15	STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2020-21) SEVENTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations contained in the Eighth Report of the Standing Committee on Chemicals and Fertilizers (Seventeenth Lok Sabha) on "Demands for Grants 2020-21" of the Ministry of Chemical and Fertilizers (Department of Pharmaceuticals)]

FOURTEENTH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

FEBRUARY, 2021/MAGHA, 1942 (SAKA)

REPORT

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
(2020-21)

(SEVENTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations contained in the Eighth Report of the Standing Committee on Chemicals and Fertilizers (Seventeenth Lok Sabha) on "Demands for Grants 2020-21" of the Ministry of Chemical and Fertilizers (Department of Pharmaceuticals)]

Presented to Lok Sabha on 11.02.2021

Laid in Rajya Sabha on 11.02.2021

LOK SABHA SECRETARIAT
NEW DELHI

FEBRUARY, 2021/MAGHA, 1942 (SASKA)

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

Smt. Kanimozhi Karunanidhi - Chairperson

MEMBERS

LOK SABHA

2	Shri Maulana Badruddin Ajmal
3	Shri Ramakant Bhargava
4	Shri Prataprao Govindrao Patil Chikhalikar
5	Shri Rajeshbhai Naranbhai Chudasama,
6	Shri Ramesh Chandappa Jigajinagi
7	Shri Kripanath Mallah
8	Shri Satyadev Pachauri
9	Smt Aparupa Poddar
10	Shri Arun Kumar Sagar
11	Shri M. Selvaraj
12	Shri Pradeep Kumar Singh
13	Shri Uday Pratap Singh
14	Shri Nandigam Suresh
15	Er. Bishweswar Tudu
16	Shri Prabhubhai Nagarbhai Vasava
17	Dr. M.K Vishnu Prasad.
18	Shri Deepak Baij
19	Dr. Manoj Rajoria
20	Shri Shriniwas Dadasaheb Patil
21	Vacant$

RAJYA SABHA

22	Shri G.C.Chandrashekhar
23	Dr. Anil Jain
24	Shri Ahmad Ashfaque Karim
25	Shri Vijay Pal Singh Tomar
26	Shri Arun Singh
27	Shri P. Selvarasu^
28	Shri A.D. Singh^
29	Shri K. Vanlalvena^
30	Vacant*
31	Vacant

SECRETARIAT

1.	Shri Manoj K. Arora	-	Officer on Special Duty
2.	Shri A.K. Srivastava	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Ms Sonia Sankhla	-	Assistant Committee Officer

^Nominated to the Committee w.e.f 22.07.2020.

**Shri Amar Singh expired on 01.08.2020.*

$ Shri H. Vasanthakuma expired on 28.08.2020

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2020-2021) having been authorised by the Committee to submit the Report on their behalf, present this Fourteenth Report (Seventeenth Lok Sabha) on Action Taken by the Government on the observations/ recommendations contained in the Eighth Report (Seventeenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2020-21) on Demand for Grants (2020-21) pertaining to the Department of Pharmaceuticals.

2. The Eighth Report (Seventeenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 20.03.2020 and laid in Rajya Sabha on 20.03.2020. The Action Taken replies of Government to all observations / recommendations contained in the Report were received on 29.06.2020. The Standing Committee on Chemicals and Fertilizers (2020-21) considered and adopted this Report at their sitting held on 12.10.2020.

3. An analysis of the Action Taken by the Government on the observations/recommendations contained in the Fourteenth Report (Seventeenth Lok Sabha) of the Committee is given in **Appendix-II.**

4. For facility of reference and convenience, the further Comments of the Committee have been printed in bold letters in **Chapter-I** of the Report**.**

New Delhi;
8 February, 2021
19 Magha, 1942 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson
Standing Committee on
Chemicals and Fertilizers

INTRODUCTORY

This Report of the Standing Committee on Chemicals and Fertilizers (2019-20) deals with the action taken by the Government on the Observations / Recommendations contained in the Eighth Report (17th Lok Sabha) of the Committee on 'Demands for Grants (2020-21)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 20.03.2020. In all, the Committee made 12 Observations / Recommendations in the Report.

1.2 The Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations/ Recommendations contained in the Eighth Report within three months from the date of presentation of the Report, i.e. by 21.06.2020. The Action Taken Replies of the Government in respect of all the 12 Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) *vide* their OM. No. 23003/3/2020 - IFD dated 29.06.2020. These Replies have been examined and categorized as follows:-

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

Rec. Nos. 1,2,3,4,5,6,7 and 10 (Total =08)
Included in Chapter-II of the Report

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

Rec. Nos. Nil (Total=Nil)

Included in Chapter-III of the Report

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

Reco. Nos.11 (Total=01)
Included in Chapter IV of the Report

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

Reco Nos. 8, 9 &12 (Total =03)

Included in Chapter V of the Report

1.3 The Committee desire that the Action Taken Notes on Observations / Recommendations contained in Chapter-I of this Report and the Final Replies in respect of Observations / Recommendations contained in Chapter-V for which final replies are still awaited should be furnished expeditiously.

1.4 The Committee will now deal with action taken by the Government on some of their Observations / Recommendations which still require reiteration or merit comments as enumerated in Chapter I.

CHAPTER 1

RECOMMENDATIONS ON WHICH FURTHER COMMENTS HAVE BEEN MADE BY THE COMMITTEE

RECOMMENDATION NO. 2

PROMOTION OF BULK DRUG /API INDUSTRY IN THE COUNTRY

1.5 While stressing on the need to promote bulk drugs/API industry in the country, the Committee had recommended as under:-

> "The Committee are concerned to note that Active Pharmaceuticals Ingredients (API)/Bulk drugs and intermediates form 63% of India's total pharma imports. Even production of some of the NLEM formulations is dependent on imported APIs and intermediates. India imports bulk drugs and intermediates largely on economic considerations as imports are cheaper than domestic production. China with a share of 67.6 % is the major source of API for the country. India, being one of the largest manufacturers of medicines and exporting to over 200 countries, dependence on a single source for import of API is a matter of concern as any disruption in the supplies could jeopardize the entire pharma sector and affect supplies of medicines both for domestic use and exports. The Committee note that the Department has constituted a Task Force on API under the Chairmanship of the Minister of State (Chemicals & Fertilizers) on 18.04.2018 to formulate a roadmap for the enhanced production of Active Pharmaceutical Ingredients (APIs) in the country. The Committee also note that Department has taken some steps viz instructions issued to the State Governments to increase the API production capacity, timely permission by State Governments and Central Drugs Standard Control Organization (CDSCO) for setting up of API Plants and diversifying import of API from countries like Italy etc. rather than relying solely on China. The Department has also planned to revive 21 API plants which were operating in 2005 and were closed down because of stiff competition from China but the revival process likely to take one and a half year. The Committee further note that the Department has made efforts in promoting Domestic API/Bulk drugs production under a sub-scheme 'Assistance to Bulk Drug Industry for Common Facility Centre' as part of the Department's umbrella scheme namely 'Scheme for Development of Pharmaceutical Industry'. Under this sub-scheme, financial assistance would be provided for creation of common facilities in any upcoming Bulk Drug Park promoted by State Governments/State Corporations. The Scheme would be implemented through a one-time grant-in-aid to be released to a State Implementing Agency (SIA) set up for the purpose. This sub-scheme has

received only an allocation of Rs 21.52 crore at BE stage of 2020-21 against the proposed fund requirement of Rs.100.00 crore. The Department has stated that the proposals received from State Governments of Andhra Pradesh, Telangana, Himachal Pradesh and Assam have been given 'in-principle' approval. However, State Government of Assam has stated that it will not be financially viable for them to establish a Bulk Drug Park in their State. The remaining three proposals will be considered for final approval after receipt of Detailed Project Reports (DPRs) and the respective State Governments have been reminded to send Detailed Project Report at the earliest. In this regard, the Committee are dismayed to note that there is no concrete effort to reverse the trend of over-dependence on imports for the API. The Scheme of Assistance to Bulk Drug Industry for Common Facility Centre was launched only during 2017-18, but the setting up of Bulk drug parks in four states under the Scheme is only at approval stage even after two years of implementation of the Scheme. It is also a matter of concern that only Rs. 21.52 crore has been allocated for the Scheme against the requirement of Rs. 100 crore. Since it is high time specially in view of spread of corona virus from China the Government pays due attention for the promotion of bulk drug industry in the country, the Committee strongly recommend that swift action should be taken to establish the proposed Bulk drug parks in four states and the feasibility of setting up these parks in other states should also be examined in a time bound manner so as to create a strong bulk drug/API manufacturing base in the country instead on relying on a foreign country on this critical sector. Immediate steps should also be initiated for revival of 21 API plants which were closed due to competition from China. The Committee is also concerned about this approach to give grants to the States to implement some kind of a cluster approach. The Committee would like the Department to examine if such a cluster approach of boosting industrial activity has resulted in any concrete benefit in any other sector. The Committee would also like the Department to examine if a new approach involving concrete benefits in the form of say, subsidized finance, free industrial land, assured buy back contracts, etc. can be formulated so that it becomes economically viable for the pharmaceutical units to procure API locally. Since this is a critical sector for the economic and physical well-being of the country, the Committee would like the Department to seriously examine the issue of creating tariff barriers so that it becomes attractive to produce API in the country. This may be taken up with Ministry of Commerce and Ministry of Finance at the highest level."

Reply of the Government

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

"Various options to reduce the country's over dependence on imports from a single country have been examined in the department. Regarding diversifying sources of import of API, it is observed that APIs produced in other source countries such as Germany, France, Italy are priced relatively much higher and Indian formulations would be rendered less cost-competitive if the critical APIs used in their preparations are procured at higher costs from these countries. All the critical APIs are also not produced by these countries.

