30

# 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 Fourth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers on the subject "Cluster Development Programme for Pharma Sector - (CDP-PS)" of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)



# THIRTIETH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

DECEMBER, 2016 / AGRAHAYANA, 1938 (SAKA)

#### THIRTIETH REPORT

# STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2016-17)

(SIXTEENTH LOK SABHA)

# MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations contained in the Twenty Fourth Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on the subject "Cluster Development Programme for Pharma Sector - (CDP-PS)" 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)

	CONTENTS	PAGE	
COMPOSITION OF THE COMMITTEE (2016-17)			
INTRODUCTION		(v)	
Chapter I	Report		
Chapter II	Observations / Recommendations which have been accepted by the Government		
Chapter III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's replies		
Chapter IV	Observations / Recommendations in respect of which replies of the Government have not been accepted by the committee		
Chapter V	Observations / Recommendations in respect of which final replies of the Government are still awaited		
	APPENDICES		
I.	Minutes of Fifth Sitting of the Standing Committee on Chemicals & Fertilizers (2016-17) held on 06.12.2016.		
II.	Analysis of Action Taken by the Government on the Recommendations contained in the Twenty Fourth Report (16th Lok Sabha) of the Standing Committee on Chemicals & Fertilizers (2016-17) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).		

#### 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.
10	Clivian II I n I

- 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 Daimary23. 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

(v)

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 Thirtieth Report (Sixteenth Lok Sabha) on Action

Taken by the Government on the observations/recommendations contained in

the Twenty Fourth Report (Sixteenth Lok Sabha) of the Standing Committee on

Chemicals and Fertilizers (2016-17) on the subject "Cluster Development

Programme for Pharma Sector - (CDP-PS)" of the Ministry of Chemicals and

Fertilizers (Department of Pharmaceuticals).

2. The Twenty Fourth Report (Sixteenth Lok Sabha) of the Standing Committee

on Chemicals and Fertilizers was presented to Lok Sabha on 28.07.2016. The

Action Taken replies of Government to all observations/ recommendations

contained in the Report were received on 24.10.2016. 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 Fourth 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

5

#### **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-Fourth Report (Sixteenth Lok Sabha) of the Committee on the Subject "Cluster Development Programme for Pharma Sector (CDP-PS)" of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 28.7.2016. In all, the Committee made 6 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-Fourth Report within three months from the date of presentation of the Report, i.e., by 28.10.2016. The Action Taken Replies of the Government in respect of all the 6 Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their O.M. No. 31026/168/2015-PI-II dated 24.10.2016. These Replies have been categorized as follows:-
  - (i) Observations / Recommendations that have been accepted by the Government:-

Sl.Nos. 1, 2 and 4 (Total =3) 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. 6 (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.No.3 and 5 (Total =2) 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 of this Report and the Final Replies in respect of Observations/Recommendations contained in Chapter IV and V which have not been accepted or replies are still awaited 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 Cluster Development Programme for Pharma Sector (CDP-PS)

#### **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 Department of Pharmaceuticals (DoP) has announced the Scheme for Cluster Development Programme for Pharma Sector (CDP-PS) in July 2014 with a vision to catalyze and encourage quality, productivity and innovation to enable the Indian pharmaceutical industry to play a leading role in a competitive global market. By this programme, the DoP aims to increase the easy access to standard testing facilities and value addition especially to SMEs through creation of common world class facilities. The Committee, appreciate the Department for announcing the CDP-PS and desire that these clusters should have all common scientific infrastructure facilities so as to reduce the cost of production of drugs by individual units. Further, the Committee, also feel that more interaction by the Department with Pharma Industry/associations to know the ground realities and practical difficulties would accelerate the implementation of the scheme. The Committee, therefore recommend that the Department may regularly have interaction with Pharma Industry and associations to expeditiously implement the scheme in a systematic, professional and transparent manner and ensure that the objectives of the Scheme are achieved at the earliest".

#### **Reply of the Government**

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

"The Government along with the Project Management Consultant (PMC) is regularly interacting with the Pharma Industries and Associations to expeditiously implement the scheme in a systematic, professional and transparent manner and to ensure that the objectives of the Scheme are achieved at the earliest. In this regard, Department of Pharmaceuticals in association with Indian Drug Manufacturers Association (IDMA) has already organised 2 seminars on Cluster Development to apprise stakeholders about the salient features of the Cluster Development Programme for Pharma Sector (CDP-PS) at different locations.

