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**STANDING COMMITTEE ON  
CHEMICALS AND FERTILIZERS  
(2013-2014)**

**FIFTEENTH LOK SABHA**

**MINISTRY OF CHEMICALS AND FERTILIZERS  
(DEPARTMENT OF PHARMACEUTICALS)**

**DEMANDS FOR GRANTS  
(2013-2014)**

*[Action Taken by the Government on the Observations/Recommendations contained in the Thirty-Fifth Report of the Standing Committee on Chemicals and Fertilizers (15th Lok Sabha) on Demands for Grants (2013-2014) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]*

**FORTY-FIRST REPORT**



**LOK SABHA SECRETARIAT  
NEW DELHI**

*December, 2013/Agrahayana, 1935 (Saka)*

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(2013-2014)

( FIFTEENTH LOK SABHA )

MINISTRY OF CHEMICALS AND FERTILIZERS  
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS  
(2013-2014)

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Chemicals and Fertilizers (15th Lok Sabha) on Demands for Grants  
(2013-2014) of the Ministry of Chemicals and Fertilizers  
(Department of Pharmaceuticals)]*

*Presented to Lok Sabha on 16.12.2013  
Laid in Rajya Sabha on 16.12.2013*



LOK SABHA SECRETARIAT  
NEW DELHI

*December, 2013/Agrahayana, 1935 (Saka)*

**CC&F No. 41**

*Price : Rs. 43.00*

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Published under Rule 382 of the Rules of Procedure and Conduct of Business in Lok Sabha (Fourteenth Edition) and printed by National Printers, New Delhi-110 028.

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COMPOSITION OF THE STANDING COMMITTEE ON  
CHEMICALS AND FERTILIZERS (2013-14)

Shri Gopinath Munde — *Chairman*

MEMBERS

*Lok Sabha*

2. Shri S. Alagiri
3. Shri Gajanan D. Babar
4. Shri Prabhatsinh P. Chauhan
5. Shri K.D. Deshmukh
6. Shri Sher Singh Ghubaya
7. Sk. Nurul Islam
8. Shri Sakti Mohan Malik
9. Shri Paswan Kamlesh
10. Shri Amarnath Pradhan
11. Shri Ashok Kumar Rawat
12. Shri Tufani Saroj
13. Shri Suresh Kumar Shetkar
14. Shri Raju Shetti
15. Shri G.M. Siddeshwara
16. Shri D. Venugopal
17. Shri Sai Prathap Annayyagari
18. Vacant
19. Vacant
20. Vacant
21. Vacant

*Rajya Sabha*

22. Shri Biswajit Daimary
23. Smt. Naznin Faruque
24. Shri A.A. Jinnah
25. Shri Brijlal Khabri
26. Shri Dilipbhai Pandya
27. Shri Raghunandan Sharma
28. Shri Ishwar Singh
29. Vacant
30. Vacant
31. Vacant

SECRETARIAT

1. Smt. Rashmi Jain — *Joint Secretary*
2. Shri U.B.S. Negi — *Director*
3. Shri A.K. Srivastava — *Additional Director*
4. Smt. Emma C. Barwa — *Under Secretary*

## INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2013-14) having been authorised by the Committee to present the Report on their behalf present this Forty-First Report (Fifteenth Lok Sabha) on Action Taken by the Government on the observations/recommendations contained in the Thirty-Fifth Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2012-2013) on Demands for Grants (2013-2014) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Thirty-Fifth Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 30.4.2013. The Action Taken replies of Government to all observations/recommendations contained in the Report were received on 22.8.2013. The Standing Committee on Chemicals and Fertilizers (2013-2014) considered and adopted this Report at their sitting held on 24 October, 2013.

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

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

NEW DELHI;  
24 October, 2013  
2 Kartika, 1935 (Saka)

GOPINATH MUNDE,  
*Chairman,*  
*Standing Committee on*  
*Chemicals and Fertilizers.*





## REPORT

### CHAPTER I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Thirty-Fifth Report (Fifteenth Lok Sabha) of the Committee on Demands for Grants (2013-14) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 30.04.2013. In all, the Committee made 10 Observations/Recommendations in the Report.

2. The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations/Recommendations contained in the Thirty-Fifth Report within three months from the date of presentation of the Report, *i.e.*, by 29.7.2013. The Action Taken Replies of the Government in respect of all the 10 Observations/Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) *vide* their O.M. No. 16(3)/2013-Fin. II, dated 22.08.2013. These have been categorized as follows:—

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

Sl. Nos. 1, 2, 4, 6, 7, 8, 9 and 10

(Total = 8)  
Chapter II

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

Sl. No. Nil

(Total = 0)  
Chapter III

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

Sl. Nos. 3 and 5

(Total = 2)  
Chapter IV

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

Sl. No. Nil

(Total = 0)  
Chapter V

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

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

**A. Need for Research and Development in the Field of Pharma Sector**

**Recommendation No. 1**

5. Emphasizing the need for Research and Development in the Field of Pharma Sector, the Committee had recommended as under:—

“The Committee note that net sales of the industry grew by 14.7% in the quarter ending June, 2012 as compared to the quarter a year ago. Again in the second quarter ending September 2012, the drugs and pharmaceuticals industry performed well. However, the Committee are concerned to note that the imports of ‘Medicinal and Pharmaceuticals Products’ had risen by 29.43 per cent in the year 2011-12 as compared to previous year. As a result of which pressure was exerted on the profit margins of the industry. According to the Department, although the country is almost self-sufficient in production of most of formulations/pharmaceuticals products, imports are resorted to on quality and economic considerations and not necessarily due to non-availability from domestic sources. Needless to say, the raw material expenses necessarily contribute towards the cost component of the quality

medicine being sold to the common consumers. The Committee, are therefore of the view that it would be imperative if the import of raw material for production of medicine is resorted only if the same is absolutely necessary for the purpose. In fact, the Committee, expect the Department to encourage innovation and also intensive research and development in the field of pharma sector so that cheap but quality inputs are available within the country itself for production of quality but cheap medicine which would ultimately benefit the common man in the country. The Committee, therefore, recommend to take appropriate steps in this direction.”

### **Reply of the Government**

6. In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“In order to encourage Pharma Innovation and Research and Development following proposals are under examination in the Department:—

- (i) In order to enhance the national potential for Drug Discovery and Innovation the Department is in the process of preparing a Detailed Project Report (DPR) in this regard. For the purpose the Department has engaged M/s. Ernst and Young Limited (M/s. E&Y) a global level consultant.
- (ii) A proposal is being examined in the Department to set up a National Centre for R&D in Bulk Drugs at Hyderabad NIPER.”

