayog& in Himalayan, Island territories and North- Eastern state as per the new incentive plan for furthering the interest of applicants.

(ii) As of now, PMBJP have three warehouses at Gurugram, Chennai and Guwahati which are strategically located at northern, southern and eastern part of the country, respectively. The fourth warehouse at Surat is under construction which shall be catering to the western part of the country. Thus, with the functioning of all the four warehouses at northern, eastern, southern and western parts of the country along with the support network of suitable Distributors established across the country in most of the States/UTs, warehousing and logistics is expected to cater to the requisite need. However, warehousing and logistics facilities can be scaled up on the basis of demand and requirement.

(iii) As of now, 37 Distributors has been appointed in most of the States/UTs across the country. Notice inviting expression of interest for appointment of Distributor for anticipated location(s) is under process. However, appointment of more Distributor can be scaled up on the basis of demand and requirement.

(iv) As per the revised incentive plan, PMBJK run by entrepreneurs/Pharmacist/NGOs/NGOs & Charitable organization that are linked with BPPI headquarters through software will get incentive up to Rs. 5.00 lakhs. The incentive will be given @ 15% of monthly purchase made from BPPI by these PMBJKs subject to ceiling of Rs 15,000/- per month up to total limit of 5.00 lakhs. It

will also cover PMBJK opened by Women entrepreneurs, Divyang, SC, ST & any entrepreneurs open 'PradhanMantriBhartiyaJanaushadhi Kendra (PMBJK)' at aspirational districts as notified by the NITI Aayog, In Himalayan, Island territories and North- Eastern state.

This will be applicable to existing PMBJK also whose existing limit of incentives of Rs 2.50 lakh is fully disbursed, moreover it will also cover the PMBJK opened in government premises to Whom one-time grant of Rs 2.50 lakh was disbursed. They will get incentive of Rs 2.50 lakh based on purchase made by them from BPPI as per other terms and conditions applicable to all PMBJKs.

In addition to this, special incentive amount of Rs. 2.00 lakhs shall be granted for PMBJK opened by the Women entrepreneurs, divyaang, SC, ST & any entrepreneurs opening PMBJK at aspirational districts (backward district) as notified by the NITI Aayog& in Himalayan, Island territories and North- Eastern state.

(v) Government is spreading awareness about the salient features of PMBJP including Janaushadhi Suvidha Oxo-Biodegradable Sanitary Napkin through various types of advertisements such Print Media, Radio advertisement, TV advertisement, Cinema Advertisements and Outdoor publicity like Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping, etc. In addition to this, BPPI 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.

(vi) As of now, BPPI is having a total of 36 on roll field staffs consisting of Jr. Marketing Officer, Marketing Officer, Sr. Marketing Officer, Assistant Manager, Deputy Manager, Area Manager and Zonal Manager in a well-defined hierarchy of command and control for the smooth implementation of the Scheme in the States/UTs. At least one field staff is present in most of the States/UTs, baring a few north eastern states and UTs. However, the north eastern states and UTs where field staffs are not deployed, implementation and monitoring of the scheme is done by field staff of the adjacent States/UTs. Even, 2 to 3 field staffs are deployed in some States/UTs depending on need and Marketing & Sales prospects of the State/UT.

Moreover, Information Technology (IT) enabled End-to-End supply chain system with Point-of-Sale (POS) application for value added services has been implemented in PMBJP. To ensure the efficient management and operation of the PMBJK, and the reporting of data and information to BPPI, a computerized point of sale system (the "POS System") consisting of all sales transactions those are fed & updated in the system including placement of online orders/ indents, outstanding amount, etc. are in place. Technical training for running the POS system and trouble-shooting are also managed and assisted by BPPI by means of installation of software and technical guidance. The basic know-how and training videos are made available to the user remotely for ease of access and ready reference.

(vii) As per the revised incentive plan, PMBJK run by entrepreneurs/Pharmacist/NGOs/NGOs & Charitable organization that are linked with BPPI headquarters through software will get incentive up to Rs. 5.00 lakhs. The incentive will be given @ 15% of monthly purchase made from BPPI by these PMBJKs subject to ceiling of Rs 15,000/- per month up to total limit of 5.00 lakhs. It will also cover PMBJK opened by Women entrepreneurs,Divyang, SC, ST & any entrepreneurs open PMBJK at aspirational districts as notified by the NITI Aayog, In Himalayan, Island territories and North- Eastern state.