#### **Comments of the Committee**

7. The Committee noted that the Department of Pharmaceuticals has announced the Scheme for Cluster Development Programme for Pharma Sector (CDP-PS) in July 2014. The Committee desired that these clusters should have all common scientific infrastructure facilities so as to reduce the cost of production of drugs by individual units. The Committee had recommended that

associations to expeditiously implement the scheme in a systematic, professional and transparent manner and ensure that the objectives of the Scheme are achieved at the earliest. In their Action Taken Reply, the Department has stated that the Government along with the Project Management Consultant (PMC) is regularly interacting with the Pharma Industries and Associations to expeditiously implement the scheme in a systematic, professional and transparent manner and to ensure that the objectives of the Scheme are achieved at the earliest. In this regard, the Department of Pharmaceuticals in association with Indian Drug Manufacturers Association (IDMA) has already organised 2 seminars on Cluster Development to apprise stakeholders about the salient features of the Cluster Development Programme for Pharma Sector (CDP-PS) at different locations. While appreciating the efforts made by the Department of Pharmaceuticals, the Committee would like to know the outcome of the efforts in terms of interest shown in this Programme by the stake holders. The Committee, therefore stress that all out efforts should be made to expedite the process and would like to be apprised about the latest status in this regard.

the Department may regularly have interaction with Pharma Industry and

B. Need for Special Purpose Vehicle (SPV) for the implementation of Cluster Development Programme.

#### **Recommendation Sl. No.2**

8. While expressing the view that Cluster Development Programme will be implemented through Special Purpose Vehicle, the Committee had recommended as under:-

"The Committee note that the Cluster Development Programme will be implemented through a Special Purpose Vehicle (SPV) which will have representatives from cluster members, financial institutions, State & Central Governments and R&D organisations with full operational autonomy to develop, operate and maintain the infrastructure. The Committee, further note that the programme is to 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 to the SPVs set up for the purpose. The State Governments role would mainly arise after the SPV and DPR are approved by Scheme Steering Committee (SSC). The Committee observe that till date SSC has held five meetings and all the meetings were held in Delhi only and whenever it was felt necessary. During the course of the evidence even the department felt that holding of SSC meeting at different places will associate the local Industry more. The Committee are of the opinion that the development of Cluster Programme is of paramount importance and fits in realizing the Make in India goal of the Government. The Committee desire that the Department should take proactive measures toward developing Cluster Development Scheme. The Committee, therefore recommend that SSC should hold more meetings at regular interval and also at different relevant places where the Pharma companies are concentrated for proper monitoring and early establishment of the scheme. The Department should also enlist the support of State Governments for making the scheme successful. 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 along with the Project Management Consultant (PMC) is regularly interacting with the Pharma Industries and Associations to expeditiously implement the scheme in a systematic, professional and transparent manner and to ensure that the objectives of the Scheme are achieved at the earliest. In this regard, Department of Pharmaceuticals in association with Indian Drug Manufacturers Association (IDMA) has already organised 2 seminars on Cluster Development to apprise stakeholders about the salient features of the Cluster Development Programme for Pharma Sector (CDP-PS) at different locations. In the meeting of the Scheme Steering Committee (SSC) held on 5/10/2016, the following decisions have been taken:

- (i) DPR submitted by M/s. Chennai Pharma Industrial Infrastructure Upgradation Complex (CPIIUC), Alathur Distt. Kanchipuram, Tamilnadu was approved by SSC.
- (ii) In the 3<sup>rd</sup> EOI called and proposal from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIICL) was received, however, they requested for in-principle approval of DPR before formation of SPV which was approved by SSC".

#### **Comments of the Committee**

10 The Committee noted that the Cluster Development Programme will be implemented through a Special Purpose Vehicle (SPV). The Committee, further noted that the programme is to 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 to the SPVs set up for the purpose. The Committee observed that till date Scheme Steering Committee (SSC) has held five meetings and all the meetings were held in Delhi only whenever it was felt necessary. During the course of the evidence even the department felt that holding of SSC meeting at different places will associate the The Committee, therefore had recommended that SSC local Industry more. should hold more meetings at regular interval and also at different relevant places where the Pharma companies are concentrated for proper monitoring and early establishment of the scheme. The Committee had also recommended that the Department should enlist the support of State Governments for making the scheme successful.

