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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 Twenty Third Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth
Lok Sabha) on "Demands for Grants 2016-17" of the Ministry of Chemicals and Fertilizers
(Department of Pharmaceuticals)]*



TWENTY NINTH REPORT

LOK SABHA SECRETARIAT
NEW DELHI

DECEMBER, 2016 /AGRAHAYANA, 1938 (SAKA)

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(2016-17)

(SIXTEENTH LOK SABHA)

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(DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations contained in the Twenty Third Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers on "Demands for Grants 2016-17" of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

Presented to Lok Sabha on 09 December 2016

Laid in Rajya Sabha on 09 December 2016

LOK SABHA SECRETARIAT
NEW DELHI
DECEMBER, 2016 /AGRAHAYANA, 1938 (SAKA)

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**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2016-17)**

Shri Anandrao Adsul - Chairperson

Members

Lok Sabha

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

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. Shri Palvai Govardhan Reddy
29. Dr. Sanjay Sinh
30. Shri Abdul Wahab
31. Smt. Roopa Ganguly

SECRETARIAT

Smt. Rashmi Jain	-	Joint Secretary
Shri A.K.Srivastava	-	Director
Shri H. RamPrakash	-	Additional Director
Shri S. Vijayaraghavan	-	Senior Committee Assistant

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 Twenty Ninth Report (Sixteenth Lok Sabha) on Action Taken by the Government on the observations/ recommendations contained in the Twenty Third Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers on "Demands for Grants 2016-17" of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Twenty Third Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 28.04.2016. The Action Taken replies of Government to all observations/ recommendations contained in the Report were received on 13.10.2016. The Standing Committee on Chemicals and Fertilizers (2016-2017) considered and adopted this Report at their sitting held on 6.12.2016.

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

4. For facility of reference and convenience the Comments of the Committee have been printed in bold letters in the body of the Report.

New Delhi;
08 December, 2016
17 Agrahayana 1938 (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 Twenty-Third Report (Sixteenth Lok Sabha) of the Committee on the Demands for Grants 2016-17 of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 28.4.2016. In all, the Committee made 9 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 Twenty-Third Report within three months from the date of presentation of the Report, i.e., by 28.7.2016. The Action Taken Replies of the Government in respect of all the 9 Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their O.M. No. 23003/1/2016-Fin.II dated 13.10.2016. These Replies have been categorized as follows:-

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

Sl.Nos. 1,2,3,4,5,6,7 and 8 (Total =8)

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. Nil (Total = Nil)

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.No. 9 (Total =1)

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 Promotion of manufacturing of bulk drugs

RECOMMENDATION SL. NO.1

5. While stressing that overdependence on imports for its bulk drugs needs is not a healthy sign for the Indian Pharmaceutical Industry the Committee had recommended as under:-

“The Committee note that the country is almost self-sufficient in case of formulations. However, for making these formulations, the basic chemical comes from China. Since the pharmaceutical industry is dominated by the private sector, they are free to import as per Foreign Trade Policy under which import of certain drugs and drugs intermediates is restricted.

The Committee also note that Indian Pharmaceutical Industry which was at one point of time leading producer in bulk drugs is now becoming increasingly dependent on China for its bulk drug needs. The Committee, further observe that in order to promote domestic production of bulk drugs, a Committee headed by Dr. V. M. Katoch was constituted which has submitted its recommendations. The Government is examining the recommendations of the Katoch Committee in consultation with the stakeholders. Besides this, three task forces have also been set up. All the three task forces have also submitted their reports, which are being examined.

The Committee are of the strong view that overdependence on imports for its bulk drugs needs is not a healthy sign for the Indian Pharmaceutical Industry. The Committee observe that the recommendations of Katoch Committee and the three task forces are essential to boost the growth of Pharmaceutical Sector and reducing the overdependence on imports. The Committee would, therefore, like the Department to examine the recommendation of the Task Forces expeditiously and implement its recommendations in a time bound manner for the promotion of manufacturing of bulk drugs in the country. The Committee would like to be informed of the action taken in this regard.

REPLY OF THE GOVERNMENT

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

“In the meeting held in PMO 5.3.2016, the following two decisions were taken:-

- (i) D/o Pharmaceuticals may proceed with the proposal for providing assistance for common facilities for 03 Greenfield Bulk Drugs/API Parks to the extent of Rs.200 crore each after seeking due approval.
- (ii) Proposal for providing support for distressed Brownfield Units should be re-examined by Secretary, Department of Pharmaceuticals in consultation with CEO, NITI Aayog.

As regards (i) above, Department had circulated a draft Expenditure Finance Committee (EFC) note to Department of Industrial Policy and Promotion, NITI Aayog and Department of Expenditure for their comments. Based on the comments received, the Department has drafted a revised scheme to provide financial assistance up to Rs.150 crore or 50% of the cost of machinery and equipment for setting up common facilities in 3 Bulk Drug Parks.

In the meantime, Department of Expenditure vide their OM No. 24(35)/PF-II/2012 dated 5th August, 2016 issued revised guidelines for making EFC/SFC notes. As per these new guidelines, the proposal has been revised and an 'in-principle' approval has been sought from the Department of Expenditure on 24.08.2016 in accordance with new guidelines.

As regards the proposal for support to distressed brownfield units, after consultation with NITI Aayog, Industry Associations have been requested to share their views on the type of intervention required from government for reviving production of the API. Reply is still awaited".

COMMENTS OF THE COMMITTEE

7. The Committee noted in their Report that Indian Pharmaceutical Industry which was at one point of time leading producer in bulk drugs is now becoming increasingly dependent on China for its bulk drug needs. The Committee, therefore earlier recommended that the recommendation of the Task Force of Katoch Committee may be examined and implemented expeditiously. In its Action Taken Reply, the Department has stated that in the meeting held in PMO on 5.3.2016, two decisions were taken (i) D/o Pharmaceuticals may proceed with the proposal for providing assistance for common facilities for 03 Greenfield Bulk Drugs/API Parks to the extent of Rs.200 crore each after seeking due approval. (ii) Proposal for providing support for distressed Brownfield Units should be re-examined by Secretary, Department of Pharmaceuticals in consultation with CEO, NITI Aayog. The Department has also drafted a revised scheme to provide financial assistance up to Rs.150 crore or 50% of the cost of machinery and equipment for setting up common facilities in 3 Bulk Drug Parks. While appreciating the initiatives taken by the Department of Pharmaceuticals, the Committee are of the view that the Department should expedite all the processes requisite for providing the common facilities and financial assistance to 3 Green Field Bulk Drugs/API Parks and make the scheme functional at the earliest. This will not only make the country self reliant but also cut the production cost of medicines. The Committee would like to know the initiatives taken to make the scheme functional and the progress made in the matter so far.

B. Need for Promotion of Indigenous Medical Devices Industry

RECOMMENDATION SL. NO.2

8. While expressing the view that the development of indigenous medical devices industry is of paramount importance and fits in realizing the Make in India goal of the Government, the Committee had recommended as under:-

“The Committee note that medical devices industry is a multi-product industry, producing wide range of products. The industry can be broadly classified as consisting of medical disposables and consumables; medical electronics, hospital equipments, surgical instruments; Implants; and Diagnostic Reagents. Globally this industry is growing quite steadily and have shown double digit growth. However, medical devices industry in India mostly depends on imports which is over 65% of the total market. The Indian medical devices industry is fragmented into small and medium enterprise category and is primarily manufacturing products such as disposables/medical supplies. Most of the requirement for high end medical equipments are met by multinational companies.