In order to address the issue of drug security in the country in the background of an expected disruption of imports of APIs owing to the COVID-19 crisis, the Department of Pharmaceuticals constituted a Committee under the Chairmanship of Dr. S. Eswara Reddy, Joint Drug Controller, CDSCO. The committee has identified a list of 58 APIs for which India is heavily dependent on imports from a single country.

A Technical Committee was constituted by DoP on 02.03.2020 under the chairmanship of Dr. Eswara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to make recommendations for the revival of fermentation industry, new technologies for manufacturing of APIs including its backward integration, costing of the projects and identification of strategic business models. The Technical Committee has examined all the 58 APIs/KSMs identified by the Drug Security Committee. The committee observed that in order to have self-sufficiency in manufacturing of these 58 KSMs/APIs, huge investment is required for setting up their manufacturing facilities. Further, depending on the nature of API/KSM, the manufacturing process, investment, facility required, etc will vary.

The Technical Committee also deliberated at length to access the feasibility of revival of closed API plants. The committee observed that most of these manufacturing facilities are completely surrounded by residential colonies, manufacturers do not have technology and technical manpower to manufacture fermentation-based products, building and civil structures are old, facilities of utilities, ETP, supply lines, electricity supplies, power backup are completely required to be replaced. Production of Fermentation-based products releases lot of foul smell by virtue of biomass produced during the process and the production capacities are not commercially viable. Therefore the committee concluded that revival of such old facilities is not commercially viable in the present context. Only Green Field projects need to be taken up with Large Volume Fermenters to ensure viable indigenous supply of such important KSMs.

On the basis of recommendations of the Technical Committee, the existing sub-scheme called “Assistance to Bulk Drug Industry for Common facility Centre” under the umbrella scheme of ‘Development of Pharmaceutical Industry’ has been revised. The revised scheme has been approved by the Union Cabinet on 20.03.20 and is now termed as “Promotion of Bulk Drug Parks”. The total size of the Scheme is Rs. 3000 Crore and tenure of the Scheme will be five years (FY 2020-21 to FY 2024-25).

The scheme will provide grant-in-aid to 3 Bulk Drug Parks with a maximum limit of Rs.1000 Crore per park or 70% of the project cost of Common Infrastructure Facilities, whichever is less. In case of hilly states and North East Region, the grant-in-aid would be Rs.1000 Crore per park or 90% of the project cost of Common Infrastructure Facilities, whichever is less. The Common Facilities at the Park would provide easy access to standard testing and infrastructure facilities and reduce the manufacturing cost significantly.

The Technical Committee identified 53 KSMs/APIs based on the therapeutic criticality, essentiality, technology involved and feasibility to manufacture indigenously. Based on its recommendations, DoP prepared a new scheme viz. Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates and Active Pharmaceutical Ingredients (APIs) In India. Under the scheme, financial incentive will be given to eligible manufacturers of 53 KSMs/Drug Intermediates and APIs on their incremental sales over the base year (FY 2019-20). For fermentation based eligible products, incentive for the first four years (2022-2023 to 2025-2026) would be 20%, for fifth year (2026-27) 15% and for sixth year (2027-2028) 5% on incremental sale of KSMs/Drug Intermediates/APIs. For chemically synthesized eligible products incentive for six years (2021-2022 to 2026-2027) would be 10% on incremental sales of KSMs/Drug Intermediates/APIs. A total outlay of Rs. 6,940 Crore has been approved for the scheme.

Regarding the Committee’s recommendation for the Department to seriously examine the issue of creating tariff barriers so that it becomes attractive to produce API in the country, it is to mention that this aspect has also been examined while drafting the Production Linked Incentive scheme and once sufficient domestic manufacturing starts happening only then the imposition of trade barriers will be considered. With the successful implementation of these schemes, it is expected that India would be well-positioned as a global hub for manufacturing of critical KSMs/Drug Intermediates and APIs along with the final drug formulations."

Comments of the Committee

1.7 The Committee note that various options to reduce the country's over dependence on imports of Active Pharmaceutical Ingredients (APIs) from a single country have been examined by the Department particularly to address the issue of drug security in the country at this juncture of disruption in imports of APIs owing to the COVID-19 crisis. In this regard, a Technical Committee was constituted by the Department of Pharmaceuticals to make recommendations for the revival of fermentation industry, new technologies for manufacturing of APIs including its backward integration, costing of the projects and identification of strategic business models. On the basis of recommendations of the Technical committee, the Department has revised the earlier Scheme of "Assistance to Bulk Drug Industry for Common facility Centre" and renamed it as "Promotion of Bulk Drug Parks" with an enhanced budget of Rs. 3000 Crore for implementation during the period of five years from 2020-21 to 2024-25. The Technical Committee also identified 53 Key Starting Materials (KSMs)/APIs based on the therapeutic criticality, essentiality, technology involved and feasibility to manufacture indigenously. In this regard, Department of Pharmaceuticals has floated a new scheme with an outlay of Rs. 6,940 Crore viz. Production Linked Incentive (PLI) Scheme for the promotion of domestic manufacturing of critical KSMs/ Drug Intermediates/ APIs in India. The Committee feel that it is high time for working in a war footing manner to create a strong base for manufacturing of above mentioned 53 KSMs/APIs which are critically essential for drug manufacturing in the country as the dependence on a single foreign country for APIs/KSMs has put the country's drug security in danger in the wake of present COVID-19 pandemic. The Committee, therefore, strongly recommend that the Department of Pharmaceuticals should take necessary steps for the effective implementation of the above two schemes in a time bound manner and to continuously monitor the effectiveness of implementation of both the schemes so as to take corrective

measures in case of any lacunae in the implementation. The progress made in regard to implementation of both the Schemes may be intimated to the Committee.

1.8 The Committee made a specific recommendation to the Department to examine if the cluster approach of boosting industrial activity has resulted in any concrete benefit in any other sector. In this regard, no reply has been given by the Department. The Committee, therefore, would like to emphasize again that the Department may examine whether a new approach involving concrete benefits to the entrepreneurs viz. subsidized finance, free industrial land, assured buy back contracts, etc. can be formulated so that it becomes economically viable for the pharmaceutical units to procure API locally. Specific replies may be given by the Department on the above recommendations.

RECOMMENDATION NO.3

TECHNOLOGICAL UPGRADATION OF PHARMACEUTICAL INDUSTRY

1.9 While stressing on the technological up-gradation of the Pharmaceuticals Industry, the Committee had recommended as under:-

"The Committee note that the World Health Organization- Good Manufacturing Practices (WHO-GMP) certificate is a mandatory requirement in most global markets for companies to be able to sell their medicines. It is difficult for the pharmaceutical Micro Small and Medium Enterprises (MSMEs) to establish and operate world class quality manufacturing and testing facilities on their own due to huge financial and technical investment involved. It is roughly estimated that 80% of the pharmaceutical MSMEs in the country are not WHO-GMP compliant. Upgrading to such standards require investment to the tune of Rs. 5-10 crore per unit as per the feedback from the stakeholders. The Committee observe that the Department has launched a scheme viz. Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) to facilitate pharmaceutical MSMEs to upgrade their plant and machinery to World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets. Under the scheme, assistance in the form of

interest subvention against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private sector will be provided to 250 pharmaceutical MSMEs of proven track record. The country requires Rs. 500 crore to Rs. 600 crore to convert the Pharma units in the country into WHO-GMP compliant. However the Committee are dismayed to note that the Department has been getting only a token allocation of Rs. 2 lakh for the scheme since 2018-19 including 2020-21 at BE stage which is a miniscule amount to start this important scheme for improving the standards of vast number of pharmaceutical MSMEs in the country and scheme has been a non-starter as no Public Sector Financial Institution(PSFI) has come on board to implement this scheme. After discussing with various stake holders, guidelines of this scheme have been revised by the Department including the selection of PSFI. The Committee would like the Department to appreciate the fact that technology upgradation to the level of WHO-GMP compliance will not happen unless the pharmaceutical SMEs are physically and financially assisted. The Committee would simultaneously want the Department to appreciate that WHO-GMP compliance not only helps the exporting pharmaceutical units but also enhances the quality of drugs available for domestic consumption. Therefore, the Committee would like the Ministry to formulate a concrete scheme involving real assistance to the SMEs for making them WHO-GMP compliant. Even if the scheme provides assistance to a few units each year (in view of paucity of funds), it should extend substantial assistance to the units beyond encouragement and guidance. The Committee in this regard recommend that swift action should be taken by the Department to implement the scheme in a time bound manner. For this to take place, the Committee strongly recommend that the Finance Ministry should enhance the budgetary allocation for this scheme so that the Department can implement this scheme for technology up-gradation of the pharmaceutical MSMEs. The Department shall also take up this matter at the highest level with the Ministry of Finance and this recommendation made by the Committee should be conveyed to Finance Ministry for necessary action at its level. In case of funding difficulties, the Department may consider to create a Special purpose Vehicle (SPV) in partnership with Private Pharmaceutical Industry who are dependent on the MSMEs sector to produce their pharmaceutical products so that a specific investment fund may be created for the technological up-gradation of Pharma MSMEs."

Reply of the Government

1.10 In reply to the afore-mentioned recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

" The department has prepared a revised Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) based on the feedback received from Industry Associations and other stakeholders. In the revised scheme, the number of pharma MSMEs to be covered is about 4,500 units. The financial implication for supporting 4500 Pharma MSMEs will be of Rs. 5,000 crores for seven-year period from 2020-2027. Further, in the revised scheme, provision is made to engage Public Sector Financial Institution (PSFI) by nomination basis as well. The department will take up the matter of enhancement of budgetary allocation with the ministry of Finance after approval of the revised scheme."

