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STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2016-17)

SIXTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations/Recommendations contained in the Thirty Second Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on "Demands for Grants (2017-18) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

सत्यमेव जयते

REPORT

LOK SABHA SECRETARIAT
NEW DELHI

August, 2017/ Shravana, 1939 (Saka)

CC&F No.37

THIRTY SEVENTH REPORT

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
(2016-17)

SIXTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations/Recommendations contained in the Thirty Seventh Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on "Demands for Grants (2017-18) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

Presented to Lok Sabha on 10.08.2017

Laid in Rajya Sabha on 10.08.2017

सत्यमेव जयते

LOK SABHA SECRETARIAT
NEW DELHI

August, 2017/ Shravana, 1939 (Saka)

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Shri Anandrao Adsul - Chairperson

MEMBERS
LOK SABHA

2. Shri George Baker
3. Smt. Anju Bala
4. Shri B.N Chandrappa
5. ShriSankar Prasad Datta
6. Smt. Veena Devi
7. Shri R. Dhruvanarayana
8. Shri Innocent
9. Shri K Ashok Kumar
10. Shri Chhedi Paswan
11. Smt. Kamla Devi Patle
12. Shri S. Rajendran
13. Shri Kotha Prabhakar Reddy
14. Dr. Kulamani Samal
15. Dr. Uma Saren
16. Dr. Krishna Pratap Singh
17. Shri Taslimuddin
18. Smt. Rekha Arun Verma
19. Shri Kirti Vardhan Singh
20. Shri Pankaj Chaudhary
21. Dr. (Smt.) Ratna De (Nag)

RAJYA SABHA

22. Shri Biswajit Daimary
23. Shri Prem Chand Gupta
24. Shri Sanjay Dattatraya Kakade
25. Shri Surendra Singh Nagar
26. Shri Narayan Lal Panchariya
27. Shri K Parasaran
28. Dr. Sanjay Sinh
29. Shri Abdul Wahab
30. Smt. Roopa Ganguly

31.* Vacant

SECRETARIAT

1.	Shri Vinod Kumar Tripathi	-	Joint Secretary
2.	Shri A.K. Srivastava	-	Director
3.	Shri R.C. Sharma	-	Deputy Secretary
4.	Shri S. Vijayaraghavan	-	Sr. Committee Assistant

** Demise of Shri Palvai Govardhan Reddy, MP (RS) on* 09.06.2017.

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INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2016-2017) having been authorised by the Committee to present the Report on their behalf, present this Thirty Seventh Report (Sixteenth Lok Sabha) on Action Taken by the Government on the observations/ recommendations contained in the Thirty Second Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2016-2017) on Demands for Grants (2017-2018) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Thirty Second Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 20.03.2017. The Action Taken replies of Government to all observations/ recommendations contained in the Report were received on 04.07.2016. The Standing Committee on Chemicals and Fertilizers (2016-2017) considered and adopted this Report at their sitting held on 09.08.2017.

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

4. For facility of reference and convenience, the observations/ recommendations of the Committee have been printed in bold letters in the body of the Report.

New Delhi;
09 August, 2017
18 Shravana, 1939 (Saka)

ANANDRAO ADSUL
Chairperson
Standing Committee on
Chemicals and Fertilizers

REPORT

CHAPTER I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Thirty-Second Report (Sixteenth Lok Sabha) of the Committee on the Demands for Grants 2017-18 of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 20.3.2017. In all, the Committee made 7 Observations / Recommendations in the Report.

2. Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the Thirty-Second Report within three months from the date of presentation of the Report, i.e., by 20.7.2017. The Action Taken Replies of the Government in respect of all the 7 Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their O.M. No. 23003/1/2017-IFD dated 4.7.2017. These Replies have been categorized as follows:-

(i) Observations / Recommendations that have been accepted by the Government :-
Sl.Nos. 6 and 7 (Total =2)

This may be included in Chapter II of the Draft Report.

(ii) Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply :-
Sl.No. Nil (Total = Nil)

This may be included in Chapter III of the Draft Report.

(iii) Observations / Recommendations in respect of which replies of the Government have not been accepted by the Committee :-
Sl.No. 5 (Total = 1)

This may be included in Chapter IV of the Draft Report.

(iv) Observations / Recommendations in respect of which final replies of the Government are still awaited:-
Sl.Nos. 1,2, 3 and 4 (Total =4)

These may be included in Chapter V of the Draft Report.

3. The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in Chapter-I and V of this Report should be furnished expeditiously.

4. The Committee will now deal with action taken by the Government on all the Observations/Recommendations which still require reiteration or merit comments.

A. Need for scheme for financing common facility centre at API Parks

Recommendation Sl. No.1

5. While stressing that dependence on imports for its bulk drugs is not good for the country the Committee had recommended as under:-

"The committee note that the vision of the department of pharmaceutical (dop), ministry of chemicals & fertilizers is to catalyze and encourage quality, productivity and innovation in bulk drug sector and to enable the Indian Bulk Drug Industry to reduce the dependency on import of bulk drugs. For this, world class quality manufacturing facilities with high level of productivity with innovative capabilities are required. However, these are on one hand very capital intensive and cannot be established and opened by bulk drug manufacturing units on their own due to financial constraints. The committee also note that the department proposes in the first instance to start a scheme for financing Common Facility Centres (CFCS) at 3 Bulk Drug/API parks in the country at a total cost of rs. 450 crores. Some of the indicative activities under this common facilities are effluent treatment plants, captive power plant, steam and cooling and water systems, incubation facilities, common logistic facilities, advance common testing centre, regulatory awareness facility centre.

The committee are of the view that industry's dependence on imports for bulk drugs is not good for the country. The committee, feel that the new scheme will help the pharma industry to concentrate on the core issue of manufacturing of bulk drugs as the common facilities will be available in the pharma bulk drug parks. The committee, therefore, recommend that the scheme for financing Common Facility Centres (cfcs) at 3 Bulk Drugs/API parks may be started immediately and completed in a fixed time frame as in-principle approval of the department of expenditure has been received for implementing the scheme.

The committee also recommend that the department may explore to start the Bulk Drug parks in the campus of Pharma PSUs where the benefit of infrastructure and expertise of the Pharma PSUs can be harnessed and the resources available this can be utilised to the maximum in order to make Indian Bulk Drug Industry a global leader in bulk drug production. The committee would like to be informed of the action taken in this regard.

<u>Reply of the Government</u>

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

"with reference to para 2 of the recommendations, it may be noted that before the scheme for financing common facilities at 3 bulk drug parks could be appraised and approved for implementation, ministry of finance's new instructions were received on 5.8.2016. As per the new instructions, a new scheme for development of pharma industry consisting of the following two existing schemes namely (i) cluster development programme for pharma sector (cdp-ps) and (ii) pharmaceutical promotion development scheme and the following three new schemes namely (i) assistance to bulk drug industry for common facilitation centre (ii) assistance to medical device industry for common facilitation centre and (iii) pharmaceutical technology upgradation assistance scheme (PTUAS)were sent to d/o expenditure for in-principle approval. Department of expenditure have suggested certain changes vide their om dated 5.4.2017. Action for evaluation of two existing schemes and in principle approval for new schemes is being taken accordingly.