The Committee also note that Department wants to establish Medical Devices Manufacturing Parks in the country and the Department of Health has initiated action to establish one park in Tamil Nadu. The Department of Pharmaceuticals want to create four or five private and Government sponsored Medical Devices Parks. The Committee, also observe that One such park is to be established in IDPL land in Hyderabad and similarly, the Government of Andhra Pradesh is going to lay foundation stone for a separate medical devices manufacturing park. The Department has also got proposals to create parks in the State of Gujarat.

The Committee are of the view that the development of indigenous medical devices industry is of paramount importance and fits in realizing the Make in India goal of the Government. It will not only be instrumental in providing quality health care to its citizens but also would be helpful in creating new job opportunities for the skilled workers of the country. The Committee, therefore, recommend that the Department should take proactive measures toward developing indigenous medical devices industry so as to reduce our dependence on imports. The Committee would also like the Department to expedite the process of establishment of those Medical Devices Manufacturing Industry Parks for which the proposals have already been received from various States. The Committee would like to know the initiatives taken to expedite the scheme and the progress made in the matter so far”.

REPLY OF THE GOVERNMENT

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

“The government had constituted a Task Force on Medical Device Sector in India-2015. The Task Force has since submitted its recommendation. These recommendations have been examined and sent to the concerned Ministries/Departments for their implementation. The Department is following up

with the concerned Ministries/ Department for early implementation of the recommendations.

The Department had circulated a draft Standing Finance Committee (SFC) note for implementation of Scheme for financing Common Facility Centers (CFCs) in Medical Device Park to Department of Industrial Policy & Promotion, NITI Aayog and Department of Expenditure for their comments. Based on the comments received, the Department has drafted a revised scheme to provide financial assistance, to the tune of Rs.25 Crore per CFC or 70% of the cost of machinery and equipment whichever is less, for setting up these facilities.

In the meantime, Department of Expenditure vide their OM No. 24(35)/PF-II/2012 dated 5th August, 2016 issued revised guidelines for formulation EFC/SFC notes. As per the new guidelines, the proposal has been revised and an 'in-principle' approval is being sought from the Department of Expenditure in accordance with new guidelines".

COMMENTS OF THE COMMITTEE

10. The Committee noted that most of the requirement for high end medical equipments are met by multinational companies. The Committee also noted that the Department wants to establish Medical Devices Manufacturing Parks in the country and the Department of Health has initiated action to establish one park in Tamil Nadu. The Department of Pharmaceuticals wants to create four or five private and Government sponsored Medical Devices Parks. Keeping in view the Committee earlier recommended that the process to establish Medical Devices Manufacturing Industry Parks may be expedited. In their Action Taken Reply, the Department had stated that the Government had constituted a Task Force on Medical Device Sector in India-2015 and it has since submitted its recommendations. These recommendations have been examined and sent to the concerned Ministries/Departments and are being followed up with them for early implementation of the recommendations. The Department has drafted a revised scheme to provide financial assistance, to the tune of Rs.25 Crore per Common Facility Centre (CFC) or 70% of the cost of machinery and equipment whichever is less, for setting up these facilities. While lauding the measures taken by the Department of Pharmaceuticals, the Committee feel that the development of indigenous medical devices industry will not only realize the dream of Make In India but also reduce the burden of imports. As such it is expedient to implement the scheme after getting the modalities of scheme approved from all the stakeholders without any delay. The Committee, therefore recommend that the recommendations of the Task Force may be implemented without any further delay by the concerned Ministries/Departments and the financial assistance as proposed

in the revised scheme should be implemented with alacrity. The Committee, would like to be informed of the steps taken 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 issue of severe cut in the outlay for its projects vigorously 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 scheme, the Committee had recommended as under:-

“The Committee note that for Annual Plan 2016-17, the Department of Pharmaceuticals proposed an outlay of Rs.2891.473 crore to the D/o Expenditure, M/o Finance but only Rs.160 crore was approved for BE 2016-17. The Committee is dismayed to note that this allocation falls far short of the urgent funds requirements projected by the Department for carrying out its laid down mandate and its Vision for development of Indian Pharmaceuticals Industry under “Make in India” initiative, to make India a largest global provider of quality medicines. The Committee observes that budget allocation for the Department is substantially less during the current year because of poor spending capacity in the past. The Committee feels that a severe cut in outlay would have an adverse impact on the implementation of the Plan Schemes being undertaken by the Department and the targets set for the 12th Five Year Plan. The Committee, therefore, recommend that the Department should take up the issue vigorously 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 schemes. The Committee would like to be informed of the action taken by the Department in this regard”.

REPLY OF THE GOVERNMENT

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

“The following schemes faced heavy cut in allocation due to less allocation of funds by the Ministry of Finance.

Sl. No	Name of Scheme which faced much less allocation as compared to outlay sought.	Amount sought (Rs in crore)	Amount allocated (Rs in crore)
1.	NIPERs	1500.98	100.00
2.	Cluster Development Scheme	60.00	10.00
3.	Setting up Pharma Promotion Council	5.00	0.01
4.	Setting up Medical Devices Promotion Council	5.00	0.01
5.	PTUAs	500.00	0.01
6.	Venture Capital Fund	500.00	0.01
7.	Jan Aushadhi	155.00	35.00
8.	IDPL	24.20	0.01
9.	HAL	111.50	0.01

The issue of enhanced allocation was taken up the level of Hon'ble Minister (Chemicals and Fertilizers) and followed up at the level of Secretary (Pharmaceuticals).

D. Need for sanction of Additional Funds for various important Plan Schemes.

RECOMMENDATION SL. NO.4

13. While expressing concern over inadequate allocation of funds for various schemes of the Department, by the Finance Ministry, the Committee had recommended as under:-

“The Committee note that BE under Plan expenditure was Rs.210 crore for 2015-16 and RE was Rs.150.38 crore against which the actual expenditure made by the Department of Pharmaceuticals was Rs.147.20 crore and for Non-Plan BE for 2015-16 was Rs.48.02 crore and RE was Rs.69.01 crore against which Actual expenditure was Rs.70.09 crore. The Committee observe that Department has been able to utilize 95% of the funds allocated under RE 2015-16. The Committee further note that the BE Plan expenditure for 2016-17 has been provided as Rs.160 crore and Non-Plan allocation is Rs.51.40 crore. The Committee also observe that Department need more funds for meeting its expenditure on various Plan Schemes like NIPER, JAS, Setting up of National Centre for R&D in Bulk Drugs, and Cluster Development Programme. These programmes are important for the development of Pharmaceutical Industries in the country and also for capacity building through NIPERS, and for expansion of Jan Aushadhi Scheme to make available generic drugs at affordable cost to common man.

The Committee, therefore recommend that the Department should strongly take up the matter with Ministry of Finance and convey the recommendations of the Committee for sanction of additional funds, for various important Plan schemes. The Committee would also like the Department to utilize the entire allocated budget and implement the Plan Schemes effectively”.

REPLY OF THE GOVERNMENT

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

“As already explained, the matter has been taken up with the Ministry of Finance for allocation of more funds for schemes where the funds are required urgently.