### **Comments of the Committee**

7. The Committee had noted that the imports of ‘Medicinal and Pharmaceuticals Products’ had risen by 29.43 per cent in the year 2011-12 as compared to the previous year. Although the country is almost self-sufficient in production of most of formulations/ pharmaceuticals products, imports were resorted to on quality and economic considerations. However, the Committee were of the view that the import of raw material for production of medicine should be resorted only if the same is absolutely necessary for the purpose. In this context, the Committee had desired that the Department should encourage innovation and also intensive research and development in the field of pharma sector so that cheap but quality inputs are available within the country itself for production of cheap but quality medicines

for the benefit of the common man in the country. In its Action Taken Reply, the Department has stated that in order to encourage Pharmacy Innovation and Research and Development, the proposals — one relating to enhance the national potential for Drug Discovery and Innovation and the second regarding setting up of a National Centre for R&D in bulk drugs at Hyderabad NIPER, are under examination in the Department. In view of the foregoing, the Committee hope that the aforesaid proposals would be vigorously pursued. However, the Committee note that the Department is conveniently silent over the issue concerning import of raw material for production of medicine. Since imported raw material would necessarily contribute to the cost component of the medicine which is ultimately passed on to the common consumers, it is but imperative that the import of raw material for production of medicine is resorted to only under extreme circumstances. The Committee, therefore, reiterate their earlier recommendation that raw material for production of medicines may be imported only when the same is absolutely necessary for the purpose. The Committee desire that the Department should formulate time bound action plan in this regard. The Committee would like to be apprised of the action taken by the Department in this regard.

- B. Allocation of funds for the remaining period of Twelfth Five Year Plan.

### Recommendation No. 3

8. While noting significantly less allocation of funds under various schemes of the Department, the Committee had recommended as under:—

“The Committee note that out of total GBS allocation of Rs. 2968.00 crore for the scheme-wise Plan Outlays during Twelfth Five Year Plan, the Department of Pharmaceuticals had proposed Rs. 567.60 crore for the year 2013-14 but the Planning Commission has approved only Rs.188.00 crore. The Committee also note that Planning Commission had indicated that the outlay of the Department be maintained at the same level as in the previous year. This was primarily due to gross underutilization of funds by the Department of during the year 2012-13. The Committee, feel that it is now the responsibility of the Department to impress upon the Planning Commission to allocate more funds for the remaining period of Twelfth Five Year Plan. The Committee expect the Department to act strongly.”

## **Reply of the Government**

9. In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“Planning Commission has been apprised about the Committee’s concern regarding enhanced allocation.”

## **Comments of the Committee**

10. The Committee had observed that out of total GBS allocation of Rs. 2968.00 crore for the scheme-wise Plan outlays during Twelfth Five Year Plan, the Department of Pharmaceuticals had proposed Rs. 567.60 crore for the year 2013-14 but the Planning Commission had approved only Rs. 188.00 crore. The Committee had noted that this was mainly due to under-utilization of funds by the Department during the year 2012-13. The Committee had, therefore, recommended that the Department should impress upon the Planning Commission to allocate more funds for remaining period of Twelfth Five Year Plan. In their Action Taken Reply, the Department has simply conveyed the concern of the Committee to the Planning Commission. Thus, the response of the Department in the matter is too casual and highly unsatisfactory. The Department has not furnished any explanation for its failure to utilize the funds timely and optimally which resulted less allocation of funds by the Planning Commission and the officers responsible therefor. The Committee are of the opinion that in the absence of any well thought out action plan for expeditious implementation of various schemes, the funds could not be utilized judiciously, optimally and timely. The Committee, therefore, desire that the Department should spell out its action plan with a view to impress upon the Planning Commission to allocate requisite funds for the remaining period of Twelfth Five Year Plan. The Department should also take action against the officers for their failure to utilize the funds timely and optimally. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

### **C. Setting up of campuses of Six New Institutes under NIPER**

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

11. While expressing concern over the delay in construction of new NIPER campuses, the Committee had recommended as under:—

“The Committee note that NIPER was declared as an “Institute of National Importance” under the Act of Parliament on

26th June 1998. NIPER is a member of Association of Indian Universities. The Committee also observe that in addition to NIPER, SAS Nagar, Mohali, the Government has set up six new NIPERs at Hajipur, Hyderabad, Ahmedabad, Rae Bareli, Guwahati and Kolkata. At present these six new NIPERs are functioning with the assistance of Mentor Institutes presently in the respective States. The work relating to construction of NIPER campuses at Guwahati and Gandhinagar has since been awarded to PSUs viz. Engineering Projects (India) Ltd. (EPIL) and Hindustan Steelworks Construction Ltd. (HSCL) respectively. The State Government of Andhra Pradesh has agreed to allot 50 acres of land for NIPER Hyderabad and the issue is being finalized. The issue of allocation of land for NIPER Kolkata, Hajipur and Rae Bareli are being pursued with the respective State Governments.

In view of the foregoing, the Committee regret to note that all six new NIPERs do not have their own campuses and still they continue to function with the assistance of Mentor Institutes even after a gap of more than 4-5 years. Considering the importance of these Institutes for the continuous growth of pharmaceuticals sector, it is but essential that all the new NIPER have their own campuses for their effective functioning for which these are meant for. In this regard the Committee reiterate its repeated recommendations on Demands for Grants 2009-10, 2010-11, 2011-12 and 2012-13 regarding completion of necessary formalities for construction of NIPER Campuses. While some progress has been made with regard to construction of NIPER Campus at Guwahati and Gandhinagar, the allotment of land for NIPER in the States of West Bengal, Bihar and Uttar Pradesh are still awaited. The Committee, therefore, recommend that the Department should vigorously and relentlessly pursue the matter with the concerned State Government so that the land is allocated for the purpose without any further delay. The Committee also expect that the Construction of NIPER campuses at Guwahati and Gandhinagar should be completed within a fixed time-frame in order to avoid time and cost overruns. The Committee would like to be apprised of the action taken by the Department in this regard."

### **Reply of the Government**

12. In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

"Following allocation of work for construction of NIPER campuses at Guwahati and Gandhinagar and signing of MoU, mobilization

funds have been released to each NIPER to start construction work.

A meeting has also been held in the Department in the Chairmanship of Secretary (Pharma) on 27.5.2013 to review the progress of the construction work.”

### Comments of the Committee

13. Expressing concern over delay in construction of NIPER Campuses, the Committee had noted that all six new NIPERs do not have their own campuses and still they continue to function with the assistance of Mentor Institutes. While the work relating to construction of NIPER campuses at Guwahati and Gandhinagar has since been awarded to PSUs and the State Government of Andhra Pradesh has agreed to allot land for NIPER Hyderabad, the allocation of land for NIPER Kolkata, Hajipur and Rae Bareli are being pursued with the respective State Governments. The Committee had, therefore, recommended that the Department should vigorously and relentlessly pursue the matter with the concerned State Governments so that land is allotted for the purpose without any further delay. The Committee had also expected that the Construction of NIPER campuses at Guwahati and Gandhinagar should be completed within a fixed time frame in order to avoid time and cost overruns. However, the Committee are dismayed to note from the Action Taken Reply of the Government that the Department does not have any action plan to set up all six new NIPER campuses within a fixed time-frame. While the mobilization funds have been released for construction of NIPER campuses at Guwahati and Gandhinagar, the Department is silent on the issue regarding the progress made with respect to allotment of land for construction of NIPER campuses at Hyderabad, Kolkata, Hajipur and Rae Bareli. The Committee, therefore, stress and recommend that the Department should vigorously and relentlessly pursue the matter with the respective State Governments for allotment of land for construction of NIPER campuses in their States. The Committee also desire that the Department should monitor the pace of progress of construction of NIPER campuses at Guwahati and Gandhinagar at regular intervals. The Committee would like to be apprised of the initiatives taken or being undertaken by the Department and the progress made in this regard.