With reference to suggestion for starting bulk drug park in the campus of pharma psus, it may be noted that the government has decided on 28.12.2016 to sell the surplus land of Indian Drugs and Pharmaceuticals limited (IDPL), Hindustan Antibiotics Ltd (HAL), and Bengal Chemical and Pharmaceuticals Limited (BCPL) to government agencies as would be required to clear their outstanding liabilities, implement Voluntary Retirement Scheme (VRS)/ Voluntary Separation Scheme (VSS) to pave way for their closure, manage the remaining land in accordance with the guidelines of department of investment pubic assets management (DIPAM) and if need be, vest it in a Special Purpose Vehicle (SPV). The government has decided that after liabilities have been met, balance sheet cleansed and VRS/VSS effected, IDPL and RDPL be closed and HAL &BCPL sold strategically. After this decision, the department cannot proceed with setting up of bulk drug parks in the campus of pharma PSUs.

Comments of the Committee

7. **The Committee noted that the Department proposes to start a scheme for Financing Common Facility Centres (CFCs) at 3 Bulk Drug/API Parks in the country and the scheme may be started immediately and completed in a fixed time frame as in-principle approval of the Department has been received for implementation of the scheme. In their Action Taken Reply the Department has stated that Department of Expenditure have suggested certain changes *vide* their OM dated 5.4.2017. Action for evaluation of the existing schemes and in-principle approval for new schemes is being taken accordingly. The Committee therefore recommend that evaluation of two existing schemes and in-principle approval for new schemes may be taken at the earliest in a time bound manner. The Committee are of the view that in the absence of any existing schemes *viz* Cluster Development Scheme for Pharma Sector and Pharmaceutical promotion Development Scheme, the growth of Pharmaceutical Industry is hampering. It is therefore expedient that these two schemes may be evaluated and implemented along with the three new schemes without any delay.**

The Committee, reiterate their early recommendation that the imports may be resorted by companies when the same is absolutely necessary for the Industry and the Pharmaceutical companies may be encouraged to produce Bulk Drugs in the country in order to make available cheap and quality drugs to the consumers in India.

The Committee are pained to note that IDPL and RDPL will be closed and HAL and BCPL would be sold strategically and as such the Department cannot proceed with setting of Bulk Drugs Park in the campus of Pharma PSUs. The Committee, therefore recommend that the Government should revisit their plan for closure of IDPL and RDPL. The Committee would like to be apprised in this regard at the earliest.

B. Need for allocation of funds as per the Demands and requirements of the Department.

Recommendation Sl. No.2

8. While expressing the view that the severe cut in outlays schemes would have an adverse impact on the implementation of projects and schemes of the Department, the Committee had recommended as under:-

"The Committee note that for the Annual Plan 2017-18, the Department of Pharmaceuticals proposed an outlay of Rs.1373.35 crore but only Rs.195.71 crore was approved by the Ministry of Finance for BE 2017-18. Hence there is very meagre allocation to NIPERs. NIPERs have been allocated an amount of Rs.100 crore only against the proposed amount of Rs.1171.36 crore.

The Committee are of the view thatthemeagre allocation of funds to NIPERs will hamper the construction activities of NIPER Guwahati and NIPER Ahmedabad and it will also affect the operationalization of new NIPERS. Besides this allocations for NPPA and assistance to PSUs is also less. The Committee, feel that severe cut in outlay schemes would have an adverse impact on the implementation of projects and scheme. The Committee are dismayed to note that approved allocation falls far short of the urgent fund requirements projected by the Department for carrying out its laid down mandate and its vision for development of Indian Pharmaceutical Industry. The Committee, therefore, recommend that the Department should take up the issue of fund allocation with the Ministry of Finance and impress upon them to allocate funds as per the Demands and requirements of the Department of Pharmaceuticals so that the project like NIPER are completed timely. The Committee, would like to be informed of the action taken in this regard".

<u>Reply of the Government</u>

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

"NIPER Division sought fund of Rs. 1171 crore (approx.) for the scheme for the BE 2017-18 and Rs. 67.56 crore fund for BE 2017-18 for Salary and Grant in Aid to NIPER Mohali. However, the Ministry of Finance has allocated only Rs. 127.73 crore. The meagre allocation made by Ministry of Finance will affect the construction activity of NIPER, Guwahati and NIPER Ahmedabadas well as the operationalization of new NIPERs. Ministry of Finance has requested NITI Ayog to carry out an evaluation of functioning of NIPERs. Based on evaluation report, Department of Pharmaceuticals would take up the matter with Ministry of Finance for allocation of additional funds for construction activities etc., by way of EFC proposal in respect of NIPERs Guwahati, Ahmedabad and Madurai.

<u>Comments of the Committee</u>

10. **The Committee note that only an amount of Rs.127.73 crore has been sanctioned against the proposed amount of Rs.1171.36 crore to NIPER. The Department in their Action Taken Reply have stated that meagre allocation made by the Ministry of Finance will affect the construction activities of NIPER Guwahati, Ahmedabad as well as the operationalization of new NIPERs. Ministry of Finance has requested NITI Aayog to carry out an evaluation of functioning of NIPERs. Based on evaluation report Department of Pharmaceuticals would take up the matter with the Ministry of Finance.**

While noting the above points, the Committee express their displeasure over the facts that till now neither the construction activities of NIPER Guwahati and Ahmedabad have been completed nor the operationalization of NEW NIPERs taken place for want of adequate funds. The Committee, therefore, recommend that the Department should take up the matter with the Ministry of Finance to get adequate allocation after the evaluation of study done by Niti Ayog. In this regard it is also expedient that Niti Ayog complete their study at the earliest so that the establishment of all NIPERs in their own campus may take place in a time bound manner and they could achieve their avowed objectives to establish its links with Pharmaceutical Industry, nurture and promote quality and excellence in Pharmaceutical Education and Research. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

C Need to Allocate funds commensurate to the outlays proposed by the Department.

Recommendation Sl. No.3

11. While expressing that the Department should take up the matter for sanction of additional funds with the Ministry of Finance and impress upon them to allocate adequate funds as per the demand of the Department for implementation of various important projects, the Committee had recommended as under:-

> "The Committee note that RE 2016-17 was Rs.211.40 crore and BE 2017-18 is Rs.247.74 crore. The Committee also observe that Rs.74.62 crore has been allocated for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and the same will be used in the effective implementation of PMBJP and opening of more Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) across the country. The Committee also note that The Department has prepared an umbrella Scheme for Development of Pharma Industry wherein schemes like Schemes for Assistance to Bulk Drugs Industry for Common Facilitation Centre, Assistance to Medical Device for Common Facilitation Centre, Cluster Development are proposed to be taken up for promoting the growth of Pharma & Medical device industry. Besides, the Pharmaceuticals Technology Up gradation Assistance Scheme(PTUAS) and Pharmaceuticals Promotion Development Scheme (PPDS) are also proposed to be continued to facilitate growth of the industry. The proposal is presently under consideration with Ministry of Finance and after its appraisal and approval, the Department will seek additional funds.
>
> The Committee, therefore, desires the Department to strongly take up the matter with the Ministry of Finance and to impress upon them for sanction of additional funds for the projects as these projects will help the Pharma Industries to achieve the goal of 'Make In India' and will also lead to reduction in imports and increase in Exports of the Pharma products and generate more employment and foreign exchange and also help the pharma sector to play a leading role in the global market".