In their Action Taken Reply, the Department of Pharmaceuticals stated that the Department of Pharmaceuticals in association with Indian Drug Manufacturers Association (IDMA) has already organised 2 seminars on Cluster Development to apprise stakeholders about the salient features of the Cluster Development Programme for Pharma Sector (CDP-PS) at different locations. In the meeting of the SSC held on 5/10/2016, two decisions have been taken (i) DPR submitted by M/s. Chennai Pharma Industrial Infrastructure Upgradation Complex (CPIIUC), Alathur Distt. Kanchipuram, Tamilnadu was approved by SSC. (ii) The 3<sup>rd</sup> EOI called and the proposal from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIICL) was received, however, they requested for in-principle approval of DPR before formation of SPV which was approved by SSC.

While appreciating the efforts made by the **Department** Pharmaceuticals, the Committee would like to stress that the SPV in respect of the above mentioned two firms may be expeditiously set up. Moreover, the Committee observed that the reply of the Department is silent about enlisting the support of State Governments. The Committee are of the view that without the support of State Governments the Scheme cannot become fully functional. The Committee, therefore, reiterate its earlier recommendation that the Department should also enlist the support of State Governments and make earnest efforts in this regard. The Committee further recommend that the meetings of the SSC should be held at different locations region wise so that the whole country gets the benefit of the scheme and other Pharma companies also become stake holders to form pharma clusters. The Committee would like to know the progress made in this regard.

C. Need to Review Terms and conditions for formation of SPVs under CDP-PS

#### **Recommendation Sl. No.3**

11. While expressing that the Department should relook the scheme and review all bottlenecks and reduce the number of members required to form SPV and also the amount to be invested, the Committee had recommended as under:-

"The Committee note that Common Facilities under the CDP-PS will consist of creation of tangible "assets" such as (i) Common Testing Facilities (ii)Training Centre (iii) R&D Centres (iv) Effluent Treatment Plant and (v) Common Logistics Centre. The Committee also note that each cluster could have its own specific requirements based on the nature of units being set up and the products proposed to be manufactured. The Scheme Steering Committee (SSC) shall approve the project components and funding thereof depending upon the merits of the proposal.

The Committee note that a minimum of 10 Pharma Companies are required to form a SPV under CDP-PS. Further each company who joins the SPV as members under CDP-PS has to invest about Rs.15 to 20 lakh. The Committee note that these conditions are coming in the way of successful implementation of the scheme. There have been suggestions to include Ayurvedic, Unani drug manufacturers and cosmetic companies also as member in the Cluster Development Programme. The Committee, therefore, recommend that Department may relook the scheme and review all bottlenecks and reduce the number of members required to form SPV and also the amount to be invested. Further suggestions for including the cosmetic and Ayurveda and all the other drug companies may also be considered in formation of clusters. The Committee, would like to know the changes made in the scheme to make it implementable".

#### **Reply of the Government**

- 12. In reply to the afore-mentioned recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-
  - "As desired by the Pharma Industry in the  $6^{th}$  Scheme Steering Committee (SSC) meeting on 29/6/2016, it was decided that Ayurvedic, Unani and Cosmetics firms shall also be considered as Pharma Firms".

#### **Comments of the Committee**

**13.** The Committee observed that Common Facilities under the CDP-PS will consist of creation of tangible "assets". such as (i) Common Testing Facilities (ii) Training Centre (iii) R&D Centres (iv) Effluent Treatment Plant and (v) Common Logistics Centre. The Scheme Steering Committee (SSC) shall approve the project components and funding thereof depending upon the merits of the proposal. The Committee also noted that a minimum of 10 Pharma Companies are required to form a SPV under CDP-PS. Further each company who joins the SPV as members under CDP-PS has to invest about Rs.15lakh to Rs.20 lakh. The Committee further noted that these conditions are coming in the way of successful implementation of the scheme. The Committee, therefore, recommended that the Department may relook the scheme and review all bottlenecks and reduce the number of members required to form SPV and also the amount to be invested. In their Action taken reply, the Department stated that as desired by the Pharma Industry in the 6th SSC meeting held on 29/6/2016, it was decided that Ayurvedic, Unani and Cosmetics firms shall also be considered as Pharma Firms.