Further Comments of the Committee

1.11 The Committee note that the Department has prepared a revised Pharmaceuticals Technology upgradation Assistance Scheme (PTUAS) with an enhanced financial outlay of Rs. 5,000 Crore for seven-years period from 2020-2027 with the objective of assisting about 4500 units. This Scheme has been prepared by the Department on the basis of feedback received from Industry Associations and other stakeholders. The Department has also stated that it will take up the matter of enhancement of budgetary allocation with the Ministry of Finance after approval of the revised scheme. The Committee feel that the revised scheme if implemented effectively and efficiently has the potential to enhance the standards of pharmaceutical MSME units in the country particularly to facilitate them to upgrade their plant and machinery to the standards of World Health Organization (WHO)- Good Manufacturing Practices (GMP) so as to enable them to participate and compete in global markets. The Committee hope that the Department would take concrete and timely steps for the early approval of the Scheme and for requisite amount of budgetary allocation for the successful implementation of the revised scheme. The Committee would like to be apprised of the progress made in this regard.

RECOMMENDATION NO 4

PROMOTION OF ADVANCED RESEARCH IN DRUGS AND MEDICAL DEVICES FIELDS

1.12 While observing that there is need to promote advanced research in drugs and medical devices fields, the Committee had recommended as under:-

> "The Committee note that Pharmaceutical industry is a knowledge intensive industry and needs continuous development of new Chemical/ biological entities, updating/improvement in the processes, develop new drug delivery systems etc. to remain competitive. To sustain its edge in domestic and export markets, Pharma industry has to invest continuously in R& D. Besides, academia-Industry linkage has been identified as a basic requirement for translating research into development (commercialization) and Innovation. The Committee note that the Department of Pharmaceuticals has also constituted an Inter-Departmental Committee (IDC) on 9th January, 2019 to institutionalize a robust mechanism to ensure economy, efficiency, effectiveness and transparency in the arena of Pharmaceutical research. Since it is very much necessary to have a strong Research and Development base in the country to remain competitive at the global level and to meet the medicines needs of this huge country, the Committee would like to recommend that the Department should take concrete steps for promoting advance research in drugs and medical devices fields in collaboration with National Institute of Pharmaceutical Education and Research (NIPER), Public Sector Undertakings like BCPL and KAPL and private research laboratories. In this regard the Committee strongly recommend that the Department shall request the Ministry of Finance to make separate budgetary allocation for Research and Development segment for pharmaceuticals sector."

Reply of the Government

1.13 In reply to the afore-mentioned recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

> **"** A new Sub-head of Research and Development in Pharma Sector under the Umbrella Scheme has been opened in Detailed Demand for Grants 2020-21 so that a proper account of funds allocated/utilized for R&D could be maintained. Department has proposed in EFC to establish a Center of Excellence in Anti-virus Discovery and Development at NIPER-Mohali at estimated cost of Rs. 160.73 crore, Centre of Excellence in Medical Device with estimated cost of Rs. 149.85 crore at NIPER-Ahmedabad and Establishment of a National Centre of R&D in Bulk Drugs (NCRDBD) with

estimated cost of Rs. 99.31 crore at NIPER-Hyderabad. These centres will augment R&D in Pharma Sector. A committee comprising experts from eminent Government as well as Private Organizations has been duly constituted with the approval of Hon'ble Minister (Chemicals and Fertilizers, Government of India) to draft and finalize policy on R&D and Innovation including Academia-Industry linkage in Pharmaceuticals and medical Devices on 29th May 2020 in pursuance of the decision taken in the presentation of the Sectoral Group of the Secretaries before the Council of Ministers, with a mandate to give its Report in three months."

Comments of the Committee

1.14 The Committee note that the Department of Pharmaceuticals has opened a new Sub-head of Research and Development in Pharma Sector under the Major Head for the Umbrella Scheme on 'Development of Pharmaceuticals Industry' in Detailed Demand for Grants 2020-21. However, no budgetary allocation has been made under this new sub-head for the year 2020-21. Actually, the Committee recommended that the Department shall request the Ministry of Finance to make separate budgetary allocation for Research and Development segment for pharmaceuticals sector. In this regard, the Committee note that the Department has proposed in Expenditure Finance Committee(EFC) to establish a Center of Excellence in Anti-virus Discovery and Development, a Centre of Excellence in Medical Device and a National Centre of R&D in Bulk Drugs (NCRDBD) at a total cost about Rs.410 crore. Since the presence of such central level research institutions/centers would provide the right platform and an enabling environment for the promotion of R&D in pharma sector, the Committee urge the Department to take immediate steps for early approval of these R&D projects in EFC and thereafter pursue the matter vigorously with the Ministry of Finance for making budgetary allocation for these projects in 2021-22 budget. Specific reply may be given on the progress made in this regard for the information of the Committee. The Committee also note that a committee comprising experts from eminent Government as well as Private Organizations has been constituted to draft and finalize policy on R&D and Innovation

including Academia-Industry linkage in Pharmaceuticals and medical Devices. This Committee has been mandated to give its Report by the end of August, 2020. In this regard, the Committee hope that the Department would take necessary follow-up steps on the basis of recommendations of that Committee for finalizing R&D and innovations in the Pharmaceutical sector. The Committee would like to be apprised of the progress made in this regard.

RECOMMENDATION NO 5

ASSISTANCE TO MEDICAL DEVICES INDUSTRY

1.15 While observing on the necessity to extend assistance to the medical device industry, the Committee had recommended as under:-

"The Committee note that the country imports almost 85% of all its medical device needs. The country largely imports high technology medical equipments and electronics which constitute 66 % of the country's import basket. The Committee note that for the year 2020-21 the Department had proposed an amount of Rs 30.00 crore under the sub-scheme 'Assistance to Medical Device Industry for Common Facility Centre' but the Finance Ministry has allocated only Rs 7.50 crore. The Committee note that in principle approvals have been given for four proposals under this sub-scheme. The Department stated that under this sub-scheme, the proposals received from State Governments of Andhra Pradesh, Telangana, Tamil Nadu and Kerala have been given 'in-principle' approval. Also, the proposal of Andhra Pradesh has been given final approval for financial assistance of Rs. 25 crore. The other three proposals will also be considered for final approval after receipt of Detailed Project Reports (DPRs) for which the concerned State Governments have been reminded by the Department. The Committee feel that the setting up of common facility for Medical Device Industry would play major role in promotion of medical device industry in the country. Therefore, the Committee strongly recommend that the Department should take concrete steps in coordination with State/UT Government concerned to implement this sub scheme effectively. The steps to be taken by the Department should involve a dedicated infrastructure with free or nearly free land, easy access to low cost finances and technological assistance as without these basic ingredients, it is not possible to motivate any entrepreneur to set up new business in a sector where imports have a lower cost in general. The Department should also pursue with the Ministry of Finance to increase budgetary allocation for this scheme keeping in mind the priority of medical devices industry for the

health sector. The Department shall also take up this matter at the highest level with the Ministry of Finance and this recommendation made by the Committee should be conveyed to Finance Ministry for necessary action at its level."

Reply of the Government

1.16 In reply to the afore-mentioned recommendations of the committee, the Department of Pharmaceuticals has stated as under:-

"The sub-scheme termed as “Assistance to Medical Device Industry for Common Facility Centre” is a Central Sector Scheme under the umbrella scheme for Development of Pharmaceutical Industry. The total size of the above sub-scheme was Rs.100 Crores for 2018-2020. The sub-scheme proposed to provide a one-time grant-in-aid to the tune of Rs. 25 Crore or 70% of the project cost, whichever is less, to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose. The purpose of the grant was to render the financial assistance for establishment of common facilities in any upcoming Medical Device Parks promoted by State Governments/State Corporations.

However, it was realized that creation of common facilities requires much more investment and the Department proposed revision of the existing sub-scheme. The revised sub-scheme is termed as “Promotion of Medical Device Parks” with an outlay of Rs. 400 Crore for financing 4 medical device parks from financial year 2020-21 to 2024-25.

The revised sub-scheme will provide grant-in-aid to 4 Medical Device Parks with a maximum limit of Rs. 100 Crore or 70% of the project cost of Common Infrastructure Facilities, whichever is less. In case of Hilly States and North East Region, the grant-in-aid would be Rs. 100 Crore per Park or 90% of the project cost of Common Infrastructure Facilities, whichever is less. The Scheme would be implemented through a State Implementing Agency (SIA) to be formed by the concerned State Government. The Scheme has been approved by the Union Cabinet on 20.03.2020. The detailed guidelines of the scheme are under preparation. For allocation of sufficient funds, the Department will take up the matter with the Ministry of Finance at the appropriate time."

Further Comments of the Committee

1.17 The Committee note that the Union Cabinet has approved the revised sub-scheme of "Promotion of Medical Device Parks" in place of the existing sub-scheme "Assistance to Medical Device Industry for Common Facility Centre" with an enhanced outlay of Rs. 400 Crore for financing 4 medical device parks from the financial year 2020-21 to 2024-25. As per the reply given by the Department, it will take up the matter of sufficient allocation of funds for the scheme with the Ministry of Finance at the appropriate time. The Committee could not understand the logic of seeking funds from the Ministry of Finance at the appropriate time when the approved scheme is to be implemented from the current financial year onwards. Since the Scheme would remain only on paper due to delays in getting the requisite amount of funds for its implementation, the Committee urge the Department to take up at the highest level with the Ministry of Finance for the allocation of funds at RE stage/supplementary demands for the implementation of the Scheme from the current financial year onwards as envisaged under the Scheme.

1.18 The Committee also note that the detailed guidelines for implementation of the scheme are under preparation in the Department. While formulating the guidelines, the Department should examine the feasibilities of providing a dedicated infrastructure in Medical Device Parks with free or nearly free land, easy access to low cost finances and technological assistance as without these basic incentives, it may be difficult to motivate any entrepreneur to set up new manufacturing units in this sector where imports have a lower cost in general when compared to domestic ability to manufacture the same medical devices. The Action Taken Reply in this regard should be furnished to the Committee.