## D. Rehabilitation Scheme for revival of sick Pharma PSUs

### Recommendation No. 7

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

“The Committee note that the Department of Pharmaceuticals has 5 running PSUs under its administrative control *viz.* Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL). Out of these KAPL and RDPL are profit making and BCPL, HAL and IDPL are BIFR referred companies. Further, being consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL. The rehabilitation scheme of IDPL is under consideration and for its revival, the Cabinet Note will be finalized after receipt of Draft Rehabilitation Scheme (DRS) prepared by the IDBI – Operating Agency (OA) appointed by BIFR. Final DRS is to be submitted by IDBI to BIFR which is expected in the month of April, 2013. As regards BCPL the Committee were informed that Statutory approvals/clearances from Drug Controller, Kolkata Development Authority (KDA), Kolkata Municipal Corporation (KMC), Factory Directorate, Pollution Control Board, Fire, Kolkata Electric Supply Corporation (CESC), Kanpur Electric Supply Authority (KESA) etc. are essential before commencement of operation of the plants under installation and commissioning. In this regard, BCPL has paid small portion of it from Capital Expenditure (CAPEX) fund and working Capital and provisional clearances for commencement of construction have been obtained except electricity. After full payment of statutory dues, final clearances are expected to be obtained within two months. The Committee also note that the process of preparation/approval of 2nd Rehabilitation Plan of HAL is underway and efforts are being made to complete the process at the earliest. Since various other agencies are also involved in the process, no time frame can be indicated by the Department of Pharmaceuticals.

In view of the foregoing, the Committee are, anguished to note that revival process of sick PSUs is still going on a snail's pace and the full revival of these sick PSUs has yet to take place. In this regard, in their earlier reports on DFG 2009-10, 2010-11 and



2011-12 the Committee, recommended that the matter needs to be pursued by the Department vigorously with all concerned. Since the revival of these units is essential in order to ensure good quality of drugs at an affordable price to the majority of the people it is all the more important for the Department as a nodal agency to make concerted and coordinated efforts so that these units are revived within a fix time frame. The Committee, therefore, reiterate its earlier recommendation that Department of Pharmaceuticals should expedite the revival of all these sick PSUs without further delay. The Committee would like to be apprised of the time bound action plan of the Department in this regard."

### **Reply of the Government**

15. In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

"The position regarding rehabilitation of such Pharma CPSEs is as under:—

#### **Hindustan Antibiotics Limited (HAL)**

Government approved the Rehabilitation Scheme for the company on 9th March 2006. It was approved by BIFR on 5th June 2007. The Rehabilitation Scheme *inter alia* involved the following:—

Sl. No.	Particulars	Amount (Rs. in crores)
1.	Cash infusion	137.59
2.	Write off/exemptions from Government of India	267.57
3.	Sacrifices by Banks, financial institutions and PSUs	103.34
	Total	508.50

The entire cash infusion of Rs. 137.59 crores has been released to the company. Government has approved writing off of loan and waiver of interest to the extent of Rs. 259.43 crores.

Further, the Government has additionally approved proposals of Rs. 30.17 crore received from HAL for setting up new powder injectable facilities for Cephalosporin and upgradation of existing vialling facilities for Betalactum (Penicillin) Antibiotics complying to WHO-GMP standards at an estimated cost of Rs. 20.17 crores

and for upgradation of manufacturing facilities of Tablet, Capsule and Liquid Sections complying to WHO-GMP standards at an estimated cost of Rs. 10.00 crore in order to make the company further viable.

HAL has completed the work on Cephalosporin. It has commissioned commercial production in February, 2009 and also obtained WHO-Certification for the same. Work relating to upgradation of existing vialling facilities for Betalactum Antibiotics has also been completed.

However, as HAL is still incurring losses, the Department is taking necessary action to seek the approval of the Cabinet and the BIFR for the 2nd Rehabilitation Scheme for HAL. HAL is also making efforts for the sale of its surplus land.

### **Bengal Chemicals and Pharmaceuticals Limited (BCPL), Kolkata**

Government approved Rehabilitation Scheme for revival of BCPL on 21.12.2006. The rehabilitation scheme, *inter alia*, involved the following:—

- (i) Cash infusion of Rs. 207.19 crore (out of Rs. 207.19 crore, Rs. 145.00 crore is meant for upgradation and modernization of manufacturing facilities conforming to WHO-GMP standards).
- (ii) Write off of Government of India Loan and waiver of interest thereon of Rs. 233.41 crores.

Government has approved writing off of GoI loans and interest of Rs. 233.41 crores and a cash infusion of Rs. 207.19 crore approved by the Government has been released. The process of upgradation and modernization of plant and machinery is underway.

### **Indian Drugs and Pharmaceuticals Limited (IDPL)**

Proposal for Revival of IDPL is under consideration. Board for Industrial and Financial Reconstruction (BIFR) has appointed Industrial Development Bank of India (IDBI) as the Operating Agency (OA). BIFR directed IDBI to submit the Final Draft Rehabilitation Scheme (DRS) to BIFR and the Ministry for consideration and the same has been submitted on 26.03.2013. A Cabinet Note on the 2nd rehabilitation package is under preparation.”

## Comments of the Committee

16. The Committee had noted that out of the five running PSUs under the administrative control of the Department, only KAPL and RDPL are profit making units and the remaining three namely HAL, BCPL and IDPL are loss making/sick units. Since the revival of these units is essential in order to ensure good quality of drugs at an affordable price to the majority of the people, the Committee had recommended that the Department of Pharmaceuticals should expedite the revival of all the sick PSUs without further delay. In its Action Taken Reply, the Department has stated that the Government had approved the Rehabilitation Scheme for HAL on 09.03.2006 and for BCPL on 21.12.2006. However, HAL is still incurring losses for which the Department is seeking the approval of the Cabinet and the BIFR for the 2nd Rehabilitation Scheme, as for BCPL, the process of its upgradation and modernization of plant and machinery is underway. In case of IDPL, a cabinet note on the 2nd Rehabilitation package is under preparation. In view of the above, the Committee regret to note that all the sick Pharma units are yet to be fully revived to sustain commercial production of drugs and medicines without any loss. Further the Department has failed to give the plausible reasons for their continuous loss. The Committee, therefore, reiterate their earlier recommendation that the Department should make concerted and coordinated efforts to expedite the revival of all the sick pharma units in a time bound manner and if felt necessary the Department may also consider to overhaul the management of these sick units. The Committee would like to be apprised of the initiatives taken or being undertaken by the Department in this regard.

E. National Centre for Research and Development in Bulk Drugs (NCRDBD) at NIPER, Hyderabad

### Recommendation No. 10

17. While noting the avowed objectives of the proposed National Centre for Research and Development in Bulk Drugs (NCRDBD) at NIPER, Hyderabad, the Committee had recommended as under:—

“The Committee note that the Department proposes to set up a National Centre for Research and Development in Bulk Drugs (NCRDBD) at NIPER, Hyderabad. The Centre would aim at development of technologies and process for cost competitiveness, environmental impact management, risk management and development of safety in manufacturing operations, knowledge transfer platform between industry and academia. The research

avenues for bulk drugs are Drugs process innovation, Drug discovery and development, Analytical chemistry, Process engineering, cleaner technology, Polymorphism, Nanotechnology etc. The Committee were informed that the proposal had been accorded in-principle approval by the Planning Commission subject to certain conditions. Keeping in view the avowed objectives of the proposed centre, the Committee desire that all necessary steps may be taken by the Department in coordination with all concerned so that the proposed centre is set up expeditiously within a fixed time frame."