This will be applicable to existing PMBJK also whose existing limit of incentives of Rs 2.50 lakh is fully disbursed, moreover it will also cover the PMBJK opened in government premises to whom one-time grant of Rs 2.50 lakh was disbursed. They will get incentive of Rs 2.50 lakh based on purchase made by them from BPPI as per other terms and conditions applicable to all PMBJKs.

In addition to this, special incentive amount of Rs. 2.00 lakhs shall be granted for PMBJK opened by the Women entrepreneurs, divyaang, SC, ST & any entrepreneurs opening PMBJK at aspirational districts (backward district) as notified by the NITI Aayog& in Himalayan, Island territories and North- Eastern state.

Comments of the Committee

(Please see Para No. 1.18, 1.19, 1.20 and 1.21 of Chapter - I of the Report)

Recommendation No. 11

Consumer Awareness, Publicity and Price Monitoring (CAPPM)

2.17 The Committee note that there are two components Under the Central Sector Scheme of NPPA, viz., 'Consumer Awareness, Publicity and Price Monitoring' (CAPPM). First component is setting up of Price Monitoring and Resource Units (PMRUs) in the States/ Union Territories. The primary function of PMRUs is to assist NPPA in price monitoring, detection of violation of the provisions of DPCO, pricing compliance, ensuring availability of medicines and consumer awareness. The second component is advertisement and publicity. During the year 2020-21 Rs. 4.5 crore was allocated at BE stage and the same was reduced to Rs.3 crore at RE stage. However, only Rs.1.78 crore has been spent as on 15.01.2021. Under the first component (Assistance to PMRUs), it is expected that total funds will be utilized up to end of the F.Y. 2020-21. As regard the 2nd Component (Advertising and Publicity) the budget has been revised from Rs. 2.00 crore to Rs. 0.50 crore. The Committee note that the mobile application 'Pharma SahiDaam' launched by NPPA is non-functional that defeats the very purpose of launching the application. A budgetary allocation (BE) of Rs.6 crore has been made for 2021-22. Out of this, Rs.5Crore has been allocated to

PMRUs and Rs.1 crore for Advertisement and publicity. The Committee also note that in order to increase the effectiveness and outreach of NPPA, 17 PMRUs have been set up in States of Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa and Madhya Pradesh. However as submitted by the Department PMRUs in only 12 States are fully functional as PMRUs in the states of Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa and Madhya Pradesh are newly set up. The Committee feel that PMRUs are functioning as crucial link between the States and NPPA as they monitor drug price regulation, ensure availability of medicines, conduct IEC activities and organize seminar/ webinar etc. and hence they should be set up in all States in a time bound manner. Moreover, the activities of NPPA in the area of advertisement and publicity are needed to be strengthened. In view of the above, the Committee recommend the following:-

i. Concerted efforts should be made by the Department of Pharmaceuticals (DoP) and NPPA to set up functional PMRUs in all the States and Union Territories latest by 2023-24 as projected under the Vision Plan of NPPA. In case of non-cooperation of any State/UT Government, the matter should be taken up at the highest level with those Governments. Alternatively, DoP and NPPA may explore the possibilities of setting up of PMRUs by the Union Government itself. If needed the increase of budgetary allocation for the purpose may be considered.

ii. Continuous monitoring by NPPA on proper functioning of PMRUs particularly with regard to price monitoring, detection of violation of the provisions of DPCO, pricing compliance and ensuring availability of medicines to the people.

iii. Awareness and publicity through print, electronic and social media about the pricing of scheduled and non scheduled drugs, availability of affordable and quality generic medicines as alternatives to branded medicines, robust grievance redressal mechanism in respect of overcharging, ensure proper functioning of Pharma SahiDaam app etc. and enhance the budgetary allocation for the same as the present allocation of Rs.1 crore is inadequate.

Reply of the Government

(i) Price Monitoring and Resource Unit (PMRU) have been set up in the eighteen (18) States as per the target set for the period up to 2020- 21, viz., Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh and Chhattisgarh, despite the pandemic situation in the country. As suggested, in case of non-cooperation by any State/UT Government, the matter would be taken up at the highest level with those Governments. The budget allocation for Grant in Aid to PMRUs for the year 2021-22 has been doubled to Rs. 5.00 Crore as against 2.50 crore in the year 2020-21.

(ii) Regular and continuous monitoring of functioning of PMRUs with regard to price monitoring, detection of violation of the provisions of DPCO, pricing compliance and ensuring availability of medicines to the people is carried out on a monthly basis. Monthly reports are obtained from PMRUs. In view of the on-going COVID pandemic

since 2020, meetings through Video Conferencing are also held. Recently, PMRUs have also initiated weekly survey on the availability of drugs used in COVID management.