Reply of the Government

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

> "In BE 2017-18, Department of Pharmaceuticals proposed Rs. 75.00 crore for PMBJP while Rs. 74.62 crore has been allocated for the scheme. The allocated funds of Rs. 74.62 crore will be used by Bureau of Pharma PSUs of India (BPPI), the implementing agency of PMBJP, in the smooth functioning of BPPI and its scheme PMBJP. Opening of more PMBJKs in the country would be attempted as project by BPPI.
>
> Further, the Department had prepared an umbrella scheme for Development of Pharma Industry under which five sub schemes viz., Schemes for Assistance to Bulk Drugs Industry for Common Facilitation Centre, Assistance to Medical Device for Common Facilitation Centre, Schemes for Cluster Development, Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) and Pharmaceutical Promotion Development Scheme (PPDS) for which Department of Expenditure were requested for giving their In- Principle approval to the proposal. The reply from Department of Expenditure has been received on 5.4.2017 .Their suggestions in terms of MoF OM No. 24(35)/PF-II/2012 dated 5.8.2016, EFC proposal for the umbrella scheme would be circulated to concerned Ministries would be circulated shortly".

<u>Comments of the Committee</u>

13. **The Committee observed that the Department has prepared an Umbrella Scheme for the Development of Pharma Industry and the proposal is under consideration with Ministry of Finance and after its apprisal and approval the Department will seek additional funds.**

In their Action Taken Reply the Department stated that Rs.74.62 crore has been allocated to PMBJP which would be utilised by Bureau of Pharma PSUs in India (BPPI) the implementing agency of PMBJP, in the smooth functioning of BPPI and its scheme PMBJP. Further, the Department of Expenditure were requested for giving in-principle approval to the five sub-schemes viz (i) Schemes for Assistance to Bulk Drugs Industry for Common Facilitation Centre (ii) Assistance to Medical Device for Common Facilitation Centre, (iii) Schemes for Cluster Development (iv) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) and (v) Pharmaceutical Promotion Development Scheme (PPDS) and the reply in this regard has been received from Department of Expenditure on 5.4.2017. The Committee, therefore, recommend that the Department of Pharmaceuticals should spell out its action plan the action proposed to be taken in respect of all the five schemes and remove bottlenecks, if any in order to implement all its five sub-schemes. The Committee, would like to be apprised of the action plan formulated by the Department for implementing the five schemes.

D Need for Promotion of Medical Devices Industry.

<u>Recommendation Sl. No.4</u>

14. While expressing concern for Development of Indigenous Medical Devices Industry the Committee had recommended as under:-

"The Committee note that Medical device industry is a multi-product industry, producing wide range of products. India is growing as a key market for Medical Devices and Diagnostics. Indian Medical Device industry depends on imports up to an extent of almost 70%. Most hi-tech innovative products and technology originate from a well-developed eco-system and innovation cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports. The Committee also note that the Department has a proposal for Scheme for Development of Common Facilitation Centres under the Umbrella Scheme for Development of Pharmaceuticals Industry. This sub-scheme proposes for Financing Common Facility Centres (CFCs) at Medical Device Parks in the country at a total cost of Rs.250 crores.

The Committee, are of the view that Developing Indigenous Medical Device Industry is of paramount importance and fits in realizing the 'Make in India' goal of the Government and it will also reduce the dependence on import of medical devices. For this world class quality manufacturing facilities with high level of productivity with innovative capabilities cannot be established and opened by medical devices manufacturing units on their own due to financial constraints. The Committee been informed that Government of India does not establish pharma parks but is only providing common facilities at Medical Device Parks thus it is imperative that it may be impressed upon State Governments/ Union Territories to set up Pharma Parks in their States/Union Territories so that the money allocated under the scheme of Common Facilities is optimally utilised. The Committee, therefore, recommend that the proposal of development of common facility centres at medical device park in the country may be planned and initiated and the matter of early allocation of funds for implementation of this important scheme may please be taken up with the Ministry of Finance at the earliest. The Committee, would like to be informed of the action taken by the Department in this regard".

Reply of the Government

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

"To promote Medical Device Sector, a sub-scheme namely "Assistance to Medical Device Industry for Common Facility Centers" has been proposed under umbrella scheme for "Development of Pharmaceuticals Industry". In Principle approval of Department of Expenditure has been sought for the umbrella scheme, which is still awaited".

Comments of the Committee

16. **The Committee noted that Medical Device Industry in India is growing as a key market for medical devices and diagnostics and the Industry depends on imports upto an extent of 70 per cent. The Committee, feel that need of the hour is Developing Indigenous Medical Devices Industry as it fits in realising the objectives of 'Make in India' goal of the Government.**

In their Action Taken Reply the Department has stated that to promote Medical Device Industry a sub-scheme namely 'Assistance to Medical Device Industry for Common Facility Centres' has been proposed under 'Umbrella Scheme for Development of Pharmaceutical Industry and in-principle approval of Department of Expenditure is still awaited.

The Committee, therefore, recommend that the Department should impress upon the Department of Expenditure to give in-principle approval to the scheme of Medical Device Industry on priority basis as it is not only vital for meeting the needs of the huge requirement of medical devices in the country but it will also save much needed foreign exchequer by way of reduction in imports of these devices. The Committee would like to be apprised of the action taken in this regard.

E Need for Revival of Pharma Public Sector Undertakings

Recommendation Sl. No.5

17. While observing that the main objective of setting up of Pharma PSUs, not the earn profits the Committee had recommended as under:-

"The Committee note that Regarding disinvestment, closure etc., a Committee under Vice Chairman, NITI Aayog after careful scrutiny and analysis of 74 loss making/ sick/ non-performing CPSEs, whose operations are of non-strategic nature, advised for revival/ sale/ closure/ management contract/ strategic disinvestment, as applicable in each case. The Committee also note that Minister of Finance, Minister of Road Transport & Highways and Minister of Chemicals & Fertilizers comprehensively examined the status of all Pharmaceutical Companies in the public sector and noted that all PSUs except KAPL are sick or incipient sick. IDPL, BCPL and HAL were declared sick and formally referred to BIFR since 1992, 1993 and 1997 respectively. The earlier revival/rehabilitation packages of IDPL, HAL & BCPL have failed to achieve desired results. The production activities in RDPL too have stopped after fire in the plant in October, 2016. HAL and RDPL are not in a position to even pay the salaries to their employees. All these companies possess substantial land assets. The Government has decided on 28.12.2016 to sell that much of surplus land of Indian

Drugs & Pharmaceuticals Limited (IDPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL) Hindustan Antibiotics Limited (HAL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL) to Government agencies as would be required to clear their outstanding liabilities, implement Voluntary Retirement Scheme(VRS)/Voluntary Separation Scheme (VSS) to pave way for their closure, manage the remaining land in accordance with guidelines of Department of Investment and Public Assets Management/ Department of Public Enterprises and if need be, vest it in a Special Purpose Vehicle (SPV). The Government has decided that after liabilities have been met, balance sheet cleansed and VRS/VSS effected, IDPL and RDPL be closed & HAL and BCPL sold strategically.