### **Reply of the Government**

18. In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

"Direction of the Committee has been noted for compliance."

### **Comments of the Committee**

19. The Committee had noted that the Department proposes to set up a National Centre for Research and Development in Bulk Drugs (NCRDBD) at NIPER Hyderabad for which in-principle approval has already been accorded by the Planning Commission subject to certain conditions. The Committee, therefore desired that the proposed centre is set up expeditiously within a fixed time frame. However, the Committee regret to note that the Department in its Action Taken Reply has neither furnished the details of its action plan or the initiatives taken or being under taken by them nor has indicated any time frame for completion of the proposed Centre. The Department is conspicuously silent over the issue. The Committee had , therefore, would like to reiterate their recommendation that the Department should take all necessary steps in coordination with all concerned with a view to expedite the completion of the proposed centre within a fixed time frame. In this context, the Department should chalk out an action plan for implementation with in a fixed time frame. The Committee would like to be apprised of the initiatives taken or being undertaken by the Department for the purpose.

## CHAPTER II

### OBSERVATIONS/RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

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

The Committee note that net sales of the industry grew by 14.7% in the quarter ending June, 2012 as compared to a year ago quarter. Again, in the second quarter ending September, 2012 the drugs and pharmaceuticals industry performed well. However, the Committee are concerned to note that the imports of 'Medicinal and Pharmaceuticals Products' had risen by 29.43 per cent in the year 2011-12 as compared to previous year. As a result of which pressure was exerted on the profit margins of the industry. According to the Department, although the country is almost self-sufficient in production of most of formulations/ pharmaceuticals products, imports are resorted to on quality and economic considerations and not necessarily due to non-availability from domestic sources. Needless to say, the raw material expenses necessarily contribute towards the cost component of the quality medicine being sold to the common consumers. The Committee, are therefore of the view that it would be imperative if the import of raw material for production of medicine is resorted only if the same is absolutely necessary for the purpose. In fact, the Committee, expect the Department to encourage innovation and also intensive research and development in the field of pharma sector so that cheap but quality inputs are available within the country itself for production of quality but cheap medicine which would ultimately benefit the common man in the country. The Committee, therefore, recommend to take appropriate steps in this direction.

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

In order to encourage Pharma Innovation and Research and Development following proposals are under examination in the Department:—

- (i) In order to enhance the national potential for Drug Discovery and Innovation the Department is in the process of preparing

a detailed Project Report (DPR) in this regard. For the purpose the Department has engaged M/s. Ernst and Young Limited (M/s. E&Y) a global level consultant.

- (ii) A proposal is being examined in the Department to set up a National Centre for R&D in Bulk Drugs at Hyderabad NIPER.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

### **Comments of the Committee**

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

### **Recommendation No. 2**

The Committee with great concern note that the budgetary allocation of Rs. 188 crore for the year 2012-13 of the Department of Pharmaceuticals was drastically reduced to Rs. 85 crore at RE stage. However, even this amount could not be utilized fully by the Department as the actual utilization during the year 2012-13 was only Rs. 42.03 crore. The Department has attributed this reduction in funds in the year 2012-13 due to non-utilisation of funds to the extent of Rs. 145.97 crore by National Institute of Pharmaceutical Education and Research (NIPER), Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), National Pharmaceuticals Pricing Authority (NPPA), Pharmaceutical Promotion and Development Scheme (PPDS) and Project Based Support to PSUs and Jan Aushadhi Scheme (JAS). However, the Committee feel that the Department being the nodal agency, cannot escape their responsibility for gross under utilization of allocated funds for the year 2012-13 under various schemes which remains less by more than 50 per cent of the allocated funds. This only reflects the poor performance of the Department in achieving its financial and physical targets. The fact that various schemes/projects of the Department are still awaiting clearance/approval of the Integrated Finance Division (IFD) and/or the Planning Commission, also show the lack of will and concerted and coordinated efforts of the Department and the Institutes under them. The Committee now expect the Department of Pharmaceuticals to expedite the process of getting clearances/approvals from Planning Commission/ Integrated Finance Division (IFD) for the speedy implementation of various schemes so that the sanctioned funds do not remain under utilized. The under utilization of funds for the year 2012-13 by the Department is inspite of the earlier recommendations of the Committee on Demands for Grants 2010-11, 2011-12 and 2012-13 to utilize the sanctioned funds

properly and timely to achieve the avowed objectives of the Department. The Committee, therefore strongly deplore the casual and lackadaisical attitude of the Department and their failure to fully utilize the funds allocated to them. The Committee, therefore, recommend that the Department should make all efforts and prepare its action plan before hand for optimum utilization of the funds meant for various schemes run by them. The Committee would like to be apprised of the steps taken by the Department in this regard.

### **Reply of the Government**

The steps taken by the Department of Pharmaceuticals to optimally utilize the allocated funds with status of the projects is as under:—

#### **(a) Project Based Support to PSUs**

- (i) **Project:** Expanding the capacity of large volume parentals – IV fluid (Rs. 1417 crore)

Status – A committee under the Chairmanship of AS and FA has been constituted *vide* Order dated 15.05.2013 to visit the plant of Hindustan Antibiotics Limited, Pune to assess the ground reality and to impress upon the Ministry of Finance to release assistance under 'Project based Support'. The Committee has visited HAL on 04.07.2013 for this purpose. The Report of the Committee has already been submitted which is under consideration in the Department.

- (ii) **Project:** Statutory obligations towards Land and Revenue and fees for obtaining statutory approvals from the State and Central Drug Controller, KDA and KMC, Factory Directorate, Pollution Control Board, Fire and Legal issues under implementation of Revival Scheme of BCPL (Rs. 9.30 crore).

Status – The proposal is under consideration. In this regard, BCPL has been requested to send a detailed proposal for consideration of Department for release of funds.

- (iii) **Project:** Terminal Dues/Gratuity of Retiring Employees (Rs. 3.00 crores), Upgradation of premises for NIPER at IDPL (Rs. 2.90 crores) and liquid oral (2nd line) at Gurgaon plant (0.29 cores).

Status – IDPL has been asked to send detailed proposals for consideration of this Department for release of funds.

**(b) Critical Assistance Scheme**

WHO GMP compliance in DRPL (6.84 crore)

Status— RDPL has been asked to send proposals for release of funds. The project for WHO GMP compliance is under process by the RDPL and RDPL is on the process of utilizing the funds earlier sanctioned for the purpose. The proposal for the further release of funds is expected to be received when the RDPL utilize the amount sanctioned earlier substantially.

**(c) Jan Aushadhi Scheme**

Jan Aushadhi Scheme (Rs. 25.00 crore)

Status— New business Plan to Jan Aushadhi Scheme has been finalized. In-principle approval of Planning Commission has been sought and awaited. EFC Meeting was convened on 05.07.2013 but has to be postponed as Planning Commission has sought some more time for appraisal.