RECOMMENDATION NO 11

DISINVESTMENT OF PROFIT MAKING PHARMA PSUS

1.19 While impressing upon the need to relook at disinvestment of profit making PSUs, the Committee had recommended as under:-

> " The Committee are concerned to note that out of five Public Sector Undertakings (PSUs) under the Department of Pharmaceuticals, Karnataka Antibiotics & Pharmaceuticals (KAPL) and Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) are profit making PSUs. The Government has decided for strategic sale of BCPL and strategic disinvestment of 100% Government of India equity in KAPL. As regards BCPL, Hon'ble High Court of Kolkata set aside the decision of its strategic sale. Now an appeal has been made before the Division bench of the Court. The Department of Pharmaceuticals opposed the strategic disinvestment of KAPL as the company is profit making and has been assigned the responsibility of being the sole manufacturer of Oxytocin for domestic consumption. This matter of sole Oxytocin production rights to KAPL is presently *sub-judice* in the Hon'ble Supreme Court. The Committee are perturbed to note the decision of NITI Aayog to sell/ disinvest these two profit making PSUs of this priority sector which is concerning the health of huge population of this vast country. Entirely leaving drug manufacturing at the hands of private sector may not be a prudent step as these PSUs may provide required quantity of essential medicines at affordable prices at times of needs particularly during epidemic and pandemic outbreak of diseases. The Committee, therefore, strongly recommend that the decision for the strategic sale/ disinvestment of KAPL and BCPL should be revisited by the Government in the public interest. The Committee should be informed of the action taken in this matter. This recommendation of the Committee should also be sent to NITI Aayog for its specific reply within three months."

Reply of the Government

1.20 In reply to the afore-mentioned recommendations of the committee, the Department of Pharmaceuticals has stated as under:-

" The recommendation of the Committee was forwarded earlier to Ministry of Finance (DIPAM) and NITI Aayog on 14.02.2020 for reconsideration of the decision of strategic sale of KAPL and BCPL. Further, as directed by the Committee, the matter is again being taken up with NITI Aayog/ Ministry of Finance for reconsideration of strategic sale of profit making PSUs."

Further Comments of the Committee

1.21 The Committee are concerned to note the Action Taken Reply given by the Department that the matter is again being taken up with NITI Aayog/ Ministry of Finance for reconsideration of strategic sale of profit making PSUs. Eighth Report of the Committee on Demands for Grants, 2020-21 pertaining to the Department of Pharmaceuticals was presented to Parliament on 20 March 2020 wherein the Committee made a specific recommendation that the that the decision on the strategic sale/ disinvestment of Karnataka Antibiotics & Pharmaceuticals (KAPL) and Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) should be revisited by the Government in the public interest. In this regard, the Committee directed that the above recommendation of the Committee should be sent to NITI Aayog for its specific reply within three months. Even though this matter was taken up by the Department with NITI Ayog on 14 February, 2020, it seems from the reply given by the Department that the above recommendation of the Committee is yet to be sent to NITI Ayog. The Committee are of the strong view that entirely leaving drug manufacturing at the hands of private sector may not be a prudent step as these PSUs may provide required quantity of essential medicines at affordable prices at times of needs particularly during epidemic and pandemic outbreak of diseases. The Committee, therefore, reiterate the earlier recommendation that the decision for the strategic sale/ disinvestment of profit making PSUs viz. KAPL and BCPL should be revisited by the Government. This recommendation of the Committee should be sent to the Ministry of Finance (DIPAM) and NITI Ayog for their specific replies within three months.

CHAPTER – II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

RECOMMENDATION NO. 1:

NEED FOR ENHANCEMENT OF BUDGETARY ALLOCATION

The Committee note that the Department of Pharmaceuticals was created on 1st July, 2008 under the Ministry of Chemicals & Fertilizers with the objective to give greater focus and thrust on the development of pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to pharmaceutical sector which required integration of work with other ministries. The total size of Indian drugs and medical devices industry is around USD 43 Billion and it is currently having a growth rate of 7-8 % in drugs sector and 15-16 % in medical device sector. Total exports of drugs and medical devices are to the tune of USD 20.15 billion with drugs contributing around 90 % of the total exports. Imports around USD 10.4 billion of which medical devices constitute around 52 %. Pharma sector is currently contributing US$ 47.28 billion which is around 1.72% of country's GDP. It is expected that the sector can contribute between USD 85 to 100 billion to Indian Economy by 2024. However, the Committee are concerned to note that there are certain issues viz. dependence on import of API mostly from China, import of more than 50% of medical devices needs of the country, non-compliance of WHO GMP standards by most of the drug manufacturers in the country, etc. which have to be immediately addressed by the Government for continuous march as a frontline drug manufacturing country. The Committee note that the Department of Pharmaceuticals has initiated a few schemes for setting up of Common Facility Centres for Pharmaceutical industry, Bulk drug (API) industry and medical devices so as to promote the holistic growth of the Pharma sector in the country particularly to reduce the import of bulk drugs and medical devices. There is also an ambitious scheme for technology upgradation of 4500 pharma SMEs to make them comply with WHO GMP standards. In this regard,

the Committee are constrained to note the inadequate budgetary allocation of only Rs. 333.58 crore as against the demand of Rs.694.05 crore made by the Department. Notwithstanding huge responsibilities of the Department to ensure quality medicines at affordable prices to the entire population of the country, budgetary allocation is hardly sufficient to fulfill this huge responsibility. The Committee also note the views expressed by the Department that the reduction in outlay would have an adverse impact on the implementation of various Schemes and will not be sufficient to achieve the targets fixed by the Department for its major Central Sector Schemes. Since it is very much necessary to make adequate level of budgetary support to the Department to enable it achieve the goals before it particularly to enable the poor and deprived sections of the society to have basic access to affordable quality medicines. The Committee further note that during the year 2019-20 the Department could utilise only 64.34 per cent of the total allocated budget i.e. Rs. 361.81 crore (as on 17.01.2020) out of Rs. 562.33 crore available at revised estimate stage. The Committee are dismayed to note the underutilization of funds by the Department, which reflects poorly on their planning and scheme implementation capabilities. Therefore, the Committee feel that on one hand the Department has to work hard effectively towards utilization of allocated funds and on the other hand there is need to enhance the budget allocation commensurate with the social mandate of the Department. The Department shall also take up this matter at the highest level with the Ministry of Finance and this recommendation made by the Committee should be conveyed to that Ministry of Finance for necessary action at its level.

Reply of the Government

As aptly pointed out by the Committee, the reduced budgetary allocation of Rs. 333.58 Crore to the department for the FY 2020-21 against the demand of Rs. 694.05 Crore is grossly inadequate in view of the pressing requirements of ongoing and new schemes. The recommendation of the Committee for taking up the matter with Ministry of Finance has been noted for compliance.

However, with regard to the concern expressed by the Committee that during FY 2019-20 the Department could utilize the funds only to the extent of 64.34% as on 17.01.2020, reflecting poorly on the planning and implementation capabilities of the Department, it is stated that Department has been allocated Rs.

562.33 crore in Revised Estimates 2019-20. The Department was able to utilize 99.63% of its RE (i.e Rs. 560.25 crore) as on 31.3.2020.

RECOMMENDATION NO. 2

PROMOTION OF BULK DRUG /API INDUSTRY IN THE COUNTRY

The Committee are concerned to note that Active Pharmaceuticals Ingredients (API)/Bulk drugs and intermediates form 63% of India's total pharma imports. Even production of some of the NLEM formulations is dependent on imported APIs and intermediates. India imports bulk drugs and intermediates largely on economic considerations as imports are cheaper than domestic production. China with a share of 67.6 % is the major source of API for the country. India, being one of the largest manufacturers of medicines and exporting to over 200 countries, dependence on a single source for import of API is a matter of concern as any disruption in the supplies could jeopardize the entire pharma sector and affect supplies of medicines both for domestic use and exports. The Committee note that the Department has constituted a Task Force on API under the Chairmanship of the Minister of State (Chemicals & Fertilizers) on 18.04.2018 to formulate a roadmap for the enhanced production of Active Pharmaceutical Ingredients (APIs) in the country. The Committee also note that Department has taken some steps viz instructions issued to the State Governments to increase the API production capacity, timely permission by State Governments and Central Drugs Standard Control Organization (CDSCO) for setting up of API Plants and diversifying import of API from countries like Italy etc. rather than relying solely on China. The Department has also planned to revive 21 API plants which were operating in 2005 and were closed down because of stiff competition from China but the revival process likely to take one and a half year. The Committee further note that the Department has made efforts in promoting Domestic API/Bulk drugs production under a sub-scheme 'Assistance to Bulk Drug Industry for Common Facility Centre' as part of the Department's umbrella scheme namely 'Scheme for Development of Pharmaceutical Industry'. Under this sub-scheme, financial assistance would be provided for creation of common facilities in any upcoming Bulk Drug Park promoted by State Governments/State Corporations. The Scheme would be implemented through a one-time grant-in-aid to be released to a State Implementing Agency (SIA) set up for the purpose. This sub-scheme has received only an allocation of Rs 21.52 crore at BE stage of 2020-21 against the proposed fund requirement of Rs.100.00 crore. The Department has stated that the proposals received from State Governments of Andhra Pradesh, Telangana, Himachal Pradesh and Assam have been given 'in-principle' approval. However, State Government of Assam has stated that it will not be financially viable for them to establish a Bulk Drug Park in their State. The remaining three proposals will be considered for final approval after receipt of Detailed Project Reports (DPRs) and the respective State Governments have been reminded to send Detailed Project Report at the earliest. In this regard, the Committee are dismayed to note that there is no concrete effort to reverse the trend of over-dependence on imports for

the API. The Scheme of Assistance to Bulk Drug Industry for Common Facility Centre was launched only during 2017-18, but the setting up of Bulk drug parks in four states under the Scheme is only at approval stage even after two years of implementation of the Scheme. It is also a matter of concern that only Rs. 21.52 crore has been allocated for the Scheme against the requirement of Rs. 100 crore. Since it is high time specially in view of spread of corona virus from China the Government pays due attention for the promotion of bulk drug industry in the country, the Committee strongly recommend that swift action should be taken to establish the proposed Bulk drug parks in four states and the feasibility of setting up these parks in other states should also be examined in a time bound manner so as to create a strong bulk drug/API manufacturing base in the country instead on relying on a foreign country on this critical sector. Immediate steps should also be initiated for revival of 21 API plants which were closed due to competition from China. The Committee is also concerned about this approach to give grants to the States to implement some kind of a cluster approach. The Committee would like the Department to examine if such a cluster approach of boosting industrial activity has resulted in any concrete benefit in any other sector. The Committee would also like the Department to examine if a new approach involving concrete benefits in the form of say, subsidized finance, free industrial land, assured buy back contracts, etc. can be formulated so that it becomes economically viable for the pharmaceutical units to procure API locally. Since this is a critical sector for the economic and physical well-being of the country, the Committee would like the Department to seriously examine the issue of creating tariff barriers so that it becomes attractive to produce API in the country. This may be taken up with Ministry of Commerce and Ministry of Finance at the highest level.