The Committee are disappointed to note that the Department has not properly considered the bottlenecks such as review of the number of members required to form SPV and also the amount to be invested by the member companies. The Committee, therefore, reiterate that its recommendation may be implemented without any further delay as the Committee are of the opinion

that this will give an impetus and boost to the development of CDP-PS. The Committee would like to be informed of the action taken in this regard.

D. Need for expedient monitoring and timely utilisation of Budgetary allocation of funds.

#### **Recommendation Sl. No.4**

14. While expressing concern over the timely utilisation of funds allocated for the current year for the Cluster Development Programme, the Committee had recommended as under:-

"The Committee note under the 12th Five Year Plan, Rs.125 crore has been allotted for the CDP-PS Scheme. The Committee observe that the maximum limit for the grant in aid from Government under this category would be Rs. 20 Crore per cluster or 70 per cent of the cost of the project, whichever is less. Government grant will be 90 per cent for Common Facility Centres (CFCs) for difficult and backward regions. Till 2015-16, the grants for cluster scheme was covered under the head of new schemes but from this budget, the allocation has been made for cluster scheme separately. The Committee, further note that no grant in aid was released under the cluster development scheme during 2015-16 as none qualified for grant in spite of two rounds of EOIs. Although, a sum of Rs. 60 crore was requested for BE 2016-17, only a provision of Rs.10 crore has been made in BE 2016-17. The Committee express their displeasure over the fact that the Department has not been successful in the last two years in implementation of the Scheme and the funds have remained unutilised. Presently, the Project Management Consultant (PMC) has been requested to review the whole process and suggest remedial measures. The Committee therefore, desire that the Department should make the scheme implementable at the earliest and that expedient monitoring and timely action may be taken to utilise the funds allocated for the current year to the utmost as it is very vital for the growth of Pharmaceutical companies especially the SME Pharma Units.

# **Reply of the Government**

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

"The directions of the Committee have been noted and the Government along with the Project Management Consultant (PMC) is regularly interacting with the Pharma Industries and Associations to expeditiously implement the scheme in a systematic, professional and transparent manner and to ensure that the objectives of the Scheme are achieved at the earliest.

In the meeting of the Scheme Steering Committee (SSC) held on 5/10/2016, the following decisions have been taken:-

(i) DPR submitted by M/s. Chennai Pharma Industrial Infrastructure Upgradation Complex (CPIIUC), Alathur Distt. Kanchipuram, Tamilnadu was approved by SSC.

(ii) In response to the 3<sup>rd</sup> EOI called, proposals from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIICL) were received. However, they requested for in-principle approval of DPR before formation of SPV which was considered favourably by the SSC".

#### **Comments of the Committee**

16. The Committee noted that under the 12th Five Year Plan, Rs.125 crore has been allotted for the CDP-PS Scheme. The Committee observed that the maximum limit for the grant in aid from Government under this category would be Rs. 20 Crore per cluster or 70 per cent of the cost of the project, whichever is less. The Committee, further noted that no grant in aid was released under the Cluster development scheme during 2015-16 as none qualified for grant in spite of two rounds of EOIs. Although, a sum of Rs. 60 crore was requested for BE 2016-17, only a provision of Rs.10 crore has been made in BE 2016-17. The Committee had also expressed its displeasures over the fact that the whatever the meagre funds given to the Department of Pharmaceuticals also remained unutilised and desired that the Department should make the scheme implementable at the earliest and that expedient monitoring and timely action may be taken to utilise the funds allocated for the current year to the utmost.

In their Action Taken Reply, the Department stated that the Government along with the Project Management Consultant (PMC) is regularly interacting with the Pharma Industries and Associations to expeditiously implement the scheme in a systematic, professional and transparent manner and to ensure that the objectives of the Scheme are achieved at the earliest. In the meeting of the Scheme Steering Committee (SSC) held on 5/10/2016, two decisions have been taken (i) DPR submitted by M/s. Chennai Pharma Industrial Infrastructure Upgradation Complex (CPIIUC), Alathur Distt. Kanchipuram, Tamilnadu was approved by SSC. (ii) In response to the 3<sup>rd</sup> EOI called, proposals from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIICL) were received. However, they requested for in-principle approval of DPR before formation of SPV which was considered favourably by the SSC. Further although, a sum of Rs. 60 crore was requested for BE 2016-17, only a provision of Rs.10 crore has been made in BE 2016-17.