**(d) Schemes pertaining to NIPER**

Status— All out efforts are being made to utilize the funds allocated to various schemes of NIPER, Necessary approvals of IFD and Planning Commission are also being expedited wherever required.

**(e) NPPA Schemes**

With the notification of National Pharmaceuticals Pricing Policy, 2012 and Drugs (Price Control) Order, 2013, (DPCO, 2013) the relevance of the Schemes has been reviewed in consultation with NPPA and the status of each scheme is as under:—

(i) Creation of NPPA Cells in States:

Status— In view of the changes in norms for pricing as envisaged in DPCO, 2013, it is felt that separate cells in States may not be required.

(ii) Scheme for Interaction with States:

Status— NPPA has already taken initiative in this regard by having regional meetings with States on regular basis. It is felt that a special scheme for the purpose is not required.



- (iii) Proposals for strengthening the existing Monitoring and Enforcement work:

Status— It has been decided to revisit the provisions of this scheme by NPPA and a view will be taken keeping in view the requirement under DPCO, 2013.

- (iv) Consumer Awareness and Publicity through Print, electronic and other media:

Status— NPPA decided to continue with Scheme during the 12th Five Year Plan. NPPA/Department has been making a concerted and coordinated effort for requisite approvals/clearances of the Scheme with Planning Commission. An Action Plan for optimum utilization of the funds for the year 2013-14 shall also be formulated by NPPA in the light of DPCO, 2013.

**(f) PTUAS**

Status— The proposal of SIDBI on soft was submitted to Planning Commission on 08.01.2013. In response, Planning Commission *vide* its letter dated 30.01.2013 requested DoP to submit proposal in EFC format. The draft scheme has been uploaded on website of the department on 30.05.2013 for seeking comments/suggestion of the various stakeholders. Department has also constituted a technical committee comprising members from Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL), Small Industrial Development Bank of India (SIDBI), Ministry of Micro, Small and Medium Enterprises (MSME), Drug Controller General (India), Indian Drug Manufacturers Association (IDMA), Confederation of Indian Pharmaceuticals Industry (CIPI) and National Institute of Pharmaceutical Education and Research (NIPER) to suggest a list of equipments and machinery required for WHO GMP/other international GMP certification and to work out their estimated cost of procurement/installation. On finalization of equipments, the proposal would be submitted to Planning Commission.

**(g) PPD Scheme**

Status— The Department is going to have a series of interactive sessions with Industry Associations to find out the issues which

could be taken up for promotion of export. Further State level interactions are being mooted to extend the benefits of the scheme.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

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

The Committee observe that the policy of the Government is to ensure availability of good quality life saving drugs at reasonable price and pay special attention to the poorer sections of the society in the matter of healthcare. Consistent with this policy, the Government of India has approved rehabilitation scheme for revival of HAL and BCPL. The rehabilitation scheme of IDPL is still under consideration. As the HAL is also still incurring losses, the Second Rehabilitation Plan of HAL is also under active consideration of the Government. An amount of Rs. 29.66 crore has been allocated for Project Based Support to aforesaid PSUs. The Committee, therefore, recommend that the Department of Pharmaceuticals should expeditiously utilize the amount earmarked for project based support to these PSUs so that the performance of the PSUs improves and the quality life saving drugs at reasonable price could be manufactured without any delay and supplied to the poor consumers. The Committee also note with concern that in case of HAL, out of Rs. 45.00 crore required for their project, a provision of Rs. 14.17 crore has been made for the year 2013-14. The Committee would, therefore, like to emphasize that a high powered Committee of the Department should visit the HAL to assess the ground reality and impress upon the Ministry of Finance to allocate the requisite amount for the rehabilitation of various schemes of HAL. The Committee would like to be informed of the progress made in this regard.

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

In pursuance of the above recommendations a committee under the Chairmanship of AS&FA of this Department is constituted *vide* this Department's Order dated 15.05.2013 to visit the plant of Hindustan Antibiotics Limited, Pune to assess the ground reality and to impress upon the Ministry of Finance to release assistance under 'Project based Support' which so far has been denied on ground of default

in repayment of loans. The constitution of the Committee may be seen as under:—

- |       |   |            |
|-------|---|------------|
| (i)   | Sh. V.K. Subburaj<br>Additional Secretary and Financial Adviser,<br>Department of Pharmaceuticals | — Chairman |
| (ii)  | Sh. Pradeep Yadav<br>Joint Secretary,<br>Department of Pharmaceuticals                            | — Member   |
| (iii) | Sh. V.K. Mehta<br>Director (Finance)<br>Department of Pharmaceuticals                             | — Member   |

The Committee has visited to HAL on 04.07.2013 for this purpose. The committee recommended for the following two projects for assistance under 'Project based support':—

- (i) Utility set-up for formulations for the Rs. 8.41 crore.
- (ii) Agro-vet Upgradation and expansion for the Rs. 6.00 crore.

The committee also recommended that this immediate investment will not only improve efficiency of the existing operations but also help in realizing revenue in the shortest possible gestation time. The assistance is very critical in sustaining the operations of the company. The committee recommended sanction of financial assistance of Rs. 14.17 crores under 'project' for the above mentioned two projects. The Committee is also of the view that the default in repayment of GoI loans may not be held against the company as a special case for sanction of assistance.

The matter has been taken up with the Planning Commission for the in-principle approval of the above mentioned two projects.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

### **Recommendation No. 6**

The Committee note that National Pharmaceutical Pricing Authority (NPPA) is, *inter-alia*, entrusted with the mandate of fixation/revision of prices of schedule bulk drugs/formulation under Drugs (Price Control) Order, 1995 (DPCO 1995) and enforcement of their prices. It is empowered to take final decisions on these matters subject to review by the Central

Government when considered necessary. In order to ensure availability of essentials drugs at affordable prices, it also monitors the prices of decontrolled drugs/formulation and oversees the implementation of the provisions of the DPCO, 1995. The Committee also note that the role of NPPA would continue under new National Pharmaceuticals Pricing Policy (NPPP), 2012 announced by the Government on 7.12.2012 and the new DPCO which is under finalization. The Committee hope that the new DPCO would help the NPPA to enforce the prices of all the medicines which are essential to take care of the health care of the large section of the people of the country. The Committee, therefore recommend that the finalization of new DPCO may be expedited within a fixed time line. The Committee would like to be apprised of the action taken by the Department in this regard.

### **Reply of the Government**

Based on the notification dated 07.12.2012 notifying the National Pharmaceuticals Pricing Policy (NPPA)-2012, the Drug Price Control Order (DPCO)-2013 has been notified on 15.05.2013.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

### **Recommendation No. 7**

The Committee note that the Department of Pharmaceuticals has 5 running PSUs under its administrative control *viz.* Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL). Out of these KAPL and RDPL are profit making and BCPL, HAL and IDPL are BIFR referred Companies. Further, being consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL. The rehabilitation scheme of IDPL is under consideration and for its revival, the Cabinet Note will be finalized after receipt of Draft Rehabilitation Scheme (DRS) prepared by the IDBI – Operating Agency (OA) appointed by BIFR. Final DRS is to be submitted by IDBI to BIFR which is expected in the month of April, 2013. As regards BCPL the Committee were informed that Statutory approvals/clearances from Drug Controller, Kolkata Development Authority (KDA), Kolkata Municipal Corporation (KMC), Factory Directorate, Pollution Control Board, Fire, Kolkata Electric Supply Corporation (CESC) Kanpur Electric Supply Authority (KESA) etc. are essential before commencement of operation of the plants under

installation and commissioning. In this regard, BCPL has paid small portion of it from Capital Expenditure (CAPEX) fund and working Capital and provisional clearances for commencement of construction have been obtained except electricity. After full payment of statutory dues, final clearances are expected to be obtained within two months. The Committee also note that the process of preparation/approval of 2nd Rehabilitation Plan of HAL is underway and efforts are being made to complete the process at the earliest. Since various other agencies are also involved in the process, no time frame can be indicated by the Department of Pharmaceuticals.