(iii) The suggestion has been noted. Depending upon the progress, additional funds will be sought at various stages, as and when required, including Supplementary and RE stage.

Recommendation No. 12

National Institute of Pharmaceutical Education and Research (NIPER)

2.18 The Committee note that National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar (Mohali) was set up as a registered society under the Societies Registration Act, 1860 and given statutory recognition by an act of Parliament, NIPER Act, 1998 and was declared as an Institute of National Importance. During 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kol-kata and Raebareli with the help of Mentor Institutes. Subsequently, NIPER at Madurai was approved in the year 2012. During 2015-16, Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh, Maharashtra and Rajasthan. Another NIPER is proposed to be set up at Bengaluru, Karnataka. With respect to the budgetary allocation made for the NIPERs for the ensuing year 2021-22, the Committee note that the Department has been allocated only Rs. 234.34 crore against its requirement of Rs. 1220 crore for NIPERs during 2020-21. Under NIPER scheme fund utilization pattern is 100 percent during the year 2018-19, 2019-20 and likely to be fully utilized during the year 2020-21 as well. One of the physical targets of the Department is to create own campus with permanent buildings for all the existing NIPERs as well as for the newly proposed NIPERS. In this regard, a proposal for up-gradation and establishment of existing seven NIPERs as well as setting up of new five NIPERs at an estimated cost of Rs. 4,300 crore sent to the Department of Expenditure in June, 2020 was returned by the Ministry of Finance indicating that the continuing schemes needs to be appraised and approved further for the period of 2021-22 to 2025-26 after 15th Finance Commission recommendations are accepted and resource position of public exchequer is clear. In pursuant to the Department of Expenditure's instructions issued dated 8th December, 2020, a fresh proposal has been sent to that Department in the revised format for consideration by the Expenditure Finance Committee (EFC). The Committee are deeply concerned to note that creation of requisite infrastructure for 6 NIPERs which were declared as Institutes of National Importance has been delayed by more than a decade. The work of construction of Permanent campus is nearing completion only in respect of Guwahati NIPER and the construction work of campus for Ahmedabad NIPER has been started recently. In this regard, the Committee feel that it is very much necessary to create own campus for NIPERs at Hyderabad, Kolkata, Raebareli and Hajipur so as to enable them function in a full fledged manner in the true spirit of Institute of National Importance. The Committee, therefore, strongly recommend that a definite time schedule should be fixed for construction of own campus with permanent buildings for these NIPERS and accordingly enhanced budgetary allocation should be made for the

purpose. The Department should pursue vigorously with the Department of Expenditure for the early EFC approval of the proposals for creation of own campus with permanent buildings for the existing NIPERs and for the setting up of five new NIPERS at Madurai, Jhalawar, Raipur, Nagpur and Bangaluru. Based on the approval, concrete steps should be taken for the construction of permanent campus for the existing NIPERS and the time bound setting up of new NIPERS.

Reply of the Government

2.19 Department has already sent a comprehensive EFC proposal to the Department of Expenditure seeking funds to the tune of Rs.4300.00 cr. for a period of five years. The proposal seeks, amongst others, funds for setting up regular campuses of existing NIPERs at Ahmedabad, Hyderabad, Kolkata, Hajipur and Raebareli. It is relevant to mention that the existing NIPER at Mohali already has a full-fledged campus, whereas the construction of campus of NIPER at Guwahati has almost been completed. Further, funds have also been sought in EFC proposal for setting up campuses of new NIPERs proposed to be set up at Madurai (Tamil Nadu), Jhalawar (Rajasthan), Nagpur (Maharashtra), New Raipur (Chhattisgarh) and Bengaluru (Karnataka). The Department is vigoursly pursuing with the Department of Expenditure for consideration/ approval of EFC proposal.

Department of Expenditure has allocated additional Rs.121.82 crore in RE 2021-22, of which Rs.71.00 cr. have been released for purchase of equipment's and Rs. 41.00 cr. for construction of NIPER Guwahati and NIPER Ahmedabad. Further, the Department of Expenditure has allotted Rs.234.34 cr. for NIPERs in Budget Estimates 2021-22.