Reply of the Government:

Various options to reduce the country's over dependence on imports from a single country have been examined in the department. Regarding diversifying sources of import of API, it is observed that APIs produced in other source countries such as Germany, France, Italy are priced relatively much higher and Indian formulations would be rendered less cost-competitive if the critical APIs used in their preparations are procured at higher costs from these countries. All the critical APIs are also not produced by these countries.

In order to address the issue of drug security in the country in the background of an expected disruption of imports of APIs owing to the COVID-19 crisis, the Department of Pharmaceuticals constituted a Committee under the Chairmanship of Dr. S. Eswara Reddy, Joint Drug Controller, CDSCO. The committee has identified a list of 58 APIs for which India is heavily dependent on imports from a single country.

A Technical Committee was constituted by DoP on 02.03.2020 under the chairmanship of Dr. Eswara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to make recommendations for the revival of fermentation industry, new technologies for manufacturing of APIs including its backward integration, costing of the projects and identification of strategic business models. The Technical Committee has examined all the 58 APIs/KSMs identified by the Drug Security Committee. The committee observed that in order

to have self-sufficiency in manufacturing of these 58 KSMs/APIs, huge investment is required for setting up their manufacturing facilities. Further, depending on the nature of API/KSM, the manufacturing process, investment, facility required, etc will vary.

The Technical Committee also deliberated at length to access the feasibility of revival of closed API plants. The committee observed that most of these manufacturing facilities are completely surrounded by residential colonies, manufacturers do not have technology and technical manpower to manufacture fermentation-based products, building and civil structures are old, facilities of utilities, ETP, supply lines, electricity supplies, power backup are completely required to be replaced. Production of Fermentation-based products releases lot of foul smell by virtue of biomass produced during the process and the production capacities are not commercially viable. Therefore the committee concluded that revival of such old facilities is not commercially viable in the present context. Only Green Field projects need to be taken up with Large Volume Fermenters to ensure viable indigenous supply of such important KSMs.

On the basis of recommendations of the Technical Committee, the existing sub-scheme called “Assistance to Bulk Drug Industry for Common facility Centre” under the umbrella scheme of ‘Development of Pharmaceutical Industry’ has been revised. The revised scheme has been approved by the Union Cabinet on 20.03.20 and is now termed as “Promotion of Bulk Drug Parks”. The total size of the Scheme is Rs. 3000 Crore and tenure of the Scheme will be five years (FY 2020-21 to FY 2024-25).

The scheme will provide grant-in-aid to 3 Bulk Drug Parks with a maximum limit of Rs.1000 Crore per park or 70% of the project cost of Common Infrastructure Facilities, whichever is less. In case of hilly states and North East Region, the grant-in-aid would be Rs.1000 Crore per park or 90% of the project cost of Common Infrastructure Facilities, whichever is less. The Common Facilities at the Park would provide easy access to standard testing and infrastructure facilities and reduce the manufacturing cost significantly.

The Technical Committee identified 53 KSMs/APIs based on the therapeutic criticality, essentially, technology involved and feasibility to manufacture indigenously. Based on its recommendations, DoP prepared a new scheme viz. Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates and Active Pharmaceutical Ingredients (APIs) In India. Under the scheme, financial incentive will be given to eligible manufacturers of 53 KSMs/Drug Intermediates and APIs on their incremental sales over the base year (FY 2019-20). For fermentation based eligible products, incentive for the first four years (2022-2023 to 2025-2026) would be 20%, for fifth year (2026-27) 15% and for sixth year (2027-2028) 5% on incremental sale of KSMs/Drug Intermediates/APIs. For chemically synthesized eligible products incentive for six years (2021-2022 to 2026-2027) would be 10% on incremental sales of KSMs/Drug

Intermediates/APIs. A total outlay of Rs. 6,940 Crore has been approved for the scheme.

Regarding the Committee's recommendation for the Department to seriously examinethe issue of creating tariff barriers so that it becomes attractive to produce API in the country, it is to mention that this aspect has also been examined while drafting the Production Linked Incentive scheme and once sufficient domestic manufacturing starts happening only then the imposition of trade barriers will be considered. With the successful implementation of these schemes, it is expected that India would be well-positioned as a global hub for manufacturing of critical KSMs/Drug Intermediates and APIs along with the final drug formulations.

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO.3

TECHNOLOGICAL UPGRADATION OF PHARMACEUTICAL INDUSTRY.

The Committee note that the World Health Organization- Good Manufacturing Practices (WHO-GMP) certificate is a mandatory requirement in most global markets for companies to be able to sell their medicines. It is difficult for the pharmaceutical Micro Small and Medium Enterprises (MSMEs) to establish and operate world class quality manufacturing and testing facilities on their own due to huge financial and technical investment involved. It is roughly estimated that 80% of the pharmaceutical MSMEs in the country are not WHO-GMP compliant. Upgrading to such standards require investment to the tune of Rs. 5-10 crore per unit as per the feedback from the stakeholders. (Ref: P4 Para 2.1) The Committee observe that the Department has launched a scheme viz. Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) to facilitate pharmaceutical MSMEs to upgrade their plant and machinery to World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets. Under the scheme, assistance in the form of interest subvention against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private sector will be provided to 250 pharmaceutical MSMEs of proven track record. The country requires Rs. 500 crore to Rs. 600 crore to convert the Pharma units in the country into WHO-GMP compliant. However the Committee are dismayed to note that the Department has been getting only a token allocation of Rs. 2 lakh for the scheme since 2018-19 including 2020-21 at BE stage which is a miniscule amount to start this important scheme for improving the standards of vast number of pharmaceutical MSMEs in the country and scheme has been a non-starter as no Public Sector Financial Institution(PSFI) has come on board to implement this

scheme. After discussing with various stake holders, guidelines of this scheme have been revised by the Department including the selection of PSFI. The Committee would like the Department to appreciate the fact that technology upgradation to the level of WHO-GMP compliance will not happen unless the pharmaceutical SMEs are physically and financially assisted. The Committee would simultaneously want the Department to appreciate that WHO-GMP compliance not only helps the exporting pharmaceutical units but also enhances the quality of drugs available for domestic consumption. Therefore, the Committee would like the Ministry to formulate a concrete scheme involving real assistance to the SMEs for making them WHO-GMP compliant. Even if the scheme provides assistance to a few units each year (in view of paucity of funds), it should extend substantial assistance to the units beyond encouragement and guidance. The Committee in this regard recommend that swift action should be taken by the Department to implement the scheme in a time bound manner. For this to take place, the Committee strongly recommend that the Finance Ministry should enhance the budgetary allocation for this scheme so that the Department can implement this scheme for technology up-gradation of the pharmaceutical MSMEs. The Department shall also take up this matter at the highest level with the Ministry of Finance and this recommendation made by the Committee should be conveyed to Finance Ministry for necessary action at its level. In case of funding difficulties, the Department may consider to create a Special purpose Vehicle (SPV) in partnership with Private Pharmaceutical Industry who are dependent on the MSMEs sector to produce their pharmaceutical products so that a specific investment fund may be created for the technological up-gradation of Pharma MSMEs.

Reply of the Government

The department has prepared a revised Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) based on the feedback received from Industry Associations and other stakeholders. In the revised scheme, the number of pharma MSMEs to be covered is about 4,500 units. The financial implication for supporting 4500 Pharma MSMEs will be of Rs. 5,000 crores for seven-year period from 2020-2027. Further, in the revised scheme, provision is made to engage Public Sector Financial Institution (PSFI) by nomination basis as well. The department will take up the matter of enhancement of budgetary allocation with the ministry of Finance after approval of the revised scheme.

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO 4

PROMOTION OF ADVANCED RESEARCH IN DRUGS AND MEDICAL DEVICES FIELDS

The Committee note that Pharmaceutical industry is a knowledge intensive industry and needs continuous development of new Chemical/ biological entities,

updating/improvement in the processes, develop new drug delivery systems etc. to remain competitive. To sustain its edge in domestic and export markets, Pharma industry has to invest continuously in R& D. Besides, academia-Industry linkage has been identified as a basic requirement for translating research into development (commercialization) and Innovation. The Committee note that the Department of Pharmaceuticals has also constituted an Inter-Departmental Committee (IDC) on 9th January, 2019 to institutionalize a robust mechanism to ensure economy, efficiency, effectiveness and transparency in the arena of Pharmaceutical research. Since it is very much necessary to have a strong Research and Development base in the country to remain competitive at the global level and to meet the medicines needs of this huge country, the Committee would like to recommend that the Department should take concrete steps for promoting advance research in drugs and medical devices fields in collaboration with National Institute of Pharmaceutical Education and Research (NIPER), Public Sector Undertakings like BCPL and KAPL and private research laboratories. In this regard the Committee strongly recommend that the Department shall request the Ministry of Finance to make separate budgetary allocation for Research and Development segment for pharmaceuticals sector.