The Committee are deeply pained to note that the Government has decided to sell surplus land of IDPL, RDPL, HAL and BCPL that after liabilities have been met, balance sheet cleansed and VRS/VSS effected IDPL and RDPL be closed and HAL and BCPL be sold strategically. The Committee, feel that the main objective of setting up Pharma PSUs were not to earn profits but to encourage indigenous production of bulk drugs and life saving drugs and formulations and to support various health programmes of the Government. The Committee observe that Pharma PSUs supply generic medicines all over the country. It is also observed that BCPL has made a stellar performance during the last two years. While in the year 2014-15 its MOU Assessment was good and Corporate Governance was fair, it became excellent both in respect of MOU Assessment and Corporate Governance during the year 2015-16. The Committee also observe that BCPL is planning to start Anti-Snake Venom Project (ASVS) project as the product is not available in the country at the moment in required quantity as both Government sector units namely BCPL and Central Research Institute (CRI), Kasuali have stopped production of ASVS for the last 10 years. Due to non availability of fund and also due to project cost escalation the project could not be commissioned. The Committee feel that the Department is not taking the matter seriously inspite of the fact that 2 lakh people are suffering from snake bite every year. The Committee, therefore recommend that BCPL may not be closed by strategically selling and instead be supported in its special cause especially when it is on the path of regaining its old glory. The Committee, further observe that funds to be allocated to Pharma PSUs had been consistently delayed due to the lackadaisical approach of the Department to impress upon the Ministry of Finance of the urgent need for funds to complete the projects resulting in untimely closure of IDPL and RDPL plants and strategic sale of BCPL and HAL. The Committee therefore recommend that even if there is any little scope for running the PSUs in PPP mode or other mode the Department should consider this and instead of closing the IDPL and RDPL and option of strategic sales of BCPL and HAL, all may be fully revived. The Committee, would like to be informed of the action taken in this regard".

Reply of the Government

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

"It is submitted that during last three years, the total sale of all the five PSUs were around Rs. 500-550 crore out of total turnover of about Rs. 2.00 lakh crore Indian Pharma Industry, which is not even 0.5% of total Indian Pharma Industry.

Total contribution of the PSUs in supply of generic medicines under PMBJP is also less than 5%.Pharma CPSUs have not been identified as priority sector by NITI Aayog's Committee on sick/ loss making/ non-performing PSUs.

The Pharma PSUs except KAPL, are incurring huge losses continuously for the past several years. Net Worth of the PSUs is in negative. As such the Government has decided to close IDPL and RDPL and strategically sell BCPL and HAL.

As regards revival of BCPL, it is submitted that although during recent year has achieved net profit but its net worth is in negative only. The Cabinet has decided not to close the company but put on strategic sale. Thus, the company will remain operational, only its management would be changed. Anti SnakeVenum Serum, can be manufactured by the company but from its own funds. Department had sought Rs. 28.10 crore under Budget Estimates (BE) for 2017-18. However, Ministry of Finance has not allocated any amount for the project".

<u>Comments of the Committee</u>

19. The Committee were deeply pained to note that the Government has decided to sell surplus land of IDPL, RDPL, HAL and BCPL and after liabilities have been met, balance sheet cleansed and VRS/VSS effected, IDPL and RDPL shall be closed and HAL and BCPL shall be sold strategically. The Committee had recommended that BCPL may not be closed by strategically selling and instead be supported in its special causes especially when it is on the path of regaining its old glory. The Committee, therefore recommended that even if there is any little scope for running the PSUs in PPP mode or other mode the Department should consider this and instead of closing the IDPL and RDPL and option of strategic sales of BCPL and HAL.

In their Action Taken replies the Committee find that Government is adamant to close IDPL and RDPL and strategically sell BCPL and HAL and the company will remain operational, only its management would be changed.

The Committee, therefore, recommend that the Department should try to sell IDPL and RDPL by strategic sales as it will make the company operational and be a morale booster to the employees of these companies and try to revive BCPL and HAL. The Committee would like to be informed of the action taken by the Government in this regard.

F PRADHAN MANTRI BHARTIYA JANAUSHADI PARIYOJANA

<u>Recommendation Sl. No.6</u>

20. While expressing the need for quick implementation of the Scheme, the Committee had recommended as under:-

"The committee note that for effective implementation of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) key areas of significance were identified and major changes in PMBJP were made by waiving application fee. An amount of Rs. 2.5 lakhs shall be extended to NGOs/agencies/individuals for establishing PMBJK in government premises like hospitals/ medical colleges/Railways/Sate Transport/ Co-operation/ Municipalities/ Post offices etc. where space is provided free of cost by Government to operating agency. Trade margins have been revised from 16% to 20% for Retailers and from 8% to 10% for Distributors.

The Committee also note that 802 JAS have been opened till 22.2.2017. The Committee also note that attainment of target of opening 3000 JAS appears to be difficult as on date and that the success of this initiative largely dependents on other agencies such as Ministry of Health & Family Welfare, different State Governments, active co-operation of Hon. Members of Parliament, Hon. Members of different

Legislative Assemblies, IMA, Hospitals run by Private Groups and Charitable Institutions, NGOs, Practicing Doctors, etc. State Governments are having their own schemes like free distribution of medicines. Non-prescription of Generic Medicines by the doctors is another critical factor.

The Committee are perturbed to note that inspite of Committee's repeated recommendations for quick implementation of the scheme initiated in 2008, the scheme has not been fully implemented throughout the country. In view of this Committee once again recommend that the Department should take up the issue on war footing level to overcome the hurdles by involving other agencies such as Ministry of Health & Family Welfare, different State Governments, IMA, Hospitals run by Private Groups and Charitable Institutions, NGOs, Practicing Doctors, etc. for compulsory prescription of generic medicines by doctors and also keeping the supply chain in preparedness so that the requirements are met fully without any delay and also to overcome the requirement of Pharmacists to man the PMBJK and try to achieve the targets of opening 3000 number of PMBJK within the specified time. The Committee would like to be informed of the action taken in this regard".

Reply of the Government

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

"For effective implementation of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' (PMBJP) and opening of more 'Pradhan Mantri Bhartiya Janaushadhi Kendras' (PMBJKs) across the country, following actions have been taken by the Government:

(i) Application fee for opening of PMBJKs was waived off so that more people can apply under the scheme.

(ii) In order to expedite the opening of more PMBJKs by March 2017, BPPI had released advertisements in various newspapers in the country during December 2016 and applications have been invited from private individuals. The response has been overwhelmingly encouraging and as on 10.04.2017, 28486 applications have been received out of which in-principle approval has been given in 24770 applications.

(iii) As on 10.04.2017, 1136 PMBJKs have been opened in the different parts of the country. Out of 1136 PMBJKs in the country, 286 PMBJKs have been opened by the Central/State Government or by Pharmacists/NGOs/Agencies/Charitable Organisations in Government building premises.