The Committee express their displeasure over the fact that the Department has not been successful in the last two years in implementation of the Scheme and the funds have remained unutilised. In view of the reply, the Committee recommend that two clusters for which approval has already been given should be provided timely grant-in-aid of the cost of the project. The Committee also reiterate its recommendation that the Department should make

the scheme implementable at the earliest and that expedient monitoring and timely action may be taken to utilise the funds allocated for the current year to the utmost as it is very vital for the growth of Pharmaceutical companies especially the SME Pharma Units.

### **E** Need for Alternative Model for Cluster Development

#### **Recommendation Sl. No.5**

17 While expressing the need for alternative model for cluster development, the Committee had recommended as under:-

"The Committee observe that Expression of Interest (EoI) for receiving the grant by Pharma Companies under the Cluster Development Programme was issued on 7.7.2015 and closed on 11.9.2015 only six EoI's were received. The Scheme Selection Committee (SSC) found that except one EoI, others did not fulfill the criteria required for receiving the grant under the scheme. The Committee observe that only one project has been given in-principle approval and that its Proposal& Detailed Project Report(DPR) is awaited. The Committee also observe that PMC has contacted representatives of the Pharma firms and Pharma Associations all over India, through telephonic discussion and also visited many clusters, such as Baddi(H.P.), Deraabassi (near Chandigarh), Maharashtra, Tamilnadu, Gujarat, Andhra Pradesh & West Bengal area. However, the Committee observe that in practice not much response has been received from SME Pharma companies for this programme.

Keeping in view of the poor response the Committee, further note that the SSC is revaluating the scheme in consultation with the stakeholders to make it more feasible so that the scheme could be successfully implemented in a time bound manner. The Committee are of the opinion that the Department of Pharmaceuticals should identify some existing locations which have the potential to emerge as a pharmaceutical cluster and in collaboration with the concerned State Governments and local pharma companies should set up the basic infrastructure facilities envisaged under CDP in a PPP mode which can be utilised by pharma units at reasonable charges which will also enable the objectives of the programme to be achieved. Therefore, the Committee recommend that the Department of Pharmaceuticals should explore the possibility of establishment of world class facilities in cities or in States where cluster of pharma companies already exist and such common facilities can be created under PPP mode".

## **Reply of the Government**

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

"The directions of the Committee have been noted. The proposals have been received from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIIC). The DPR from APIIC has been received by the Project Management Consultant (PMC)".

#### **Comments of the Committee**

The Committee observed that out of six EoIs received, the SSC found that only one EoI fulfilled the criteria required for receiving the grant under the scheme. The Committee also observed that in practice not much response has been received from SME Pharma companies for this programme. The Committee further noted that keeping in view of the poor response, SSC was revaluating the scheme in consultation with the stakeholders to make it more feasible so that the scheme could be successfully implemented in a time bound manner. The Committee were of the opinion that the Department of Pharmaceuticals should identify some existing locations which have the potential to emerge as a pharmaceutical cluster and in collaboration with the concerned State Governments and local pharma companies should set up the basic infrastructure facilities envisaged under CDP in a PPP mode which can be utilised by pharma units at reasonable charges which will also enable the objectives of the programme to be achieved.

In their Action Taken Reply, the Department has stated that the directions of the Committee have been noted. The Department has mentioned that a proposal have been received from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIIC). The DPR from APIIC has been received by the Project Management Consultant (PMC).

The Committee observed that no comments have been made by the Department regarding the development of existing Pharma Companies in the country. The Committee, therefore, reiterate its suggestion that the Department of Pharmaceuticals should identify some existing locations which have the potential to emerge as a pharmaceutical cluster and in collaboration with the concerned State Governments and Pharma Companies explore the possibility of establishment of world class facilities under PPP mode.

#### F. Need for allowing PSU Pharma Companies to establish clusters

#### Recommendation Sl. No. 6

While expressing that the need for allowing PSU Pharma companies to establish clusters, the Committee had recommended as under:-

"In order to give thrust to the scheme, the Committee desire that the Department should also consider entrusting creation of clusters to PSU pharmaceutical companies like IDPL and HAL etc. These companies have huge vacant land and also infrastructure facilities that are required for pharmaceutical companies. These PSUs pharma companies may be encouraged to utilise land available with them for setting up of clusters along with the creation of common world class facilities in the clusters through SPV or PPP mode. The Department of Pharmaceuticals may also provide suitable grant for

creation of such facilities. The Committee are of the opinion that this may benefit as good revenue stream to the PSU pharma companies by utilization of their vacant land. The Committee, therefore, recommend that during the review of the scheme, the Department may seriously consider allowing the PSU pharma companies to utilise their vacant land for promotion of pharmaceutical clusters".