In view of the foregoing, the Committee are, anguished to note that revival process of sick PSUs is still going on a snail's space and the full revival of these sick PSUs has yet to take place. In this regard, in their earlier reports on DFG 2009-10, 2010-11 and 2011-12 the Committee, recommended that the matter needs to be pursued by the Department vigorously with all concerned. Since the revival of these units is essential in order to ensure good quality of drugs at an affordable price to the majority of the people it is all the more important for the Department as a nodal agency to make concerted and coordinated efforts so that these units are revived within a fix time frame. The Committee, therefore, reiterate its earlier recommendation that Department of Pharmaceuticals should expedite the revival of all these sick PSUs without further delay. The Committee would like to be apprised of the time bound action plan of the Department in this regard.

### **Reply of the Government**

The position regarding rehabilitation of such Pharma CPSEs is as under:—

**HAL:** Government approved the Rehabilitation Scheme for the company on 9th March 2006. It was approved by BIFR on 5th June, 2007. The Rehabilitation Scheme *inter alia* involved the following:—

S.No.	Particulars	Amount (Rs. in crores)
1.	Cash infusion	137.59
2.	Write off/exemptions from Government of India	267.57
3.	Sacrifices by Banks, financial institutions and PSUs	103.34
	Total	508.50

The entire cash infusion of Rs. 137.59 crores has been released to the company. Government has approved writing off of loan and waiver of interest to the extent of Rs. 259.43 crores.

Further, Government has additionally approved proposals of Rs. 30.17 crore received from HAL for setting up new powder injectable facilities for Cephalosporin and upgradation of existing vialling facilities for Betalactum (Penicillin) Antibiotics complying to WHO-GMP standards at an estimated cost of Rs. 20.17 crores and for upgradation of manufacturing facilities of Tablet, Capsule and Liquid Sections complying to WHO-GMP standards at an estimated cost of Rs. 10.00 crore in order to make the company further viable.

HAL has completed the work on Cephalosporin. It has commissioned commercial production in February, 2009 and also obtained WHO-Certification for the same. Work relating to upgradation of existing vialling facilities for Betalactum Antibiotics has also been completed.

However, as HAL is still incurring losses, the Department is taking necessary action to seek the approval of the Cabinet and the BIFR for the 2nd Rehabilitation Scheme for HAL. HAL is also making efforts for the sale of its surplus land.

### **Bengal Chemicals and Pharmaceuticals Limited (BCPL), Kolkata**

Government approved Rehabilitation Scheme for revival of BCPL on 21.12.2006. The rehabilitation scheme, *inter alia*, involved the following:—

- (i) Cash infusion of Rs. 207.19 crore (Out of Rs. 207.19 crore, Rs. 145.00 crore is meant for upgradation and modernization of manufacturing facilities conforming to WHO-GMP standards).
- (ii) Write off of Government of India Loan and waiver of interest thereon of Rs. 233.41 crores.

Government has approved writing off of GoI loans and interest of Rs. 233.41 crores and a cash infusion of Rs. 207.19 crore approved by the Government has been released. The process of upgradation and modernization of plant and machinery is underway.

### **Indian Drugs and Pharmaceuticals Limited (IDPL)**

Proposal for Revival of IDPL is under consideration. Board for Industrial and Financial Reconstruction (BIFR) has appointed Industrial Development Bank of India (IDBI) as the Operating Agency (OA).

BIFR directed IDBI to submit the Final Draft Rehabilitation Scheme (DRS) to BIFR and the Ministry for consideration and the same been submitted on 26.03.2013. A Cabinet Note on the 2nd rehabilitation package is under preparation.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

### **Comments of the Committee**

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

### **Recommendation No. 8**

The Committee note that the Department of Pharmaceuticals has notified the National Pharmaceutical Pricing Policy-2012 (NPPP-2012) on 7.12.2012. The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required essential medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of Pharmaceutical industry, thereby meeting the goals of employment and shared economic well being for all. Under this policy all the medicines as under National List of Essential Medicines (NLEM)-2011 that takes care of the healthcare needs of the majority of the population of the country will come under Price Control. As a result therefore 25 per cent of the total domestic pharma market will come under the price control and the prices of nearly 63 per cent of medicines under NLEM-2011 will decrease substantially. The Committee, in its Report No. 29 had also recommended that the mandate of NPPA regarding fixing/revision of pricing of drugs should be broadened to include all the 348 essential drugs and medicines listed by the Department of Pharmaceuticals. The Committee, therefore, expect the Department of Pharmaceuticals to take up follow up steps to implement the Policy expeditiously without any further delay. The Committee would like to be apprised of the status of implementation of the policy within three months of the presentation of the Report.

### **Reply of the Government**

Based on the notification dated 07.12.2012 notifying the National Pharmaceutical Pricing Policy (NPPP)-2012, the Drug Price Control Order (DPCO)-2013 has been notified on 15.05.2013 and put on Department of Pharmaceuticals website [www.pharmaceuticals.gov.in](http://www.pharmaceuticals.gov.in) on 16.05.2013.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

### **Recommendation No. 9**

The Committee note that in November, 2008, the Department launched Generic Drug Campaign by opening the first Jan Aushadhi Generic Drug Campaign Store (JAS) at Amritsar Civil Hospital on 25.11.2008. Since then 147 JAS have been opened (till 31st January, 2013). The main objective of the campaign was to make available quality generic drugs at affordable prices to all through the Jan Aushadhi Generic Drug Stores which are quite cheaper than the branded medicine. The Government intends to open up one JAS in each district of the country. A revised Business Plan of Jan Aushadhi Scheme in this regard is under consideration of the Department and the same will be ready by April, 2013 as informed by the Department. At present only the medicines manufactured by the Central Pharma Public Sector Undertakings (CPSUs) under the Department of Pharmaceuticals are being sold at the existing Jan Aushadhi Stores and as such, the range of medicines being supplied by these CPSUs is limited, beside limited coverage of the therapeutic categories. In order to tide over this situation and to increase the range of medicines. BPPI has initiated a proposal to improve the supply chain, which would adequately address the issue of wider coverage of the therapeutic categories, and the same is under consideration of the Government. The Committee believe that the proposal initiated by BPPI will be finalized expeditiously without any undue delay. The Committee are distressed to note that the response from some of the States for the Jan Aushadhi Scheme is not very affirmative, without which it would be difficult to implement the scheme successfully in the entire country. As recommended by the Committee in their reports on Demands for Grants for the year 2012-13 the Department should open JAS in a mission mode, in coordination with State Governments. The Committee recommended that Department should explore options like opening up of JAS through public-private partnership and also individual entrepreneurs should also be encouraged to open JAS. Further, the Department should rope in State PSUs and private manufacturers to increase the coverage of generic drugs at JAS. The Committee would like to be apprised of the action taken by the Department in this regard.