(iv) On increasing trade margins of Retailers and Distributors, people have shown the interest from across the country for doing the business under the scheme. As a result of which 1136 PMBJKs have been opened in the country and 44 Distributors have been appointed while 6 more distributors have been considered to be appointed. Besides this, 8 Carrying & Forwarding (C&F) agents have been appointed while 6 more C&F agents have been considered to be appointed.

(v) In order to encourage doctors to prescribe generic medicines, the Medical Council of India has amended the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 on 08.10.2016 to provide a new para 1.5 regarding use of generic names of drugs which provides as under:
"Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs."

(vi) Rule 65 of Drugs & Cosmetics Rule, 1945 does not permit Pharmacist to substitute the brand prescribed by the Doctor by a generic drug. In order to allow Pharmacists to substitute generic drugs against the branded drugs in doctor prescriptions, Secretary (Pharma) wrote to Secretary (H&FW) vide D.O. No. 31026/87/2015-PI-II dated 08.06.2016 for making appropriate amendments in Rule 65 of D&C Rules, 1945. Department is periodically pursuing the matter with Ministry of Health & Family Welfare.

(vii) For directing the Doctors working in the Government hospitals for mandatory prescription in generic names of the drugs, Secretary (Pharma) has written to Secretary (H&FW)".

Comments of the Committee

22. **The Committee were perturbed to note that inspite of Committee's repeated recommendations for quick implementation of the Jan Aushadhi scheme initiated in 2008, the scheme had not been fully implemented throughout the country. The Committee had therefore recommended that the Department should take up the issue on war footing level by involving other agencies. The Department in their Action Taken Reply stated that as on 10.4.2017 1130 PMBJK have been opened in different parts of the country and 44 distributors have been appointed. To encourage doctors to prescribe generic medicines Medical Council of India has amended Indian Medical Council Regulations 2002. While appreciating the various efforts made by the Department of Pharmaceuticals the Committee hope that the all out efforts shall be made to make Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) successful. The Committee would like to be apprised of the action taken in this regard.**

G National Pharmaceuticals Pricing Authority.

Recommendation Sl. No. 7

23. While expressing that the Department should strongly take up the issue of One Time Settlement of the recovery of overcharged amount, the Committee had recommended as under:-

"The Committee note that National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers was formed by the Govt. of India vide Resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

The Committee also note that NPPA has initiated about 1493 cases of overcharging as on 31st December, 2016 (1285 cases under DPCO 1995 and 208 cases under DPCO 2013), where demand notices have been issued to pharmaceuticals companies. The demanded amount works out to Rs. 5037.64 crore (Rs.4956.48 crore under DPCO 1995 and Rs.81.16 crore under DPCO 2013) for sale of medicine at prices higher than that fixed by NPPA /Government. However only an amount of Rs. 640.16 crore (Rs 536.81 crore under DPCO 1995 and Rs.103.35 crore under DPCO 2013) has been recovered on 31st December, 2016 from pharmaceutical companies. This includes an amount of Rs. 215 crore deposited by pharmaceutical companies in response to the verdict of the Supreme Court delivered on 20th July, 2016. Out of the balance outstanding amount of Rs. 4359.93 crore, Rs. 3460.32 crore is still locked up in litigation. The Committee, feel that time and money are wasted in legal disputes and every year the outstanding amount locked in litigation increases causing great loss to the exchequer, The Committee feel that had the One Time Settlement proposal been approved, by the Ministry of Finance almost all the outstanding amount would have been recovered and there would have been no litigation charges also. The Committee, therefore recommend that the Department should strongly take up the issue with the Ministry of Finance about the advantages of One Time Settlement as it will not only help in the early settlement of the outstanding amount but also save the expenditure incurred on the litigation. The Committee desire to be apprised of the detailed action taken in this regards".

Reply of the Government

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

"The proposal for having a Scheme for One Time Settlement for overcharging cases of DPCO- 1979 DPCO-1987 and DPCO-1995 is being suggested for inclusion in the proposed National Pharmaceuticals Policy, 2017 being contemplated by the Department".

Comments of the Committee

25. **The Committee noted that NPPA had initiated about 1493 cases of overcharging as on 31st December 2016 for sale of medicines at higher prices that that fixed by NPPA/Government. The Committee felt that a lot of time and money were wasted in legal dispute and every year the outstanding amount locked in litigation increases causing great loss to the exchequer. The Committee felt that had the One Time Settlement Proposal been approved by the Ministry of Finance, almost all the outstanding amount would have been recovered and there would be no litigation charges pending. The Department in its action taken replies has stated that the proposal for having a scheme for One Time Settlement for recovery of overcharging cases of DPCO 1979, DPCO 1987 and DPCO 1995 is being suggested for inclusion in the proposed National Pharmaceuticals Policy, 2017 and being contemplated by the Department.**

While appreciating the initiative taken by the Department to include One-Time Settlement Scheme for Overcharging cases in the proposed National Pharmaceutical Policy, 2017, the Committee hope that the National Pharmaceutical Policy, 2017 should be finalised in this calendar year at the earliest which would solve the long pending issues of litigation of overcharging at the earliest and thus augment the revenue of the Department. The Committee would like to be apprised in this regard at the earliest.

CHAPTER – II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendation Sl. No.6

The committee note that for effective implementation of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) key areas of significance were identified and major changes in PMBJP were made by waiving application fee. An amount of Rs. 2.5 lakhs shall be extended to NGOs/agencies/individuals for establishing PMBJK in government premises like hospitals/ medical colleges/Railways/Sate Transport/ Co-operation/ Municipalities/ Post offices etc. where space is provided free of cost by Government to operating agency. Trade margins have been revised from 16% to 20% for Retailers and from 8% to 10% for Distributors.

The Committee also note that 802 JAS have been opened till 22.2.2017. The Committee also note that attainment of target of opening 3000 JAS appears to be difficult as on date and that the success of this initiative largely dependents on other agencies such as Ministry of Health & Family Welfare, different State Governments, active co-operation of Hon. Members of Parliament, Hon. Members of different Legislative Assemblies, IMA, Hospitals run by Private Groups and Charitable Institutions, NGOs, Practicing Doctors, etc. State Governments are having their own schemes like free distribution of medicines. Non-prescription of Generic Medicines by the doctors is another critical factor.

The Committee are perturbed to note that inspite of Committee's repeated recommendations for quick implementation of the scheme initiated in 2008, the scheme has not been fully implemented throughout the country. In view of this Committee once again recommend that the Department should take up the issue on war footing level to overcome the hurdles by involving other agencies such as Ministry of Health & Family Welfare, different State Governments, IMA, Hospitals run by Private Groups and Charitable Institutions, NGOs, Practicing Doctors, etc. for compulsory prescription of generic medicines by doctors and also keeping the supply chain in preparedness so that the requirements are met fully without any delay and also to overcome the requirement of Pharmacists to man the PMBJK and try to achieve the targets of opening 3000 number of PMBJK within the specified time. The Committee would like to be informed of the action taken in this regard".