Reply of the Government

A new Sub-head of Research and Development in Pharma Sector under the Umbrella Scheme has been opened in Detailed Demand for Grants 2020-21 so that a proper account of funds allocated/utilized for R&D could be maintained. Department has proposed in EFC to establish a Center of Excellence in Anti-virus Discovery and Development at NIPER-Mohali at estimated cost of Rs. 160.73 crore, Centre of Excellence in Medical Device with estimated cost of Rs. 149.85 crore at NIPER-Ahmedabad and Establishment of a National Centre of R&D in Bulk Drugs (NCRDBD) with estimated cost of Rs. 99.31 crore at NIPER-Hyderabad. These centres will augment R&D in Pharma Sector. A committee comprising experts from eminent Government as well as Private Organizations has been duly constituted with the approval of Hon'ble Minister (Chemicals and Fertilizers, Government of India) to draft and finalize policy on R&D and Innovation including Academia-Industry linkage in Pharmaceuticals and medical Devices on 29th May 2020 in pursuance of the decision taken in the presentation of the Sectoral Group of the Secretaries before the Council of Ministers, with a mandate to give its Report in three months.

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO 5

ASSISTANCE TO MEDICAL DEVICES INDUSTRY

The Committee note that the country imports almost 85% of all its medical device needs. The country largely imports high technology medical equipments and electronics which constitute 66 % of the country's import basket. The

Committee note that for the year 2020-21 the Department had proposed an amount of Rs 30.00 crore under the sub-scheme 'Assistance to Medical Device Industry for Common Facility Centre' but the Finance Ministry has allocated only Rs 7.50 crore. The Committee note that in principle approvals have been given for four proposals under this sub-scheme. The Department stated that under this sub-scheme, the proposals received from State Governments of Andhra Pradesh, Telangana, Tamil Nadu and Kerala have been given 'in-principle' approval. Also, the proposal of Andhra Pradesh has been given final approval for financial assistance of Rs. 25 crore. The other three proposals will also be considered for final approval after receipt of Detailed Project Reports (DPRs) for which the concerned State Governments have been reminded by the Department. The Committee feel that the setting up of common facility for Medical Device Industry would play major role in promotion of medical device industry in the country. Therefore, the Committee strongly recommend that the Department should take concrete steps in coordination with State/UT Government concerned to implement this sub scheme effectively. The steps to be taken by the Department should involve a dedicated infrastructure with free or nearly free land, easy access to low cost finances and technological assistance as without these basic ingredients, it is not possible to motivate any entrepreneur to set up new business in a sector where imports have a lower cost in general. The Department should also pursue with the Ministry of Finance to increase budgetary allocation for this scheme keeping in mind the priority of medical devices industry for the health sector. The Department shall also take up this matter at the highest level with the Ministry of Finance and this recommendation made by the Committee should be conveyed to Finance Ministry for necessary action at its level.

Reply of the Government

The sub-scheme termed as "Assistance to Medical Device Industry for Common Facility Centre" is a Central Sector Scheme under the umbrella scheme for Development of Pharmaceutical Industry. The total size of the above sub-scheme was Rs.100 Crores for 2018-2020. The sub-scheme proposed to provide a one-time grant-in-aid to the tune of Rs. 25 Crore or 70% of the project cost, whichever is less, to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose. The purpose of the grant was to render the financial assistance for establishment of common facilities in any upcoming Medical Device Parks promoted by State Governments/State Corporations.

However, it was realized that creation of common facilities requires much more investment and the Department proposed revision of the existing sub-scheme. The revised sub-scheme is termed as "Promotion of Medical Device Parks" with an outlay of Rs. 400 Crore for financing 4 medical device parks from financial year 2020-21 to 2024-25.

The revised sub-scheme will provide grant-in-aid to 4 Medical Device Parks with a maximum limit of Rs. 100 Crore or 70% of the project cost of Common Infrastructure Facilities, whichever is less. In case of Hilly States and North East Region, the grant-in-aid would be Rs. 100 Crore per Park or 90% of the project cost of Common Infrastructure Facilities, whichever is less. The Scheme would be implemented through a State Implementing Agency (SIA) to be formed by the

concerned State Government. The Scheme has been approved by the Union Cabinet on 20.03.2020. The detailed guidelines of the scheme are under preparation. For allocation of sufficient funds, the Department will take up the matter with the Ministry of Finance at the appropriate time.

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO 6

PRADHAN MANTRI BHARTIYA JANAUSHADI PARIYOJANA (PMBJP)

The Committee note that the Department of Pharmaceuticals has launched a Scheme called "Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)" with the objective of making quality generic medicines available at affordable prices to all. Presently 6141 PMBJP Kendras are functional across the country and out of this, 524 PMBJP Kendras are functional in 117 aspirational districts which are considered relatively backward 697 districts of the country have been already covered and the target has been fixed to cover all districts by 31st March, 2020. The Government of India has requested the State Governments to provide space in government hospitals for the opening of Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs). As on date the product basket of PMBJP comprises of 900 drugs and 154 surgicals. (Ref:P4-5/Para2.3). Further, the Committee are pleased to note that the Bureau of Pharma PSUs of India (BPPI) which is the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), is increasing self-sufficiency and reducing dependence on grants provided by Department of Pharmaceuticals (DoP) as envisaged in the guidelines of the scheme. Under the Vision Plan of BPPI the target is to open 1000 more Kendras by 31st March 2024, to enhance basket of medicines up to 2000 drugs and 300 surgicals, and establishment of an effective IT-enabled logistics and supply-chain system for ensuring real-time distribution of medicines at all outlets to avoid stock outs. Since PMBJP Kendras can play a vital role in providing quality medicines at affordable prices, the Committee recommend the following:-

i. Concrete steps should be taken to open more number of PMBJP Kendras in all Tehsil (sub districts) of the country with particular emphasis on opening PMBJP Kendras in the rural, hilly and remote areas of the country.
ii. Initiative should be made to open PMBJP Kendras in Primary Health Centres and Government hospitals across the country and for this purpose State/UT Governments should be impressed upon at the highest level to provide free space at PHCs and Government hospitals to open PMBJP Kendras in their premises.
iii. Presently there are four warehouses of BPPI at Gurgaon, Chennai, Bengaluru and Guwahati. Two more are likely to be opened each in Western and Central India. Since the absence of warehouse in each state may result in longer time for delivery of drugs to PMBJP Kendras, the

Committee recommend that warehouses may be opened in each state for timely distribution and delivery of medicines to PMBJP Kendras.

iv. The feasibility of providing financial assistance to PMBJP Kendras to provide basic infrastructure support to them viz. refrigerators etc. for storing the medicines safely in them may be examined for implementation.

v. The Public Sector Enterprises under the Department viz. KAPL and BCPL may be given equal opportunity to sell their products for PMBJP scheme so as to enable their successful running with profit and at the same time ensuring procurement of quality medicines under the scheme.

vi. The Department should also examine a better way to compensate the *Jan Aushadhi* store owners where their compensation could be based on the number of medicines sold rather than percentage of the value which is already extremely low.

Reply of the Government

(i) The recommendation has been noted. The SFC for the period till 2024-25 has approved additional incentives for PMBJP kendras opened in inspirational districts (backward districts), in Himalayan and Island territories and North-Eastern States.

(ii) The State/ UT governments have been requested at various levels up to the level of Hon'ble Minister of Chemicals and Fertilizers for allotment of rent free space at prominent place of the PHC/CHC, Civil Hospitals for opening of Janaushadhi Kendras. Further, BPPI has entered MoUs with various State Governments like Jharkhand, Uttar Pradesh, Meghalaya, Maharashtra etc. for opening of Janaushadhi Kendra in Primary Health Centers and Government hospitals. As a result of these efforts, 919 PMBJP kendras have been opened inside government hospitals/premises till 20.05.2020.

(iii) In addition to the warehouses of BPPI for supporting end-to-end supply chain system, 34 Distributors in various states/UTs are also serving the purpose of distribution of medicines to PMBJP Kendras across the country. These distributors maintain their individual warehouses and keep required inventory. Any kendras has option to either directly place order to BPPI or procure from the distributors.

(iv) The **S**FC for the financial year 2020-2021 to 2024-2025 has approved additional financial one time grantsof Rs 2 lakhs for basic infrastructure, viz., furniture, fixtures & IT infrastructure for PMBJK opened in aspirational districts (backward districts), in Himalayan, Island territories and North-Eastern States. The same additional incentive is available to stores opened by women entrepreneur, Divyang, SC and ST entrepreneurs.

(v) BPPI is a society formed by Pharma PSUs and their MDs are members of the Governing Council. BPPI procures medicines through open e-tendering on the Central Public Procurement (CPP) portal from WHO-GMP certified drug manufacturers. There is no restriction on Public Sector Enterprises under the Department as well as private companies for participation in tenders of BPPI. For effective supplies, BPPI enters in to Rate Contract with the Private companies and

Public Sector Enterprises under the Department viz. KAPL, BCPL, etc.at competitive rates, wherever feasible.

(vi) The SFC for the financial year 2020-2021 to 2024-2025has enhanced incentive up to Rs. 5.00 lakh @ 15% of monthly purchase made subject to a ceiling of Rs 15,000/- per month. Further, additional one time grant of Rs 2 lakhs is also to be provided for stores opened in backward areas.