The progress of expenditure allocated in the Budget for the Department is being monitored regularly by Secretary, Department of Pharmaceuticals to ensure speedy implementation of Plan Schemes”.

E. National Institute of Pharmaceutical Education & Research.

RECOMMENDATION SL. NO.7

15. While observing that the Department should impress upon the Ministry of Finance to grant the required amount of funds for the expeditious construction of new NIPERs

where land has already been allocated and construction activities have been initiated in full swing, the Committee had recommended as under:-

“The Committee note that the foundation stone for NIPER Ahmedabad has been laid on 16.12.2015 and for the construction work BOQ has already been approved and without the approval of funds, tender cannot be released and construction work could not be started. The Department proposed an amount of Rs.197.29 crore. However, only an amount of Rs.21.96 crore has been allocated for the above stated purpose during 2016-17. With regard to NIPER, Guwahati, the construction work has already been started. The Department proposed an amount of Rs.174.70 crore for the purpose. However, only an amount of Rs.19.50 crore has been allocated for the above stated purpose during 2016-17 which is not sufficient. With regard to NIPER Hyderabad, the Committee observe that Memorandum of Understanding (MoU) has been signed between NIPER, Hyderabad and National Project Construction Corporation (NPCC) Ltd. on 09.12.2015 for construction of NIPER campus as well as National Centre for Research and Development in Bulk Drugs(NCRDBD). The Department has sought Rs.193.02 crore for NIPER, Hyderabad and Rs.36.75 crore for NCRDBD. However, only an amount of Rs.35 crore for NIPER, Hyderabad and Rs.0.01 crore for NCRDBD has been allocated during 2016-17. The fund allocated is proposed to be utilized in meeting Establishment expenditure and for construction activities of new campus for NIPER, Hyderabad. With regard to NIPER, Rae Bareilly possession of land has been taken. The funds required for meeting expenses for establishment related and essential expenditure to run the Institute and for construction activities of new campus for NIPER, Rae Bareilly. In the proposed BE 2016-17, the Department has sought Rs.176.59 crore. However, an amount of Rs.07.00 crore has been allocated during 2016-17. With regard to NIPER Madurai For setting up of NIPER in Tamil Nadu, Government of Tamil Nadu has allocated land at Madurai. In the proposed BE 2016-17, the Department has sought Rs.174.10 crore. However, an amount of Rs.1.00 crore has been allocated during 2016-17 for the above said purpose. The Committee are of the view that due to lesser allocation of funds the construction of new NIPERs is going to be affected adversely. The Committee, therefore recommend that the Department should impress upon the Ministry of Finance to grant the required amount of funds for the expeditious construction of new NIPERs where land has already been allocated and construction activities have been initiated in full swing, as this will address the demand of pharmaceutical industry to meet the requirement of highly skilled manpower and also boost research and development in the sector”.

REPLY OF THE GOVERNMENT

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

“NIPER Division proposed Rs.1500.98 crore for allocation for 2016-17, so that construction of NIPER Campuses would be completed timely. However, against this, only Rs.100 crore has been allocated under NIPER Scheme. The Department has taken up the matter with the Ministry of Finance for allocation of additional funds”.

COMMENTS OF THE COMMITTEE ON ACTION TAKEN REPLY ON RECOMMENDATIONS NOS. 3, 4 AND 7

17. The Committee had observed in their Report that budget allocation for the Department is substantially less during the year 2016-17 because of poor spending capacity in the past. The Committee felt that a severe cut in outlay would have an adverse impact on the implementation of the Plan Schemes being undertaken by the Department and the targets set for the 12th Five Year Plan. The Committee also observed that the Department need more funds for meeting its expenditure on various Plan Schemes like NIPER, JAS, Setting up of National Centre for R&D in Bulk Drugs, and Cluster Development Programme. These programmes are important for the development of Pharmaceutical Industries in the country and also for capacity building through NIPERS, and for expansion of Jan Aushadhi Scheme to make available generic drugs at affordable cost to common man. The Committee, therefore earlier recommended that the Department should strongly take up the matter with Ministry of Finance for sanction of required funds.

In their Action Taken replies of the recommendation No.3, 4 and 7 the Department has stated that the matter has been taken up with the Ministry of Finance for allocation of more funds for schemes where the funds are required urgently. The progress of expenditure allocated in the Budget for the Department is being monitored regularly by the Secretary, Department of Pharmaceuticals to ensure speedy implementation of Plan Schemes. The Department has also stated that NIPER Division proposed Rs.1500.98 crore for allocation for 2016-17, so that construction of NIPER Campuses would be completed in time. However, against this, only Rs.100 crore has been allocated under NIPER Scheme. The Department has taken up the matter with the Ministry of Finance for allocation of additional funds. The Department has further stated that the schemes of the Department which faced serious cut are NIPERs, Cluster Development Scheme, Setting up

Pharma Promotion Council, PTUAs, Venture Capital Fund, Jan Aushadhi, IDPL, HAL and the issue of enhanced allocation was taken up at the level of Hon'ble Minister (Chemicals and Fertilizers) and followed up at the level of Secretary (Pharmaceuticals).

The Committee feel that the plan schemes such as NIPER, Jan Aushadhi Scheme, Setting up of National Centre for R&D in Bulk Drugs, and Cluster Development Programme are vital for the development and growth of pharmaceuticals sector in the country to give benefit to common man and to achieve the objective of 'Make In India'. Therefore, the schemes should not suffer for want of money and reiterate their earlier recommendation that earnest efforts should be made at the highest level to get the requisite funds for the schemes for smooth functioning of plan schemes.

F. National Pharmaceutical Pricing Authority (NPPA)

RECOMMENDATION SL. NO.5

18 While expressing the need for quick recovery of overcharged amount the approval by the Ministry of Finance for need for One Time Settlement (OTS), the Committee had recommended as under:-

"The Committee note that the National Pharmaceutical Pricing Authority (NPPA), is an independent body of experts in the Ministry of Chemicals and Fertilizers. Its functions inter-alia includes 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. However, the Committee are dismayed to note that Since inception of NPPA, there are 1389 cases as on 29.02.2016 (1250 cases under DPCO 1995 & 139 cases under DPCO 2013) where demand notices have been issued by NPPA to Pharmaceutical companies for recovery of overcharged amount.

The Committee also observes that NPPA has prepared a draft for One Time Settlement (OTS) with an aim of quick recovery of overcharged amount and sent to Department of Pharmaceuticals for its formal approval. The earlier proposal sent two years back to Ministry of Finance was not accorded approval by it. The Committee, therefore recommend that the Department should take up the matter with Ministry of Finance again by strongly putting its case for One Time Settlement Scheme with full justification. The Committee desire to be apprised of the detailed action in this regard".

REPLY OF THE GOVERNMENT

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

“A proposal on ‘One Time Settlement Scheme’ in respect of cases pertaining to recoveries of overcharged amount under DPCO 1979, DPCO 1995 and DPCO 2013 is under active consideration of the Department in consultation with NPPA”.