Reply of the Government

For effective implementation of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana'(PMBJP) and opening of more 'Pradhan Mantri Bhartiya Janaushadhi Kendras' (PMBJKs) across the country, following actions have been taken by the Government:

(i) Application fee for opening of PMBJKs was waived off so that more people can apply under the scheme.

(ii) In order to expedite the opening of more PMBJKs by March 2017, BPPI had released advertisements in various newspapers in the country during December 2016 and applications have been invited from private individuals. The response has been overwhelmingly encouraging and as on 10.04.2017, 28486 applications have been received out of which in-principle approval has been given in 24770 applications.

(iii) As on 10.04.2017, 1136 PMBJKs have been opened in the different parts of the country. Out of 1136 PMBJKs in the country, 286 PMBJKs have been opened by the Central/State Government or by Pharmacists/NGOs/ Agencies/ Charitable Organisations in Government building premises.

(iv) On increasing trade margins of Retailers and Distributors, people have shown the interest from across the country for doing the business under the scheme. As a result of which 1136 PMBJKs have been opened in the country and 44 Distributors have been appointed while 6 more distributors have been considered to be appointed. Besides this, 8 Carrying & Forwarding (C&F) agents have been appointed while 6 more C&F agents have been considered to be appointed.

(v) In order to encourage doctors to prescribe generic medicines, the Medical Council of India has amended the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 on 08.10.2016 to provide a new para 1.5 regarding use of generic names of drugs which provides as under: Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs.

(vi) Rule 65 of Drugs & Cosmetics Rule, 1945 does not permit Pharmacist to substitute the brand prescribed by the Doctor by a generic drug. In order to allow Pharmacists to substitute generic drugs against the branded drugs in doctor prescriptions, Secretary (Pharma) wrote to Secretary (H&FW) vide D.O. No.31026/87/2015-PI-II dated 08.06.2016 for making appropriate amendments in Rule 65 of D&C Rules, 1945. Department is periodically pursuing the matter with Ministry of Health & Family Welfare.

(vii) For directing the Doctors working in the Government hospitals for mandatory prescription in generic names of the drugs, Secretary (Pharma) has written to Secretary (H&FW).

Comments of the Committee

(Please see Para No.22 of Chapter- I of the Report)

Recommendation Sl. No. 7

The Committee note that National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers was formed by the Govt. of India vide Resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

The Committee also note that NPPA has initiated about 1493 cases of overcharging as on 31st December, 2016 (1285 cases under DPCO 1995 and 208 cases under DPCO 2013), where demand notices have been issued to pharmaceuticals companies. The demanded amount works out to Rs. 5037.64 crore (Rs.4956.48 crore under DPCO 1995 and Rs.81.16 crore under DPCO 2013) for sale of medicine at prices higher than that fixed by NPPA /Government. However only an amount of Rs. 640.16 crore (Rs 536.81 crore under DPCO 1995 and Rs.103.35 crore under DPCO 2013) has been recovered on 31st December, 2016 from pharmaceutical companies. This includes an amount of Rs. 215 crore deposited by pharmaceutical companies in response to the verdict of the Supreme Court delivered on 20th July, 2016. Out of the balance outstanding amount of Rs. 4359.93 crore, Rs. 3460.32 crore is still locked up in litigation. The Committee, feel that time and money are wasted in legal disputes and every year the outstanding amount locked in litigation increases causing great loss to the exchequer, The Committee feel that had the One Time Settlement proposal been approved, by the Ministry of Finance almost all the outstanding amount would have been recovered and there would have been no litigation charges also. The Committee, therefore recommend that the Department should strongly take up the issue with the Ministry of Finance about the advantages of One Time Settlement as it will not only help in the early settlement of the outstanding amount but also save the expenditure incurred on the litigation. The Committee desire to be apprised of the detailed action taken in this regards.

Reply of the Government

The proposal for having a Scheme for One Time Settlement for overcharging cases of DPCO- 1979 DPCO-1987 and DPCO-1995 is being suggested for inclusion in the proposed National Pharmaceuticals Policy, 2017 being contemplated by the Department.

Comments of the Committee

(Please see Para No.25 of Chapter- I of the Report)

CHAPTER – III

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

-NIL-

CHAPTER – IV

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

Recommendation Sl. No.5

The Committee note that Regarding disinvestment, closure etc., a Committee under Vice Chairman, NITI Aayog after careful scrutiny and analysis of 74 loss making/ sick/ non-performing CPSEs, whose operations are of non-strategic nature, advised for revival/ sale/ closure/ management contract/ strategic disinvestment, as applicable in each case. The Committee also note that Minister of Finance, Minister of Road Transport & Highways and Minister of Chemicals & Fertilizers comprehensively examined the status of all Pharmaceutical Companies in the public sector and noted that all PSUs except KAPL are sick or incipient sick. IDPL, BCPL and HAL were declared sick and formally referred to BIFR since 1992, 1993 and 1997 respectively. The earlier revival/rehabilitation packages of IDPL, HAL & BCPL have failed to achieve desired results. The production activities in RDPL too have stopped after fire in the plant in October, 2016. HAL and RDPL are not in a position to even pay the salaries to their employees. All these companies possess substantial land assets. The Government has decided on 28.12.2016 to sell that much of surplus land of Indian Drugs & Pharmaceuticals Limited (IDPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL) Hindustan Antibiotics Limited (HAL) and Bengal Chemicals & Pharmaceuticals Limited (BCPL) to Government agencies as would be required to clear their outstanding liabilities, implement Voluntary Retirement Scheme(VRS)/Voluntary Separation Scheme (VSS) to pave way for their closure, manage the remaining land in accordance with guidelines of Department of Investment and Public Assets Management/ Department of Public Enterprises and if need be, vest it in a Special Purpose Vehicle (SPV). The Government has decided that after liabilities have been met, balance sheet cleansed and VRS/VSS effected, IDPL and RDPL be closed & HAL and BCPL sold strategically.

The Committee are deeply pained to note that the Government has decided to sell surplus land of IDPL, RDPL, HAL and BCPL that after liabilities have been met, balance sheet cleansed and VRS/VSS effected IDPL and RDPL be closed and HAL and BCPL be sold strategically. The Committee, feel that the main objective of setting up Pharma PSUs were not to earn profits but to encourage indigenous production of bulk drugs and life saving drugs and formulations and to support various health programmes of the Government. The Committee observe that Pharma PSUs supply generic medicines all over the country. It is also observed that BCPL has made a stellar performance during the last two years. While in the year 2014-15 its MOU Assessment was good and Corporate Governance was fair, it became excellent both in respect of MOU Assessment and Corporate Governance during the year 2015-16. The Committee also observe that BCPL is planning to start Anti-Snake Venom Project (ASVS) project as the product is not available in the country at the moment in required quantity as both Government sector units namely BCPL and Central Research Institute (CRI), Kasuali have stopped production of ASVS for the last 10 years. Due to non availability of fund and also due to project cost escalation the project could not be commissioned. The Committee feel that the Department is not taking the matter seriously inspite of the fact that 2 lakh people are suffering from snake bite every year. The Committee, therefore recommend that BCPL may not be closed by strategically selling and instead be supported in its special cause especially when it is on the path of regaining its old glory. The Committee, further observe that funds to be allocated to Pharma PSUs had been consistently delayed due to the lackadaisical approach of the Department to impress upon the Ministry of Finance of the urgent need for funds to complete the projects resulting in untimely closure of IDPL and RDPL plants and strategic sale of BCPL and HAL. The

Committee therefore recommend that even if there is any little scope for running the PSUs in PPP mode or other mode the Department should consider this and instead of closing the IDPL and RDPL and option of strategic sales of BCPL and HAL, all may be fully revived. The Committee, would like to be informed of the action taken in this regard".