Recommendation No. 13

Setting up of modern laboratories in NIPERS and faculty/staff welfare

2.20 Grants in aid to NIPERs include the purchase of equipment by the existing NIPERs and payment of salary to faculty / staff. In this regard, the Committee recommend the following:-

i. Apart from construction of own campuses for NIPERs, due attention should be paid for setting up modern laboratories with state of the art equipments for imparting pharmaceutical education in a holistic manner and for Research and Development in the field. Requisite amount of budgetary allocations should be made for the purpose. The Committee may be informed about the progress in this regard.

ii. The Committee note that NIPERs have been directed to earn at least 1/3rd of their salary to reduce dependency on Government Grants. While it is prudent that the NIPERs need to strive to be self-reliant for meeting at least part of their operational expenses through fees from students, testing fee from equipments, projects, consultancies etc, the Committee are of the view that the interests of faculty and staff should be protected till they reach their full potential and hence recommend that NIPERs should be provided enough budgetary grants so as to

meet the salary requirements of faculty and staff till they become self reliant with permanent building and strong laboratory facilities.

Reply of the Government

2.21 (i) In addition to Rs. 333.82 crore released during the year 2020-21 for purchase of equipment's (calculate by deducting funds for construction of campus of Guwahati and Ahmedabad from the total releases made under Capital head), the Department has released additional Rs.71.00 crore in the month of March, 2021 for purchase of equipment's by NIPERs. Further, during the FY 2021-22, fund will also be released for setting up modern laboratories/purchase of equipment's by NIPERs from the allocated BE Rs.234.34 crore. In addition, funds have been sought for up-gradation of laboratories and setting of Centers of Excellences in the EFC proposal.

(ii) The direction to NIPERs is a step towards making the institutes self-reliant. It, however, does not imply that the funds towards salary requirements of faculty and staff will not be made available by the Department. Funds towards salary are made available under budget head of Grants in Aid – General/ Salary under the annual Budget Estimates. Further, in the EFC proposal sent to the Ministry of Finance for next five years, funds for salary and allowances of faculty and staff of NIPERs have been sought.

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 WHICH REQUIRE REITERATION

Recommendation No. 2

Major issue of drug security associated with overdependence on imported API/Bulk Drugs

4.1 The Committee note that pharmaceuticals has been identified as one of the champion sectors, which forms around 1.72 percent of the country's GDP but there is an urgent need to pay attention to major issue of drug security associated with overdependence on imported API/Bulk Drugs which if not handled can adversely affect the competitiveness of the domestic pharmaceutical sector in the years to come. In this regard, the Department of Pharmaceuticals has informed that the Active Pharmaceutical Ingredients (API)/Bulk drugs and intermediates form 63% of India's total pharma imports. Even production of some of the National List of Essential Medicines (NLEM) formulations is dependent on imported APIs and intermediates. India imports bulk drugs and intermediates largely on economic considerations. China with a share of 67.6 % is the major source for API. India, being one of the largest manufacturers of medicines and exporting these to over 200 countries, dependence on a single source for import of API is a matter of serious concern as any disruption in the supplies could jeopardize the pharma sector and affect the supplies of medicines both for domestic use and exports. In this regard, the Committee observed that during the early 90s, India was self-reliant in manufacturing APIs. However, with the rise of China as a producer of API, it captured the Indian market with its low-cost API manufacturing industry. The worst hit was the Indian fermentation based bulk drug Industry facing severe competition from overseas players mainly from China. Local production slowly stopped when China started exporting these bulk drugs at very low prices in India. The cost of production of these bulk drugs was low in China due to multiplicity of factors including low cost of capital followed by aggressive government funding models, tax incentives, availability of subsidized utilities such as electricity, steam, brine, effluent treatment etc. In order to negate imports, the Department has issued guidelines dated 30.12.2020 for implementation of Public Procurement (Preference to Make in India) Order dated 16.09.2020 issued by Department for Promotion of Industry and Internal Trade, to Pharmaceuticals Sector which classify the suppliers for providing preference in public procurement based on their minimum local content for pharmaceuticals formulations. In 2020, the Committee under chairmanship of Dr Eswara Reddy identified APIs with high degree of import dependence. Further, a Production linked incentive scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country has been launched by the Government. The committee is also given to understand that Department has no policy to favourably distinguish between Pharma companies which manufacture drugs from domestically produced critical Key Starting Materials(KSMs)/Drug Intermediates (DI) and Active Pharmaceutical Ingredients (APIs) in comparison to those companies which

manufacture drugs by importing API/KSM/DI from other countries. Since it is very much necessary to stop the dumping of cheap raw material in the country by China, there is a need to curtail this trend and therefore, the Committee recommend that the following measures should be taken:-

i. NITI Ayog and the Department of Pharmaceuticals to make an indepth study of various concessions being provided by China to its bulk drug industry and to initiate immediate appropriate measures in a war footing manner for the creation of a very strong API/bulk drug/KSM industry in the country as a viable competitor and alternative source country for API/bulk drug/KSMs

ii. Need to provide manufacturing support infrastructure viz. subsidized utilities such as electricity, water, steam, brine, effluent treatment plant etc and help create economies of scale for fermentation based bulk drug Industry clusters.