#### **Reply of the Government**

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

"M/s Hindustan Antibiotic Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL) are sick public sector pharmaceutical companies which have been referred to BIFR since 1992 and 1997 respectively. The Cabinet has constituted a Committee of 3 Ministers to comprehensively examine and recommend the suitable course of action for all the Pharma Sector CPSUs".

#### **Comments of the Committee**

22. The Committee observed that Pharma PSUs may be encouraged to utilise land available with them for setting up of Clusters alongwith the creation of common world class facilities in the clusters through SPV or PPP mode. The Committee are of the opinion that this would be helpful in generating good revenue to pharma PSUs.

In their Action Taken Reply, the Department stated that M/s Hindustan Antibiotic Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL) are sick public sector pharmaceutical companies which have been referred to BIFR since 1992 and 1997 respectively. The Cabinet has constituted a Committee of three Ministers to comprehensively examine and recommend the suitable course of action for all the Pharma Sector CPSUs.

The Committee observe that Department of Pharmaceuticals has not commented anything about the recommendation of the Committee to utilise vacant land of PSUs for setting up Pharma Clusters of world class standard and instead gave a stereotyped reply that HAL and IDPL have been referred to BIFR since 1992 and 1997 respectively and Cabinet has constituted a Committee of three Ministers to examine and report for suitable course of action. The Committee, therefore recommend that apart from ongoing process of revival of these sick PSUs, the Department should explore the feasibility of setting up of world class Pharma Clusters in the vacant land of companies such as HAL and IDPL. The Committee would like to be apprised about the action taken in this regard.

#### **CHAPTER - II**

# OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

#### **Recommendation Sl. No.1**

The Committee note that the Department of Pharmaceuticals (DoP) has announced the Scheme for Cluster Development Programme for Pharma Sector (CDP-PS) in July 2014 with a vision to catalyze and encourage quality, productivity and innovation to enable the Indian pharmaceutical industry to play a leading role in a competitive global market. By this programme, the DoP aims to increase the easy access to standard testing facilities and value addition especially to SMEs through creation of common world class facilities. The Committee, appreciate the Department for announcing the CDP-PS and desire that these clusters should have all common scientific infrastructure facilities so as to reduce the cost of production of drugs by individual units. Further, the Committee, also feel that more interaction by the Department with Pharma Industry/associations to know the ground realities and practical difficulties would accelerate the implementation of the scheme. The Committee, therefore recommend that the Department may regularly have interaction with Pharma Industry and associations to expeditiously implement the scheme in a systematic, professional and transparent manner and ensure that the objectives of the Scheme are achieved at the earliest".

#### **Reply of the Government**

The Government along with the Project Management Consultant (PMC) is regularly interacting with the Pharma Industries and Associations to expeditiously implement the scheme in a systematic, professional and transparent manner and to ensure that the objectives of the Scheme are achieved at the earliest. In this regard, Department of Pharmaceuticals in association with Indian Drug Manufacturers Association (IDMA) has already organised 2 seminars on Cluster Development to apprise stakeholders about the salient features of the Cluster Development Programme for Pharma Sector (CDP-PS) at different locations.

#### **Comments of the Committee**

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

#### **Recommendation Sl. No.2**

The Committee note that the Cluster Development Programme will be implemented through a Special Purpose Vehicle (SPV) which will have representatives from cluster members, financial institutions, State & Central Governments and R&D organisations with full operational autonomy to develop, operate and maintain the infrastructure. The Committee, further note that the programme is to 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 to the SPVs set up for the purpose. The State Governments role would mainly arise after the SPV and DPR are approved by Scheme Steering Committee (SSC). The Committee observe that till date SSC has held five meetings and all the meetings were held in Delhi only and whenever it was felt necessary. During the course of the evidence even the department felt that holding of SSC meeting at different places will associate the local Industry more. The Committee are of the opinion that the development of Cluster Programme is of paramount importance and fits in realizing