Reply of the Government

It is submitted that during last three years, the total sale of all the five PSUs were around Rs. 500-550 crore out of total turnover of about Rs. 2.00 lakh crore Indian Pharma Industry, which is not even 0.5% of total Indian Pharma Industry.

Total contribution of the PSUs in supply of generic medicines under PMBJP is also less than 5%.Pharma CPSUs have not been identified as priority sector by NITI Aayog's Committee on sick/ loss making/ non-performing PSUs.

The Pharma PSUs except KAPL, are incurring huge losses continuously for the past several years. Net Worth of the PSUs is in negative. As such the Government has decided to close IDPL and RDPL and strategically sell BCPL and HAL.

As regards revival of BCPL, it is submitted that although during recent year has achieved net profit but its net worth is in negative only. The Cabinet has decided not to close the company but put on strategic sale. Thus, the company will remain operational, only its management would be changed. Anti SnakeVenum Serum, can be manufactured by the company but from its own funds. Department had sought Rs. 28.10 crore under Budget Estimates (BE) for 2017-18. However, Ministry of Finance has not allocated any amount for the project.

Comments of the Committee

(Please see Para No.19 of Chapter- I of the Report)

CHAPTER – V

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

Recommendation Sl. No.1

The committee note that the vision of the department of pharmaceutical (dop), ministry of chemicals & fertilizers is to catalyze and encourage quality, productivity and innovation in bulk drug sector and to enable the indian bulk drug industry to reduce the dependency on import of bulk drugs. For this, world class quality manufacturing facilities with high level of productivity with innovative capabilities are required. However, these are on one hand very capital intensive and cannot be established and opened by bulk drug manufacturing units on their own due to financial constraints. The committee also note that the department proposes in the first instance to start a scheme for financing common facility centres (cfcs) at 3 bulk drug/api parks in the country at a total cost of rs. 450 crores. Some of the indicative activities under this common facilities are effluent treatment plants, captive power plant, steam and cooling and water systems, incubation facilities, common logistic facilities, advance common testing centre, regulatory awareness facility centre.

The committee are of the view that industry's dependence on imports for bulk drugs is not good for the country. The committee, feel that the new scheme will help the pharma industry to concentrate on the core issue of manufacturing of bulk drugs as the common facilities will be available in the pharma bulk drug parks. The committee, therefore, recommend that the scheme for financing common facility centres (cfcs) at 3 Bulk Drugs/API parks may be started immediately and completed in a fixed time frame as in-principle approval of the department of expenditure has been received for implementing the scheme.

The committee also recommend that the department may explore to start the bulk drug parks in the campus of Pharma PSUs where the benefit of infrastructure and expertise of the Pharma PSUs can be harnessed and the resources available this can be utilised to the maximum in order to make indian bulk drug industry a global leader in bulk drug production. The committee would like to be informed of the action taken in this regard.

Reply of the Government

With reference to para 2 of the recommendations, it may be noted that before the scheme for financing common facilities at 3 bulk drug parks could be appraised and approved for implementation, ministry of finance's new instructions were received on 5.8.2016. As per the new instructions, a new scheme for development of pharma industry consisting of the following two existing schemes namely (i) cluster development programme for pharma sector (cdp-ps) and (ii) pharmaceutical promotion development scheme and the following three new schemes namely (i) assistance to bulk drug industry for common facilitation centre (ii) assistance to medical device industry for common facilitation centre and (iii) pharmaceutical technology upgradation assistance scheme (PTUAS)were sent to d/o expenditure for in-principle approval. Department of expenditure have suggested certain changes vide their om dated 5.4.2017. Action for evaluation of two existing schemes and in principle approval for new schemes is being taken accordingly.

With reference to suggestion for starting bulk drug park in the campus of pharma psus, it may be noted that the government has decided on 28.12.2016 to sell the surplus land of Indian Drugs and Pharmaceuticals limited (IDPL), Hindustan Antibiotics Ltd (HAL), and Bengal Chemical and Pharmaceuticals Limited (BCPL) to government agencies as would be required to clear their outstanding liabilities, implement Voluntary Retirement Scheme (VRS)/ Voluntary Separation Scheme (VSS) to pave way for their closure, manage the remaining land in accordance with the guidelines of department of investment pubic assets management (DIPAM) and if need be, vest it in a special purpose vehicle (spv). The government has decided that after liabilities have been met, balance sheet cleansed and vrs/vss effected, IDPL and RDPL be closed and HAL &BCPL sold strategically. After this decision, the department cannot proceed with setting up of bulk drug parks in the campus of pharma PSUs.

Comments of the Committee

(Please see Para No.7 of Chapter- I of the Report)

Recommendation Sl. No.2

The Committee note that for the Annual Plan 2017-18, the Department of Pharmaceuticals proposed an outlay of Rs.1373.35 crore but only Rs.195.71 crore was approved by the Ministry of Finance for BE 2017-18. Hence there is very meagre allocation to NIPERs. NIPERs have been allocated an amount of Rs.100 crore only against the proposed amount of Rs.1171.36 crore.

The Committee are of the view thatthemeagre allocation of funds to NIPERs will hamper the construction activities of NIPER Guwahati and NIPER Ahmedabad and it will also affect the operationalization of new NIPERS. Besides this allocations for NPPA and assistance to PSUs is also less. The Committee, feel that severe cut in outlay schemes would have an adverse impact on the implementation of projects and scheme. The Committee are dismayed to note that approved allocation falls far short of the urgent fund requirements projected by the Department for carrying out its laid down mandate and its vision for development of Indian Pharmaceutical Industry. The Committee, therefore, recommend that the Department should take up the issue of fund allocation with the Ministry of Finance and impress upon them to allocate funds as per the Demands and requirements of the Department of Pharmaceuticals so that the project like NIPER are completed timely. The Committee, would like to be informed of the action taken in this regard.

Reply of the Government

NIPER Division sought fund of Rs. 1171 crore (approx.) for the scheme for the BE 2017-18 and Rs. 67.56 crore fund for BE 2017-18 for Salary and Grant in Aid to NIPER Mohali. However, the Ministry of Finance has allocated only Rs. 127.73 crore. The meagre allocation made by Ministry of Finance will affect the construction activity of NIPER, Guwahati and NIPER Ahmedabadas well as the operationalization of new NIPERs. Ministry of Finance has requested NITI Ayog to carry out an evaluation of functioning of NIPERs. Based on evaluation report, Department of Pharmaceuticals would take up the matter with Ministry of Finance for allocation of additional funds for construction activities etc., by way of EFC proposal in respect of NIPERs Guwahati, Ahmedabad and Madurai.