COMMENTS OF THE COMMITTEE

20. The Committee were informed earlier that since inception of NPPA, there are 1389 cases as on 29.02.2016 (1250 cases under DPCO 1995 & 139 cases under DPCO 2013) where demand notices have been issued by NPPA to Pharmaceutical companies for recovery of overcharged amount. It was also informed to the Committee earlier that NPPA has prepared a draft for One Time Settlement (OTS) with an aim of quick recovery of overcharged amount and the draft was sent to Department of Pharmaceuticals for its formal approval. The earlier proposal sent two years back to Ministry of Finance was not accorded approval by them. The Committee, therefore earlier recommended that the Department may take up the proposed OTS with Ministry of Finance for early finalisation. In their Action Taken Reply, the Department has stated that the proposal of OTS in respect of cases pertaining to recoveries of overcharged amount under DPCO 1979, DPCO 1995 and DPCO 2013 is under active consideration of the Department in consultation with NPPA.

The Committee did not appreciate such a casual Action Taken Reply from the Department of Pharmaceuticals. The Committee observed that the earlier proposal of the Department was not approved by Ministry of Finance and still the Department has not finalised the proposal submitted by NPPA. The Committee therefore, express its displeasure over the pace of such an important decision and reiterate its earlier recommendation for expeditious finalisation of One Time Settlement so that the cases with regard to recovery of overcharged amount from Pharma Companies can be solved with its implementation.

G. Need for Cluster Development Programme for Pharma Sector.

RECOMMENDATION SL. NO. 6

21. While expressing that the scheme be expeditiously implemented in a systematic, professional and transparent manner and ensure that the Steering Committee reviews the responses received in the EOIs at the earliest, the Committee had recommended as under:-

“The Committee observe that Cluster Development Programme for Pharma Sector is a Central Sector Scheme which was approved in February 2014. . The total size of the scheme CDPPS is proposed as Rs.125 Crore for 12th Five Year Plan. The Committee also note that the Scheme would be implemented on a Public Private

Partnership (PPP) format through one time grant –in – aid to be released in various phases for creation of identified infrastructure and common facilities in the form of Common Facility Centers(CFC) to Special Purpose Vehicles (SPVs) set up for the purpose. Assistance under the Scheme will be Rs.20.00 Crore per cluster or 70% of the cost of the project, whichever is less for creation of common facilities for Common Testing Facilities, Training Centre, Effluent Treatment Plant, R&D Centre, Common Logistics Centre.

Projects and Development India Limited (PDIL) has been chosen as the Project Management Consulting (PMC) for implementing the scheme. PDIL have called for EOI/SPV for the 1st Phase, out of the six EOIs, one was found suitable by the Scheme Selection Committee (SSC) to be located in Tamilnadu. SSC has requested PDIL to call fresh EOI which they have done and the last date of receipt of the EOIs was 31/12/2015. After that PDIL has extended the date till 31.01.2016. The meeting of SSC was held on 23/02/2016 to review the response to EOIs and implementation of the Scheme.

The Committee recommends the Department to implement the scheme expeditiously in a systematic, professional and transparent manner and ensure that the Steering Committee reviews the responses received in the EOIs at the earliest so that there is concrete progress in this regard. The Committee would like to be apprised about the progress made in the matter”.

REPLY OF THE GOVERNMENT

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

“After Launch of the Programme, Project Monitoring Consultant (PMC)/Department of Pharmaceuticals invited Expression of Interest (EOI) on 07.07.2015 from SPVs for participation in the programme. In response, EOIs were received from six SPVs, out of which 1 SPV, i.e. M/s Chennai Pharma Industrial & Infra Structure Upgradation Complex, Alathur was found suitable in the 3rd SSC meeting held on 13.10.2015. The SPV was asked to submit their Proposal & DPR but the same are still awaited from the party. In order to make the scheme more attractive, on the request of the Pharma Industry, the Department of Pharmaceuticals in the 6th SSC meeting on 29/6/2016 decided that Ayurvedics, Unani and Cosmetics firms shall also be considered as Pharma Firms for participation under the scheme. Following the decision PMC has invited fresh EOI by 16.9.2016”.

COMMENTS OF THE COMMITTEE

23. The Committee noted that the Projects and Development India Limited (PDIL) has been chosen as the Project Management Consultant for implementing the Cluster Development Programme. PDIL has called for Expression of Interest /SPV for the 1st Phase, where out of six EOIs, one was found suitable. Scheme Selection Committee (SSC) had requested to call for fresh EOI where last date for submission was fixed as 31.1.2016. The Committee, further noted that the 4th

meeting of SSC was held on 23/02/2016 to review the response to EOIs and implementation of the Scheme. The Committee therefore earlier recommended the Department to implement the scheme expeditiously.

In their Action Taken Reply, the Department has stated that out of six SPVs one SPV, i.e. M/s Chennai Pharma Industrial & Infra Structure Upgradation Complex, Alathur was only found suitable in the 3rd SSC meeting held on 13.10.2015. The SPV was asked to submit their Proposal & DPR but the same are still awaited from the party. In order to make the scheme more attractive, on the request of the Pharma Industry, the Department of Pharmaceuticals in the 6th SSC meeting held on 29/6/2016 decided that Ayurvedic, Unani and Cosmetics firms shall also be considered as Pharma Firms for participation under the scheme. Following the decision PMC has invited fresh EOI by 16.9.2016.

Considering the Action Taken Replies, the Committee expect the Department to assist the M/s Chennai Pharma Industrial & Infra Structure Upgradation Complex, Alathur to finalize the proposal and DPR. The Committee, also, recommend that the Department should speed up EOI process for early implementation of Cluster Development Programme. The Committee would like to be apprised of the progress made in this regard.

H. Public Sector Undertakings

RECOMMENDATION SL. NO.9

24. While expressing concern over the slow progress in the revival of sick Pharma PSUs, the Committee had recommended as under:-

“The Committee note that out of the five Central Public Sector Enterprises (CPSEs) under the administrative control of Department of Pharmaceuticals, three viz. Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and are referred to Board for Industrial & Financial Reconstruction (BIFR). The Rajasthan Drugs & Pharmaceuticals Limited (RDPL) reported losses for the first time during the year 2013-14. The Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) is the only profit making CPSE.

Bengal Chemical and Pharmaceuticals Ltd

The Committee also notes that the performance of Bengal Chemical and Pharmaceuticals Limited is improving. The Government sanctioned a rehabilitation package which has been implemented now it is on its way to progress. Turnover of the Company was Rs.50 crore in 2013-14. Last year, it was Rs.23 crore. This year, it is going to touch Rs.100 crore and it is likely to make up a gross profit of Rs.8 to Rs.10 crore. BCPL have two pending projects, one at Kanpur

and the other is a more prestigious anti-snake venom project. It requires Rs.27 crore investments and if it is sanctioned for anti-snake venom project, it can be supplied to entire country and can also be exported.

Hindustan Antibiotics Ltd.

The Committee note with regard to HAL, Salary for 17 months is pending. The Committee also notes that each time whenever salary is to be given, the Department has to go to the Finance Ministry. The Department has worked out a rehabilitation package for Hindustan Antibiotics Limited. It is sending the proposal for simplified rehabilitation package to the Cabinet, for both IDPL and HAL. The action for revival of the HAL would be initiated once the approval of Cabinet is accorded. The Committee also feels that if the Cabinet note is approved, the official process will take nine months to get the first installment of payment after selling of the land. Till that time, it will be difficult for the employees of HAL to meet their ends meet. In this context, the Committee strongly feel that Department should strive to provide some interim relief to the employees of HAL so as to improve morale of the employees.