(ii) Reclassify suppliers into three categories Class-I with 100 percent local content, Class-II 80 percent local content and Class-III with 60 percent local content and provide progressive incentives like zero duty on 100 percent local content suppliers and rationally increase duty on other two category of suppliers for both public and private procurements done in Pharmaceutical sectors.

(iv) Enhance the budget allocation for the scheme Promotion of Bulk Drugs during RE stage for the year 2021-22 to make effective stride in establishing 3 Bulk Drug Parks in the country and expand the scheme to establish more Bulk Drug parks in future.

(v) Department of Pharmaceuticals to frame a comprehensive incentive policy for domestic bulk drugs producers.

This recommendation may also be sent to NITI Ayog for Action Taken Reply by both the Department of Pharmaceuticals and NITI Ayog.

Reply of the Government

4.2 As directed by Committee, the recommendation was also shared with NITI Aayog.

Regarding points (i),(ii) & (v) above: Department of Pharmaceuticals in consultation of NITI Aayog has launched following three schemes for promoting domestic manufacturing of bulk drugs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries:-

i. Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India;

ii. Scheme for Promotion of Bulk Drug Parks; and

iii. Production Linked Incentive Scheme for Pharmaceuticals.

Regarding point (iii) above: Department of Pharmaceuticals vide order dated 30.12.2020 has issued guidelines for implementation of Public Procurement (Preference to Make in India) (PPO) Order, 2017 to Pharmaceuticals Sector. The guidelines provide the percentage of local content which is to be used for providing preference in public procurement of goods & services related to Pharmaceuticals Sector as per PPO Order. The percentage of local content has been fixed at equal to or more than 80% for 'Class-I Local Supplier', more than 50% but less than 80% for 'Class-II Local Supplier' and less than or equal to 50% for 'Non-Local Supplier'.

Regarding point (iv) above: The Cabinet has granted approval of 3 Bulk Drug Parks. Department will seek additional funds in R.E. Stage for establishment of the parks. As and when the 3 three Bulk Drug Parks will be established, the department will approach to Cabinet for establishing new bulk drug parks in the country.

Comments of the Committee

(Please see Para No. 1.10, 1.11 and 1.12 of Chapter - I of the Report)

Recommendation No. 10

National Pharmaceutical Pricing Authority (NPPA)

4.3 The Committee note that the National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals is entrusted with the responsibilities of fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. However, the Committee are concerned to note that NPPA fixes ceiling prices of only scheduled formulations which constitutes only about 17.2 per cent of the total formulations. The rest of 82.8 per cent of medicines are in the non-scheduled segment and the NPPA does not fixes ceiling price of those medicines/drugs. However, their price increase is permitted only up to 10 per cent of MRP per annum. So, there is a limitation of regulatory powers of NPPA in fixing and monitoring of prices of non-scheduled drug formulations. Since the expenditure on medicines constitutes more than 50 per cent of expenditure on health, it is very much affecting poor families who struggle to cope with the high cost of medicines for treatment of any disease. The Committee feel that there is immediate need to increase the percentage of regulation of medicines from 17.2 percent to at least 50 percent within a year by incorporating suitable policy changes in this regard. Moreover, the Committee also feel that there is a need to regulate the prices of medicines charged by private hospitals from the patients as a part of the overall treatment charges. In view of the above, the Committee recommend the following:-

i. There is a need for introducing policy changes in the National Pharmaceutical Pricing Policy, 2012 and Drug Price Control Order (DPCO) wherein NPPA should be given autonomy to regulate the base prices of at least 50 percent of all drugs sold in the domestic market, to expand NPPA price regulation function in an effective way beyond the scheduled drugs mentioned in the National List of Essential Medicine (NLEM);

ii. Apart from fixing the prices of scheduled drugs, NPPA should also fix the ceiling prices of all non-scheduled drug formulations which are prescribed more often by medical practitioners for treating many of the common ailments;

iii. Department of Pharmaceuticals and NPPA should examine critically whether it is necessary to permit 10% increase of MRP of non-scheduled drugs per annum particularly when the prices of raw materials, etc does not increase and appropriate steps should be initiated on the basis of outcome of the such critical examination;

iv. Also examine the rationalization of fixation of Maximum Retail Price (MRP), as MRP itself is fixed on the higher side and subsequent 10 percent increase in price per annum makes the cost of drugs unaffordable for the common people; and

v. Department of Pharmaceuticals and NPPA should also examine the issues pertaining to high prices of medicines charged by private hospitals.