Comments of the Committee

(Please see Para No.10 of Chapter- I of the Report)

Recommendation Sl. No.3

The Committee note that RE 2016-17 was Rs.211.40 crore and BE 2017-18 is Rs.247.74 crore. The Committee also observe that Rs.74.62 crore has been allocated for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and the same will be used in the effective implementation of PMBJP and opening of more Pradhan Mantri Bhartiya

Janaushadhi Kendra (PMBJK) across the country. The Committee also note that The Department has prepared an umbrella Scheme for Development of Pharma Industry wherein schemes like Schemes for Assistance to Bulk Drugs Industry for Common Facilitation Centre, Assistance to Medical Device for Common Facilitation Centre, Cluster Development are proposed to be taken up for promoting the growth of Pharma & Medical device industry. Besides, the Pharmaceuticals Technology Up gradation Assistance Scheme(PTUAS) and Pharmaceuticals Promotion Development Scheme (PPDS) are also proposed to be continued to facilitate growth of the industry. The proposal is presently under consideration with Ministry of Finance and after its appraisal and approval, the Department will seek additional funds.

The Committee, therefore, desires the Department to strongly take up the matter with the Ministry of Finance and to impress upon them for sanction of additional funds for the projects as these projects will help the Pharma Industries to achieve the goal of 'Make In India' and will also lead to reduction in imports and increase in Exports of the Pharma products and generate more employment and foreign exchange and also help the pharma sector to play a leading role in the global market ".

Reply of the Government

In BE 2017-18, Department of Pharmaceuticals proposed Rs. 75.00 crore for PMBJP while Rs. 74.62 crore has been allocated for the scheme. The allocated funds of Rs. 74.62 crore will be used by Bureau of Pharma PSUs of India (BPPI), the implementing agency of PMBJP, in the smooth functioning of BPPI and its scheme PMBJP. Opening of more PMBJKs in the country would be attempted as project by BPPI.

Further, the Department had prepared an umbrella scheme for Development of Pharma Industry under which five sub schemes viz., Schemes for Assistance to Bulk Drugs Industry for Common Facilitation Centre, Assistance to Medical Device for Common Facilitation Centre, Schemes for Cluster Development, Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) and Pharmaceutical Promotion Development Scheme (PPDS) for which Department of Expenditure were requested for giving their In-Principle approval to the proposal. The reply from Department of Expenditure has been received on 5.4.2017 .Their suggestions in terms of MoF OM No. 24(35)/PF-II/2012 dated 5.8.2016, EFC proposal for the umbrella scheme would be circulated to concerned Ministries would be circulated shortly".

Comments of the Committee

(Please see Para No.13 of Chapter- I of the Report)

Recommendation Sl. No.4

The Committee note that Medical device industry is a multi-product industry, producing wide range of products. India is growing as a key market for Medical Devices and Diagnostics. Indian Medical Device industry depends on imports up to an extent of almost 70%. Most hi-tech innovative products and technology originate from a well-developed eco-system and innovation cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports. The Committee also note that the Department has a proposal for Scheme for Development of Common Facilitation Centres under the Umbrella Scheme for Development of Pharmaceuticals Industry. This sub-scheme proposes for Financing Common Facility Centres (CFCs) at Medical Device Parks in the country at a total cost of Rs.250 crores.

The Committee, are of the view that Developing Indigenous Medical Device Industry is of paramount importance and fits in realizing the 'Make in India' goal of the Government and it will also reduce the dependence on import of medical devices. For this world class quality manufacturing facilities with high level of productivity with innovative capabilities cannot be established and opened by medical devices manufacturing units on their own due to financial constraints. The Committee been informed that Government of India does not establish pharma parks but is only providing common facilities at Medical Device Parks thus it is imperative that it may be impressed upon State Governments/ Union Territories to set up Pharma Parks in their States/Union Territories so that the money allocated under the scheme of Common Facilities is optimally utilised. The Committee, therefore, recommend that the proposal of development of common facility centres at medical device park in the country may be planned and initiated and the matter of early allocation of funds for implementation of this important scheme may please be taken up with the Ministry of Finance at the earliest. The Committee, would like to be informed of the action taken by the Department in this regard".

Reply of the Government

To promote Medical Device Sector, a sub-scheme namely "Assistance to Medical Device Industry for Common Facility Centers" has been proposed under umbrella scheme for "Development of Pharmaceuticals Industry". In Principle approval of Department of Expenditure has been sought for the umbrella scheme, which is still awaited".

Comments of the Committee

(Please see Para No.16 of Chapter- I of the Report)

New Delhi;
09 August, 2017
18 Shravana, 1939 (Saka)

ANANDRAO ADSUL
Chairperson
Standing Committee on
Chemicals and Fertilizers

Appendix – II

MINUTES OF THE EIGHTEENTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2016-17)

The Committee sat on Wednesday, the 09 August, 2017 from 1500 hrs. to 1540 hrs. in Room No. 139, Parliament House Annexe, New Delhi.

PRESENT

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri George Baker
3. Smt. Anju Bala
4. Smt. Veena Devi
5. Shri K. Ashok Kumar
6. Smt. Kamla Devi Patle
7. Shri S. Rajendran
8. Dr. Kulamani Samal
9. Dr. Ratna De (Nag)

RAJYA SABHA

10. Shri Narayan Lal Panchariya

SECRETARIAT

1.	Shri Vinod Kumar Tripathi	-	Joint Secretary
2.	Shri A. K. Srivastava	-	Director
3.	Shri R. C. Sharma	-	Deputy Secretary

2. At the outset, the Hon'ble Chairperson welcomed the Members of the Committee.

3. The Committee thereafter took up for consideration the following Draft Action Taken Reports on :-

(i) Demands for Grants 2017-18' of Department of Fertilizers;
(ii) Demands for Grants 2017-18' of Department of Pharmaceuticals;
(iii) Demands for Grants 2017-18' of Department of Chemicals and Petrochemicals; and
(iv) Implementation of policy on promotion of city compost of Department of Fertilizers.

4. After some deliberations the Draft Action Taken Reports were adopted by the Committee without any changes. The Committee authorised the Chairperson to make consequential changes, if any, arising out of the factual verification of the Action Taken Reports by the Department of Fertilizers, Department of Pharmaceuticals and Department of Chemicals and Petrochemicals of the Ministry of Chemicals and Fertilizers.

5. The Committee thereafter decided to hold its next meeting on 23rd August, 2017.

The Committee then adjourned.

Appendix – II

(*Vide* Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE THIRTY-SECOND REPORT (SIXTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2016-17) ON 'DEMANDS FOR GRANTS (2017-18)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	7
II	Observations / Recommendations which have been accepted by the Government: (*Vide* Recommendation Nos. 6 and 7)	2
	Percentage of Total	29%
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- NIL	0
	Percentage of Total	0%
IV	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (*Vide* Recommendation No. 5)	1
	Percentage of Total	14
V	Observations / Recommendations in respect of which final replies of the Government are still awaited: (*Vide* Recommendation Nos 1,2,3 and 4)	4
	Percentage of Total	57%