the Make in India goal of the Government. The Committee desire that the Department should take proactive measures toward developing Cluster Development Scheme. The Committee, therefore recommend that SSC should hold more meetings at regular interval and also at different relevant places where the Pharma companies are concentrated for proper monitoring and early establishment of the scheme. The Department should also enlist the support of State Governments for making the scheme successful. 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 along with the Project Management Consultant (PMC) is regularly interacting with the Pharma Industries and Associations to expeditiously implement the scheme in a systematic, professional and transparent manner and to ensure that the objectives of the Scheme are achieved at the earliest. In this regard, Department of Pharmaceuticals in association with Indian Drug Manufacturers Association (IDMA) has already organised 2 seminars on Cluster Development to apprise stakeholders about the salient features of the Cluster Development Programme for Pharma Sector (CDP-PS) at different locations. In the meeting of the Scheme Steering Committee (SSC) held on 5/10/2016, the following decisions have been taken:-

- (i) DPR submitted by M/s. Chennai Pharma Industrial Infrastructure Upgradation Complex (CPIIUC), Alathur Distt. Kanchipuram, Tamilnadu was approved by SSC.
- (ii) In the 3<sup>rd</sup> EOI called and proposal from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIICL) was received, however, they requested for in-principle approval of DPR before formation of SPV which was approved by SSC.

#### **Comments of the Committee**

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

#### **Recommendation Sl. No.4**

The Committee note under the 12th Five Year Plan, Rs.125 crore has been allotted for the CDP-PS Scheme. The Committee observe that the maximum limit for the grant in aid from Government under this category would be Rs. 20 Crore per cluster or 70 per cent of the cost of the project, whichever is less. Government grant will be 90 per cent for Common Facility Centres (CFCs) for difficult and backward regions. Till 2015-16, the grants for cluster scheme was covered under the head of new schemes but from this budget, the allocation has been made for cluster scheme separately. The Committee, further note that no grant in aid was released under the cluster development scheme during 2015-16 as none qualified for grant in spite of two rounds of EOIs. Although, a sum of Rs. 60 crore was requested for BE 2016-17, only a provision of Rs.10 crore has been made in BE 2016-17. The Committee express their displeasure over the fact that the Department has not been successful in the last two years in implementation of the Scheme and the funds have remained unutilised. Presently, the Project Management Consultant (PMC) has been requested to review the whole process and suggest remedial measures. The Committee therefore, desire that the Department should make the scheme implementable at the earliest and that expedient monitoring and timely action may be taken to utilise the funds allocated for

the current year to the utmost as it is very vital for the growth of Pharmaceutical companies especially the SME Pharma Units.

#### **Reply of the Government**

The directions of the Committee have been noted and the Government along with the Project Management Consultant (PMC) is regularly interacting with the Pharma Industries and Associations to expeditiously implement the scheme in a systematic, professional and transparent manner and to ensure that the objectives of the Scheme are achieved at the earliest.

In the meeting of the Scheme Steering Committee (SSC) held on 5/10/2016, the following decisions have been taken:-

- (i) DPR submitted by M/s. Chennai Pharma Industrial Infrastructure Upgradation Complex (CPIIUC), Alathur Distt. Kanchipuram, Tamilnadu was approved by SSC.
- (ii) In response to the 3<sup>rd</sup> EOI called, proposals from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIICL) were received. However, they requested for in-principle approval of DPR before formation of SPV which was considered favourably by the SSC.

#### **Comments of the Committee**

(Please see Para No.16 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. 6**

In order to give thrust to the scheme, the Committee desire that the Department should also consider entrusting creation of clusters to PSU pharmaceutical companies like IDPL and HAL etc. These companies have huge vacant land and also infrastructure facilities that are required for pharmaceutical companies. These PSUs pharma companies may be encouraged to utilise land available with them for setting up of clusters along with the creation of common world class facilities in the clusters through SPV or PPP mode. The Department of Pharmaceuticals may also provide suitable grant for creation of such facilities. The Committee are of the opinion that this may benefit as good revenue stream to the PSU pharma companies by utilization of their vacant land. The Committee, therefore, recommend that during the review of the scheme, the Department may seriously consider allowing the PSU pharma companies to utilise their vacant land for promotion of pharmaceutical clusters.

### Reply of the Government

M/s Hindustan Antibiotic Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL) are sick public sector pharmaceutical companies which have been referred to BIFR since 1992 and 1997 respectively. The Cabinet has constituted a Committee of 3 Ministers to comprehensively examine and recommend the suitable course of action for all the Pharma Sector CPSUs.