### **Reply of the Government**

As of now (31.5.2013), 154 Jan Aushadhi Stores have been opened in twelve States, namely, Punjab, Haryana, Odisha, Andhra Pradesh, Rajasthan, Delhi, Uttarakhand, West Bengal, Jammu and Kashmir, Jharkhand, Himachal Pradesh, including UT of Chandigarh. Out of this,



91 stores are functional and 63 are non-functional. To take this campaign forward, BPPI had taken up the matter with the State Governments and the status is as under:—

1. As regards Uttar Pradesh, the Principal Secretary, Health and Family Welfare Department, convened a meeting on 16th April, 2013 to take a decision with regard to opening up of Jan Aushadhi Stores in the State. It was informed in the meeting that the State Government is now giving free medicines to all the indoor and outdoor patients visiting the Government Hospitals. In view of this, they were not interested in opening of Jan Aushadhi Stores in the District Hospitals. However, they were interested in opening Jan Aushadhi Stores in the Medical Colleges located in the State and also having Jan Aushadhi Stores as the Upbhokta Sangh Stores located in the State. In this regard, the State Government has to send a comprehensive proposal to the BPPI which is still awaited.
2. As regards opening up of Jan Aushadhi Stores in other States, BPPI officials had a meeting with Secretary, Department of Health and Family Welfare, and Mizoram at Aizawl in January, 2013. A draft MoU was sent to Secretary, Department of Health and Family Welfare, and Mizoram on 28th January, 2013 followed by a reminder letter dated 8th April, 2013 to Secretary, Department of Health and Family Welfare, and Mizoram.
3. As a result of continuous persuasion with the Government of Arunachal Pradesh, they have recently intimated that they propose to open Jan Aushadhi Stores at 19 places to benefit the public by making available quality generic medicines at affordable prices and are in the process of identifying the space and the agencies for managing the JASs.
4. As regards Tamil Nadu, after the meeting with the Secretary, Cooperation, Food, Consumer Affairs and Secretary, Health and Family Welfare, Government of Tamil Nadu, with regard to their proposal to sell generic unbranded medicines through 191 pharmacies run by Triplicane Urban Cooperative Society, Kamadhenu, a society recognized by the Ministry of Cooperation Food and Consumer Affairs, a Tripartite draft MoU was sent to the Secretary, Cooperation, Food and Consumer Protection, Government of Tamil Nadu on 5th June,

2012. In response to the MoU, a letter was received from the Secretary, Cooperation, Food and Consumer Protection enclosing therewith a letter from Triplicane Urban Cooperative Society seeking clarifications, which was responded by BPPI on 17th October, 2012 followed by a reminder letter dated 10th April, 2013. Their response is still awaited.

5. Request has also been received from the State Government of Sikkim, who have shown interest for opening up of Jan Aushadhi Stores. BPPI officials would be meeting Secretary (H&FW) to discuss and finalize the modalities of opening of the stores, Government of Sikkim.
6. Recently request has also been received from Director of Health Services, Government of Tripura, for opening up of Jan Aushadhi Stores in some parts of Tripura State on pilot basis. BPPI officials would visit Tripura shortly to finalize the modalities for opening up of Jan Aushadhi Stores.
7. It is also pertinent to mention here that Director, Directorate of Health Services, Chhattisgarh *vide* its letter dated 7th May, 2013 has informed BPPI that State Government of Chhattisgarh is interested to open Jan Aushadhi Stores in District Hospitals of Chhattisgarh through Red Cross Societies and requested BPPI to send the formalities/guidelines to be followed in regard to opening up of the stores. BPPI officials would visit Chhattisgarh shortly to finalize the modalities for opening up of Jan Aushadhi Stores.
8. In Delhi, BPPI have received two requests – one from Senior General Manager, Delhi Consumer's Co-operative Store Ltd., Moti Nagar and the other from President, Muni Shri Nagraj Spiritual Centre, NirmanVihar, Delhi to open Jan Aushadhi Store in their premises at Karampura, Delhi and NirmanVihar, Delhi. The Delhi Consumer's Cooperative Stores Ltd., Moti Nagar, New Delhi has completed all the formalities and they are going to open a Jan Aushadhi Store at their Head Quarter at Karampura, Delhi, on 4th June, 2013. As regards opening up of Jan Aushadhi Store by Muni Shri Nagraj Spiritual Centre, NirmanVihar, Delhi, a draft MoU was sent to them through email on 1st February, 2013 and after some clarifications, they are ready to execute the MoU which is under process.

The revised Business Plan proposes to open the field for opening up of Jan Aushadhi Stores to individuals and private NGOs etc. on specific terms and conditions and it is expected that this will give a boost to opening of new Jan Aushadhi Stores.

As regards therapeutic coverage, it is proposed to have a basket of 361 medicines, out of which 138 medicines are being manufactured by 5 CPSUs in-house and it is proposed to procure remaining 223 medicines through open tenders from State PSUs and private sector companies. The revised Business Plan has been sent to Planning Commission for necessary action.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

### **Recommendation No. 10**

The Committee note that the Department proposes to set up a National Centre for Research and Development in Bulk Drugs (NCRDBD) at NIPER Hyderabad. The Centre would aim at development of technologies and process for cost competitiveness, environmental impact management, risk management and development of safety in manufacturing operations, knowledge transfer platform between industry and academia. The research avenues for bulk drugs are Drugs process innovation, Drug discovery and development, Analytical chemistry, Process engineering, cleaner technology, Polymorphism, Nanotechnology etc. The Committee were informed that the proposal had been accorded in-principle approval by the Planning Commission subject to certain conditions. Keeping in view the avowed objectives of the proposed centre, the Committee desire that all necessary steps may be taken by the Department in coordination with all concerned so that the proposed centre is set up expeditiously within a fixed time frame.

### **Reply of the Government**

Direction of the Committee has been noted for compliance.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

### **Comments of the Committee**

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

### **CHAPTER III**

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

— NIL —

## CHAPTER IV

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

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

The Committee note that out of total GBS allocation of Rs. 2968.00 crore for the scheme wise Plan Outlays during Twelfth Five Year Plan, the Department of Pharmaceuticals had proposed Rs. 567.60 crore for the year 2013-14 but the Planning Commission has approved only Rs. 188.00 crore. The Committee also note that Planning Commission had indicated that the outlay of the Department be maintained at the same level as in the previous year. This was primarily due to gross underutilization of funds by the Department of Pharmaceuticals during the year 2012-13. The Committee, feel that it is now the responsibility of the Department to impress upon the Planning Commission to allocate more funds for the remaining period of Twelfth Five Year Plan. The Committee expect the Department to act strongly.

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

Planning Commission has been apprised about the Committee's concern regarding enhanced allocation.