Reply of the Government

4.4 (i) & (ii) - The objective of the National Pharmaceuticals Pricing Policy (NPPP), 2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – 'essential medicines' – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well-being for all. The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are (i) Essentiality of Drugs, (ii) Control of Formulations prices only, and (iii) Market Based Pricing.

The current Drugs (Prices Control) Order (DPCO), 2013 is based on NPPP, 2012. National Pharmaceutical Pricing Authority (NPPA) gets its mandate from the DPCO. NPPA fixes the ceiling price of scheduled medicines specified in the Schedule-I (Schedule I of DPCO is the National List of Essential Medicines which is notified by Ministry of Health and Family Welfare from time to time) of the DPCO, 2013 in accordance with the provisions of the DPCO. All manufactures of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. A manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation branded or generic launched by it. However, as per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum as per Para 20 of the DPCO, 2013. So far as regulation of drugs used for

common ailments prescribed by the medical practitioners are concerned, it is stated that all the essential drugs are included in the NLEM by the Committee of experts under MHFW from time to time. In addition to above, Para 19 of DPCO, 2013 empowers the Government "*to fix ceiling price of any drug in extraordinary circumstances, if it considers necessary so to do in public interest for such period as it may deem fit*".

The recommendation of the Committee for introducing policy changes in the National Pharmaceutical Pricing Policy, 2012 and Drug Price Control Order (DPCO) have been noted.

(iii) & (iv) - DPCO, 2013 is framed as per the principles laid down in the NPPP, 2012. The policy marked a shift to market-based pricing based on one of the principles enunciated in NPPP, 2012. Thus, DPCO, 2013 does not consider the aspect of cost while fixing the ceiling price of scheduled formulations.

(v) As per the provisions of the DPCO, no manufacturer can sell a scheduled or non-scheduled formulation at a price more than the MRP. If any complaint regarding overcharging by hospital(s) is received, NPPA initiates action in case of violations against the manufacturers as per the provisions of DPCO, 2013.

Comments of the Committee

(Please see Para No. 1.24 and 1.25 of Chapter - I of the Report)

CHAPTER – V

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

Recommendation No. 4

Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)

5.1 The Committee are dismayed to note that the important sub scheme of Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) remains a non-starter since its approval in 2016. Only a token allocation of Rs. 1 lakh was provided for the sub scheme for the financial years 2019-20 and 2020-21. Even though the Department had demanded Rs. 185 crore for the sub scheme, again only a token allocation of Rs. 1 lakh has been made by the Ministry of Finance for 2020-21. This clearly shows the lack of faith in Department's credentials to implement this important scheme which aims to facilitate small and medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to WHO GMP standards so as to enable them to participate and compete in global markets. As per the sub scheme, assistance in the form of interest subvention against the sanctioned loan by any scheduled commercial bank/financial institution, both in public and private sector will be provided to 900 Pharma SMEs of proven track record. The scheme is to be implemented by a Public Sector Financial Institution (PSFI). But everything remains on paper without any concrete action to implement the scheme. Non receipt of applications for financial assistance was the reason given by the Department for the non-moving of the scheme ahead. In this regard, the recommendations made in third party evaluation viz. need for enough brain storming to set one liner objective for the Scheme, need for implementation with liberal terms and conditions and opening of the scheme to MSME sector instead of SME sector are worth for consideration. It is a matter of serious concern that the Department could not appoint Public sector Financial Institution (PSFI) during the last 4 years of implementation of the scheme. Since it is very much necessary to raise the standards of Pharma production units to that of WHO GMP standards in order to medicines/drugs of highest standards to the people of the country and also for the export purpose, the Committee strongly recommend that the Department should take prompt steps for the early Expenditure Finance Committee approval of the scheme for implementation of the sub scheme from 2021-22 to 2025-26. PSFI should be appointed immediately after the EFC approval and prompt steps should be taken for the successful implementation the schemes from 2021-22 onwards. The Progress made in this regard should be intimated to this committee within 3 months.