Indian Drugs & Pharmaceuticals Ltd.

The Committee further notes that Cabinet note for revival of sick PSUs namely Indian Drugs & Pharmaceuticals Ltd (IDPL) is being finalized. The Committee also feels that the Government has to take a call on whether they want to revive IDPL or close it down because regular man power has virtually vanished. The Committee further observes that the situation in IDPL has made a turn around with an operating cash profit of Rs.4.38 crore made last year. This year, the turnover is touching Rs.85 crore and will perhaps be the highest in-house production ever achieved in the last 20 years. The Committee further note that IDPL is managing its own cash flow through its deposits, and is using it for working capital needs. The IDPL unit of Hyderabad will be inaugurated and It will be Good Manufacturing Practice (GMP) plant. The Committee, feel that Government support is needed for revival of IDPL.

The Committee is of the view that steps to rehabilitate all the sick PSUs should be quickened. The Committee, therefore recommend that the Department should make vigorous efforts in coordination with all concerned authorities to rehabilitate the Pharma PSU's and meet their immediate requirement expeditiously.

REPLY OF THE GOVERNMENT

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

“Notes for approval of Cabinet for the revival of Hindustan Antibiotics Limited (HAL) & Indian Drugs & Pharmaceuticals Limited (IDPL), were submitted in April 2016. As per the decision of Cabinet, the matter relating to revival of HAL has been referred to a Committee of Ministers (i.e. Minister of Finance, Minister of Road Transport & Highways and Minister of Chemicals & Fertilizers) to review the Pharma PSUs and suggest further course of action. Department of Pharmaceuticals

has been directed by the Committee of Ministers to appoint a Consultant to develop a concept note and prepare a report/document on the issue of revival of these Pharmaceuticals Units. The process of appointment of Consultant has already been initiated by HAL”.

COMMENTS OF THE COMMITTEE

26. The Committee had observed earlier that out of 05 Central Public Sector Enterprises (CPSEs) under the administrative control of Department of Pharmaceuticals, Karnataka Antibiotic Private Limited (KAPL) is the only profit making CPSE while Indian Drugs and Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL) are sick and were referred to Board for Industrial & Financial Reconstruction. Rajasthan Drug and Pharmaceuticals Limited reported losses for the first time during the year 2013-14. In this regard it was observed that the turnover of BCPL was Rs. 50 Crore in 2013-14, Rs. 23 Crore during the year 2014-15 and going to touch Rs. 100 Crore this year thus likely to make a gross profit Rs. 8 to 10 Crore this year. In respect of IDPL the Committee also observed that IDPL has made a turnaround with an operating cash profit of Rs. 4.38 Crore during the last year and it is expected that this year the turnover would touch Rs. 85 Crore and will perhaps the highest in house production for the last 20 years. As regard the HAL, salary of its employees is pending for the last many months and each time whenever salary is given the Department has gone to Finance Ministry. The Committee were further informed that Cabinet Note for revival of IDPL and HAL was being finalized. The Department was in the process of sending the proposal for simplified rehabilitation package to the Cabinet for both IDPL and HAL. The action for revival would be initiated once the approval of Cabinet is accorded. Further in case the Cabinet Note is approved it would take nine months to get first installment of payment of HAL employees after selling of the land. Till that time it would be difficult for the employees to meet their ends. In this context the committee had recommended that the Department should try to provide some interim relief to the employees of HAL so as to improve their morale. The Committee also recommended that the steps to rehabilitate the sick PSUs should be quickened.

In their Action Taken Reply the Department has stated that Notes for approval of Cabinet for the revival of Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL), were submitted in April 2016. As per the decision of Cabinet, the matter relating to revival of HAL has been referred to a Committee of Ministers to view the Pharma PSUs and suggest further course of action. Department of Pharmaceuticals has been directed by the Committee of

Ministers to appoint a consultant to develop a concept note and prepare a report/document on the issue of revival of these Pharmaceuticals Units. The process of appointment of Consultant has already been initiated by HAL. However, the Department has not commented anything about the latest position of Cabinet decision regarding revival of IDPL.

For the revival of IDPL, the Committee observe though IDPL has made a turnaround this year but still a revisit on the functioning of IDPL is expedient. For HAL the Committee recommend that the Department of Pharmaceuticals should coordinate with all concerned including consultant to prepare the concept paper to expedite the revival of the HAL in a time bound manner. As regards the salary to HAL employees the Committee are dismayed to note that the Department has not commented on the recommendation of the Committee to provide some interim relief to the employees of the HAL. The Committee, therefore reiterate its earlier recommendation and hope that the decision for salary of HAL employees shall be taken at the earliest as it will be morale booster and succor to loyal staff. The Committee would like to be apprised of the action taken by the Department in this regard.

CHAPTER – II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

RECOMMENDATION SL. NO.1

The Committee note that the country is almost self-sufficient in case of formulations. However, for making these formulations, the basic chemical comes from China. Since the pharmaceutical industry is dominated by the private sector, they are free to import as per Foreign Trade Policy under which import of certain drugs and drugs intermediates is restricted.

The Committee also note that Indian Pharmaceutical Industry which was at one point of time leading producer in bulk drugs is now becoming increasingly dependent on China for its bulk drug needs. The Committee, further observe that in order to promote domestic production of bulk drugs, a Committee headed by Dr. V. M. Katoch was constituted which has submitted its recommendations. The Government is examining the recommendations of the Katoch Committee in consultation with the stakeholders. Besides this, three task forces have also been set up. All the three task forces have also submitted their reports, which are being examined.

The Committee are of the strong view that overdependence on imports for its bulk drugs needs is not a healthy sign for the Indian Pharmaceutical Industry. The Committee observe that the recommendations of Katoch Committee and the three task forces are essential to boost the growth of Pharmaceutical Sector and reducing the overdependence on imports. The Committee would, therefore, like the Department to examine the recommendation of the Task Forces expeditiously and implement its recommendations in a time bound manner for the promotion of manufacturing of bulk drugs in the country. The Committee would like to be informed of the action taken in this regard.

REPLY OF THE GOVERNMENT

In the meeting held in PMO 5.3.2016, the following two decisions were taken:-

- (i) D/o Pharmaceuticals may proceed with the proposal for providing assistance for common facilities for 03 Greenfield Bulk Drugs/API Parks to the extent of Rs.200 crore each after seeking due approval.
- (ii) Proposal for providing support for distressed Brownfield Units should be re-examined by Secretary, Department of Pharmaceuticals in consultation with CEO, NITI Aayog.

As regards (i) above, Department had circulated a draft Expenditure Finance Committee (EFC) note to Department of Industrial Policy and Promotion, NITI Aayog and Department of Expenditure for their comments. Based on the comments received, the Department has drafted a revised scheme to provide financial assistance up to Rs.150 crore or 50% of the cost of machinery and equipment for setting up common facilities in 3 Bulk Drug Parks.

In the meantime, Department of Expenditure vide their OM No. 24(35)/PF-II/2012 dated 5th August, 2016 issued revised guidelines for making EFC/SFC notes. As per these new

guidelines, the proposal has been revised and an 'in-principle' approval has been sought from the Department of Expenditure on 24.08.2016 in accordance with new guidelines.