#### **Comments of the Committee**

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

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

#### **Recommendation Sl. No.3**

The Committee note that Common Facilities under the CDP-PS will consist of creation of tangible "assets" such as (i) Common Testing Facilities (ii)Training Centre (iii) R&D Centres (iv) Effluent Treatment Plant and (v) Common Logistics Centre. The Committee also note that each cluster could have its own specific requirements based on the nature of units being set up and the products proposed to be manufactured. The Scheme Steering Committee (SSC) shall approve the project components and funding thereof depending upon the merits of the proposal.

The Committee note that a minimum of 10 Pharma Companies are required to form a SPV under CDP-PS. Further each company who joins the SPV as members under CDP-PS has to invest about Rs.15 to 20 lakh. The Committee note that these conditions are coming in the way of successful implementation of the scheme. There have been suggestions to include Ayurvedic, Unani drug manufacturers and cosmetic companies also as member in the Cluster Development Programme. The Committee, therefore, recommend that Department may relook the scheme and review all bottlenecks and reduce the number of members required to form SPV and also the amount to be invested. Further suggestions for including the cosmetic and Ayurveda and all the other drug companies may also be considered in formation of clusters. The Committee, would like to know the changes made in the scheme to make it implementable".

# **Reply of the Government**

As desired by the Pharma Industry in the 6<sup>th</sup> Scheme Steering Committee (SSC) meeting on 29/6/2016, it was decided that Ayurvedic, Unani and Cosmetics firms shall also be considered as Pharma Firms.

#### **Comments of the Committee**

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

#### **Recommendation Sl. No.5**

The Committee observe that Expression of Interest (EoI) for receiving the grant by Pharma Companies under the Cluster Development Programme was issued on 7.7.2015 and closed on 11.9.2015 only six EoI's were received. The Scheme Selection Committee (SSC) found that except one EoI, others did not fulfill the criteria required for receiving the grant under the scheme. The Committee observe that only one project has been given in-principle approval and that its Proposal& Detailed Project Report(DPR) is awaited. The Committee also observe that PMC has contacted representatives of the Pharma firms and Pharma Associations all over India, through telephonic discussion and also visited many clusters, such as Baddi(H.P.), Deraabassi (near Chandigarh), Maharashtra, Tamilnadu, Gujarat, Andhra Pradesh & West Bengal area. However, the Committee observe that in practice not much response has been received from SME Pharma companies for this programme.

Keeping in view of the poor response the Committee, further note that the SSC is revaluating the scheme in consultation with the stakeholders to make it more feasible so that the scheme could be successfully implemented in a time bound

manner. The Committee are of the opinion that the Department of Pharmaceuticals should identify some existing locations which have the potential to emerge as a pharmaceutical cluster and in collaboration with the concerned State Governments and local pharma companies should set up the basic infrastructure facilities envisaged under CDP in a PPP mode which can be utilised by pharma units at reasonable charges which will also enable the objectives of the programme to be achieved. Therefore, the Committee recommend that the Department of Pharmaceuticals should explore the possibility of establishment of world class facilities in cities or in States where cluster of pharma companies already exist and such common facilities can be created under PPP mode".

# **Reply of the Government**

The directions of the Committee have been noted. The proposals have been received from M/s Andhra Pradesh Industrial Infrastructure Corporation Limited (APIIC). The DPR from APIIC has been received by the Project Management Consultant (PMC).

#### **Comments of the Committee**

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

New Delhi; 08 December, 2016 17 Agrahayana 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
- Smt. Anju Bala 3.
- Shri B. N. Chandrappa 4.
- 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

#### **RAIYA 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

r 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.
- 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.
- It was also decided in the meeting that presentation of 02 Action Taken Reports 5. shall take place in both the Houses on 9.12.2016.
- 6. The Committee thereafter decided to hold its next meeting 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-FOURTH REPORT (SIXTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2015-16) ON THE SUBJECT CLUSTER DEVELOPMENT PROGRAMME FOR PHARMA SECTOR (CDP-PS) (2016-17) OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	6			
II	Observations / Recommendations which have been accepted by the Government:	3			
	(Vide Recommendation Nos.1, 2 and 4)				
	Percentage of Total	50%			
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:-  (Vide Recommendation No.6)	1			
	Percentage of Total	17%			
V	Observations / Recommendations in respect of which final replies of the Government are still awaited:  (Vide Recommendation Nos. 3 and 5)	2			
	Percentage of Total	33%			