RECOMMENDATION NO 7

SCHEME FOR DEVELOPMENT OF PHARMACEUTICAL INDUSTRY

The Committee note that the Department has an umbrella scheme namely 'Scheme for Development of Pharmaceutical Industry'. Its objective is to increase the efficiency and competitiveness of domestic pharmaceutical industry so as to enable them to play a lead role in the global market and to ensure accessibility, availability and affordability of quality pharmaceuticals of mass consumption. This scheme is a Central Sector Scheme (CSS) with a total financial outlay of Rs. 480 crore for a three year period starting from 2017-18 to 2019-20 and comprises of the following five sub-schemes:- (a) Cluster Development Programme for Pharma Sector (CDP-PS) (renamed as Assistance to Pharmaceutical Industry for Common Facilities); (b)Assistance to Bulk Drug Industry for Common Facility Centre; (c) Assistance to Medical Device Industry for Common Facility Centre;(d) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS); and (e) Pharmaceutical Promotion and Development Scheme. The Department admitted that despite the best efforts made by the Government, the sub scheme 'Assistance to Pharma Industry for Common Facilities' under the umbrella scheme "Development of Pharmaceutical Industry" did not receive a good response in 2017-18, 2018-2019 and 2019-2020. For the sub-scheme "Assistance to Bulk Drug Industry for Common Facility Centre", "Assistance to Medical Device Industry for Common Facility Centre" and "Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) only token amount was sanctioned during the period. The Department has now received proposals from the State Governments for setting up Common Facility Centres under these two sub-schemes and in-principle approvals have also been given for setting up of these Centres. Since the Department requires budgetary allocation for implementation of these sub-schemes, the Department had sought an amount of Rs. 144.01 crore from the Ministry of Finance for the implementation of Umbrella Scheme of "Development of Pharmaceuticals Industry" during 2020-21 but only Rs. 42.05 crore has been provided to the Department.

The Committee note that during the last 3 year that is 2017-18, 2018-19 and 2019-20 the Department has been allocated 12.03 crore, 4.00 crore & 3.49 crore respectively as Revised Estimate allocation. Out of this the percentage utilisation was only 15.18%, 70.25% and 77.07% respectively. Though the percentage utilisation has increased over a period of time but the Department is unable to utilise 100% allocation. The Committee also note that for the year 2020-21 the Department has been allocated Rs. 42.05 crore against their demand of Rs.144.01 crore. Though the allocation has increased substantially by Rs. 38.56 crore as compared to last year Revised Estimate figures, but the Department has

asked for more allocation that is Rs. 144.01 crore for implementation of the umbrella scheme of Development of Pharma Industries. The Committee hope that the Department would be able utilise their initial allocation and ask for more allocation in the Supplementary Demand For Grants (2020-21) by reflecting their good physical and financial progress.

Reply of the Government

The recommendation of the committee has been noted. The department would do its best to utilise the funds allocated initially to it and to seek more funds by showing good progress.

RECOMMENDATION NO 10

CONSUMER AWARENESS, PUBLICITY AND PRICE MONITORING SCHEME

The Committee note that the sub-scheme of Consumer Awareness, Publicity and Price Monitoring (CAPPM) has two components viz. Price Monitoring and Consumer Awareness and Publicity. Under the first component, Price Monitoring and Resource Units (PMRUs) are set up in Stats/UTs. 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. They are also responsible for collection, compilation and analysis of market-based data of scheduled as well as non-scheduled formulations. Eleven Price Monitoring and Resource Units (PMRUs) have so far been set up in States of Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh and Mizoram. Six more PMRUs are targeted to be set up during 2020-21 (Ref: Para 4.28 Chapter-IV). The Committee note that during the year 2019-20 Rs 4.00 crore was allocated at both BE and RE stages under this scheme from which Rs. 2.00 crore was for opening PMRUs and another Rs 2.00 crore was for publicity and consumer awareness campaigns. The allocation has been increased slightly to Rs 4.50 crore for 2020-21. However, the Committee observe that during 2019-20, NPPA could utilise only Rs. 2.32 crore approx. till 18.2.2020. Out of which only 0.59 crore was spent on consumer awareness and publicity purpose. This shows that NPPA is unable to utilise even the meagre sum of Rs. 2.00 crore for consumer awareness and publicity. The Committee while taking note that the allocation of Rs. 4.50 crore for the year 2020-21 is quite nominal for both the components *viz.* PMRUs and consumer awareness and publicity purpose have their apprehension that the Department would be able to fully utilize this meagre amount. The Committee is deeply concerned that on the one hand the Government is committed to provide low cost health services for all citizens, while on the other hand, the pharmaceutical companies continue to charge extremely high prices even for the routine medicines. While the physical 'offerings' by the Government are extremely promising (Jan Aushadhi Yojana, Pradhan Mantri Swasthya Suraksh Yojana, etc.), the consumers have to be educated in an aggressive manner. This requires large volume of funds as these funds will have a huge impact on the well-being of the citizens of the country. The Committee, therefore recommend that the Department should augment their scheme of Consumer Awareness, Publicity and Price Monitoring (CAPPM) by optimum utilization of funds for both the components i.e. PMRUs and consumer awareness

and publicity and thereafter seek for additional allocation in their Supplementary Demand for Grants 2020-21. Further the Committee recommend that Department and NPPA should take active steps to open PMRUs in all 37 States/UTs in a time bound manner so that the hands of NPPA are strengthened and is empowered to monitor the quality and standards of the drugs sold in the market across the country.

Reply of the Government

As per the revised target for the year 2019-20, PMRUs have been set up in total 12 States/ UTs, viz., Kerala, Gujarat, Odisha, Rajasthan, Haryana, Nagaland, Tripura, Uttar Pradesh, Punjab, Andhra Pradesh, Mizoram and Jammu & Kashmir. There are two components of CAPPM scheme viz. (i) 'Grant in Aid General to PMRU' and (ii) 'Advertising and Publicity' with Budget Estimate (B.E.) of Rs. 2/- Crore each (Total B.E. of Rs. 4/- Crore). During the F.Y. 2019-20 the position of BE, RE and actual expenditure incurred under each component of CAPPM scheme is mentioned as below:

(Rs. In crore)

Sl. No.	**Particulars**	**BE**	**RE**	**Amount Utilization Incurred %**
1	Grant in Aid General to PMRU	2.00	2.00	2.00 (100%)
2	Advertising and Publicity	2.00	2.00*	*100% Approx.

In view of the above the NPPA was able to utilise almost 100% amount under both the components of CAPPM Scheme for the F.Y. 2019-20.

Keeping in view the utilisation of Budget of Rs. 4 crore during the F.Y. 2020-21, the allocation of budget of Rs. 4.5 crore for the F.Y. 2020-21 is justified as with the current setup of 12 PMRUs and target to set-up additional six (6) PMRUs in the States/UTs during the F.Y. 2020-21 the activities will be increased.

The suggestion of the Committee to take active steps for setting up of PMRUs in all the States/ UTs in a time bound manner is well noted.

CHAPTER – III

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

NIL

CHAPTER – IV

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

RECOMMENDATION NO 11

DISINVESTMENT OF PROFIT MAKING PHARMA PSUS

The Committee are concerned to note that out of five Public Sector Undertakings (PSUs) under the Department of Pharmaceuticals, Karnataka Antibiotics & Pharmaceuticals (KAPL) and Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) are profit making PSUs. The Government has decided for strategic sale of BCPL and strategic disinvestment of 100% Government of India equity in KAPL. As regards BCPL, Hon'ble High Court of Kolkata set aside the decision of its strategic sale. Now an appeal has been made before the Division bench of the Court. The Department of Pharmaceuticals opposed the strategic disinvestment of KAPL as the company is profit making and has been assigned the responsibility of being the sole manufacturer of Oxytocin for domestic consumption. This matter of sole Oxytocin production rights to KAPL is presently *sub-judice* in the Hon'ble Supreme Court. The Committee are perturbed to note the decision of NITI Aayog to sell/ disinvest these two profit making PSUs of this priority sector which is concerning the health of huge population of this vast country. Entirely leaving drug manufacturing at the hands of private sector may not be a prudent step as these PSUs may provide required quantity of essential medicines at affordable prices at times of needs particularly during epidemic and pandemic outbreak of diseases. The Committee, therefore, strongly recommend that the decision for the strategic sale/ disinvestment of KAPL and BCPL should be revisited by the Government in the public interest. The Committee should be informed of the action taken in this matter. This recommendation of the Committee should also be sent to NITI Aayog for its specific reply within three months.

Reply of the Government

The recommendation of the Committee was forwarded earlier to MoF (DIPAM) and NITI Aayog on 14.02.2020 for reconsideration of the decision of strategic sale of KAPL and BCPL. Further, as directed by the Committee, the matter is again being taken up with NITI Aayog/ Ministry of Finance for reconsideration of strategic sale of profit making PSUs.

COMMENTS OF THE COMMITTEE

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

CHAPTER-V

RECOMMENDATION NO 8

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATIONAL AND RESEARCH (NIPER)

The Committee note that there are seven NIPERs at Mohali, Guwahati, Ahmedabad, Hajipur, Raebareli, Kolkata and Hyderabad. Out of these only NIPER-Mohali, which was established in 1998, is fully operational and others which were operational since 2007-08 are functioning only with the help of Mentor Institutes. These new NIPERs are lacking infrastructure and regular academic and other staff. The Department had made additional demand of Rs 300.00 crore for NIPERs during 2019-20 but only Rs.10.00 crore was added at RE stage as token supplementary fund after re-appropriation from matching savings from another scheme to make the total allocation to Rs 160 crore from Rs. 150.00 crore at BE stage in 2019-20. The Committee note that an amount of Rs. 450.00 crore was sought for the Scheme of NIPERs by the Department for the year 2020-21. However, the Department submitted that only Rs. 202.45 crore has been allocated, which will affect the implementation of the various activities of the NIPERs particularly the construction of campuses for NIPERs. In this regard, the Committee note that the Expenditure Finance Committee (EFC) in its meeting held on 26.03.2018 recommended for continuation and strengthening of the existing six NIPERs, namely, Ahmedabad, Guwahati, Hyderabad, Hajipur, Kolkata and Raebareli during the period 2017-18 to 2019-20 at a total cost of Rs. 959.53 crore. However, the construction of 90% of campus of NIPER, Guwahati has only been achieved during the period. EFC also allocated Rs. 465 crore for equipping the laboratories of the six existing NIPERs. The EFC also recommended that setting up of the proposed four new NIPERs at Madurai and in the states of Maharashtra, Chhattisgarh and Rajasthan be deferred. It suggested that the same may be reviewed in the year 2020 by the Department during the Fifteenth Finance Commission period (2020-25). The Department is in the process of preparing a fresh EFC proposal for the existing and newly proposed NIPERs seeking sufficient funds for construction of their campuses, equipping the laboratories as well as other administrative and academic expenses. It will seek funds as proposed/ approved under the fresh EFC. The Committee are dismayed to note that the proposal for the purchase of equipment for NIPERs has been deferred till the approval of the fresh EFC proposal beyond March, 2020.The Committee note that the NIPERs have been set up as Institutes of National Importance but the inordinate delay in allocation of requisite amount of fund since their inception is ruining the purpose for which these Institutes were set up. The Committee therefore strongly recommend that the Government look into this matter on priority basis and make adequate budget allocations for these institutes to construct

building infrastructure, upgrade their laboratories and appoint regular staff and faculty.