As regards the proposal for support to distressed brownfield units, after consultation with NITI Aayog, Industry Associations have been requested to share their views on the type of intervention required from government for reviving production of the API. Reply is still awaited.

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION SL. NO.2

The Committee note that medical devices industry is a multi-product industry, producing wide range of products. The industry can be broadly classified as consisting of medical disposables and consumables; medical electronics, hospital equipments, surgical instruments; Implants; and Diagnostic Reagents. Globally this industry is growing quite steadily and have shown double digit growth. However, medical devices industry in India mostly depends on imports which is over 65% of the total market. The Indian medical devices industry is fragmented into small and medium enterprise category and is primarily manufacturing products such as disposables/medical supplies. Most of the requirement for high end medical equipments are met by multinational companies.

The Committee also note that Department wants to establish Medical Devices Manufacturing Parks in the country and the Department of Health has initiated action to establish one park in Tamil Nadu. The Department of Pharmaceuticals want to create four or five private and Government sponsored Medical Devices Parks. The Committee, also observe that One such park is to be established in IDPL land in Hyderabad and similarly, the Government of Andhra Pradesh is going to lay foundation stone for a separate medical devices manufacturing park. The Department has also got proposals to create parks in the State of Gujarat.

The Committee are of the view that the development of indigenous medical devices industry is of paramount importance and fits in realizing the Make in India goal of the Government. It will not only be instrumental in providing quality health care to its citizens but also would be helpful in creating new job opportunities for the skilled workers of the country. The Committee, therefore, recommend that the Department should take proactive measures toward developing indigenous medical devices industry so as to reduce our dependence on imports. The Committee would also like the Department to expedite the process of establishment of those Medical Devices Manufacturing Industry Parks for which the proposals have already been received from various States. The Committee would like to know the initiatives taken to expedite the scheme and the progress made in the matter so far".

REPLY OF THE GOVERNMENT

The government had constituted a Task Force on Medical Device Sector in India-2015. The Task Force has since submitted its recommendation. These recommendations have been examined and sent to the concerned Ministries/Departments for their implementation. The Department is following up with the concerned Ministries/Department for early implementation of the recommendations.

The Department had circulated a draft Standing Finance Committee (SFC) note for implementation of Scheme for financing Common Facility Centers (CFCs) in Medical Device Park to Department of Industrial Policy & Promotion, NITI Aayog and Department of Expenditure for their comments. Based on the comments received, the Department has drafted a revised scheme to provide financial assistance, to the tune of Rs.25 Crore per CFC or 70% of the cost of machinery and equipment whichever is less, for setting up these facilities.

In the meantime, Department of Expenditure vide their OM No. 24(35)/PF-II/2012 dated 5th August, 2016 issued revised guidelines for formulation EFC/SFC notes. As per the new guidelines, the proposal has been revised and an 'in-principle' approval is being sought from the Department of Expenditure in accordance with new guidelines".

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION SL. NO.3

The Committee note that for Annual Plan 2016-17, the Department of Pharmaceuticals proposed an outlay of Rs.2891.473 crore to the D/o Expenditure, M/o Finance but only Rs.160 crore was approved for BE 2016-17. The Committee is dismayed to note that this allocation falls far short of the urgent funds requirements projected by the Department for carrying out its laid down mandate and its Vision for development of Indian Pharmaceuticals Industry under "Make in India" initiative, to make India a largest global provider of quality medicines. The Committee observes that budget allocation for the Department is substantially less during the current year because of poor spending capacity in the past. The Committee feels that a severe cut in outlay would have an adverse impact on the implementation of the Plan Schemes being undertaken by the Department and the targets set for the 12th Five Year Plan. The Committee, therefore, recommend that the Department should take up the issue vigorously 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 schemes. The Committee would like to be informed of the action taken by the Department in this regard".

REPLY OF THE GOVERNMENT

The following schemes faced heavy cut in allocation due to less allocation of funds by the Ministry of Finance.

Sl. No	Name of Scheme which faced much less allocation as compared to outlay sought.	Amount sought (Rs in crore)	Amount allocated (Rs in crore)
1.	NIPERs	1500.98	100.00
2.	Cluster Development Scheme	60.00	10.00
3.	Setting up Pharma Promotion Council	5.00	0.01
4.	Setting up Medical Devices Promotion Council	5.00	0.01
5.	PTUAs	500.00	0.01
6.	Venture Capital Fund	500.00	0.01
7.	Jan Aushadhi	155.00	35.00
8.	IDPL	24.20	0.01
9.	HAL	111.50	0.01

The issue of enhanced allocation was taken up the level of Hon'ble Minister (Chemicals and Fertilizers) and followed up at the level of Secretary (Pharmaceuticals).

COMMENTS OF THE COMMITTEE

(Please see Para No.17 of Chapter- I of the Report)

RECOMMENDATION SL. NO. NO.4

The Committee note that BE under Plan expenditure was Rs.210 crore for 2015-16 and RE was Rs.150.38 crore against which the actual expenditure made by the Department of Pharmaceuticals was Rs.147.20 crore and for Non-Plan BE for 2015-16 was Rs.48.02 crore and RE was Rs.69.01 crore against which Actual expenditure was Rs.70.09 crore. The Committee observe that Department has been able to utilize 95% of the funds allocated under RE 2015-16. The Committee further note that the BE Plan expenditure for 2016-17 has been provided as Rs.160 crore and Non-Plan allocation is Rs.51.40 crore. The Committee also observe that Department need more funds for meeting its expenditure on various Plan Schemes like NIPER, JAS, Setting up of National Centre for R&D in Bulk Drugs, and Cluster Development Programme. These programmes are important for the development of Pharmaceutical Industries in the country and also for capacity building through NIPERS, and for expansion of Jan Aushadhi Scheme to make available generic drugs at affordable cost to common man.

The Committee, therefore recommend that the Department should strongly take up the matter with Ministry of Finance and convey the recommendations of the Committee for sanction of additional funds, for various important Plan schemes. The Committee would also like the Department to utilize the entire allocated budget and implement the Plan Schemes effectively.

REPLY OF THE GOVERNMENT

As already explained, the matter has been taken up with the Ministry of Finance for allocation of more funds for schemes where the funds are required urgently.

The progress of expenditure allocated in the Budget for the Department is being monitored regularly by Secretary, Department of Pharmaceuticals to ensure speedy implementation of Plan Schemes.

COMMENTS OF THE COMMITTEE

(Please see Para No.17 of Chapter- I of the Report)

RECOMMENDATION SL. NO.5

The Committee notes that the National Pharmaceutical Pricing Authority (NPPA), is an independent body of experts in the Ministry of Chemicals and Fertilizers. Its functions inter-alia includes 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. However, the Committee are dismayed to note that Since inception of NPPA, there are 1389 cases as on 29.02.2016 (1250 cases under DPCO 1995 & 139 cases under DPCO 2013) where demand notices

have been issued by NPPA to Pharmaceutical companies for recovery of overcharged amount.

The Committee also observes that NPPA has prepared a draft for One Time Settlement (OTS) with an aim of quick recovery of overcharged amount and sent to Department of Pharmaceuticals for its formal approval. The earlier proposal sent two years back to Ministry of Finance was not accorded approval by it. The Committee, therefore recommend that the Department should take up the matter with Ministry of Finance again by strongly putting its case for One Time Settlement Scheme with full justification. The Committee desire to be apprised of the detailed action in this regard.