Reply of the Government

5.2 The EFC Note has already been sent to Department of Expenditure. Further recommendations are noted for compliance.

Recommendation No. 14

Disinvestment of Public Sector Undertakings (PSUs)

5.3 The Committee note there are five Public Sector Undertakings (PSUs) under the aegis of the Department of Pharmaceuticals. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL) and Hindustan Antibiotics Limited (HAL) are presently functional. While the first two are profit making, the third one is sick. Indian Drugs & Pharmaceuticals Limited (IDPL) and Rajasthan Drugs & Pharmaceuticals Limited (RDPL) are under closure. In 2016, The Government of India decided for strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru, strategic sale of BCPL and closure of HAL. At that point of time, both BCPL and HAL were loss making but BCPL has turned into profit making PSU as it was able to reduce procurement cost substantially, financial leakages, etc. due to concrete steps taken such as centralization of Procurement System, Accounting System and HRM Record Maintenance System. On Similar lines, HAL has been able to improve sales turnovers over the last few years, though still making losses with a number of initiatives taken, such as downsizing manpower through VRS scheme, product diversification and cost cutting measures. In the aftermath of COVID 19 pandemic, Minister of Chemicals and Fertilizers had requested NITI Aayog to reconsider the decision of disinvestment of KAPL including Hindustan Antibiotics Limited (HAL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL). The Department is following up this matter with NITI Aayog for reconsideration of disinvestment/ feasibility of merger through in-depth examination by the Aayog itself or by awarding a comprehensive study to an independent agency on priority. Even though there is a strong private pharmaceutical industry, the Committee are of the firm view that it is very much necessary to retain functional public sector pharmaceutical units as the coexistence of both the public and private sector pharmaceutical industry is beneficial to the country particularly to make available quality medicines at affordable prices to all sections of the society including poor and needy. Moreover, the Government is committed to provide drug security at affordable cost for the people of the country. This can be ensured only with the strengthening of Pharmaceutical PSUs because private sector is driven by profit motive and market demand sentiment which does not cater to the needs of the lower middle class, poor and down trodden people for the availability of quality drugs at affordable prices. Keeping in view the wellbeing of the common people the, Committee, therefore, strongly recommend the following:-

i. The proposal of strategic disinvestment of KAPL, which is a profit making mini ratna PSU, should be dropped.

ii. The proposal of strategic sale of BCPL which has emerged as a profit making PSU should also be dropped.

iii. The proposal for closure of HAL should also be dropped and corrective measures should be taken to make it profit making on the lines of BCPL.

iv. Rather than disinvestment/sale, the Government should consider various measures for successful/profitable running of PSUs including reforms at

administrative/ management level like professionalization of Board of Pharma PSUs, promotion of Corporate Governance practices etc. to safeguard the interest of the common people who are dependent on affordable and quality medicines produced by Pharmaceutical PSUs.

Reply of the Government

5.4 The Union Cabinet had decided on 28.12.2016 to strategically disinvest HAL & BCPL. Separately the CCEA on 01.11.2017 had decided to strategically disinvest 100% of Central Govt. equity in KAPL based on the Cabinet note moved by DIPAM.

Being a Policy decision, earlier I Minister (C&F) vide D.O. dated 03.07.2020 and 23.12.2020 has requested to Vice Chairman, NITI Aayog for reconsideration of the decision of disinvestment of three pharma PSUs namely KAPL, BCPL & HAL. Further, Secretary (P) vide D.O. dated 29.07.2020, 26.10.2020, and 27.11.2020 has requested to CEO, NITI Aayog to get the feasibility to merger of the pharma PSUs under disinvestment and examined in depth either by the Aayog itself or by awarding a comprehensive study to an independent agency on priority. However, reply is still awaited.

Comments of the Committee

(Please see Para No. 1.28 of Chapter - I of the Report)

Recommendation No. 16

Rajasthan Drugs & Pharmaceuticals Limited (RDPL)

5.5 The Committee note that Rajasthan Drugs & Pharmaceuticals Limited (RDPL) set up in 1978, was declared Sick PSU in October 2016 and now is under the process of closure having liabilities of 75.29 crore. During the years 2019-20 and 2020-21, Rs. 48.71 crore and Rs. 2.40 crore was provided respectively as loan assistance to RDPL for repayment of liabilities. For the year 2021-22 Rs. 3.00 crore has been allocated at BE stage. The Committee also note that Department of Pharmaceuticals did not refer the matter of sickness of Rajasthan Drugs & Pharmaceuticals Limited (RDPL) to Board for Industrial & Financial Reconstruction (BIFR)/National Company Law Tribunal (NCLT) for detail scrutiny about its financial conditions/ management output/ business revival and to take appropriate action thereon. The Committee feel that since RDPL is incipient sick PSU with net worth of Rs. 21.32 crore and operational loss of only Rs. 12.60 crore there is a scope for turnaround of this PSU into profit making one as it happened in case of BCPL by making innovative and sound business revival plans with help of independent industry experts. Therefore, the Committee strongly recommend the Department to prepare an innovative revival plan for RDPL.