Reply of the Government

Department has sent a EFC Note to the Department of Expenditure seeking funds of Rs. 4300.00 crore to set up regular campuses of all NIPERs (Ahmedabad, Hyderabad, Kolkata, Hajipur, Raebareli, Jhalawar, Nagpur, New Raipur and Bengaluru) Centres of Excellence at three NIPERs (Mohali, Ahmedabad & Hyderabad) to have well equipped laboratories and Product Development Centres at each NIPER etc. More than 50% of the posts sanctioned by Department of Expenditure have already been filled-up by NIPERs. The remaining will be filled up shortly after restrictions imposed due to COVID 19 are lifted.

RECOMMENDATION NO 9

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

The Committee note that the National Pharmaceutical Pricing Authority (NPPA), was established through a Government of India resolution dated 29th August , 1997 as an independent body of experts for price control of essential and life saving medicines. NPPA is an attached office of the Department of pharmaceuticals and implements the National Pharmaceuticals Pricing Policy 2012 and the Drugs (Prices Control) Orders as amended from time to time which were issued by the Department. The Committee note that National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) has the objective 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 pharma industry, thereby meeting the goals of employment and shared economic well-being for all. In pursuance to the NPPP-2012, the Drugs (Prices Control) Order, 2013 (DPCO-2013) was made to regulate the prices of medicines. In this regard, the Committee note that the NPPA regulates 19 to 20 percent of drugs prices based on market averages. But for the remaining non-scheduled drugs which are almost 80 percent, companies are free to fix price as per market dynamics and their annual price cannot increase more than 10 percent. The Committee therefore strongly recommend that ambit of scheduled drugs should be increased so that NPPA can control the prices of more drugs. The Committee also recommend that NPPA should monitor effectively to ensure that the annual price increase shall not increase more than 10% and strict action should be taken against those drug manufacturing companies which increase the price of medicines beyond 10%. National Pharmaceutical Pricing Authority capped the Trade Margin of all the non-scheduled formulations of select 30 Anti-Cancer drugs (42 molecules) as recommended by Expert Committee of Ministry of Health

& Family Welfare, under the 'Trade margin Rationalization Approach' and as a result, a the total 526 brands of these medicines have shown reduction in MRP. The Committee while appreciating the policy of Trade Margin Rationalization (TMR) as a forward step in the direction of making branded medicines affordable to poor and deprived patients, recommend that the Department in coordination with NPPA should extend the benefits of TMR to more non-scheduled drugs and medical devices and the action taken in this regard should be conveyed to the Committee.

Reply of the Government

(i) The National List of Essential Medicines (NLEM) is issued by the Ministry of Health & Family Welfare (MoHFW). The Department of Pharmaceuticals (DoP) includes the formulations in schedule-I of the DPCO, 2013 which are called scheduled formulations by adopting the medicine listed in the NLEM. The NPPA fixes the ceiling prices of scheduled formulations listed in Schedule-I of the DPCO. A Standing National Committee on Medicines (SNCM) has been constituted by the Ministry of Health & Family Welfare in July, 2018 to review and revise the National list of Essential Medicines (NLEM) by way of additions and deletions in the existing NLEM in the context of contemporary knowledge of use of therapeutic products in health & hygiene of general public.

(ii) During stakeholder consultation with various pharma associations on the issue of trade margin capping, the associations representing pharma MSMEs have conveyed their opposition to bringing any ceilings on trade margins saying that it will be detrimental to the MSMEs. Covid Pandemic and lockdown measures have already impacted these MSMEs adversely. In such a scenario, DoP is not proposing to bring TMR at present.

(iii) The ceiling price fixed by the NPPA is applicable across the board. The ceiling price are also to be followed in medicines supplied / sold by the hospitals.

(iv) The issue regarding 'hospitals charging patients for medicines which are never administered' at recommendation 9 (para 4.28 of Chapter IV) has been referred to MoHFW on 29.05.2020 by Department of Pharmaceuticals as desired by the Committee.

RECOMMENDATION NO. 12

SETTLEMENT OF LIABILITIES OF CLOSED PHARMA PSUS

The Committee also note that the Government is in the process of settling the liabilities including payment of dues to employees of closed PSUs under the Department viz Indian Drugs& Pharmaceuticals Ltd. (IDPL), Hindustan Antibiotics

Ltd (HAL) and Rajasthan Drugs and Pharmaceuticals Limited (RDPL) through sale of their movable and immovable properties. Since this is a time consuming process, the Government has approved a budgetary support to the tune of Rs. 330.35 crore as loan to these three PSUs for settling pending salaries/ VRS dues of their employees. Out of total sanction of Rs. 230.15 crore to HAL, Department has released only Rs. 116.30 crore to HAL on 30.12.2019. RDPL was provided the entire sanctioned loan of Rs. 43.70 crore. It is understood that IDPL is yet to be given its sanctioned loan of Rs. 6.50 crore. Since it is very much necessary to settle the salaries/VRS dues of these three closed PSUs, the Committee recommend that the Department should release entire amount of loan sanctioned to HAL and IDPL for the purpose within a definite period of time. The Committee further note that during the year 2020-21 an amount to the tune of Rs. 7.18 crore has been allocated. The Committee have their doubt that this meagre amount of Rs. 7.18 crore would be able to settle pending salaries/VRS dues of the employees of the above mentioned PSUs. The Committee therefore recommend to revisit this allocation to ensure that all employees get their salary/VRS dues in time.

Reply of the Government

All funds as sanctioned/ allocated by the Ministry of Finance in respect of PSUs during the year 2019-20, were released (Rs.4.28 crores to IDPL, Rs.280.16 crore to HAL and Rs.48.71 crores to RDPL). The request for additional allocation apart from the BE of Rs.7.18 crore provided in the current Financial year 2020-21 shall be taken up with them on priority basis.

New Delhi;

8 February, 2021
19 Magha, 1942 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson
Standing Committee on
Chemicals and Fertilizers

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Appendix – II

(*Vide* Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE EIGHTH REPORT (SEVENTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2019-20) ON DEMAND FOR GRANTS (2020-21) OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS).

I	Total No. of Recommendations	12
II	Observations / Recommendations which have been accepted by the Government: (*Vide* Recommendation Nos. 1, 2,3,4,5,6,7,11,13 and 14)	8
	Percentage of Total	66.66%
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation No. Nil)	Nil
	Percentage of Total	0.0%
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. Nil)	1
	Percentage of Total	8.33%
V	Observations / Recommendations in respect of which final replies of the Government are still awaited: (*Vide* Recommendation Nos. 8,9,10 and 12)	3
	Percentage of Total	25.00%

MINUTES OF THE FIRST SITTING OF THE
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2020-21)

The Committee sat on Monday, the 12th October, 2020 from 1100 hrs. to 1145hrs. in Committee Room 'B', Parliament House Annexe, New Delhi

Ms. Kanimozhi Karunanidhi - Chairperson

MEMBERS
LOK SABHA

2. Shri Deepak Baij
3. Shri Ramesh Chandappa Jigajinagi
4. Shri Kripanath Mallah
5. Shri Satyadev Pachauri
6. Shri Arun Kumar Sagar
7. Shri Uday Pratap Singh
8. Shri Indra Hang Subba

RAJYA SABHA

9. Shri M.V. Shreyams Kumar
10. Shri Jaiprakash Nishad
11. Shri Anthiyur P. Selvarasu
12. Shri Arun Singh
13. Shri A.D. Singh
14. Shri Vijay Pal Singh Tomar
15. shri K. Vanlalvena

SECRETARIAT

1. Shri Manoj K. Arora - Officer on Special Duty (LSS)
2. Shri Anil Kumar Srivastava - Director
3. Shri Panna Lal - Under Secretary

Session I

XXXX XXXX XXXX

Session-II

XXXX XXXX XXXX

2. The Committee thereafter took up for consideration and adoption of following draft Action Taken Reports:

(i) Action Taken Report on Demands for Grants 2019-20 (Department of Chemicals and Petrochemicals);

(ii) Action Taken Report on Demands for Grants 2019-20 (Department of Fertilizers);

(iii) Action Taken Report on Demands for Grants 2019-20 (Department of Pharmaceuticals);

(iv) Action Taken Report on Study of System of Fertilizer Subsidy (Department of Fertilizers).

(v) Action Taken Report on Demands for Grants 2020-21 (Department of Chemicals and Petrochemicals);

(vi) Action Taken Report on Demands for Grants 2020-21 (Department of Fertilizers);

(vii) Action Taken Report on Demands for Grants 2020-21 (Department of Pharmaceuticals).

3. After deliberations, the Committee adopted the draft Action Taken Report(s) unanimously without any change/amendments. The Committee also authorized the Chairperson for finalize and present the Action Taken Reports to the Parliament.

4. The Committee also decided to hold its next sitting tentatively in the second week of November, 2020.

The Committee then adjourned.

XXXX matters not related to this report.