REPLY OF THE GOVERNMENT

A proposal on 'One Time Settlement Scheme' in respect of cases pertaining to recoveries of overcharged amount under DPCO 1979, DPCO 1995 and DPCO 2013 is under active consideration of the Department in consultation with NPPA.

COMMENTS OF THE COMMITTEE

(Please see Para No. 20 of Chapter- I of the Report)

RECOMMENDATION SL. NO.6

The Committee observes that Cluster Development Programme for Pharma Sector is a Central Sector Scheme which was approved in February 2014. . The total size of the scheme CDPPS is proposed as Rs.125 Crore for 12th Five Year Plan. The Committee also note that the Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant –in – aid to be released in various phases for creation of identified infrastructure and common facilities in the form of Common Facility Centers(CFC) to Special Purpose Vehicles (SPVs) set up for the purpose. Assistance under the Scheme will be Rs.20.00 Crore per cluster or 70% of the cost of the project, whichever is less for creation of common facilities for Common Testing Facilities, Training Centre, Effluent Treatment Plant, R&D Centre, Common Logistics Centre.

Projects and Development India Limited (PDIL) has been chosen as the Project Management Consulting (PMC) for implementing the scheme. PDIL have called for EOI/SPV for the 1st Phase, out of the six EOIs, one was found suitable by the Scheme Selection Committee (SSC) to be located in Tamilnadu. SSC has requested PDIL to call fresh EOI which they have done and the last date of receipt of the EOIs was 31/12/2015. After that PDIL has extended the date till 31.01.2016. The meeting of SSC was held on 23/02/2016 to review the response to EOIs and implementation of the Scheme.

The Committee recommends the Department to implement the scheme expeditiously in a systematic, professional and transparent manner and ensure that the Steering Committee reviews the responses received in the EOIs at the earliest so that there is concrete progress in this regard. The Committee would like to be apprised about the progress made in the matter.

REPLY OF THE GOVERNMENT

After Launch of the Programme, Project Monitoring Consultant (PMC)/Department of Pharmaceuticals invited Expression of Interest (EOI) on 07.07.2015 from SPVs for participation in the programme. In response, EOIs were received from six SPVs, out of which 1 SPV, i.e. M/s Chennai Pharma Industrial & Infra Structure Upgradation Complex, Alathur was found suitable in the 3rd SSC meeting held on 13.10.2015. The SPV was asked to submit their Proposal & DPR but the same are still awaited from the party. In order to make the scheme more attractive, on the request of the Pharma Industry, the Department of Pharmaceuticals in the 6th SSC meeting on 29/6/2016 decided that Ayurvedics, Unani and Cosmetics firms shall also be considered as Pharma Firms for participation under the scheme. Following the decision PMC has invited fresh EOI by 16.9.2016.

COMMENTS OF THE COMMITTEE

(Please see Para No. 23 of Chapter- I of the Report)

RECOMMENDATION SL. NO.7

The Committee note that the foundation stone for NIPER Ahmedabad has been laid on 16.12.2015 and for the construction work BOQ has already been approved and without the approval of funds, tender cannot be released and construction work could not be started. The Department proposed an amount of Rs.197.29 crore. However, only an amount of Rs.21.96 crore has been allocated for the above stated purpose during 2016-17. With regard to NIPER, Guwahati, the construction work has already been started. The Department proposed an amount of Rs.174.70 crore for the purpose. However, only an amount of Rs.19.50 crore has been allocated for the above stated purpose during 2016-17 which is not sufficient. With regard to NIPER Hyderabad, the Committee observe that Memorandum of Understanding (MoU) has been signed between NIPER, Hyderabad and National Project Construction Corporation (NPCC) Ltd. on 09.12.2015 for construction of NIPER campus as well as National Centre for Research and Development in Bulk Drugs (NCRDBD). The Department has sought Rs.193.02 crore for NIPER, Hyderabad and Rs.36.75 crore for NCRDBD. However, only an amount of Rs.35 crore for NIPER, Hyderabad and Rs.0.01 crore for NCRDBD has been allocated during 2016-17. The fund allocated is proposed to be utilized in meeting Establishment expenditure and for construction activities of new campus for NIPER, Hyderabad. With regard to NIPER, Rae Bareilly possession of land has been taken. The funds required for meeting expenses for establishment related and essential expenditure to run the Institute and for construction activities of new campus for NIPER, Rae Bareilly. In the proposed BE 2016-17, the Department has sought Rs.176.59 crore. However, an amount of Rs.07.00 crore has been allocated during 2016-17. With regard to NIPER Madurai For setting up of NIPER in Tamil Nadu, Government of Tamil Nadu has allocated land at Madurai. In the proposed BE 2016-17, the Department has sought Rs.174.10 crore. However, an amount of Rs.1.00 crore has been allocated during 2016-17 for the above said purpose. The Committee are of the view that due to lesser allocation of funds the construction of new NIPERs is going to be affected adversely. The Committee, therefore recommend that the Department should impress upon the Ministry of Finance to grant the required amount of funds for the expeditious construction of new NIPERs where land has already been allocated and construction activities have been initiated in full swing, as this will address the demand of pharmaceutical industry to meet the requirement of highly skilled manpower and also boost research and development in the sector.

REPLY OF THE GOVERNMENT

NIPER Division proposed Rs.1500.98 crore for allocation for 2016-17, so that construction of NIPER Campuses would be completed timely. However, against this, only Rs.100 crore has been allocated under NIPER Scheme. The Department has taken up the matter with the Ministry of Finance for allocation of additional funds.

COMMENTS OF THE COMMITTEE

(Please see Para No.17 of Chapter- I of the Report)

RECOMMENDATION SL. NO.8

The Committee note that making quality medicines available at affordable prices remains a key challenge to the Government. To provide relief to common man and to ensure availability of generic medicines at affordable prices to all, the Department of Pharmaceuticals launched a Jan Aushadhi Campaign in November 2008 in collaboration with State Governments. The Committee notes that Jan Aushadhi Scheme is being implemented by the Department of Pharmaceuticals through Bureau of Pharma PSUs of India. The Committee note that as on 10 March 2016, 263 stores spread over 21 States/UTs are functional in the country.

The Committee also note that during the Budget Speech, 2016-17 the Finance Minister announced that the Government will reinvigorate the supply of generic drugs and open 3000 stores under Prime Minister's Jan Aushadhi Yojana towards this objective. The Committee observe that BE for 2015-16 for Jan Aushadhi Scheme was Rs.35 crore and the RE 2015-16 was Rs.16.92 crore and the Actual Expenditure during 2015-16 was Rs.16.91 crore which shows full utilization. During 2016-17, the BE for Jan Aushadhi Scheme has been fixed at Rs.35 crore similar to previous year. The Committee is to point out that in order to achieve the 3000 stores objectives during the year the allocations may not be sufficient and more funds would be required during the course of the year. The Committee desire that Jan Aushadhi Stores should be opened in a well distributed manner in the country and the Department should ensure that all States, regions and difficult areas are also covered so that the scheme would serve its intended purpose. The Committee would also suggest that the Department should also commission more mobile vans to supply medicines to distant areas, far flung areas, difficult terrains so that the population at large can benefit from the scheme. The Committee observe that the State Governments have their own free drugs scheme and are hesitant and non-cooperative in certain places which makes this scheme difficult to take off. The doctors may also be sensitized and encouraged to prescribe such generic drugs that are available with Jan Aushadhi Stores. The Committee, therefore recommend that Department may utilize the allocated funds completely and promote the Scheme more effectively so that the objective of providing affordable medicines to all citizens is met.