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

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

The Committee note that NIPER was declared as an "Institute of National Importance" under the Act of Parliament on 26th June 1998. NIPER is a member of Association of Indian Universities. The Committee, also observe that in addition to NIPER, SAS Nagar, Mohali, the Government has set up six new NIPERs at Hajipur, Hyderabad, Ahmedabad, Rae Bareli, Guwahati and Kolkata. At present these

six new NIPERs are functioning with the assistance of Mentor Institutes presently in the respective States. The work relating to construction of NIPER campuses at Guwahati and Gandhinagar has since been awarded to PSUs *viz* Engineering Projects (India) Ltd. (EPIL) and Hindustan Steelworks Construction Ltd. (HSCL) respectively. The State Government of Andhra Pradesh has agreed to allot 50 acres of land for NIPER Hyderabad and the issue is being finalized. The issue of allocation of land for NIPER Kolkata, Hajipur and Rae Bareli are being pursued with the respective State Governments.

In view of the foregoing, the Committee regret to note that all six new NIPERs do not have their own campuses and still they continue to function with the assistance of Mentor Institutes even after a gap of more than 4-5 years. Considering the importance of these Institutes for the continuous growth of pharmaceuticals sector, it is but essential that all the new NIPER have their own campuses for their effective functioning for which these are meant for. In this regard the Committee reiterate its repeated recommendations on Demands for Grants 2009-10, 2010-11, 2011-12 and 2012-13 regarding completion of necessary formalities for construction of NIPER Campuses. While some progress has been made with regard to construction of NIPER Campus at Guwahati and Gandhinagar, the allotment of land for NIPER in the States of West Bengal, Bihar and Uttar Pradesh are still awaited. The Committee, therefore, recommend that the Department should vigorously and relentlessly pursue the matter with the concerned State Government so that the land is allocated for the purpose without any further delay. The Committee also expect that the Construction of NIPER campuses at Guwahati and Gandhinagar should be completed within a fixed time frame in order to avoid time and cost overruns. The Committee would like to be apprised of the action taken by the Department in this regard.

### **Reply of the Government**

In reply to the aforesaid recommendation of the Committee, the Department of Pharmaceuticals has stated as under:—

“Following allocation of work for construction of NIPER campuses at Guwahati and Gandhinagar and signing of MoU, mobilization funds have been released to each NIPER to start construction work.

A meeting has also been held in the Department in the Chairmanship of Secretary (Pharma) on 27.5.2013 to review the progress of the construction work.”

[Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) F. No. 16(3)/2013-Fin.II, dated 22.08.2013]

### **Comments of the Committee**

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

## CHAPTER V

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH  
REPLIES OF THE GOVERNMENT ARE OF INTERIM NATURE

— NIL —

NEW DELHI;  
24 October, 2013  
2 Kartika, 1935 (Saka)

GOPINATH MUNDE,  
*Chairman,*  
*Standing Committee on*  
*Chemicals and Fertilizers.*



## APPENDIX I

### MINUTES OF THE SECOND SITTING OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2013-14)

The Committee sat on Thursday, the 24 October, 2013 from 1500 hrs. to 1600 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

#### PRESENT

Shri Gopinath Munde — *Chairman*

#### MEMBERS

##### *Lok Sabha*

2. Shri S. Alagiri
3. Shri Gajanan D. Babar
4. Shri Prabhatsinh P. Chauhan
5. Shri Sher Singh Ghubaya
6. Sk. Nurul Islam
7. Shri Shakti Mohan Malik
8. Shri Paswan Kamlesh
9. Shri Amarnath Pradhan
10. Shri Tufani Saroj
11. Shri Suresh Kumar Shetkar
12. Shri Raju Shetti
13. Shri D. Venugopal

##### *Rajya Sabha*

14. Shri Biswajit Daimary
15. Smt. Naznin Faruque

16. Shri A.A. Jinnah
17. Shri Brijlal Khabri
18. Shri Dilipbhai Pandya
19. Shri Raghunandan Sharma
20. Shri Ishwar Singh

SECRETARIAT

1. Smt. Rashmi Jain — *Joint Secretary*
2. Shri U.B.S. Negi — *Director*
3. Shri A.K. Srivastava — *Additional Director*

2. At the outset, the Chairman welcomed the members of the Committee.

3. The Committee thereafter took up the following draft Reports for consideration:

- (a) Draft Action Taken Report on the action taken by the Government on the observations/recommendations contained in the Thirty-fourth report (15th Lok Sabha) on "Demands for Grants 2013-14" of the Department of Chemicals and Petrochemicals.
- (b) Draft Action Taken Report on the action taken by the Government on the observations/recommendations contained in the Thirty-fifth report (15th Lok Sabha) on "Demands for Grants 2013-14" of the Department of Pharmaceuticals.

4. The draft Report relating to the Department of Chemicals and Petrochemicals was adopted by the Committee without any amendments. However, the draft Report relating to the Department of Pharmaceuticals was adopted with some amendments as indicated in the *Annexure*.

5. The Committee decided to seek opinion of stakeholders and the public at large on the subject 'Jan Aushadhi Scheme' by giving advertisements in print and electronic media.

6. The Committee authorised the Chairman to present the Reports to both Houses of Parliament.

*The Committee then adjourned.*

## ANNEXURE

(Vide Para 4 of the Minutes)

Para No.	Page No.	Line	Amendments/modifications (in the Comments portion of the draft Report)
7	4	3 from below	<i>Insert</i> the following sentence before the last sentence: "The Committee desire that the Department should formulate time bound action plan in this regard."
10	5	11 from below	<i>After</i> 'the Planning Commission' of the last sentence, <i>add</i> the following: "and the officers responsible therefor".
10	5	4 from below	<i>Insert</i> the following sentence before the last sentence: "The Department should also take action against the officers for their failure to utilize the funds timely and optimally."
13	7	2 from below	<i>After</i> 'the Department' of the last sentence, <i>insert</i> the following: "and the progress made"
16	11	8 from below	<i>Insert</i> the following sentence before the last two sentences: "Further the Department has failed to give the plausible reasons for their continuous loss."
16	11	4 from below	<i>After</i> 'in a time bound manner' and, before the last sentence, <i>add</i> the following: "and if felt necessary the Department may also consider to overhaul the management of these sick units".

## APPENDIX II

(Vide Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE  
RECOMMENDATIONS CONTAINED IN THE THIRTY-FIFTH  
REPORT (FIFTEENTH LOK SABHA) OF THE STANDING  
COMMITTEE ON CHEMICALS AND FERTILIZERS  
(2012-13) ON 'DEMANDS FOR GRANTS (2013-14)  
OF THE MINISTRY OF CHEMICALS AND  
FERTILIZERS (DEPARTMENT OF  
PHARMACEUTICALS)

I.	Total No. of Recommendations:	10
II.	Observations/Recommendations which have been accepted by the Government:	
	(Vide Recommendation at Sl. Nos. 1, 2, 4, 6, 7, 8, 9 and 10)	8
	Percentage of Total :	80%
III.	Observations/Recommendations which the Committee do not desire to pursue in view of the Government's reply:	
	Nil	00
	Percentage of Total :	Nil
IV.	Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee and which require reiteration:	
	(Vide Recommendation at Sl. Nos. 3 and 5)	2
	Percentage of Total :	20%
V.	Observations/Recommendations in respect of which final replies of the Government are still awaited:	
	Nil	00
	Percentage of Total :	Nil



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