Reply of the Government

5.6 As per decision of the Union Cabinet on 28.12.2016, RDPL is being closed. RDPL stopped its production since 2016. In 2019-20, Budgetary support of Rs.43.70

crore was provided to RDPL to meet VRS dues and unpaid salary dues of employees. However, of the total employees, only 99 employees accepted VRS and 25 employees have approached the Hon'ble High Court of Rajasthan, Jaipur Bench against retrenchment.

Since, RDPL is a joint sector PSU (with 51:49 share between Government of India and Government of Rajasthan), earlier Government of Rajasthan was approached to take over the PSU by transfer of Government of India share. Of late, Government of Rajasthan has shown interest about revival of the PSU and is expected to submit detailed proposal.

New Delhi;
16 November, 2021
25 Kartika, 1943 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals and Fertilizers

MINUTES OF THE FIRST SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2021-22)

The Committee sat on Tuesday, the 16th November, 2021 from 1500 hrs. to 1700.hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

K. KANIMOZHI - CHAIRPERSON
MEMBERS

LOK SABHA

2. Shri Dibyendu Adhikari
3. Shri Prataprao Patil Chikhlikar
4. Shri Kripanath Mallah
5. Shri Parbhubhai Nagarbhai Vasava
6. Shri Satyadev Pachauri
7. Shri Arun Kumar Sagar
8. Shri Pradeep Kumar Singh
9. Shri Uday Pratap Singh

RAJYA SABHA

10 Shri Ayodhya Rami Reddy Alla
11 Shri G.C.Chandrashekhar
12 Dr. Anil Jain
13 Shri Anthiyur P. Selvarasu
14 Shri Arun Singh

SECRETARIAT

1.	Shri N. K. Jha	-	Director
2.	Shri C. Kalyanasundaram	-	Additional Director
3.	Shri Kulvinder Singh	-	Deputy Secretary
4.	Shri Panna Lal	-	Under Secretary

2. At the outset, the Chairperson welcomed the Members to the newly constituted Committee and apprised them that the sitting has been convened to consider Memorandum No.1 regarding selection of subjects for examination during the year (2021-22) and also to discuss the future course of action of the Committee during the tenure.

3. The Committee then considered Memorandum No. 1 and after discussion selected the following subjects pertaining to the Ministry of Chemicals and Fertilizers for detailed examination during 2021-22:-

I. <u>MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF FERTILIZERS)</u>

1. Nano-fertilizers for sustainable crop production and maintaining soil health.

2. Tax structure on fertilizers sector in terms of GST and import duties – analysis of the tax structure of raw material and final products and its impact on self-sufficiency and use of fertilizers.
3. Prices, Availability and distribution of fertilizers.

II. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF CHEMICALS AND PETROCHEMICALS)

4. Vision 2024 - To establish India as a leading manufacturer of chemicals and petrochemicals.
5. Insecticides – promotion and development including safe usage - licensing regime for insecticides.
6. Disposal of toxic waste from Bhopal Gas Leak site.
7. Environmental Impact of Petrochemical products.

III. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

8. Promotion of Medical Device Industry.
9. Availability of Medicines and Medical devices for COVID Management.
10. Self sufficiency of key starting Material and intermediates.

4. The Committee then considered and adopted the following draft Action Taken Reports unanimously without any amendment/change:-

i. XXX XXX XXX

ii. XXX XXX XXX

iii. XXX XXX XXX

iv. XXX XXX XXX

v. ATR on the recommendations/observations of the Committee contained in the Twenty First Report on "Demands for Grants (2021-22)" (Department of Pharmaceuticals).

vi. XXX XXX XXX

vii. XXX XXX XXX

5 The Committee also authorised the Chairperson to finalize and present the Action Taken Reports to the Parliament in the ensuing session.

***The Committee then adjourned*.**

Appendix – II

(*Vide* Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE TWENTY FIRST REPORT (SEVENTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS ON THE SUBJECT 'DEMANDS FOR GRANTS (2021-22)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	16
II	Observations / Recommendations which have been accepted by the Government: (*Vide* Recommendation Nos. 1,3,4,5,6,7,8,9,11,13,15)	11
	Percentage of Total	68.75%
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation Nos. Nil)	NIl
	Percentage of Total	0%
IV	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (*Vide* Recommendation No. 2,10)	2
	Percentage of Total	12.50%
V	Observations / Recommendations in respect of which final replies of the Government are still awaited: (*Vide* Recommendation No. 4,14,16)	3
	Percentage of Total	18.75%