REPLY OF THE GOVERNMENT

The Jan Aushadhi Scheme has been revamped with the approval of Hon'ble Minister (Chemicals & Fertilizers) on 30.9.2015. A target of 3000 Jan Aushadhi Stores has been proposed to be opened by the end of 2016-17. As on 30.09.2016, a total of 448 Jan Aushadhi Stores have been opened. To achieve the target of opening of 3000 Stores by the

end of March 2017, Rs.35 Crore have been allocated for 2016-17 against the demand of Rs.115.89 Crore. Out of Rs.35 Crore, Rs.22.78 Crore have been released to Bureau of Pharma PSUs of India (BPPI). It is expected that the allocation under the scheme for 2016-17 will be fully utilized. Supply chain and public awareness is being improved. Basket of medicines has been increased and the scheme is picking up.

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

-NIL-

CHAPTER – V

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

RECOMMENDATION NO.9

The Committee note that out of the five Central Public Sector Enterprises (CPSEs) under the administrative control of Department of Pharmaceuticals, three viz. Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and are referred to Board for Industrial & Financial Reconstruction (BIFR). The Rajasthan Drugs & Pharmaceuticals Limited (RDPL) reported losses for the first time during the year 2013-14. The Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) is the only profit making CPSE.

Bengal Chemical and Pharmaceuticals Ltd

The Committee also notes that the performance of Bengal Chemical and Pharmaceuticals Limited is improving. The Government sanctioned a rehabilitation package which has been implemented now it is on its way to progress. Turnover of the Company was Rs.50 crore in 2013-14. Last year, it was Rs.23 crore. This year, it is going to touch Rs.100 crore and it is likely to make up a gross profit of Rs.8 to Rs.10 crore. BCPL have two pending projects, one at Kanpur and the other is a more prestigious anti-snake venom project. It requires Rs.27 crore investments and if it is sanctioned for anti-snake venom project, it can be supplied to entire country and can also be exported.

Hindustan Antibiotics Ltd.

The Committee note with regard to HAL, Salary for 17 months is pending. The Committee also notes that each time whenever salary is to be given, the Department has to go to the Finance Ministry. The Department has worked out a rehabilitation package for Hindustan Antibiotics Limited. It is sending the proposal for simplified rehabilitation package to the Cabinet, for both IDPL and HAL. The action for revival of the HAL would be initiated once the approval of Cabinet is accorded. The Committee also feels that if the Cabinet note is approved, the official process will take nine months to get the first installment of payment after selling of the land. Till that time, it will be difficult for the employees of HAL to meet their ends meet. In this context, the Committee strongly feel that Department should strive to provide some interim relief to the employees of HAL so as to improve morale of the employees.

Indian Drugs & Pharmaceuticals Ltd.

The Committee further notes that Cabinet note for revival of sick PSUs namely Indian Drugs & Pharmaceuticals Ltd (IDPL) is being finalized. The Committee also feels that the Government has to take a call on whether they want to revive IDPL or close it down because regular man power has virtually vanished. The Committee further observes that the situation in IDPL has made a turn around with an operating cash profit of Rs.4.38 crore made last year. This year, the turnover is touching Rs.85 crore and will perhaps be the highest in-house production ever achieved in the last 20 years. The Committee further note that IDPL is managing its own cash flow through its deposits, and is using it for working capital needs. The IDPL unit of Hyderabad will be inaugurated and It will be

Good Manufacturing Practice (GMP) plant. The Committee, feel that Government support is needed for revival of IDPL.

The Committee is of the view that steps to rehabilitate all the sick PSUs should be quickened. The Committee, therefore recommend that the Department should make vigorous efforts in coordination with all concerned authorities to rehabilitate the Pharma PSU's and meet their immediate requirement expeditiously.

REPLY OF THE GOVERNMENT

Notes for approval of Cabinet for the revival of Hindustan Antibiotics Limited (HAL) & Indian Drugs & Pharmaceuticals Limited (IDPL), were submitted in April 2016. As per the decision of Cabinet, the matter relating to revival of HAL has been referred to a Committee of Ministers (i.e. Minister of Finance, Minister of Road Transport & Highways and Minister of Chemicals & Fertilizers) to review the Pharma PSUs and suggest further course of action. Department of Pharmaceuticals has been directed by the Committee of Ministers to appoint a Consultant to develop a concept note and prepare a report/document on the issue of revival of these Pharmaceuticals Units. The process of appointment of Consultant has already been initiated by HAL.

COMMENTS OF THE COMMITTEE

(Please see Para No.26 of Chapter- I of the Report)

New Delhi;
08 December, 2016
17Agrahayana 1938 (Saka)

ANANDRAO ADSUL
Chairperson
Standing Committee on
Chemicals and Fertilizers

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

The Committee sat on Wednesday, the 07 December, 2016 from 1615 hrs. to 1700 hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri George Baker
3. Smt. Anju Bala
4. Shri B. N. Chandrappa
5. Smt. Veena Devi
6. Shri R. Dhruvanarayana
7. Smt. Kamla Devi Patle
8. Dr. Kulamani Samal
9. Smt. Rekha Arun Verma
10. Shri Kirti Vardhan Singh

RAJYA SABHA

11. Shri Biswajit Daimary
12. Shri Narayan Lal Panchariya
13. Shri K. Parasaran
14. Shri Palvai Govardhan Reddy
15. Smt. Roopa Ganguly

SECRETARIAT

- | | | |
|--------------------------|---|---------------------|
| 1. Smt. Rashmi Jain | - | Joint Secretary |
| 2. Shri A. K. Srivastava | - | Director |
| 3. Shri H. Ram Prakash | - | Additional Director |
| 4. Shri Nishant Mehra | - | Under Secretary |

2. At the outset, the Hon'ble Chairperson welcomed the members of the Committee.
3. The Committee thereafter took up for consideration the Draft Action Taken Reports on 'Demands for Grants 2016-17' and on the subject 'Cluster Development Programme for Pharma Sector' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals). After some deliberations the Draft Action Taken Reports were adopted by the Committee without any changes.
4. 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 Pharmaceuticals of the Ministry of Chemicals and Fertilizers.
5. It was also decided in the meeting that presentation of 02 Action Taken Reports shall take place in both the Houses on 9.12.2016.
6. The Committee thereafter decided to hold its next meeting on 6th January, 2017.

The Committee then adjourned.

(Vide Para 3 of the Introduction)**ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE TWENTY-THIRD REPORT (SIXTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2015-16) ON 'DEMANDS FOR GRANTS (2016-17)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)**

I	Total No. of Recommendations	9
II	Observations / Recommendations which have been accepted by the Government: (Vide Recommendation Nos.1, 2,3,4 5, 6, 7 and 8)	8
Percentage of Total		89%
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- NIL	00
Percentage of Total		00
IV	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- NIL	00
Percentage of Total		00
V	Observations / Recommendations in respect of which final replies of the Government are still awaited: (Vide Recommendation No 9)	1
Percentage of Total		11%